
VINNO 6PRO_VINNO 6_VINNO 6EXP Basic User Manual

VINNO 6PRO_VINNO 6_VINNO 6EXP


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CAUTION

In the United States, Federal law restricts this device to sale, distribution, and use by or on order of a licensed physician.

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1 General

1.1 Introduction

VINNO 6PRO_VINNO 6_VINNO 6EXP (hereinafter referred to as "this device") is a professional digital color ultrasonic diagnostic system. It transmits ultrasound waves into the body tissues and displays the echo images of the tissues and blood flow accordingly.

Principles of operation

Medical ultrasound images are created by computer and digital memory from the transmission and reception of mechanical high-frequency waves applied through a probe. The mechanical ultrasound waves spread through the body, producing an echo where density changes occur. For example, in the case of human tissue, an echo is created where a signal passes from an adipose tissue (fat) region to a muscular tissue region. The echoes return to the probe where they are converted back into electrical signals.

These echo signals are highly amplified and processed by several analog and digital circuits that use filters with many frequency and time response options to transform the high-frequency electrical signals into a series of digital image signals which are stored in memory. Once in memory, the image can be displayed in real-time on the image monitor.

A probe is an accurate, solid-state device, providing multiple image formats. The digital design and use of solid-state components provides highly stable and consistent imaging performance with minimal required maintenance.

1.2 Contact Information

This device is developed and manufactured by VINNO Technology (Suzhou) Co., Ltd, China. Contact information is as follows:

Customer service representatives are available worldwide to answer questions and to provide maintenance and service. Please contact the local VINNO representative for assistance. You can also contact the following office for referral to a customer service representative, or visit VINNO website: www.vinno.com.

Telephone: 4008873806

Fax: + 86 512 62873801

Address: 5F Building A, 4F Building C, No.27 Xinfu Road, Suzhou Industrial Park,

215123, China

Authorized European Representative:



WellKang Ltd (www.CE-marking.eu)
Enterprise Hub, NW Business Complex,
1 Beraghmore Road, Derry, BT48 8SE,
Northern Ireland, UK

1.3 About this document

- Before attempting to use this device, read and fully understand all contents in the document to properly operate this device, paying particular attention to all: Warnings, Cautions, Notes, and Notices. Due to space limitations, this manual does not make perfect, any problem please contact VINNO technical staff.
- In order to use the device correctly, keep this manual with the device at all times.
- This manual accompanies the VINNO 6PRO_VINNO 6_VINNO 6EXP only.
- The most extensive configuration is described within this manual, including the maximum number of the options and the accessories. Not every function, option or accessory described may have been purchased or licensed on your device.
- This manual forms part of the accompanying documentation for this product. The remaining documents in the set are listed: Advanced Technical Manual, Service Manual.

1.4 Product description

This device is a professional, premium performance real-time scanning system. The various probes make many applications possible.

This device provides the following diagnostic possibilities:

- B mode, M mode
- CF and PDI mode
- Spectral Doppler: pulsed wave and continuous wave (PW and CW)
- Tissue Doppler (TD)
- Volume mode: 3D and 4D (real time 3D)

Intended use:

This device is indicated for Abdominal; Fetal/Obstetrics; Gynecology; Transvaginal; Urology(including prostate); Transrectal; Cardiac(adult and child); Peripheral Vascular; Small Organs/Parts(thyroid, breast, testicle, Musculo-skeletal Conventional and Superficial); Pediatrics(including neonatal

cephalic); interventional(nerve block and vascular access); Intraoperative (abdominal, brain) and Adult Cephalic diagnostic Ultrasound applications. The device output is a valuable assisting medical tool for the diagnosis of disease, abnormality or follow-up. The systems support a complete family of curved, endocavity, linear, phased array, intra-operative, and mechanical 3D probes.

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

Patient population

Age: all ages (incl. embryos and fetuses)

Location: worldwide

Sex: male and female

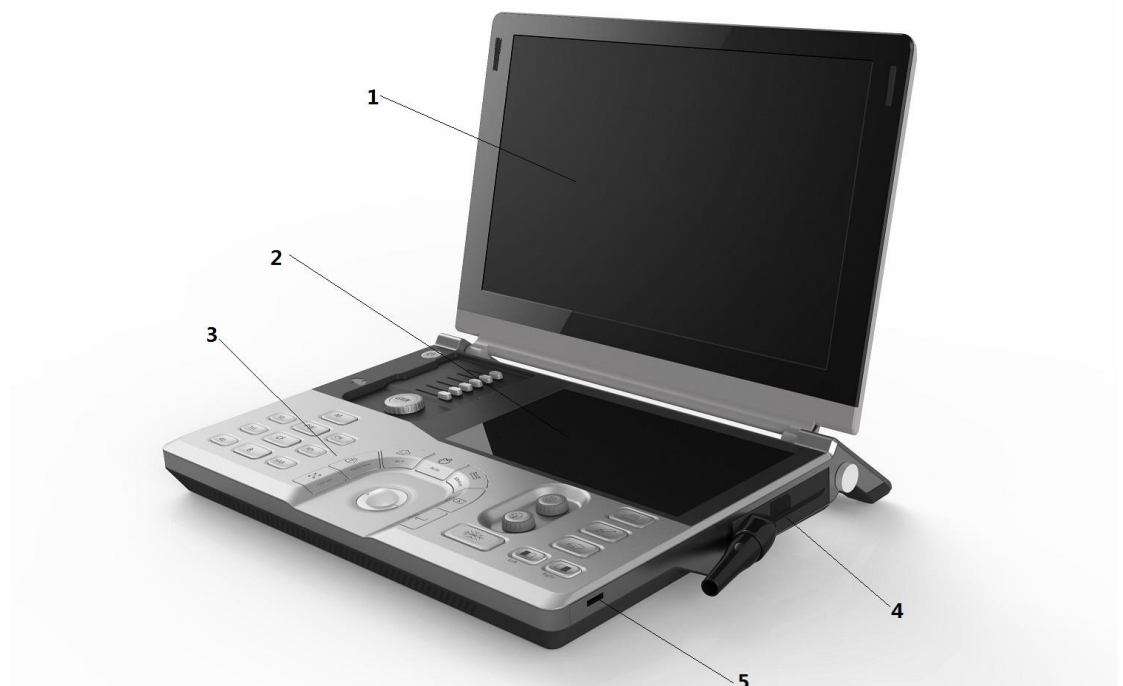
Weight: all weight categories

Contraindication

The products are not intended for ophthalmic use or any use causing the acoustic beam to pass through the eye.

1.5 Mechanical system

1.5.1 System layout



1. Monitor

2. Touch Panel

-
- 3. Control Panel
 - 4. Probe Port
 - 5. ECG Port

1.5.2 Mechanical adjustment

The image screen panel allows to move forward and backward and tilted to different degrees. It can also be laid down into a flat position in order to be convenient and protected during transportation.

1.5.3 Keyboard

1.5.3.1 Touch panel

Except for the functions triggered by the control panel, the touch panel represents the main operator interface for operation.

The touch panel is highly sensitive and consists of a flat monitor. It is easy to operate even under dim light conditions and allows for comfortable access to the control menu.

Notes:

This touch panel can be blocked by a strong magnetic field. Avoid magnetic field interference. The touch panel may be impacted by any foreign body lying on it. To guarantee maximum performance, it is recommended to clean the touch panel regularly.

