PHILIPS

IntelliVue

X3

Multi-Measurement
Module and
Patient Monitor

Monitoring on the move

Philips 867030 technical data sheet

For software revision M.0

"IntelliVue X3" yra kompaktiškas, universalus ir nešiojamas pacientų stebėjimo prietaisas su spalvotu jutikliniu ekranu.

1.2.1.1. The IntelliVue X3 is a compact, versatile, and portable patient monitoring device with a color touchscreen display. The state-of-the-art display with its modern multi-touch screen allows easy interaction by sliding and tapping with one or two fingers - smartphone style.

Chemically resistant housing together with Antimicrobial Corning® Gorilla® Glass designed for improved damage resistance, make the X3 a robust monitor designed to withstand challenges associated with in-hospital mobile monitoring.

Full integration into the IntelliVue patient monitoring solution helps providing best possible care for patients across all levels of acuity and supports institution-wide standardization. A dual-purpose patient monitor, the X3 can be used as:
· A multi-measurement module for the IntelliVue family of patient monitors.
· A stand-alone patient/transport monitor.

By automatically turning from a multi-measurement module into a fully functional transport monitor, without the need for changing cables on the patient, the X3 supports the streamlining of clinical workflows and reduces transport preparation time.

The X3 can simultaneously monitor ECG (using 3-, 5-, 6-,

Monitorius saugo duomenis tendencijų duomenų bazėse. Galite matyti lentelių tendencijas (gyvybinius parametrus) ir dokumentuoti jas spausdintuve, prijungtame prie centrinės stoties arba arba pagrindiniame (paciento) monitoriuje.

or 10-lead sets, including arrhythmia and ST monitoring), respiration, SpO_2, NBP, two invasive pressures, temperature, and CO_2.

The X3 can be used with adult, pediatric, and neonatal patients in a hospital environment and during patient transport inside hospitals. The monitor stores data in trend databases. You can see tabular trends (vital signs) and document them on a printer connected to a central station or a host monitor. You can view measurement trend graphs, including horizon trends, to help you identify changes in the patient's physiological condition.

1.2.3.1. The monitor can operate using battery power for over five hours with basic monitoring configuration (see page 8) to let you reliably monitor patients during in-hospital transfer.

The X3 is powered from one of the following sources:
· A user-exchangeable rechargeable battery. **1.2.3.2.**
· A host monitor, for example, an MX500 connected to the X3. **1.2.1.2.**
· AC mains using the optional docking solution IntelliVue Dock (867043), or the External Power Supply (M8023A).

During in-hospital transport the measurement extensions (867039, 867040, and 867041) are powered by the X3, without requiring the use of the IntelliVue Battery Extension (865297).

12 EKG derivacijų monitoravimas, naudojant 5 EKG elektrodus (kabelius), naudojant EASI metodą

Measurement Features

- Compact, rugged, lightweight monitor with a comprehensive set of built-in clinical measurements.
- ECG monitoring using any combination of 3 to 10 electrodes.
- 12-lead ECG monitoring with five electrodes using the EASI placement method, with six electrodes using the Hexad placement method, or with 10 electrodes using conventional electrode placement.
- Multi-lead arrhythmia, and ST segment analysis at the bedside on all available leads.
- Mainstream/sidestream CO_2
- Second Philips FAST SpO_2[1] for Dual SpO_2 applications
- Dual[2] invasive pressure, and a temperature measurement.
- Choice of Philips FAST SpO_2, Nellcor[3] OxiMax SpO_2, Masimo[4] rainbow SET SpO_2.
- With the Masimo rainbow SET technology, the measurement device has options to monitor SpCO, SpMet, SpHb/SpOC, PVI, and rainbow acoustic (RRac) measurements.
- IntelliVue XDS Database, enables the collection and storage of vital signs information (numeric data only – no waves), for example, heart rate, pressure, … on an external SQL database.

