User Manual

English

5000 Compact Series Ultrasound Systems

PHILIPS

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1 Read This First

This manual is intended to assist you with the safe and effective operation of your Philips product. Before attempting to operate the product, read this manual and strictly observe all warnings and cautions. Pay special attention to the information in the "Safety" section.

The user information for your Philips product describes the most extensive configuration of the product, with the maximum number of options and accessories. Some functions described may be unavailable on your product's configuration.

Transducers are available only in countries or regions where they are approved. For information specific to your region, contact your local Philips representative.

NOTE

"L12-5" refers to the L12-5 50 transducer.

Philips makes no representation or warranty to the user or any other party with respect to the adequacy of this document for any particular purpose or with respect to its adequacy to produce a particular result. The user's right to recover damages caused by fault or negligence on the part of Philips shall be limited to the amount paid by the user to Philips for the provision of this document. In no event shall Philips be liable for special, collateral, incidental, direct, indirect or consequential damage, losses, costs, charges, claims, demands, or claims for lost profits, data, fees, or expenses of any nature or kind.

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Non-Philips product names may be trademarks of their respective owners.

CAUTION

United States federal law restricts this device to sale by or on the order of a physician.

Intended Audience

This document is intended for sonographers, physicians, and biomedical engineers who operate and maintain your product.

Before you use your system and user information, you need to be familiar with ultrasound techniques. Sonography training and clinical procedures are not included here.

Intended Use/Indications for Use

This product is intended to be installed, used, and operated only in accordance with the safety procedures and operating instructions given in the product user information, and only for the purposes for which it was designed. For indications for use for transducers, see "Indications for Use and Supporting Transducers" on page 108. However, nothing stated in the user information reduces your responsibility for sound clinical judgment and best clinical procedure.

The clinical environments where the systems can be used include physicians' offices, clinics, hospitals, surgical suites, and clinical point-of-care for diagnosis of patients.

The intended use of the 5000 Compact series ultrasound systems is diagnostic ultrasound imaging and fluid flow analysis of the human body with the following Indications for Use: Abdominal, Cardiac Adult, Cardiac Pediatric, Carotid, Cerebral Vascular, Cephalic (Adult), Cephalic (Neonatal), Fetal Echo, Fetal/Obstetric, Gynecological, Intraoperative (Vascular), Lung, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Pediatric, Peripheral Vessel, Small Parts, Transesophageal (Cardiac), Transrectal, Transvaginal, and Urology.

WARNING

Do not use the system for purposes other than those intended and expressly stated by Philips. Do not misuse the system, and do not use or operate the system incorrectly.

Installation, use, and operation of this product are subject to the law in the jurisdictions in which the product is used. Install, use, and operate the product *only* in such ways that do not conflict with applicable laws or regulations, which have the force of law.

Use of the product for purposes other than those intended and expressly stated by Philips, as well as incorrect use or operation, may relieve Philips or its agents from all or some responsibility for resultant noncompliance, damage, or injury.

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WARNING

System users are responsible for image quality and diagnosis. Inspect the data that is being used for the analysis and diagnosis, and ensure that the data is sufficient both spatially and temporally for the measurement approach being used.

Clinical Benefits

The expected clinical benefits of the 5000 Compact series ultrasound systems are related to the device's intended purpose to provide diagnostic ultrasound imaging and fluid flow analysis of the human body. These clinical benefits can be broadly described as providing real-time noninvasive or minimally invasive visualization of the internal organs and anatomy to assist in providing a medical evaluation and diagnosis to direct patients' medical care. Because the 5000 Compact series ultrasound systems provide images of human anatomy without the use of ionizing radiation, the systems can provide information about a patient's health status, without the risks of some other medical imaging modalities.

Warnings

Before using the system, read these warnings and the "Safety" section.

WARNING

Do not remove the protective covers on the system; hazardous voltages are present inside. Covers must be in place while the system is in use. All internal adjustments and replacements must be made by your authorized service representative.

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WARNING

To avoid electrical shock, use only supplied power cords and connect only to properly grounded wall (wall/mains) outlets.

WARNING

Do not operate this system in the presence of flammable gases or anesthetics. Explosion can result. The system is *not* compliant in AP/APG environments as defined by IEC 60601-1.

WARNING

Medical equipment must be installed and put into service according to the special electromagnetic compatibility (EMC) guidelines provided in the "Safety" section.

WARNING

The use of portable and mobile radio-frequency (RF) communications equipment can affect the operation of medical equipment. For more information, see "Recommended Separation Distance" on page 96.

User Information Components

The user information provided with your product includes the following components:

- *User Information* USB media: Includes all of the user information, except the *Operating Notes*.
- *Operating Notes*: Contains information that clarifies certain product responses that might be misunderstood or cause user difficulty.
- *Care and Cleaning of Ultrasound Systems and Transducers*: Included on the USB media. Describes care and cleaning procedures for your ultrasound system and transducers.

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- *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*: Included on the USB media. Provides information about compatible cleaning and disinfecting products for your ultrasound system and transducers.
- *User Manual*: Provided with the product and included on the USB media. The *User Manual* introduces you to features and concepts, helps you set up your system, and includes important safety information. This manual also includes procedures for basic operation. For detailed operating instructions, see the *Help*.
- *User Information Update*: If required, contains updated information about the product.
- *Help*: Available on the system in some languages and included on the USB media, the *Help* contains comprehensive instructions for using the system. The *Help* also provides reference information and descriptions of all controls and display elements. To display the *Help*, touch **Utilities**, touch the **System** tab, and then touch **Help**.
- *Quick Guide*: Provided with the product and included on the USB media. The *Quick Guide* outlines basic features and step-by-step instructions for common functions.
- *Acoustic Output Tables*: Included on the USB media, it contains information about acoustic output and patient-applied part temperatures.
- *Medical Ultrasound Safety*: Included on the USB media, it contains information on bioeffects and biophysics, prudent use, and implementing ALARA (as low as reasonably achievable).
- *Shared Roles for System and Data Security*: Included on the USB media, it contains guidelines to help you understand security recommendations for your Philips product and information on Philips' efforts to help you prevent security breaches.
- *Using Ultrasound to Manage COVID-19 Related Lung and Cardiac Complications*: Included on the USB media, it contains imaging instructions and information pertinent to healthcare professionals engaged in the diagnosis and management of COVID-19 patients.
- *Collaboration Live User Manual*: Included on the USB media, it contains information about using the Collaboration Live platform on your ultrasound system.

You can find user information here:

www.philips.com/IFU

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Product Conventions

Your product uses certain conventions throughout the interface to make it easy for you to learn and use:

- Three unlabeled controls are used with the trackpad. Those controls, above the main trackpad, operate somewhat similarly to computer mouse buttons. The trackpad arbitration icon, at the bottom of the display, indicates the current functions of the trackpad controls. For more information, see “Trackpad” on page 162.
- Tabs along the top of the monitor display let you choose additional sets of setup options. Tabs along the top of the touch screen let you choose additional pages of controls.
- To type text into a text field, tap the field and use the touch-screen keyboard or, if the system is on an optional cart, use the retractable keyboard.
- To display a list, tap . To scroll through a list, tap the arrows at either end of the scroll bar, drag the scroll box up or down, or touch the trackpad with two fingers and move them up and down (see “Trackpad” on page 162).
- Controls on the control panel include buttons, touch slide controls, and a trackpad (see “Trackpad” on page 162). Press a button to activate or deactivate its function. You can disable press behavior for soft key controls (see “Disabling Press Behavior for Soft Key Controls” on page 166).
- Controls on the touch screen include buttons, soft-key knob labels, and sliders. To use a touch screen button, simply touch it. To use a touch screen knob label, touch the label and adjust the corresponding knob, which is directly below it on the control panel. If two knob labels are available for the knob, you must first touch the knob label that you want to adjust. To use a slider, swipe the slider button, or touch a location on the slider, to move the slider button. For more information, see “Touch Screen Controls” on page 157.
- Many tabs on the touch screen contain multiple pages of controls. To display the next page, place your finger on the touch screen and swipe to the left. To return to the previous page, place your finger on the touch screen and swipe to the right.
- Some areas of the display include chevrons . Selecting  displays or hides additional information, options, or fields.

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User Information Conventions

The user information for your product uses the following typographical conventions to assist you in finding and understanding information. Additionally, for information about the trackpad, see "Trackpad" on page 162 and "Trackpad Touch Gestures" on page 163.

- All procedures are numbered, and all subprocedures are lettered. You must complete steps in the sequence they are presented to ensure success.
- Bulleted lists indicate general information about a particular function or procedure. They do not imply a sequential procedure.
- Control names and menu items or titles are spelled as they are on the system, and they appear in bold text. Exceptions are the trackpad and the controls above it, which are unlabeled.
- Symbols appear as they appear on the system.
- The *pointer* is the cursor used to select elements on the display.
- *Point* means to position the tip of the pointer or cursor on an item on the display.
- *Tap* or *select* means to move the pointer to an object and tap the trackpad or the left trackpad control to "highlight" the object (such as an item in a list), or in the case of a check box or when selecting options, to fill the object. You can also tap to select, highlight, and manipulate some objects on the display. *Deselect* means tapping the object to remove the highlight or fill.
- *Right-tap* means to point at an item and then tap the right trackpad control.
- *Drag* means to place the pointer over an object and then press and hold the left trackpad control while moving your finger on the trackpad.
- *Hover* means to pause the pointer over an item on the display.
- *Touch* means to press a button on the touch screen, located above the control panel. You can also touch to select, highlight, and manipulate some objects on the touch screen.
- *Swipe* means to touch the touch screen with the tip of your finger and move your finger in a quick motion either to the left or to the right. This action displays an additional touch screen, if one is available.

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- In a procedure step, *use* followed by a control name means that the control location might vary depending on your system configuration and setups. For example, it may be a soft key in some instances but a touch screen control in others.
- The left side of the system is to your left as you stand in front of the system, facing the system. The front of the system is nearest to you as you operate it.
- Transducers and pencil probes both are referred to as transducers, unless the distinction is important to the meaning of the text.

Information that is essential for the safe and effective use of your product appears throughout your user information as follows:

WARNING

Warnings highlight information vital to the safety of you, the operator, and the patient.

CAUTION

Cautions highlight ways that you could damage the product and consequently void your warranty or service contract or ways that you could lose patient or system data.

NOTE

Notes bring your attention to important information that will help you operate the product more effectively.

Upgrades and Updates

Philips is committed to innovation and continued improvement. Upgrades may be announced that consist of hardware or software improvements. Updated user information will accompany those upgrades.

Customer Comments

If you have questions about the user information, or you discover an error in the user information, in the USA, please call Philips at 800-722-9377; outside the USA, please call your local customer service representative. You can also send e-mail to the following address:

techcomm.ultrasound@philips.com

Supplies and Accessories

To order transducer covers, bite guards, biopsy guides, and other supplies, contact CIVCO Medical Solutions:

CIVCO Medical Solutions

102 First Street South, Kalona, IA 52247-9589

Telephone: 800-445-6741 (USA and Canada), +1 319-248-6757 (International)

Fax: 877-329-2482 (USA and Canada), +1 319-248-6660 (International)

E-mail: info@civco.com

Internet: www.civco.com

You can order ECG trunk cables, lead sets, and electrodes from any supplier. Order only shielded AAMI or IEC ECG trunk cables and lead sets, and AAMI or IEC electrodes.

To order the items listed in the following table, see the referenced information and then contact your Philips representative.

System Supplies or Accessories

Item	Additional Information
Barcode scanner	See "Barcode Scanner" on page 204.
Cables	See "Approved Cables for Electromagnetic Compliance" on page 88.
Foot switch	See "Connecting the Foot Switch" on page 124.

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Item	Additional Information
Printers	See “External Printers” on page 126.
USB storage devices	See “USB Storage Devices” on page 202.
Transducers	See “Indications for Use and Supporting Transducers” on page 108.

Customer Service

Customer service representatives are available worldwide to answer questions and to provide maintenance and service. Please contact your local Philips representative for assistance. You can also contact the following office for referral to a customer service representative, or visit this "Contact Us" website:

www.healthcare.philips.com/main/about/officelocator/index.wpd

Philips Ultrasound LLC
22100 Bothell Everett Hwy
Bothell, WA 98021-8431
USA
800-722-9377

The Philips Customer Services Portal provides an online platform that helps you manage your Philips products and services across all modalities:

https://www.philips.com/customer-services-portal

Regulatory Representatives

Australian Sponsor

Philips Electronics Australia Ltd
65 Epping Road
North Ryde NSW 2113
Australia

Brazilian Representative

Responsável Técnico
Thiago Medeiros de Abreu
CREA/SP: 5070149021

Detentor do Registro
Philips Medical Systems Ltda.
Av. Marcos Penteado de Ulhoa Rodrigues, 401 Setor Parte 39 – Tamboré
Barueri/SP, Brasil – CEP 06460-040

Malaysian Authorized Representative

Wakil Diberi Kuasa:
Philips Malaysia Sdn. Berhad
196001000018 (3690-P)
Level 9, Menara Axis
2 Jalan 51A/223
46100 Petaling Jaya
Selangor Darul Ehsan, Malaysia

Telephone: 03-7965 7488

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Recycling, Reuse, and Disposal

Philips is concerned with helping protect the natural environment and helping ensure continued safe and effective use of this system through proper support, maintenance, and training. Philips designs and manufactures equipment in compliance with relevant guidelines for environmental protection. As long as the equipment is properly operated and maintained, it presents no risk to the environment. However, the equipment may contain materials that could be harmful to the environment if disposed of incorrectly. Use of such materials is essential for the implementation of certain functions and for meeting certain statutory and other requirements.

The European Union Directive on Waste Electrical and Electronic Equipment (WEEE) requires producers of electrical and electronic equipment to provide reuse and treatment information for each product. This information is provided in a Philips Recycling Passport. Such recycling passports for Philips ultrasound systems can be requested on this website:

www.philips.com/a-w/about/sustainability/sustainable-planet/circular-economy/product-recycling-services

Recycling, reuse, and disposal information in this document is directed mainly at the entity with legal authority over the equipment. Operators are usually uninvolved in disposal, except in the case of certain batteries.

Passing Your System to Another User

If you pass this system to another user who will use the system for its intended purpose, then pass it on in its complete state. Particularly, ensure that all the product-support documentation, including all instructions for use, are passed on to the new user. Make the new user aware of the support services that Philips provides for installing, commissioning, and maintaining the system, and for comprehensive operator training. Existing users must remember that passing on medical electrical equipment to new users may present serious technical, medical, privacy, and legal risks. The original user may remain liable, even if the equipment is given away.

Philips strongly advises you to seek advice from your local Philips representative before agreeing to pass on any equipment.

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After you pass the system to a new user, you might still receive important safety-related information, such as bulletins and medical device corrections and removals. In many jurisdictions the original owner has a clear duty to communicate such safety-related information to new users. If you are unable or unprepared to do this, inform Philips about the new user, so that Philips can provide the new user with safety-related information.

Final Disposal of Your System

Final disposal is when you dispose of the system in such a way that it can no longer be used for its intended purposes.

WARNING

Do not dispose of this system (or any parts of it) with industrial or domestic waste. The system may contain materials such as lead, tungsten, or oil, or other hazardous substances that can cause serious environmental pollution. The system also contains privacy-sensitive information, which should be properly removed (scrubbed). Philips advises you to contact your Philips service organization before disposing of this system.

Philips gives support for the following:

- Recovery of useful parts
- Recycling of useful materials by competent disposal companies
- Safe and effective disposal of equipment

For advice and information, contact your Philips service organization, or see the following website:

www.healthcare.philips.com/us/about/sustainability/recycling

Perchlorate Material

In this system, perchlorate material is present in lithium coin cells or batteries. Special handling may apply to those items. For more information, see this website:

www.dtsc.ca.gov/hazardouswaste/perchlorate

Discarding Batteries

Batteries should be discarded if there are visual signs of damage. Batteries should be discarded in an environmentally safe manner. Properly dispose of batteries according to local regulations.

WARNING

Do not disassemble, puncture, or incinerate batteries. Be careful not to short the battery terminals, because that could result in a fire hazard.

WARNING

Use caution when handling, using, and testing the batteries. Do not short circuit, crush, drop, mutilate, puncture, apply reverse polarity, expose to high temperatures, or disassemble. Misuse or abuse could cause physical injury.

WARNING

If electrolyte leakage occurs, wash your skin with large amounts of water, to prevent skin irritation and inflammation.

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2 Safety

Read this information before using your ultrasound system. It applies to the ultrasound system, transducers, recording devices, and any optional equipment. This section covers only general safety information. Safety information that applies only to a specific task is included in the procedure for that task.

This device is intended for use by, or by the order of, and under the supervision of a licensed physician qualified to direct the use of the device.

Report any serious safety incident that occurs in relation to the ultrasound system to Philips and to the competent authority of the country in which the user and patient are established.

WARNING

Warnings highlight information vital to the safety of you, the operator, and the patient.

CAUTION

Cautions highlight ways that you could damage the product and consequently void your warranty or service contract or ways that you could lose patient or system data.

Basic Safety

WARNING

Do not use the system for any application until you have read, understood, and know all the safety information, safety procedures, and emergency procedures contained in this "Safety" section. Operating ultrasound systems without a proper awareness of safe use could lead to fatal or other serious personal injury.

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WARNING

Do not use the system for any application until you are adequately and properly trained on ultrasound techniques. Sonography training and clinical procedures are not included in the system user information. If you are unsure of your ability to use ultrasound techniques safely and effectively, do not use the system. Operating ultrasound systems without proper and adequate training could lead to fatal or other serious personal injury.

WARNING

Do not operate the system with patients unless you have an adequate understanding of its capabilities and functions. Using the system without such understanding may compromise the system's effectiveness and the safety of the patient, you, and others.

WARNING

Never attempt to remove, modify, override, or frustrate any safety device on the system. Interfering with safety devices could lead to fatal or other serious personal injury.

WARNING

Consult current peer-reviewed medical literature, professional guidelines and protocols, and medical experts regarding appropriate techniques, potential complications, and awareness of hazards prior to using ultrasound devices. Adhere to current evidence-based practices and standard-of-care methods in the use of ultrasound devices to prevent or reduce the occurrence of injuries to patients and users.

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Electrical Safety

This equipment has been verified by a recognized third-party testing agency as a Class I device with Type BF and Type CF isolated patient-applied parts, and Type B non-isolated patient-applied parts. (The system meets the safety standard recommended by U.S. Food and Drug Administration (FDA).) For maximum safety, observe these warnings and cautions:

WARNING

Do not connect the ultrasound system to the same circuit used for life-support devices.

WARNING

Shock hazards may exist if this system, including all externally mounted recording and monitoring devices, is not properly grounded. Protection against electrical shock is provided by grounding the chassis with a three-wire cable and plug. The system must be plugged into a grounded outlet. The grounding wire must not be removed or defeated.

WARNING

Shock hazards may exist if this system (when mounted on its cart or plugged directly into an AC power source), including all externally mounted recording and monitoring devices, is not properly grounded. Protection against electrical shock is provided by grounding the cart or the AC power adapter with a three-wire cable and plug, which must be plugged into a grounded outlet. The grounding wire must not be removed or defeated.

WARNING

Use only the AC adapter supplied with your system.

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WARNING

To avoid the risk of electrical shock, never connect the system power cord to a power strip or an extension cord. When using the power cord, always connect it directly to a grounded wall outlet.

WARNING

Use only Type BF and Type CF transducers for invasive procedures. Type B transducers are insufficiently electrically isolated for invasive use.

WARNING

Do not remove the protective covers on the system; hazardous voltages are present inside. Covers must be in place while the system is in use. All internal adjustments and replacements must be made by your authorized service representative.

WARNING

Do not operate this system in the presence of flammable gases or anesthetics. Explosion can result. The system is *not* compliant in AP/APG environments as defined by IEC 60601-1.

WARNING

To avoid risk of electrical shock hazards, always inspect the transducer before use. Check the face, housing, and cable before use. Do not use if the face is cracked, chipped, or torn; the housing is damaged; or the cable is abraded.

WARNING

To avoid risk of electrical shock hazards, always turn off the system, disconnect the main power cord from the wall outlet, remove the system battery, and wait at least 30 seconds before cleaning or servicing the system.

WARNING

All patient-contact devices, such as transducers, pencil probes, and ECG leads not specifically indicated as defibrillation-proof, must be removed from patient contact before application of a high-voltage defibrillation pulse. See **"Defibrillators" on page 40****.**

WARNING

During transesophageal echocardiographic (TEE) procedures, either remove the TEE transducer from the patient or disconnect the TEE transducer from the system immediately following image acquisition.

WARNING

Ultrasound equipment in normal operation, as with other medical electronic diagnostic equipment, uses high-frequency electrical signals that can interfere with pacemaker operation. Though the possibility of interference is slight, be alert to this potential hazard and stop system operation immediately if you note interference with a pacemaker.

WARNING

When using additional peripheral equipment powered from an electrical source other than the ultrasound system, the combination is considered to be a medical system. It is your responsibility to comply with IEC 60601-1 and test the system to those requirements. If you have questions, contact your Philips representative.

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WARNING

Do not use nonmedical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the nonmedical peripherals receive power from an isolated power outlet on the Philips ultrasound system, or from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601-1.

WARNING

The system and patient-applied parts meet the standard IEC 60601-1. Applied voltages exceeding the standard, although unlikely, may result in electrical shock to the patient or operator.

WARNING

Connection of optional devices not supplied by Philips could result in electrical shock. When such optional devices are connected to your ultrasound system, ensure that the total system earth leakage current does not exceed 500 µA.

WARNING

To avoid risk of electrical shock, do not use any transducer that has been immersed beyond the specified cleaning or disinfection level.

WARNING

To avoid risks of electrical shock and fire hazards, inspect the system power cord and plug regularly. Ensure that they are not damaged in any way.

WARNING

Do not drape the power cord over any of the cable hooks or the handle on the system cart. Damage to the cord or power receptacle unit can occur if the cart is raised.

WARNING

Electrosurgical units (ESUs) and other devices intentionally introduce radio frequency electromagnetic fields or currents into patients. Because imaging ultrasound frequencies are coincidentally in the radio frequency range, ultrasound transducer circuits are susceptible to radio frequency interference. While an ESU is in use, severe noise interferes with the black-and-white image and completely obliterates the color image.

WARNING

To avoid risk of a burn hazard, do not use transducers with high-frequency surgical equipment. A burn hazard may result from a defect in the high-frequency surgical neutral electrode connection.

WARNING

Concurrent failures in an electrosurgical unit (ESU) or other device and in the outer layer of the TEE transducer shaft can cause electrosurgical currents to return along the transducer conductors. This could burn the patient, and the ultrasound system and the transducer could also be damaged. Be aware that a disposable transducer cover provides no protective electrical insulation at ESU frequencies.

WARNING

Using cables, transducers, and accessories other than those specified for use with the system may result in increased emissions from, or decreased immunity of, the system.

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WARNING

Shock hazards may exist if you service the system with the batteries installed.

Defibrillators

Observe the following warnings when a defibrillation is required while using the ultrasound system.

WARNING

Before defibrillation, always remove all patient-applied parts from the patient; however, defibrillation-proof ECG leads may remain connected. The system will reestablish normal physio operation within 8 seconds after the application of a defibrillation pulse.

WARNING

Before defibrillation, always disconnect invasive transducers that remain in contact with the patient from the system.

WARNING

A disposable transducer cover provides no protective electrical insulation against defibrillation.

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WARNING

A small hole in the outer layer of the transducer opens a conductive path to grounded metal parts of the transducer. The secondary arcing that could occur during defibrillation could cause patient burns. The risk of burns is reduced, but not eliminated, by using an ungrounded defibrillator.

Use defibrillators that do not have grounded patient circuits. To determine whether a defibrillator patient circuit is grounded, see the defibrillator service guide, or consult a biomedical engineer.

Fire Safety

Fire safety depends on fire prevention, isolating the cause, and extinguishing the fire. If you see evidence of smoke or fire, disconnect system power. Observe the following warnings when using the system.

WARNING

On electrical or chemical fires, use only extinguishers that are specifically labeled for those purposes. Using water or other liquids on an electrical fire can lead to fatal or other serious personal injury. Before attempting to fight a fire, if it is safe to do so, attempt to isolate the product from electrical and other supplies, to reduce the risk of electrical shock.

WARNING

Use of electrical products in an environment for which they were not designed can lead to fire or explosion. Fire regulations for the type of medical area being used should be fully applied, observed, and enforced. Fire extinguishers should be available for both electrical and nonelectrical fires.

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WARNING

Damage to lithium-ion batteries may result in fire.

Mechanical Safety

A list of precautions related to mechanical safety follows; observe these precautions when using the system on or off an optional cart.

WARNING

Be aware of the wheels on the system cart, especially when moving the system. The system could cause injury to you or others if it rolls over feet or into shins. Use caution when going up or down ramps.

WARNING

When attempting to overcome an obstacle, do not push the system from either side with excessive force, which could cause the system to tip over.

WARNING

Position external peripheral devices away from the system. Ensure that they are secure. Do not stack them on the system.

WARNING

When positioning the monitor and touch screen, move each carefully to avoid pinching hands or extremities.

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WARNING

Never park the system on an incline.

WARNING

Use caution when going up or down inclines. Improperly handled, the system can cause injury to you or others.

WARNING

If you park the system on a floor that is tilted 10 degrees or more and set the caster brakes, one of the braked casters might not be touching the floor, which can cause the system to move.

WARNING

The brakes are intended as a convenience. To increase cart security, use wheel chocks when the system is parked.

WARNING

To avoid injury, Philips recommends against lifting the system cart.

WARNING

When transporting the system, secure the system so that it cannot roll or tip. Engage the caster locks, and use wheel chocks and restraining straps. Do not attempt to hold the system in place manually during transport. Never strap or secure the system at any point on the control panel or monitor.

WARNING

To avoid damaging the monitor, follow the mechanical safety guidelines provided in this manual. If the monitor is damaged, contact your authorized service representative before using the system.

WARNING

If system operation is abnormal after you move or transport the system, contact your Philips representative immediately. System components are installed securely and can withstand considerable shock, but excessive shock can cause a system failure.

CAUTION

Ensure that the cables for all patient-applied parts are secure before moving the system. Use the cable management system to ensure that transducer cables are protected from damage.

CAUTION

Do not roll the system over transducer cables or power cables.

Equipment Protection

Follow these precautions to protect your system:

WARNING

To avoid improper operation, do not place the system adjacent to nor stacked with other equipment. If it becomes necessary to stack the system with or place it adjacent to other equipment, verify normal operation before use.

CAUTION

Excessive bending or twisting of cables on patient-applied parts may cause failure or intermittent operation of the system. Do not roll the system over cables, which may damage them.

CAUTION

Improper cleaning, disinfection, or sterilization of a patient-applied part may cause permanent damage. For cleaning, disinfection, and sterilization instructions, see *Care and Cleaning of Ultrasound Systems and Transducers* and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*.

CAUTION

Do not submerge the transducer connector in solution. The cables and transducer bodies are liquid-tight, but the connectors are not.

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CAUTION

Do not use abrasive cleaners, or acetone, MEK, paint thinner, or other strong solvents on the system, peripherals, or transducers.

CAUTION

For optimal performance, connect your ultrasound system to a circuit dedicated solely for the system. Do not connect life-support devices to the same circuit as the ultrasound system.

CAUTION

If systems, transducers, and peripherals have been in an environment below 10°C (50°F), allow them to reach room temperature before connecting or turning them on. Allow 24 hours for complete normalization. Otherwise, condensation inside the devices could cause damage. If the device was only briefly exposed to temperatures below 10°C (50°F), then the time required for the device to return to room temperature could be significantly less than 24 hours.

CAUTION

To avoid damaging the flat-panel display in the monitor, do not store the system where the ambient temperature exceeds 65°C (149°F).

CAUTION

To avoid damaging the touch screen, do not raise it above the maximum 60-degree angle.

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Product Compatibility

Do not use your system in combination with other products or components, unless Philips expressly recognizes those other products or components as compatible. For information about such products and components, contact your Philips representative.

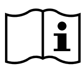
Changes and additions to the system should be made only by Philips or by third parties expressly authorized by Philips to do so. Such changes and additions must comply with all applicable laws and regulations that have the force of law within the jurisdictions concerned, and best engineering practices.

WARNING

System changes and additions that are made without the appropriate training or by using unapproved spare parts may void the warranty. As with all complex technical products, maintenance by unqualified persons or using unapproved spare parts carries serious risks of system damage and personal injury.

Symbols

The International Electrotechnical Commission (IEC) has established a set of symbols for medical electronic equipment that classify a connection or warn of potential hazards. The following symbols may be used on your product, its accessories, or its packaging.

Symbol	Standards and Reference	Reference Description	Additional Information
Safety			
	ISO 15223-1, Symbol 5.4.4 ISO 7000-0434A	Caution (ISO 7000-0434A).	--
	ISO 15223-1, Symbol 5.4.3 ISO 7000-1641	Consult instructions for use.	--

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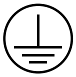
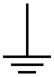
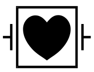
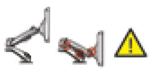
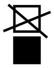
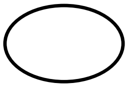
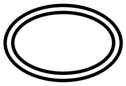
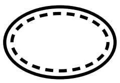
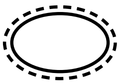
Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 7010, Symbol M002	Refer to instruction manual/booklet.	--
	IEC 60417, Symbol 5019	Protective Earth; Protective ground.	--
	IEC 60417, Symbol 5017	Earth; ground.	--
	IEC 60417, Symbol 5021	Equipotentiality.	--
	IEC 60417, Symbol 5840	Type B applied part.	Non-isolated patient connection.
	IEC 60878, Symbol 5333 IEC 60417, Symbol 5333	Type BF applied part.	Isolated patient connection.
	IEC 60417, Symbol 5335	Type CF applied part.	Isolated patient connection for applied part intended for intraoperative use, including direct cardiac application and contact with major vessels.
	IEC 60417, Symbol 5334	Defibrillation-proof Type BF applied part.	--
	IEC 60417, Symbol 5336	Defibrillation-proof Type CF applied part.	--

Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.4.2 ISO 7000-1051	Do not reuse.	--
	ISO 7010, Symbol P017	No pushing.	Warns of system overbalance due to external force.
	IEC 60417, Symbol 5036	Dangerous Voltages.	Appears adjacent to high-voltage terminals, indicating the presence of voltages greater than 1,000 Vac (600 Vac in the United States).
	IEC 62570	MR Unsafe.	System is MR unsafe and presents a projectile hazard. Keep outside of the MRI scanner room. When color reproduction is not practical, the icon may be printed in black and white.
Rx only	--	--	Rx Only. (USA federal law restricts this device to sale by or on the order of a physician.)
	--	--	Indicates a hazard to patients with pacemakers. Do not place field generator within 200 mm (8 in) of a patient with a pacemaker.
	--	--	Indicates a possible pinch hazard when positioning the monitor.
	ISO 7010, Symbol W024	Warning: Crushing of hands.	--

Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	Warns that the system should not be used stacked with other equipment. If the system is used stacked with or adjacent to other equipment, verify normal operation before use.
	ISO 15223-1, Symbol 5.2.8 ISO 7000-2606	Do not use if package is damaged.	--
	--	--	Consult the electronic instructions for use (eIFU).
	ISO 15223-1, Symbol 5.2.7 ISO 7000-2609	Non-sterile.	--
	ISO 15223-1, Symbol 5.2.3 ISO 7000-2501	Sterilized using ethylene oxide.	--
	ISO 15223-1, Symbol 5.2.11	Single sterile barrier system.	--
	ISO 15223-1, Symbol 5.2.12	Double sterile barrier system.	--
	ISO 15223-1, Symbol 5.2.13	Single sterile barrier system with protective packaging inside.	--
	ISO 15223-1, Symbol 5.2.14	Single sterile barrier system with protective packaging outside.	--

Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.1.4 ISO 7000-2607	Use-by date.	--
	IEC 60417, Symbol 5134	Electrostatic sensitive devices.	Identifies ESD (electrostatic-discharge) sensitivity of a connector that is not tested as specified in IEC 60601-1-2. Do not touch exposed connector pins. Touching exposed pins can cause electrostatic discharge, which can damage the product.
	IEC 60417, Symbol 5140	Non-ionizing electromagnetic radiation.	Indicates that interference may occur in the vicinity of equipment marked with this symbol (IEC 60601-1-2).
Environmental			
IPX1	IEC 60529	Degrees of protection provided by enclosures (transducers).	Indicates that the device is protected against the effects of vertically falling water.
IPX4	IEC 60529	Degrees of protection provided by enclosures (foot-operated device).	Indicates that the device is protected against the effects of splashing liquids.
IPX7	IEC 60529	Degrees of protection provided by enclosures (foot-operated devices).	Indicates that the device is protected against the effects of immersion.
IPX8	IEC 60529	Degrees of protection provided by enclosures (foot-operated device or transducer).	Indicates that the device is protected against the effects of immersion for up to 60 minutes.

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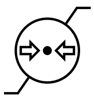
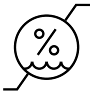
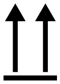
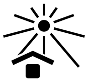
Symbol	Standards and Reference	Reference Description	Additional Information
IP44	IEC 60529	Degrees of protection provided by enclosures.	Indicates that the equipment inside the enclosure is protected against ingress of solid foreign objects having a diameter of 1.0 mm and greater. Indicates that water splashed against the enclosure from any direction shall have no harmful effect.
IP47	IEC 60529	Degrees of protection provided by enclosures (foot-operated device or transducer).	Indicates that the equipment inside the enclosure is protected against ingress of solid foreign objects having a diameter of 1.0 mm and greater. Indicates that the device is protected against the effects of immersion.
IP67	IEC 60529	Degrees of protection provided by enclosures.	Indicates that the equipment inside the enclosure is protected against ingress of dust and effects of immersion for up to 30 minutes at 1 m of submersion.
	IEC 60417, Symbol 5957	For indoor use only.	--
	ISO 15223-1, Symbol 5.3.7 ISO 7000-0632	Temperature limit.	Indicates the temperature range (noncondensing) for transport and storage. Does not apply to media.
	ISO 15223-1, Symbol 5.3.9 ISO 7000-2621	Atmospheric pressure limitation.	Atmospheric pressure range for transport and storage.

Symbol	Standards and Reference	Reference Description	Additional Information
	ISO 15223-1, Symbol 5.3.8 ISO 7000-2620	Humidity limitation.	The relative humidity range (noncondensing) for transport and storage.
	ISO 7000, Symbol 0623	This way up.	Points toward the side of the shipping crate that should be kept facing up.
	ISO 15223-1, Symbol 5.3.4 ISO 7000-0626	Keep dry.	--
	ISO 15223-1, Symbol 5.3.1 ISO 7000-0621	Fragile, handle with care.	--
	ISO 15223-1, Symbol 5.3.2 ISO 7000-0624	Keep away from sunlight.	--

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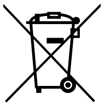
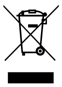
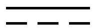
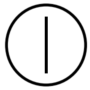
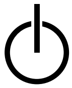
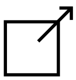
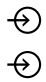
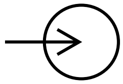
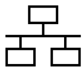
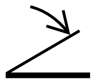
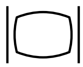
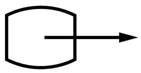
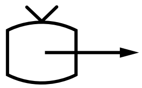
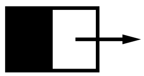
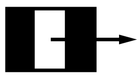
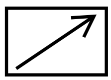
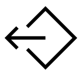
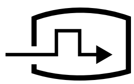
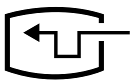
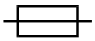
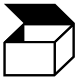
Symbol	Standards and Reference	Reference Description	Additional Information
	EN 50419:2006 WEEE Directive 2002/96/EC	WEEE symbol. Indicates the need for separate collection for electrical and electronic equipment in compliance with the Waste Electrical and Electronic Equipment (WEEE) Directive. When accompanied by Pb or Hg, components of the device may contain lead or mercury, respectively, which must be recycled or disposed of in accordance with local, state, or federal laws.	--
	--	Product contains hazardous material. Dispose of properly. (Required by WEEE Directive; see EN 50419.)	--
	IEC 60878, Symbol 1135 ISO 7000-1135	General symbol for recovery/recyclable.	Do not throw away. Dispose of in accordance with local, state, or federal laws.
Connectors and Ports			
	IEC 60417, Symbol 5032	Alternating current.	--

Symbol	Standards and Reference	Reference Description	Additional Information
	IEC 60417, Symbol 5031	Direct current.	--
	IEC 60417, Symbol 5010	"ON"/"OFF" (Push-Push).	
	IEC 60417, Symbol 5009	Stand-by.	On/Off control with Stand-by.
	--	--	On a two-position power switch, represents On (I) and Off (O).
	--	--	Connection for a pencil probe.
	--	--	Connection for a pencil probe.
	--	--	Connection for a transducer.
	--	--	Connection for ECG and physio leads.
	--	--	Connection for ECG and physio leads.
	--	--	Print remote output.

Symbol	Standards and Reference	Reference Description	Additional Information
	-	-	Input port for audio left/right, VHS/ S-VHS, microphone, CD, or DVD.
	--	--	Output port for audio left/right, VHS/ S-VHS, video patient monitor, black-and-white printer, or interlaced RGB output port.
	IEC 60417, Symbol 5034	Input.	--
	ISO 7000, Symbol 3650	USB Port.	--
	--	FireWire (IEEE 1394) input/ output port.	--
	IEC 60878 Symbol 5988	Computer Network.	Ethernet connection.
	IEC 60878, Symbol 5850	Serial Interface.	RS-232 serial port.
	--	--	System microphone.
AUX POWER ISOLATE OUTPUT	--	--	Isolated auxiliary power provided for connection of Philips-approved remote accessories.

Symbol	Standards and Reference	Reference Description	Additional Information
	IEC 60417, Symbol 5114	Foot switch.	--
	IEC 60878, Symbol 5051	Television Monitor.	SVGA, DVI-I, DisplayPort, or HDMI connection.
	IEC 60878, Symbol 5529A	Video Output.	S-Video connection.
	--	--	Video output. S-Video connection.
	--	--	B/W Composite video output connection.
	--	--	Color composite video output connection.
	IEC 60878, Symbol 0093	Remote Control.	Video print trigger connection.
	--	--	VGA or parallel output port.
 	--	--	DVI video output receptacle.

Symbol	Standards and Reference	Reference Description	Additional Information
	IEC 60417, Symbol 5016	Fuse.	Identifies fuse boxes or their locations. For continued protection from fire and shock, replace fuses only with fuses of the same type and rating.
Product Data Identifiers			
	--	--	Identifies the total mass of the system, including its safe working load, in kilograms. Indicates compliance with IEC 60601-1, Cl. 7.2.21.
	IEC 60878, Symbol 2794 ISO 7000-2794	Packaging unit.	--
GMDN	--	--	Global Medical Device Nomenclature Code.
GTIN	--	--	Global Trade Item Number.
LOT	ISO 15223-1, Symbol 5.1.5 ISO 7000-2492	Batch code.	--
MD	--	--	Indicates that the item is a medical device.
MOD	--	--	Model name for the device.

Symbol	Standards and Reference	Reference Description	Additional Information
#	--	--	Model number for the device and configurations.
REF	ISO 15223-1, Symbol 5.1.6 ISO 7000-2493	Catalog Number.	--
SH	--	--	System hardware.
SN	ISO 15223-1, Symbol 5.1.7 ISO 7000-2498	Serial Number.	--
SVC	--	--	Service part number / field-replaceable unit (FRU) number.
UDI	--	--	Unique Device Identifier.
UPN	--	--	Universal part number.
	--	--	Unique Device Identifier, 2D barcode.
	ISO 15223-1, Symbol 5.1.3 ISO 7000-2497	Date of Manufacture.	--
	ISO 15223-1, Symbol 5.1.1 ISO 7000-3082	Manufacturer.	--

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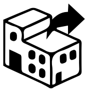
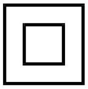
Symbol	Standards and Reference	Reference Description	Additional Information
	IEC 60417	Country of Manufacture.	--
	ISO 7000-3724	Distributor.	--
	ISO 7000-3725	Importer.	--
Regulatory Compliance			
	IEC 60878, Symbol 5172	Class II Equipment.	--
	--	--	UL (Underwriters Laboratories) classification symbol.
Complies with IMDA Standards DA102408	--	--	Indicates that the electrical and electronic equipment is in compliance with Infocomm Media Development Authority (IMDA) Standards.
	--	--	With an identification code (for example, 2ATC9-PHC-11AC1), indicates that the system uses an embedded, FCC-approved wireless adapter.
	--	--	With an identification code (for example CCAI15LP0780T9), indicates that the system uses an embedded NCC-approved (Taiwan) wireless adapter.

Symbol	Standards and Reference	Reference Description	Additional Information
	--	--	CSA (CSA International) classification symbol.
CE	European Commission Medical Device Directive 93/42/EEC 2007/47/EC EU MDR 2017/745, Article 20, Annex 5	CE Mark of Conformity	--
CE 0086	European Commission Medical Device Directive 93/42/EEC 2007/47/EC EU MDR 2017/745, Article 20, Annex 5	CE0086 - CE Mark of Conformity	--
CE 2797	European Commission Medical Device Directive 93/42/EEC 2007/47/EC EU MDR 2017/745, Article 20, Annex 5	CE2797 - CE Mark of Conformity	--
EC REP	ISO 15223-1, Symbol 5.1.2	Authorized Representative in the European community.	--
EAC	--	--	Customs Union Mark of Conformity (EurAsian Conformity Mark).
50	--	--	Chinese Environmentally Friendly Use Period symbol.

Symbol	Standards and Reference	Reference Description	Additional Information
UA.TR.116	--	--	Indicates that the system conforms with the Ukrainian Scientific Institute of Certification (UA.TR.116).
	--	--	Australian and New Zealand (RCM) Regulatory Compliance Mark indicates compliance with electrical safety, EMC, EME, and telecommunications requirements.
	--	--	KC (Korea Certification) mark for electrical and electronic equipment.
Segurança SGS OCP 0040	--	--	INMETRO mark as issued by SGS. Indicates third-party approval in Brazil.
Segurança TÜV Rheinland OCP 0004 INMETRO	--	--	INMETRO mark as issued by TUV. Indicates third-party approval in Brazil.

Biological Safety

This section contains information about biological safety and a discussion of the prudent use of the system.

A list of precautions related to biological safety follows; observe these precautions when using the system. For more information, see *Medical Ultrasound Safety* on your *User Information* USB media.

WARNING

Do not use the system if an error message on the display indicates that a hazardous condition exists. Note the error code, turn off power to the system, and call your authorized service representative.

WARNING

Do not use a system that exhibits erratic or inconsistent image updating. Discontinuities in the scanning sequence indicate a hardware failure that must be corrected before use.

WARNING

Perform ultrasound procedures prudently. Use the ALARA (as low as reasonably achievable) principle.

WARNING

Use only acoustic standoffs that have been approved by Philips. For information on ordering approved accessories, see **"Supplies and Accessories" on page 26****.**

WARNING

Verify the alignment of the biopsy guide before use. See the "Biopsy Guides" section.

WARNING

Verify the condition of the biopsy needle before use. Do not use a bent biopsy needle.

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WARNING

Transducer covers may contain natural rubber latex and talc. Those covers may cause allergic reactions in some individuals. See **"FDA Medical Alert on Latex" on page 65****.**

WARNING

In contrast studies using a high-MI acoustic field, capillary rupture, due to microbubble expansion within a capillary in an acoustic field, can cause extravasation. References: (1) Skyba, D.M., Price, R.J., Linka, A.Z., Skalak, T.C., Kaul, S. "Direct in vivo visualization of intravascular destruction of microbubbles by ultrasound and its local effects on tissue." ***Circulation*****, 1998; 98:290-293. (2) van Der Wouw, P.A., Brauns, A.C., Bailey, S.E., Powers, J.E., Wilde, A.A. "Premature ventricular contractions during triggered imaging with ultrasound contrast."** ***Journal of the American Society of Echocardiography*****, 2000; 13(4):288-94.**

WARNING

Preventricular contractions can be caused by the oscillations of microbubbles when a high-MI acoustic field is triggered in the heart at the end of systole. In a very sick patient with certain risk factors, theoretically, this could lead to ventricular fibrillation. Reference: van Der Wouw, P.A., Brauns, A.C., Bailey, S.E., Powers, J.E., Wilde, A.A. "Premature ventricular contractions during triggered imaging with ultrasound contrast." ***Journal of the American Society of Echocardiography*****, 2000; 13(4):288-94.**

WARNING

If a sterile transducer cover becomes compromised during an intraoperative application involving a patient with transmissible spongiform encephalopathy, such as Creutzfeldt-Jakob disease, follow the guidelines of the U.S. Centers for Disease Control and this document from the World Health Organization: WHO/CDS/ APH/2000/3, WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. The transducers for your system cannot be decontaminated using a heat process.

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WARNING

If the system becomes contaminated internally with bodily fluids carrying pathogens, you must immediately notify your Philips service representative. Components inside the system cannot be disinfected. In that case, the system must be disposed of as biohazardous material in accordance with local or federal laws.

WARNING

Select the correct application when starting an exam, and remain in that application throughout the exam. Some applications are for parts of the body that require lower limits for acoustic output.

WARNING

When used off the cart, the AC adapter and the system should not be placed on the floor or on a patient's bed. You can place it on a table or chair.

FDA Medical Alert on Latex

March 29, 1991, Allergic Reactions to Latex-Containing Medical Devices

Because of reports of severe allergic reactions to medical devices containing latex (natural rubber), the FDA is advising health care professionals to identify their latex sensitive patients and be prepared to treat allergic reactions promptly. Patient reactions to latex have ranged from contact urticaria to systemic anaphylaxis. Latex is a component of many medical devices, including surgical and examination gloves, catheters, intubation tubes, anesthesia masks, and dental dams.