1.5.3.2 Control Panel



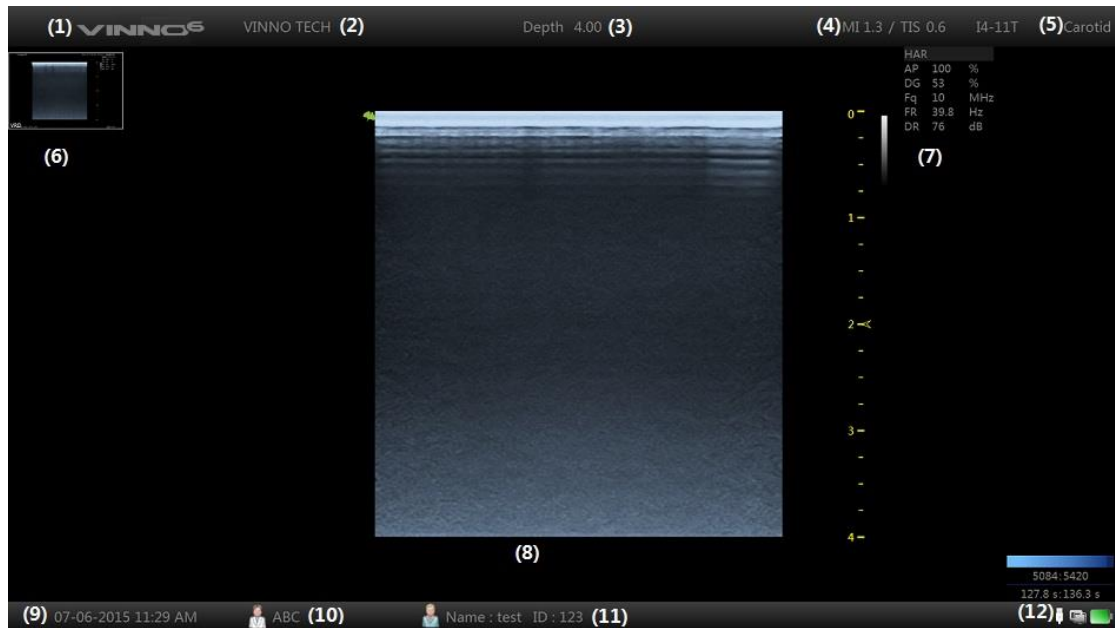
- (1) TGC: these 6 section slides can adjust TGC (Time Gain Control) in 6 different positions.
- (2) Gain: adjust the gain in every mode.
- (3) M: press this key to enter M mode.
- (4) TD: press this key to enter TD mode.
- (5) PW: press this key to enter PW mode.
- (6) CW: press this key to enter CW mode.
- (7) TVI: press this key to enter TVI mode.
- (8) CF: press this key to enter CF mode.
- (9) PDI: press this key to enter PDI mode.
- (10) 4D: press this key to enter 3D/4D mode
- (11) B: press this key to enter B mode.
- (12) HAR: press this key to enter Harmonic imaging.
- (13) Cursor: once pressing this key, the cursor will be displayed on the screen. It can be moved using the trackball.
- (14) M/D line: push this key to display the desired line in M mode or PW/CW mode. Moving the trackball can change the line position.
- (15) ROI size: ROI stands for range of interest. Pushing this key allows the operator to change the size of ROI by operating the trackball - up or down movement allows to enlarge or reduce the ROI size vertically, right or left movement to enlarge or reduce the ROI size horizontally).
- (16) Auto: automatically optimizes the relevant image such as B mode image, color and pulse wave.

-
- (17) Measure: to view the image measurements. The measurement items can be selected in the measurement menu.
- (18) Clear: to erase the annotation, body pattern or measurement result on the display. Pushed once, it will erase the last one. If held for a longer period (minimum 2 seconds), it will erase all results.
- (19) Enter: to confirm the action identified by an arrow.
- (20) Rotation/Steer: in 3D/4D mode, this key allows operator to rotate the rendering images. In CF mode, this key can steer an interest box such as the color interest box and the 2D linear image.
- (21) Depth: changes scanning depth. Zoom: Rotate this key to zoom in/out the image after it is pressed.
- (22) Freeze: freezing and unfreezing scanning.
- (23) Print: the function of this key can be defined during system set-up. By default it is set as the print function. However, it can also be set to save to USB or save to HDD.
- (24) Save to USB: the function of this key can be defined during system set-up. By default set to store images to the U disk through the USB port.
- (25) Save to HDD: the function of this key can be defined during system set-up session. By default set to store images on the clipboard to the Hard disk. After this key is pressed before the image is frozen (by pressing "Freeze" key), it will store the cine loop from the most recent session (the cine loop time can be changed in the system settings). After the image is frozen, it will store the last frame single image.
- (26) Left: this key can generate a dual image display. The left image is the active one and the right image is the static one.
- (27) Right: this key can generate a dual image display. The right image is the active one and the left image is the static one.
- (28) Standby: switches the device on and standby.
- (29) Trackball: operator can use the trackball to move the cursor, or the line, or the ROI box, etc.

1.6 Optional peripheral devices

Black/white video printer (USB)
Digital color printer (USB)
LAN printer / Wireless printer

1.7 Display annotation



- (1) VINNO: manufacturer's trade mark.
- (2) Hospital Name: it can be modified by the operator to enter a particular name. The default is empty.
- (3) Depth: indicates how deep the scan image is reaching.
- (4) MI, TI: indicate the size of Acoustic Mechanical and Thermal Index.
- (5) Probe and application: show what the current probe and application are selected and used.
- (6) Clip board images: this field displays the batch of the temporarily stored images, which are stored in HDD.
- (7) This field indicates some of the parameters such as digital gain, frequency, frame rate, acoustic output power. The displayed parameters are different in different modes.
- (8) Image area: it is the field where the image is displayed, including all mode images such as B, CF/PDI, M, and PW/CW.
- (9) Date, Time: this field indicates the current date and time. This date and time can be modified in the system setting menu.
- (10) Perf. Physician: this field shows the performing physician's name.
- (11) Patient information: this field shows the current patient name and ID. If there is some information of OB input when new the patient, display "GA" too.
- (12) USB/Network status: Show USB icon, file server icon, network icon and Bluetooth icon. And the battery information.

1.7.1 Parameter term explanation

All parameters in the parameter field are abbreviated and stand for the following

meanings.

AP: Acoustic Power

DG: Digital Gain

Fq: Frequency

WF: Wall Filter

DR: Dynamic Range

FR: Frame Rate

SD: Sample Depth

1.8 On line manual

In the system setting menu of the touch panel, there is a “Show Manual” key. By selecting this key, the operator manual will be displayed for operator to refer to.

2 Safety

2.1 Introduction

This device is designed for the safety of the patient and operator. Before operating the device, read this chapter thoroughly with care please. The manufacturer guarantees the safety and reliability of the device only if all cautions and warnings are followed. Strictly observe all Warnings, Cautions, Notes and Safety markings within this document and on the machine.

Icon description:

Several levels of safety precautions may be found in this manual. Different levels of concern are identified by one of the following icons with signal words.



WARNING

Indicates a hazard which, if not avoided, could result in death or serious injury.



CAUTION

Indicates a hazard which, if not avoided, could result in moderate or minor injury and property damage.

2.2 Owner responsibility

Notice against operator modification:



WARNING

Never modify this device, including the system components, the software, the cables and any other device components or accessories. A safety hazard may occur resulting from unauthorized modification. Do not attempt to disassemble the device if you are not trained and authorized by the manufacturer.

The operator must familiarize themselves with these safety measures and avoid situations that can result in injury or damage.

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). Please contact VINNO before disposing of this system.

Do not use this device during service or maintenance.

2.3 Regulatory Notice

This device has been tested to meet all applicable requirements.

According to 93/42 EEC(Medical Devices Directive) amended by 2007/47/EC, it is a class IIa medical device.

Conformity to Standards:

The following standards have been used and the product is therefore certified in compliance with:

IEC 60601-1:2005/A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests










IEC 60601-1-6:2010/A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability












IEC 60601-2-37:2007/A1:2015 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of

ultrasonic medical diagnostic and monitoring equipment
 IEC 61157:2007/AMD1:2013 Standard means for the reporting of the
 acoustic output of medical diagnostic ultrasonic equipment
 ISO 10993-1:2018 Biological evaluation of medical devices -- Part 1:
 Evaluation and testing within a risk management process
 IEC 62304:2006/A1:2015 Medical device software - Software life cycle
 processes
 IEC 62366:2007/A1:2014 Medical devices - Application of usability
 engineering to medical devices

Council Directive 93/42/EEC amended by 2007/47/EC on Medical Device
 WEEE according to 2012/19/EU
 RoHS according to 2011/65/EU

2.4 Label Icon description

Label	Description	Location
	This is the indicator for company address.	Rear of unit
	This is the indicator for part number.	Rear of unit
	This is the serial number indicator.	Rear of unit
	This indicates manufacture time.	Rear of unit
	Unique Device Identification.	Rear of unit
	General Warning Sign.	Rear of unit
	MUST read the document accompanying the device!	Rear of unit
	This is type BF equipment, in which protection against the electric shock does not rely on the basic insulation only. (The operator shall) Provide additional safety precautions such as double insulation or reinforced insulation for protective earthing or reliance upon installation conditions.	Rear of unit
	Equipment Type CF, indicates the equipment which has a floating applied part, possessing a degree of protection suitable for direct cardiac contact.	Rear of unit

	This symbol indicates that the waste of electrical and the electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.	Rear of unit
	Standby button Warning: system shutdown using the “Standby” button does not disconnect the ultrasound unit from the main voltage. To disconnect the ultrasound unit from the main voltage after the system shutdown, plug out the power cable from the main outlet.	Control panel
	Warning: dangerous voltage. This is a warning mark for an electric shock hazard to indicate there is a potential electric shock risk.	Rear of unit
	Do not put hands here. There is a risk of hands crush.	Rear of console
	This is the equipotential connection mark. The operator needs to connect the equipotential points of the device in order to reach the same potential.	Rear of unit
	This is the protective earthing mark to indicate which device or part is protected by earthing.	Inside of unit
	Authorized European Representative Address.	Operator Manual
	This product carries the CE Mark. 0197 for VINNO.	Rear of unit
	GOST Symbol. Russia Regulatory Country Clearance.	Rear of unit
	These symbols are for China RoHS. Not applicable for other countries.	Probe connector
		Rear of unit
4kg	This indicates the approximate weight of the system in kilograms	Rear of unit
CLASS I	This indicates the electrical safety classification of the product	Rear of unit
CLASSE I	Portuguese translation of the electrical safety classification.	Rear of unit

2.5 Safety and Warning notices

2.5.1 Acoustic output

Definition of the acoustic output parameters:

Thermal Index: TI is an estimate of the temperature increase of the soft tissue or bone. There are three thermal index categories:

- **TIS:** soft tissue thermal index, the main TI category. Used for the applications that does not image (or visualize) bones.
- **TIB:** bone thermal index (bone located in a focal region). Used for the fetal application.
- **TIC:** cranial bone thermal index (bone located close to the surface). Used for the transcranial application.