6.1 colio įstrižainės modernus TFT tipo ekranas

Usability Features

- Capacitive multi-touch screen as input device.
- Intuitive smartphone-style operation.
- **1.2.2.2.** • 6.1 inch state-of-the-art TFT flat-panel display with 1024 x 480 resolution, wide viewing angle, large numerics, permanently visible alarm limits[5], and up to five real-time
- **1.2.2.4.** waves. **kreivių vaizdavimas (maks. iki 5) realiu laiku**
- Ambient Light Sensor for optimal backlight brightness.
- Multiple screen layouts to adapt to various clinical scenarios.
- Screen layouts are easily adjustable, allowing flexible display of measurement information.
- The monitor can be used in either the vertical or horizontal position, the display adapts to the orientation.
- Simple menu hierarchy and customizable SmartKeys provide fast access to all primary monitoring tasks.
- Temperature, height, and weight can be configured either in metric or imperial units. Pressure measurements can be displayed in kPa or mmHg. Gases can be displayed in kPa, or mmHg.
- Patient data management with tabular and graphic trends.
- Settings "Profiles" for rapid case turnover.
- Patented "AutoLimits" help caregivers to manage alarms more effectively.
- Timers application lets you define and set clinical timers to notify you when a specific time period has expired.
- Capable of functioning in a wireless infrastructure (Smart Hopping – 1.4 GHz, or WLAN).
- Additional independent display capability using IntelliVue XDS Remote Display.
- Bedside information access using the IntelliVue XDS Clinical Workstation.

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1. Only available with Philips FAST SpO_2

2. Enabling dual pressure capability requires the use of a dual pressure cable or dual pressure adapter. See "Invasive Pressure Accessories" on page 23 for related options.

3. The following are trademarks and registered trademarks of a Medtronic company: Nellcor, OxiMax.

4. The following are trademarks and registered trademarks of the Masimo Corporation: Masimo, SET, rainbow, rainbow acoustic.

5. Dependent on screen layout.

- Ergonomic carrying handle. (optional).
- User exchangeable battery.

Indications for Use

The monitor is indicated for use by health care professionals whenever there is a need for monitoring the physiological parameters of patients.

The monitor is intended to be used for monitoring and recording of, and to generate alarms for, multiple physiological parameters of adults, pediatrics, and neonates. The monitor is intended for use by trained health care professionals in a hospital environment.

The monitor is also intended for use during patient transport inside the hospital environment.

The monitor is only for use on one patient at a time. It is not intended for home use. Not a therapeutic device. The monitor is for prescription use only.

Rx only: U.S. Federal Law restricts this device to sale by or on the order of a physician).

The ECG measurement is intended to be used for diagnostic recording of rhythm and detailed morphology of complex cardiac complexes (according to AAMI EC11).

ST segment monitoring is intended for use with adult patients only and is not clinically validated for use with neonatal and pediatric patients.

The Integrated Pulmonary Index (IPI) is intended for use with adult and pediatric (1 to 12 years) patients only. The IPI is an adjunct to and not intended to replace vital sign monitoring.

The derived measurement Pulse Pressure Variation (PPV)[6] is intended for use with sedated patients receiving controlled mechanical ventilation and mainly free from arrhythmia. The PPV measurement has been validated only for adult patients.

Hospital Environment

The monitor is suitable for use in all medically used rooms which fulfill the requirements regarding electrical installation according to IEC 60364-7-710 "Requirements for special installations or locations – Medical locations", or corresponding local regulations.

Main Components

Monitor

The monitor has a color TFT display with a wide viewing angle, providing high-resolution waveform and data presentation. The display, processing unit, and measurements are integrated into one device.

User Interface

The color graphical user interface is designed for fast and intuitive operation, and ensures that clinicians quickly feel at ease using the monitor.
- Configurable SmartKeys with intuitive icons allow monitoring tasks to be performed quickly and easily, directly on the monitor screen.
- Waves and numerics are color coded, colors are customizable.
- The monitor displays up to five waves simultaneously. For

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6. Not available in the USA and territories relying on FDA market clearance.

12-lead ECG monitoring, it can display 12 real-time ECG waves, with a rhythm strip and all ST values.
- Flexible screen layout allows you to quickly adapt to different clinical scenarios, for example, from your standard monitoring screen, to for example, to a Big Numerics screen, or to 12-lead monitoring to acquire a diagnostic 12-lead ECG.
- Change to a different screen layout by simply swiping – with two fingers – across the screen.
- The Basic Help provides on-screen operating help, explaining INOP and alarm messages.
- Screen content automatically adjusts to the monitor orientation.

1.2.2.5.