Reports to the FDA of allergic reactions to latex-containing medical devices have increased lately. One brand of latex cuffed enema tips was recently recalled after several patients died as a result of anaphylactoid reactions during barium enema procedures. More reports of latex sensitivity have also been found in the medical literature. Repeated exposure to latex both in medical devices and in other consumer products may be part of the reason that the prevalence of latex sensitivity appears to be increasing. For example, it has been reported that 6% to 7% of surgical personnel and 18% to 40% of spina bifida patients are latex sensitive.

Proteins in the latex itself appear to be the primary source of the allergic reactions. Although it is not now known how much protein is likely to cause severe reactions, the FDA is working with manufacturers of latex-containing medical devices to make protein levels in their products as low as possible.

FDA’s recommendations to health professionals in regard to this problem are as follows:

- When taking general histories of patients, include questions about latex sensitivity. For surgical and radiology patients, spina bifida patients and health care workers, this recommendation is especially important. Questions about itching, rash or wheezing after wearing latex gloves or inflating a toy balloon may be useful. Patients with positive histories should have their charts flagged.
- If latex sensitivity is suspected, consider using devices made with alternative materials, such as plastic. For example, a health professional could wear a non-latex glove over the latex glove if the patient is sensitive. If both the health professional and the patient are sensitive, a latex middle glove could be used. (Latex gloves labeled “Hypoallergenic” may not always prevent adverse reactions.)
- Whenever latex-containing medical devices are used, especially when the latex comes in contact with mucous membranes, be alert to the possibility of an allergic reaction.
- If an allergic reaction does occur and latex is suspected, advise the patient of a possible latex sensitivity and consider an immunologic evaluation.
- Advise the patient to tell health professionals and emergency personnel about any known latex sensitivity before undergoing medical procedures. Consider advising patients with severe latex sensitivity to wear a medical identification bracelet.

The FDA is asking health professionals to report incidents of adverse reactions to latex or other materials used in medical devices. (See the October 1990 FDA Drug Bulletin.) To report an incident, contact the FDA Problem Reporting Program, MedWatch, at 1-800-332-1088, or on the Internet:

www.fda.gov/Safety/MedWatch/

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For a single copy of a reference list on latex sensitivity, write to: LATEX, FDA, HFZ-220, Rockville, MD 20857.

ALARA Education Program

The guiding principle for the use of diagnostic ultrasound is defined by the "as low as reasonably achievable" (ALARA) principle. The decision as to what is reasonable has been left to the judgment and insight of qualified personnel. No set of rules can be formulated that would be sufficiently complete to dictate the correct response to every circumstance. By keeping ultrasound exposure as low as possible, while obtaining diagnostic images, users can minimize ultrasonic bioeffects.

Since the threshold for diagnostic ultrasound bioeffects is undetermined, it is the sonographer's responsibility to control total energy transmitted into the patient. The sonographer must reconcile exposure time with diagnostic image quality. To ensure diagnostic image quality and limit exposure time, an ultrasound system provides controls that can be manipulated during the exam to optimize the results of the exam.

The ability of the user to abide by the ALARA principle is important. Advances in diagnostic ultrasound, not only in the technology but in the applications of that technology, have resulted in the need for more and better information to guide the user. The output display indices are designed to provide that important information.

There are a number of variables which affect the way in which the output display indices can be used to implement the ALARA principle. These variables include index values, body size, location of the bone relative to the focal point, attenuation in the body, and ultrasound exposure time. Exposure time is an especially useful variable, because it is controlled by the user. The ability to limit the index values over time supports the ALARA principle.

Applying ALARA

The decision as to the amount of acoustic output is, in the final analysis, up to the system operator. This decision must be based on the following factors: type of patient, type of exam, patient history, ease or difficulty of obtaining diagnostically useful information, and the potential localized heating of the patient due to transducer surface temperatures. Prudent use of the system occurs when patient exposure is limited to the lowest index reading for the shortest amount of time necessary to achieve acceptable diagnostic results.

Although a high index reading does not mean that a bioeffect is actually occurring, a high index reading should be taken seriously. Every effort should be made to reduce the possible effects of a high index reading. Limiting exposure time is an effective way to accomplish this goal.

There are several system controls that the operator can use to adjust the image quality and limit the acoustic intensity. These controls are related to the techniques that an operator might use to implement ALARA. These controls can be divided into three categories: direct, indirect, and receiver controls.

Acoustic Output Limits

Limits for Non-Ophthalmic Applications

- $I_{spta.3}$ < 720 mW/cm^2
- MI < 1.9
- TI < 6.0

Limits for Ophthalmic Applications

- $I_{spta.3}$ < 50 mW/cm^2
- MI < 0.23
- TI < 1.0

Direct Controls

Application selection and the output-power control directly affect acoustic intensity. There are different ranges of allowable intensity or output based on your selection. Selecting the correct range of acoustic intensity for the application is one of the first things that occurs in any exam. For example, peripheral vascular intensity levels are not recommended for fetal exams. Some systems automatically select the proper range for a particular application, while others require manual selection. Ultimately, the user has the responsibility for proper clinical use. The ultrasound system provides both automatic (default) settings and manual (user-selectable) settings.

Output power has direct impact on acoustic intensity. Once the application has been established, the power control can be used to increase or decrease the intensity output. The power control allows you to select intensity levels less than the established maximum. Prudent use dictates that you select the lowest output intensity that is consistent with good image quality.

Indirect Controls

The choice of imaging mode determines the nature of the ultrasound beam. 2D is a scanning mode; Doppler is a stationary or unscanned mode. A stationary ultrasound beam concentrates energy in a single location. A moving or scanned ultrasound beam disperses the energy over an area and the beam is concentrated on the same area for a fraction of the time as that of an unscanned mode.

Focus of the ultrasound beam affects the image resolution. To maintain or increase resolution at a different focus requires a variation in output over the focal zone. This variation of output is a function of system optimization. Different exams require different focal depths. Setting the focus at the proper depth improves the resolution of the structure of interest.

Transducer selection indirectly affects intensity. Tissue attenuation changes with frequency. The higher the transducer operating frequency, the greater the attenuation of the ultrasonic energy. A higher transducer operating frequency requires more output intensity to scan at a deeper depth. To scan deeper at the same output intensity, a lower transducer frequency is required. Using more gain and output beyond a point, without corresponding increases in image quality, can mean that a lower frequency transducer is needed.

Receiver Controls

Receiver controls are used by the operator to improve image quality. These controls have no effect on output. Receiver controls only affect how the ultrasound echo is received. These controls include gain, time gain compensation (TGC), dynamic range, and image processing. The important thing to remember, relative to output, is that receiver controls should be optimized before output is increased. For example, before increasing output, optimize gain to improve image quality.

An Example of Applying the ALARA Principle

An ultrasound scan of a patient's liver begins with selecting the appropriate transducer frequency. After selecting the transducer and the application, which are based on patient anatomy, adjustments to output power should be made to ensure that the lowest possible setting is used to acquire an image. After the image is acquired, adjusting the focus of the transducer, and then increasing the receiver gain to produce a uniform representation of the tissue follows. If an adequate image can be obtained with the increase in gain, then a decrease in output should be made. Only after making these adjustments should you increase output to the next level.

Having acquired the 2D display of the liver, Color can be used to localize blood flow. As with the 2D image display, gain and image processing controls must be optimized before increasing output.

In summary: Select the correct transducer frequency and application for the job; start with a low output level; and optimize the image by using focus, receiver gain, and other imaging controls. If the image is not diagnostically useful at this point, then increase output.

Additional Considerations

Ensure that scanning time is kept to a minimum, and ensure that only medically required scanning is performed. Never compromise quality by rushing through an exam. A poor exam may require a follow-up, which ultimately increases exposure time. Diagnostic ultrasound is an important tool in medicine, and like any tool, it should be used efficiently and effectively.

Output Display

The system output display comprises two basic indices: a mechanical index and a thermal index.

The thermal index further consists of the following indices: soft tissue (TIS), bone (TIB), and cranial bone (TIC). Only one of these is displayed at any time. Each transducer application has a default selection that is appropriate for that combination. The TIB, TIS, or TIC is continuously displayed over the range of 0.0 to maximum output, based on the transducer and application, in increments of 0.1. For the location of the output display, see "Image Area" on page 188.

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The application-specific nature of the default setting is also an important factor of index behavior. A default setting is a system control state that is preset by the manufacturer or the operator. The system has default index settings for the transducer application. The default settings are invoked automatically by the ultrasound system when power is turned on, when new patient data is entered into the system database, or when an application change occurs.

The decision as to which of the three thermal indices to display should be based on the following criteria:

- Appropriate index for the application: TIS is used for imaging soft tissue, TIB for a focus at or near bone, and TIC for imaging through bone near the surface, as in a cranial exam.
- Mitigating factors that might create artificially high or low thermal index readings: location of fluid or bone, or blood flow. For example, is there a highly attenuating tissue path so that the actual potential for local zone heating is less than the thermal index displays?
- Scanned modes versus unscanned modes of operation affect the thermal index. For scanned modes, heating tends to be near the surface; for unscanned modes, the potential for heating tends to be deeper in the focal zone.
- Always limit ultrasound exposure time. Do not rush the exam. Ensure that the indices are kept to a minimum and that exposure time is limited without compromising diagnostic sensitivity.

Mechanical Index (MI) Display

Mechanical bioeffects are threshold phenomena that occur when a certain level of output is exceeded. The threshold level varies, however, with the type of tissue. The potential for mechanical bioeffects varies with peak rarefactional pressure and ultrasound frequency. The MI accounts for these two factors. The higher the MI value, the greater the likelihood of mechanical bioeffects occurring. There is no specific MI value that means that a mechanical effect is actually occurring. The MI should be used as a guide for implementing the ALARA principle.

Thermal Index (TI) Displays

The TI informs the user about the conditions that exist that might lead to an increase in temperature at the surface of the body, within the body tissue, or at the point of focus of the ultrasound beam on bone. That is, the TI informs the user of the potential for temperature rise in body tissue. It is an estimate of temperature increase in body tissue with specific properties. The actual amount of any temperature rise is influenced by factors such as tissue type, vascularity, mode of operation, and others. The TI should be used as a guide for implementing the ALARA principle.

The bone thermal index (TIB) informs the user about potential heating at or near the focus after the ultrasound beam has passed through soft tissue or fluid; for example, at or near second- or third-trimester fetal bone.

The cranial bone thermal index (TIC) informs the user about the potential heating of bone at or near the surface; for example, cranial bone.

The soft tissue thermal index (TIS) informs the user about the potential for heating within soft homogeneous tissue.

Mechanical and Thermal Indices Display Precision and Accuracy

The MI and TI precision is 0.1 unit on the system.

The MI and TI display accuracy estimates for the system are given in *Acoustic Output Tables*, on your *User Information* USB media. Those accuracy estimates are based on the variability range of transducers and systems, inherent acoustic output modeling errors, and measurement variability, as discussed in this section.

The displayed values should be interpreted as relative information to help the system operator achieve the ALARA principle through prudent use of the system. The values should not be interpreted as actual physical values in interrogated tissue or organs. The initial data that is used to support the output display is derived from laboratory measurements based on the measurement standards in IEC 62359: Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields. The measurements are then put into algorithms for calculating the displayed output values.

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Many of the assumptions used in the process of measurement and calculation are conservative in nature. Overestimation of actual *in situ* intensity exposure, for the vast majority of tissue paths, is built into the measurement and calculation process. For example:

- The measured water tank values are derated using a conservative, industry standard, attenuation coefficient of 0.3 dB/cm-MHz.
- Conservative values for tissue characteristics were selected for use in the TI models. Conservative values for tissue or bone absorption rates, blood perfusion rates, blood heat capacity, and tissue thermal conductivity were selected.
- Steady State temperature rise is assumed in the industry standard TI models, and the assumption is made that the ultrasound transducer is held steady in one position long enough for steady state to be reached.

A number of factors are considered when estimating the accuracy of the displayed values: hardware variations, estimation algorithm accuracy, and measurement variability. Variability among transducers and systems is a significant factor. Transducer variability results from piezoelectric crystal efficiencies, process-related impedance differences, and sensitive lens-focusing parameter variations. Differences in system pulser voltage control and efficiencies is also a contributor to variability. There are inherent uncertainties in the algorithms used to estimate acoustic output values over the range of possible system operating conditions and pulser voltages. Inaccuracies in laboratory measurements are related to, among others, differences in hydrophone calibration and performance, positioning, alignment, and digitization tolerances, and variability among test operators.

The conservative assumptions of the output estimation algorithms of linear propagation, at all depths, through a 0.3 dB/cm-MHz attenuative medium is not considered in the accuracy estimate for the display. Neither linear propagation, nor uniform attenuation at the 0.3 dB/cm-MHz rate, occur in water tank measurements or in most tissue paths in the body. In the body, different tissues and organs have dissimilar attenuation characteristics. In water, there is almost no attenuation. In the body, and in particular, in water tank measurements, nonlinear propagation and saturation losses occur as pulser voltages increase.

Therefore, the display accuracy estimates are based on the variability range of transducers and systems, inherent acoustic output modeling errors, and measurement variability. Display accuracy estimates are not based on errors in, or caused by measuring according to, the IEC 62359 measurement standards, or the effects of nonlinear loss on the measured values.

Control Effects

Controls Affecting the Indices

As various system controls are adjusted, the TI and MI values may change. This will be most apparent as the output power control is adjusted; but other system controls affect the on-screen output values.

Power

The output power control affects the system acoustic output. Two real-time output values are on the display: TI and MI. They change as the system responds to power-control adjustments.

Other Control Effects

- **2D Depth:** An increase in 2D depth will automatically decrease the 2D frame rate. This will decrease the TI. The system may also automatically choose a deeper 2D focal depth. A change of focal depth may change the MI. The MI displayed is that of the zone with the largest MI value.
- **Application:** Acoustic output defaults are set when you select an application. Factory defaults vary with transducer, application, and mode. Defaults have been chosen below the FDA limits for intended use.
- **Imaging Mode Controls:** When a new imaging mode is selected, both the TI and MI may change to default settings. Each mode has a corresponding pulse repetition frequency and maximum intensity point. In combined or simultaneous modes, the TI is the sum of the contribution from the modes enabled, and the displayed MI is the largest of the MI values associated with each mode and focal zone enabled. The system will return to the previously selected state if a mode is turned off and then reselected.

Related Guidance Documents

For more information about ultrasonic bioeffects and related topics, see the following:

- "Bioeffects and Safety of Diagnostic Ultrasound." AIUM Report, January 28, 1993.

- "American Institute of Ultrasound in Medicine Bioeffects Consensus Report." *Journal of Ultrasound in Medicine*, Vol. 27, Issue 4, April 2008.
- Third Edition of the AIUM "Medical Ultrasound Safety" document, 2014. (A copy of this document is provided with each system.)
- "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" FDA, June 2019.
- IEC 62359: Ultrasonics - Field Characterization - Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields.
- WFUMB. "Symposium on Safety of Ultrasound in Medicine: Conclusions and Recommendations on Thermal and Non-Thermal Mechanisms for Biological Effects of Ultrasound." *Ultrasound in Medicine and Biology*, 1998: Vol. 24, Supplement 1.

Acoustic Output and Measurement

Since the initial use of diagnostic ultrasound, the possible human bioeffects from ultrasound exposure have been studied by various scientific and medical institutions. In October 1987, the American Institute of Ultrasound in Medicine (AIUM) ratified a report prepared by its Bioeffects Committee ("Bioeffects Considerations for the Safety of Diagnostic Ultrasound." *Journal of Ultrasound in Medicine*, Vol. 7, No. 9 Supplement, September 1988), sometimes referred to as the Stowe Report, which reviewed available data on possible effects of ultrasound exposure. Another report, “Bioeffects and Safety of Diagnostic Ultrasound,” dated January 28, 1993, provides more-current information.

The acoustic output for this system has been measured and calculated in accordance with IEC 62359: Ultrasonics - Field Characterization - Test Methods for the Determination of Thermal and Mechanical Indices Related to Medical Diagnostic Ultrasonic Fields, and the June 2019 FDA document "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers."

In Situ, Derated, and Water Value Intensities

All intensity parameters are measured in water. Since water absorbs very little acoustic energy, these water measurements represent a worst case value. Biological tissue does absorb acoustic energy. The true value of the intensity at any point depends on the amount and type of tissue and the frequency of the ultrasound that passes through the tissue. The intensity value in the tissue, *In Situ*, has been estimated by using the following formula:

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In Situ = Water $[e^{-0.23alf}]$

Where:

Variable	Value
In Situ	*In Situ* intensity value
Water	Water value intensity
e	2.7183
a	Attenuation factor
Tissue	a(dB/cm-MHz)
Amniotic Fluid	0.006
Brain	0.53
Heart	0.66
Kidney	0.79
Liver	0.43
Muscle	0.55
l	Skin line to measurement depth (cm)
f	Center frequency of the transducer/system/mode combination (MHz)

Since the ultrasonic path during an examination is likely to pass through varying lengths and types of tissue, it is difficult to estimate the true *in situ* intensity. An attenuation factor of 0.3 is used for general reporting purposes; therefore, the *In Situ* value which is commonly reported uses the formula:

In Situ derated = Water $[e^{-0.069lf}]$

Since this value is not the true *in situ* intensity, the term “derated” is used.

Mathematical derating of water based measurements using the 0.3 dB/cm-MHz coefficient may yield lower acoustic exposure values than would be measured in a homogenous 0.3 dB/cm-MHz tissue. This is true because nonlinearly propagating acoustic energy waveforms experience more distortion, saturation, and absorption in water than in tissue, where attenuation present all along the tissue path will dampen the buildup of nonlinear effects.

The maximum derated and the maximum water values do not always occur at the same operating conditions; therefore, the reported maximum water and derated values may not be related by the *in situ* (derated) formula. For example: A multi-zone array transducer that has maximum water value intensities in its deepest zone may have its largest derated intensity in one of its shallowest focal zones.

Conclusions Regarding Tissue Models and Equipment Survey

Tissue models are necessary to estimate attenuation and acoustic exposure levels *in situ* from measurements of acoustic output made in water. Presently, available models may be limited in their accuracy because of varying tissue paths during diagnostic ultrasound exposures and uncertainties in acoustical properties of soft tissues. No single tissue model is adequate for predicting exposures in all situations from measurements made in water, and continued improvement and verification of these models is necessary for making exposure assessments for specific applications.

A homogeneous tissue model with an attenuation coefficient of 0.3 dB/cm-MHz throughout the beam path is commonly used when estimating exposure levels. The model is conservative in that it overestimates the *in situ* acoustic exposure when the path between the transducer and the site of interest is composed entirely of soft tissue, because the attenuation coefficient of soft tissue is generally higher than 0.3 dB/cm-MHz. When the path contains significant amounts of fluid, as in many first- and second-trimester pregnancies scanned transabdominally, this model may underestimate the *in situ* acoustical exposure. The amount of underestimation depends on each specific situation. For example, when the beam path is longer than 3 cm and the propagation medium is predominantly fluid (conditions that may exist during transabdominal OB scans), a more accurate value for the derating term is 0.1 dB/cm-MHz.

Fixed-path tissue models, in which soft tissue thickness is held constant, sometimes are used to estimate *in situ* acoustical exposures when the beam path is longer than 3 cm and consists largely of fluid. When this model is used to estimate maximum exposure to the fetus during transabdominal scans, a value of 1 dB/cm-MHz may be used during all trimesters.

The maximum acoustic output levels of diagnostic ultrasound devices extend over a broad range of values:

- A survey of 1990-equipment models yielded mechanical index (MI) values between 0.1 and 1 at their highest output settings. Maximum MI values of approximately 2 are known to occur for currently available equipment. Maximum MI values are similar for real-time 2D, M-mode, PW Doppler, and Color flow imaging.
- Computed estimates of upper limits to temperature elevations during transabdominal scans were obtained in a survey of 1988 and 1990 PW Doppler equipment. The vast majority of models yielded upper limits less than 1°C and 4°C for exposures of first-trimester fetal tissue and second-trimester fetal bone, respectively. The largest values obtained were approximately 1.5°C for first-trimester fetal tissue and 7°C for second-trimester fetal bone. Estimated maximum temperature elevations given here are for a “fixed-path” tissue model and are for devices having Ispta (derated) values greater than 500 mW/cm^2. The temperature elevations for fetal bone and tissue were computed based on calculation procedures given in Sections 4.3.2.1 through 4.3.2.6 in "Bioeffects and Safety of Diagnostic Ultrasound" (AIUM Report, January 28, 1993).

Acoustic Output Tables

Acoustic output tables are in *Acoustic Output Tables*, on your *User Information* USB media.

Acoustic Measurement Precision and Uncertainty

All table entries have been obtained at the same operating conditions that give rise to the maximum index value in the first column of the tables. Measurement precision and uncertainty for power, pressure, intensity, and center frequency are listed in the following tables.

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NOTE

Per ISO/IEC Guide 98-3 (Uncertainty of Measurement - Part 3: Guide to the Expression of Uncertainty in Measurement), measurement precision on the following quantities is determined by making repeated measurements and stating the standard deviation as a percentage.

Acoustic Measurement Precision

Quantity	Precision (Percentage Standard Deviation)
Pr is the underated peak rarefactional pressure measured in megapascals (MPa).	Pr: 5.4%
P is the ultrasonic power in milliwatts (mW).	6.2%
f_{awf} is the center frequency in megahertz (MHz).	<1%
PII.3 is the derated spatial-peak pulse intensity integral in joules per square centimeter (J/cm^2).	PII.3: 3.2%

Acoustic Measurement Uncertainty

Quantity	Measurement Uncertainty (Percentage, 95% Confidence Value)
Pr is the underated peak rarefactional pressure measured in megapascals (MPa).	Pr: ±11.3%
P is the ultrasonic power in milliwatts (mW).	±10%
f_{awf} is the center frequency in megahertz (MHz).	±4.7%
PII.3 is the derated spatial-peak pulse intensity integral in joules per square centimeter (J/cm^2).	PII.3: +18% to -23%

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Operator Safety

The following issues and situations can affect operator safety when you are using an ultrasound system.

Repetitive Strain Injury

Repetitive ultrasound scanning has been associated with carpal tunnel syndrome (CTS) and related musculoskeletal problems. Some investigators have looked at a large population of sonographers with different types of equipment. An article, with feedback from a smaller geographical area, makes the following recommendations:

- Maintain your joints in optimum positions with a balanced posture while scanning.
- Allow frequent breaks to give soft tissue a chance to recuperate from awkward positions and repetitive movement.
- Avoid gripping the transducer with excessive force.

Repetitive Strain References

Pike, I., et al. "Prevalence of Musculoskeletal Disorders and Related Work and Personal Factors Among Diagnostic Medical Sonographers." *Journal of Diagnostic Medical Sonographers*, Vol. 13, No. 5: 219-227, September 1997.

Necas, M. "Musculoskeletal Symptomatology and Repetitive Strain Injuries in Diagnostic Medical Sonographer." *Journal of Diagnostic Medical Sonographers*, 266-227, November/December 1996.

Foot Switch Warning

WARNING

The foot switch is not intended for use in wet locations, such as emergency rooms and operating theaters.

Philips Transducers

Use only transducers that are approved by Philips for use with your Philips ultrasound system. For a list of the transducers that are compatible with your ultrasound system, see "Indications for Use and Supporting Transducers" on page 108.

Glutaraldehyde Exposure

The United States Occupational Safety and Health Administration (OSHA) has issued a regulation covering levels of acceptable glutaraldehyde exposure in the working environment. Philips does not sell glutaraldehyde-based disinfectants with its products.

To reduce the presence of glutaraldehyde fumes in the air, be sure to use a covered or ventilated soaking basin. Such systems are commercially available. The most-current information about disinfection products and Philips transducers can be found on the Philips Transducer Care website:

www.Philips.com/transducercare

Infection Control

Issues related to infection control affect the operator and the patient. Follow the infection-control procedures established in your facility for the protection of both the staff and the patient.

Handling Contaminated Transducers

The primary area of concern is the handling of transducers that have contacted infected patients. Always wear gloves when you handle transducers used in TEE, endocavity, intraoperative, and biopsy procedures that have not been previously disinfected.

Clean and disinfect transducers according to the instructions for the type of transducer. For the correct procedure, see *Care and Cleaning of Ultrasound Systems and Transducers*.

Removing Blood and Infectious Material from the System

It is important to clean and maintain the ultrasound system and peripherals. If the equipment has come in contact with blood or infectious material, clean and disinfect the system and peripherals according to the instructions in the “System Maintenance” section.

ECG Cables and Lead Sets

For information on cleaning ECG cables and lead sets, see “Cleaning the System and ECG Equipment” on page 357.

Disposable Drape

If you believe contamination of the system might occur during an exam, take universal precautions and cover the system with a disposable drape. Consult your facility's rules regarding equipment use in the presence of infectious disease.

Electromagnetic Compatibility

Electromagnetic compatibility (EMC) is defined as the ability of a product, a device, or a system to function satisfactorily in the presence of the electromagnetic phenomena that exists in the location of the product, the device, or the system being used; and, in addition, to not introduce intolerable electromagnetic disturbances to anything in that same environment.

Electromagnetic immunity is the ability of a product, a device, or a system to function satisfactorily in the presence of electromagnetic interference (EMI).

Electromagnetic emissions is the ability of a product, a device, or a system to introduce intolerable electromagnetic disturbances into the use environment.

Your system has been manufactured in compliance with existing electromagnetic compatibility requirements. Use of this system in the presence of an electromagnetic field can cause momentary degradation of the image quality. If this occurs often, review the environment in which the system is being used to identify possible sources of radiated emissions. These emissions could be from other electrical devices used within the same room or an adjacent room, or from portable and mobile RF communications equipment such as cellular phones and

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pagers, or from the existence of radio, TV, or microwave transmission equipment located nearby. In cases where electromagnetic interference (EMI) is causing disturbances, it may be necessary to relocate your system.

The system is classified as Group 1, Class A equipment in accordance with international standard CISPR 11 for radiated and conducted electromagnetic disturbances. Compliance with this standard allows the system to be used in all establishments except domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. If the system is used in a residential environment (for which CISPR 11 Class B is normally required), you may need to relocate or reorient the system to offer adequate protection from radio frequency communication services.

WARNING

Using cables, transducers, or accessories other than those specified for use with the system may result in increased emissions or decreased immunity of the system.

CAUTION

Medical equipment has special precautions regarding EMC and must be installed and put into service according to the EMC information provided in the system's accompanying documents.

This section includes information on electromagnetic emissions and immunity as it applies to the system. Ensure that the operating environment of your system meets the conditions specified in the referenced information. Operating the system in an environment that does not meet these conditions may degrade system performance.

The information and warnings contained in this and other sections should be observed when installing and using the system to ensure its EMC.

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NOTE

See the other electrical-safety warnings and cautions in this section.

Wireless Network Radio-Frequency Emissions

The following information applies to the system and any radio-frequency (RF) device included in or with the system. For information on related labeling, see “Symbols” on page 47.

U.S. Federal Communications Commission (FCC) Part 15 Compliance Statement

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference.
- This device must accept any interference received, including interference that may cause unwanted operation.

This product does not contain any user-serviceable components. Any changes or modifications to this equipment not expressly approved by Philips may cause harmful RF interference and will invalidate the warranty and all applicable regulatory certifications and approvals, including authority to operate this device.

RF Exposure

The product complies with the FCC portable RF exposure limit for an uncontrolled environment and is safe for intended operation as described in this manual. RF exposure is further reduced by keeping the product as far as possible from the user’s body or, if available, by setting the device to lower output power.

Industry Canada Radio Standards Notice

This device complies with Canadian Radio Standards Specification RSS-210.

This device complies with Industry Canada license-exempt RSS standards. Operation is subject to the following two conditions:

- This device may not cause interference.

- This device must accept any interference received, including interference that may cause unwanted operation of the device.

For 5-GHz transmitters or devices co-located with 5-GHz transmitters:

- The device for operation in the band 5,150 to 5,250 MHz is for indoor use only, to reduce the potential for harmful interference to co-channel mobile satellite systems.
- The maximum antenna gain permitted for devices in the bands 5,250 to 5,350 MHz and 5,470 to 5,725 MHz shall comply with the equivalent isotropically radiated power (EIRP) limit.
- The maximum antenna gain permitted for devices in the band 5,725 to 5,825 MHz shall comply with the EIRP limits specified for point-to-point and non-point-to-point operation as appropriate.
- High-power radars are allocated as primary users (priority users) of the bands 5,250 to 5,350 MHz and 5,650 to 5,850 MHz. Those radars may interfere with or damage LE-LAN devices.

RF Exposure

The product complies with the Canada portable RF exposure limit for an uncontrolled environment and is safe for intended operation as described in this manual. RF exposure is further reduced by keeping the product as far as possible from the user’s body or, if available, by setting the device to lower output power.

European Community Compliance Statement

The wireless technology radio device used in this product complies with the essential requirements and other relevant provisions of Directive 2014/53/EU. This product is intended to be connected to the Publicly Available Interfaces and used throughout the European Economic Area.

For compliance and conformance information for the wireless technology radio device that is specific to your country, see “Customer Service” on page 27.

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ECG Signal

WARNING

Operation of your system with ECG signals below 0.25 mV may cause inaccurate results.

The amplitude of the electrocardiogram (ECG) signal is critical for reliable frame triggering. Frame triggering should be used only when a clean, noise-free ECG waveform is observed on the Physio display. The ECG signal should be at least 0.25 mV to ensure reliable triggering when the system is used in the presence of the electromagnetic phenomena described in this section and elsewhere in your system user information.

Electrostatic Discharge Precautions

Electrostatic discharge (ESD), commonly referred to as a static shock, is a naturally occurring phenomenon that results in the flow of an electrical charge from a higher charged object or person to a lower charged object or person. ESD is most prevalent during conditions of low humidity, which can be caused by heating or air-conditioning. During low humidity conditions, electrical charges naturally build up on individuals and objects and can create static discharges.

The following cautions can help to reduce ESD effect:

CAUTION

Do not touch transducer connector pins or the system's transducer receptacle.

CAUTION

Handle the transducer by the metal connector housing.

CAUTION

Make contact with a metal surface of the system before connecting a transducer to the system.

CAUTION

The following precautions can help to reduce ESD: anti-static spray on carpets; anti-static spray on linoleum; anti-static mats; or a ground wire connection between the system and the patient table or bed.

CAUTION

On connectors labeled with the ESD sensitivity symbol , do not touch the connector pins, and always observe the preceding ESD precautions when handling or connecting transducers.

Also, your service representative can install the antistatic chain provided with the system.

NOTE

Electrostatic discharges (ESDs) may cause the ECG heart rate display to increase by 10% to 15% for a few seconds after the discharge. However, the ECG heart rate display will return to normal within 4 seconds.

Electromagnetic Emissions

The system is intended for use in the electromagnetic environment specified in the table. The customer or the user of the system should ensure that it is used in such an environment.

Electromagnetic Emissions: Environment Guidance

Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions, CISPR 11	Group 1 Class A	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions, CISPR 11	Class A	The system is suitable for use in all establishments except domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions, IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions, IEC 61000-3-3	Complies	

CAUTION

This is a radiated emissions Class A device. This device may cause radio interference. In a domestic environment it may be necessary to take mitigation measures.

Approved Cables for Electromagnetic Compliance

Cables connected to the system may affect its emissions. Use only the cable types and lengths listed here.

WARNING

Using cables, transducers, or accessories other than those specified for use with the system may result in increased emissions or decreased immunity of the system.

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Approved Cables

Cable	Type	Length
ECG 3-lead safety connector patient trunk cable, AAMI	Shielded	2.7 m (9 ft)
ECG 3-lead safety connector patient trunk cable, IEC	Shielded	2.7 m (9 ft)
ECG Aux input	Shielded	<3 m (<9.8 ft)
Video output	Shielded	Any
LAN	Twisted pair	Any
USB	Shielded	<3 m (<9.8 ft)

Approved Transducers for Electromagnetic Compliance

The imaging transducers used with the system may affect its emissions. The transducers listed in “Supported Transducers” on page 250, when used with the system, have been tested to comply with the Group 1, Class A emissions, as required by international standard CISPR 11. Use only those transducers.

WARNING

Using cables, transducers, or accessories other than those specified for use with the system may result in increased emissions or decreased immunity of the system.

Approved Accessories for Electromagnetic Compliance

Accessories used with the system may affect its emissions. The accessories listed here, when used with the system, have been tested to comply with the Group 1, Class A emissions as required by international standard CISPR 11. Use only the accessories listed here.

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When connecting other accessories to the system, such as a remote video monitor or computer, it is the user's responsibility to ensure the electromagnetic compatibility of the system. Use only CISPR 11 or CISPR 22, Class A- or Class B-compliant devices, unless otherwise noted.

WARNING

Using cables, transducers, and accessories other than those specified for use with the system may result in increased emissions from, or decreased immunity of, the system.

Approved Accessories

Accessory	Manufacturer	Model Number
Black-and-white image printer, on-cart	Sony	UP-D898MD/SYN UP-D897MD/SYN
Ultrasonic imaging transducer	Philips	Use only the transducers listed in "Indications for Use and Supporting Transducers" on page 108.

Electromagnetic Immunity

The system conforms to the professional healthcare environment intended use and the corresponding immunity test levels specified by IEC 60601-1-2 Edition 4, and is not intended for sale to the general public.

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CAUTION

Cables, transducers, and accessories connected to the system may affect its immunity to the electromagnetic phenomena listed here. Use only approved accessories, cables, and transducers to minimize the chance of performance degradation of the system due to those types of electromagnetic phenomena.

CAUTION

If the system is connected to other customer-supplied equipment, such as a local area network (LAN) or a remote printer, Philips cannot guarantee that the remote equipment will work correctly in the presence of electromagnetic phenomena.

NOTE

The guidelines specified here may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

NOTE

At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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Electromagnetic Immunity: Environment Guidance

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic discharge (ESD), IEC 61000-4-2	± 8 kV contact, ± 2, 4, 8, 15 kV air	Same as IEC 60601-1-2 test level	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst, IEC 61000-4-4	± 2 kV for power supply lines, ± 1 kV for input/ output lines > 3 m	Same as IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Surge, IEC 61000-4-5	± 0.5, ± 1, ± 2 kV common mode ± 0.5, ± 1 kV differential mode on AC line	Same as IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on AC lines, IEC 61000-4-11	Dips: 100% for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° Dips: 100% for 1.0 cycle at 0° Dips: 30% for 30 cycles at 0° Interruption: 100% for 5 seconds	Same as IEC 60601-1-2 test level	Mains power quality should be that of a typical commercial or hospital environment. If you require continued operation during power mains interruptions, Philips recommends that the system be powered from an uninterruptible power supply or a battery.

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Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
Power frequency magnetic fields, IEC 61000-4-8	30 A/m	Same as IEC 60601-1-2 test level	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Conducted RF, IEC 61000-4-6	3 VRMS (0.15–80 MHz) 6 VRMS (ISM bands) AM 80% depth 1 kHz tone on AC line and I/O cables	Same as IEC 60601-1-2 test level	See “Electromagnetic Interference” on page 94.
Radiated RF, IEC 61000-4-3	3 V/m (80–2,700 MHz) AM 80% depth 1 kHz tone	Same as IEC 60601-1-2 test level	See “Electromagnetic Interference” on page 94.
Proximity fields from RF wireless communications, IEC 61000-4-3	385 MHz 27 V/m, 450 MHz 28 V/m, 710 MHz 9 V/m, 745 MHz 9 V/m, 780 MHz 9 V/m, 810 MHz 28 V/m, 870 MHz 28 V/m, 930 MHz 28 V/m, 1,720 MHz 28 V/m, 1,845 MHz 28 V/m, 1,970 MHz 28 V/m, 2,450 MHz 28 V/m, 5,240 MHz 9 V/m, 5,500 MHz 9 V/m, 5,785 MHz 9 V/m	Same as IEC 60601-1-2 test level	See “Electromagnetic Interference” on page 94.

Although most remote devices comply with their applicable standards for immunity, those device requirements may not be as stringent as those required for medical equipment. It is the responsibility of the installer and the user of this remote customer-supplied equipment to ensure that it functions properly in the electromagnetic environment where the system is installed. The installer or the user of such a system should consult with experts in the field of electromagnetic compatibility and safety for guidance to ensure the safe and effective use of the created system.

Electromagnetic Interference

Electromagnetic interference may appear in many ways on the system and depends on the mode the equipment is operating in, the imaging control settings, the type of transducer being used, the type of electromagnetic phenomena, and the intensity level of the phenomena.

WARNING

If electromagnetic interference is present or intermittent, use caution when continuing to use the system.

NOTE

Electromagnetic phenomena are not always present and may be transitory in nature. It may be extremely difficult to identify the source of the interference.

The following table describes a few typical interferences seen in imaging systems. It is impossible to describe all manifestations of interference, because it depends on many parameters of the transmitting device, such as the type of modulation used by the signal carrier, the source type, and the transmitted level. It is also possible for the interference to degrade the imaging system's performance and not be visible in the image. If the diagnostic results are suspicious, other means should be used to confirm the diagnosis.

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Typical Interference on Ultrasonic Imaging Systems

Imaging Mode	ESD[1]	RF[2]	Power Line[3]
2D or 3D	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	For sector imaging transducers, white radial bands or flashes in the center lines of the image. For linear imaging transducers, white vertical bands, sometimes more pronounced on the sides of the image.	White dots, dashes, or diagonal lines near the center of the image.
Color	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	Color flashes, radial or vertical bands, increase in background noise, or changes in image color.	Color flashes, dots, dashes, or changes in the color noise level.
Doppler	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	Horizontal lines in the spectral display or tones, abnormal noise in the audio, or both.	Vertical lines in the spectral display, "popping" noise in the audio, or both.
M-mode	Change of operating mode, system settings, or system reset. Brief flashes in the displayed or recorded image.	Increase in the image background noise or white M-mode lines.	White dots, dashes, diagonal lines, or increase in image background noise.

1. Electrostatic discharge (ESD) caused by discharging of electric charge buildup on insulated surfaces or persons.
2. Radio frequency (RF) energy from RF transmitting equipment such as portable phones, handheld radios, wireless devices, commercial radio and TV stations, and so on.

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3. Conducted interference on power lines or connected cables caused by other equipment, such as switching power supplies, electrical controls, and natural phenomena such as lightning.

Recommended Separation Distance

The following table provides recommended separation distances, which are guidelines on the distances that any RF transmitting equipment should be kept away from the ultrasound system to reduce the risk of interference with the system. Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range as noted in the table. Interference may occur in the vicinity of equipment marked with the following symbol: .

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level in the table, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

WARNING

To avoid degrading system performance, keep portable RF communications equipment (including peripherals such as antenna cables and external antennas) at least 30 cm (12 in) away from any part of the ultrasound system, including cables.

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NOTE

For transmitters rated at a maximum output power not listed in the following table, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE

At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE

The recommended separation distance guidelines in the following table may not apply to all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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The information provided here, in conjunction with "Electromagnetic Interference" on page 94, provides guidance on conducted and radiated interference from portable and fixed RF transmitting equipment.

Recommended Separation Distances by Transmitter Frequency

Rated Maximum Output Power of Transmitter (Watts)	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.4\sqrt{P}$
0.01	0.12 m (4.7 in)	0.12 m (4.7 in)	0.24 m (9.5 in)
0.1	0.38 m (15 in)	0.38 m (15 in)	0.76 m (30 in)
1	1.2 m (3.9 ft)	1.2 m (3.9 ft)	2.4 m (7.9 ft)
10	3.8 m (12.5 ft)	3.8 m (12.5 ft)	7.6 m (25 ft)

Rated Maximum Output Power of Transmitter (Watts)	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.4\sqrt{P}$
100	12 m (39.4 ft)	12 m (39.4 ft)	24 m (78.7 ft)

Ultrasound systems can be sensitive to RF interference in the transducer passband. For example, for a 5-MHz imaging transducer, the frequency range of interference from a 3-V/m field may be from 2 to 10 MHz and manifest itself as described in "Electromagnetic Interference" on page 94.

Sensitivity to interference depends on operating mode and imaging control settings. The order of increasing sensitivity to interference as a function of operating mode is 2D mode, 3D mode, M-mode, Color mode, PW Doppler mode, and CW Doppler mode. Ultrasound systems are more sensitive to interference in the CW Doppler or PW Doppler operating modes, but the probability of interference is lower than in 2D mode or Color mode, because the susceptible frequency range is lower. Therefore, you are more likely to see interference in 2D or Color modes.

As an example, if a portable transmitter has maximum radiated power of 1 W and an operating frequency of 156 MHz, it should only be operated at distances greater than 1.2 m (3.9 ft) from the system. Likewise, a 0.01-W Bluetooth wireless LAN device operating at 2.4 GHz should be placed no closer than 0.24 m (9.5 in) from any part of the system.

Avoiding Electromagnetic Interference

A medical device can either generate or receive electromagnetic interference. The EMC standards describe tests for both emitted and received interference. Emission tests deal with interference generated by the device being tested. The ultrasound system does not generate interference based on the tests described in the referenced standards.

An ultrasound system is designed to receive signals at radio frequencies and is therefore susceptible to interference generated by RF energy sources. Examples of other sources of interference are medical devices, information technology products, and radio and television transmission towers. Tracing the source of radiated interference can be a difficult task. Customers should consider the following in an attempt to locate the source:

- Is the interference intermittent or constant?
- Does the interference show up only with one transducer or with several transducers?
- Do two different transducers operating at the same frequency have the same problem?
- Is the interference present if the system is moved to a different location in the facility?
- Can the EMC coupling path be attenuated? For example, placement of a transducer or printer close to an ECG cable can increase electromagnetic interference. Moving the cable or other medical equipment away from the location of the transducer or printer can result in reduced electromagnetic interference.

The answers to these questions will help determine if the problem resides with the system or the scanning environment. After you answer the questions, contact your Philips service representative.

Use Restrictions Due to Interference

The physician must determine if an artifact caused by radiated interference will have a negative impact on image quality and the subsequent diagnosis.

Measurement Accuracy

You can use the ultrasound system to make measurements and calculate results from ultrasound images. The measurements and calculations are then used with other clinical data to make a diagnosis.

Making a diagnosis based solely on measurements and calculations is not recommended. There are numerous factors to consider when using quantified data from any ultrasound imaging system. A careful analysis of those factors indicates that the accuracy of each measurement and calculation is highly dependent on image quality. Image quality in turn is highly dependent on system design, operator scanning technique, familiarity with system controls and, most important, patient echogenicity.

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WARNING

System users are responsible for image quality and diagnosis. Inspect the data that is being used for the analysis and diagnosis and ensure that the data is sufficient both spatially and temporally for the measurement approach being used.

Measurement Precision

When making a measurement, accurate placement of the calipers is important. Also essential are the following techniques for ensuring that your images provide clinically meaningful measurements:

- Use the monitor controls and the imaging controls to adjust the display for maximum sharpness.
- Use leading edges (closest to the transducer) or borders for start and stop points of the measurement.
- Maintain a consistent transducer orientation for each type of measurement.
- Ensure that the area of interest fills as much of the display as possible.
- Avoid using color values for precise flow velocity quantification.
- Account for Doppler velocity dynamics, angle correction, and measurement constraints.
- Minimize Doppler aliasing.

Measurement Resolution

Resolution is proportional to the transducer frequency. Penetration is inversely proportional to the transducer frequency. Resolution is always best near the focal zone of the transducer where the ultrasound beam is narrowest. Measurements are most accurate near the focal depth, and less accurate away from the focal point as the acoustic beam widens.

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Effects of Display Size

The precision with which a caliper can be placed in an image can be improved by making sure that the area of interest fills as much of the display as possible. In 2D imaging, distance and area measurements are improved by minimizing the display depth and using the zoom function where possible. In M-mode and Doppler imaging, time measurements are improved by using the highest possible sweep speed. In Doppler imaging, velocity measurement accuracy is improved by using the smallest possible vertical scale setting.

Variations in Speed of Sound

Ultrasound imaging and Doppler algorithms assume that the speed of sound is constant at 1,540 m/s, but the speed of sound varies for different tissue types. In cardiovascular applications, where soft tissues, blood, and fatty layers are all involved, the error is random but is typically on the order of 2% to 5%.

Color and CPA Precision

The accuracy of a measurement made in Color or Color Power Angio (CPA) imaging is subject to the same limitations as a similar type of measurement made on a grayscale image. Color flow values are estimates of the mean velocity and do not necessarily represent peak velocities. The method of choice for quantifying flow for any application is spectral analysis using pulsed or continuous-wave Doppler imaging.

Doppler Measurement Limitations

Lower frequency transducers are capable of measuring higher velocity flows. Sample volume size is limited laterally by the acoustic beam. Penetration is best with low frequency transducers. Doppler peak velocity measurements could be affected by factors that affect the visibility of weak signals, such as sensitivity, gain, and reject.

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Doppler Velocity Resolution

In computing velocity spectra, the velocity field (the area where flow exists) is assumed to be stationary. In cardiovascular applications, velocity fields do not remain constant, owing to the pumping action of the heart. The dynamics of blood flow places a practical upper limit on velocity resolution and spectral edge sharpness. The acoustic beam width determines the extent to which velocities can be differentiated in composite blood flow patterns.

Doppler Angle Correction

Doppler velocity measurements are most accurate when the acoustic beam is aligned parallel with blood flow. Deviations from the parallel alignment of up to 20 degrees for Doppler angles result in measurement errors of 6% or less. For larger alignment errors (Doppler angles exceeding 20 degrees), the measurement accuracy falls off rapidly, and use of angle correction is recommended (vascular applications only).