Mechanical Index: MI is the estimated likelihood of tissue damage due to the cavitations.

Safety statement:



CAUTION

Although no harmful biological effects have been demonstrated for ultrasound frequencies, intensities and exposure times, we recommend the operator to use the lowest acoustic output settings producing acceptable diagnostic information.

System controls affecting acoustic output:

The TI and MI show the highest possible acoustic intensity for a given mode, obtainable only when the combination of control settings that results in maximum output is selected. Most settings result in a much lower output.

There are several notes as follows:

- The duration of an ultrasound examination is as important as the acoustic output, since the patient exposure to output is directly relevant to the ultrasound scanning time.
- The better image quality can accelerate the clinical result, reducing the overall duration of an examination. Therefore, any image quality improvement can help to reduce patient exposure.

Probe selection:

As long as the appropriate application is available, any probe of this device can

be used and meet the limitation of the acoustic output requirement.

Application selection:

Selecting the probe and application will provide the acoustic output within the limitation of the acoustic output requirement.

Changing imaging modes:

Acoustic output depends on the imaging mode selected. The choice of mode will greatly affect the energy absorbed by the tissue. After a combined mode is completed, such as 2D and CF mode, the total acoustic output comprises contributions from each individual mode.

Concerning surrounding fetal exposure:

Always be aware of the acoustic output level by observing the acoustic output display. The operator is recommended to become familiar with this device's controls affecting the acoustic output.

OB examination:



CAUTION

Prior to an ultrasound examination, the patient should be informed of the clinical applications which include specific benefits, potential risks and alternatives. In addition, if the patient requires information about the exposure time and intensity, they should be provided. An ultrasound examination should not be performed to satisfy the family's desire to know the fetal sex: according to several countries' laws, which include China, using an ultrasound examination to detecting the fetal sex (gender) is prohibited.

2.5.2 Patient Safety



WARNING

The concerns listed in this section can seriously affect the safety of the patient undergoing a diagnostic ultrasound examination.

Patient Identification:

Always include proper identification with all patient data and verify the accuracy of the patient's name and/or the identity number after entering the data. Ensure all recorded data has the correct patient ID. Identification errors can result in an incorrect diagnosis.

Diagnostic Information:

The images and calculations provided by this device are intended for use by the

competent the operator, as a diagnostic tool. They are explicitly not to be regarded as the sole basis for the clinical diagnosis. The operator is encouraged to study the literature and reach their own professional conclusions regarding the clinical utility of this device.



CAUTION

Special care is required to ensure the maximum privacy of the patient information.

2.5.3 Probe Safety

Mechanical hazards:



CAUTION

Damaged probes or the improper use of probes may result in injury or increased the risk of infection. The operator needs to frequently inspect the probe for damage, in particular looking for sharp or rough surface damage.



WARNING

Never use intensive force when manipulating the intra cavity probes. The operator is required to be familiar with all instructions and precautions provided with probes.

Electrical Hazard:



WARNING

Probes are powered by electricity and can injure the patient or operator when exposed to contact with the conductive solution. A damaged probe may increase the risk of electric shock. Inspect probes frequently for cracks or openings in the housing and holes in and around the acoustic lens, or other damage.

2.5.4 Personnel and equipment safety

Explosion hazard:



WARNING

Never operate this device in the presence of flammable or explosive liquids, vapors or gases. The operator should be aware of the points to prevent such explosion hazards as follows:

- If flammable substances are detected in the environment, do not plug in or turn on this device. In addition, do not unplug or turn the device off if it has

been turned on before.

- If flammable substances are detected, evacuate and ventilate the area before turning off this device.

Electrical Hazard:



WARNING

- Internal circuits of this device use high voltages, capable of causing serious injury or death by the electric shock.
- The OPERATOR MUST NOT touch accessible LIVE parts of USB, DVI, Audio ports and the PATIENT simultaneously.
- USB, DVI and Audio ports: ONLY connect the PARTS or DEVICES which DO NOT have the external electrical hazard risk.
- USB port max output 5V 0.5A.
- Please use USB devices which meet IEC 60950.

Any configurations by such connection must comply with the requirements of the IEC60601-1. It is the responsibility of the person who connects the parts or devices and configures a medical system to verify that this device complies with the requirements of the IEC60601-1. If you have any questions, contact your service representative for information.

To avoid injury:



WARNING

- Do not remove this device's protective covers. No operator-serviceable parts are inside. If servicing is required, contact a qualified technician.
- Connect the attachment plug to a hospital-grade earthing socket to ensure adequate earthing.
- To avoid the risk of electric shock, this equipment must only be connected to a supply main with protective earth.
- Never use any adaptor or converter of a three-prong-to two-prong type to connect with a main power plug. The protective earth connection will be lost.
- Do not place liquids on or above this device. Conductive fluids seeping into the active circuit components may cause a short circuit, which can result in an electrical fire.
- An electrical hazard may exist if any light, monitor or visual indicator remains on after this device is turned off.



CAUTION

Do not use this device if a safety problem is known to exist. This device needs to be verified by qualified service personnel before returning to

use.

Biological hazard:



CAUTION

Beware of biological hazards after performing trans-vaginal procedures. To avoid the risk of disease transmission:

- Use protective barriers such as probe glove and follow sterilization procedures as required.
- Thoroughly clean the probes after each patient examination and disinfect or sterilize as needed.
- Follow all in-house infection control policies as they apply to the personnel and equipment.

Pacemaker hazard:



WARNING

The possibility of this device interfering with pacemakers is minimal. However, as this device generates high frequency electrical signals, the operator should be aware of the potential hazard.

Monitor:



WARNING

- To avoid injuries or system damage, NEVER place any object or liquid on the monitor.
- DO NOT place any object on the ventilation slots. Blocking the ventilation slots obstructs proper airflow and may result in fire, electric shock, or equipment damage.
- DO NOT scratch or press on the panel with any sharp objects, such as a pencil or pen, as this may result in damage to the monitor.

2.5.5 Electrical Safety

Internally connected peripheral devices:



CAUTION

This device, together with the internal connected peripheral devices, such as the printers or the DVDRW, meets all the standards listed in chapter 2.1. This statement is applicable only when tested peripherals listed in chapter 14 are plugged into the AC outlets provided in this device.

External connection of other peripheral devices:

**CAUTION**

Other external devices, such as laser cameras, printers and external monitors, usually exceed the medical standard allowable current leakage. If they are plugged into separate AC outlets and then connected to this device, it represents a violation of patient safety standards. Suitable electrical isolation of such external AC outlets may be required to meet the electrical leakage limit requirement.

Device movement:**CAUTION**

When moving this device, rotate the control panel to be in the middle from the left and right view, and also push the control panel as far back as possible then move it to the lowest position.

ECG Use:**CAUTION**

Do not use this device's ECG wave for diagnosis and monitoring. Only use an ECG cable which is approved by VINNO.

Defibrillator Use:**CAUTION**

Do not use this device with a defibrillator.

Use of Electrosurgical unit:**CAUTION**

DO NOT use high-frequency surgical equipment with the device.

**CAUTION**

Keep the Electrosurgical unit away from ECG leads to avoid the potential interference to the ECG wave. To avoid a burn hazard, do not use this device with high-frequency surgical equipment.

Electromagnetic Compatibility (EMC):

This device can produce and use the radiation RF energy.

All types of electronic equipment may characteristically cause the electromagnetic interference with other equipment, either transmitted through air or connecting cables. The term EMC indicates the capability of this device to curb the electromagnetic influence from other equipment and at the same time not affect other equipment with the similar electromagnetic radiation from itself.

This product is designed to fully comply with the EN60601-1-2 (IEC60601-1-2), Class A, in medical electric equipment EMC regulations.

Proper installation following the service manual is required in order to achieve the full EMC performance of the product.

In the event of issues relevant to EMC, (turning on/off this device is able to evaluate whether an EMC-relevant problem has occurred), the operator (or qualified service personnel) should try the measures (one or more) to address and solve the problem as follows:

Determine the identity of the affected equipment and replace the affected equipment (one or more).

Relocate this device or the affected equipment to increase the distance in between.

Use a different power supply source from the affected equipment for this device's power supply.

Call your service personnel for more advice please.

General Information

1. Products equipped with a power source plug should be plugged into a fixed power socket that features the protective earthing conductor. Never use any adaptor or converter to connect with a power source plug (i.e. three prong-to-two prong converter).