- Usability evaluated through usability study conducted by an independent human factors consulting group.

Touchscreen

The monitor is supplied with a capacitive multi-touch screen. Touch a screen element to get to the actions linked to that element, for example, touch a measurement numeric and the setup menu for that measurement opens. Touch a wave to enter the setup menu for that wave. To scroll through lists and menus you can "swipe" over the screen, similar to using a smartphone. The touchscreen supports the use of medical gloves.

Simulated Keyboard

If alpha or numeric data entry is required, for example to enter patient demographics, an on-screen keyboard will automatically appear on the screen.

Mounting

The mounting options available enable flexible, space saving placement of the monitor for an ergonomic work space.
- Bedhanger Mount - ideally suited for mounting the IntelliVue X3 during in-hospital patient transport. When mounted the monitor is facing upwards to support direct access to the monitor screen.
- Fix Clamp Mount - ideally suited for mounting the IntelliVue X3 for stationary use to, for example, an IV pole or wall-mounted rail.
- Rotatable Quick Claw Mount - ideally suited for mounting the IntelliVue X3 during or following in-hospital patient transport. Enables quick release and supports the rotation of the mounted monitor.

Extending Measurements

The X3 is compatible with Philips measurement extensions. The extensions allow you to add specific measurements to those already integrated into the X3. The measurement extensions connect to the X3 and use the X3 settings. Trend data and measurement settings from the measurements in the extensions are stored in the X3.

Measurement Extensions

- The **867039 Hemodynamic extension**: adds temperature, two pressures, and optionally cardiac output/PiCCO to the X3.
- The **867040 Capnography extension**: adds mainstream/ sidestream capnography, and optionally temperature, two pressures, and cardiac output/PiCCO[1] to the X3.
- The **867041 Microstream CO_2 extension**: adds Microstream CO_2, and optionally temperature, two pressures, and cardiac output/PiCCO[2] to the X3.
- The **M3012A Hemodynamic extension**: adds temperature, pressure, an additional pressure or a temperature and optionally cardiac output/PiCCO to the X3.
- The **M3014A Capnography extension**: adds mainstream or sidestream capnography, and optionally one pressure plus either a pressure or a temperature and cardiac output/PiCCO to the X3.
- The **M3015A Microstream CO_2 extension**: adds Microstream CO_2, and optionally either pressure or temperature to the X3.
- The **M3015B Microstream CO_2 extension**: adds Microstream CO_2, two pressures, and a temperature to the X3.

Measurements from the M3012A, M3014A, and M3015A/B measurement extensions are only available when the extension is connected to an X3, and this is running on external power. This is the case when the X3 is connected to:
- An IntelliVue Dock (867043)
- The External Power Supply (M8023A)
- The IntelliVue Battery Extension (865297)
- An IntelliVue host monitor

Applications for Specific Care Settings

Critical and Cardiac Care Features

- The monitor performs multi-lead **arrhythmia analysis** on the patient's ECG waveform at the bedside. It analyzes for ventricular arrhythmias, calculates heart rate, and generates alarms, including asystole, bradycardia, ventricular and atrial fibrillation.
- Up to 12 leads of **ST segment analysis** can be performed on adult patients at the bedside, measuring ST segment elevation and depression, and generating alarms and events. The user can trend ST changes, set high and low alarm limits, and set both ST and isoelectric measurement points. ST points can be set either relative to the J-point or directly by selecting a numeric value. Using ST Snippets, one-second wave segments can be compared with a baseline segment for each measured ST lead. The monitor also offers independent ST Elevation (STE) analysis and alarming using automated ISO and J-point determination and measuring the ST segment directly at the J-point (J +0). This is based on the recommendations for measuring ST Elevation published by the American Heart Association, the American College of

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1. PiCCO is not available for the 867040 Capnography extension in the USA and territories relying on FDA market clearance.

2. Cardiac output/PiCCO is not available for the 867041 Microstream CO_2 extension in the USA and territories relying on FDA market clearance.

Cardiology and the European Society of Cardiology.