Doppler Aliasing

Pulsed-wave Doppler uses signal sampling techniques to compute a velocity spectrum. A theoretical limit exists for the maximum measurable velocity. When measuring high velocities, the sampling rate, which is determined largely by the sample volume depth, may be insufficient; and velocity wraparound (aliasing) may occur. A possible result could be that normal, high-velocity, laminar flows would be perceived as turbulence. Aliasing can be minimized in some cases by moving the baseline, increasing the velocity scale, or using a lower frequency transducer. In continuous-wave Doppler, aliasing is virtually eliminated.

Clinical Formulas

Some formulas used in clinical applications are based on assumptions or approximations, for example:

- Volume formulas may assume a specific three-dimensional shape.
- Pressure formulas use a simplified version of equations from fluid mechanics.

All formulas used in the ultrasound system are based on extensive clinical references from medical literature. For complete descriptions, see the *Help*.

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WARNING

You are solely responsible for custom measurements and calculations and the accuracy of elements entered into the equations.

Algorithmic and Acquisition Errors

In general, there are two types of errors that can be introduced into a displayed measurement: algorithmic and acquisition.

Algorithmic error is the error introduced by making the basic measurements with acquisition errors as input to higher order calculations for display to the user. This error is associated with floating point versus integer type math, and is also subject to errors introduced by rounding versus truncating results for a given level of significant digit display of the values. The acquisition errors of the inputs are not carried forward into these higher calculations.

Acquisition errors are introduced by ultrasound machine electronics, relating to the front end signal acquisition, signal conversion, and the display of the image on the screen. These machine errors are also introduced by generation of a pixel scale factor, application of that factor to the caliper positions on the screen, and the subsequent measurement display. Calipers and readouts must be used against a known phantom image displayed on the screen; it is impossible to state or test a tolerance of a machine acquisition error by itself.

Accuracy Tables

The measurements provided by the system do not define a specific physiological or anatomic parameter. Rather, what is provided is a measurement of a physical property such as distance or velocity for evaluation by the clinician.

For each of the measurements available on the system, the measurement accuracy is shown in the following tables. Measurements listed are accurate to the percentage or units listed, whichever is greater.

2D Measurement Range and Accuracy

Measurement	Accuracy	Range
Axial Distance	±1% or 1 mm	0.01 to 25 cm
Lateral Distance	±2% or 2 mm	0.01 to 35 cm
Diagonal Distance	±2% or 2 mm	0.01 to 25 cm
Skin Line Registration	±1 mm	--

2D Hip Angle Measurement Accuracy

Measurement	Accuracy
Alpha Angle	±3 degrees
Beta Angle	±3 degrees

M-Mode Measurement Range and Accuracy

Measurement	Accuracy	Range
Time	±2% or 4 ms	0.01 to 27.5 seconds
Depth	±2% or 1 mm	0.01 to 25 cm
Slope	±0.1% or 1 LSD	--

Doppler Measurement Range and Accuracy

Measurement	Accuracy	Range
Velocity	±1% full scale	PW: 0.1 cm/s to 8.8 m/s
		CW: 0.1 cm/s to 19.3 m/s
Time Difference	±2 columns or 4 ms	10 ms to 27.5 seconds

3D Measurement Range and Accuracy

Measurement	Accuracy	Range
Axial Distance	±1% or 1 mm	0.01 to 25 cm

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Measurement	Accuracy	Range
Azimuthal Distance	±2% or 2 mm	0.01 to 33 cm
Elevation Distance	±2% or 2 mm	0.01 to 32 cm
Diagonal Distance (through volume)	±3% or 3 mm	0.01 to 40 cm
2D Area	±5% or 0.4 cm^2	0.01 to 1,000 cm^2
2D Circumference	±4% or 3 mm	0.03 to 160 cm
Ellipsoid Volume	±9% or ± 0.7 cm^3	0.01 to 2,000 cc
Stacked Contour Volume	±9% or ± 0.7 cm^3	0.01 to 2,300 cc

Panoramic Measurement Range and Accuracy

Measurement	Accuracy	Range
Distance	±5%	30 to 600 mm

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3 System Overview

Use this section to acquaint yourself with the ultrasound system and its components.

System Capabilities

The 5000 Compact series ultrasound systems are intended for the uses listed in “Intended Use/ Indications for Use” on page 19. The optional cart is ergonomically designed to be both highly mobile and adjustable for a range of users and operating conditions. You can use the system for 2D, freehand 3D, 4D (mechanical transducers), Tissue Doppler Imaging, Contrast, M-mode, Doppler, and Color imaging. Stress echocardiography and general-imaging exam protocols are system options. QLAB Advanced Quantification Software Q-Apps are also available as options. The system supports a wide range of transducers. The system provides measurement tools, analysis options, and DICOM network capabilities.

Measurements

The system provides tools for measuring the size, speed, duration, distance, area, and volume. Additionally, the following application-specific tools are available:

- 2D Trace By Points
- 3D Volume
- Aliasing Velocity
- Angle
- Area
- Cardiac dP/dt Volume flow
- Circumference
- Continuous Trace
- Curved Distance
- Distance

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- Ellipse
- Heart Rate
- High Q automatic Doppler analysis
- Physio
- Simpson's Method
- Time/Slope
- Velocity
- Volume

After you perform measurements, the system makes the pertinent calculations and organizes the measurements, calculations, and patient information into a patient report.

Transducer Types

Available transducer types include sector array, linear array, curved array, nonimaging Doppler, endocavity, intraoperative, transesophageal, volume, and xMATRIX array.

Indications for Use and Supporting Transducers

WARNING

Unless the transducer used is indicated for ophthalmic use, the device is not intended for ophthalmic use or any application that causes the acoustic beam to pass through the eye.

WARNING

Intraoperative transducers used in animal studies should not be used on humans. Intraoperative transducers used in human studies should not be used on animals. Transducer disinfection procedures for cross-usage between animals and humans have not been validated.

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CAUTION

United States federal law restricts this device to sale by or on the order of a physician.

Use only transducers that are approved by Philips for use with your Philips ultrasound system.

The following are the transducers supported by the 5000 Compact series systems and the indications for use available on each.

System Transducers and Indications for Use

Transducer	Indications for Use
3D9-3v	Fetal Echo, Fetal/OB, GYN, Transvaginal, Urology
C5-1	Abdominal, Fetal Echo, Fetal/OB, GYN, Lung, Pediatric, Urology
C6-2	Abdominal, Fetal Echo, Fetal/OB, GYN, Lung, Pediatric, Urology
C8-5	Abdominal, Carotid, Cerebral Vascular, Neonatal Cephalic, Pediatric, Peripheral Vessel
C9-2	Abdominal, Fetal Echo, Fetal/OB, GYN, Musculoskeletal (Conventional), Pediatric
C9-4v	Fetal Echo, Fetal/OB, GYN, Transrectal, Transvaginal, Urology
C10-3v	Fetal Echo, Fetal/OB, GYN, Transrectal, Transvaginal, Urology
D2cwc	Cardiac Adult, Cardiac Pediatric
D2tcd	Adult Cephalic, Cerebral Vascular
D5cwc	Cerebral Vascular, Peripheral Vessel
eL18-4	Abdominal, Carotid, Fetal/OB, Lung, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Pediatric, Peripheral Vessel, Small Parts
L12-3	Carotid, Cerebral Vascular, Fetal/OB, Lung, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Neonatal Cephalic, Ophthalmic, Pediatric, Peripheral Vessel, Small Parts
L12-3ERGO	Carotid, Cerebral Vascular, Fetal/OB, Lung, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Neonatal Cephalic, Ophthalmic, Pediatric, Peripheral Vessel, Small Parts

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Transducer	Indications for Use
L12-4	Abdominal, Carotid, Cerebral Vascular, Fetal/OB, Musculoskeletal (Conventional), Lung, Musculoskeletal (Superficial), Neonatal Cephalic, Ophthalmic, Pediatric, Peripheral Vessel, Small Parts
L12-5 50	Abdominal, Carotid, Cerebral Vascular, Fetal/OB, Musculoskeletal (Conventional), Musculoskeletal (Superficial), Pediatric, Peripheral Vessel, Small Parts
L15-7io	Abdominal, Carotid, Cerebral Vascular, Intraoperative (Vascular), Musculoskeletal (Conventional), Musculoskeletal (Superficial), Ophthalmic, Peripheral Vessel, Small Parts
L18-5	Abdominal, Carotid, Cerebral Vascular, Musculoskeletal (Conventional), Musculoskeletal (Superficial),Pediatric, Peripheral Vessel, Small Parts
S4-2	Abdominal, Adult Cephalic, Cardiac Adult, Cardiac Pediatric, Lung
S5-1	Abdominal, Adult Cephalic, Cardiac Adult, Cardiac Pediatric, Lung
S8-3	Abdominal, Cardiac Adult, Cardiac Pediatric, Fetal Echo, Fetal/OB, Neonatal Cephalic, Pediatric
V6-2	Abdominal, Fetal Echo, Fetal/OB
X7-2t	Cardiac Adult, Transesophageal (Cardiac)
X8-2t	Cardiac Adult, Transesophageal (Cardiac)

Contraindications

None known.

Image Acquisition and Review

You can acquire and review single images and cineloop sequences. Images and cineloop sequences can be transferred via USB devices, or sent over a network to an archive server or a printer.

Stress Echo capabilities also use the ability to acquire and review image loops. Stress Echo protocols of up to 10 stages are used to assess cardiac wall motion at various heart rates.

Peripheral devices are available for recording images and exams. You can connect a black-and-white image printer or a report printer.

Patient Data Protection

The data security feature, if enabled on your system, limits access to previously stored patient data and images. To gain access to such data, you must first log on to the system using a password. When you are finished using the system, you can log off manually, or you can simply shut down the system, which logs you off automatically. The system stores a record of each user logon.

This data protection feature can be used to help meet the requirements of the U.S. Health Insurance Portability and Accountability Act (HIPAA).

For more information on protecting patient data, see "System Security" on page 184.

System Options

In addition to the standard features available in the system, other features are available as purchasable options. The types of options available include clinical options, QLAB Advanced Quantification Software, imaging capabilities, and connectivity capabilities.

Imaging Options

The following imaging options are available on the system. Some options require specific transducers and applications.

- 3D/4D (mechanical transducers)
- Anatomical M-Mode
- AutoScan
- Color (3D imaging and Doppler)

- Continuous-wave Doppler
- Exam protocols
- Freehand 3D
- High Q Doppler
- iSCAN Intelligent Optimization
- Pulsed-wave Doppler
- Simultaneous 2D (Doppler and M-Mode)
- Tissue Doppler Imaging (TDI)
- XRES image processing

Connectivity Capabilities

The following features are standard:

- Image and waveform export to removable media
- Image export to USB devices
- Printing to DICOM printers
- Printing to local printers
- Printing report pages
- Wireless DICOM transfer
- DICOM Networking
- Image and waveform export to network storage servers
- DICOM Modality Worklist
- DICOM Performed Procedure Step (PPS)
- DICOM Storage Commit (SC)
- DICOM Structured Reporting (SR)
- DICOM Query/Retrieve
- Digital Navigation Link (DNL)

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QLAB Advanced Quantification Software Options

The following QLAB Q-Apps are supported for use on your ultrasound system.

NOTE

The Elastography Quantification Q-App is not available in the United States.

NOTE

The Elastography Analysis Q-App is available only in the United States.

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Q-Apps for 5300 Compact Ultrasound Systems

Q-App	System		
	5300G	5300P	5300W
Auto 2D Quantification (a2DQ)	X	X	--
AutoStrain Left Ventricle (AutoStrain LV)	X	X	--
Elastography Analysis (EA)	X	X	X
Elastography Quantification (EQ)	X	X	X
Fetal Heart Navigator (FHN)	X	--	X
General Imaging 3D Quantification (GI3DQ)	X	--	X
Intima Media Thickness (IMT)	X	X	--
MicroVascular Imaging (MVI)	X	X	--
Region of Interest Quantification (ROI)	X	X	X
Strain Quantification (SQ)	X	X	--

Q-Apps for 5500 Compact Ultrasound Systems

Q-App	System			
	5500CV	5500G	5500P	5500W
Auto 2D Quantification (a2DQ)	X	X	X	--
AutoStrain Left Ventricle (AutoStrain LV)	X	X	X	--
Elastography Analysis (EA)	--	X	X	X
Elastography Quantification (EQ)	--	X	X	X
Fetal Heart Navigator (FHN)	--	X	--	X
General Imaging 3D Quantification (GI3DQ)	--	X	--	X
Intima Media Thickness (IMT)	X	X	X	--
MicroVascular Imaging (MVI)	--	X	X	X
Region of Interest Quantification (ROI)	X	X	X	X
Strain Quantification (SQ)	X	X	X	--

Stress Echocardiography

Stress Echocardiography (Stress Echo) is a protocol-driven study that allows a cardiologist to assess cardiac wall motion at various heart rates by acquiring views of the heart at different stages of the study. Stress Echo includes these Philips protocols:

- Exercise 2-Stage
- Exercise 3-Stage
- Pharmacological 4-Stage
- Quantitative 4-Stage
- Wall Motion and Contrast

You can create custom presets based on those protocols.

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Data Security

A data security feature is available to help maintain the confidentiality of archived patient files. For more information, see “System Security” on page 184.

The following data security options are also purchasable:

- **Government Security**: If the **Government Security** licensed option is purchased and enabled, the **Remote Access Configuration** options described in “Configuring Remote Access” on page 134 are not available.
- **SafeGuard**: Protects the system against malware and viruses by preventing unauthorized software from running on the system. When **SafeGuard** detects malware (unauthorized software or an attempt to change software installed on the system), the  icon appears in the tools and icons area on the display. To view details, select the  icon.
- **Security Plus**: Allows you to configure user management, audit logging, and data encryption.

System Components

The components include the monitor, control panel, transducer receptacles, ECG/physio receptacles, and AC adapter/battery charger. The system can be attached to an optional cart. The cart height is adjustable to accommodate a range of operator heights and operating positions. For more information about the cart options, see “System Cart” on page 118.

System Components

1	Monitor (lid)
2	Control panel
3	Transducer holder
4	Black-and-white printer
5	Multiport adapter (depending on your cart configuration)
6	Storage bin
7	Cart base (includes the cart power source and wheel controls)

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Video Monitor

The system video monitor is a 39.6 cm (15.6 in) high-resolution display with a wide viewing angle. On the optional cart, the system is adjustable to accommodate different operating heights. The lid of the system should be closed to protect the display and the control panel while moving the system (see “Moving the System” on page 136). Two light sensors on the control panel can automatically reduce the brightness of both the monitor and the controls on the control panel when room lighting is dim.

Data Connections

You can transfer exam data and images onto USB devices connected to a USB port on the system. For more information, see “USB Devices” on page 202.

Data Port Locations

1	Network port
2	External monitor port (DisplayPort)

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3	USB ports (two on the system, two on the cart)

Peripherals

Peripheral devices are available for printing images and studies. You can connect a black-and-white image printer or a report printer. External peripheral devices cannot be placed on the system cart, and they must be disconnected before moving the cart.

System Cart

The system has four cart options that provide transport for the system, storage for transducers and supplies, adjustable system height, and wheels that swivel for maneuverability.

Features Available on the Optional Carts

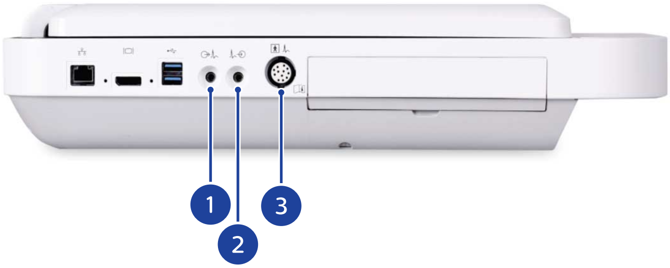
Cart Feature	Cart Option			
	Standard	Extended	Deluxe	Premium
AC adapter (+24 Vdc output)[1]	X	–	–	–
Ethernet extender (one port) and USB hub (two ports), including built-in power and data cabling	X	X	X	X
Retractable keyboard	X	X	X	X
Multiport adapter connects to the system transducer receptacle to enable connection of up to three transducers	–	–	X	X
Three medical-grade batteries provide up to 3 hours of additional scanning when the system is disconnected from an AC power source[2]	–	X	X	X
Printer shelf with built-in power and data cabling	–	–	–	X

1. The AC adapter is installed on the Standard cart only. However, the adapter is shipped with the Extended, Deluxe, and Premium carts.

2. Additional scanning time applies to new, fully charge batteries only. Batteries lose capacity as they age.

Physio (ECG) Receptacles

For physio support, your system includes input receptacles for both high-level and low-level ECG, pulse, phono, and auxiliary signals. Also, an analog output receptacle allows connection of external monitoring devices. The ECG receptacles are on the left side of the system. For more information about using physio features, see the *Help*.



ECG and Physio Receptacles

1	ECG out/Trigger out
2	ECG in/Trigger in
3	ECG/Physio connector

Wheel Controls

On the optional cart, all four wheels swivel to aid in maneuvering the system. All of the wheels on the cart have wheel controls you can engage and disengage independently. Brakes help keep the cart stationary while in use.

For more information, see "Using the Wheel Controls" on page 131.

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4 Preparing the System

The information and procedures in this section will help you prepare the system for use. Preparations include connecting transducers and external devices, moving the system, and ensuring that system operating requirements are met.

Connecting Devices

In addition to the devices installed in the system cart, the system supports external devices. These devices include printers, a barcode scanner, a foot switch, and a color monitor.

WARNING

When using additional peripheral equipment powered from an electrical source other than the ultrasound system, the combination is considered to be a medical system. It is your responsibility to comply with IEC 60601-1 and test the system to those requirements. If you have questions, contact your Philips representative.

WARNING

Do not use nonmedical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the nonmedical peripherals receive power from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601-1.

WARNING

All external devices and peripherals that you connect to the system must meet the safety standards defined by IEC 60601-1 or IEC 60950-1. This applies to all USB, HDMI, and serial input/output connections.

WARNING

Philips ultrasound systems are tested to the requirements of IEC 60601-1, with on-cart peripherals that are powered by the built-in system isolation. The system peripherals meet general electrical safety usage requirements.

WARNING

Off-cart devices connecting to the ultrasound system must comply with the applicable IEC or national standards, such as IEC 60601-1, IEC 60950, or the equivalent.

CAUTION

Using accessories, transducers, peripherals, or cables not supplied with the ultrasound system or recommended by Philips can affect the system in the form of increased emissions or decreased immunity to external EMI/EMC occurrences. Non-specified peripherals, and cables in some cases, can also increase leakage current or compromise the safety of the grounding scheme.

CAUTION

If systems, transducers, and peripherals have been in an environment below 10°C (50°F), allow them to reach room temperature before connecting or turning them on. Allow 24 hours for complete normalization. Otherwise, condensation inside the devices could cause damage. If the device was only briefly exposed to temperatures below 10°C (50°F), then the time required for the device to return to room temperature could be significantly less than 24 hours.

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NOTE

Any device that is not purchased from Philips or a Philips-authorized agent is not covered under a Philips service agreement or warranty.

Configuring Local Printers

WARNING

Multi-image prints made on small-size paper are intended only for reference and should not be used for diagnostic purposes. Text annotation and scaling markers may not be visible on such prints.

NOTE

Before adding a local printer, connect the printer to the ultrasound system.

You can add a local printer to the system and then, in the setups, associate it with either a touch screen control or an **Acquire** control. You can print only to a printer that has been selected. You can also change other printing parameters.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **Acquisition/Capture**.
4. Tap the **Archive/Printer** tab.
5. To assign a printer to an **Acquire** control, do the following:
   a. From the **Acquisition Type** list, select a type.
   b. Under **Destination(s)**, select a printer.

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6. To assign a printer to a touch screen control, do the following:
    a. Under **Select a Touch Screen Button**, select the name of the control that you want to assign.
    b. Under **Destination(s) for the Button**, select a printer.
7. To exit the setups, touch **Close**.

Connecting the Foot Switch

The foot switch is available as an option.

1. Turn off the system.
2. Connect the foot switch cable to an available USB port on the system.

Connecting an External Monitor

WARNING

When using additional peripheral equipment powered from an electrical source other than the ultrasound system, the combination is considered to be a medical system. It is your responsibility to comply with IEC 60601-1 and test the system to those requirements. If you have questions, contact your Philips representative.

WARNING

Do not use nonmedical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the nonmedical peripherals receive power from an isolated power outlet on the Philips ultrasound system, or from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601-1.

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CAUTION

When connecting an external monitor *for the first time*, make sure that the system is connected to AC power and is powered on. For subsequent connections, the system can be powered on or powered off.

NOTE

To maintain image quality, make sure the resolution of the external monitor is 1080p or higher.

You can connect a compatible external color monitor to the receptacle on the left side of the system. This receptacle provides standard DisplayPort digital output. The power cord for the external monitor plugs directly into a wall socket.

For monitors and video projectors requiring other connectors, such as VGA or DVI, an active DisplayPort to DVI/VGA/HDMI adapter is required.

The DisplayPort output includes the entire display. The aspect ratio of the screen is 16:9. To display this properly, select the 16:10 or 16:9 mode on the monitor or projector, if available. Also, you may be able to adjust the horizontal and vertical image size controls to create the correct aspect ratio. You can best judge the aspect ratio by displaying the circle test pattern on the system.

The system provides connections for connecting an external monitor. The setups must be configured to operate the monitor.

1. Configure system setups:
    a. Touch **Utilities**.
    b. On the **System** tab, touch **Setups**.
    c. Tap **System Settings**, and then tap the **Display** tab.
    d. Select a setting for **External Video DisplayPort Format**.
    e. To exit the setups, touch **Close**.

2. Connect the external monitor.

External Printers

You can connect external printers to your system.

WARNING

Images printed on a report printer are intended only for reference and should not be used for diagnostic purposes.

Supported External Printers

Printer Type	Printer Manufacturers and Model Numbers
Black-and-white image printers	Sony UP-D898MD/SYN Sony UP-D897MD/SYN

For more information, see "Configuring Local Printers" on page 123 and the "Printing" section in the *Help*.

Connecting an External Printer

WARNING

Do not use nonmedical peripherals, such as report printers, within 1.5 m (5 ft) of a patient, unless the nonmedical peripherals receive power from an isolation transformer that meets medical safety standards, as defined by standard IEC 60601-1.

1. Turn off the system and unplug the power cord from the power source.

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2. Connect a standard USB cable between the USB port on the printer and a USB port on the system.
3. Connect the printer’s power cord into the back of the printer, and plug the other end into an appropriate power source.
4. Plug the system's power cord into an appropriate power source.
5. Turn on the printer, and then turn on the system. The system installs the printer drivers automatically.
6. After the system installs the new printer drivers, restart the system.

Attaching the System to the Cart

The optional carts include a locking system to attach the system securely.

CAUTION

Never move the cart with the system on it, unless the system is properly attached to the cart.

1. Place the system toward the rear end of the cart tray.

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NOTE

Do not place the system at the front of the tray and slide it over the tray to the rear pins.

2. With the system at an angle, slide the system onto the pins at the rear of the tray making sure that the pins seat fully into the holes in the rear of the system.

NOTE

When aligning the system with the tray pins, make sure the angle of the system does not exceed 45 degrees.

3. Lower the front of the system onto the cart until the front latch snaps into place.
4. Ensure that the front latch is fully engaged and that the system is firmly attached to the cart.
5. Connect all required cables to the system.

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NOTE

To allow the system to monitor the cart batteries and display the available charge for those batteries, make sure to attach the cart's USB cable to one of the system's USB ports.

Removing the System from the Cart

The optional system cart includes a front latch mechanism for securely attaching the system.

CAUTION

Remove the system from the cart only when you are holding the system securely by the handle.

1. Disconnect all cables from the system.
2. If the system configuration includes the Multiport adapter, remove the connector and put it in the holder on the cart.

Multiport Adapter Connector Holder

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3. Grasp the handle of the system, release the front latch, and then slide the system forward slightly, away from the rear pins and off the cart.
4. Lift the system off the cart.

NOTE

Do not drag the system to the front of the tray to remove it.

Adjusting Cart Height

You can adjust the height of the cart to suit different operating positions and operator heights.

WARNING

Do not drape the power cord over any of the cable hooks or the handle on the system cart. Damage to the cord or power receptacle can occur if the cart is raised.

CAUTION

Do not use the system handle to raise or lower the system. Use only the handles on the sides of the cart for this purpose.

1. Ensure that the system is securely attached to the cart.
2. Press the lever on the left side of the cart and raise or lower the system.
3. Release the lever to lock the position.

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Cart Height-Adjustment Lever

Using the Wheel Controls

WARNING

Never park the system on an incline.

WARNING

The brakes are intended as a convenience. To increase cart security, use wheel chocks when the system is parked.

WARNING

If you park the system on a floor that is tilted 10 degrees or more and set the brakes, one of the braked casters might not be touching the floor, which can cause the system to move.

The wheels on the system cart swivel to aid in maneuvering the system. The front wheels have brake controls that you can engage and disengage independently. The brakes help keep the cart stationary while in use. For the front wheel controls:

- To engage the brake, press the gray **ON** lever.
- To release the brake, press the gray **OFF** lever.

The steering lock on the rear wheels helps to control the direction of the system when moving or transporting it. For the rear wheel controls:

- To engage the steering lock, press the green lever.
- To engage the brake, press the red lever.
- To release both the steering lock and the brake, press the gray **OFF** lever or lift the corresponding lever.

Front Wheel Controls

Rear Wheel Controls

Configuring the System

The ultrasound system is configured using the setups and **Philips SupportConnect**. The configuration items in **Philips SupportConnect** are intended for use by field service engineers and First Responder service providers. The system configuration items in **Philips SupportConnect** include network configuration, DICOM network settings, printer configuration, remote service and remote access, log files, and access to optional services.

Standard Network Support

The system supports standard wired and wireless network functions.

Configuring DNS Settings

If your system does not use Dynamic Host Configuration Protocol (DHCP) to specify the addresses of domain name servers, you must enter the domain name server (DNS) settings for your system before you connect your system to either a wired or wireless network. If you have questions, see your network administrator.

To configure a wired network or a wireless network, see the *Help*.

1. Press **Support**.
2. Tap **Network/DICOM**.
3. Tap **DNS Settings**.
4. If your network administrator specified DNS IP addresses, tap **Use the Following DNS Server IP Addresses (In Order)** and add one or more DNS addresses.
5. If your network administrator specified DNS suffixes, tap **Append Given Name With One of the Following DNS Suffixes (In Order)** and add one or more DNS suffixes.
6. Tap **Save**.
7. Close the **DNS Settings** tab.
8. To exit **Philips SupportConnect**, touch **Close**.

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Connecting the System to a Network

To use connectivity features, the system must be connected to a network. The network receptacle on the system supports Gigabit, 10Base-T, and 100Base-T Ethernet LAN. A Philips field service engineer or your network administrator must configure the system for network connectivity.

For information on changing the network configuration for the system, see "System Administration" in the *Help*.

The system supports both wired and wireless networks.

For information on configuring networks, see "System Administration" in the *Help*.

Remote Access

The Remote Access feature is intended for use by a site administrator. It allows a Philips field service engineer to access your system remotely to run tests, to record system behavior, to conduct analysis, to monitor the system, and to download necessary software.

The  (Remote Access is Enabled) icon indicates that the Remote Access feature is active.

Configuring Remote Access

Before a Philips representative can remotely access your system, it must be configured to allow remote access. Typically, your Philips field service engineer configures the remote access. However, if your site uses a proxy server to access the Internet, and if your network administrator changes the proxy server location or password, you need to reconfigure the remote access. You have full control over the remote access settings, and no one can access the system remotely without your permission.

1. Press **Support**.
2. Tap the **Remote Services** tab.
3. Tap **Remote Connection Tool**.
4. Tap **Configure Proxy**.
5. Enter the information for the proxy server.

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6. Tap **Connect**.
7. If the proxy server settings are correct, the **OK** message appears. If the test settings are incorrect, or the test fails, the **Failed to Connect** message appears.
8. To exit **Philips SupportConnect**, touch **Close**.

Enabling a Remote Access Session

NOTE

If the **Government Security** licensed option is purchased and enabled, **Remote Access Configuration** options are not available.

1. Press **Support**.
2. Tap the **Remote Services** tab.
3. Tap **Remote Access Configuration**.
4. Select one of the following:
   - If you want the remote user to have full control over your ultrasound system, tap **Enable Remote Access**.
   - If you want the remote user to be able to observe but not control your ultrasound system, tap **Enable Remote View**.
5. If **Remote Session** is disabled, tap **Disabled** to enable remote sessions.
6. Read the **Enable Remote Connection Disclaimer**. Do one of the following:
   - If you accept the conditions, tap **Accept** to enable remote access or remote view.
   - If you do not accept the conditions, tap **Reject**. Remote access remains disabled.
7. To schedule remote access to be available only for a specified period, tap **Schedule Session Later**, and enter the start and end date and time.
8. Read the **Schedule Remote Connection Disclaimer**. Do one or more of the following:

- If you accept the conditions, tap **Accept** to schedule the session, and then set the start and end dates and times for the remote session.
- If you do not accept the conditions, tap **Reject**. The session will not be scheduled.
- To enable the remote access session to start without requiring the acceptance from the system user, select **Automatically Accept Incoming Connections**, and then tap **Schedule Remote Access**.
- To enable a remote view session, tap **Schedule Remote View**, and then set the start and end dates and times for the remote view.

9. To exit **Philips SupportConnect**, touch **Close**.

NOTE

You can disconnect the remote access session at any time during or after a session by tapping the (Remote Access Session is Active) icon.

Moving the System

Before moving a system that is not mounted on a cart, Philips recommends that you disconnect the AC adapter, ECG leads, and transducers. If you will be using the system again within 20 minutes, close the lid without turning the system off to put the system into the low-power portability mode. (Portability mode must be enabled in the setups.) If you will *not* be using the system within 20 minutes, turn it off before closing the lid and moving the system. For more information, see "Power Management" on page 170.

Observe the following warnings and cautions before moving a system that is mounted on a cart.

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WARNING

Be aware of the wheels on the system cart, especially when moving the system. The system could cause injury to you or others if it rolls over feet or into shins. Use caution when going up or down ramps.

WARNING

When attempting to overcome an obstacle, do not push the system from either side with excessive force, which could cause the system to tip over.

WARNING

Position external peripheral devices away from the system. Ensure that they are secure. Do not stack them on the system.

WARNING

When positioning the monitor and touch screen, move each carefully to avoid pinching hands or extremities.

WARNING

Disconnect any external hardcopy devices prior to moving the system.

WARNING

Never park the system on an incline.

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WARNING

Use caution when going up or down inclines. Improperly handled, the system can cause injury to you or others.

WARNING

If you park the system on a floor that is tilted 10 degrees or more and set the caster brakes, one of the braked casters might not be touching the floor, which can cause the system to move.

WARNING

The brakes are intended as a convenience. To increase cart security, use wheel chocks when the system is parked.

WARNING

To avoid injury, Philips recommends against lifting the system cart.

WARNING

To avoid damaging the monitor, follow the mechanical safety guidelines provided in this manual. If the monitor is damaged, contact your authorized service representative before using the system.

CAUTION

Ensure that the cables for all patient-applied parts are secure before moving the system. Use the cable management system to ensure that transducer cables are protected from damage.

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CAUTION

Do not roll the system over transducer cables or power cables.

CAUTION

When transporting the system in a vehicle, avoid exposing the monitor to direct sunlight. Exposure to direct sunlight can permanently damage the monitor.

Preparing and Moving

WARNING

Do not drape the power cord over any of the cable hooks or the handle on the system cart. Damage to the cord or power receptacle unit can occur if the cart is raised.

1. Do one of the following:
   - If you will be using the system within 20 minutes, make sure the system is configured to use low-power transport mode before you close the lid (see “Changing Power Management Settings” on page 173).
   - If you will *not* be using the system within 20 minutes, turn off the system by pressing ⏻ (On/Off).
2. Retract the keyboard, if it is extended.
3. Lower the touch screen.
4. Close the lid.
5. Disconnect all external cables, including those to power, network, and external devices.
6. If the system is attached to a cart, perform the following:

- Secure all cables, transducers, and accessories so that they do not interfere with the wheels.
- To increase stability, press the lever on the left side of the cart and press the system to its lowest position.
- Release the wheel brakes.

7. Move the cart using the cart handle.

CAUTION

Do not use the system handle to move the cart.

Positioning the System in Confined Spaces

1. Release the wheel brakes.
2. Move the system in any direction using the cart handle.
3. When the system is in position, set the wheel brakes.

Setting Up After Moving

CAUTION

If the system behaves abnormally after moving, contact your Philips representative immediately. The components are installed securely and can withstand considerable shock; however, excessive shock can cause a system failure.

With the system in position, set the brakes, connect the power, network, and other cables from the system to the appropriate wall receptacles.

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1. Open the lid and position the monitor where you want it.
2. Raise the touch screen and position it at the preferred angle. The maximum adjustable angle for the touch screen is 60 degrees.
3. Do one of the following:
   - If transport mode is disabled, press (On/Off) to turn on the system.
   - If transport mode is enabled, simply open the lid to resume operation.

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5 Using the System

The topics that follow will help you understand and use the features of the system.

Turning the System On and Off

The ⏻ (On/Off) control is on the upper left section of the control panel. The lighting of the control changes to indicate its status. The different indicators are described in the following table.

NOTE

Optional carts also have an On/Off control on the rear of the battery enclosure on the back of the system.

You can set the system to display a shutdown-confirmation dialog box after ⏻ is pressed (see “Enabling Shutdown Confirmation” on page 145).

Power Status and Indicators

System Status	Power Cord Status	Power Control Indicator	Sleep Control Indicator
Power off[1]	Disconnected	Unlit	Unlit
Power off	Connected[3]	Lit white	Unlit
Power on	Connected[3]	Lit green	Lit white
Transport mode	Disconnected	Blinking green	Unlit
Sleep Mode on[2]	Disconnected	Blinking green	Unlit
Sleep Mode on[2]	Connected[3]	Blinking green	Unlit

1. System has no battery or a discharged battery.

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2. Applicable only to systems with an installed, charged battery.
3. When connected, the system is energized and is charging the battery, if installed. For battery status, see “Battery Indicators” on page 174.

CAUTION

If you press and hold the ⏻ (On/Off) control to force the system to shut down, you will have to wait longer than usual to use your system the next time you turn it on. You may also corrupt files, which can result in an inoperative system or the loss of patient data. Wait 90 seconds (or 3 minutes if DICOM activity is occurring) before forcing the system to shut down.

NOTE

For the system, if battery power is unavailable (indicated by the (No Battery Power) icon), or if the battery charge level is critically low (indicated by the (Low Battery Power) icon), connect the system power cord to a wall outlet. The system shuts down automatically when the system battery charge level reaches the critically low state.

NOTE

For the carts with batteries, if battery power is unavailable (indicated by the (No Battery Power) icon), or if the battery charge level is critically low (indicated by the (Low Battery Power) icon), connect the cart power cord to a wall outlet.

NOTE

For a system on a cart with batteries, the cart batteries will charge the system battery until they are depleted.

1. When the system is off, press the ⏻ (On/Off) control to turn it on.
2. When the system is on, close all dialog boxes by selecting **Close** or **Done**, end all exams to avoid losing exam data, and then press the ⏻ (On/Off) control to turn it off. A confirmation message appears briefly on the display immediately before the system turns off.
3. If the system does not turn off after 90 seconds (or 3 minutes if DICOM activity is occurring), press and hold the ⏻ (On/Off) control for 7 to 10 seconds to force the system to turn off.
4. To break the connection from the main power supply, remove the ultrasound system plug from the wall outlet.

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Enabling Shutdown Confirmation

You can set the system to display a shutdown-confirmation dialog box after the ⏻ (On/Off) control is pressed.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings**, and then tap the **Display** tab.
4. Under **Control Panel Power Button**, select **Confirm Shutdown**.
5. To exit the setups, touch **Close**.

Setting the System Time and Date

The system includes a clock/calendar function, which displays the time and date on the imaging display, and provides a time stamp on patient studies and acquired images.

The system automatically adjusts the date for leap years and can be configured to update for daylight saving time automatically. It does not automatically set the time zone.

NOTE

The system time and date cannot be set when a study is active. Philips recommends that you check the system time and date periodically before a study, and set the correct time and date, if necessary.

NOTE

If you change the system date while a study is paused, existing results for date-dependent calculations in the paused study are not recalculated by the system at any time.

NOTE

When you enter invalid characters in the time and date setups on the **Header** tab of **System Settings**, some characters are displayed and then erased, but others are not displayed at all. An invalid date may be displayed in the setups but not saved when you close the setups. After changing a date and exiting the setups, always check the date on the imaging display.

NOTE

This system supports the Network Time Protocol (NTP), which keeps your system's time accurate by synching with the NTP server. To activate this feature, your site administrator must create a connection to an NTP server. For instructions, see the *Help*.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.

3. Tap **System Settings** and then tap the **Header** tab.
4. In **Set Time**, select a **Format** (**12 hours** or **24 hours**), select the time in the **Time** box, and then use the number keys to enter the correct setting. Select **Am** or **Pm**, if necessary.
5. In **Set Date**, select a **Format**, select the **Date**, and then use the number keys to enter the correct setting.
6. In **Time Zone**, select a time zone. And if you want to, select **Automatically Adjust Clock for Daylight Saving Time**.
7. To exit the setups, touch **Close**.
8. Verify the date and time on the imaging display.
9. If you changed the system date, to ensure that the system uses the correct date for all OB calculations, restart the system.

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Monitor Settings

You can change the monitor brightness and tint in the setups. The system can automatically optimize the brightness of the controls and the image on the monitor based on ambient light.

Monitor Tints

In the setups, you can change the tint of the system display. The **Monitor Tint** setting affects only the appearance of images on the monitor; it does not affect saved or exported images.

The following tint settings are available:

- **0** provides the maximum dynamic range and most-balanced tint. Use it to match the look of the system display to a review station display that is set to the sRGB standard.
- **1** is balanced toward a blue tint, for users who prefer a cooler tint.
- **2** is balanced toward a brown tint, for users who prefer a warmer tint.
- **3** provides a balanced tint similar to **sRGB** but with an increase in the color brightness.

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- **4** is balanced toward a blue tint, for users who prefer a tint cooler than tint **1**. It is designed to increase overall image contrast, which may influence image quality perception without making the image too bright.

NOTE

Rendered 3D volumes are particularly susceptible to changes in display tint. Some clinicians prefer the following settings for viewing 3D volumes: set **Default Monitor Tint** to **1** or **2** and set **Default Monitor Brightness** to **1**.

Changing the Monitor Tint

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings**, and then tap the **Display** tab.
4. Select the appropriate **Default Monitor Tint** setting.
5. To exit the setups, touch **Close**.

Temporarily Changing the Monitor Tint

You can also change the monitor tint temporarily, if a transducer is connected to the system.

1. Touch **Utilities**.
2. On the **System** tab, turn **Monitor Tint** to the setting that you want.

Changing the Monitor Brightness

You can change the default brightness of the monitor image in the setups. The system uses this default value to set monitor brightness each time the system is turned on.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.

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3. Tap **System Settings**, and then tap the **Display** tab.
4. Select a setting for **Default Monitor Brightness** from **1** (darkest) to **7** (lightest).
5. To exit the setups, touch **Close**.

Temporarily Changing the Monitor Brightness

You can also change the monitor brightness temporarily, if a transducer is connected to the system.

1. Touch **Utilities**.
2. On the **System** tab, turn **Monitor Brightness** to the setting that you want.

Changing the Monitor Black Level

You can set the default monitor black level. Setting **1** provides the largest contrast ratio and the greatest display of dynamic range. Higher black levels more closely match the contrast ratio of the review display and improve off-cart image consistency.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings**, and then tap the **Display** tab.
4. Select a setting for **Default Monitor Black Level** from **1** (darkest) to **6** (lightest).
5. To exit the setups, touch **Close**.

Temporarily Changing the Monitor Black Level

You can also change the monitor black level temporarily, if a transducer is connected to the system.

1. Touch **Utilities**.
2. On the **System** tab, turn **Monitor Black Level** to the setting that you want.

Automatic Display Dimming

To preserve monitor life and prevent burned-in display artifacts, the system automatically dims the display after more than 2 hours of operation with no control changes. The system restores full brightness as soon as you use any system control.

System Controls

System controls are on the control panel and the touch screen.

Control Panel

The control panel contains the main imaging controls. These controls include buttons, touch controls, the touch screen, and a trackpad. The control panel also allows you to select imaging modes, review and annotate images, perform measurements and calculations, and access **Philips SupportConnect**.

Control Panel

1	On/Off and Sleep Mode controls
2	Philips SupportConnect control
3	Touch screen
4	Soft key and mode controls
5	TGC controls
6	Trackpad

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NOTE

TGC and LGC controls are also available on the touch screen for some imaging modes.

Adjusting Control Panel Brightness

The control panel and touch screen brightness controls in the setups allow you to adjust the brightness of the control panel and touch screen to compensate for changes in ambient light.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings**, and then tap the **Display** tab.
4. Select a setting for **Default Control Panel Brightness**.
5. To exit the setups, touch **Close**.

Temporarily Changing Control Panel Brightness

You can also change the control panel brightness temporarily.

Touch **Utilities**, and then turn **CP Brightness** to select your preferred brightness level.

Acquire Controls

You can configure the **Acquire 1** and **Acquire 2** controls for a variety of acquisition functions and image destinations.

Configurable Functions and Image Destinations for Acquire Controls

Acquire Controls Functions	Local Printer	Network Printer (Including DICOM)	Storage Server
Acquire Loop	--	--	X
Acquire Frame	X	X	X

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Acquire Controls Functions	Local Printer	Network Printer (Including DICOM)	Storage Server
Acquire Frame (frozen image) or Loop (live imaging)	X (frame only)	X (frame only)	X
Print to Configured Printer	X	X	--

For more information, see “Configuring Local Printers” on page 123 and the “Printing” section in the *Help*.

Configuring Acquire Controls

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **Acquisition/Capture**, and then tap the **Archive/Printer** tab.
4. For each **Acquire** control, select a function from the **Acquisition Type** menu and then tap a destination in the **Destination(s)** list. You can assign multiple destinations to each **Acquire** control.
5. To exit the setups, touch **Close**.

For information about configuring acquisition and capture settings, printing images or clips, or adding images to a report, see the *Help*.

Setting the Depth Control

The **System Settings** display in the setups provides an option for you to select how the **Depth** control responds when you turn it.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings**, and then tap the **Mode** tab.
4. Under **Depth Control**, do one of the following:

- To increase depth when the control is turned clockwise, select **Increase Clockwise**.
- To increase depth when the control is turned counterclockwise, select **Increase Counter Clockwise**.

5. To exit the setups, touch **Close**.

Using the TGC Controls

The TGC touch controls on the control panel allow you to increase or decrease the amplification of the signal to adjust the brightness of the image at different depths.

NOTE

You can also adjust the TGC settings on the touch screen. For more information, see “Touch Screen Controls” on page 157.

To adjust the TGC controls, do one of the following:

- Touch a location on one of the lines.
- Swipe your finger along a line.
- Touch the arrow at either end of a line.

To reset the TGC curve, touch  (Reset).

To lock the TGC controls, touch  (Lock).

Specifying Freeze Actions

You can specify that the system automatically launch measurement or analysis tools (with or without calipers), the touch screen keyboard, annotations, or body markers when you press **Freeze**.

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You can configure the freeze actions separately by application. For example, you can specify that the **Calc Package** touch screen appears when you press **Freeze** in an **OB** exam, but that the **Label** touch screen appears when you press **Freeze** in an **Abdominal** exam.

Freeze actions are disabled when:

- An exam protocol is being recorded or is running.
- High Q measurements are active.
- Q-Apps are running.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings**, and then tap the **Display** tab.
4. In the **Freeze Key Launches This Touch Screen** area, select a behavior from the **Launch Touch Screen and Status** column for one or more applications.

Touch Screen

The touch screen is embedded in the control panel just above the soft keys. The screen is flat when the lid is closed, but can be raised up to 60 degrees and adjusted to reduce glare when room lighting is bright. The touch screen displays controls that are used to select applications and imaging modes, controls that are specific to the current operating mode, and soft key labels that change according to the current functions of the buttons on the control panel.

See “Touch Screen Layout” on page 155 and “Touch Screen Controls” on page 157.

Touch Screen Layout

The controls on the touch screen are organized by function.

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Touch Screen

A	**Workflow area**: Contains tools that enable the major workflow activities for starting, performing, and completing an exam.
1	Transducer selection controls
2	Tools
B	**Tabs**: Contains mode-specific or application-specific controls in different tabs.
C	**Controls**: The main area of the touch screen, which shows the controls for the currently selected tab in the current mode or application.
3	Sub-mode controls: Displays controls that activate sub-modes within 2D imaging.
4	Grouping panel: Groups controls for **2D**, **3D**, and **View**.

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5	Page indicator: Touch the indicator to go to the next page of controls, or swipe the screen to move between pages.
D	**Soft key labels**: Displays the labels for the current functions of the soft key controls. Some modes and applications have two rows of labels, some have one row, while others have no soft key control labels.
6	General-purpose soft keys
7	Dynamic soft keys

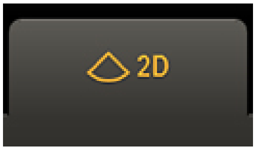
Touch Screen Controls

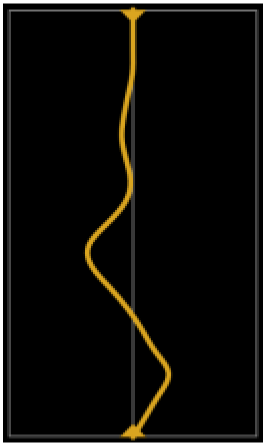
The color and state of the backlight on the soft key controls and their labels indicates the status of controls and modes:

- White backlight: available but inactive
- Amber backlight: active
- Gray (off) backlight: unavailable

For multiuse controls, such as **Res/Spd**, touch the control to change the active function.