2. Locate this device as far away as possible from other electronic equipment. These products are suitable for hospitals or clinics except for near active HF surgical equipment and the RF shielded room of and medical system for magnetic resonance imaging, where the intensity of EM disturbances is high..

3. Be sure to use only the cables provided by or designated by VINNO company. Connect these cables following the installation procedures (i.e. wire power cables separately from signal cables).

4. For designation of the Peripheral Equipment Connectable to this Product, refer to the operator manual. These Peripherals can be connected to the product without compromising its EMC performance.

5. Avoid using equipment not designated for this device. Failure to comply with this instruction may result in poor EMC performance of the product.

6. Notice against Operator Modification:

Never modify this product. Unilateral operator modification may cause the degradation in EMC performance and may lead to the serious hazards for the patient and the operator.

Modification of the product includes:

a. Changes in the cables (length, material, wiring etc.)

b. Changes in the system insulation/layout.

c. Changes in the system configuration/components.

d. Changes in the securing system parts (cover open/close).

7. Operate this device with all covers closed. If a cover is opened for any reason, ensure that is shut before starting/resuming operation.

NOTE: Operating this device with any cover open may affect EMC performance.

Essential performance

The ability to display physiological images as input for diagnosis by trained physician.

The ability to display physiological traces as aid for diagnosis by trained physician.

The ability to display quantified data including distance, angle, square, etc, as input for diagnosis by trained physician.

The display of ultrasound indices as aid for safe use of the unit

The applied parts of the device, i.e. probes, ECG, shall not produce excessive leakage currents, as defined by IEC 60601-1.

The device shall not produce unintended or excessive ultrasound output energy that exceeds safe limits defined by IEC 60601-2-37

The device shall maintain contact temperatures of applied parts at safe limits, as defined by the IEC 60601-2-37

The device shall not produce nor be influenced by electromagnetic interference that exceeds safe limits, as defined by IEC 60601-2-37

The applied parts of the device, i.e. transducer assemblies, shall be protected against ingress of liquids for a min. rating of IPX7, as defined by IEC 60601-2-37



Do not use the following devices near this VINNO Ultrasonic system: Devices which transmit radio waves such as cellular phones, radio transceivers, mobile radio transmitter, radio-controlled toy, etc. Use of these devices can cause this VINNO Ultrasonic system to perform outside the certified specifications. Keep these devices powered off when kept near this device.

Medical staff in charge of this device is required to instruct technicians, patients and other people who may be around this device to fully comply with the above regulations.

Endocavity probes can't be used on body surface, if the probe is energized, it will not meet the electromagnetic compatibility requirements, may cause harmful interference to other devices in the environment.

All endocavity probes are certificated by EMC.



Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased

electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Information of all the cables					
Port No.	Name	Type*	Cable Max. >3m	Cable Shielded	Comments (Sip/Sop lines must include description of use)
0	Enclosure	N/E	—	—	
1	Mains	AC	>3m	Unshielded	AC mains port
2	Probe	PC	<3m	Unshielded	Ultrasound diagnostic
3	ECG	PC	>3m	Unshielded	Only to be used for reference purposes in normal ultrasound scanning
4	USB (2 pcs)	SIP/SOP	<3m	Shielded	USB port for data transmission, for connection with USB device
5	LAN	SIP/SOP	>3m	Unshielded	For connection of the EUT to local area network
6	USB port for printer	SIP/SOP	>3m	Shielded	For connection to external printer
7	Foot switch	SIP/SOP	>3m	Unshielded	Signal port for connection to foot switch
8	VCR audio output	SIP/SOP	<3m	Shielded	Audio port for connection to external sound box
Supplementary information:					
*Note: AC = AC Power Port; DC = DC Power Port; N/E = Non-Electrical; Batt=Battery					
Sip/Sop = Signal Input/output Port; PC – Patient-Coupled Cable; TP = Telecommunication Ports					



WARNING

Even though this product comply with EMC requirements for a Group 1, Class A Medical device as stated in IEC 60601-1-2, this equipment still can be electromagnetic influenced by other electronic equipment

The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Electromagnetic emission:

Guidance and manufacturer's declaration – electromagnetic emissions	
This device is suitable for use in the specified electromagnetic environment and it has meets the following standard's emission requirements.	
Phenomenon	Professional healthcare facility environment

Conducted and radiated RF emissions	CISPR 11, Group 1, Class A
Harmonic distortion	IEC 60601-3-2, Class A
Voltage fluctuations and flicker	IEC 61000-3-3



WARNING

Radiated, conducted electromagnetic signals or electrical fast transient pulse group can cause distortion, degradation, or artifacts in the ultrasound image which may impair the ultrasound system's essential performance.

Electromagnetic immunity:

Guidance and manufacturer's declaration – electromagnetic immunity		
This device is suitable for use in the specified electromagnetic environment and it has meets the following immunity test levels. Higher immunity levels may cause the device's essential performance lost or degraded.		
Phenomenon	Basic EMC standard or test method	Professional healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air
Radiated RF EM fields	IEC 61000-4-3	3V/m 80MHz-2.7GHz 80%AM at 1 kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances"
Rated power frequency	IEC 61000-4-8	30A/m; 50 Hz or 60 Hz
Electric fast transients	IEC 61000-4-4	±2kV, 100kHz repetition frequency
		For input a.c. power port; d.c. power lines or signal input/output lines whose length exceeding 3m
Surges	IEC 61000-4-5	Line to line: ±0.5kV, ±1kV Line to earth: ±0.5kV, ±1kV, ±2kV
		For input a.c. power port; all d.c. power ports connected permanently to cables > 3m; Output signal output lines connected directly to outdoor cables
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V in 0.15 MHz - 80 MHz 6 V in ISM and/or amateur radio bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz or 2 Hz (test performed at 2 Hz is worst case as identified for risk management) (system compliant to 10 V immunity test level)
		For:

		input a.c. power port; All d.c. power ports connected permanently to cables > 3 m All patient-coupled cables SIP/SOP whose maximum cable length $\geq 3\text{m}$
Voltage dips	IEC 61000-4-11	0% UT: 0.5 cycle at 0o, 45o, 90o, 135o, 180o, 225o, 270o and 315o
		0% UT: 1 cycle and 70% UT: 25/30 cycle sine phase at 0o.
Voltage interruptions	IEC 61000-4-11	0% UT: 250/300 cycle
UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60 Hz		



WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Recommended separation distances:

Recommended separation distances between portable and mobile RF communications equipment and this device						
Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or system's basic safety and essential performance may be affected. This VINNO has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2: 2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this ultrasound diagnostic system as recommended below.						
Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460 RFS 460	FM ± 5 kHz Deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800;		2	0.3	28

1845		CDMA 1900; GSM 1900; DECT; LTE Band 1,3,4,25; UMTS	Pulse modulation 217 Hz			
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE B	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

3 Start the system

3.1 General

The first installation must only be performed by authorized personnel. The system has a default setting which is applicable for most cases. Experienced operator can change the default setting and store it as an operator-defined setting.

This device must be in the proper environment. This applies to in the operation, storage and transport. Requirements of the environments are listed as shown below:

Requirement	Temperature	Humidity	Air pressure
Transport/shipping	-5 - 50°C	10 - 80%	700 - 1060 hPa
Storage	-5 - 50°C	10 - 80%	700 - 1060 hPa
Operation	10 - 40°C	30 - 75%	700 - 1060 hPa

3.2 Safety warnings



CAUTION

When this device is moved from a cold environment such as the stock room into a warm room, it is necessary to wait several hours for the machine to dehumidify before starting the machine due to the temperature change of the environment.

3.3 Power on / Boot up

1. Connect the power cable to this device. Plug the power cable into a hospital grade power socket with the proper rated voltage.
2. Or use the battery.
3. Push the "Standby" switch on the control panel. After the system is switched on and booted up for a couple of minutes, the 2D image for the previously selected transducer is displayed. If no probe is connected in the previous selected transducer, the "Probe & App" menu will appear the touch panel screen so that select probes operator. All peripherals which are connected to the outlets of this device can be switched on only after the system is switched on.



4. The color of “Standby” button: Orange means standby, green means on.



WARNING

The MAINS plug or an appliance coupler is used as the disconnect device, the disconnect device shall remain readily operable.

3.4 Power off / Shutdown



CAUTION

To avoid loss of the current patient data as well as all the measurement data, it is necessary to save the data to one patient in any mode menu of the touch panel screen before switching off this device. If not saved, this device will display a warning after re-booting.

Push the “ON/OFF” switch on the control panel to shut down the system.



WARNING

System shutdown using the “Standby” button does not disconnect the ultrasound unit from the main voltage. To disconnect the ultrasound unit from the main voltage after the system shutdown, plug out the power cable from the main outlet.