Types of Touch Screen Controls

Control Type	Action
	Touch a tab to display a different set of controls. Touching the tab in this example displays controls associated with **2D** mode.
	Touch to turn a function on or off. The control is amber when the function is on. In this example, XRES imaging is on.

Control Type	Action
	To change the value of the soft key control label displayed in amber, turn the associated soft key control. To change the active soft key control label, press the soft key control or touch the label displayed in white. You can disable press behavior for soft keys. See "Disabling Press Behavior for Soft Key Controls" on page 166.
	Touch either arrow to cycle through the control's available options.
	Touch the chevron to display the control's available options.
	To adjust the TGC slider, touch and hold a spot on the line and move your finger to drag it into position. To reset the TGC curve, touch the center, gray line.

You can configure many acquisition-related touch screen controls to automatically send images to selected destinations, either at the end of an exam or after you print or acquire an image.

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Image Destinations for Touch Screen Controls

Configurable Touch Screen Control	Local Printer	Network Printer (Including DICOM)	Storage Server
Acquire Report	X	X	X
Acquire Screen	X	X	X
Alt Print	X	--	--
Capture	--	--	X
Print Screen	X	X	X
Save 3D	--	--	X
Save 3D Clip	--	--	X
Save 4D	--	--	X
Save All	--	--	X
Save Clip	--	--	X
Save MPR Clips	--	--	X
Save Sweep	--	--	X

Configuring Touch Screen Controls

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **Acquisition/Capture**, and then tap the **Archive/Printer** tab.
4. Tap a touch screen control, and then tap a destination in the **Destination(s) for the Button** list. You can assign multiple destinations to a touch screen control.
   - Under **Acquire Button Assignments**, indicate the acquisition type and destination for each control. You can assign multiple types and destinations to each acquisition control.

- Under **Touch Screen Buttons**, tap a touch screen control, and then tap a destination in the **Destination(s) for the Button** list. You can assign multiple destinations to a touch screen control.

5. Repeat step 4 for each control that you want to configure.
6. To exit the setups, touch **Close**.

For information about configuring acquisition and capture settings, printing images or clips, or adding images to a report, see the *Help*.

Adjusting Audio Feedback

You can set the system to provide audio feedback each time you touch the trackpad, the trackpad controls, the TGC controls, a soft key control on the control panel or use the keyboard on the touch screen. You can turn the audio feedback on or off and adjust the volume of the audio feedback to compensate for background noise in your work area. The audio feedback is off by default.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings**, and then tap the **Display** tab.
4. Select a setting for **Touch Audio Feedback Setting**.
5. Select a setting for **Touch Screen Keyboard Audio Feedback Setting**.
6. To exit the setups, touch **Close**.

Utilities Touch Screen

The **Utilities** touch screen displays these sub-tabs:

- **Physio**: contains the controls for the physio features. For details about physio controls, see the *Help*.
- **System**: contains controls that allow you to temporarily adjust system configurations for an exam. You can also access **Setups** from this tab to make permanent changes to the system. For details about the system controls, see the *Help*.

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System Tab Touch Screen Controls

This topic describes the touch screen controls for the **System** tab on the **Utilities** touch screen. Some of the controls are visible immediately, and others may be visible only when particular transducers or presets are active.

To use a touch screen control or change its setting, touch it. If it is in the bottom row, you can also turn or press the knob directly below it.

System Tab Touch Screen Controls

Name	Description
Accept Prior to Store	A control used to display image loops for approval before they are stored.
Capture Type	A control used to select the capture type: **Prospective** captures a specified acquired loop length (for a number of beats or seconds after the **Acquire** control is pressed). **Retrospective** captures a specified loop length from the imaging buffer after the **Acquire** control is pressed.
CP Brightness	A control used to adjust the brightness of the control panel and the touch screen display.
Delete User Presets	A control used to delete all custom (user-defined) presets.
Erase Text Annotations on Unfreeze	A control used to erase all text annotations on a frozen image when the system returns to live imaging.
Export IQ Optimization	A control used to start the **Export IQ Wizard**.
EV Brightness	A control used to adjust the brightness of an image displayed on an external monitor.
EV Contrast	A control used to adjust the contrast of an image displayed on an external monitor.
External Video Brightness/ Contrast	A control used to show and hide the **EV Brightness** and **EV Contrast** controls.
Help	A control used to display the system *Help*.
Hide Image Info	A control used to show and hide image information in the imaging display.

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Name	Description
Hide Patient Info	A control used to show and hide the patient information in the patient bar. See “Hiding Patient Name and ID on Images” on page 228.
Hide Thumbnails	A control used to show and hide the image thumbnail pane in the imaging display.
Loop Length	A control used to set the duration of the **Loop Type** in either heart beats or time.
Loop Type	A control used to set the loop type to either time (in seconds) or beats (heart beats). The loop type selected depends on whether or not ECG is active and if the R-wave is detected.
Monitor Black Level	A control used to set the level of darkness of the monitor background.
Monitor Brightness	A control used to adjust monitor brightness to compensate for changes in ambient light. Use this control to quickly make temporary adjustments to the monitor brightness setting in the setups. Turn **Monitor Brightness** to select a setting from **1** (darkest) to **7** (lightest).
Monitor Tint	A control used to adjust the tint of the system display. This control affects only the appearance of images on the monitor; it does not affect saved or exported images.
Print Screen	A control used to save an image of the full screen to the system hard drive and a copy of an image to the same destination devices as the **Print** control. **Print Screen** is available in live imaging, in Review mode, and when the image is frozen.
Setups	A control used to access the system parameters that you can change.

Trackpad

The trackpad is near the bottom of the control panel.

The tools and icons area of the imaging display includes a trackpad arbitration icon that identifies the function assigned to each trackpad control. The functions of the controls change to match your current task. There are trackpad assignments for each major system mode, protocols, labels, body markers, calculations, and measurements.

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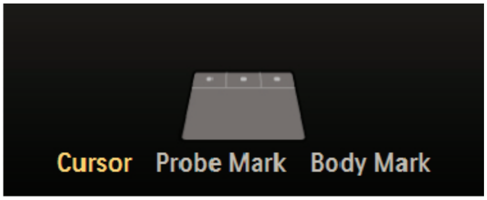


Trackpad Arbitration Icon

For example, the functions of the left and right trackpad controls can allow you to:

- Cycle through cineloop sequences when the image is frozen or in Review.
- Erase traces.
- Select measurements within a group.
- Scroll through items from right-to-left (left control) and left-to-right (right control).

The labels under the trackpad arbitration icon indicate the functions that are available for the entire trackpad.

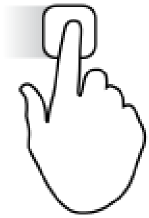
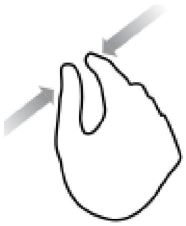
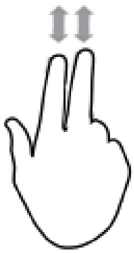
NOTE

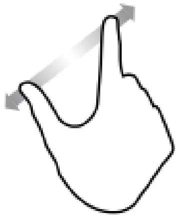
For some measurements, the trackpad functions become available only after you press **Measure**.

You can also configure the trackpad controls. For more information, see the system *Help*.

Trackpad Touch Gestures

The following touch gestures are used with the trackpad to control your system.

Gesture	Name	Description
	Double-tap	Touch the trackpad briefly twice with the same finger. Use in place of tapping the middle trackpad control.
	Drag	Touch the trackpad with a finger and move the finger across the trackpad without lifting the finger.
	Pinch	Touch the trackpad with two fingers and move them toward each other.
	Scroll	Touch the trackpad with two fingers and move them up and down to scroll through a list.

Gesture	Name	Description
	Spread	Touch the trackpad with two fingers and move them apart.
	Tap	Touch the trackpad briefly with your finger to select a control. Also, touch the trackpad, move the finger to position the pointer over a control or object, and then tap the trackpad. Use in place of tapping the left trackpad control.
	Two-finger tap	Touch the trackpad briefly with two fingers. Use in place of tapping the right trackpad control.

Configuring the Trackpad Controls

You can configure the left, middle, and right trackpad controls for the measurements that you perform. You also can adjust the sensitivity of the trackpad to suit your preferences.

For more information, see the system *Help*.

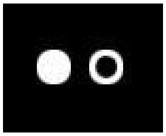
Soft Key Controls

Soft key controls (knobs that can pressed and turned) are between the mode controls and the touch screen. Two rows of labels for soft key functions and settings appear along the bottom of the touch screen. Each column of labels corresponds to the soft key below it on the control panel. The soft keys select imaging features and settings. The functions of the soft keys change depending on the mode, the application, the preset, and the transducer.

Sometimes, two functions are available for a soft key. Only one of the functions can be active at a time. By default, pressing the corresponding knob on the control panel or touching the label selects the active function. You can disable press behavior for soft key controls (see “Disabling Press Behavior for Soft Key Controls” on page 166). The label for active functions is amber. The label for inactive functions is white.

Many modes offer two or more pages of soft keys. To display the second page, place your finger on the touch screen and swipe to the left. To return to the first page, place your finger on the touch screen and swipe to the right.

You can also touch the page indicator, above the soft keys, to display the next available page of soft keys. The page indicator shows how many pages of soft keys are available and which one is displayed. For example, this page indicator shows that the first of two available soft key pages is selected:



Soft Key Page Indicator

Disabling Press Behavior for Soft Key Controls

Soft key controls (knobs that can pressed and turned) are between the mode controls and the touch screen. Sometimes, two functions are available for a soft key. Only one of the functions can be active at a time. Pressing the corresponding knob on the control panel or touching the label selects the active function.

For nonimaging functions, you can disable the press behavior for selecting the active function for soft key controls. Disabling press behavior prevents unintentional presses when you turn a soft key control.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings**.
4. Tap the **Mode** tab.
5. In **Unlabeled Knobs Below Touch Screen**, select **Pressing Knob Will Not Change Assignment**. To re-enable press behavior, select **Pressing Knob Changes Assignment**.
6. To exit the setups, touch **Close**.

To change the function of a soft key control after you have disabled press behavior, touch the soft key's corresponding touch screen label.

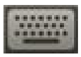
Using the Keyboards

When attached to an optional cart, the system has two keyboards, which you can use to enter patient data, exam comments, image annotation, and your logon password.

Touch Screen Keyboard

One keyboard is on the touch screen. That keyboard may appear automatically during certain activities.

To use the touch screen keyboard:

1. If necessary, touch  (keyboard) to display the keyboard.
2. When you are done typing, touch **Close**.

Retractable Keyboard

A retractable keyboard is at the top of the cart, beneath the system.

To use the retractable keyboard:

1. Push in the keyboard to unlatch it, then pull the keyboard forward.
2. When you are done typing, push in the keyboard in completely.

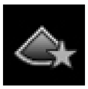
Setting the Default Caps Lock Status

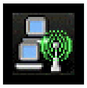
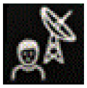
You can set the **Caps Lock** key to be on or off by default when the system is turned on.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings**, and then tap **Display**.
4. Under **Default Caps Lock Setting**, tap **Locked at Power Up** or **Unlocked at Power Up**.

Status Icons

Status icons on the display let you control certain features and check the status of tasks. Status can be indicated by colors or symbols within an icon, and by the absence of an icon.

Icon	Description
	Indicates the patient data security status.
	Displayed when the iSCAN Intelligent Optimization or AutoSCAN feature is on.
	Displayed when a physio trace is active.
	Displayed when Send on Demand is available.
	Displayed when remote access is enabled, but there is no active remote session.

Icon	Description
	Displayed when a remote session is active.
	Displayed when the system is acquiring an image or an image is opening in the **Review** pane.
	Indicates the status of a remote session: • No dot: Enabled but not active • Green dot: Enabled and active • Red X: Disabled
	Indicates the status of a Network Packet Capture: • Green dot: Enabled and running • Red X: Enabled but not running
	Indicates the status of the network and exports: • Green dot: Connected • Red X: Disconnected or error Tap the icon to view details of network status or export queue.
	Indicates the status of the wireless network: • Green dot: Connected • Red X: Disconnected or error • Blue vertical bands: Strength of wireless signal Tap the icon to open the **DICOM Setup** dialog box. This icon appears only if the DICOM licensed options are installed.

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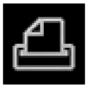
Icon	Description
	Indicates the status of the current print job: • Icon is displayed: a printer is available. • Green dot: a print job is being printed. • Red X: a print job has failed; an error occurred.
	Indicates the status of Collaboration Live: • No dot: Connected. • Green dot: New message. • : Not connected.

Enabling or Disabling Tooltips

Tooltips are available for the imaging settings that appear on the imaging display.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings**, and then tap the **Display** tab.
4. Under **Tool Tips**, select **Show** or **Hide**.
5. To exit the setups, touch **Close**.

Power Management

The system includes a power management feature to maximize the length of time that the system can operate on battery power. This feature also monitors the power level of the battery and notifies you when the system needs your attention. Additionally, the power management feature can shut down the system before the battery loses power. For more information, see “Changing Power Management Settings” on page 173.

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CAUTION

Operating the system when the batteries have a low charge level increases battery stress and shortens battery life. To extend the life of the batteries, plug the system into a wall outlet whenever the battery charge level is 25% or lower.

CAUTION

When shipping the system, make sure the battery is removed to prevent electrical discharge.

Please note the following about battery operation:

- To ensure the best diagnostic imaging capability, do not operate the system without the installed battery.
- To extend the battery power, press **Freeze** to stop ultrasound transmission when the system is not in use.
- When the system is turned on, is disconnected from AC power, and is not in Sleep Mode, the batteries will power the system until they are discharged to a critically low state.
- The batteries discharge if the system power is off for several days and the system is not connected to AC power. If the lid is up and the battery icon is black, or if the lid is closed and the power LED on the left rear side of the system is black, connect the system to an AC power outlet to operate the system.
- If the system is turned on and in Sleep Mode, but is not connected to an AC power source, the battery powers the system. If the system is turned on, in Sleep Mode, and connected to an AC power source, the battery charges.
- If a battery needs to be replaced, contact your Philips service representative.

- If power from the system battery is unavailable (indicated by the (No Battery Power) icon), or if the system battery charge level is critically low (indicated by the (Low Battery Power) icon), connect the system power cord to a wall outlet. The system shuts down automatically when the system battery charge level reaches the critically low state.
- For the carts with batteries, if battery power is unavailable (indicated by the (No Battery Power) icon), or if the battery charge level is critically low (indicated by the (Low Battery Power) icon), connect the cart power cord to a wall outlet.

Sleep Mode

Sleep Mode uses battery power and allows quick startup of the system. It does not eliminate power consumption and should be used only for short periods of time, such as when you transport the system between exam locations. The Sleep Mode control () is in the upper left corner of the control panel, next to the (On/Off) control. When the system is in Sleep Mode, it freezes live imaging, pauses any open study, exits any QLAB study, and terminates any remote connection. Awaken the system to resume normal system operation.

When the system is on battery power, the Sleep Mode time-out is approximately 40 minutes. The system remains in Sleep Mode until it is awakened or powered off, or until the batteries discharge to a critically low state. If the system batteries discharge to a critically low state, the system safely shuts down from Sleep Mode.

When you close the lid without turning off the system, the power management feature can put the system into a low-power transport mode to conserve battery power. Opening the lid when the system is in transport mode resumes normal operation. In the setups, you can change the settings for transport mode, including enabling or disabling it. For more information, see “Changing Power Management Settings” on page 173.

To put the system in Sleep Mode, press .

To awaken the system, connect the power cord to restore AC power, and press .

For information on the Sleep Mode status indicators, see “Turning the System On and Off” on page 143.

NOTE

When the system is in Sleep Mode and is connected to AC power, the system remains in Sleep Mode until it is awakened.

Changing Power Management Settings

You can change the settings for transport mode and the battery level warnings in the setups.

NOTE

To ensure that the system maintains a low power state when the lid is closed, you must enable transport mode.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings**, and then tap the **Power Management** tab.
4. Under **Transport Mode**, do either of the following:
   - To set the system to enter a low-power state when you close the lid, select **Transport mode enabled when display lid is shut**.
   - To set the interval between entering transport mode and the start of system shutdown, select a time under **Time before transition to full shutdown (mins)**.
5. Under **Battery Level Warnings**, do either of the following:
   - To set when the low-battery warning is displayed, select a time under **Time remaining at low battery warning (mins)**.
   - To set when the critical-battery warning is displayed, select a time under **Time remaining at critical battery warning (mins)**.
6. To return the system to default power management settings, tap **Reset Defaults**.

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7. To exit the setups, touch **Close**.

Battery Indicators

Battery status indicators on the system display show the battery charge level for the battery on the system (see “System Battery Status Indicators” on page 174) and the batteries on the cart (see “Cart Battery Status Indicators” on page 176). Status changes may take several seconds to appear on the display.

In addition to the display indicators in the following tables, indicator lights on the system and the cart provide the status of the system battery and cart batteries, respectively, when the system is shut down or the system lid is closed.

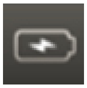
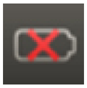
The system has one indicator light near the USB ports on the left side of the system that provides a color-coded status:

- Yellow: System battery is charging.
- Green: System battery is charged.
- Unlit: System battery is disconnected, not installed, or has no charge.

The cart has five indicator lights on the rear of the battery compartment that display the available charge of the batteries. Each indicator light represents a battery charge of approximately 20%.

System Battery Status Indicators

Indicator	Description
	The system is running on AC power and the battery charge is 80% to 100%.
	The system is running on AC power and the battery charge is 60% to 80%.

Indicator	Description
	The system is running on AC power and the battery charge is 40% to 60%.
	The system is running on AC power and the battery charge is 20% to 40%.
	The system is running on AC power and the battery charge is 0% to 20%.
	The system is running on AC power and the battery is not charged.
	The system is running on AC power and the battery is disconnected or not installed.
	The system is running on battery power and the battery charge is 80% to 100%.
	The system is running on battery power and the battery charge is 60% to 80%.
	The system is running on battery power and the battery charge is 40% to 60%.
	The system is running on battery power and the battery charge is 20% to 40%.
	The system is running on battery power and the battery charge is 0% to 20%.

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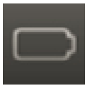
Indicator	Description
	The system is running on battery power and the battery has no charge.

Cart Battery Status Indicators

NOTE

Batteries are available on the Extended, Deluxe, and Premium carts. For more information on the available carts, see “System Cart” on page 118.

Indicator	Description
	The cart is running on AC power and the battery charge is 80% to 100%.
	The cart is running on AC power and the battery charge is 60% to 80%.
	The cart is running on AC power and the battery charge is 40% to 60%.
	The cart is running on AC power and the battery charge is 20% to 40%.
	The cart is running on AC power and the battery charge is 0% to 20%.

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Indicator	Description
	The cart is running on AC power and the battery is not charged.
	The cart is running on AC power and the battery is disconnected or not installed.
	The cart is running on battery power and the battery charge is 80% to 100%.
	The cart is running on battery power and the battery charge is 60% to 80%.
	The cart is running on battery power and the battery charge is 40% to 60%.
	The cart is running on battery power and the battery charge is 20% to 40%.
	The cart is running on battery power and the battery charge is 0% to 20%.
	The cart is running on battery power and the battery has no charge.

AC Adapters

When not on a cart, the system receives its power from an AC power source through the AC adapter and power cable, much like any laptop computer. The adapter also charges the system battery. Battery charging occurs even when the system is turned off.

When on a cart, the AC adapter in the cart base provides power to the system. If the cart has the battery option, the cart AC adapter also charges the cart batteries.

For more information about cart options, see "System Cart" on page 118.

Using the System AC Adapter

This procedure describes using the system AC adapter and connecting the power cable when the system is off the cart. When the system is on a cart, the AC adapter in the cart's base provides power to the system.

For more information about cart options, see "System Cart" on page 118.

WARNING

Use only the AC adapter supplied with your system.

WARNING

Connect the system only to a hospital-grade outlet.

WARNING

When using the AC adapter with the system, do not place them on the floor or on a patient bed. Place them on a table or chair.

CAUTION

When disinfecting the AC adapter, do not spray it with disinfectant; instead, unplug the adapter and wipe it with disinfectant, being careful to avoid getting any liquid inside the adapter. For more information, see "Cleaning and Disinfecting the AC Adapter" on page 359.

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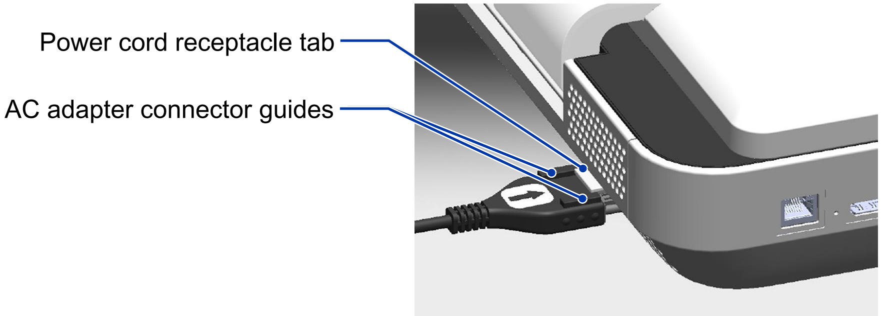
1. Connect the AC adapter to the power receptacle on the back of the system. The connector is designed to be inserted only in the correct orientation.



Connecting the AC Adapter

2. Connect the power cable of the AC adapter to a wall outlet.
3. To charge the battery, do one of the following:
   - To recharge while using the system, turn the system on.
   - To recharge when not using the system, leave the system off.

Battery Operation

For portable operation, the system is powered by an internal lithium polymer battery. To protect the battery and prolong its life, follow these guidelines.

Some of the optional carts include batteries that (when connected) provide enough power to operate the system and recharge the system battery simultaneously.

WARNING

Attempting to open batteries or incinerate them can result in serious injury. Do not strike, puncture, drop, or throw batteries.

WARNING

Do not immerse batteries in liquid or short the battery contacts with liquid or metal objects.

WARNING

Keep batteries clean and dry.

WARNING

Wipe the cell or battery terminals with a clean, dry cloth if they become dirty.

WARNING

Keep batteries out of the reach of children.

WARNING

If a battery has been cracked, punctured, or otherwise compromised, place it in a heavy-duty resealable plastic bag, and dispose of it as hazardous material, in accordance with local, state, or federal laws.

WARNING

If a battery leaks or emits a strong odor, remove it from the system and store it away from any ignition source. Avoid contact with the fluid. If you get fluid on your skin, wash the area with copious amounts of water and seek medical assistance.

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WARNING

If a damaged battery must be shipped, place the battery in a heavy-duty resealable plastic bag and ship it by ground as Class 9 hazardous material. Do not ship damaged batteries by air.

CAUTION

Do not operate the system at ambient temperatures below 10°C (50°F) or above 40°C (104°F).

CAUTION

Use only batteries supplied by Philips in your system.

CAUTION

Before using a battery for the first time, charge it in the system for one hour.

CAUTION

Do not store or charge batteries in direct sunlight or at ambient temperatures below -30°C (-22°F) or above 70°C (158°F).

CAUTION

Recharge batteries immediately after use. Storing discharged batteries will damage their capacity. For storage, the batteries should be charged to at least 40% of capacity.

CAUTION

Remove batteries from the system if it will not be used within two weeks.

CAUTION

When shipping systems, remove batteries and protect them against damage during shipping.

CAUTION

Batteries can be safely cleaned using isopropyl alcohol (70% solution in water) or mild soap and water.

CAUTION

Batteries are sealed and safe for normal use, provided that the operating instructions are observed and provided that their cases have not been compromised.

CAUTION

For storage longer than six months, charge batteries to approximately the 50% charge level **.**

CAUTION

Batteries can be charged only when they are in the system.

Installing the System Battery

Use the following procedure to install or replace the system battery.

WARNING

Before removing the system battery, ensure that the system is powered off and disconnected from AC power.

1. Turn off the system and wait for it to finish powering down.
2. If the system is connected to AC power, disconnect it.
3. Lift the battery cover on the left side of the system.
4. Do one of the following:
   - To remove the battery, grip the battery handle and pull the battery out of the compartment.
   - To install the battery, slide the side of the battery opposite the handle into the compartment, and then push the battery into place.
5. Lower the cover and ensure that it is seated securely.

System Battery Cover

System Security

The data security feature, if enabled on your system, limits access to previously stored patient data and images. To gain access to such data, you must first log on to the system using an ID and a password. When you are finished using the system, you can log off manually or simply shut down the system, which logs you off automatically. If necessary, you or your site administrator can change your password. See “Changing Your Password” on page 185.

Guest access allows you to perform an exam, but you cannot access patient data nor can you enter Review after you end the exam.

The data security feature is set up by your site administrator. For more information, see the *Help*.

Logging On to the System

When data security is enabled, you must log on to the system before you are able to view or load patient files.

1. Tap  (**Data Security Locked: Login**) at the bottom of the imaging display.
2. If prompted, review the logon message and tap **OK**.
3. In the **Data Security Logon** dialog box, type your user name.
4. Press the **Tab** key and type your password. (If you forget your system password, contact your site administrator.)
5. Tap **Login** to log on to the system and start the valid access period.

Logging Off of the System

If you do not log off, the system automatically logs you off when you shut down the system or after the system has been inactive for the length of time shown in **Auto Log Off** on the **User Settings** tab of the **Data Security** setups.

1. Tap  (**Log Off**) at the bottom of the imaging display.

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2. In the **LogOff** dialog box, tap **Yes**.

NOTE

Logging off of the system does not change the current patient, but it does deny further access to protected patient data.

Changing Your Password

If the data security feature is enabled on your system, you must log on to the system to gain access to patient data and images.

After the site administrator has given you a password for the system, you can change it as needed, unless your site administrator has enabled remote user management. If remote user management is enabled, you cannot change your password on the system. For instructions, see your site administrator. Passwords must conform to the password policy, if the site administrator has set one.

NOTE

The **Auto Log Off** time shown on the **User Settings** display indicates how long the system can be inactive before you are logged off automatically. Only the site administrator can change this setting.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **Data Security**.
4. On the **User Settings** tab, tap **Change Password**.
5. For **Old Password**, type your current password, and then press the **Tab** key.

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6. For **New Password**, type the new password you want to use, and then press the **Tab** key.
7. For **Confirm Password**, type your new password again.
8. Tap **OK**.
9. To exit the setups, touch **Close**.

System and Data Security

Because of its size, the system is an easy target for theft if it is not secured. When the system is not being used, secure it using a standard laptop cable lock.

Follow the instructions included with the cable lock to secure the system to an immovable object. A Kensington lock receiver is on the left side of the system, near the rear.

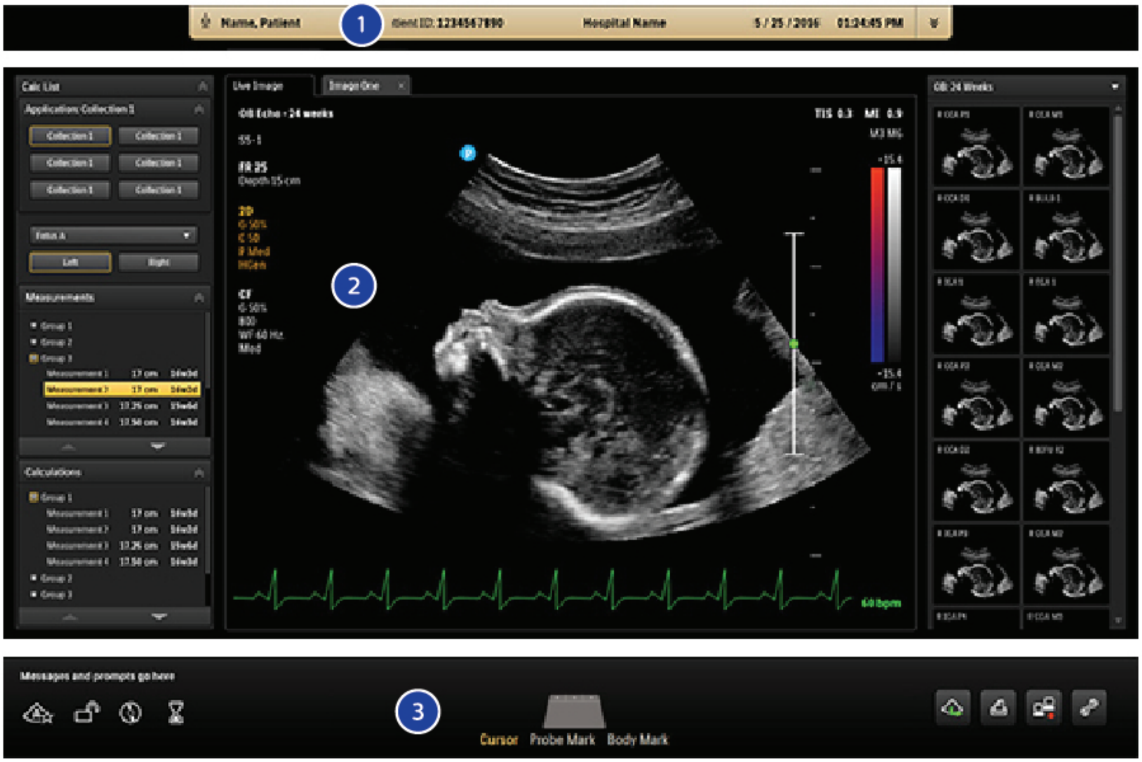
Kensington Lock Receiver

Because system theft could expose patient health information, export patient data and images regularly to removable media or to a DICOM-compatible device on a network. After exporting such data, delete it from the system.

For more information about keeping your system and data secure see "System Administration" in the *Help* and *Shared Roles for System and Data Security*.

Imaging Display

The imaging display contains three, distinct regions:

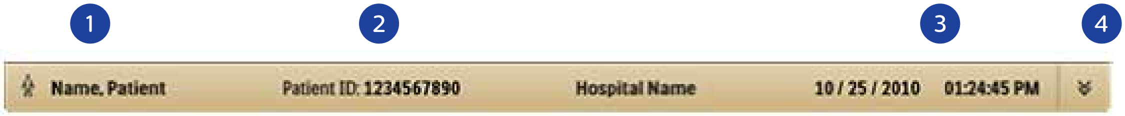


Imaging Display

1	Patient bar
2	Image area
3	Tools and icons

Patient Bar

After you start an exam, patient and exam data appear in the patient bar, which is directly above the ultrasound image. With the **Header** setting in the **System Settings** setups, you can select three of the five additional information options to display on the patient bar: **Patient Birth Date**, **Patient Gender**, **Institution Name**, **System Model**, and **Performed By**.



Patient Bar

1	Patient name
2	Patient ID
3	Date and time
4	Expand patient bar icon: Tap to view all of the available patient data during an exam.

Image Area

The image area is approximately in the center of the display and includes the following:

- *Status bar*: Indicates the current status of the image (live or frozen).
- *Left pane*: Lists available calculations and protocols, and the calculations and measurements being performed; displays calculation results; and provides other tools as necessary. Tabs at the top of the left pane enable you to switch among those lists. To hide the left pane, select , in the top right corner of the pane.
- *Imaging area*: Displays the live image (or other applications, such as Q-Apps), a depth scale that includes the focus setting (to the right of the image), a TGC curve, a grayscale bar, and a color bar (to the right of the depth scale). In M-mode and Doppler, the sweeping display appears either below the 2D image or to the right of it, depending on the format you select.
- *Thumbnail pane*: Displays thumbnail images from the current exam.

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For general imaging, a scan plane orientation marker  appears at the top left of the image. For cardiac exams, the orientation marker appears at the top right of the image. The marker corresponds to the orientation marker on the transducer. The marker always follows the orientation of the image. When you invert the image by using **Left/Right** or **Top/Bottom**, the marker position changes accordingly.

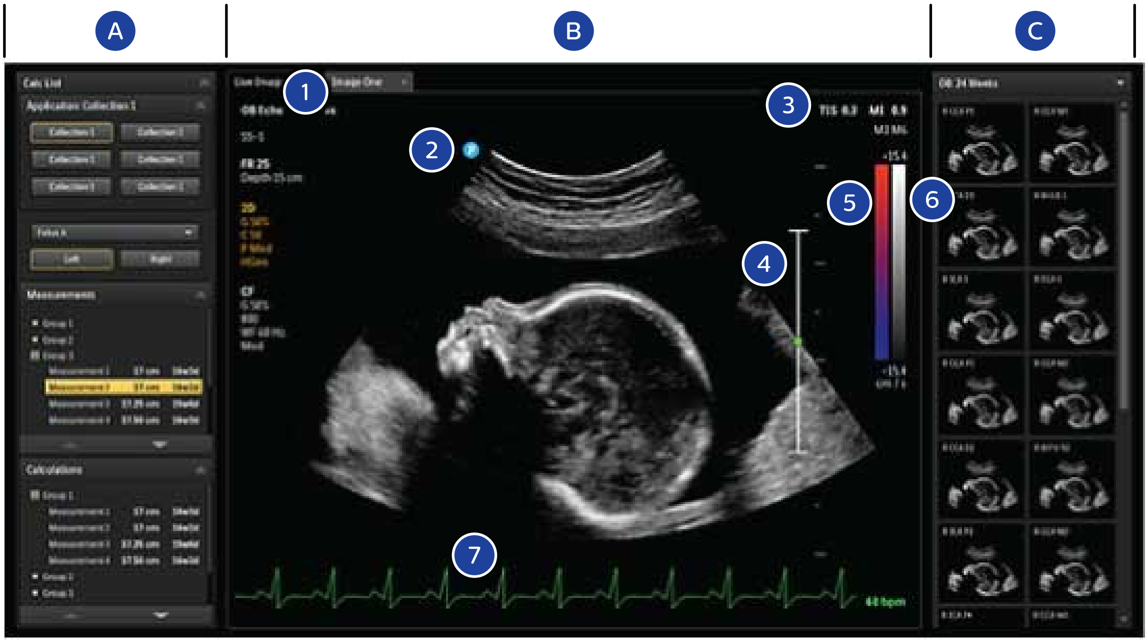

Image Area

A	Left pane
B	Imaging area
1	Status bar
2	Scan plane orientation marker
3	MI and TI values
4	Focal indicator

5	Color bar
6	Grayscale bar
7	Physio display
C	Thumbnail images

Tools and Icons

The tools and icons area displays:

- Status icons: These icons simply provide status of system features and cannot be selected.
- Trackpad arbitration icon: The labels above and to the left and right of the trackpad image correspond to the function currently assigned to the middle trackpad control (which is above the trackpad) and the left and right trackpad controls, respectively. The labels next to the trackpad image indicate the functions that are available for the entire trackpad. For details, see “Trackpad” on page 162.
- System management icons: These icons show status and can be selected. When an icon is selected, a dialog displays with additional status information or available actions.

For definitions of status and system management icons, see “Status Icons” on page 168.

Tools and Icons

1	Status icons
2	Trackpad arbitration status
3	System Management icons (interactive)

Displaying the Image Area on the Touch Screen

You can display live 2D, 3D, and 4D images on the touch screen.

You can control the TGC and LGC on the live imaging touch screen.

1. Press or touch **2D**.
2. Swipe until you see the live image on the touch screen.

Resizing the Image Area

You can set the image area to occupy the entire display with the MaxVue display. The MaxVue display hides the left and right panes and minimizes the trackpad arbitration icon. You can show the panes as needed. In the setups, you can also change the appearance of the trackpad arbitration icon (see "Changing the MaxVue Trackpad Arbitration Icon" on page 192).

NOTE

Calipers, measurements, and arrows disappear when changing from the standard display to the MaxVue display.

1. To enable the MaxVue display, touch **MaxVue**. To disable the MaxVue display, touch **MaxVue** again.
2. To display the left or right pane, do one of the following:
   - Hover the cursor over the left side or right side of the display. The pane remains displayed as long as the cursor is over it.
   - Tap (Pin) for the pane that you want to display. The becomes an amber color. To unpin the pane, tap again. If you restart the system, the pane will be unpinned.

Setting MaxVue Display for System Startup

You can set up the system to start with the MaxVue display already enabled. After the system is running, you can still disable or reenable the MaxVue display by touching **MaxVue**.

1. Touch **Utilities**.

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2. On the **System** tab, touch **Setups**.
3. Tap **System Settings** and then tap **Display**.
4. Under **MaxVue on Power Up**, select **On**.
5. Touch **Close**.

Changing the MaxVue Trackpad Arbitration Icon

For the MaxVue display, you can select from two appearances for the trackpad arbitration icon area (trackpad legend):

- The text-only ("thin") display hides the trackpad arbitration icon but shows the trackpad arbitration text. To see the trackpad arbitration icon, move the pointer to the bottom of the display.
- The watermark display shows a transparent trackpad arbitration icon and transparent trackpad arbitration text, which you can reposition.

1. To set the appearance of the trackpad arbitration icon, do the following:
   a. Touch **Utilities**.
   b. On the **System** tab, touch **Setups**.
   c. Tap **System Settings** and then tap **Display**.
   d. Under **Trackpad Legend Style for MaxVue**, select either **Watermark Trackpad Legend** or **Thin Toolbar Trackpad Legend**.
2. To reposition the watermark trackpad arbitration icon, press **Pointer** to display the cursor, and then tap the trackpad arbitration icon and drag it to the location you want.

Emergency Studies

If the site administrator has enabled the data security feature on your system, it is important to understand how to start a study in an emergency situation.

In an emergency, you can start a study without entering patient data. During an emergency study, the system provides a temporary ID for image acquisition and report editing. You should change the temporary ID to correct the patient data before you end the study. Otherwise, the temporary ID is the only identifier for that study.

You can start an emergency study without logging in when the system restriction mode is set to **Only Patient Data Is Locked** by your site administrator. However, when the system restriction mode is set to **Complete System Is Locked (Both Imaging and Patient Data Require Login)**, the user must log in as registered user, even to perform an emergency exam.

Temporary ID

Use the temporary ID feature to start an exam quickly. This feature allows you to perform an exam without first entering patient data. When you select this feature, the system enters unique, temporary placeholders for the patient's last name and ID. Using the temporary ID feature allows you to perform an exam as you would normally.

When you use the temporary ID workflow, images can be sent to a PACS or to a DICOM printer before entering actual patient data, if the system is configured to send or print images as you scan.

For an exam started with a temporary ID, edit patient data before ending the exam. For information on editing patient data, see the *Help*. After the exam is ended, you cannot change patient data. When the patient data is changed, all images are automatically resent to any local printers that they were previously sent to.

If your system is connected to a DICOM Worklist Server, you can load patient data to replace the temporary ID data. For information on replacing a patient with a modality worklist patient, see the *Help*.

NOTE

If you have configured a DICOM Performed Procedure Step server, PPS messages are sent for the temporary ID. If you edit patient data before you end the exam, PPS "discontinue" messages are sent for the temporary ID.

You can print images before you enter patient data (if the system is configured to print images as you scan), but those images are labeled only with the temporary ID.

Starting Emergency Studies

In an emergency, you can use the temporary ID feature to start an exam without first having to enter patient data. Just tap **Use Temporary ID** after you acquire an image.

You can create a temporary ID when starting a protocol, printing, acquiring an image, or saving a volume.

1. Touch **Patient** and then do one of the following:
   - Tap **Use Temporary ID** on the **Patient Data** display.
   - Touch **Temporary ID** on the touch screen keyboard.
2. When the exam is finished, do the following:
   a. Touch **End Exam**.
   b. In the **Temporary Patient Study** dialog box, tap **End Exam**.

Setting the Auto Freeze Function

The Auto Freeze function stops imaging and freezes the image, if a control is not manipulated within the **Wait** time that you specify. The default time is 15 minutes. After Auto Freeze is activated, press **Freeze** to restart imaging.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings** and then tap the **Display** tab.
4. Under **Auto Freeze**, select **On**, and then select the **Wait** time.
5. To exit the setups, touch **Close**.

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Transducer Receptacles and Cable Management

The system includes one receptacle for imaging transducers and one receptacle for a continuous-wave Doppler probe. When the system is connected to a cart configured with the Multiport adapter, the system uses the Multiport adapter's three receptacles for imaging transducers.

Transducer Receptacles

1	Primary receptacle for a directly connected transducer or the Multiport adapter connector
2	CW Doppler probe receptacle

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Multiport Adapter Transducer Receptacles

When a transducer is not in use, store it in one of the transducer holders on the system cart, and place the transducer connector in one of the holders on the cart. To prevent cables from being stepped on or run over by the cart, always loop transducer cables over the cable hangers.

Transducer Holders and Cable Hangers

1	Transducer holders
2	Cable hangers

Using the Easy-Clip Transducer Cable Managers

Easy-clip transducer cable managers keep transducer cables off the floor, while taking the weight of the cable when you are using the transducer. Cable managers can be disassembled for cleaning, if necessary (see “Cleaning and Maintaining the System” on page 352). Cable managers may need to be replaced approximately every six months.

1. Place the transducer in a holder.
2. Attach the handle hook of the easy-clip cable manager to the system handle. Make sure the handle hook is oriented correctly, with the cable clips suspended from the inside of the system handle.

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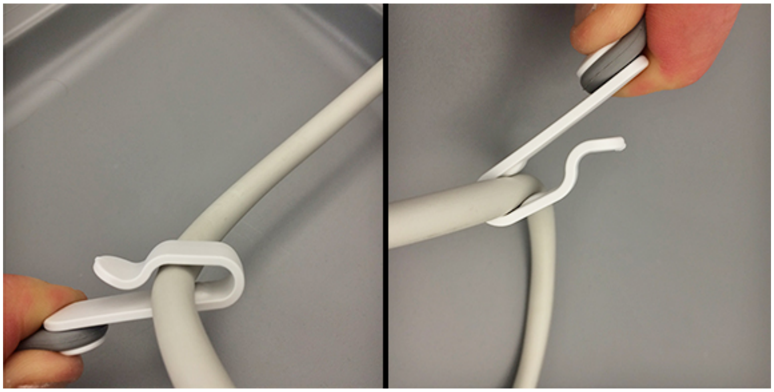
Correct Orientation of the Handle Hook

CAUTION

To avoid damage to the transducer cable and the easy-clip cable manager, do not force a large transducer cable into the smaller end of the clip.

3. With the transducer cable hanging free (not from a cable hanger), find the middle of the transducer cable, and then press it into the clip. (Insert only one cable into each clip.) The clip can accommodate transducer cables with large and small diameters:



Positions for Large (left) and Small (right) Cables

4. Lower the transducer cable, and allow it to hang from the cable manager. Reposition the clip until the entire transducer cable is off the floor and away from the wheels.

Connecting Transducers

The system has one imaging transducer receptacle and one Doppler probe receptacle. Both receptacles are on the right side of the system. Three additional transducer receptacles are available on the Multiport adapter.

- To connect an imaging transducer to the system, insert its connector fully into the receptacle and move the locking lever up.
- To connect an imaging transducer to the Multiport adapter on the cart, ensure that the locking lever is positioned to the right, insert its connector fully into the receptacle, and move the locking lever to the left.
- To connect a Doppler probe, insert its connector into the receptacle until it latches.

Connecting a Transducer to the System

Connecting a Transducer to the Multiport Adapter

Selecting a Transducer

When you turn on the system, the system initializes the default transducer and preset. For information on default transducers and presets, see “Setting the Default Transducer and Preset” on page 210 and “Default Transducer” on page 249.

NOTE

If the **Unsupported Transducer** message appears, disconnect and reconnect the transducer and ensure that all connected transducers are compatible with your system configuration.

You can connect or disconnect a transducer during live imaging without damaging the transducer or the system.

1. Touch the transducer name to select it.
2. Touch the preset that you want to use.

After you select the preset, the system calibrates the transducer, enables the transducer for operation, and updates system status to reflect the transducer type and the preset you selected.

Selecting a Preset

When the system is turned on, the system selects the same preset that was in use when the system shut down (unless it is incompatible with the initially selected transducer). For more information, see “Setting the Default Transducer and Preset” on page 210.

During system operation, you can select a different preset for the selected transducer.

1. Touch the transducer name to select it.
2. Touch the preset that you want to use.

Physio Feature

The system can display three physio traces, each representing a physiological input. These inputs can include low-level ECG, high-level ECG, respiratory, pulse, phono, and auxiliary signals. (Low-level ECG comes from leads connected to the patient; high-level ECG comes from a patient monitor or other similar equipment.) Heart rate, derived from the ECG signal, is displayed on the screen whenever ECG is connected and displayed.

WARNING

The Physio feature is intended to provide the R-wave trigger for ultrasound image capture. The Physio trace is used to provide a qualitative assessment of lead connections. The Physio feature is not intended to be used as a monitoring device or to make a diagnostic determination.

USB Devices

The system supports USB-based storage devices only, including external hard disk drives, DVD writers, and flash memory devices.

For details about USB storage devices, see “USB Storage Devices” on page 202.

USB Storage Devices

The capacity of the USB storage device is usually indicated on the device. You can use USB storage devices for tasks for which you would use a CD or DVD.

The system assigns a drive letter to each connected USB device. The assigned letter varies from system to system.

When you use a USB cable to connect a USB device to system, use a short cable, or follow the cable recommendations of the drive manufacturer.

Before using USB storage devices, see “Selecting Compatible USB Media” on page 204.

WARNING

Connecting externally powered USB hard disk drives to the system involves electrical safety risks. If you connect such drives to the system, you must observe the electrical safety warnings in the "Safety" section. Philips recommends that you use only USB hard disk drives powered from the USB connector, or use USB flash memory devices.

CAUTION

When transferring data to or from a USB device, be sure the transfer is complete before removing the USB device. For USB devices that have an indicator, be sure the indicator is no longer flashing before removing the device.

CAUTION

Ultrasound systems may become vulnerable to security breaches when they accept removable media. Removable USB storage devices may contain viruses. Philips recommends that you use a virus-free system to scan and format USB storage devices before connecting them to the ultrasound system.

CAUTION

Philips does not recommend that you use USB storage devices for long-term storage. Follow your IT department's recommended practices for intended use of USB storage devices. For more information about security on the ultrasound system, see *Shared Roles for System and Data Security*, included on your *User Information* USB media.

Dirty or corroded connections can cause malfunctions. To ensure proper operation, confirm that the USB connections are clean.

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Do not use any hard drive that does not comply with the USB Power Delivery specification, because it may cause temporary loss of USB port functionality. Do not use a USB hard drive that requires an external AC power source, because it may compromise the system's electrical safety.

If an optional cart is used with the system, it includes a USB hub that has been tested and approved by Philips. Do not use additional hubs, because they may draw more power than the USB 3.0 standard and may cause temporary loss of USB port functionality.

Selecting Compatible USB Media

You can use USB storage devices and USB hard drives for import and export operations. For best results, use USB 2.0 compatible media with a write speed of at least 35 MB/s. (Those devices are usually also compatible with USB 3.0.)

System USB ports meet the USB Power Delivery specification, and you can use them to power USB hard drives that conform to that specification.

The system supports the following USB devices:

- Single-partition USB storage devices
- USB storage devices that do not use or contain any antivirus or other executable software
- USB hard disk devices that conform to the USB Power Delivery specification
- USB 2.0 compatible devices

NOTE

The system supports devices that are both USB 2.0 and USB 3.0 compliant.

Barcode Scanner

Your ultrasound system supports an optional barcode scanner for the following uses:

- Enter patient data

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- Select and review an exam
- Select a patient from a worklist

The system supports only barcodes that contain one type of information (for example, patient ID, patient name, or medical record number). If you want to scan more than one type of patient data, each type of data must be in its own barcode.

Supported Symbologies

The barcode scanner supports the following symbologies:

- Aztec
- Code 39
- Code 128
- DataMatrix
- EAN/UPC (EAN8, EAN13, UPCa, UPCe)
- Interleaved 2 of 5
- MaxiCode
- PDF417
- QR code
- UCC/EAN-128

NOTE

Only barcode scanners that conform to Philips standards and that have been configured to read your site's barcode symbology can be used with the system.

Configuring the Barcode Scanner

Before you use your barcode scanner, you must configure it.

1. Connect a Philips-approved barcode scanner to a USB port on your ultrasound system.

2. Scan the following barcode and verify that you hear a two-tone beep:

Configuration Barcode

Customizing the System for the Barcode Scanner

You can customize your system to populate specific fields, or search with specific filters, automatically when a barcode is scanned.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings**, and then tap the **Patient Data** tab.
4. Under **Barcode Settings**, do any of the following:
   - To identify the field that is selected by default when you touch **Patient**, select the field name from the **Scanned Field** menu.
   - To identify an additional field to be selected automatically after the **Scanned Field** is populated, select the field name from the **Second Field** menu.
   - To identify the filter that is displayed by default in the **Worklist** tab of the **Patient Data** form, select the filter name from the **Find** menu.
   - To identify the filter that is displayed by default in **Review Exam**, select the filter name from the **Find** menu.
5. To exit the setups, touch **Close**.

NOTE

Before you can use the Modality Worklist feature, you must specify the DICOM Modality Worklist server. For details, see "System Administration" in the *Help*.

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Entering Patient Data from a Barcode

CAUTION

This system cannot interpret the type of data in your barcode. It is your responsibility to ensure that the correct information is scanned into the appropriate field.

1. Connect a Philips-approved barcode scanner to a USB port on your ultrasound system.
2. Touch **Patient**. The field set up to be populated first with barcode data is selected automatically.
3. Scan the barcode.
4. Confirm that the correct fields are populated with the scanned information.
5. If you have set up a second field to receive barcode data, that field is selected automatically. Scan the second barcode to input data into that field.
6. If you want to input scanned barcode data in other fields, select the field manually, and then repeat steps 3 and 4.
7. When you are finished, tap **Done**.

Selecting and Opening an Exam from a Barcode

1. Connect a Philips-approved barcode scanner to a USB port on your ultrasound system.
2. Touch **Review**. The filter option that you selected in the setups is displayed automatically.
3. Scan the barcode.
4. If the search yields only one exam, the system opens that exam automatically. If the search yields multiple exams, tap the exam you want, and then tap **Open**.

Selecting Worklist Patients from a Barcode

1. Connect a Philips-approved barcode scanner to a USB port on your ultrasound system.

2. Touch **Patient**, and then tap **Worklist**. The filter option that you selected in the setups is displayed automatically.
3. Scan the barcode.
4. If the search yields only one patient file, the system opens that patient file automatically. If the search yields multiple patient files, tap the file you want, and then tap **Open**.

NOTE

Before you can use the Modality Worklist feature, you must specify the DICOM Modality Worklist server. For details, see "System Administration" in the *Help*.

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6 Customizing the System

You can customize your system to increase efficiency and streamline your workflow. You can do the following:

- Create presets designed specifically for the exams you perform.
- Change system settings to reflect your needs.
- Add options to enhance your imaging abilities.
- Create custom procedures for specific patients, transducers, and presets.

Presets

A preset is a group of settings that optimizes the system for a specific type of exam. Presets establish many initial settings, such as gain value, color map, filter, and items on the touch screen.

When you turn on your system, the default preset is active. Before you begin an exam, be sure that the appropriate preset is active.

Each transducer has one default preset and may also have several additional factory presets that you can select. You cannot delete the factory presets. However, they provide a starting point from which you can create your own presets. You can create and store up to 53 presets per transducer/application combination, depending on the space available on the touch screen. If you need to create more than 53 presets per transducer, you can save presets to a USB storage device and restore them when you need to use them.

The available presets are determined by the selected transducer.

NOTE

Presets are available only if you purchased the corresponding application-package option.

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Setting the Default Transducer and Preset

You can set a default transducer and preset so that each time the system is turned on, that transducer and preset are initiated automatically. The system selects the default transducer regardless of which receptacle it is connected to. If the default transducer is not connected when the system is turned on, the system initiates the transducer connected to the leftmost connector and the first available preset for that transducer.

1. Touch the name of the transducer you want to use.
2. Touch the preset you want.
3. Touch the transducer name a second time.
4. Touch **Set Default**.

Applications and Presets

Applications are broad areas of medical study. Within each application, there are Philips presets for specific areas of study. For example, within the **Small Parts** application, the presets are **Breast**, **Thyroid**, and **Testicle**. The transducer touch screen lists the available preset combinations for the selected transducer.

You specify how the system will be set up for operation by selecting a preset.

Hiding Factory Presets

You can select which factory presets are hidden or shown. By default, all presets are shown. You can hide all factory presets, all the factory presets for a transducer, or individual presets. You cannot choose to hide the current, active preset.

1. Touch **Utilities**.
2. On the **System** tab, touch **Hide Factory Presets**.
3. In **Hide Factory Presets**, do any of the following:
    - To hide a preset or a collection of presets, select it.
    - To show a hidden preset or collection of presets, deselect it.

- To clear all the selections, tap **Clear All**.

4. Tap **OK**.

2D Quick Save Presets

2D Quick Save presets provide a quick way to set imaging parameters to the values you prefer for a specific exam type. When you create a 2D Quick Save preset, you can specify the default calculations package, annotation, body marker, application, preset, and transducer. A 2D Quick Save preset stores the primary imaging mode and settings that are active when you create the preset.

After you create a 2D Quick Save preset, it appears on the transducer touch screen when the associated transducer is selected. When you select a Quick Save preset, the system automatically invokes the settings in the preset. You can copy existing Quick Save presets onto removable media and load them into another ultrasound system of the same model and number. You can also delete existing Quick Save presets.

3D Quick Save Presets

For some transducer-preset combinations, the 3D Quick Save preset feature provides a quick way to set 3D imaging parameters to the values you prefer for a specific 2D preset. A 3D Quick Save preset stores the settings that are active when you create the preset as a subset of the current 2D preset.

NOTE

The 3D Quick Save presets store the **Top/Bottom** and **Left/Right** imaging orientations; however, 2D orientation settings are inherited in 3D when you activate 3D imaging from 2D imaging.

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After you create a 3D Quick Save preset, it appears on one of the **3D Standby** touch-screen pages when the associated transducer and 2D preset are selected. When you select a Quick Save preset, the system automatically invokes the settings in the preset. You can copy existing 3D Quick Save presets onto removable media and load them into another ultrasound system of the same model and number. You can also delete an existing 3D Quick Save preset, but you cannot modify it. A maximum of eight 3D Quick Save presets can be saved.

Creating 2D Quick Save Presets

You can create a new 2D Quick Save preset that is based on an existing preset. You can do this even during an exam, while using the preset.

1. Touch the transducer name.
2. Touch the preset on which you want to base your Quick Save preset.
3. Adjust the system controls to create the settings for your preset. (You can select an imaging mode, an image orientation, the number of focal zones, and so on.)
4. Swipe the touch screen, from right to left, to view the next page.
5. Touch **Save Preset**.
   - For the **Quick Save Label**, type the name of the new preset.
   - For **Calculation Package**, select a calculation package.
   - For **Annotation/Body Marks**, select the annotation and body mark you want as the defaults.
6. Tap **OK**.

CAUTION

The system does not save all settings correctly when you create a Quick Save preset in Elastography mode. Instead, adjust the image manually.

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NOTE

When you select a Quick Save preset, the layout always appears as **4-up** in **3D**, **4D**, **STIC**, or **iSTIC**, regardless of the layout format that was active when you created the Quick Save preset. To change the layout format, touch **Layout**.

Creating 3D Quick Save Presets

1. Touch the transducer name.
2. Touch the transducer preset on which you want to base your 3D Quick Save preset.
3. Press **3D** and start 3D imaging.
4. Adjust the system controls to create the settings for your preset.
5. Touch **Save 3D Preset**.
6. For the preset name, type the name of the new preset. Preset names are not case-sensitive.
7. Tap **OK**.

Using 3D Quick Save Presets

1. Press **3D** and start 3D imaging.
2. Go to the second or third page of the touch-screen controls.
3. Under **3D Presets**, select the preset to use.

Modifying 2D Quick Save Presets

You can modify a 2D Quick Save preset that you created. You can do this even during an exam, while using the preset.

1. Touch the transducer name.
2. Touch the preset that you want to modify.
3. Adjust the system controls to modify the settings for your preset.

4. Touch **Save Preset**. You may need to swipe the touch screen, from right to left, to view this control.
5. In the **Save Preset** dialog box, complete the following:
   - For the **Quick Save Label**, type the name of the preset that you are modifying.
   - For **Calculation Package**, leave the selection as-is.
   - For **Annotation/Body Marks**, leave the selection as-is.
6. When you are prompted to overwrite the existing setting for the preset, tap **OK**.

Deleting Quick Save Presets

You can delete any Quick Save preset on the system except the active 2D preset.

1. If a preset you want to delete is active, deactivate it by touching the associated transducer name and a different preset.
2. Touch **Utilities**.
3. On the **System** tab, touch **Delete User Presets**.
4. In **User Presets Deletion**, select the preset to delete.
5. Tap **Delete**.
6. Tap **Cancel**.

Copying Quick Save Presets to Removable Media

NOTE

If you receive an error message when exporting data to a DVD or when viewing exam data on a DVD, you may need to eject the DVD from the drive and re-insert it.

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You can copy Quick Save presets to a USB storage device. This function is useful for archiving presets and for sharing presets with other ultrasound systems of the same model and number. When you copy Quick Save presets, all available data is copied.

1. Connect a USB device to a USB port on the system.
2. On the control panel, press **Support**.
3. Tap **System Management**.
4. Tap **Backup/Restore**.
5. From the **Select the Media Device** menu, select the removable media that you are using.
6. Tap **Backup**. The backup list shows the data that is backed up.
7. If a dialog box indicates that the media is too full to complete the copy process, replace the media and tap **Backup** again.
8. After the backup is complete, tap **Close**.
9. Tap **Done**.

Loading Quick Save Presets from Removable Media

1. Connect the USB device containing the data to a USB port on the system.
2. On the control panel, press **Support**.
3. Tap **System Management**.
4. Tap **Backup/Restore**.
5. From the **Select the Media Device** menu, select the media type that you are using.
6. Tap **Restore**.
7. Deselect the data that you do not want to import.
8. After the import is complete, tap **OK**.
9. To exit **Philips SupportConnect**, touch **Close**. A displayed message might prompt you to restart the system.

System Setups

Setups are system parameters that you can change. By changing setups, you can customize the system to meet your operating preferences.

Setups are organized into six standard categories: **System Settings**, **Analysis**, **Annotations**, **Acquisition/Capture**, **Data Security**, and **Report Templates**. An additional category, **Setups Wizard**, helps you quickly prepare your system for use.

Changes in setups take effect immediately and remain in effect until you change them again or load setups from a USB device.

NOTE

The institution name exported with DICOM data always reflects the name shown in the setups at the time the exam ended. Philips recommends restarting the system after changing **Institution Name** in the setups.

Procedures for using setup options and descriptions of settings are included throughout the *Help*.

Changing Setups

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Select a setup category on the left side of the setups display.
4. Select a tab or sub-tab at the top of the setups display.
5. Enter text or make selections necessary to set up your system.
6. To exit the setups, touch **Close**.

Hiding the Doppler Velocity Minus Sign

You can choose to include only the numeric value of the Doppler velocity measurements. Doppler velocity is marked as negative (-) when the flow is moving away from the transducer. When reporting on the measurements, you may want only the value, not the direction of flow. When hidden, the negative sign does not appear on the displayed or printed patient reports; however, the sign is still part of the number and is visible when editing a patient report and is included in DICOM structured reports exported from the system.

The option to hide the Doppler velocity minus sign is available in all calculation packages except Adult Echo and Pediatric Echo.

NOTE

When **Hide Doppler Velocity Minus Sign** is enabled, the sign value, whether visible or not, is still considered in calculations performed with the reported value. The system includes the sign value in calculations.

NOTE

If you want to display the selector of the instance with the maximum absolute value, select **(Max(Abs))** for the **Selector** value. For information on setting the measurement selector, see the *Help*.

To specify the display of the Doppler velocity minus sign:

1. In the setups, select **Analysis**.
2. Select the tab of the calculations package that you want to change, and then tap **Tools and Results**.
3. Under **Hide Doppler Velocity Minus Sign**, select **On** or **Off**.
4. To exit the setups, touch **Close**.

System Options

In addition to the standard features available in the system, other features are available as purchasable licensed options.

To add licensed options to your system, you purchase them from your Philips representative. Once purchased, they are installed in your system by a Philips field service engineer.

Installing Temporary Options

You can temporarily install up to five licensed options. You can then evaluate those options for a fixed length of time, which is set by Philips. Before you can install temporary options, you must request and receive an activation key for each option that you want to install. The installation process requires restarting the system, so be sure that the last exam has been closed before installing options.

1. Contact your Philips representative to obtain a key code for each licensed option you want to evaluate.
2. After you receive the key code, touch **End Exam** to ensure that the last exam has been closed.
3. Press **Support**.
4. In **Philips SupportConnect**, select the **Options** tab.
5. Tap **Temporary Options**.
6. Tap **Enable Temporary Option**, and type the key code.
7. Tap **OK**.
8. To enter another key code, tap **Enable Temporary Option** again, and type the next key code.
9. Touch **Close**.

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Custom Procedures

You can automate a variety of workflows by creating custom procedures for specific patients, transducers, and presets.

Creating a Custom Procedure

When you create a custom clinical procedure, the **Patient Data** tab of the **System Settings** setups lists all transducers and presets available for the system, including transducers and presets unsupported by your system's purchased configuration and imaging options. Select only the transducers and presets supported by your system's configuration and options.

1. Touch **Utilities**.
2. On the **System** tab, touch **Setups**.
3. Tap **System Settings** and then tap the **Patient Data** tab.
4. Under **Procedure Setup**, do one of the following:
   - To create a new procedure, tap **Create New**.
   - To modify an existing procedure or create a new procedure from an existing procedure, select an item from the **Procedure** list, and then tap **Modify**.
   - To delete an existing procedure, select an item from the **Procedure** list, and then tap **Delete**.
5. For new or modified procedures, complete the following:
   - **Procedure Name**: Enter the name of a new procedure, or modify the name of an existing procedure.
   - **Study Type**: Enter the type of study for which the new or modified procedure is intended.
   - **Gender**: Select the gender of the patient.
   - **Study Description**: Enter a brief, meaningful description of the study in which the new or modified procedure is used.

- **Transducer**: Select a transducer from a list of all of the transducers that are supported by the system.
- **Preset**: Select a preset from a list of all of the presets that are available for the selected transducer.

NOTE

To link a custom clinical procedure to a modality worklist patient, the custom procedure's **Procedure Name** must match the patient's **Study Description** code.

6. Tap **Save** and then touch **Close**.

To use the new custom procedure, see “Selecting a Custom Procedure” on page 220.

Selecting a Custom Procedure

Custom procedures are available from the **Patient Data** form.

NOTE

Custom procedures are linked to specific transducers. If the transducer required for the procedure is unconnected, procedures that use it do not appear in the **Procedure** menu.

1. Touch **Patient**.
2. In the **Clinical Procedure** section of the **Patient Data** form, select the custom procedure from the **Procedure** menu.
3. Tap **Done**.
4. Start the exam.

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Report Templates

Report templates let you easily customize patient reports. You can create custom report templates from existing system-defined report templates either on the ultrasound system or on a Windows PC. You can modify, delete, import, and export custom templates.

Custom report templates can be backed up and restored as part of the system's **Backup/ Restore** feature.

You can specify a report template as the default template for a particular application. For more information, see the system *Help*.

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7 Performing an Exam

This section guides you through procedures commonly used in performing patient exams with the system. These procedures include entering patient data; acquiring, annotating, and reviewing images; and making measurements and calculations.

NOTE

Have a backup system present during critical exams to ensure completion of the exam in the event that the primary system fails. If a backup system is unavailable, then address any patient-specific clinical symptoms according to standard patient-management protocols.

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New Patient Exams

WARNING

Failing to end the current exam before starting a new exam can result in data being acquired and stored under the wrong patient name. If you turn off the system without ending the exam, the system pauses the exam before shutting down.

You start an exam by entering patient data into the system in one of the following ways:

- If the Modality Worklist feature is disabled or unused on your system, you enter patient data into the **Patient Data** form.
- If your system is connected to a DICOM network with the Modality Worklist feature enabled, you can select an exam to load patient data instead of entering that information manually. See “Selecting in the Worklist” on page 226.
- If you have a barcode scanner, you can enter data into the system by scanning a patient's barcode. See “Entering Patient Data from a Barcode” on page 207.

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If you want to start an exam without first entering patient data, you can select **Use Temporary ID** after you acquire an image. For more information, see "Temporary ID" on page 193 and "Starting Emergency Studies" on page 194.

The system uses a unique ID to identify each patient. You can enter an ID, or you can have the system create one automatically. Stored images, fetal growth graphs, and reports are stored based on the patient ID.

If the sonographer name needs to be different on images within the exam, end the current exam and append a new exam with the images from the new sonographer.

An accession number is an optional entry assigned to each patient file by an institution for internal information-management purposes.

The exam date is set by the system when you first acquire an image during the exam.

Entering Patient Data

If you are not using the worklist option, you start an exam by entering patient data into the system.

If you want to start an exam without first entering patient data, you can select **Use Temporary ID** after you acquire an image.

NOTE

You can clear all patient data from the **Patient Data** form by selecting **Clear**. Do not use this control unless you want to delete all of the patient data you have entered into the form.

NOTE

On the **Patient Data** tab of the **System Settings** setups, you can choose to display or hide the **Proceed to Protocol** control on the **Patient Data** form.

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1. Touch **Patient**.
2. On the **Patient Data** form, type the patient information. To move your cursor through the form, use any of the following:
   - Use the **Tab** key or the **Enter** key to move the cursor from field to field.
   - In the **Comments** and **Study Description** fields, press **Shift+Enter** to move to the next line.

   To delete text from a field, highlight the text and use **Delete** or **Backspace**, or press **Erase** on the control panel.
3. For **Study Type**, select the study you will be performing. It is important to select the correct study type at this time. Selecting a study type after you have entered patient data and exited the **Patient Data** form does not update the report with the correct study type.
4. Enter the pertinent study information for the patient.
5. If you have created a custom procedure for this patient, select the custom procedure from the **Procedure** menu. (For information about custom procedures, see "Custom Procedures" on page 219.)
6. Do one of the following:
   - To begin a new exam, tap **Done**.
   - To select and begin a protocol, tap **Proceed to Protocol**.

Manually Editing OB Dates

The **LMP**, **Conception**, or **Established Due Date** (EDD) data can be used to generate fetal growth percentiles or SDs and all trending data during a patient's OB exam. These dates must be correct to ensure that correct percentiles, deviations, and trending data are generated. It is important to note the following:

- To ensure an accurate gestational age (GA), you must enter a **Conception** *or* an **LMP** date *or* an **Established Due Date** in the **Patient Data** form at the start of every OB exam. Those dates are not saved in the patient's data.
- If an **LMP** or a **Conception** date is entered, the **EDD(c)** is calculated, and the system uses the GA generated from the **LMP** or **LMP(c)** date to calculate the fetal growth percentiles or SDs.

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- If the **Established Due Date** is entered manually, the **LMP(c)** date is calculated, and the system uses the GA calculated from the **LMP(c)** date to calculate the fetal growth percentiles or SDs.
- If the **Established Due Date** is entered manually, the **LMP** and **Conception** fields are no longer available.

NOTE

The **Established Due Date** supersedes the **EDD(c)**.

NOTE

If the **LMP** field is unavailable in the **Patient Data** form for OB exams, then the **LMP** field is unavailable for the same patient's Breast, Fetal Echo, and GYN exams and reports.

1. Start a new exam for the patient.
2. Complete the **New Patient Information** section of the **Patient Data** form.
3. In the **Clinical Procedure** section, for **Study Type**, select **OB**.
4. Enter new dates in the **LMP** or **Conception** field, *or* the **Established Due Date** field, enter the new data, and then tap **Done**.

Selecting in the Worklist

If your modality worklist supports it, the **Additional Info** tab in the **Worklist** tab on the **Patient Data** form includes the following read-only information, available after you select a patient in the worklist:

- **Requested Procedure ID**
- **Code Meaning (Requested Procedure)**
- **Code Meaning (Scheduled Procedure)**

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- **Procedure Step Description**
- **Other Patient IDs**
- **Modality**

1. Touch **Patient**.
2. On the **Patient Data** form, tap the **Worklist** tab.
3. On the worklist, select the exam you want, and tap **Close**.

The system loads the patient information, and you are ready to begin an exam for that patient.

Searching in the Worklist

If necessary, you can search for a specific exam by using **Patient Search** on the **Patient Data** form.

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NOTE

If you create a query for a Russian (Cyrillic) patient name on a PACS, storage device, or worklist server that is not configured with the Specified Character Set attribute for Russian (Cyrillic) characters, the patient name is displayed incorrectly. To perform such a query, use the patient ID or accession number instead. The Russian character set is applied to the patient name and other results information that you retrieve and upload to the system from a query.

1. Touch **Patient**, and then tap the **Worklist** tab.
2. To search for a patient by exam date, tap **Search**.
3. To further specify the date criteria, do one of the following:
   - Select the **Exam Date**.
   - Select **Today**; select **±** (plus or minus), **+**, or **–**; and then select the number of days.

NOTE

You can also search for a patient by last name, patient ID, modality, accession number, or procedure ID.

4. Tap **Search**.
5. Select the patient from the worklist.
6. Tap **Done**.

Hiding Patient Name and ID on Images

WARNING

Images printed without the patient name and ID could be incorrectly associated with another patient. One way to alleviate this risk is to configure the DICOM printer so that the patient data that is included in the header of the image file is printed along with the image. However, some printers do not support that feature.

NOTE

If the intent of hiding the patient name and ID is patient privacy, be aware that if the original file name includes the patient name, you will need to rename the file when you export it.

The patient name and ID are displayed in the patient bar, which is outside of the image area and not acquired in an image. However, patient information is overlaid on to an image when it is printed. To hide the patient name and ID on the printed image and the display, touch **Utilities**, and then touch **Hide Patient Info** on the **System** tab. All other information displayed in the patient bar (time, institution name, and so on) remains in the overlay and is included on the printed image.

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To retain patient data on exported images, see “Retaining Patient Data on Exported Images” on page 229.

Retaining Patient Data on Exported Images

You can set the following patient information to display automatically at the top of exported exam images by selecting **Burn Patient Information Into Images** in the **Acquisition/Capture** setups:

- Patient name
- Date of birth
- ID
- Gender
- Acquisition date and time
- Performed by information
- Institution name
- System model

NOTE

To ensure that all of the header information is included when you select **Burn Patient Information Into Images**, be sure to deselect **Fixed Length of Printed and Acquired Patient Info Fields** on the **Header** tab in **System Settings**.

Selecting a Transducer

When you turn on the system, the system initializes the default transducer and preset. For information on default transducers and presets, see “Setting the Default Transducer and Preset” on page 210 and “Default Transducer” on page 249.

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NOTE

If the **Unsupported Transducer** message appears, disconnect and reconnect the transducer and ensure that all connected transducers are compatible with your system configuration.

You can connect or disconnect a transducer during live imaging without damaging the transducer or the system.

1. Touch the transducer name to select it.
2. Touch the preset that you want to use.

After you select the preset, the system calibrates the transducer, enables the transducer for operation, and updates system status to reflect the transducer type and the preset you selected.

Imaging Modes

Your ultrasound system offers a set of imaging modes to accommodate a variety of imaging applications in 2D, 3D/4D, M-mode (including Anatomical M-mode), pulsed-wave Doppler, continuous-wave Doppler, Color Doppler, Color Power Angio (CPA) Imaging, Tissue Doppler Imaging, Harmonic imaging (tissue and contrast), and combined modes.

NOTE

Some modes are available on your system only if the corresponding option has been purchased and installed.

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Capturing Images and Loops

You can capture and save a single frame or a cineloop sequence. The captured frame or cineloop sequence is saved in the patient study, and a thumbnail of it is available in the live imaging display and the **Review** display. Images are automatically exported across the network, either when you capture or print an image, or when you end an exam, depending on your selection for **Send Images/Clips** on the **Acquisition/Capture** tab in the **Acquisition/Capture** setups.

Use the **Freeze** control to stop and start system image acquisition and update. Pressing **Freeze** results in the system entering cineloop pause and assigning the trackpad to manual cineloop review (frame-by-frame).

During acquisition, a spinning hourglass icon appears at the bottom of the display. When the capture is complete, a thumbnail of the image is displayed.

Do one of the following:

- To capture a single image, press **Freeze** and then press the **Acquire** control that is configured to capture single images.
- To capture a cineloop sequence, while in live imaging or while reviewing a cineloop sequence, press the **Acquire** control that is configured to capture cineloop sequences. Capturing during live imaging saves prospective or retrospective frames, as specified in **Live Capture Type** in the setups. A prospective capture captures a specified acquired loop length. A retrospective capture captures a specified loop length that was acquired previously. A retrospective capture captures a loop that ends when you press the **Acquire** control. Capturing while reviewing a cineloop sequence saves all retrospective frames in the cineloop sequence.

You can configure the **Acquire** controls in the **Acquisition/Capture** setups. By default, the **Acquire** controls behave as follows:

- **Acquire 1** captures single frames when the image is frozen and captures loops when the image is live.
- **Acquire 2** captures single frames, regardless of the imaging state.

However, if an **Acquire** control is set to acquire a still frame, you can use it to acquire the frame without freezing the image.

For information on configuring the **Acquire** controls, see “Configuring Acquire Controls” on page 153.

NOTE

If you press **Acquire 1** in a non-simultaneous mode while a live M-mode or Doppler trace is active, you capture a cineloop sequence. If you press **Acquire 1** in a simultaneous mode, you capture a single image.

NOTE

When an image is captured, you will hear a beep to confirm that the loop or image was saved in the patient's study. Do not press **Review** until you hear the beep.

NOTE

If you attempt to capture a loop that was imported from media, only a frame of the loop is captured and displayed in the appending exam.

Annotation

You can place text labels and arrows on an image to identify anatomical structures and locations. You can also annotate an image with a body marker graphic that indicates the part of the anatomy that you are scanning.

Trackpad Functionality in Annotation

Use the touch screen to select annotation labels and body markers, and use the trackpad to position them on the imaging display. The trackpad arbitration icon identifies the function available for each trackpad control as you add labels and body markers.

When adding labels the following functionality is available:

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- **Cursor** trackpad function: Select an existing label.
- **Move Label** trackpad function: Move the selected label.
- Main area of trackpad: Move the highlighted label or move the cursor location in the label.

NOTE

The cursor flashes when text can be added or edited. The label turns amber when the label is selected and can be moved or edited.

When adding body markers the following functionality is available:

- **Body Mark** trackpad function: Highlight and move body marker and the transducer icon.
- **Probe Mark** trackpad function: Highlight and move the position of the transducer icon.

Adding Labels

1. Press **Label**.

NOTE

If you tap a trackpad control, unfreeze the image, or change the imaging mode or settings that affect the trackpad assignment, annotation mode goes into standby. To return to annotation, press **Label**.

2. Touch **Labels**.
3. Use the trackpad to position the text cursor on the display, or touch **Home** to return to the home location.
4. Do any of the following:
    - To display predefined labels, touch a label control to display its text.

- To add text, touch **Keyboard** and type the text that you want to appear on the display.
- To display an arrow, press the **Arrow** soft key, position the arrow with the trackpad, and then tap to fix the position. (If you add an arrow in MaxVue and then exit MaxVue, the system removes the arrow. To retain arrows on the image, place them in standard view.)
- To erase an arrow, touch **Erase Last**. **Erase Last** removes arrows from the display starting with the last arrow added.
- To erase the last word typed, touch **Erase Last**. **Erase Last** removes any arrows on the display before removing words, and then it removes words, starting with the last word added.
- To erase the current line of the annotation display, touch **Erase Line**.
- To erase all labels and arrows, touch **Erase All**.
- To move the text cursor to the home position, touch **Home**.
- To set a new home position, position the cursor and touch **Set Home**.
- To exit annotation mode, press and hold **Label**.
- Use the **Erase** control. For information on **Erase**, see the *Help*.
- Use text replace. For information on text replace, see the *Help*.

NOTE

You can set the system to erase all text annotations on unfreeze: On the **Utilities** touch screen, under **System**, touch **Erase Text Annotations on Unfreeze**, or in the **System Settings** setups, on the **Display** tab, select the setting.

NOTE

You can cycle, left to right, through the sub-tabs on the **Label** tab by pressing **Label** on the control panel.

Adding Labels Using the Keyboard

You can add and format labels using the touch screen keyboard or a USB keyboard

1. Press **Label**.
2. Touch **Keyboard** on the touch screen.
3. Use the trackpad to position the text cursor on the display.
4. Type the text that you want to add. To center labels or improve line breaks, you can use spaces before and after the words that you type.
5. To erase text, touch the **Backspace** key.
6. When finished, press **Label** again to remove the text cursor.
7. To remove text, press **Label** and then touch **Erase Last** or **Erase All**.

NOTE

You can set the system to erase all text annotations on unfreeze: On the **Utilities** touch screen, under **System**, touch **Erase Text Annotations on Unfreeze**, or in the **System Settings** setups, on the **Display** tab, select the setting.

NOTE

You can cycle, left to right, through the sub-tabs on the **Label** tab by pressing **Label** on the control panel.

Adding an Image Title

You can add a title to the image display.

1. Press **Label**.
2. Touch **Keyboard**.
3. Touch **Title**.

4. Type the text that you want to add for the title.
5. To erase text, use the **Backspace** key.
6. When you are finished, touch **Title** again.

Displaying Body Markers

NOTE

During Review, the **Body Markers** touch screen is available only when **1-up** is selected for **Layout**. You can add body markers and system-provided labels to single frame images and loops in Review. You can type text in single frame images in Review.

1. To open the Body Markers tab and place the default body marker, press **Markers**.
2. Do any of the following:
   - To highlight and move the marker and the transducer icon, tap the right trackpad control. Use the trackpad to move the body marker, and then tap the left trackpad control to release it.
   - To highlight and move only the transducer icon, tap the left trackpad control. Use the trackpad to move the body marker, and then tap the right trackpad control to release it.
   - To change the orientation of the transducer icon, turn **Marker** or turn **Rotate Probe**.
   - To resize the marker, turn **Body Mark Size**.
   - To resize the transducer icon on the body marker, turn **Probe Mark Size**.
   - To remove a marker, touch **Erase Body Mark**.
   - To move the marker to the home position, touch **Home**.
   - To set a new home position, position the cursor and touch **Set Home**.
   - To close the **Body Markers** touch screen, touch another tab or press and hold **Label** or press **Markers**.

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Printing

WARNING

Multi-image prints made on small-size paper are intended only for reference and should not be used for diagnostic purposes. Text annotation and scaling markers may not be visible on such prints.

You can print single-frame images and reports to a local printer, usually installed in the system, or to DICOM printers on a network.

Two print controls are available for printing images, **Print** and **Alt Print**. The **Acquire 1**, **Acquire 2**, **Acquire Screen**, and **Acquire Report** controls also have print capabilities associated with them. In the setups, you can assign each of these controls separately to one or more image printers. In addition, you can select whether the controls print the entire display or just the image area.

NOTE

If you print a monochrome image while a Chroma map is selected, the system sends the image to the color printer. Also, if you export a monochrome image while a Chroma map is selected, the system sends the image as a color image. This is normal. To ensure that black-and-white images are sent to the black-and-white printer, set **Chroma Map** to **Off**.

Printing in Live Imaging

You can print live or frozen images during an exam. To print using the **Acquire** control that is configured for printing, a printer must be assigned to those controls in the setups.

1. Display the live or frozen image you want to print.
2. Do one of the following:

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- Press the **Acquire** control that is configured for printing on the system control panel.
- Touch **Alt Print** on the touch screen.
- Touch **Print Screen** on the **Utilities** tab.

NOTE

If your print setting includes multiple images per page, the printer will not print an image until the total number is reached. For example, if you have a 2x2 format selected, the printer will not print the page until you have captured four images or, if the number captured is less than four, until the end of the exam.

NOTE

During an exam, do not switch between printing images during the exam and printing at the end of the exam. Printing images both during the exam and at the end of the exam causes the printer to print erratically on multiple pages.

Review

During or after an exam, you can use Review to examine and compare images acquired in the exam. You can also review multiple exams for one patient.

In Review, you can look at the images or cineloop sequences that you stored. You can view, export, print, and delete the stored images. You can also perform analysis on images in Review. Images can be stored on the ultrasound system hard drive, on removable media, or on DICOM-compatible devices on a network. You can display images within an exam in several layouts and you can display images from different exams.

The system cannot display native data images exported from an ultrasound system of a different model and number. To view those images, use QLAB software instead.

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Starting Review

NOTE

Make sure at least one transducer is connected to the system before you touch **Review**. Without a connected transducer, the system stops responding and requires a restart to continue functioning.

1. Touch **Review** to enter Review mode. You can also double-tap a thumbnail image in an active exam to open that image in Review mode.
2. To return to live imaging, touch **Review** again or touch **Close**.

Navigating Thumbnails and Images

NOTE

When reviewing images of an exam loaded from the patient directory, thumbnails are unavailable in some circumstances. For example, exams copied from DVD to the hard drive may not have thumbnails, if the images they contain are no longer in their native format.

In Review, you can view small images, called *thumbnails*. Thumbnails are located on the right side of the display. From these thumbnails, you can also display one or more images in their original format.

Do any of the following:

- To view a thumbnail full screen, double-tap it. (If the image represents a 3D data set, it opens in 3D review mode.) To return to the review screen, double-tap the full screen image or set **Layout** to **4-up**.

- To move up or down through available thumbnails quickly, drag the scroll bar (located on the right side of the thumbnails if there are more than eight thumbnails available) or touch the trackpad with two fingers and move them up and down (see “Trackpad” on page 162).
- To jump to the page that contains the corresponding image, tap a thumbnail.
- To move backward or forward through the available images, one page at a time, turn **Review Page**.
- To select an image, either tap the image or tap the number in its corresponding thumbnail.

Measurement and Analysis

The measurement tools appear on the touch screen. Touching a tool label on the touch screen launches the tool. (The labels of inactive tools are gray.)

Measurement tools provide measurements and derived calculations. Various methods are available for generating results. The two primary methods allow you to “measure then label” or “label then measure.” Either way, the results can appear on the display, on printed pages, and in patient reports, where they are available for your analysis.

The **Analysis** setups provide the configuration capability that allows you to create your own calculation lists, including collections, groups, measurements, and calculations. In addition, the measurements and calculations can be associated with system and custom tables and equations.

The ultrasound system supports a number of measurement and quantification methods. The basic measurements report the size, speed, or duration of image data. The image data may be contained in a 2D ultrasound image, a Physio region, an M-mode trace, or a Doppler spectral trace. The accuracy of the measurement depends, in part, on the ability of the operator.

Measurements are available if the image scaling data is available. This prevents measurements on Doppler or M-mode still images in Review that do not include scaling information in the trace data, or on imported image loops that use different scaling parameters.

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Measurements must be labeled for the results to appear in patient reports. Unlabeled measurements appear in the results but are not retained, unless they are associated with a labeled measurement.

Labeled measurements and calculations are stored in the patient data and report. The information is labeled according to the measurement or calculation label. Within the report, the information is organized by the calculations package. The values displayed can be the results of multiple measurements.

Calculations packages are system options that are associated with transducers and presets. A calculations package contains one or more collections that organize measurements and calculations into a coherent tool for diagnostic analysis. The **Calc Package** tab provides access to the various measurements and calculations in the available calculations packages.

The measurements and their derived calculations included with the calculations packages are based on medical references.

See the "References" section in the *Help.*

NOTE

Ensure that you follow current medical practices when identifying specific measurement points on an image.

Performing a 2D Depth Measurement

A 2D depth measurement uses a single caliper point to measure the distance between an area of interest and the skin line.

NOTE

Not all transducers display echoes at the skin line.

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NOTE

You cannot measure 2D depth above the skin line.

1. Obtain the image that you want to measure and press **Freeze**.
2. Press or touch **Measure**, and then touch **Tools**.
3. Touch **2D Depth**. A caliper appears on the 2D image.
4. Use the trackpad to position the caliper.
5. To complete the measurement, tap **End**.

Performing a 2D Distance Measurement

A 2D distance measurement uses two calipers to measure the length of a straight line between the two points. You can set the display of the line in the setups.

1. Obtain the 2D image you want to measure and press **Freeze**.
2. Press or touch **Measure**, and then touch **Tools**.
3. Touch **Distance**.
4. Use the trackpad to position the caliper for the first end point and tap to anchor it.
5. Use the trackpad to position the caliper for the second end point. The results update as the distance between the calipers changes.
6. To complete the measurement, tap **End**.

Measuring M-Mode Distance

1. Start M-mode by pressing the **M-mode** soft key, and then tap **Update** to update the M-mode display.
2. Obtain an M-mode display and press **Freeze**.
3. Press or touch **Measure**, and then touch **Tools**.
4. Touch **Distance**.

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5. Use the trackpad to position the vertical time caliper and tap **Distance**.
6. Use the trackpad to position the horizontal depth caliper. The distance between the depth calipers appears in the results. Tap **Set**.
7. To make additional measurements, repeat step 5 and step 6.
8. To complete the measurements, tap **End**.

Estimating the Doppler Velocity on a Sweeping Display

You can estimate the velocity on a live Doppler image.

1. Press **PW**.
2. Tap the middle trackpad control to update the Doppler display.
3. Obtain the Doppler image you want to measure (a spectral waveform).
4. Press or touch **Measure**, and then touch **Tools**.
5. Touch **Distance**.
6. Use the trackpad to position the horizontal cursor.
7. Use the Doppler scale to estimate the velocity.

Measuring Then Labeling

The measure-then-label method of obtaining results uses caliper controls for making measurements, without first having to select measurement labels. These measurements are not explicitly associated with a report region and do not appear in the report unless associated with a labeled measurement.

After making a measurement, you can choose whether to assign the value to a label.

NOTE

The measurement will be lost if you unfreeze the image or change modes before you assign a label to it.

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Obtaining a Typical Labeled Measurement

This general procedure describes how to measure by using a typical labeled measurement tool.

Guided or complex tools require specialized procedures, found in the *Help*.

1. Obtain the image you want to measure and press **Freeze**.
2. Press or touch **Measure**.
3. Do one or more of the following:
   - On the **Calc Package** tab of the touch screen, touch a collection and then a measurement label.
   - In the **Calc List**, tap a collection and then tap a measurement label.
4. If a set of associated measurements are required, touch or tap a group label to display multiple measurement labels.
5. Touch or tap a measurement label and make the measurement. First, the caliper or trace tool appears on the display. Then, as you make the measurement, the results and derived calculations appear in the results and are simultaneously added to the patient report.
6. For each measurement label within a group, touch or tap a label and make the measurement.
7. To complete the measurement, tap **End**.

Ending an Exam

WARNING

Failing to end the current exam before starting a new exam can result in data being acquired and stored under the wrong patient name. If you turn off the system without ending the exam, the system pauses the exam before shutting down.

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Each time you finish an exam, you must end the exam to save images, reports, and other exam data. You can end an exam in the current exam display or with the current exam open in the Review display. You cannot end a paused exam while in the Patient Directory.

You will not be able to end the exam until the system has saved exam data for the current exam. (The system saves exam data when you acquire an image.) Ending an exam stores all exam data, clears the **Patient Data** form, and prepares for the next exam.

You can configure the system to end exams after a period of system inactivity. For instructions, see the *Help*.

When the exam is complete, touch **End Exam**.

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8 Transducers

The transducer is the most important factor in image quality. Optimal imaging cannot be obtained without the correct transducer. The system is optimized for use based on your transducer selection.

For information on connecting transducers, see “Connecting Transducers” on page 199. For more information on caring for and maintaining transducers, see *Care and Cleaning of Ultrasound Systems and Transducers* and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*.

Disinfect new transducers before performing the first study. Clean and disinfect the transducer immediately after each use to protect patients and personnel from pathogens. Establish and clearly post a cleaning procedure that includes the steps described in *Care and Cleaning of Ultrasound Systems and Transducers*.

Transducer Safety

WARNING

Use only Philips transducers and Philips-approved biopsy guides, covers, brackets, supplies, components, and accessories. Other brands may not properly fit Philips transducers. Improper installation may result in patient injury.

WARNING

Always remove the transducer from the patient before defibrillation.

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WARNING

Before defibrillation, if you cannot remove the transducer from the patient, always disconnect invasive transducers that remain in contact with the patient from the system.

WARNING

To limit potential harm when scanning neonatal, pediatric, and medicated patients, minimize the time spent imaging at temperatures above 41°C (106°F).

CAUTION

When handling a transducer, do not bump the transducer on hard surfaces.

The system limits patient contact temperature to 43°C (109°F), and acoustic output values to their respective U.S. Food and Drug Administration limits. A power-protection circuit protects against over-current conditions. If the power monitor protection circuit senses an over-current condition, then the drive voltage to the transducer is shut off immediately, preventing overheating of the transducer surface and limiting acoustic output. Validation of the power protection circuit is done under normal system operation.

Transducers other than transesophageal (TEE) transducers and Doppler transducers are rated minimum IPX7 in accordance with IEC 60529. TEE transducers are rated minimum IPX1 (control area) and IPX7 (endoscope area) in accordance with IEC 60529. Doppler transducers are rated minimum IPX1.

Selecting a Transducer

When you turn on the system, the system initializes the default transducer and preset. For information on default transducers and presets, see “Setting the Default Transducer and Preset” on page 252 and “Default Transducer” on page 249.

NOTE

If the **Unsupported Transducer** message appears, disconnect and reconnect the transducer and ensure that all connected transducers are compatible with your system configuration.

You can connect or disconnect a transducer during live imaging without damaging the transducer or the system.

1. Touch the transducer name to select it.
2. Touch the preset that you want to use.

After you select the preset, the system calibrates the transducer, enables the transducer for operation, and updates system status to reflect the transducer type and the preset you selected.

Default Transducer

When you turn on a system that includes the Multiport adapter, the active transducer is the one in the leftmost transducer receptacle if:

- Multiple imaging transducers are connected.
- The default transducer is not connected.
- No transducer is set as the default during system shutdown.

When you turn on a system that *does not* include the Multiport adapter, the active transducer is the imaging transducer if:

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- Both an imaging transducer and a Doppler probe are connected.
- The default transducer is not connected.
- No transducer is set as the default during system shutdown.

When you turn on a system, with or without the Multiport adapter, the active transducer is the Doppler transducer if:

- No imaging transducer is connected.
- No imaging transducer is set as the default during system shutdown.

During system operation, you can select between an imaging transducer and the Doppler transducer. When you connect a transducer to the system, it is selected automatically. For more information about connecting a transducer, see "Connecting Transducers" on page 199.

Supported Transducers

For the systems that support each transducer, see the following table.

NOTE

Some transducers may not be supported on every version of a system.