3.5 Probe and application selection

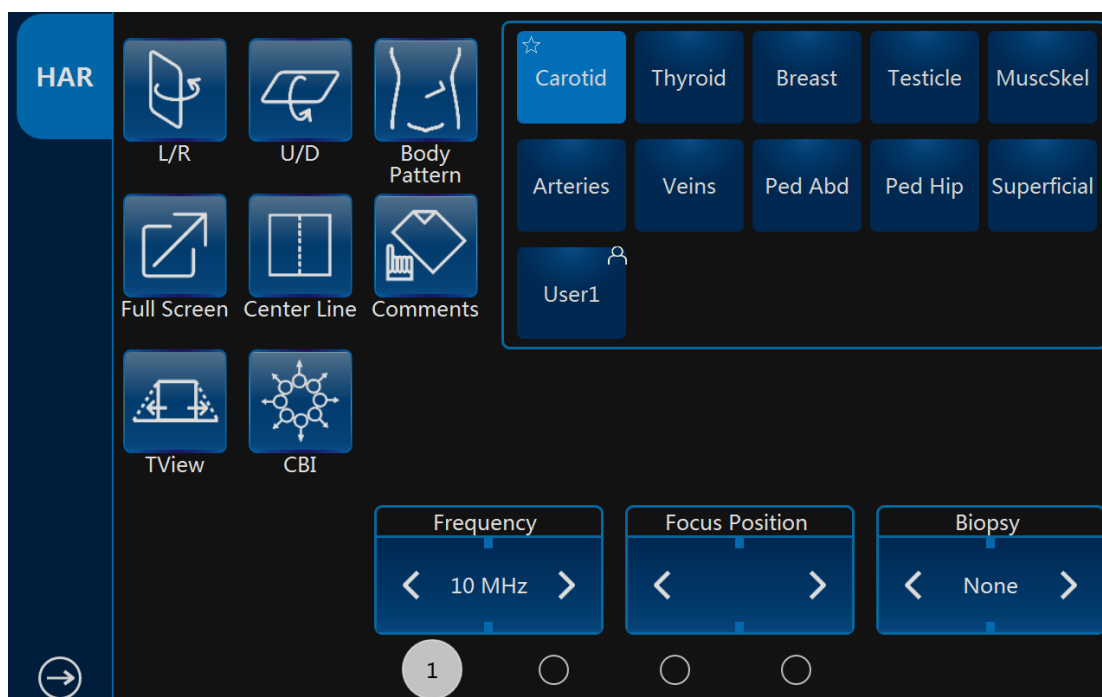
3.5.1 Plug probe connector into this device

The probe plug process is as follows:

1. Plug the probe connector into an available probe slot.
2. Push the lock on the top of the probe connector to lock the connector.

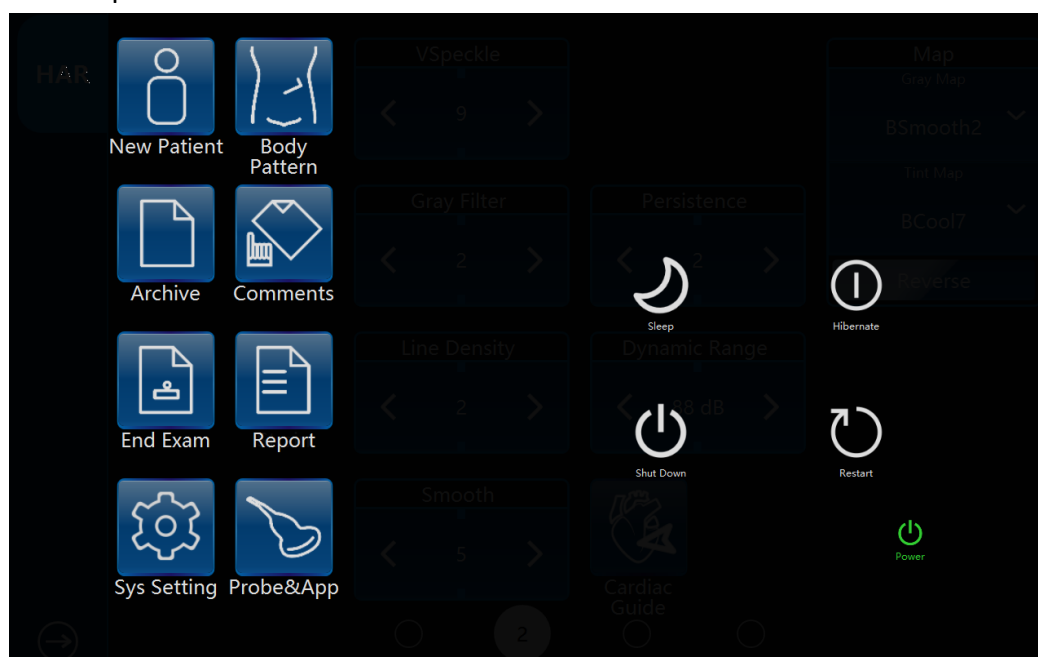
3.5.2 Probe and application selection

Select application on the first page of the main menu as below.

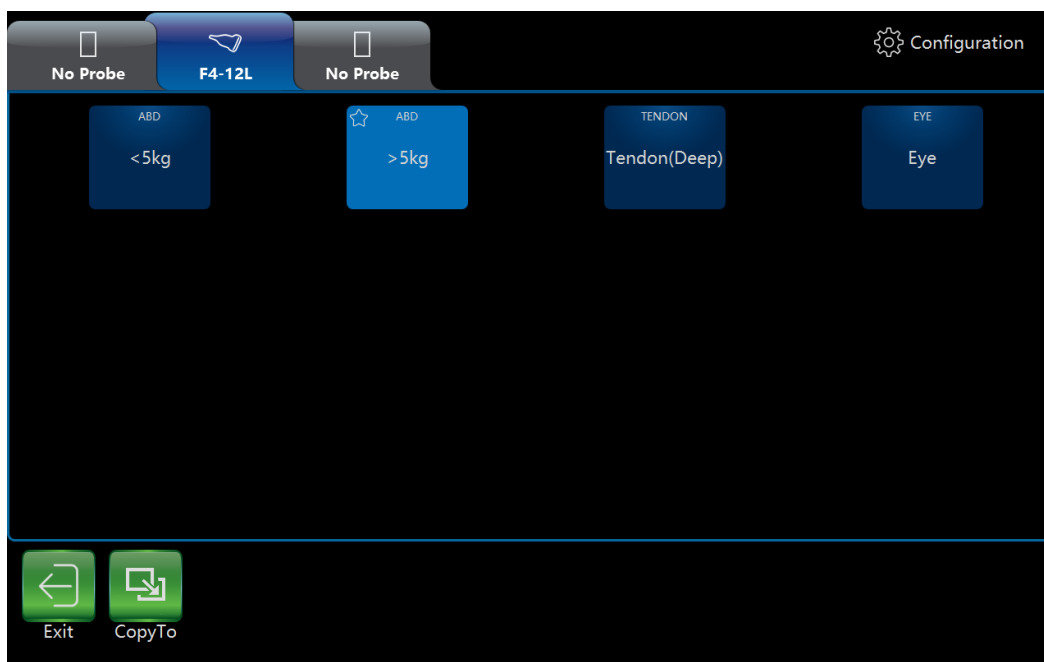


Operator defined setting:

Slide the touch panel from the left edge, open the menu as below. In this menu, "New Patient", "Archive", "End Exam", "Sys Setting", "Body Pattern", "Comments" and "Report" can be selected.



Select "Probe&App", in this page the operator can rename the user-defined application, set one application as default, and reset all changes. And also add one user-defined application, or delete one user-defined application.



Touch “Edit”, applications can be hidden by un-selecting them.

3.6 Image Storage

Select “Store to HDD” to save VRD, DICOM or AVI image to the system hardisk, select “Store to USB” to save VRD, DICOM or AVI image to the connected USB device. In system setting, the format of storing image can be configured, please refer 12.4. In 3D/4D mode, the operation of image storage is similar.

The image saved in the hardisk will be displayed in the clipboard. The operator can select the saved images after enable “Cursor” to replay. Save the image during scanning, it will be cine. Save the image after freeze the system, it will be one frame. When replay one cine image saved in 3D/4D mode, the operator needs to select “Auto Rotate” or “Auto Cine”.

Please use the specified USB device.

Show “<” and “>” at the bottom of the clipboard. Click “<” to replay the previous image, click “>” to replay the next image.

3.7 Freeze image

Pressing “Freeze” on the bottom right of the control panel enables the system to switch from the scan mode to the frozen mode. When the key is orange backlit, it is in frozen mode which means the image is static. When the key is green backlit, it is real scan mode in which the scan image is in real time.

Select “New Patient”, “Archive”, “Probe & App”, “Sys Setting” or “Body Pattern”, the system will switch to frozen mode.