Transducers and Supported 5300 Compact Systems

Transducer	5300G	5300P	5300W
3D9-3v	X	--	X
C6-2	X	X	X
C8-5	X	X	--
C9-4v	X	X	X
D2cwc	X	X	--

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Transducer	5300G	5300P	5300W
D2tcd	X	X	--
D5cwc	X	X	--
L12-3	X	X	--
L12-3ERGO	X	X	--
L12-4	X	X	X
L12-5 50	X	X	X
L15-7io	X	X	--
L18-5	X	X	--
S4-2	X	X	--
S8-3	X	X	--
V6-2	X	--	X
X7-2t	X	X	--
X8-2t	X	X	--

Transducers and Supported 5500 Compact Systems

Transducer	5500CV	5500G	5500P	5500W
3D9-3v	--	X	--	X
C5-1	X	X	X	X
C6-2	X	X	X	X
C8-5	X	X	X	--
C9-2	X	X	--	X
C9-4v	--	X	X	X
C10-3v	--	X	X	X

Transducer	5500CV	5500G	5500P	5500W
D2cwc	X	X	X	--
D2tcd	X	X	X	--
D5cwc	X	X	X	--
eL18-4	X	X	X	X
L12-3	X	X	X	--
L12-3ERGO	X	X	X	--
L12-4	X	X	X	X
L12-5 50	--	X	X	X
L15-7io	X	X	X	--
L18-5	X	X	X	--
S4-2	X	X	X	--
S5-1	X	X	X	--
S8-3	X	X	X	--
V6-2	--	X	--	X
X7-2t	X	X	X	--
X8-2t	X	X	X	--

Setting the Default Transducer and Preset

You can set a default transducer and preset so that each time the system is turned on, that transducer and preset are initiated automatically. The system selects the default transducer regardless of which receptacle it is connected to. If the default transducer is not connected when the system is turned on, the system initiates the transducer connected to the leftmost connector and the first available preset for that transducer.

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1. Touch the name of the transducer you want to use.
2. Touch the preset you want.
3. Touch the transducer name a second time.
4. Touch **Set Default**.

xMATRIX Array Transducers

xMATRIX array transducer technology provides volume acquisitions of the beating heart with remarkable image quality.

The following xMATRIX array transducers are available with this system:

- X7-2t
- X8-2t

Acoustic Artifacts

The transducer adds its own signature to the echo information in the form of beam width effects, axial resolution limitations, and frequency characteristics. The control choices made by the sonographer that affect amplification, signal processing, and echo signal display can lead to significant differences in the displayed appearance of echo data. Following is a brief discussion of acoustic artifacts. An understanding of the physical basis for the production of signals displayed on ultrasound images is helpful in minimizing artifacts on images and interpreting the results of studies.

An artifact is an echo displayed in a different position than its corresponding reflector in the body. Artifacts can also be caused by intervening tissue properties. Artifacts can originate from external noise, reverberations, multi-path reflections, or misadjusted equipment. They can also come from the ultrasonic beam geometry and unusual changes in beam intensity. Artifacts and their manifestations are listed below, and following are some definitions of various artifacts.

- Added objects displayed as speckle, section thickness, reverberation, mirror image, comet tail, or ring down

- Missing objects due to poor resolution
- Incorrect object brightness due to shadowing or enhancement
- Incorrect object location due to refraction, multi-path reflections, side lobes, grating lobes, speed error, or range ambiguity
- Incorrect object size due to poor resolution, refraction, or speed error
- Incorrect object shape due to poor resolution, refraction, or speed error

Acoustic saturation occurs when received signals reach a system's high-amplitude limit. At that point the system becomes unable to distinguish or display signal intensities. At the point of saturation, increased input will not increase output.

Aliasing occurs when the detected Doppler frequency exceeds the Nyquist limit. It is characterized on the spectral display by the Doppler peaks going off the display, top or bottom, and then continuing on the other side of the baseline. On the Color display an immediate change in color from one Nyquist limit to the other is seen.

Comet tail is a form of reverberation artifact produced when two or more strong reflectors are close together and have a high propagation speed. In this case, sound does not travel directly to a reflector and back to the transducer; and a strong linear echo appears at the reflector and extends deeper than the reflector.

Enhancement is an increased relative amplitude of echoes caused by an intervening structure of low attenuation.

Focal enhancement, also known as **focal banding**, is the increased intensity in the focal region that appears as a brightening of the echoes on the display.

Mirror imaging artifact is most commonly seen around the diaphragm; this artifact results from sound reflecting off another reflector and back.

Mirroring is the appearance of artifacts on a spectral display when there is improper separation of forward and reverse signal processing channels. Consequently, strong signals from one channel mirror into the other.

Multi-path positioning and **refraction** artifacts describe the situation in which the paths to and from a reflector are different. The longer the sound takes traveling to or from a reflector, the greater the axial error in reflector positioning (increased range). Refraction and multi-path positioning errors are normally relatively small and contribute to general degradation of the image rather than to gross errors in object location.

Propagation speed errors occur when the assumed value for propagation speed by the ultrasound system is incorrect. If the actual speed is greater than that assumed, the calculated distance to a reflector is too small, and the reflector will be displayed too far from the transducer. Speed error can cause a structure to be displayed with incorrect size and shape.

Range ambiguity can occur when reflections are received after the next pulse is transmitted. In ultrasound imaging, it is assumed that for each pulse produced, all reflections are received before the next pulse is sent out. The ultrasound system calculates the distance to a reflector from the echo arrival time assuming that all echoes were generated by the last emitted pulse. The maximum depth to be imaged unambiguously by the system determines its maximum pulse repetition frequency.

Reverberation is the continuing reception of a particular signal because of reverberation rather than reflection from a particular acoustic interface. This phenomenon is analogous to the effect created by mirrors positioned on opposite walls when an object, a head for instance, is placed between the mirrors. The image of the head is reflected back and forth infinitely between the two mirrors, creating the optical illusion of multiple heads. Reverberations are easily identifiable, because they are equally spaced on the display.

Scattering is the diffuse, low-amplitude sound waves that occur when acoustic energy reflects off tissue interfaces smaller than a wavelength. In diagnostic ultrasound, Doppler signals come primarily from acoustic energy back-scattered from red blood cells.

Shadowing is the reduction in echo amplitude from reflectors that lie behind a strongly reflecting or attenuating structure. This phenomenon occurs when scanning a lesion or structure with an attenuation rate higher than that of the surrounding tissue. The lesion causes a decrease in beam intensity, which results in decreased echo signals from the structures beyond the lesion. Consequently, a dark cloud behind the lesion image forms on the display. This cloud, or shadow, is useful as a diagnostic clue.

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Side lobes (from single-element transducers) and **grating lobes** (from array transducers) cause objects that are not directly in front of the transducer to be displayed incorrectly in lateral position.

Speckle appears as tissue texture close to the transducer but does not correspond to scatterers in tissue. It is produced by ultrasound wave interference and results in general image degradation.

Spectral broadening is a display phenomenon that occurs when the number of energy-bearing Fourier frequency components increases at any given point in time. As a consequence, the spectral display is broadened. Spectral broadening can indicate the disturbed flow caused by a lesion, and therefore it is important diagnostically. However, broadening can also result from interaction between flow and sample volume size, in which case it is an artifact.

Speed of sound artifacts occur if the sound propagation path to a reflector is partially through bone, and the speed of sound is greater than in the average soft tissue. Echo position registration artifacts will be produced. Reflectors appear closer to the transducer than their actual distance because of this greater speed of sound, resulting in a shorter echo transit time than for paths not containing bone.

Acoustic Artifacts in 3D Imaging

Acquisition, rendering, and editing artifacts are specific to 3D volume images. Acquisition artifacts are related to patient motion, organ motion, or position-sensing errors. Rendering artifacts include elimination of structures by limiting the region of interest boundaries, thresholding that eliminates structures, and adjacent structure artifacts that add additional information or hide structures. Editing artifacts result from data deleted from a rendered image.

Color and Color Power Angio artifacts relating to gain may also be confusing in rendered images. A color flash artifact can occur when the gain is set high and the transducer or patient moves. When the gain is set too high, the color ROI box fills with color flash. When the gain is set low, color bleed can occur. When the gain is set too low, insufficient color data renders the image undiagnosable.

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Color gain, directional, and motion artifacts can present themselves in 3D imaging. Color and Color Power Angio gain artifacts are mainly related to the use of excessive gain resulting in random color patterns in the 3D image that might be interpreted as diagnostically significant. Directional artifacts are due to aliasing or directional confusion: The velocity range must be set properly, and the relationship between the transducer orientation and the flow vector must be understood. Patient motion can produce flash artifacts that are less obvious in 3D images than in 2D imaging.

Dropout and shadowing are present in 3D imaging although they are more difficult to recognize due to different and unfamiliar displays. Acoustic shadowing and other artifacts look very different when displayed in 3D volumes and may be more difficult to recognize than on standard 2D imaging. Those artifacts may produce apparent defects, such as limb abnormalities or facial clefts, where they are not present. Acquiring data from multiple orientations may avoid artifacts of this type.

Fetal limb deficit artifacts are specific to 3D volume images. Partially absent fetal limb bones have been demonstrated. One explanation for the missing limbs was shadowing caused by adjacent skeletal structures. Overcoming the limb deficit artifact can be accomplished by changing the transducer position and the acquisition plane.

Motion artifacts in 3D volumes can be caused by patient motion, fetal movement, cardiac motion, and movement of adjacent structures. Patient motion can produce flash artifacts that are more obvious in 3D images than in 2D imaging.

Pseudoclefting and pseudonarrowing artifacts may be related to limb deficit artifacts. Artifacts may be present in 3D imaging of the fetal face. Being aware of pseudoclefting of the fetal face and pseudonarrowing of the fetal spine can help the sonographer understand and identify these artifacts. As with 2D imaging, it is important to verify putative physical defects by using additional images and other modalities.

Resolution, attenuation, and propagation artifacts are all common to 3D imaging. Careful scrutiny of the original 2D images is necessary to identify and preclude these types of artifacts from the 3D volume image.

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Non-TEE Transducer Temperature Sensing

Some non-TEE transducers include the Auto-Cool safety feature to protect the patient and the transducer from excessive heat, which can be caused by long transducer use in specific modes and applications. The transducers contain built-in temperature sensors that monitor the temperature of the patient-applied part to prevent potential burning of skin.

The Auto-Cool warning appears when the temperature approaches the error threshold. When the temperature reaches the maximum temperature allowed, scanning stops and a message appears saying that the Auto-Cool is in progress. When the temperature drops below the threshold, the system starts scanning, and the warning message disappears.

For information on temperature sensing for TEE transducers, see “TEE Temperature Sensing” on page 321.

Auto-Cool Threshold Temperatures for Patient-Applied Part

Transducer	Warning Threshold Temperature	Error Threshold Temperature When Scanning Stops
eL18-4	42.0°C (107.6°F)	42.5°C (108.5°F)

Ensuring Safe Non-TEE Transducer Temperatures

To ensure patient safety and to avoid unnecessary interruption while scanning, follow these suggestions for non-TEE transducers:

- Transducers heat up faster when scanning in the air than when scanning a patient. When the transducer is not in use, press **Freeze** to ensure the image is frozen.
- Select the shortest wait time for the **Auto Freeze** setting on the **Display** tab of the **System Settings** display in the setups (see “Setting the Auto Freeze Function” on page 194).
- If the Auto-Cool warning appears when you are using high acoustic power modes such as Color, Doppler, or Tissue Harmonic Imaging, temporarily switching to fundamental 2D mode or freezing the image can help cool the transducer.
- Temporarily reduce the acoustic output power. When you reduce the power, the image quality and Doppler sensitivity also decrease.

For information on ensuring safe temperatures for TEE transducers, see “Ensuring Safe TEE Temperatures” on page 321.

Transducer Covers

For procedures for using transducer covers, see the instructions provided with the covers.

WARNING

To prevent contamination by blood-borne pathogens, legally marketed sterile transducer covers with sterile ultrasound transmission gel are required for intraoperative applications, and during needle guidance and biopsy procedures. Protective covers are recommended for transesophageal, transrectal, and intravaginal procedures; in China and Japan, the covers are mandatory. Philips recommends the use of legally marketed sterile covers.

WARNING

Latex and talc are commonly used in sheaths marketed to help with infection control in transesophageal, endocavity, and intraoperative imaging applications and during needle guidance and biopsy procedures. Examine the packaging to confirm latex and talc content. Studies have shown that patients can experience allergic reactions with natural rubber latex. See the FDA Medical Alert, March 29, 1991, reprinted in “FDA Medical Alert on Latex” on page 65.

WARNING

In intraoperative applications, transducers that have undergone high-level disinfection must be used with sterile ultrasound transmission gel and a legally marketed sterile transducer cover.

WARNING

Inspect transducer covers before and after use.

WARNING

Do not apply the transducer cover until you are ready to perform the procedure.

WARNING

If an installed transducer cover is cut or contaminated before use, the transducer should be cleaned and disinfected or sterilized. Install a new transducer cover; for applications requiring sterile covers, install a new legally marketed sterile cover.

WARNING

If a sterile transducer cover becomes compromised during an intraoperative application involving a patient with transmissible spongiform encephalopathy, such as Creutzfeldt-Jakob disease, follow the guidelines of the U.S. Centers for Disease Control and this document from the World Health Organization: WHO/CDS/ APH/2000/3, WHO Infection Control Guidelines for Transmissible Spongiform Encephalopathies. The transducers for your system cannot be decontaminated using a heat process.

WARNING

Sterile transducer covers are disposable and must not be reused.

For more information on connecting transducers, see “Connecting Transducers” on page 199.
For more information on caring for and maintaining transducers, see *Care and Cleaning of Ultrasound Systems and Transducers* and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*.

Ultrasound Transmission Gels

For proper transmission of the acoustic beam, use the ultrasound transmission gel supplied by or recommended by Philips, or another glycol-, glycerol-, or water-based acoustic coupling medium.

WARNING

Legally marketed sterile transducer covers with sterile ultrasound transmission gel are required for intraoperative applications, and during needle guidance and biopsy procedures.

CAUTION

Do not use lotion-based products, mineral oil, or water-based gels that contain mineral oil. Such products may damage the transducer and void the warranty.

CAUTION

Do not use hand sanitizing gels.

CAUTION

Do not apply the transducer gel until you are ready to perform the procedure. Transducers should not be left soaking in gel.

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CAUTION

Gels listed here are recommended because of their chemical compatibility with product materials.

Some recommended gels include:

- Aquasonic 100
- Aquasonic Clear
- Carbogel-ULT
- EcoVue
- Scan
- Ultra Phonic

For additional compatibility information, call Philips at 800-722-9377 (North America) or your local Philips representative (outside North America).

Transducer Transport

Transport used transducers in a spill-proof, closed container with appropriate contamination labeling. To avoid damage to the lens, ensure that the container holds the transducer in place. During transportation, prevent all patient-contact parts from contacting non-patient-contact parts.

When you transport cleaned and disinfected transducers, ensure that any containers used for transport are also cleaned and disinfected before you place the clean transducers in the containers.

For more information, see “Storage for Transport” on page 263.

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Transducer Storage

Use the appropriate guidelines for storing transducers for transport, and daily and long-term storage.

CAUTION

Before storing transducers, ensure that they are thoroughly dry. If it is necessary to dry the transducer lens (acoustic window) after cleaning, use a soft, dry, lint-free cloth and a gentle blotting motion. Aggressive wiping or scrubbing can damage the lens.

Storage for Transport

CAUTION

Before storing transducers, ensure that they are thoroughly dry. If it is necessary to dry the transducer lens (acoustic window) after cleaning, use a soft, dry, lint-free cloth and a gentle blotting motion. Aggressive wiping or scrubbing can damage the lens.

If a carrying case is provided with your transducer, always use the carrying case to transport the transducer from one site to another. Follow these guidelines to properly store transducers for transport:

- Make sure that the transducer is clean and disinfected before placing it in the case to avoid contaminating the lining of the carrying case.
- Place the transducer in the case carefully to prevent kinking of the cable.
- Before closing the lid, make sure no part of the transducer is protruding from the case.
- Wrap the case in plastic material containing air-filled pockets (such as Bubble Wrap material), and pack the wrapped case in a cardboard carton.

- To avoid damaging the shaft or steering mechanism of TEE transducers, do not bend or coil the flexible shaft of the transducer in less than a 0.3-m (1-ft) diameter circle.

Daily and Long-Term Storage

Follow these guidelines to protect your transducer:

- Always store transducers in the transducer holders on the side of your system or on a securely mounted wall rack when you are not using them.
- Ensure the transducer holders are clean before storing transducers (see *Care and Cleaning of Ultrasound Systems and Transducers*).
- When storing transducers, use the cable-management clips, if available, to secure the transducer cable.
- Avoid storing transducers in areas of temperature extremes or in direct sunlight.
- Store transducers separately from other instruments to avoid inadvertent transducer damage.
- Before storing transducers, make sure they are thoroughly dry.
- For TEE transducers, be sure the distal tip is straight and protected before storing the transducer.
- Never store a TEE transducer in the carrying case, except to transport it.

Transducer Maintenance

For information about transducer maintenance, see “Transducer Care” on page 352, *Care and Cleaning of Ultrasound Systems and Transducers*, and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*.

Transducer Electrical Safety Testing

Electrical safety tests should be performed regularly to ensure patient safety. These tests are designed to:

- Verify the integrity of the insulating layers of all transducers.
- Detect abnormalities that could prove dangerous to a patient or an operator and to ensure that system safety and functions have not been compromised.

Electrical safety tests also should be performed when a transducer has been perforated or damaged.

This subsection provides two electrical leakage current tests for transducers:

- To check a transducer for electrical leakage while it is connected to the ultrasound system while the system sends normal operating voltages to the transducer, see "Transducer Leakage Current Test (Source)" on page 272.
- To check a transducer directly for electrical leakage, see "Transducer Isolation Leakage Current Test (Sink)" on page 278.

This subsection also provides a stand-alone test for TEE transducers ("Stand-Alone TEE Transducer Leakage Test" on page 271).

WARNING

Only a technically qualified person should perform the procedures.

WARNING

There is a possible risk of infection from handling transducers that have been cleaned and disinfected improperly. Before testing the transducers, clean and disinfect the transducer according to the instructions provided on the "Transducer Care" website: www.philips.com/transducercare

NOTE

Before proceeding with any transducer test, thoroughly inspect the transducer. If the transducer is a TEE transducer, check that its steering controls are working properly.

NOTE

Stand-alone test devices can perform indication-of-leakage tests *only*. The devices cannot diagnose the problem or provide a mitigation. Any stand-alone test failure indicates the need for complete safety testing of the transducer with the ultrasound system. For assistance, contact the authorized Philips representative.

NOTE

Safety testing can be dictated by the government regulation for your region. If additional tests are required to meet local country requirements, you may perform those required tests. For more information, contact your local Philips representative.

Preparing to Test

Before performing the safety procedures, check the following.

System

- Unplug all peripherals (network connections, printers, monitors, laptops, and so on) from the system before beginning any safety test. Connected peripherals may cause erroneous results.
- If the system has a ground bonding strap, a ground bonding brush, or an antistatic chain, insulate the strap, the brush, or the chain from the floor with an insulated sheet or another insulated item, such as a notebook.
- If the system being tested uses batteries during normal system operation, install the batteries to support the system during safety testing.

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- Inspect:
  - System enclosure for damage, such as exposed metal parts or circuitry
  - External cabling for wear, cracks, holes, and bare wires
  - Power connectors for damage or missing pins

Transducers

For all transducers, check for damage to the connector, the cable, the housing, or the lens.

For TEE transducers, check for bite marks or damage to the transducer shaft.

WARNING

To avoid risk of electrical shock, do not use any transducer that has been immersed beyond the specified cleaning or disinfection level.

NOTE

If you suspect damage to the TEE transducer shaft, perform the TEE transducer leakage test ("Stand-Alone TEE Transducer Leakage Test" on page 271). This procedure will assist in determining if the hole has compromised the electrical isolation of the shaft.

Equipment

Calibrate the safety analyzers or digital multimeters for the variables directly involved with safety procedures, specifically:

- Voltage (V - volts)
- Current (I - amperes)
- Resistance (R - ohms)

Ensure that the safety analyzers or digital multimeters are equipped internally with the required measuring device (MD = IEC 60601-1) that is appropriate for conducting loaded/weighted patient leakage current tests.

Transducer Testing Equipment

The following tools are required for transducer safety tests:

- Electrical measuring device (approved by IEC or AAMI), such as
  - Fluke DALE 601 electrical safety analyzer
  - Fluke ESA620 electrical safety analyzer
  - Fluke ESA612 electrical safety analyzer
  - Fluke 177 digital multimeter or other digital multimeters (for general electrical measurements)
- Nonconductive test container (Recommended: Fluke 2558630, Cleaning/Testing basin)
- Test lead (Recommended: Fluke 2801776, Conductive Probe)
- Adapter cable for safety analyzer (Optional: Fluke 3472633, Ultrasound Test Cable Adapter)
- 0.9% saline solution. If 0.9% saline solution is not available, mix 9 g (0.32 oz) of table salt per 1 liter (33.8 oz) of tap water. You can also use one of the approved conductive disinfectants listed in *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers* on the "Transducer Care" website:
  www.philips.com/transducercare

NOTE

This testing information is intended to provide general information about how to perform electrical safety tests pertinent to Philips ultrasound systems and transducers. To use the specific safety analyzer or digital multimeter, follow the user information provided by the equipment manufacturer.

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Transducer Testing Background

The transducer safety tests include figures, procedures, and results. The figures are generic and pertain to multiple safety analyzers and digital multimeters. As expected, operation of various test equipment differs due to control locations and functions. For information on safety analyzers or digital multimeters, see the user information provided by the equipment manufacturer.

Figures

The safety test figures may include the following symbols.

Figure Symbols

Symbol	Definition	Notes
	Indicates that the Type CF applied part has an isolated patient connection.	Type CF devices (transducers and test leads) typically are used close to the heart and have stricter limits than Type BF devices. Look for the symbol on the device.
	Indicates that the Type CF applied part has an isolated, defibrillation-proof patient connection.	
	Indicates that the Type BF applied part has an isolated patient connection.	Type BF devices (transducers and test leads) have less-stringent limits than Type CF devices due to how they are used on the patient. Look for this symbol on the device.
	Indicates that the Type BF applied part has an isolated, defibrillation-proof patient connection.	
	Indicates that the Type B applied part has a non-isolated patient connection.	The Type B device symbol is used primarily on older transducers. To avoid damaging the transducer, do not perform isolation tests on transducers with this symbol.
	Indicates the alternating current (AC) voltage power source.	--

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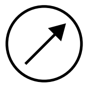
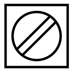
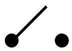
Symbol	Definition	Notes
	Indicates the placement of the safety analyzer or digital multimeter.	--
	Indicates the ground lug on the ultrasound system.	The ground lug is a thick metal pin, commonly found on the back of the ultrasound system near the power supply.
I	Indicates current.	--
	Indicates that a circuit is open.	--
	Indicates that a circuit is closed.	--

Procedures

The procedures are generic and pertain to multiple safety analyzers or digital multimeters.

Tables

The tables identify the conditions, limits, and results for each procedure.

NOTE

The limits referenced in the safety procedures are prescribed by the IEC. Local regulations may require additional tests. Measured values cannot exceed the IEC limits.

Transducer IPX Ratings

During testing, the transducer is immersed in a saline solution or an approved conductive disinfectant. Check the IPX rating on the transducer connector before you start testing.

All imaging transducers are rated at a minimum IPX7 in accordance with IEC 60529, “Degrees of Protection Provided by Enclosures (IP code).” This rating indicates that the device is protected against the effects of immersion.

Doppler (nonimaging) transducers are rated IPX1. This rating indicates that the device is protected against the effects of vertically falling water.

For all TEE transducers, the control module is rated IPX1, while the endoscope is rated IPX7, in accordance with IEC 60529.

For more information about IPX symbols, see “Symbols” on page 47.

Stand-Alone TEE Transducer Leakage Test

If your institution requires IAC accreditation, you are required to conduct a stand-alone test on TEE transducers before every use.

NOTE

To perform the stand-alone test, see the user information provided by the equipment manufacturer.

The stand-alone test uses a pass/fail threshold of 185 µA. If the TEE transducer fails the stand-alone test, complete the following:

- Thoroughly inspect the transducer for physical damage.
- Perform “Transducer Leakage Current Test (Source)” on page 272.
- Perform “Transducer Isolation Leakage Current Test (Sink)” on page 278.

If the transducer passes the source and sink leakage tests, and the sink current is less than the 600-µA limit applied to Type BF transducers, the transducer is safe for use. However, the transducer should be tested using the source and sink procedures in this manual to monitor the transducer for leakage increases between uses.

If the transducer fails *any* of the tests, contact your authorized service representative.

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Transducer Leakage Current Test (Source)

The Transducer Leakage Current Test (Source) checks a transducer for electrical leakage while it is connected to the ultrasound system. The system sends normal operating voltages to the transducer, and leakage is measured using a safety analyzer. The diagrams in this procedure show the basic electrical conditions for each phase of the test.

WARNING

The Transducer Leakage Current Test (Source) can be hazardous. Avoid any contact with line voltage. Do not touch the conductive part of the system enclosure or the lead at any time during the test when the ground connection is open.

WARNING

Only a technically qualified person should perform this procedure.

CAUTION

To avoid damaging the transducer, do not immerse the connector.

CAUTION

To avoid corroding the control handle of a TEE transducer, do not immerse the handle or allow saline solution to contact the control handle.

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CAUTION

On TEE transducers, do not crimp the flexible shaft or cable. Do not bend the shaft into a circle with a diameter of less than 0.3 m (1 ft).

CAUTION

Depths are not the same between transducer manufacturers. If you are working with approved non-Philips transducers, to avoid damaging the transducer, verify the immersion depth before immersion.

CAUTION

Changing from normal to reverse polarity during a test procedure may damage the ultrasound system. Some ultrasound systems contain computers and hard drives. Rapidly cycling system power by using the polarity switch may damage these components. To prevent damage, power up the system with the safety analyzer set to normal polarity, take the measurement, and power down the system. Change the polarity on the safety analyzer, power up the system, and take the reverse polarity measurement. Do not turn the system power off during startup. Consider this caution whenever you change the polarity.

NOTE

Stand-alone test devices can perform indication-of-leakage tests *only*. The devices cannot diagnose the problem or provide a mitigation. Any stand-alone test failure indicates the need for complete safety testing of the transducer with the ultrasound system. For assistance, contact the authorized Philips representative.

NOTE

Perform the electrical safety tests regularly.

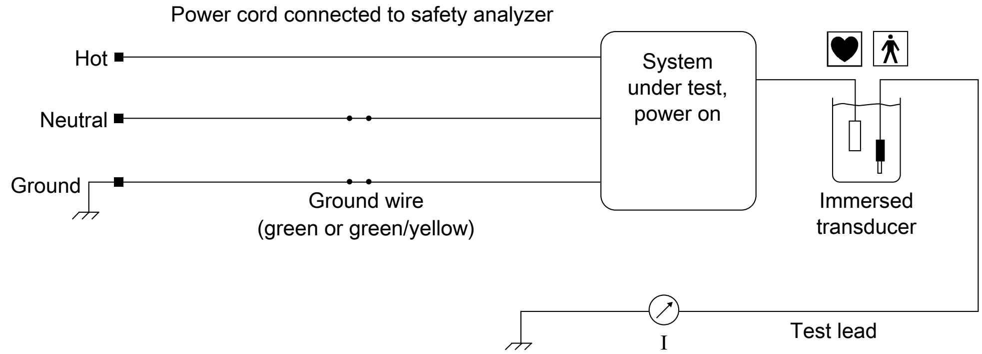
For descriptions of the symbols used in the figures in this procedure, see “Transducer Testing Background” on page 269.

1. Gather the equipment needed to perform the electrical safety test procedure (see “Transducer Testing Equipment” on page 268).
2. Set the safety analyzer mode to test all leads.
3. Fill a nonconductive test container with enough saline solution to completely cover the appropriate parts of the transducer (described in step 9).
4. Connect the test lead to the appropriate jack on the safety analyzer.
5. Rest the probe end of the test lead on the edge of the nonconductive test container to partially immerse the metal prong or prongs in the saline solution.
6. Plug the safety analyzer into an available wall outlet. Plug the ultrasound system power plug into the test receptacle on the safety analyzer.
7. Turn on the ultrasound system.
8. Connect the transducer to be tested to the system.
9. Read the safety messages preceding this procedure, refer to the information in “Transducer IPX Ratings” on page 270, and then carefully immerse the transducer as follows:
    - For transthoracic and endocavity transducers, immerse the handle including the head and up to 5 cm (2 in) from the cable strain relief.
    - For TEE and laparoscopic transducers, immerse the part of the flexible shaft that enters the body of the patient, up to the end of the immersion depth markers.
    - For Doppler (nonimaging) transducers, immerse *only* the part that makes contact with the body of the patient.
10. Set the safety analyzer to read leakage current in microamperes (µA).
11. Make sure that the transducer is selected and that the image is not frozen.
12. Obtain an image with the transducer.

NOTE

For normal condition and single-fault condition 1 (open ground) measurements, the transducer must be imaging to measure the maximum leakage current.

13. Read the current in normal condition (see the following diagram). Check that the value is within the limit specified for the normal condition in the table following this procedure. (Match the transducer type symbol on the transducer connector or cable with the symbol in the following diagram.) Record the result.



Transducer Leakage Current Test (Source): Normal Condition

14. Reverse the polarity on the safety analyzer, and then make sure that the transducer is selected and that the image is not frozen. Read the current in reverse polarity. Check that the value is within the limit specified for the normal condition in the table following this procedure. Record the result.
15. Read the current with single-fault condition 1 (see the following diagram) imposed in normal polarity. Record the result.

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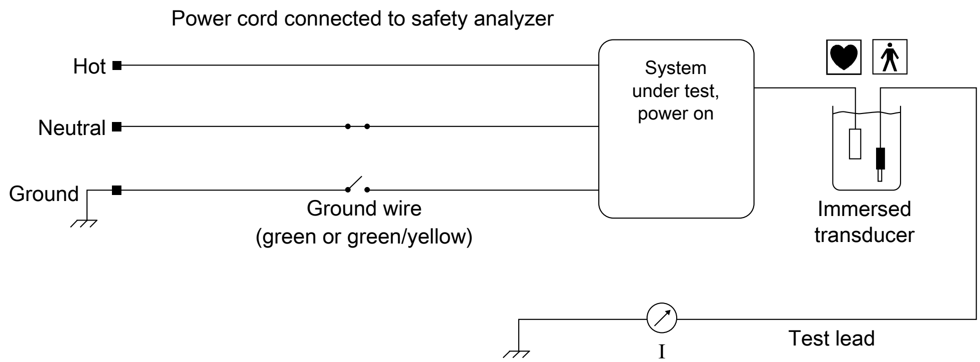
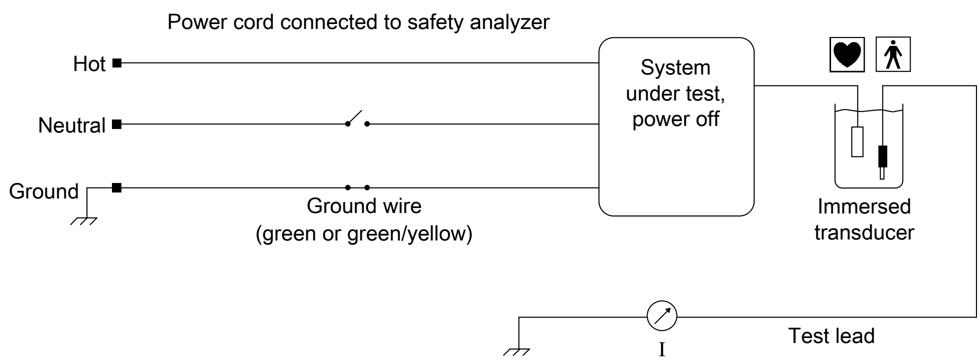


Transducer Leakage Current Test (Source): Single-Fault Condition 1

16. Reverse the polarity on the safety analyzer, and then read the current with single-fault condition 1 (see the preceding diagram). Compare this result to the result obtained in step 15. The higher of the two results is the recorded value for single-fault condition 1.
17. Check that the current values measured in step 15 and step 16 are within the limit specified for single-fault condition 1 in the table following the procedure.
18. Turn off the ultrasound system, and then read the current with single-fault condition 2 (see the following diagram) imposed in normal polarity. Record the result.



Transducer Leakage Current Test (Source): Single-Fault Condition 2

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19. With the ultrasound system still off, read the current with single-fault condition 2 (see the preceding diagram) imposed for reverse polarity. Record the result, and compare it to the result obtained in step 18. The higher of the two results is the recorded value for single-fault condition 2.
20. Check that the current values measured in step 18 and step 19 are within the limit specified for the single-fault condition 2 in the table following the procedure.

CAUTION

Values exceeding the limits may indicate a fault in the transducer housing or the cable cover. Contact the authorized Philips representative for assistance. Do not continue with other tests or use the system, until the problem is corrected.

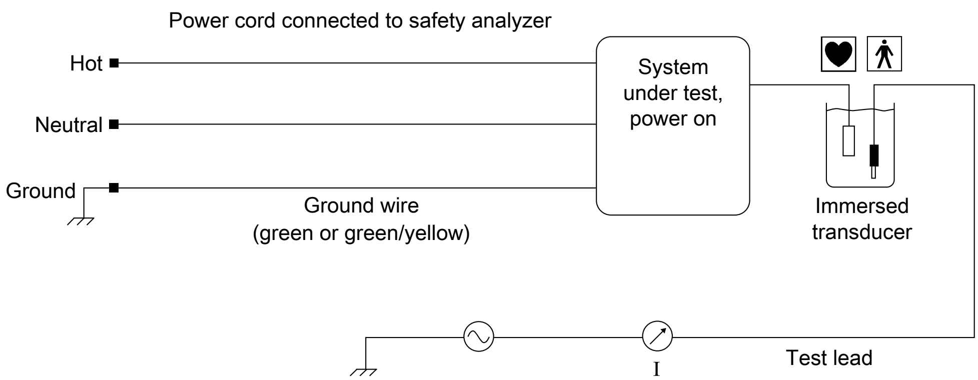
Transducer Leakage Current Test (Source) Results

Condition	AC Polarity	IEC Limits (Maximum Values)	Recorded Value
Normal	Normal	Type CF: ≤ 10 µA	Higher between normal and reverse polarity
	Reverse	Type BF: ≤ 100 µA	
Single-fault condition 1	Normal	Type CF: ≤ 50 µA	Higher between normal and reverse polarity
	Reverse	Type BF: ≤ 500 µA	
Single-fault condition 2	Normal	Type CF: ≤ 50 µA	Higher between normal and reverse polarity
	Reverse	Type BF: ≤ 500 µA	

Transducer Isolation Leakage Current Test (Sink)

The following diagram shows the basic electrical concept of the Transducer Isolation Leakage Current Test (Sink). The transducer is immersed in a nonconductive test container of saline solution. AC voltage from an AC power source is introduced into the saline solution, and leakage current in the transducer is measured using a safety analyzer.

For descriptions of the symbols used in the diagram in this procedure, see "Transducer Testing Background" on page 269.



Transducer Isolation Leakage Current Test (Sink)

WARNING

The Transducer Isolation Leakage Current Test (Sink) is hazardous. It applies line voltage through the test leads to the housing of the transducer. Avoid accidental contact with the line voltage. Do not touch the chassis, the test leads, or the transducer cables while performing the test. Keep the test leads and transducer cables at least 20 cm (8 in) from any grounded or conductive surfaces.

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WARNING

Only a technically qualified person should perform this procedure.

CAUTION

To avoid damaging the transducer, do not immerse the connector.

CAUTION

To avoid corroding the control handle of a TEE transducer, do not immerse the handle or allow saline solution to contact the control handle.

CAUTION

On TEE transducers, do not crimp the flexible shaft or cable. Do not bend the shaft into a circle with a diameter of less than 0.3 m (1 ft).

CAUTION

Depths are not the same between transducer manufacturers. If you are working with approved non-Philips transducers, to avoid damaging the transducer verify the immersion depth before immersion.

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CAUTION

Changing from normal to reverse polarity during a test procedure may damage the ultrasound system. Some ultrasound systems contain computers and hard drives. Rapidly cycling system power by using the polarity switch may damage these components. To prevent damage, power up the system with the safety analyzer set to normal polarity, take the measurement, and power down the system. Change the polarity on the safety analyzer, power up the system, and take the reverse polarity measurement. Do not turn the system power off during startup. Consider this caution whenever you change the polarity.

NOTE

Stand-alone test devices can perform indication-of-leakage tests *only*. The devices cannot diagnose the problem or provide a mitigation. Any stand-alone test failure indicates the need for complete safety testing of the transducer with the ultrasound system. For assistance, contact the authorized Philips representative.

NOTE

Perform the electrical safety tests regularly.

NOTE

During the isolation test, *do not* impose open ground or open neutral conditions.

1. Gather the equipment needed to perform the electrical safety test procedure (see “Transducer Testing Equipment” on page 268).
2. Set the safety analyzer mode to test all leads.
3. Fill a nonconductive test container with enough saline solution to completely cover the appropriate parts of the transducer (see step 9).

4. Connect a test lead to the appropriate jack on the safety analyzer.
5. Rest the probe end of the test lead on the edge of the nonconductive test container to partially immerse the metal prong or prongs in the saline solution.
6. Plug the safety analyzer into an available wall outlet. Plug the ultrasound system power plug into the test receptacle on the safety analyzer.
7. Turn on the ultrasound system.
8. Connect the transducer to the system.
9. Read the safety messages preceding this procedure, refer to the information in "Transducer IPX Ratings" on page 270, and then carefully insert the transducer as follows:
    - For transthoracic and endocavity transducers, immerse the handle including the head and up to 5 cm (2 in) from the cable strain relief.
    - For TEE and laparoscopic transducers, immerse the part of the flexible shaft that enters the body of the patient, up to the end of the immersion depth markers.
    - For Doppler (nonimaging) transducers, immerse the part that makes contact with the body of the patient *only*.
10. Set the safety analyzer to read leakage current in microamperes (µA).
11. Measure the isolation leakage current of the transducer. Record the value, and check that it is within the limit specified in the table following the procedure.
12. Repeat step 11 for reverse polarity. Record the value, and check that it is within the limit specified in the table following the procedure.

CAUTION

Values exceeding the limits may indicate a fault in the transducer housing or the cable cover. Contact the authorized Philips representative for assistance. Do not continue with other tests or use the system, until the problem is corrected.

Transducer Isolation Leakage Current Test (Sink) Results

Condition	AC Polarity	Limits (Maximum Values)	Recorded Value
Normal	Normal	Type CF: ≤ 50 µA	Higher between normal and reverse polarity
	Reverse	Type BF: ≤ 600 µA [1]	

1. While the IEC standard maximum limit is 5,000 µA, Philips suggests testing with a more conservative limit for business reasons.

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9 Intraoperative Transducers

An intraoperative transducer is used during surgery to help the surgeon locate and visualize anatomical structures, to visualize blood flow patterns and quantify velocities, and to image and measure anatomical and physiological parameters of interest to the surgeon.

For information on connecting transducers, see "Connecting Transducers" on page 199. For more information on caring for and maintaining transducers, see *Care and Cleaning of Ultrasound Systems and Transducers* and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*.

Disinfect new transducers before performing the first study. Clean and disinfect the transducer immediately after each use to protect patients and personnel from pathogens. Establish and clearly post a cleaning procedure that includes the steps described in *Care and Cleaning of Ultrasound Systems and Transducers*.

WARNING

Always remove the transducer from the patient before defibrillation.

WARNING

Before defibrillation, if you cannot remove the transducer from the patient, always disconnect invasive transducers that remain in contact with the patient from the system.

Operators of Intraoperative Transducers

Philips intraoperative transducers are designed to be used under the guidance of physicians who are properly trained in intraoperative ultrasound imaging techniques according to currently approved relevant medical practices. Philips recommends that physicians operating any Philips intraoperative transducer have the following qualifications:

- Proficiency in recognizing and interpreting imaging patterns
- Thorough familiarity with the safe operation, care, and maintenance of the ultrasound system and the intraoperative transducers
- Thorough familiarity with the latest intraoperative methods through literature and seminars

Intended Uses for Intraoperative Transducers

Intraoperative studies are performed by surgeons, anesthesiologists, or sonographers to obtain images that can be used for the following purposes:

- Helping a surgeon locate and visualize anatomical structures before, during, or after a surgical procedure
- Helping a surgeon visualize blood flow patterns and quantify velocities before, during, or after a surgical procedure
- Imaging and measuring anatomic and physiologic parameters before, during, or after a surgical procedure

WARNING

Intraoperative transducers used in animal studies should not be used on humans. Intraoperative transducers used in human studies should not be used on animals. Transducer disinfection procedures for cross-usage between animals and humans have not been validated.

WARNING

Type BF ( ) intraoperative transducers are not intended to come into contact with the central nervous system or central cardiovascular system.

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Patient Safety During Intraoperative Studies

To operate an intraoperative transducer, you must be under the guidance of a physician who is properly trained in intraoperative ultrasound imaging techniques, according to currently approved relevant medical practices. You also must be thoroughly familiar with the safe operation, care, and maintenance of the ultrasound system used with the transducer, as well as proficient at interpreting the images generated.

To help ensure patient safety when using an intraoperative transducer, observe the following guidelines:

- Scrutinize the entire transducer before each use. (See *Care and Cleaning of Ultrasound Systems and Transducers*.)
- Use mandatory protective equipment, including a legally marketed sterile protective transducer cover, during intraoperative studies. For information about using transducer covers, see “Preparing Transducers for Intraoperative Use” on page 289.
- Operate the transducer properly.
- Do not allow water or other liquids to drip onto the transducer connector, the interior of the system, or the control panel.
- Maintain a sterile field.
- Ensure that no part of the transducer contacts the patient's skin or tissue for a prolonged length of time.
- Use procedures or an appropriate device to avoid or minimize pressure between the patient and the transducer external components.
- Always monitor any pressure points where the transducer components contact the patient.

For electrical safety test procedures, see “Transducer Electrical Safety Testing” on page 265.

WARNING

All intraoperative studies intended for direct contact with the patient's heart must be performed with a Type CF classified transducer. If your transducer is not labeled Type CF on the transducer connector, contact your Philips service representative.

WARNING

In intraoperative applications, use a legally marketed sterile transducer cover and Sterile Aquasonic, sterile Ultra Phonic gel, or other sterile gels provided with the transducer cover.

WARNING

Always remove the transducer from the patient before defibrillation.

WARNING

Before defibrillation, if you cannot remove the transducer from the patient, always disconnect invasive transducers that remain in contact with the patient from the system.

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Patient-Contact Parts

WARNING

Latex and talc are commonly used in sheaths marketed to help with infection control in transesophageal, endocavity, and intraoperative imaging applications, and during needle guidance and biopsy procedures. Examine the packaging to confirm latex and talc content. Studies have shown that patients can experience allergic reactions with natural rubber latex. See the FDA Medical Alert, March 29, 1991, reprinted in **"FDA Medical Alert on Latex" on page 65****.**

NOTE

The ultrasound system and transducers discussed here do not contain natural rubber latex that contacts humans. Natural rubber latex is not used on any Philips ultrasound transducers.

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Preventing Intraoperative Transducer Problems

WARNING

If you find any signs of damage to the transducer, patient safety may be compromised. Do not use the transducer, and contact your Philips service representative.

Meticulous inspection and correct and careful operation of intraoperative transducers are imperative to patient safety. The situations listed here affect safe operation as well as the ability to service mechanical problems under the Philips warranty or service contract. Transducer repairs necessitated by misuse are not covered and can be very costly, often requiring complete disassembly and rebuilding of the transducer.

There are three primary areas of transducer misuse:

- Cuts and abrasions on the transducer insulation and lens from sharp instruments such as scalpels, scissors, and clamps
- Improper disinfection techniques, causing fluid to enter the transducer or damage transducer materials
- Damage caused by dropping the transducer on a hard surface

To minimize the chance of damage, Philips strongly recommends that you clearly post stringent protocols for the care of intraoperative transducers, based on the information provided here.

Electrical Safety and Intraoperative Transducers

All Philips ultrasound systems and transducers comply with common medical device electrical safety standards.

Intraoperative transducers intended for direct contact with the patient’s heart are classified as a Type CF isolated patient-applied part, as described in IEC 60601-1. There are no exposed conductive surfaces on the transducer head.

For electrical safety information about intraoperative transducers, see “Leakage Current and Intraoperative Transducers” on page 288.

For safety information on electrosurgical units, pacemakers, defibrillators, and related topics, see “Electrical Safety” on page 35.

Leakage Current and Intraoperative Transducers

WARNING

Only a technically qualified person should perform leakage current test procedures.

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WARNING

Leakage current tests should be performed if the transducer has been dropped or if cracks or cuts are found on the transducer.

Philips transducers approved for intraoperative use are labeled on the transducer connector as Type BF ( ) or Type CF ( ) in accordance with IEC 60601-1. Type CF transducers provide the highest degree of protection against electric shock and are suitable for all patient applications, including direct cardiac and intraoperative applications. Type BF transducers are not suitable for direct cardiac applications.

Leakage hazards are further reduced when the ultrasound system is plugged into an isolated power outlet, which is standard in most operating rooms.

Regularly perform the leakage current tests found in "Transducer Electrical Safety Testing" on page 265. The frequency of testing should be based on the procedures established by the hospital for operating-room-based equipment.

Preparing Transducers for Intraoperative Use

1. Place 20 cc of sterile gel or saline into the transducer cover.
2. Carefully inspect each transducer cover before use, and discard it if you find tears or blemishes. Also inspect each transducer cover after use. If you find a tear, the patient or the transducer may have been contaminated.
3. Insert the transducer into the transducer cover and unfurl the transducer cover until it covers the transducer and its cable. The cover must be unfurled far enough to maintain the sterile field.
4. Use a sterile elastic band or clip to hold the proximal end of the transducer cover in place.
5. Ensure that wrinkles and bubbles over the face of the transducer are minimized. Check the transducer cover for tears or damage before proceeding.

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6. When operating the transducer, make sure that proper orientation is maintained to avoid interpretation confusion.

NOTE

To achieve good acoustic contact, make sure that the imaging surface is moist.

NOTE

Imaging improves with adequate coupling between the patient surface and the transducer-cover surface. Sterile water is a good acoustic-coupling agent during surgery.

Disposable Drapes

During studies in which you believe contamination of the ultrasound system can occur, Philips recommends that you take universal precautions and cover the system with a disposable drape. Consult your hospital's rules regarding equipment use in the presence of infectious disease.

Accessories for Intraoperative Transducers

For information on ordering accessories, see “Supplies and Accessories” on page 26.

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10 Transesophageal Transducers

A transesophageal echocardiography (TEE) study is performed with a transducer mounted in a flexible shaft, which is positioned in the esophagus or stomach. TEE transducers offer images that are unobstructed by lungs and ribs, making them important diagnostic tools for conditions that transthoracic echocardiography cannot adequately image.

All transesophageal transducers are rated minimum IPX1 (control area) and IPX7 (endoscope area) in accordance with IEC 60529.

The system supports the X7-2t TEE and X8-2t TEE transducers. The imaging array in the X7-2t and X8-2t transducers can also be rotated electronically using controls on the control panel

Disinfect new transducers before performing the first study. Clean and disinfect the transducer immediately after each use to protect patients and personnel from pathogens. Establish and clearly post a cleaning procedure that includes the steps described in *Care and Cleaning of Ultrasound Systems and Transducers*.

For information on connecting transducers, see "Connecting Transducers" on page 199. For more information on caring for and maintaining transducers, see *Care and Cleaning of Ultrasound Systems and Transducers* and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*.

WARNING

Always remove the transducer from the patient before defibrillation.

WARNING

Before defibrillation, if you cannot remove the transducer from the patient, always disconnect invasive transducers that remain in contact with the patient from the ultrasound system.

Operators of TEE Transducers

Philips TEE transducers are designed for use under the guidance of physicians who are properly trained in esophagogastroscopy techniques, according to currently approved relevant medical practices. Philips recommends that physicians operating any Philips TEE transducer have the following qualifications:

- Proficiency in recognizing and interpreting transesophageal imaging patterns
- Thorough familiarity with the safe operation, care, and maintenance of the ultrasound system and TEE transducers
- Thorough familiarity with the latest TEE methods through literature and seminars

Patient Safety During TEE Studies

Philips recommends that you practice using the TEE transducer controls before performing any procedure mentioned here. You must also be thoroughly familiar with the safe operation, care, and maintenance of the ultrasound imaging system used with the TEE transducer, as well as proficient at interpreting the images generated.

You can help ensure patient safety when using a TEE transducer by following these guidelines:

- Have a backup system present during critical exams to ensure completion of the exam in the event that the primary system fails. If a backup system is unavailable, then address any patient-specific clinical symptoms according to standard patient-management protocols.
- Use informed judgment when selecting patients for TEE studies. See “Patient Selection for TEE Transducer Use” on page 316.
- Insert, remove, and operate the transducer properly.
- Ensure that the transducer handle does not rest on or touch the patient.
- Use protective equipment, such as a bite guard and a legally marketed sterile transducer cover during a TEE study. See “TEE Accessories and Supplies” on page 326.
- Minimize the possibility of transducer tip fold-over. This problem has occurred rarely, but its consequences can be serious. See “Tip Fold-Over” on page 319.

- Ensure that no part of the transducer, including external components (shaft, handle, cable), contacts the patient's skin or tissue for a prolonged length of time.
- Use procedures or an appropriate device, such as a TEE transducer holder, to avoid or minimize pressure between the patient and the transducer external components (shaft, handle, cable).
- Always monitor any pressure points where the transducer components contact the patient.
- Verbally prepare each patient for the procedure before the study. See “Preparing Patients for TEE Studies” on page 317.
- Scrutinize the entire transducer, turn on the system, and test all of the transducer controls and related system controls, before inserting the TEE transducer into the patient's esophagus. See “Checking the TEE Transducer” on page 315.
- Do not allow water or other liquids to come in contact with the interior of the system, the interior of the transducer connector, or the inside of the transducer control handle.

To prevent tissue damage such as pressure necrosis, gastroesophageal lacerations, bleeding, tearing of adhesions, ligament damage, and perforation, observe the following warnings and cautions.

WARNING

Never apply excessive force when inserting or withdrawing a TEE transducer, or when operating the transducer deflection controls.

WARNING

Do not allow the transducer to remain at a maximum deflection for long periods of time.

WARNING

Whenever the TEE transducer is not being used during a procedure, ensure that it is in freewheeling mode and unplugged from the system.

WARNING

Set the brake on to restrict the medial/lateral movement of the TEE transducer during insertion.

WARNING

To prevent tissue damage, Philips recommends that the tip of the TEE transducer be straightened and both detent brakes released before you reposition the transducer or withdraw the transducer from the patient. In the neutral position, the tip is straight when the indicators on the control wheels are aligned and point toward the center of the array rotation button.

WARNING

Bite guards are mandatory; protective transducer covers are recommended for TEE transducers, but in China and Japan, the covers are mandatory. See **"Electrical Safety and TEE Transducers" on page 299****.**

CAUTION

To avoid damaging flexible shaft cables, be sure that the distal tip of the transducer is in the neutral (straight) position when inserting a transducer into, or removing it from, the transducer cover.

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The TEE transducers are classified as Type BF isolated patient-applied parts, as described in IEC 60601-1. There are no exposed conductive surfaces distal to the transducer handle. To ensure safe operation of this transducer, read the cautions and warnings in the "Safety" section, especially those that address electrosurgical units, pacemakers, and defibrillators.

The following table summarizes patient safety problems, describes how to prevent them, and lists the sections in this manual where details are provided.

WARNING

If you encounter an irregularity not listed in the following table, do not use the transducer. Potentially serious consequences could result. Contact your Philips representative.

Ensuring Patient Safety During TEE Studies

Problem	Effect on Patient	Prevention	See
Mechanical damage	Severe trauma, cuts, bleeding, perforations	Inspect the transducer, using both sight and touch, before the study.	"Checking the TEE Transducer" on page 315
Electrical damage	Esophageal burns	Check the transducer for frayed insulation, kinks, or other abnormalities. Follow procedures for checking electrical safety.	"Electrical Safety and TEE Transducers" on page 299
Biting, scraping transducer	Tooth damage, esophageal burns	Always use a bite guard.	"Bite Guards" on page 326
Insufficient cleaning protocol	Spread of illness or disease	Thoroughly clean and disinfect the transducer after each use. Cover the tip and shaft with a transducer cover. Cover the imaging system with a disposable drape if highly pathogenic organisms are known or suspected.	*Care and Cleaning of Ultrasound Systems and Transducers*, and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*

Problem	Effect on Patient	Prevention	See
Improper insertion or withdrawal	Esophageal cuts, bleeding, ligament damage, perforations	To prevent improper insertion or withdrawal when using a TEE transducer, never use force when inserting, removing, or manipulating the transducer. During insertion, set the brake to restrict the medial/lateral controls. During withdrawal, release both brakes to place both steering knobs in the freewheeling position.	"TEE Study Guidelines" on page 318
Pressure necrosis	Death of esophageal lining tissue	Keep deflection controls in freewheeling mode and unplug the transducer from the system when not imaging. Minimize the pressure applied to deflection area and distal tip. Do not let the distal tip displace a tissue area for more than 5 consecutive minutes.	"TEE Study Guidelines" on page 318
Prolonged pressure between patient and device	Device-related pressure ulcers or injuries	As appropriate, minimize prolonged pressure by any part of the transducer, including the external components, and the patient's skin or tissue. Frequently monitor any potential pressure points between the TEE transducer and the patient's skin or tissue.	"TEE Study Guidelines" on page 318
Increased transducer temperature	Esophageal burns	Use the TEE preset that has been established to minimize the effects of temperature. For febrile patients, use the Auto-Cool feature.	"Entering Patient Temperature" on page 324
Improper patient position	Transient unilateral vocal cord paralysis	Never use the transducer during any procedure requiring extreme neck flexion, such as sitting craniotomies.	"TEE Study Guidelines" on page 318

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Problem	Effect on Patient	Prevention	See
Nonisolated ESUs	Electrical burns	Only use isolated-output electrosurgical units (ESUs). The ESU label or service guide or your biomedical department should identify whether or not the ESU is isolated. Unplug transducer from the system when you are not imaging.	"Electrical Safety and TEE Transducers" on page 299
Defibrillation issues	Electrical burns	Remove the transducer from the patient before defibrillation.	"Electrical Safety and TEE Transducers" on page 299

For electrical safety test procedures, see "Transducer Electrical Safety Testing" on page 265.

Patient-Contact Parts

WARNING

Latex and talc are commonly used in sheaths marketed to help with infection control in transesophageal, endocavity, and intraoperative imaging applications, and during needle guidance and biopsy procedures. Examine the packaging to confirm latex and talc content. Studies have shown that patients can experience allergic reactions with natural rubber latex. See the FDA Medical Alert, March 29, 1991, reprinted in "FDA Medical Alert on Latex" on page 65.

NOTE

The ultrasound system and transducers discussed here do not contain natural rubber latex that contacts humans. Natural rubber latex is not used on any Philips ultrasound transducers.

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Preventing TEE Transducer Problems

WARNING

If you find any signs of damage to the transducer, patient safety may be compromised. Do not use the transducer, and contact your Philips representative.

Meticulous inspection and correct and careful operation of the TEE (transesophageal) transducer is imperative to patient safety. The situations listed here affect safe operation as well as the ability to service mechanical problems under the Philips one-year warranty or service contract. Transducer repairs necessitated by misuse of the transducer are not covered and can be very costly, often requiring complete disassembly and rebuilding of the transducer.

There are three primary areas of transducer misuse:

- Cuts and abrasions on the transducer and insulation from teeth or sharp instruments such as scalpels, scissors, and clamps
- Improper disinfection techniques, including allowing fluid to enter the connector or transducer handle and the use of unapproved disinfectants
- Consistently applying too much force to the control wheels of a TEE transducer, which can break the steering mechanism

Review the following table to familiarize yourself with specific problems, to learn how to avoid them, and to identify the sections in this manual where details are provided. Philips also strongly recommends that you clearly post stringent protocols for TEE transducer care, based on the information in this manual, to minimize the chance of damage.

WARNING

For any other irregularity not listed in the following table, do not use the transducer. Potentially serious consequences could result. Contact your Philips representative.

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Preventing TEE Transducer Equipment Problems

Problem	Effect on Equipment	Prevention	Reference
Current leakage	Serious electrical hazards	Check the transducer for cuts, frayed insulation, kinks, or other abnormalities.	“Checking the TEE Transducer” on page 315
Biting transducer	Mechanical and electrical hazards	Cover the patient's teeth with a bite guard (mandatory). Cover the distal tip and flexible shaft with a transducer cover (recommended, but in China and Japan, mandatory).	“Bite Guards” on page 326
Forcing deflection controls	Steering mechanism broken	Operate the deflection controls gently.	“X7-2t Deflection Controls” on page 306 and “X8-2t Deflection Controls” on page 311
Incorrect storage	Possible damage to highly sensitive elements, cuts in flexible shaft	Suspend the transducer from a wall-mounted rack and the distal tip with a tip protector when not in use.	“Transducer Storage” on page 263
Internal exposure to liquids	Severe transducer damage that affects the image quality, the steering mechanism, and electrical safety	Never sterilize the transducer by using steam, heat, or ethylene oxide (EtO). Never immerse the steering mechanism in any disinfectant or liquid.	*Care and Cleaning of Ultrasound Systems and Transducers* and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*

Electrical Safety and TEE Transducers

All Philips ultrasound systems and transducers comply with common medical device electrical safety standards.

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For the TEE transducers discussed in this document, the insertion tube and tip are Type BF (), as described in IEC 60601-1. There are no exposed conductive surfaces distal to the transducer handle. Within the flexible shaft, all active circuits and conductors are surrounded by a chassis-grounded shield that runs the length of the transducer.

For electrical safety information about TEE transducers, see "Leakage Current and TEE Transducers" on page 300 and "Reducing Risks of Using TEE Transducers" on page 301.

For safety information on electrosurgical units, pacemakers, defibrillators, and related topics, see "Electrical Safety" on page 35.

Leakage Current and TEE Transducers

WARNING

Only a technically qualified person should perform leakage current test procedures.

WARNING

Leakage current tests should be performed if the transducer has been dropped or if cracks or cuts are found on the transducer.

NOTE

Stand-alone test devices can perform indication-of-leakage tests *only*. The devices cannot diagnose the problem or provide a mitigation. Any stand-alone test failure indicates the need for complete safety testing of the transducer with the ultrasound system. For assistance, contact the authorized Philips representative.

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If the outer layer of the TEE transducer shaft is punctured or cracked, a patient's esophagus could be exposed to chassis leakage current. This leakage current is not hazardous provided that the ground connector (third wire) in the ultrasound system power cable is intact and connected to a properly grounded wall outlet. Even if the ground connector breaks, leakage current is in compliance with the limits noted in IEC 60601-1.

Leakage hazards are further reduced when the ultrasound system is plugged into an isolated power outlet, which is standard in most operating rooms.

Regularly perform the leakage current tests found in "Transducer Electrical Safety Testing" on page 265. The frequency of testing should be based on the procedures established by the hospital for operating-room-based equipment.

Reducing Risks of Using TEE Transducers

WARNING

Always remove the transducer from the patient before defibrillation.

WARNING

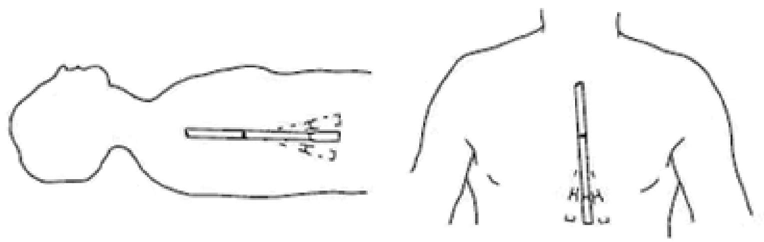
Before defibrillation, if you cannot remove the transducer from the patient, always disconnect invasive transducers that remain in contact with the patient from the ultrasound system.

To reduce the possibility of electrical risks associated with use of TEE transducers, follow these recommendations:

- Visually and tactually inspect a TEE transducer for bumps, cracks, and cuts before each TEE exam. A small bump on the shaft surface could indicate that a strand from the ground shield has broken and is beginning to puncture the outer layer. If you suspect a problem with the flexible shaft, perform the electrical safety check procedure. See “Transducer Electrical Safety Testing” on page 265.
- Use electrosurgical units (ESUs) that have isolated outputs. Return fault/ground fault detection circuits provide additional protection. To determine if an ESU has an isolated output, read the label on the ESU, see the ESU service guide, or ask a biomedical engineer.
- Require periodic electrical safety checks to ensure that the grounding system in your area remains intact.
- If the transducer is left in a patient during periods when imaging is not taking place, unplug the transducer from the system to reduce the possibility of leakage current or ESU interaction. Also make sure that the deflection control brakes are off and that the transducer is in freewheeling mode.

TEE Deflection Control Basics

The deflection controls on the TEE transducer move the deflection area, located between the distal tip and flexible shaft. The deflection area bends when you operate the controls, permitting anterior, posterior, and lateral positioning.



Deflection Control Movement

To prevent tissue damage such as pressure necrosis, gastroesophageal lacerations, bleeding, tearing of adhesions, ligament damage, and perforation, observe the following warnings. See “TEE Transducer References” on page 328.

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WARNING

Never apply excessive force when inserting or withdrawing a TEE transducer, or when operating the transducer deflection controls.

WARNING

Set the brake on to restrict the medial/lateral movement of the TEE transducer during insertion.

WARNING

To prevent tissue damage, Philips recommends that the tip of the TEE transducer be straightened and both detent brakes released before you reposition the transducer or withdraw the transducer from the patient. In the neutral position, the tip is straight when the indicators on the control wheels are aligned and point toward the center of the array rotation button.

WARNING

Whenever the TEE transducer is not being used during a procedure, ensure that it is in freewheeling mode and unplugged from the system.

WARNING

Do not allow the TEE transducer to remain at a maximum deflection for long periods of time.

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Philips

WARNING

Bite guards are mandatory; protective covers are recommended for TEE transducers, except in China and Japan, where protective transducer covers are mandatory for TEE transducers.

WARNING

To avoid damaging flexible shaft cables, be sure that the distal tip of the transducer is in the neutral (straight) position when inserting a transducer into, or removing it from, the transducer cover.

Using the X7-2t TEE Transducer

Philips recommends familiarizing yourself with the controls and parts of the TEE transducer before using it in a study.

WARNING

Use the X7-2t transducer only on patients weighing at least 30 kg (66 lb), to ensure that the esophagus can comfortably accommodate the transducer.

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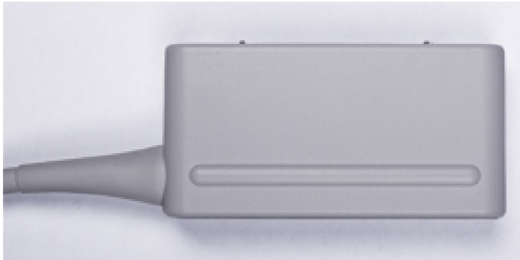
TEE Transducer Components

Component	Description
	Distal tip
	Transducer connector
	Transducer handle

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Component	Description
	Deflection controls

X7-2t Deflection Controls

The smaller knob controls medial/lateral movement, while the larger knob controls anterior/posterior movement. To place the tip of the TEE transducer into the neutral position, align the ribs on each knob with the center of the array rotation buttons (as shown in the following table).

The knobs can be controlled by a detent brake that holds the tip position without locking it in place. This allows the tip to straighten if it meets additional resistance. When the detent brake actuator is rotated to the right (as shown in the following table) both knobs are in the freewheeling mode. When the detent brake actuator is centered, the small knob (medial/lateral movement) is in the detent mode, and when the actuator is rotated to the left, both knobs are in the detent mode.

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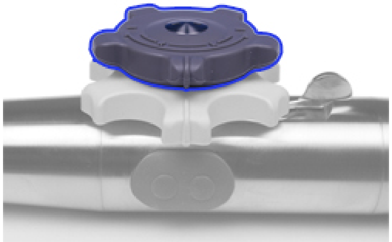
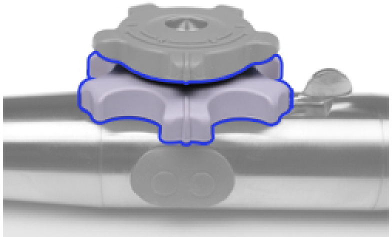
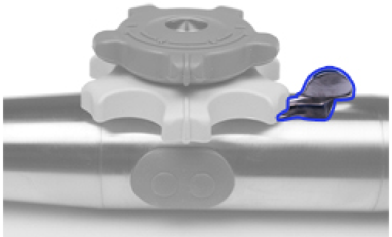
X7-2t Transducer Controls

Control	Description
	Medial/lateral control
	Anterior/posterior control
	Detent brake actuator

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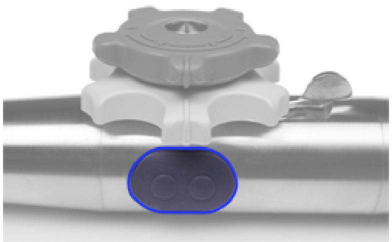
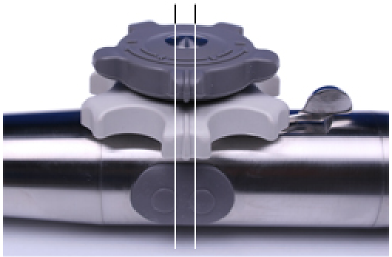
Control	Description
	Image plane rotation buttons
	Neutral position indicators, showing no deflection

Manipulating the X7-2t Tip

Review the warnings and caution in “Patient Safety During TEE Studies” on page 292 and “TEE Deflection Control Basics” on page 302 before using the transducer in a study.

1. Turn the detent brake actuator fully away from the image plane rotation buttons to put both knobs into freewheeling mode.
2. Turn the large knob to deflect the tip in the anterior/posterior plane.
3. Turn the small knob to deflect the tip in the medial/lateral plane.
4. When the tip is positioned properly, do one of the following:
   - Turn the detent brake actuator fully toward the image plane rotation buttons to put both knobs in detent mode.
   - Center the detent brake actuator to put only the small knob (medial/lateral movement) in the detent mode.

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Rotating the X7-2t Image Plane

You can rotate the image plane on the X7-2t TEE transducer to achieve a 360-degree view of the heart. Rotation stops when you release either button.

The current degree of rotation appears in either the upper or lower part of the display, depending on image orientation. Because the center of the image array is the pivot point, you can achieve a 360-degree view.

► To rotate the X7-2t transducer image plane using the transducer controls, do either of the following:

- To rotate the imaging plane toward the 180-degree position, press the image plane rotation button that is distal to the system.
- To rotate the imaging plane toward the 0-degree position, press the button that is proximal to the system.

► To rotate the X7-2t transducer image plane using a system control, use the **Seek Angle** soft key.

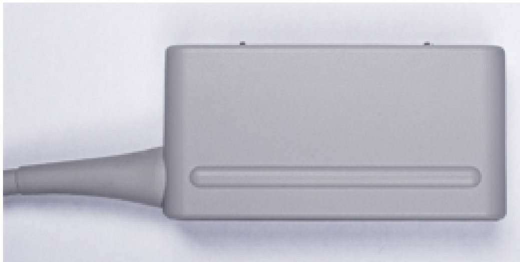
Using the X8-2t TEE Transducer

Philips recommends familiarizing yourself with the controls and parts of the transducer before using it in a study.

WARNING

Use the X8-2t transducer only on patients weighing at least 30 kg (66 lb), to ensure that the esophagus can comfortably accommodate the transducer.

TEE Transducer Components

Component	Description
	Distal tip
	Transducer connector
	Transducer handle

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Component	Description
	Deflection controls, image plane rotation buttons, and configurable middle button

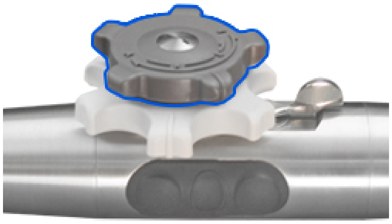
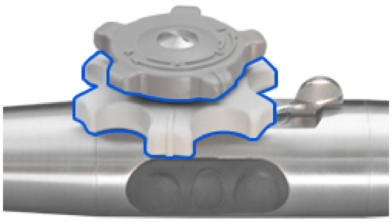
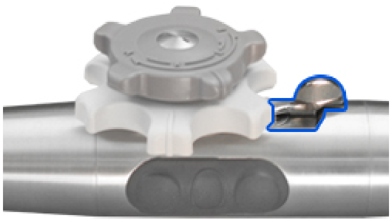
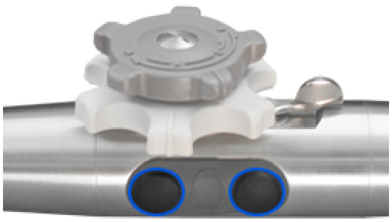
X8-2t Deflection Controls

The smaller knob controls medial/lateral movement, while the larger knob controls anterior/ posterior movement. To place the tip of the TEE transducer into the neutral position, align the ribs on each knob with the middle button between the array rotation buttons (as shown in the following table).

The knobs can be controlled by a detent brake that holds the tip position without locking it in place. This allows the tip to straighten if it meets additional resistance. When the detent brake actuator is rotated to the right (as shown in the following table) both knobs are in the freewheeling mode. When the detent brake actuator is centered, the small knob (medial/ lateral movement) is in the detent mode, and when the actuator is rotated to the left, both knobs are in the detent mode.

The middle button, between the image plane rotation buttons, can be configured for various functions (see “Configuring the X8-2t Middle Button” on page 314).

X8-2t TEE Transducer Controls

Control	Description
	Medial/lateral control
	Anterior/posterior control
	Detent brake actuator
	Image plane rotation buttons

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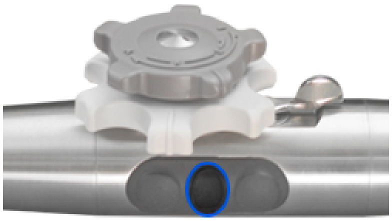
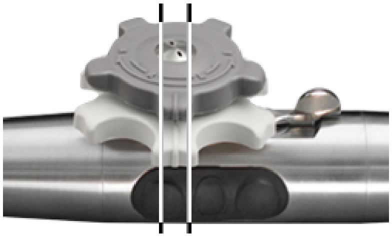
Control	Description
	Middle button (configurable)
	Neutral position indicators, showing no deflection

Manipulating the X8-2t Tip

Review the warnings and caution in “Patient Safety During TEE Studies” on page 292 and “TEE Deflection Control Basics” on page 302 before using the transducer in a study.

1. Turn the detent brake actuator fully away from the image plane rotation buttons to put both knobs into freewheeling mode.
2. Turn the large knob to deflect the tip in the anterior/posterior plane.
3. Turn the small knob to deflect the tip in the medial/lateral plane.
4. When the tip is positioned properly, do one of the following:
    - Turn the detent brake actuator fully toward the image plane rotation buttons to put both knobs in detent mode.
    - Center the detent brake actuator to put only the small knob (medial/lateral movement) in the detent mode.

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Rotating the X8-2t Image Plane

You can use the transducer controls or a control on the ultrasound system to rotate the image plane to achieve a 360-degree view of the heart.

To rotate the X8-2t transducer image plane using the transducer controls, do either of the following:

- To rotate the imaging plane toward the 180-degree position, press the image plane rotation button that is distal to the system.
- To rotate the imaging plane toward the 0-degree position, press the button that is proximal to the system.

NOTE

Rotation stops when you release the control.

To rotate the image plane on the X8-2t transducer, use the **Seek Angle** soft key.

Configuring the X8-2t Middle Button

1. Connect and select the X8-2t transducer.
2. On the 2D tab, touch **TEE Button**.
3. Select one of the following:
    - **None**, to have the button do nothing.
    - One of the listed control names, to have the button perform the function of the control of the same name.

The selected function appears on the **TEE Button** control.

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Checking the TEE Transducer

Before each TEE exam, carefully inspect the transducer and try the controls, as described in the subordinate topics.

TEE Transducer Inspection

Carefully inspect the entire surface of the distal tip and flexible shaft for protrusions, holes, dents, abrasions, cuts, burrs, or cracks that could be extremely hazardous to both you and your patient.

Carefully feel the tip and shaft, and inspect the entire transducer. If you suspect an electrical problem, follow the electrical safety check procedure described in “Transducer Electrical Safety Testing” on page 265.

Also check for excessive flexibility in the tip, particularly in the medial/lateral direction. Do not use the transducer if the tip is extremely flexible. If you have any questions about tip flexibility, contact your Philips service representative.

TEE Transducer Controls Inspection

Use the deflection controls to position the tip in every possible direction, both to ensure that the controls work properly and to get used to the feel of the TEE transducer. Make sure that the controls operate smoothly without binding, and that you can achieve all possible positions easily before introducing the TEE transducer into the patient.

Test the detent brakes and freewheeling mode. Remember that the controls must be in freewheeling mode (no deflection and no brake resistance) when repositioning or withdrawing the transducer, as well as whenever you are not imaging.

See “Manipulating the X7-2t Tip” on page 308 and “Manipulating the X8-2t Tip” on page 313.

Special Considerations for TEE Studies

Special considerations regarding TEE studies are advisable for patients with existing gastroesophageal abnormalities, such as esophageal varices, hiatal hernia, tumor, diverticula, esophageal webs and rings, fistulae, or peptic ulcers, as well as for patients who have had anti-reflux procedures. In addition, you should do the following:

- Consider the patient's size and ability to accommodate the transducer tip and shaft.
- Check the patient's history for gastroesophageal disease or difficulty swallowing.
- Evaluate the potential overall effects of any treatment that the patient is undergoing, such as mediastinal radiation, chemotherapy, anticoagulation, or steroid therapy.
- Be aware that you may discover unsuspected esophageal pathology during a study. Be alert for congenital problems with the esophagus or stomach, particularly with pediatric patients.
- When examining a patient with an above-normal temperature, use the Auto-Cool feature and enter the patient temperature. The Auto-Cool feature is described in "TEE Temperature Sensing" on page 321.

This list is not comprehensive. Rather, it suggests areas to investigate when considering TEE for a particular patient.

Patient Selection for TEE Transducer Use

Although the TEE transducers can provide clinical data not available from other instruments, you should consider which patients can safely use the TEE transducers.

WARNING

The ability of a patient to swallow or accommodate the transducer should be considered.

WARNING

You must consider any history of gastroesophageal diseases as well as the possible effects of other therapies that the patient is undergoing. You must also consider all gastroesophageal abnormalities or difficulty swallowing.

The following table lists the minimum patient weight when using TEE transducers.

TEE Transducer Minimum Patient Weight

TEE Transducer	Minimum Patient Weight
X7-2t	30 kg (66 lb)
X8-2t	30 kg (66 lb)

Preparing Patients for TEE Studies

These suggestions for pre-study patient preparation do not constitute an exhaustive list of all possible factors to explore before performing transesophageal echocardiography, nor do they imply medical protocols. Instead, they reflect basic guidelines resulting from extensive consultation with physicians throughout the design, development, and clinical investigation periods of Philips TEE transducers.

- Besides gathering routine background information such as current medication and allergies, investigate any history of chronic obstructive lung disease, esophageal strictures, varices, or bleeding.
- Thoroughly explain the procedure to the patient before the study.
- Inform the patient not to eat or drink for at least 6 hours before the study.
- Advise the patient that he or she should not plan to drive after the study, because sedatives are often used.
- Follow institutional guidelines for obtaining patient consent for a transesophageal echocardiography (TEE) study.
- Be sure that the recent ECG, CBC, and SMA6 are available as a baseline.

TEE Study Guidelines

During a TEE study, an assistant can provide oral and pharyngeal suctioning of the patient and can monitor the patient's blood pressure and general responses. For unexpected occurrences, an emergency cart with basic life-support equipment should be ready. Throughout the study, it is important to carefully monitor the patient's reactions and to ensure that ventilation and vital signs are stable.

In the operating room, do not use TEE transducers during surgical procedures requiring extreme neck flexion, such as sitting craniotomies. The following are important guidelines for TEE studies. (See "TEE Transducer References" on page 328.)

- Minimize the possibility of transducer tip fold-over. This problem has occurred rarely, but its consequences can be serious. See "Tip Fold-Over" on page 319.
- Maintain a patent airway. For surgical patients, endotracheal intubation establishes a stable, patent airway before insertion of the transducer. For patients who are awake, carefully monitor the patient's breathing at all times.
- Minimize the possibility of pressure necrosis (tissue death). Do not let the distal tip displace any one segment of tissue for more than 5 consecutive minutes. Also make sure the deflection area and the distal tip are in the position of least potential pressure. Be sure that the transducer is in a freewheeling mode and unplugged whenever you are not imaging.
- Prevent potential esophageal damage. Philips recommends that you stop TEE scanning and unplug the transducer from the system during periods of poor perfusion, circulatory arrest, or the hypothermic phase of open heart surgery. To discontinue scanning, unlock the transducer connector.
- Before each TEE study, carefully inspect the transducer, as described in "Checking the TEE Transducer" on page 315. A thorough inspection procedure is required for the safety of the patient and you, and to ensure the continued correct functioning of the transducer.
- Never use excessive force when inserting, operating, or withdrawing a transducer, and make sure the deflection area is straight during insertion and withdrawal. Forceful insertion, manipulation, or withdrawal of a transducer can result in lacerations, bleeding, perforation, tearing of adhesions, and ligament damage. Also be aware that the tip can fold over, causing similar damage.

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- Refrain from handling the distal tip whenever possible. If you must handle the distal tip, grasp it on the sides. Do not touch the top or bottom. Support the transducer’s proximal head, either by having an assistant hold the steering mechanism or by clamping the transducer at the steering mechanism. Ensure that the clamp does not interfere with steering, and do not clamp any part of the flexible shaft, as this will damage the transducer.

Tip Fold-Over

On rare occasions, the tip of a TEE transducer has folded over during insertion. The effects can be serious if the situation is handled incorrectly. The esophagus can be scraped, perforated, or otherwise damaged.

Recognizing Tip Fold-Over

The TEE transducer tip might be folded over in the patient if you encounter any of the following:

- Resistance to advancing or removing the transducer
- Fixation of the control knobs in the maximum flexion position
- Extreme difficulty in obtaining an image

Correcting Tip Fold-Over

If you suspect the transducer tip is folded over, Philips' physician consultants recommend that you gently try to manipulate the transducer. If the tip does not have the brake on and it is not jammed in a doubled-over position, and you can move it forward, advance the transducer into the stomach. Then straighten the tip and remove the transducer.

If you cannot move the tip in any direction, Philips' consultants recommend that you X-ray the patient to evaluate the situation. You might also want to involve a gastroenterologist or anesthesiologist.

Preventing Tip Fold-Over

The following steps can prevent the tip from folding over. This list is not exhaustive; other factors can also be involved.

Using Correct Insertion Technique

You may find transducer insertion easier if you guide the transducer into the patient's mouth with your fingers. You also may want to set the brake to restrict medial/lateral tip movement.

WARNING

All patients should wear a bite guard during a TEE exam. A bite guard protects against dangerous transducer mechanical and electrical malfunction caused by involuntary biting. Even anesthetized patients require bite guards to prevent damage to both their teeth and to the transducer. For information on bite guards available from Philips, see **"Bite Guards" on page 326****.**

WARNING

Do not use the deflection brake on pediatric patients.

Avoid the following when inserting any TEE transducer into a patient:

- Any excessive flexion of the transducer tip, particularly in the medial/lateral direction
- Catching the tip in pharyngeal recesses
- Insertion when a patient is being uncooperative or is having a convulsion or spasm

Reviewing Patient Esophageal Pathology

Carefully review a patient's medical history for obstructing pathologies or anatomical irregularities before performing a TEE exam.

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Ensuring Proper Transducer Maintenance

Thoroughly examine the transducer and test the controls before each exam. Be sure to check for excessive flexibility in the tip. See “TEE Transducer Inspection” on page 315.

TEE Temperature Sensing

The transesophageal transducers contain built-in temperature sensors near the distal tip. The sensor monitors the transducer’s temperature to prevent potential burning of esophageal tissue. The patient’s actual temperature is required to accurately estimate the distal tip temperature. By default the system assumes that the patient temperature is 37°C (98.6°F). You must manually enter the actual patient temperature if it is above 37°C (98.6°F).

The Auto-Cool feature provides warning messages at two points:

- At 41.0°C (105.8°F), the **TEE Auto Cool Imminent** message appears.
- At 42.5°C (108.5°F), the **TEE Auto Cool In Progress** message appears, and the system automatically stops scanning.

WARNING

If the patient temperature is above 37°C (98.6°F) and the Patient Temp control is set below the actual patient temperature, then the system can overestimate the temperature of the TEE transducer's distal tip. This can prematurely trigger the Auto-Cool feature. If the patient temperature is at or near 37°C (98.6°F) and the Patient Temp control is set above the actual patient temperature, then the system can underestimate the temperature of the distal tip. This can expose patients to excessive temperatures.

Ensuring Safe TEE Temperatures

To ensure patient safety and to avoid unnecessary interruption while scanning, follow these suggestions:

- Ensure distal-tip-temperature accuracy by entering an accurate patient core temperature.

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- Before introducing a TEE transducer, decrease the transducer temperature by using the **Output Power** control to decrease acoustic output, and then keep the control at the lowest possible setting during the exam.
- Use the TEE Manual Auto-Cool safety feature to enter the patient temperature if it is above 37°C (98.6°F) as described in “Entering Patient Temperature” on page 324.
- If the transducer temperature begins to rise when you are using high-power modes such as Color, Tissue Harmonic Imaging, and Doppler, temporarily switching to fundamental 2D mode or freezing the image can help cool the transducer.

Manual Auto-Cool Feature

Use the TEE Manual Auto-Cool safety feature to enter above-normal patient temperatures. When the temperature display is enabled, you can see both the patient temperature and the distal tip temperature while scanning.

NOTE

The patient temperature shown on the ultrasound display is always either 37°C (98.6°F) or the temperature that you manually enter. The system does not monitor or report the actual patient temperature.

If the distal tip temperature reaches 41°C (105.8°F), a warning message appears and the transducer temperature is displayed in inverse video. If the temperature reaches 42.5°C (108.5°F), the system enters Auto-Cool, during which it displays a message and stops scanning. It exits Auto-Cool and returns to normal operation when the temperature falls below 42°C (107.6°F). If the transducer temperature continues to 43.5°C (110.3°F), the transducer is automatically deselected. If the patient temperature is higher than 37°C (98.6°F), the system shutdown temperature adjusts accordingly. You must manually disconnect and then reconnect the transducer to resume imaging.

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WARNING

To avoid the risk of esophageal burn for adult patients, minimize the time spent imaging at distal tip temperatures in excess of 42°C (107.6°F). Exposure should be limited to 10 minutes or less at 42°C (107.6°F) or higher.

WARNING

Sufficient data on thermal tolerance of the esophagus in neonate and pediatric patients does not exist, but it is likely these patients are more vulnerable than adults. Minimize the time spent imaging at distal tip temperatures in excess of 41°C (105.8°F).

Using the Temperature Display

Both the patient temperature (assumed or entered) and the transducer temperature appear in the lower left corner of the display when enabled. On the display, the patient temperature is labeled **PAT T**, and the transducer temperature is labeled **TEE T**.

A less-than sign (<) after **TEE T** indicates that the transducer's distal tip temperature is below the patient temperature (**PAT T**) assumed by the system, which is either 37°C (98.6°F) or the temperature you entered.

1. Connect the transducer and select a preset.
2. Swipe to the second touch screen.
3. Touch **Temp Display** to display or hide the temperature display.
4. Touch **Temp Units** to switch the temperature scale between Fahrenheit and Celsius.

NOTE

If you want the temperature display enabled by default, turn on the temperature display and then create a preset as described in “Creating 2D Quick Save Presets” on page 212.

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Patient Temperature

Entering a patient’s temperature enables the Auto-Cool feature to calculate tip temperature more accurately, which can prevent unnecessary interruptions while scanning. If a patient’s temperature is above normal, entering a temperature can avoid exposing the patient to excessive temperatures.

Always check the patient’s temperature before inserting a TEE transducer. If it is above normal, whether from fever or therapeutic heating from a cardiac bypass heart-lung machine, perform the procedure in “Entering Patient Temperature” on page 324 before inserting the transducer. Also, follow that procedure if a patient’s temperature rises during a study.

Measure the patient’s core temperature, or more specifically, the actual temperature in the esophagus. For patients undergoing surgery, determine the temperature in the esophagus by direct measurement or by monitoring the temperature of blood returning from the bypass pump heat exchanger.

For closed-chest situations, rectal temperature is the best estimate of core temperature. You can also use oral temperatures, even though they can be one degree lower than the core temperature. If you measure an auxiliary temperature, which can be two degrees lower than the core temperature, add one or two degrees.

Entering Patient Temperature

1. If necessary, select the TEE transducer.
2. Turn **Pat Temp** to enter the patient's measured temperature.

NOTE

Each time you turn off or reset the system, or enter a new patient ID, the system assumes that the patient temperature is 37°C (98.6°F).

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Resuming Imaging After Auto-Cool

WARNING

The Reconnect the Transducer error message is often caused by a poorly seated transducer connector, but it could be caused by a failure in the Auto-Cool safety logic. In the case of a logic failure, distal tip temperatures could reach 46.5°C (115.7°F) in hyperthermic patients (40°C to 41°C or 104°F to 106°F) before the error causes scanning to stop. At this temperature, esophageal burns may occur (**see “TEE Transducer References” on page 328****).**

If the distal tip temperature drops below 42.5°C (108.5°F), the system resumes imaging. If the Auto-Cool message persists longer than 1 minute or an error message appears, contact your Philips service representative.

The system shuts down if the patient-applied part temperature of the TEE transducer exceeds 42.5°C (108.5°F), given an entered patient temperature of 37°C (98.6°F). If the patient temperature is higher than 37°C (98.6°F), the system shutdown temperature adjusts accordingly. You may need to restart the system by pressing the (On/Off) control.

1. Move the locking lever to the unlocked position, and pull the connector out of the receptacle.
2. Reseat the connector in the receptacle and move the locking lever to the locked position.
3. Select the transducer and preset.
4. If the system does not resume imaging after the transducer has initialized, shut down the system and then restart it.

Patient Care After a TEE Study

Follow your institutional guidelines for post-TEE studies. Additionally, you might want to include the following recommendations in your guidelines as part of your post-TEE study routine.

- Inspect the patient’s throat for any bleeding.
- Examine the patient for postural hypotension or difficulty walking.
- Instruct the patient to contact you immediately if he or she experiences any fever, chills, chest pain, or bleeding.
- Instruct the patient not to eat or drink for at least 2 hours or until swallowing returns to normal after anesthesia has worn off. It is especially important that the patient not ingest hot foods or fluids during this period.
- Follow up with a call to the patient the day after the study to make sure there are no complications.

TEE Accessories and Supplies

Each TEE transducer comes with disposable bite guards and a disposable tip protector. Bite guards, TEE transducer covers, tip protectors, and disposable drapes are described here. For information on ordering TEE accessories, see “Supplies and Accessories” on page 26.

Bite Guards

WARNING

The M2203A bite guard strap contains natural rubber latex, which may cause allergic reactions. For more information, see “FDA Medical Alert on Latex” on page 65.

CAUTION

Damage caused when patients bite or scrape a TEE transducer is not covered in the transducer warranty or your service contract. Use bite guards to help prevent such accidents.

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All patients must wear a bite guard during a TEE study. A bite guard prevents dangerous transducer mechanical and electrical malfunctions caused by involuntary biting. Even anesthetized patients require bite guards to prevent damage to their teeth and to the transducer. Philips supplies disposable bite guards that are suitable for both awake and anesthetized patients.

TEE Transducer Covers

WARNING

Transducer covers may contain natural rubber latex and talc. Those covers may cause allergic reactions in some individuals. For more information, see **"FDA Medical Alert on Latex" on page 65****.**

Philips recommends the use of a legally marketed sterile transducer cover during every TEE study.

For procedures on using transducer covers (protective sheaths), see the instructions provided with the covers.

Tip Protectors

When not using a carrying case to transport a TEE transducer, use a tip protector on its distal tip. The tip protector helps prevent serious damage to the transducer lens. Philips supplies tip protectors designed for each of its TEE transducers.

Disposable Drapes

During studies in which you believe contamination of the imaging system can occur, Philips recommends that you take universal precautions and cover the system with a disposable drape. Consult your hospital's rules regarding equipment use in the presence of infectious disease.

TEE Transducer References

Cucchiara, R.F., et al. "Air Embolism in Upright Neurosurgical Patients: Detection and Localization by Two-dimensional Transesophageal Echocardiography." *Anesthesiology*, 353-355, 1984.

Gussenhoven, Elma, et al. "Transesophageal Two-dimensional Echocardiography: Its Role in Solving Clinical Problems." *Journal of the American College of Cardiology*, 975-979, 1986.

Radwin, Martin, et al. "Transesophageal Echocardiography: Intubation Techniques." *Philips Application Note 5091-2804E*, 1992.

Urbanowitz, John H., et al. "Transesophageal Echocardiography and Its Potential for Esophageal Damage." *Anesthesiology*, Vol. 72, No. 1, 1990.

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11 Endocavity Transducers

Endocavity transducers provide high-resolution endocavity imaging for obstetric and GYN applications. The system supports the 3D9-3v, C9-4v, and C10-3v endocavity transducers.

Disinfect new transducers before performing the first study. Clean and disinfect the transducer immediately after each use to protect patients and personnel from pathogens. Establish and clearly post a cleaning procedure that includes the steps described in *Care and Cleaning of Ultrasound Systems and Transducers*.

For information on connecting transducers, see "Connecting Transducers" on page 199. For more information on caring for and maintaining transducers, see *Care and Cleaning of Ultrasound Systems and Transducers* and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*.

WARNING

Always remove the transducer from the patient before defibrillation.

WARNING

Before defibrillation, if you cannot remove the transducer from the patient, always disconnect invasive transducers that remain in contact with the patient from the ultrasound system.

Operators of Endocavity Transducers

Philips endocavity transducers are designed for use under the guidance of physicians who are properly trained in endocavity ultrasound imaging techniques, according to currently approved relevant medical practices. Philips recommends that physicians operating any Philips endocavity transducer have the following qualifications:

- Proficiency in recognizing and interpreting imaging patterns
- Thorough familiarity with the safe operation, care, and maintenance of the system and endocavity transducers
- Thorough familiarity with the latest endocavity methods through literature and seminars

Patient Safety During Endocavity Studies

To operate an endocavity transducer, you must be under the guidance of a physician who is properly trained in endocavity ultrasound imaging techniques, according to currently approved relevant medical practices. You also must be thoroughly familiar with the safe operation, care, and maintenance of the ultrasound system used with the transducer, as well as proficient at interpreting the images generated.