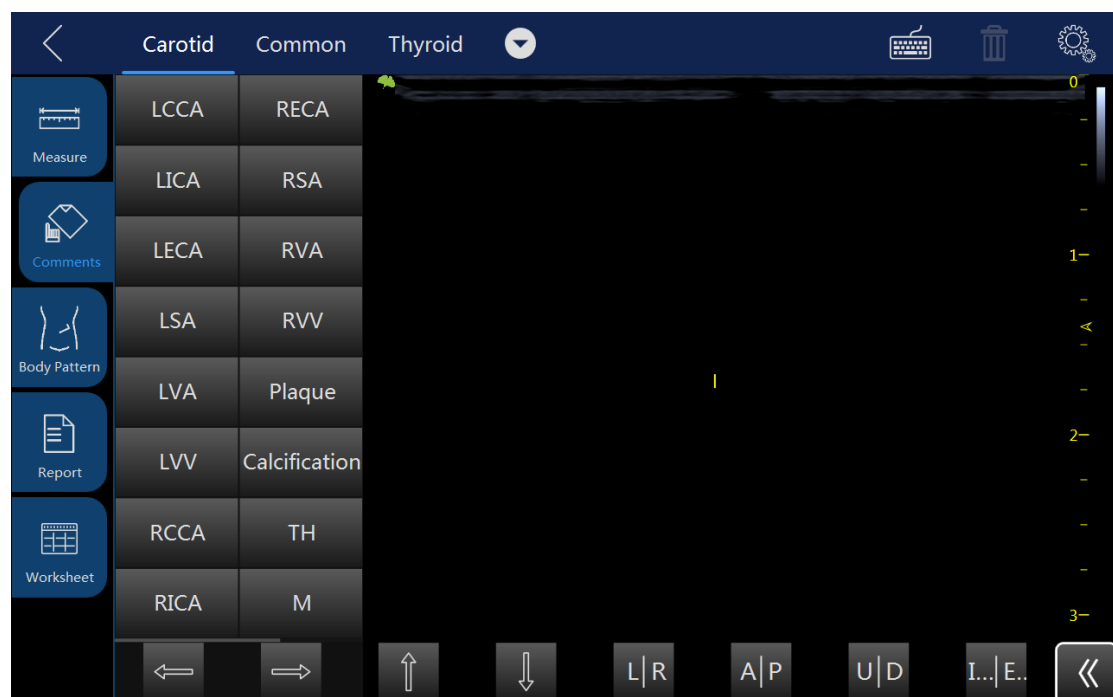
3.8 Patient data

Normally the operator needs to input a new patient's information before scanning the new patient. Alternatively, pull up an old patient's data from the archive for a new examination of the old patient. Read chapter 4 for reference.

3.9 Image Annotation

3.9.1 Character Annotation

Select "Comments" button.



After the "Comments" is selected, the touch screen will display as above. On the left side there are some frequent terms to be selectable in order to quickly add those comments to the image screen by dragging those terms. Those words will be different based on different applications and probes.

Select and hold a certain section of the image area, and after that an alphanumeric keyboard will appear for adding annotations. By touching and holding the previous comment, it can be edited. After the other field is selected, the previous annotation will become a confirmed annotation.

The operator can add their own terms in configuration page.


After the trash icon is selected, this button will be highlighted and there will be a delete sign appearing besides each comment, the comment can be deleted by

touching the delete sign. After the “Delete” is selected again, this key will return to normal and the delete sign for each comment will disappear.

Alphanumeric keyboard shown as shown below



Notes:

1. Select “CapsLock”, operator can input capitals.
2. Select “⇧”, operator can input symbols.
3. Select , the alphanumeric keyboard will be closed.

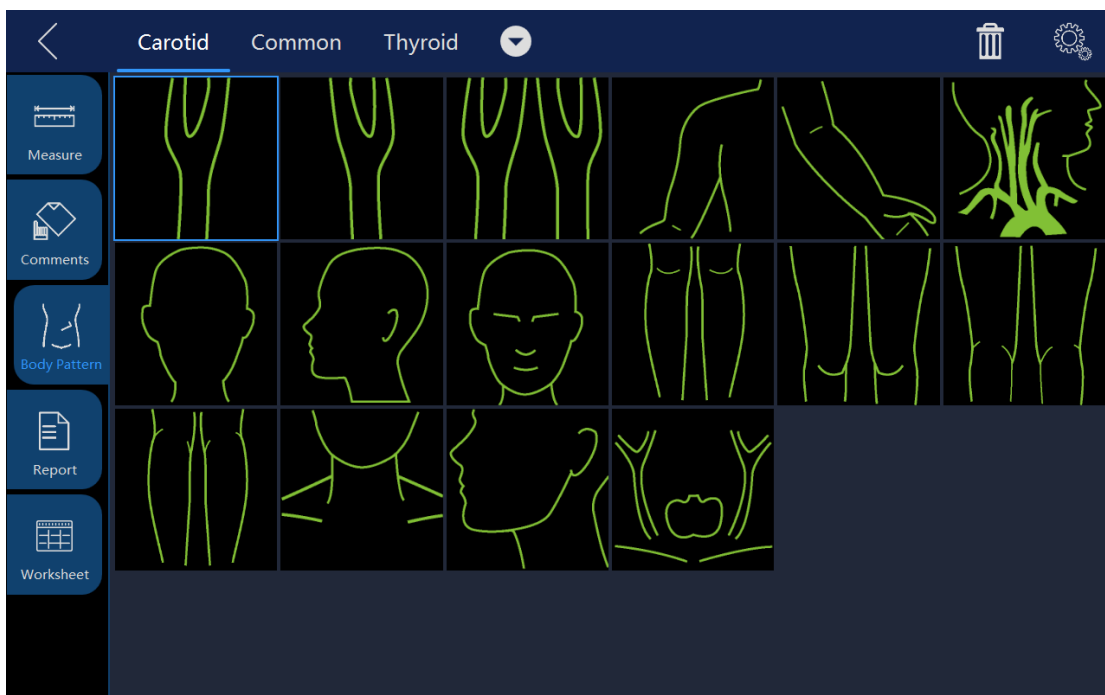
3.9.2 Arrow Indicator

Drag arrow indicators on the comment screen to move them to the image area to indicate the nidus. Arrow can be rotated after it is selected.



3.9.3 Body Pattern

After the “Body Pattern” is selected, all body patterns will display for the operator to select. After one of those patterns is selected, the body pattern box will turn green and the body pattern will appear on the bottom-right side of the image screen for reference. Now, rotate “Rotation/Steer” key to change the probe indicator’s orientation in the body pattern. Use the trackball to move the probe indicator in the different position of the body pattern symbol. The touch panel will go back to the previous menu by selecting “<”. Enable “Cursor” key, and put the cursor on the body pattern, then move the trackball to change the body pattern’s position. Press “Enter” to fix the body pattern’s position.

The touch panel screen after entering the body pattern status is as shown below:

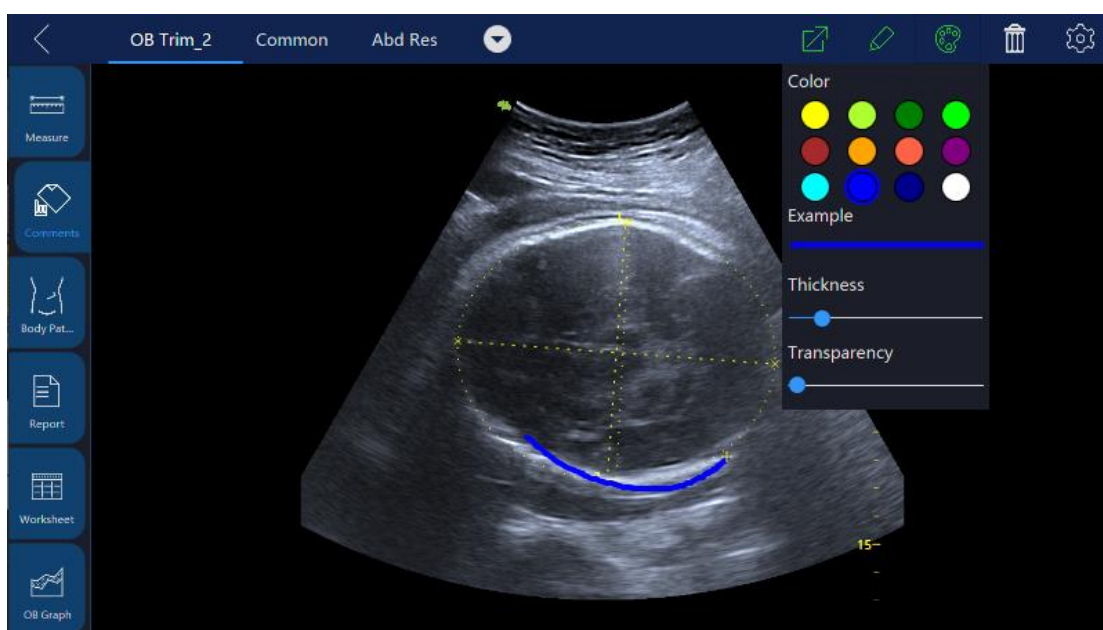



Select different applications can show different body patterns.

Select  to enter configuration page, select  to import body patterns from a USB memory stick. In this case, the operator has to copy a body pattern from his own PC in JPEG, BMP, PNG format.

In system setting, the size of body pattern can be adjusted, please refer 12.1.

3.9.4 Use finger to draw comments



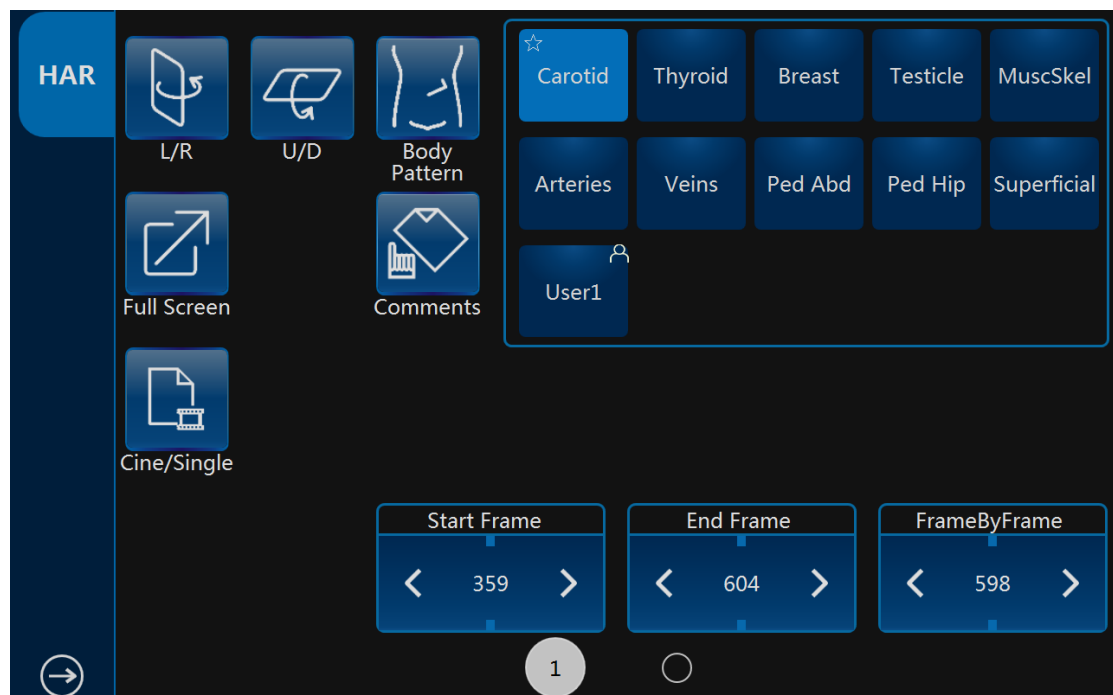
Touch  and then use finger to draw comment mark in free style. The mark color, thickness, and opacity can be adjusted.

3.10Cine Mode

While scanning a certain number of frames, the most recent examination images sequence will be stored in the cineloop memory after “Freeze” key is pressed. The sequence will be replayed continuously. By moving the trackball horizontally the sequence can be reviewed frame by frame. This length of cineloop depends on the number of the scan lines, the scan depth and other parameters.

In freeze mode, the touch panel UI is as shown below.

Adjusting the parameters on the touch panel UI can manage the image.



Note:

1. Cine/Single: can switch the display image from the cine mode to the single image mode. Highlighted button means cine mode and non-highlighted button means single mode. The time span of auto cine can be configured in “Sys Setting”.
2. Start Frame, End Frame: control which frame to start from and which to end in order to display continuously as a loop.
3. Speed: controls cine speed as 400%, 200%, 100%, 60%, 50%, 40%, 20%.

3.11 Zoom function

After “Depth” key is pressed, the system will enter pre-zoom mode, press “Depth” key again enter zoom. In zoom mode, there are two image displays. The normal image with ROI is on the left. The zoomed image is on the right. Use the trackball to move the ROI position. Rotating the “Depth” key can make the amplification smaller or larger. Clockwise makes the ROI size smaller, but a larger amplification can be achieved. Alternatively, a counterclockwise rotation makes the ROI larger, but the amplification is smaller.

3.12 ECG Trace

EKG modulį sudaro viena jungtis į kurią galima įkišti elektrodų laidų komplektą. Nuskaitymas vaizdas sinchronizuojamas su EKG pėdsakais. M arba PW/CW režimu sekimas sinchronizuojamas su konkrečiu nuskaitymu. Naudodami atitinkamus klavišus pagrindiniame kiekvieno režimo meniu, sureguliuokite tokius parametrus kaip stiprinimas, padėtis ir pėdsakų nuskaitymo greitis.

3.12

The ECG module consists of a single connector into which a set of electrode cables can be inserted. The scanning image is synchronized with the ECG traces. In M or PW/CW mode, the trace is synchronized to the particular scanning. Adjust parameters such as the gain, position and scanning rate of the trace using the relevant keys in the main menu of each mode.



CAUTION

Do not use the ECG waveform of this device for diagnosis or monitoring. It is only to be used for reference purposes in normal ultrasound scanning.

Connecting the internal ECG:

The ECG cable is a modular cable consisting of two different cable parts:

- The Trunk: a single cable connecting to this device is at one end with a six-pin plug, and a cable splitter device at the other end.
- A triple color-coded electrode cable: each electrode cable is attached to the corresponding electrode by a color-coded press-on type connector.

The electrode complies with IEC standards. Names and color codings refer to the following description:

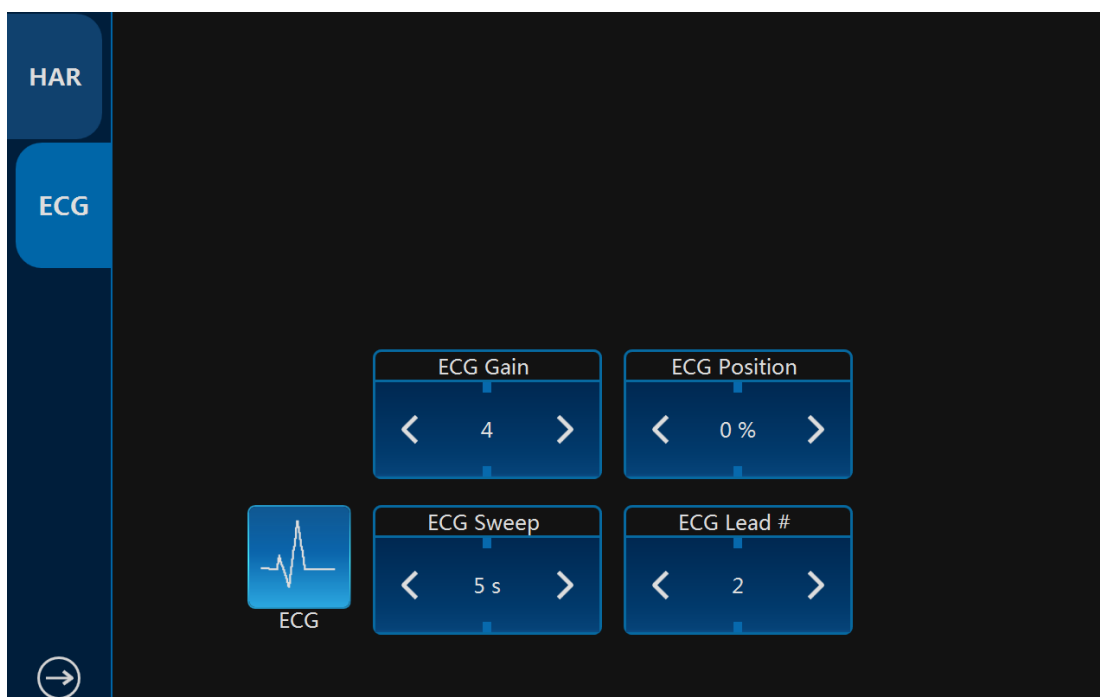
Yellow (L): p/n 412680-106

Red (R): p/n 412680-108

Black (N): p/n 412680-107

3.12.1 ECG trace operation

ECG: There is an ECG button in the menu of every mode. The operator can enable or disable it. After it is enabled, the button is highlighted and ECG menu will display. It is enabled by default in Cardiac applications.



In ECG menu, adjust several parameters by up/down buttons, such as the ECG Gain, the ECG position, the ECG Sweep, and the ECG Lead#.

ECG Gain: The amplitude of the ECG wave can be changed.

ECG Sweep: To change lateral scan, adjust the speed of the ECG wave. This function is available only in 2D and CF mode. This parameter is adjusted by selecting the “ECG sweep” button on the touch panel. ECG sweep speed is the same as M mode and PW lateral scan sweep speed. Alternatively, sweep speed can be adjusted in M and PW mode.

ECG Position: This can be moved up and down in order to position the ECG of the relevant imaging as desired.

ECG Lead #: This allows the operator to select which lead’s ECG wave to display on the screen.