To help ensure patient safety when using an endocavity transducer, observe the following guidelines:

- Scrutinize the entire transducer before each use (see *Care and Cleaning of Ultrasound Systems and Transducers*).
- Operate the transducer properly.
- Do not allow water or other liquids to drip onto the transducer connector, the interior of the system, or the control panel.
- Use sterile ultrasound transmission gel when performing all endocavity studies.
- Legally marketed sterile protective covers are recommended for endocavity procedures; the protective covers are mandatory in China and Japan.
- Ensure that no part of the transducer contacts the patient's skin or tissue for a prolonged length of time.
- Use procedures or an appropriate device to avoid or minimize pressure between the patient and the transducer external components.
- Always monitor any pressure points where the transducer components contact the patient.

For electrical safety test procedures, see “Transducer Electrical Safety Testing” on page 265.

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WARNING

Always remove the transducer from the patient before defibrillation.

WARNING

Before defibrillation, if you cannot remove the transducer from the patient, always disconnect invasive transducers that remain in contact with the patient from the ultrasound system.

Preventing Endocavity Transducer Problems

WARNING

If you find any signs of damage to the transducer, patient safety may be compromised. Do not use the transducer, and contact your Philips service representative.

Meticulous inspection and correct and careful operation of endocavity transducers are imperative to patient safety. The situations listed here affect safe operation as well as the ability to service mechanical problems under the Philips warranty or service contract. Transducer repairs necessitated by misuse are not covered and can be very costly, often requiring complete disassembly and rebuilding of the transducer.

There are three primary areas of transducer misuse:

- Cuts and abrasions on the transducer insulation and lens from sharp instruments such as scalpels, scissors, and clamps
- Improper disinfection techniques, causing fluid to enter the transducer or damage transducer materials
- Damage caused by dropping the transducer on a hard surface

To minimize the chance of damage, Philips strongly recommends that you clearly post stringent protocols for the care of endocavity transducers, based on the information provided here.

Electrical Safety and Endocavity Transducers

All Philips ultrasound systems and transducers comply with common medical device electrical safety standards.

For electrical safety information about endocavity transducers, see “Leakage Current and Endocavity Transducers” on page 332.

For safety information on electrosurgical units, pacemakers, defibrillators, and related topics, see “Electrical Safety” on page 35.

Leakage Current and Endocavity Transducers

WARNING

Only a technically qualified person should perform leakage current test procedures.

WARNING

Leakage current tests should be performed if the transducer has been dropped or if cracks or cuts are found on the transducer.

Philips transducers approved for endocavity use are labeled on the transducer connector as Type BF () or Type CF () in accordance with IEC 60601-1. Type CF transducers provide the highest degree of protection against electric shock and are suitable for all patient applications, including endocavity applications.

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Leakage hazards are reduced further when the ultrasound system is plugged into an isolated power outlet, which is standard in most operating rooms.

Regularly perform the leakage current tests found in “Transducer Electrical Safety Testing” on page 265. The frequency of testing should be based on the procedures established by the hospital for operating-room-based equipment.

Preparing Transducers for Endocavity Use

1. Place 20 cc of sterile gel or saline into the transducer cover.
2. Carefully inspect each transducer cover before use, and discard it if you find tears or blemishes. Also inspect each transducer cover after use. If you find a tear, the patient or the transducer may have been contaminated.
3. Insert the transducer into the transducer cover and unfurl the transducer cover until it covers the transducer and its cable. The cover must be unfurled far enough to maintain the sterile field.
4. Use a sterile elastic band or clip to hold the proximal end of the transducer cover in place.
5. Ensure that wrinkles and bubbles over the face of the transducer are minimized. Check the transducer cover for tears or damage before proceeding.
6. When operating the transducer, make sure that proper orientation is maintained to avoid interpretation confusion.

NOTE

To achieve good acoustic contact, make sure that the imaging surface is moist.

NOTE

Imaging improves with adequate coupling between the patient surface and the transducer-cover surface. Sterile water is a good acoustic-coupling agent during surgery.

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Patient-Contact Parts

WARNING

Latex and talc are commonly used in sheaths marketed to help with infection control in transesophageal, endocavity, and intraoperative imaging applications, and during needle guidance and biopsy procedures. Examine the packaging to confirm latex and talc content. Studies have shown that patients can experience allergic reactions with natural rubber latex. See the FDA Medical Alert, March 29, 1991, reprinted in **"FDA Medical Alert on Latex" on page 65****.**

NOTE

The ultrasound system and transducers discussed here do not contain natural rubber latex that contacts humans. Natural rubber latex is not used on any Philips ultrasound transducers.

Biopsy with Endocavity Transducers

Endocavity transducers are biopsy capable.

For more information on the biopsy guide feature, see the "Biopsy Guides" section.

NOTE

CIVCO Medical Solutions supplies biopsy kits for Philips transducers that are biopsy capable. For information on proper attachment of a biopsy bracket, consult the manufacturer's instructions.

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12 Biopsy Guides

The biopsy guide feature helps you position transducers with biopsy needle-guide attachments. The biopsy guide feature displays guidelines on the image that show the anticipated path of the needle. You can use those guidelines to ensure that the needle or instrument is following the correct path.

Starter kits, which include the biopsy guide or biopsy guide bracket and procedure kits, are available from Philips. Biopsy guides and supplies are available from CIVCO Medical Solutions (see “Supplies and Accessories” on page 26).

For detailed information about using, cleaning, and sterilizing biopsy guides and brackets, see the instructions provided with the biopsy starter kits, guides, and brackets.

WARNING

Do not attempt to use the biopsy guide until you have read the instructions for selecting the display, installing the legally marketed sterile transducer cover, and verifying alignment of the biopsy guide.

WARNING

Biopsy guidelines are intended as guides only. Never use biopsy guidelines as an absolute reference.

WARNING

Biopsy guidelines do not take into account the possible bending of the needle.

NOTE

The biopsy guides for the L12-5 50 mm and L18-5 transducers have infinite-angle capability and can be installed on either side of the transducer; they do not constrain the biopsy needle to a particular path. Because the needle path is unpredictable, the **Biopsy** control is unavailable, and the biopsy graphics do not appear on the display when you are using these transducers. A biopsy with these transducers is a manual action.

Biopsy Guides and Supported Transducers

The following transducers support the use of biopsy guides.

Transducers That Support Biopsy Guides	
3D9-3v	L12-4
C5-1	L12-5 50
C6-2	L18-5
C8-5	mC7-2
C9-2	S4-2
C9-4v	S5-1
C10-3v	V6-2
eL18-4	
L12-3	

Attaching and Removing a Biopsy Guide

Detailed information about attachment and removal of biopsy guides is provided with the biopsy starter kits, guides, and brackets.

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WARNING

Do not attempt to use the biopsy guide until you have read the instructions for selecting the display, installing the legally marketed sterile transducer cover, and verifying alignment of the biopsy guide.

WARNING

Inspect all components and the transducer. Ensure that the biopsy guide you are using is the correct one for the transducer, the system, and system software. Your Philips representative can verify this information for you.

WARNING

Use only Philips transducers and Philips-approved biopsy guides, covers, brackets, supplies, components, and accessories. Other brands may not properly fit Philips transducers. Improper installation may result in patient injury.

WARNING

Some biopsy guides must be installed over a legally marketed sterile transducer cover.

WARNING

After each use, biopsy guides must be either sterilized or disposed of, depending upon the type. See the instructions included with the biopsy guide.

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Biopsy Guideline Display

WARNING

Do not attempt to use the biopsy guide until you have read the instructions for selecting the display, installing the legally marketed sterile transducer cover, and verifying alignment of the biopsy guide.

The system generates a biopsy guideline through the displayed real-time ultrasound image to indicate the anticipated path of the needle. You can use that guideline to ensure that the needle or instrument is following the correct path.

When the biopsy display is active, a biopsy guideline is displayed, entering from the left or right side of the screen, depending on the application and image presentation you have selected. You can change the image presentation by touching **Left/Right** or **Top/Bottom**. Image presentation is defined by the location of the orientation marker.

When depth is changed, the biopsy display redraws to reflect the new relationships at the new depth setting.

Biopsy Guides Touch Screen Controls

This topic describes the touch screen controls associated with the named mode. Some of the controls are visible immediately and others may be visible only when particular transducers or presets are active. The available tools depend on the sub-tab displayed on the touch screen.

To use a touch screen control or change its setting, touch it. If it is in the bottom two rows, turn the knob directly below it.

Name	Description
Biopsy	A control used to display the biopsy guideline.

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Name	Description
Biopsy Angle	A control used to change the angle of the biopsy guideline.
Hide Guide Line	A control used to hide the biopsy guideline when the image is frozen.

Displaying the Biopsy Guideline

WARNING

When using a transducer with an infinite-angle biopsy guide, do not display a fixed-angle biopsy guideline.

The biopsy guideline can have a single, fixed path or multiple paths. The system determines which guideline to display based on the type of biopsy guide available for the transducer you have selected.

NOTE

The following procedure applies specifically to non-intervention applications.

1. Connect the transducer.
2. Touch a preset.
3. Touch the **2D** tab.
4. Touch **Biopsy**.
5. To change the angle of the biopsy guideline, touch **Biopsy Angle**.
6. To hide the biopsy guideline, touch **Hide Guide Line** when the image is frozen.

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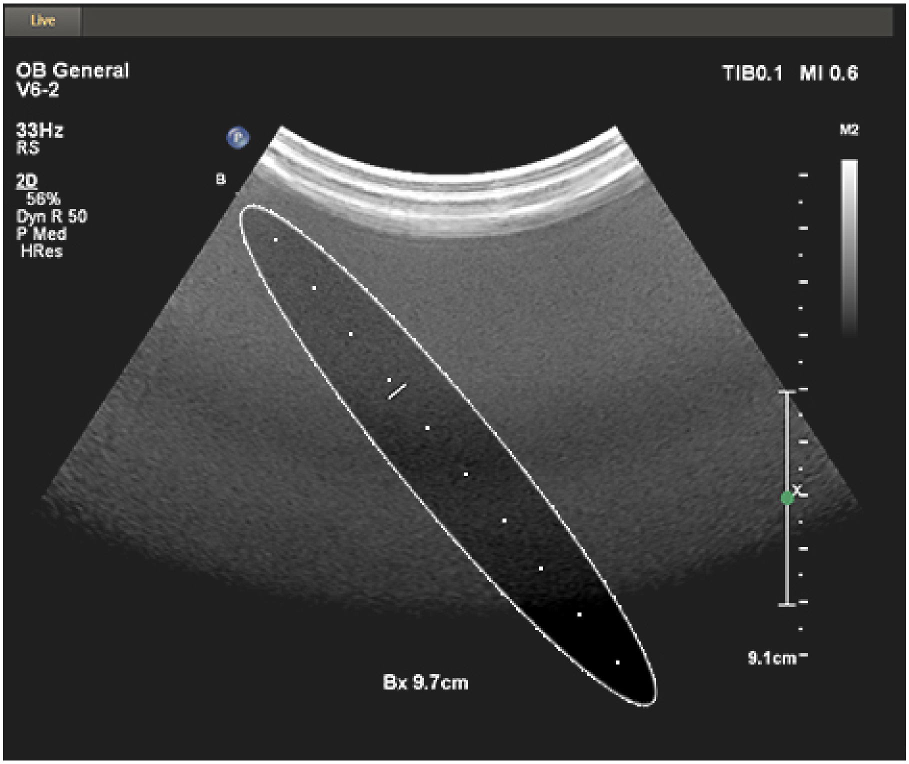
Moving the Biopsy Depth Cursor

A depth cursor appears on the biopsy guideline. The distance from the origin of the biopsy guide needle path to the depth cursor appears at the bottom of the imaging display.

Move your finger on the trackpad to move the depth cursor along the guideline. The **Bx** measurement value changes to reflect the distance between the biopsy guide reference point origin and the depth cursor.



Biopsy Depth

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Biopsy Guide Alignment

Perform the alignment verification before each use of the biopsy guide. The procedure verifies the system, transducer, and biopsy guide relationships.

WARNING

Alignment verification is necessary before performing procedures with the biopsy guide.

WARNING

Do not use the biopsy guide if the needle is not following the intended path. Contact your Philips representative.

WARNING

The needle used for this alignment verification must not be used for the actual procedure. Always use a new, sterile needle for each biopsy procedure.

WARNING

To assist in an accurate projection of the needle, use a straight, new needle for each alignment procedure.

Preparation for Alignment Verification

Assemble the following items before performing the alignment verification:

- Transducer

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- Biopsy guide or bracket (The bracket is not disposable. The type of bracket you use depends upon the transducer you are using. For the correct bracket, contact CIVCO Medical Solutions; see “Supplies and Accessories” on page 26.)
- Needle guide (Contact CIVCO for the needle guide that fits your biopsy guide bracket.)
- Sterile procedure kit (disposable)
- New, straight, biopsy needle
- Beaker of water (or water bath)

Verifying the Biopsy Guide Alignment

WARNING

If the needle enters from the unexpected side of the display or cannot be seen, verify that the biopsy guide is correctly mounted on the transducer and that the orientation of the transducer is correct. If the needle is still not following the expected path along the guideline, do not use the biopsy guide. Contact your Philips representative.

1. Attach the biopsy guide. Although some transducers require the use of a second transducer cover for biopsy procedures, a second transducer cover is unnecessary for this alignment verification.
2. Connect the transducer to the system, and select the appropriate applications and preset.
3. Set the system depth for the procedure to be performed.
4. Display the biopsy guideline.
5. Without changing the position of the biopsy depth cursor, note the default depth shown at the bottom of the display.
6. Immerse the transducer no more than 6 mm (0.25 in) into the water bath.

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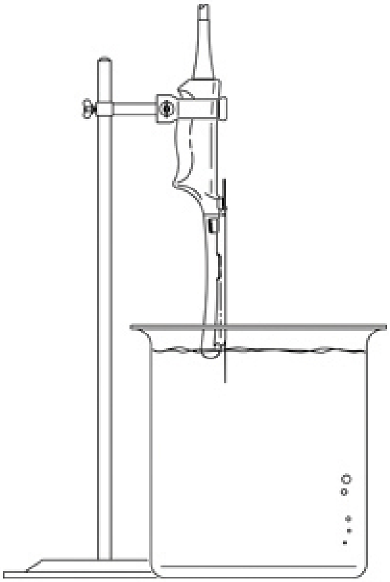

Immersing the Transducer

7. Select a new, straight needle that matches the needle-gauge size on the biopsy guide clip you are using (if applicable), select the guide channel on the biopsy guide (**A**, **B**, and so on), and use the **Biopsy** soft key to select the matching biopsy angle setting.
8. Insert the straight, new needle into the biopsy guide.
9. Move the needle down into the water bath until its ultrasound image is visible on the video display.
10. Verify that the needle, as seen on the video display, falls along the guideline along the entire depth of the guideline display. The biopsy guideline is intended only to provide an indication of the expected path of the needle. Actual position must be verified by identifying the echoes from the needle.
11. Remove the needle from the biopsy guide.
12. From the tip of the needle, measure a distance equal to the value noted in step 5. Mark this point on the needle.
13. Immerse the transducer no more than 6 mm (0.25 in) into the water bath.

14. Insert the needle into a guide channel that corresponds to the size of the needle and the angle you selected. Continue sliding the needle in until the mark on the needle aligns with the origin on the biopsy guide. (The origin is the point at which the needle enters the biopsy guide.)
15. Move the biopsy depth cursor to the tip of the needle, as seen on the display, and verify that the displayed depth is within 4 mm (0.16 in) of the value noted in step 5.
16. Confirm that the needle is visible along its expected path. If so, then the biopsy guide is properly aligned.

Performing a Biopsy Procedure

WARNING

To prevent contamination by blood-borne pathogens, legally marketed sterile transducer covers with sterile ultrasound transmission gel are required for intraoperative applications, and during needle guidance and biopsy procedures. Protective covers are recommended for transesophageal, transrectal, and intravaginal procedures; in China and Japan, the covers are mandatory. Philips recommends the use of legally marketed sterile covers.

WARNING

Before the biopsy procedure, perform alignment verification at the selected depth to ensure that the biopsy guide and the needle have been installed properly.

WARNING

Use a straight, new, sterile needle for each procedure.

WARNING

Do not perform the biopsy guide procedure if the needle is not visible.

WARNING

The biopsy guideline is intended only to provide an indication of the expected path of the needle. Actual position must be verified by identifying the echoes from the needle.

WARNING

If the needle is not following the expected path, discontinue the procedure and contact your Philips representative.

WARNING

Thin needles can bend when entering tissue. Actual position must be verified by identifying the echoes from the needle.

WARNING

Reverberation or other tissue artifacts may produce false needle images, which can cause confusion in locating the actual needle image. Ensure the needle path is along the guideline, and that you are not using a false needle image to locate the needle.

WARNING

When using a transducer with an infinite-angle biopsy guide, do not display a fixed-angle biopsy guideline.

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WARNING

Philips does not recommend anatomical survey of the prostate with the biopsy guide attached.

1. Install the transducer cover and the biopsy guide according to the instructions provided with the biopsy guide.
2. Select a new, straight needle that matches the needle-gauge size on the biopsy guide clip you are using (if applicable), and select the guide channel on the biopsy guide.
3. Set the system imaging controls for the biopsy procedure.
4. Touch a preset.
5. Touch the **2D** tab.
6. Touch **Biopsy**.
7. If the transducer supports multiple biopsy guides, select the biopsy guide you are using.
8. Orient the transducer to match image presentation. Use the display orientation marker .
9. If necessary, apply sterile acoustic coupling gel to the patient.
10. Begin scanning the patient. Position the transducer so that the puncture target is intersected by the guideline on the display.
11. Do one of the following:
    - For guides with a single angle, insert the needle into the needle guide groove closest to the transducer.
    - For guides with multiple angles, insert the needle into the needle guide groove that corresponds to the angle you previously selected.
12. Perform the puncture by sliding the needle through the groove in the guide until the needle, as shown on the display, intercepts the target.

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13. If you are using a biopsy guide bracket and procedure kit, you can remove the transducer from the patient while the needle is still inserted in the patient: Separate the needle from the biopsy guide by pulling the tab up so that the clip snaps out of the needle guide, allowing the clip (still attached to the needle) and needle to separate from the biopsy guide (still attached to the transducer).
14. Remove the biopsy guide after use.

Biopsy Guide Maintenance

WARNING

The biopsy procedure kit components are disposable and must not be reused.

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For information and instructions on cleaning, disinfecting, and sterilizing the biopsy guide, see the instructions provided with the biopsy guide.

Needle Visualization

The Needle Visualization feature provides optimized visualization of the needle during procedures that use standard biopsy needles. Needle Visualization is available in a specific area of the image. This area is defined by a dashed border superimposed on the image, and it is tied to the approach and angle setting that you select before starting the procedure.

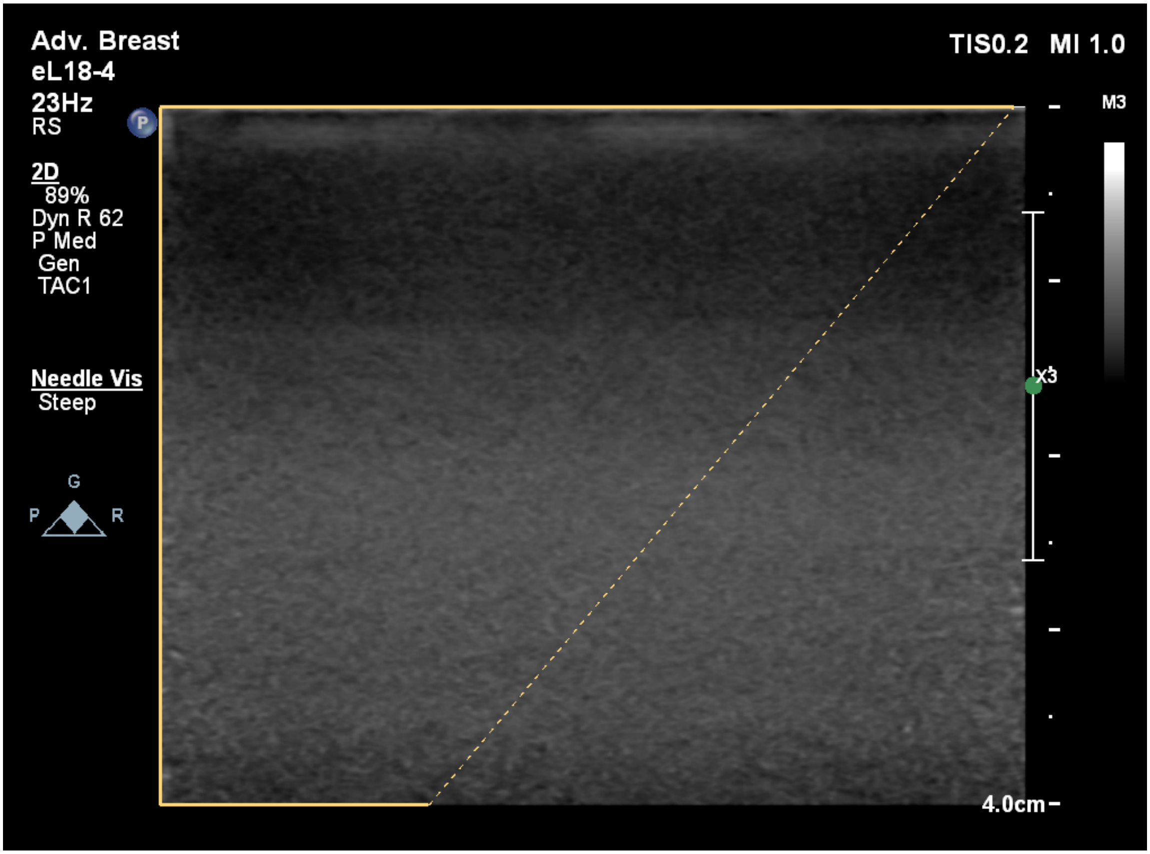
WARNING

When Needle Visualization is on, the image may exhibit increased specular reflectors and reverberation artifacts.

Philips

WARNING

The needle is enhanced only in the area defined by amber lines (the region of enhancement). If the tip of the needle extends beyond this area, it may not be visualized. For maximum needle visualization, ensure that the target is centered within the region of enhancement.



Needle Visualization Area with Steep Needle Path

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The Needle Visualization feature is available only with the eL18-4 transducer. It is available only in 2D imaging.

Needle Visualization Touch Screen Controls

This topic describes the touch screen controls associated with the named mode. Some of the controls are visible immediately and others may be visible only when particular transducers or presets are active. The available tools depend on the sub-tab displayed on the touch screen.

To use a touch screen control or change its setting, touch it. If it is in the bottom two rows, turn the knob directly below it.

Name	Description
Needle Approach	A control used to select to approach the target from the left or the right.
Needle Path	A control used to select the needle path from predefined trajectory angles.
Needle Visualization	A control used to display or hide the Needle Visualization guideline.

Using Needle Visualization

WARNING

When Needle Visualization is on, the image may exhibit increased specular reflectors and reverberation artifacts.

WARNING

The needle is enhanced only in the area defined by amber lines (the region of enhancement). If the tip of the needle extends beyond this area, it may not be visualized. For maximum needle visualization, ensure that the target is centered within the region of enhancement.

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1. When you are ready to start the procedure, select an eL18-4 transducer, and then select a preset that supports Needle Visualization.
2. Ensure that 2D imaging is selected and all other imaging modes are off.
3. To turn on Needle Visualization, touch **Needle Visualization**. Needle Visualization is active within the solid and dotted lines.
4. While imaging the target, use **Needle Approach** to select a right or left approach. The needle approach is from the corner where the solid lines meet.
5. Use **Needle Path** to set the needle trajectory angle to **Shallow**, **Medium**, or **Steep**. For best results, select a needle angle perpendicular to the dotted amber line.
6. Start the procedure.
7. To identify specular reflectors or reverberation artifacts, turn Needle Visualization off and on by touching **Needle Visualization**.
8. When the procedure is complete, touch **Needle Visualization** to turn off Needle Visualization.

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13 System Maintenance

Maintenance should be performed regularly and as needed.

Because the system is a piece of medical equipment that contains several circuit boards, extensive service diagnostics, and complex operating software, Philips recommends that only trained personnel service the system.

For 5000 Compact series ultrasound systems, preventive maintenance, as performed by your service provider, is not required for the system, the optional carts, or the supported transducers. However, if preventive maintenance is required by your region, you can purchase that service.

For information about system and transducer maintenance, see "Cleaning and Maintaining the System" on page 352 and "Transducer Care" on page 352. To request preventive maintenance or corrective maintenance, contact your authorized service provider. For contact information, see "Customer Service" on page 27.

WARNING

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

CAUTION

Follow all instructions provided to avoid damage during cleaning, disinfection, and sterilization. Failure to do so could void your warranty.

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Transducer Care

CAUTION

Do not apply adhesive films, such as Tegaderm, to the transducer lens. Application of such films can damage the lens.

All Philips transducers require proper care, cleaning, and handling. Reasonable care includes inspection, cleaning, and disinfection or sterilization. Disinfect new transducers before performing the first study. Transducers must be cleaned and disinfected or sterilized after each use. You must also carefully inspect all parts of the transducer before each use. Check for cracks or other damage that jeopardizes the integrity of the transducer. Report any damage to your Philips representative and discontinue use of the transducer.

For detailed instructions on how to clean, disinfect, and maintain each type of transducer used with the system, including disinfectant compatibility, see *Care and Cleaning of Ultrasound Systems and Transducers* and *Disinfectants and Cleaning Solutions for Ultrasound Systems and Transducers*. Information on compatible disinfectants is also available at:

www.philips.com/transducercare

Cleaning and Maintaining the System

It is important to clean and maintain the ultrasound system and peripherals. Thorough cleaning is particularly important for pieces of peripheral equipment, because they contain electromechanical devices. If exposed to constant and excessive environmental dust and humidity, these devices will suffer in both performance and reliability.

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Disinfectants and Cleaners for System Surfaces

The compatibility of disinfection and cleaning solutions varies depending on the item on which they are used.

It is your responsibility to appropriately clean and disinfect your device in accordance with the device manufacturer's instructions and with your institution's policies for cleaning and disinfecting of medical devices.

The products in the following table are compatible with these system surfaces:

- ECG trunk cables, leads, and electrodes
- External plastic and painted surfaces of system and cart
- System control panel
- Monitor screens and touch screens
- Easy-clip transducer cable managers

Cleaning Solutions for All Surfaces	Cleaning Solutions for Monitor Screens and Touch Screens	Disinfectants for System Surfaces and Touch Screens
Mild soap solution[1]	• Mild soap solution[1] • Cleaners designed for screens • Purified water	• 70% isopropyl alcohol (IPA) (Not approved for touch screens) • Opti-Cide3 (QUAT/IPA based) • Oxivir Tb (accelerated hydrogen peroxide based) • Protex spray or wipes • Sani-Cloth HB (QUAT based) • Sani-Cloth Plus (QUAT/IPA based) • PI-Spray II (QUAT based)

1. Mild soap solutions do not contain any harsh ingredients and are not irritating to the skin. They must not contain fragrance, oils, or alcohols. Hand sanitizers are not approved for use.

CAUTION

Do not use abrasive cleaners, or acetone, MEK, paint thinner, or other strong solvents on the system, peripherals, or transducers.

CAUTION

Do not use Sani-Cloth AF3 or Super Sani-Cloth to disinfect the system.

CAUTION

Do not spill or spray liquid into any system seams, ports, or transducer receptacles.

CAUTION

On monitor screens and touch screens, use microfiber cloth; do not use paper towels.

CAUTION

On monitor screens, do not use glass cleaners, Dispatch spray, or products containing bleach. Repeated use of such cleaners or products may damage the monitor screen surface. Immediately wipe away approved disinfectants or cleaners to prevent residue buildup. Use cleaners specifically designed for cleaning LCDs or OLEDs.

CAUTION

On touch screens, do not use Dispatch spray or products containing bleach or alcohol. Repeated use of such cleaners or products may damage the touch screen surface. Immediately wipe away approved disinfectants or cleaners to prevent residue buildup.

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CAUTION

System surfaces and transducers are resistant to ultrasound gel, alcohol, and disinfectants, but if you use those substances, you must wipe them off to prevent permanent damage.

Cleaning and Disinfecting the System and ECG Equipment

The system control panel and other outer surfaces are most likely to be affected by liquid spills and other materials such as excessive amounts of gel. These materials may seep into electrical components under the panel and cause intermittent failures. During preventive maintenance, look for potential problems including loose knobs and worn controls.

WARNING

Always use protective eyewear and gloves when cleaning, disinfecting, or sterilizing any equipment.

WARNING

The system contains high voltages and has the potential of shock during maintenance. To avoid risk of electrical shock hazards, always turn off the system, disconnect the main power cord from the wall outlet, and wait at least 30 seconds before cleaning the system.

CAUTION

Use only compatible cleaners and disinfectants on system surfaces.

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CAUTION

Ensure that the system brakes are locked before performing maintenance or cleaning.

CAUTION

Do not use abrasive cleaners, or acetone, MEK, paint thinner, or other strong solvents on the system, peripherals, or transducers.

CAUTION

To avoid damage to the monitor screen or touch screen, do not touch them with any sharp object such as pencils or calipers. Take care not to scratch the face of the screen while cleaning.

CAUTION

On monitor screens and touch screens, use microfiber cloth; do not use paper towels.

CAUTION

When cleaning the system control panel, monitor screens, touch screen, and keyboard, take care not to get any solution inside the housings. Do not spill or spray liquid on the controls, into the system cabinet, or into the transducer receptacles.

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CAUTION

Do not spray disinfectant directly on system surfaces. When wiping, do not allow disinfectant to pool or run on system surfaces. In either case, disinfectant may leak into the system, damaging the system and voiding the warranty. Wipe only with a cloth or applicator that is lightly dampened.

CAUTION

System surfaces and transducers are resistant to ultrasound gel, alcohol, and disinfectants, but if you use those substances, you must wipe them off to prevent permanent damage.

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Cleaning the System and ECG Equipment

Before cleaning the system and ECG equipment, read "Disinfectants and Cleaners for System Surfaces" on page 353.

1. Before cleaning, turn off the system, unplug the power cord from the power source, and ensure that the system brakes are locked.
2. To clean monitor screens and touch screens:
   a. Remove dust with a soft, dry, lint-free cloth. Philips recommends using a microfiber cloth.
   b. Use a liquid screen cleaner specifically designed for LCDs or OLEDs. Spray the liquid onto the cleaning cloth and gently wipe the screen clean. You can also use pre-moistened screen wipes.
   c. Dry the screen with a soft, dry, lint-free cloth.
3. To clean the control panel, remove any solid matter around the keys or the controls with a cotton swab or toothpick to ensure that solids are not pushed into the cabinet. Gently wipe with a soft cloth moistened with soap and potable water.
4. Wipe the remaining external surfaces of the system and the cart with a soft cloth lightly moistened (damp; not dripping) with soap and potable water:

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- Painted and plastic surfaces
- ECG trunk cables, leads, and electrodes
- Easy-clip transducer cable managers

You may use a 70% isopropyl alcohol solution for stubborn stains or inks, and then wash with soap and potable water.

5. Gently remove any residue with a soft cloth moistened with purified water.
6. Dry the equipment to prevent potential corrosion.

If the equipment has come in contact with blood or infectious material, see "Disinfecting System Surfaces and ECG Equipment" on page 358.

Disinfecting System Surfaces and ECG Equipment

Before disinfecting the system and ECG equipment, read "Disinfectants and Cleaners for System Surfaces" on page 353.

1. Before cleaning and disinfecting, turn off the system, disconnect the power cord from the power source, and ensure that the system brakes are locked.
2. Clean the system according to the procedures in "Cleaning the System and ECG Equipment" on page 357.
3. Choose a disinfectant compatible with your system and follow the label instructions for preparation, temperature, and solution strength. If a pre-mixed solution is used, be sure to observe the solution expiration date.
4. Wipe system surfaces with the disinfectant, following disinfectant label instructions for wipe durations, solution strengths, and disinfectant contact duration. Ensure the solution strength and duration of contact are appropriate for the intended clinical application.
5. Dry the equipment to prevent potential corrosion.

Cleaning the Trackpad

Cleaning the trackpad regularly prolongs its useful life and prevents service calls.

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CAUTION

Do not use Sani-Cloth AF3 or Super Sani-Cloth. Severe damage occurs to the knobs and plastic surfaces.

Clean dust and debris from the trackpad and the surrounding area with a lint-free cloth, small brush, or cotton swab moistened with alcohol.

Cleaning and Disinfecting the AC Adapter

WARNING

Always use protective eyewear and gloves when cleaning and disinfecting any equipment.

CAUTION

Do not immerse the AC adapter.

CAUTION

Keep moisture and liquid away from the AC adapter. Do not spill or spray liquid on the adapter.

1. Disconnect the AC adapter from the system and the wall outlet.
2. Wipe the AC adapter with a dry cloth. If spot cleaning is necessary, wipe with a cloth dampened with mild soap solution and water.

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3. Remove any solid matter with a cotton swab or toothpick to ensure that solids are not pushed into the adapter.
4. If disinfection is necessary, wipe with an alcohol-moistened towelette or cloth.
5. Wipe the AC adapter with a dry cloth until thoroughly dry before connecting it into the system or wall outlet.

Printer Maintenance

Before performing any maintenance on a device, observe the following warnings and cautions:

WARNING

If the device is internal to the system, turn off the system and disconnect the system from the wall outlet. If the device is external to the system, disconnect the device from the wall outlet.

CAUTION

Do not scratch the roller or allow dirt and dust to contact the roller of a printer.

CAUTION

Do not use abrasive cleaners, or acetone, MEK, paint thinner, or other strong solvents on the system, peripherals, or transducers.

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CAUTION

Do not unplug the system from the wall outlet until the system is completely off. If you unplug your system before the shutdown message appears, you will have to wait longer than usual to use your system the next time you turn it on. You may also corrupt files, which can result in an inoperative system or the loss of patient data.

Periodically clean the external surfaces of a device with a soft cloth. Difficult stains may be removed with a cloth lightly dampened with a mild detergent solution.

Troubleshooting

The troubleshooting table contains a list of symptoms and the actions to take to correct the problems.

Troubleshooting

Symptoms	Corrective Action
The system does not power up. The monitor indicator light is off.	1. Verify the power connections. 2. Check the battery status indicator on the left side of the system or the indicators on the rear of the cart battery compartment.
No image displays on the monitor.	1. After power up, the system requires about 20 seconds to initialize. During this time the monitor is blank. 2. After 20 seconds, adjust the monitor brightness.
No audio comes from the system speakers.	Adjust the volume to ensure that the speakers are not muted.
An error message is displayed.	Run the system test (see “Testing the System” on page 363).

Symptoms	Corrective Action
An error message indicates that the system is above normal operating temperature.	1. Do one of the following: – To power down the system immediately, tap **OK**. – To continue scanning, tap **Continue**. The system powers down automatically in 5 minutes. 2. After the system powers down, make sure that the system fan and intake vents are not blocked. 3. Restart the system. 4. If the error message recurs, power down the system and contact your authorized service representative.

Error Messages

The system displays error messages in response to operating or error conditions detected by the system.

The error messages must be noted and reported to your Philips representative, who may ask you to run the system test (see “Testing the System” on page 363).

Test Patterns

The system test patterns were created by the American Association of Physicists in Medicine Task Group 18 (TG-18). These patterns are provided to test the image quality of the system, peripheral devices, review stations, or a PACS.

For information on using these test patterns, read IEC publication 62563-1.

Using the Test Patterns

To use the test patterns you must transfer the images to the patient directory and then print out the images.

1. Touch **Review**.
2. In **Patient Directory**, under **Source**, tap **Hard Drive**, and then tap **Test Imgs**.
3. Select **TG18 Test Patterns** or **Test Patterns**.
4. Tap **Import**. A status message indicates that the transfer is in progress.
5. Select **TG18 Test Patterns** or **Test Patterns** from the exam selection list, and then tap **Open**.
6. Do any of the following:
   - To send a test pattern to a local printer, double-tap a test pattern to display it full-screen, and tap **Print**.
   - To send a test pattern to a DICOM printer or archive server, tap a test pattern number to select it, tap **Print To**, select a device, and tap **OK**.
7. Follow the instructions in IEC 62563-1.

Testing the System

The system test is a comprehensive test of the system operational status. This test includes numerous subtests. If a subtest fails, the system completes the remaining subtests. The system test displays only a pass-fail result on the system monitor. If the system test fails, notify your Philips service representative.

Run the system test any time a system error is displayed, or if you suspect problems with the system. If an error message is displayed during the test, restart the system with the (On/Off) control.

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NOTE

The system test may require several minutes to run.

1. Turn on the system.
2. Disconnect all transducers from the system.
3. Press **Support**.
4. In **Philips SupportConnect**, tap the **Test/Utilities** tab.
5. Tap **System Test**.
6. In the **System Test** area, tap **Run**. The system displays a message when the test is complete, indicating whether the test passed or failed.
7. If the test fails, contact your Philips service representative for instructions about how to export the log files.
8. Restart the system as explained in “Turning the System On and Off” on page 143.

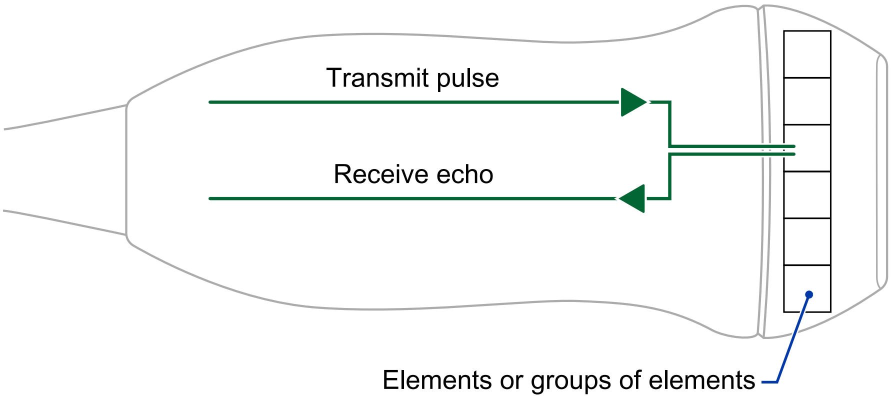
Transducer Element Check

You run the transducer element check from **Philips SupportConnect**. You may use this test as part of a regularly scheduled transducer quality assurance program or if you suspect that the transducer has been damaged.

During the test, the system transmits a pulse to each element for standard transducers or to a group of elements for xMATRIX transducers. The echoes received from the transducer demonstrate that the transducer can transmit and receive, and indicate that the signals received are fairly uniform in strength.

NOTE

The transducer element check is a licensed option available only in the United States.



Transducer Test Signal Path

Running the Transducer Element Check Test

1. Press **Support**.
2. Tap the **Test/Utilities** tab.
3. Tap **Hardware Utilities**.
4. Disconnect all transducers, and then tap **Yes**.
5. Under **Interactive Utilities**, tap **Transducer**, and then tap **Run Test**.
6. Connect the transducer to the system.

NOTE

Make sure the transducer face is clean, dry, and not touching anything.

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7. Under **Transducer Test**, tap the transducer name, and then tap **Run**.
8. Note the outcome of the test in the **Results** field:
   - **Test Passed**: Indicates all transducer checks were successfully completed, and therefore, the transducer is ready for use.
   - **Needs Evaluation**: Indicates that potential issues were detected in the transducer elements.
9. If **Needs Evaluation** is the result, tap **Export** to create a log of the issues that were detected in the transducer elements, and then contact your authorized service representative. For more information, see "Exporting Log Files" in the *Help*.
10. Tap **Close**.

For Assistance

If you are unable to correct a problem, call your local Philips representative.

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14 Specifications

Philips reserves the right to change specifications contained herein or discontinue manufacture at any time without prior notice. Current specifications are supplied with each system purchased or are available from your authorized service representative.

System Dimensions

System Only

- Width: 41.2 cm (16.2 in)
- Height: 8.7 cm (3.4 in) with monitor lid open; 38.5 cm (15.2 in)
- Length: 40.7 cm (16 in)
- Weight: 10.6 kg (23.3 lb) with battery

Cart (all cart configurations, unless otherwise noted)

- Width: 56 cm (22 in)
- Height:
  - 100.1 cm (39.4 in) with cart fully raised
  - 82 cm (32.2 in) with cart fully lowered
- Depth:
  - Top: 60.8 cm (23.9 in)
  - Base: 55.9 cm (22 in)
- Weight:
  - Standard Cart: 39.3 kg (86.6 lb)
  - Extended Cart: 40.1 kg (88.4 lb)
  - Deluxe Cart: 43.9 kg (96.7 lb)
  - Premium Cart: 46.6 kg (102.7 lb)
- Weight (storage trays, maximum allowable capacity):

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- Cart handle storage tray: 1 kg (2.2 lb)
- Cart small storage tray: 2 kg (4.4 lb)
- Cart large storage tray: 2 kg (4.4 lb)

Endocavity and TEE Transducer Specifications

Transducer	Maximum Insertion Portion Width	Working Length (Intended Insertion Length)	Field of View
3D9-3v	27.3 mm	165 mm	155.5 degrees
C9-4v	25.9 mm	165 mm	172 degrees
C10-3v	25.9 mm	165 mm	129 degrees
X7-2t	17.9 mm	1,014 mm	89 degrees
X8-2t	17.9 mm	1,014 mm	89 degrees

Display

Gray Shades

256 in 2D, M-mode, and Doppler

Scan Lines

Up to 1,024 scan lines, depending on transducer and mode

Monitor

- 15.6-in (39.6 cm) wide-format, high-definition, flat-panel TFT/IPS display
- 24-bit color

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Connections

Input Signals

- Single Doppler-only transducer receptacle
- Single transducer receptacle or three transducer receptacles, depending upon system configuration

Output Signals

- External printer
- Physio analog signal
- USB serial data
- Video: Digital DisplayPort

Data Connections

- Digital Navigation Link (DNL)
- Ethernet network (Gigabit, 10Base-T, and 100Base-T)
- USB 2.0 devices or USB 3.0 devices at USB 2.0 speeds
- Wireless network (IEEE 802.11 b/g/n)
- Wireless network adapters

Modality Interface

DICOM standard. DICOM conformance statements for Philips products are available at this website:

https://www.philips.com/healthcare/resources/support-documentation/dicom-ultrasound

Physio

- ECG amplitude range: 0.15 mV to 5.0 mV
- Duration of the QRS wave: 40 ms to 120 ms

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- Lower Frequency Cut-off: 0.70 Hz ±10%
- Upper Frequency Cut-off: 17 Hz ±10%
- Nominal Input Amplitude: ±5 mV peak
- Minimum QRS Wave Amplitude: 0.05 mV

Peripherals

- Barcode scanner
- Black-and-white report printer
- External monitor
- Foot switch
- USB-supported external devices (for example, black-and-white image printer, DVD player/recorder)

Electrical Parameters

Maximum power consumption varies depending on system configuration.

System Powered by AC Adapter (Stand-alone)

- Power consumption: 310 VA maximum
- 5300 Ultrasound System: 100-240 Vac, 50-60 Hz, 250 VA
- 5500 Ultrasound System: 100-240 Vac, 50-60 Hz, 250 VA
- 5500 CV Ultrasound System: 100-240 Vac, 50-60 Hz, 250 VA
- System battery (1 unit per ultrasound system): 14.4 Vdc, 98 Wh*

System Attached to Cart

- Power consumption: 660 VA maximum (depending on system configuration)
- Standard Cart: 100-240 Vac, 50-60 Hz, 250 VA (using cart mounted AC adapter)
- Extended Cart 100-240 Vac, 50-60 Hz, 450 VA (using UPS)

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- Deluxe Cart 100-240 Vac, 50-60 Hz, 450 VA (using UPS)
- Premium Cart 100-240 Vac, 50-60 Hz, 450 VA (using UPS)
- Cart batteries (3 units per cart on the Extended, Deluxe, and Premium carts): 14.4 Vdc, 98 Wh*

* System battery provides 30 minutes of imaging when the system disconnected from the AC adapter or after the cart batteries are drained.

Power must be available through a grounded outlet.

In the United States, power to the AC connector or AC adapter must be available through a grounded, hospital-grade outlet.

Environmental Limits

Operating and Storage Limits for Systems and Transducers

Parameter	Operating Limits	Storage Limits
Pressure	525 mmHg to 795 mmHg (700 hPa to 1,060 hPa)	427 mmHg to 795 mmHg (570 hPa to 1,060 hPa)
Humidity	15% to 80% non-condensing	0% to 93% relative humidity
Temperature	10°C to 40°C (50°F to 104°F)	-20°C to 60°C (-4°F to 140°F)[1]

1. V6-2 transducer temperature storage limits: -10°C to 60°C (14°F to 140°F).

NOTE

If the system is stored for prolonged periods at or near the low end of the storage temperature range, the system clock may need to be reset.

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Safety and Regulatory Requirements

Classification

- Class I equipment with Type BF and Type CF isolated applied parts
- Ordinary Equipment/Continuous Operation
- Non-AP/APG

Electromechanical Safety Standards Met

The system complies with the requirements of IEC 60601-1, Medical Electrical Equipment, General Requirements for Safety, including all applicable collateral and particular standards, as well as all applicable national deviations.

Compliance

Philips products comply with relevant international and national standards and laws. Information on compliance will be supplied by your local Philips representative, or the manufacturer, on request.

Security

The system complies with the United States Federal Information Processing Standard (FIPS).

Service Life

Service life is defined by IEC 60601-1 as the amount of time that a medical device is expected to remain safe for use. The service life for medical device components may be defined by hours of use or number of times used.

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NOTE

Regular maintenance is necessary for a medical device or component to perform for its expected service life.

NOTE

Preventive maintenance is not required for the system, the optional carts, or the supported transducers. For more information, see “System Maintenance”.

The service life for the system is 7 years.

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