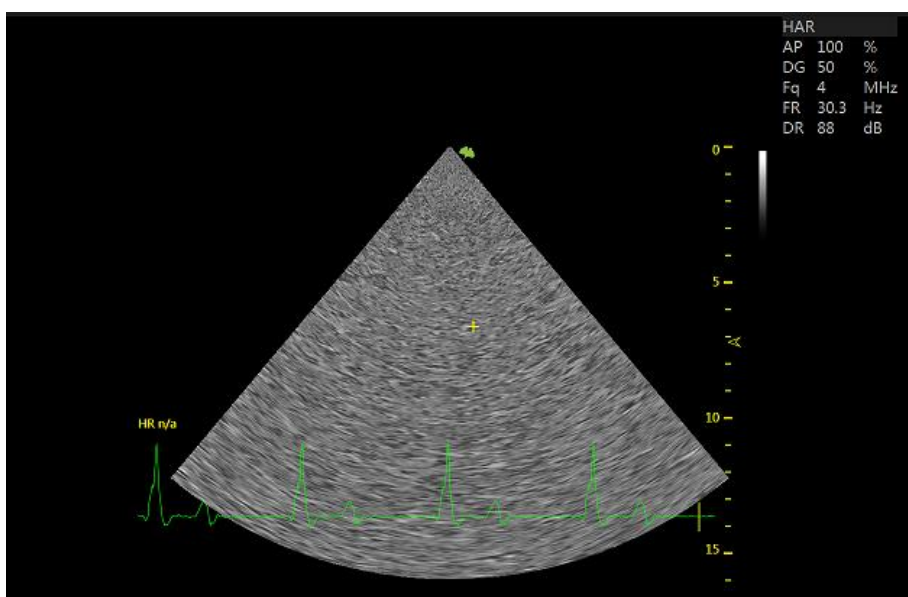
The ECG wave of different leads can be selected as follows:

- Lead I: Record ECG between the right arm and the right leg.
- Lead II: Record ECG between the right arm and the left leg.
- Lead III: Record ECG between the left arm and the left leg.

The ECG signal input can be either from an internal or external ECG device. The internal input is to connect the standard electrode leads to this device, so that the operator can access the ECG wave in the system. The external input means that connect one special cable to connect with an external ECG device which inputs the ECG signal to this device.

Note: To connect an external ECG device, a special cable is available. Please contact VINNO to obtain.

The ECG trace image displays in the screen as shown below:



3.13 Multiple display formats

This operation which described hereby is only for B mode, CF/PDI mode, PW/CW mode and M mode. 3D and 4D mode operations are different from these operations; the operator can refer to the 3D and 4D chapters accordingly.

There are two approaches to have multiple display formats. One is to press “L” and “R” keys. The other is to select buttons on the touch panel (“Dual”, “Quad”, and “A”, “B”, “C” and “D”).

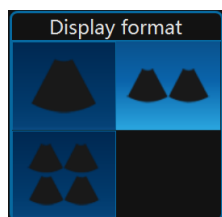
“Left” and “Right” key to be dual display:

If the initial format is single image display, after “Left” on the control panel is pressed, the system will display two images. The left side image is real time and the right image is the last frame static image at the same mode. By pressing “Left” again, the system returns to the single image display. Pressing “Right”, the right image will be real time and the left side image will be the last frame static image.

If the initial format is single image display, after “Right” on the control panel is pressed, the system will display two images. The right image will be real time and the left side image will be the last frame static image at the same mode. If “Right” is pressed again, the system will go back to the single image display. If

“Left” is pressed, the left side image will be real time and the right image will be the last frame static image.

Use “Dual” button on the touch panel to go into dual display format:



(The first button is single display, the second is dual and the third one is quarter.)

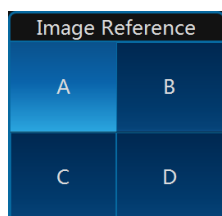
After “Dual” on the touch panel is selected, the system will have dual image display. “A” position image will be real time and “A” button will be highlighted by default. “B” position image will be last frame static image at the same mode.

Select “B” button to active the “B” position image. The “B” button will be highlighted.

Selecting the single display format button will go back to the normal one image display.

Use “Quad” button on the touch panel to go into quarter display format:

“A”, “B”, “C” and “D” button are as shown below:



After “Quarter” on the touch panel is selected, the system will have quarter image display. “A” position image will be real time and “A” button will be highlighted by default, and the “A” button is highlighted. The “B”, “C” and “D” are the last frame static image.

Select the “B”, “C” or “D” button to activate “B”, “C” or “D” position image. Only one image can be activated at one time.

3.142D Image size change

In B mode, slide the touch panel to the left. There is a parameter “Image Angle”. These parameters are used to adjust the image size.

3.15 Customized UI Layout

Users can enable it from this interface:

"System Setting->UI style->Adjust Param Layout"

It mainly realizes the following functions:

- Redefine the layout of buttons on the interface.
- Redefine the size of probe application area.
- Redefine the parameters corresponding to the spin buttons.
- Different applications can define different layouts.

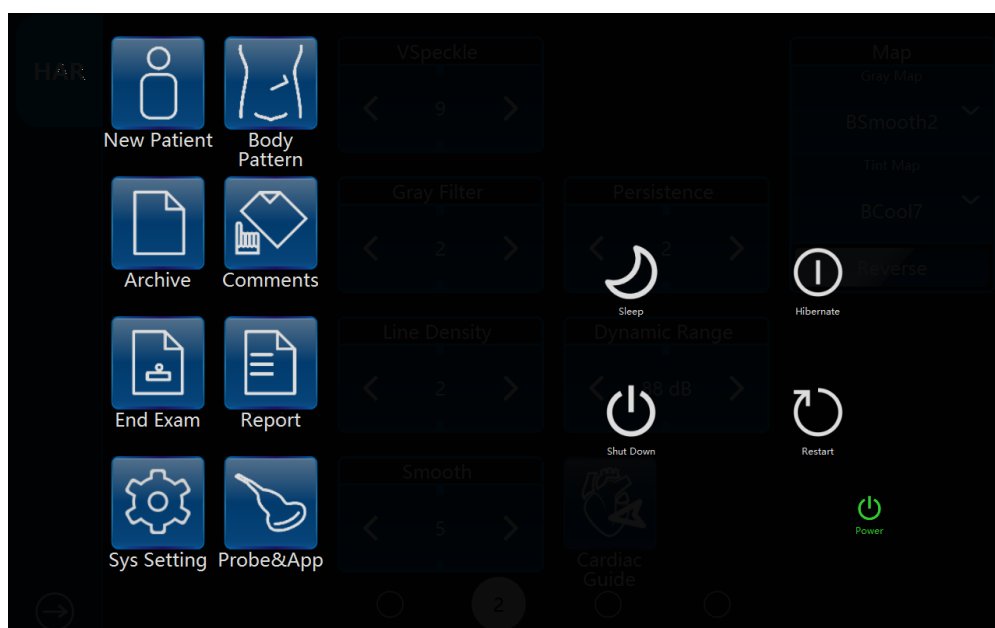
3.16 VWork

VWork can be enabled from this interface "System Setting->Optional functions->VWork", which supports to add twelve kinds of commonly used interfaces and functions into the step.

Users can perform the following operations:

- Define a workflow, unit or steps, and then the machine will automatically run according to predefined steps.
- Run/Ignore/Redo specific steps
- Clone the factory sample and modify the unit/steps, or create new steps from stretch.

3.17 Hibernate



Hibernation mode can be set in functions of System Setting.

- Enter System Setting, choose “Power Saving” in Function of General.
- “Power Key Options” can be change between “Shut Down” and “Hibernate”.
- Choose “Hibernate”, the system will switch to hibernation state after put off the power key. Or choose “Shut Down”, the system will be off directly when put off the power key.

(Hibernation only apply to windows 10 system.)

4 Prepare for an examination and Patient data archive

Before starting an examination, it is recommended to enter a new patient's information before begin to scan. The patient information can also be entered while scanning, but the operator has to determine whether the corresponding image belongs to the patient or not before storing. The operator can pull out the patient's information from the archive and start a new examination. The patient information is the same as before.

For new patient information, the recommendations are as follows:

1. Patient ID.
2. Patient name.
3. Birth date/age, gender.

This is stored together with the patient's images and will be transferred with the images of the corresponding patient to the archive.

The information and application data below may differ in different examinations and we recommend that it should also be entered.

1. Physician, operator.
2. Basic data in relevant application category.

4.1 Beginning a New Patient

After "New Patient" on the touch panel is selected, the system will be in frozen status and the "Freeze" key on the control panel is highlighted to show this. The patient screen will be displayed as shown below. Press "Freeze" on the control panel or select "X" on the touch panel to go back to the main menu without saving the information. If the operator inputs some information on this page, and select "v" the system will create a "new patient" record and store this information to start scanning.

When enter "New Patient" page, there will be an auto ID in "Patient ID", the operator can use this ID or input her/his own one. If set "prefix" in system setting, the prefix will be added.