- **QT/QTc interval monitoring** provides the measured QT interval, the calculated heart-rate corrected QTc value, and a ∆QTc value, which tracks variation in the QT interval in relation to a baseline value.
- **ST Map** application shows ST changes over time in two multi-axis spider diagrams.
- **STE Map** adds gender-specific STE (ST Elevation) limits to ST Map. ST values violating these limits are indicated in red.
- Optional **12-lead ECG** data can be measured in diagnostic quality using conventional electrode placement with 10 electrodes. Alternatively it can be measured using the EASI lead system with five electrodes in EASI placement, or the Hexad lead system with six electrodes in standard placement[1].
- 12 realtime ECG waveforms can be displayed simultaneously. Diagnostic 12-lead ECG can be captured, reviewed, and stored on the patient monitor before it is sent to the Information Center. Local printout is available, in harmonized layout.
- High-performance pulse oximetry technologies perform accurately even in cases with low perfusion.
- Choice of sidestream or mainstream CO_2 monitoring for high-quality measurements with intubated and non-intubated patients
- Integrated Pulmonary Index (IPI) enables clinicians to quickly and easily assess a patient's ventilatory status and monitor changes in a patient's condition, facilitating more timely interventions.
- Pulse Pressure Variation (PPV)[2] is calculated from beat-to-beat arterial pressure values. Pulse pressure is the difference between the systolic and the diastolic pressure values for a single beat. Pulse pressure variation is defined as the maximal pressure less the minimum pressure divided by the average of these two pressures.

Trends

Trends are patient data collected over time and displayed in graphic, tabular or histogram form to give you a picture of how your patient's condition is developing. Trend information is stored in the trends database for continuously-monitored measurements, such as ECG, as well as for aperiodically measured parameters, such as noninvasive blood pressure.

- The **Trends database** stores patient data from up to 50 individual measurement parameters. The measurement information can be sampled every 12 seconds, 1 minute, or 5 minutes, and stored for a period ranging from 4 to 48 hours.
  Each NBP measurement generates a column in the Vital Signs trend table. The values for the other measurements are added to provide a complete vital signs set for the NBP measurement time.
- **Horizon Trends** provide a graphical representation of changes to a patient's measurements to make information clearer at a glance.

Transport Features

Combining its role as multi-measurement module with that of stand-alone monitor, the X3 is particularly suited to transport situations. When the X3 is disconnected from the host monitor, it continues to monitor the patient as a stand-alone monitor running on battery power, eliminating the need for a separate transport monitor. When the X3 is reconnected to a host monitor, it resumes its role as multi-measurement module, uploading trend data, patient demographic information and measurement settings, supporting a gap free medical record.

- The compact portable design offers seamless in-hospital transport across all levels of patient monitoring, simply unplug and go.
- Specially-designed mounting solutions let you quickly disconnect the monitor for transport and reconnect to the mount after transport.
- The universal admission/discharge/transfer (ADT) feature means that all ADT information is shared between the networked monitor and the Information Center. Information need only be entered once.
- The monitor can operate using battery power for over five hours - in a basic monitoring configuration (see page 8) - to let you reliably monitor patients during procedures or in-hospital transfers.
- The IntelliVue Battery Extension (865297) extends the battery runtime to up to 15 hours.
- During in-hospital transport the monitor powers the measurement extensions (867039, 867040, and 867041) without requiring the use of the battery extension. For the measurement extensions M3012, M3014, M3015A, and M3015B, the battery extension is required.
- Enhanced ruggedness due to:
  - Ruggedized structural design
  - Deploying chemically resistant housing materials designed to resist deterioration from cleaning and disinfection agents
  - Antimicrobial Corning® Gorilla® Glass[3]
  - Improved ingress protection.

Patient Data Documentation

- An extensive range of Patient Reports can be printed:
  - 12-lead ECG Reports
  - Alarm Limit Reports
  - Vital Signs
  - Graphic Trends
  - Realtime Wave Reports
- Report templates can be defined in advance, enabling print-outs tailored to each hospital's specific requirements to be started quickly. Reports can be printed on a printer connected to a central station, or via the IntelliVue XDS Printing Service, and they can be initiated manually or automatically at user-defined intervals.
- The IntelliVue XDS Printing Service allows printing of reports, waveform captures, and trends from the monitor to an off-the-shelf printer or to an electronic file.

Viewing Reports on the Host Monitor

All reports stored in the print database of the X3, can be reviewed on the host monitor (with the appropriate monitor option). Most reports will be displayed as a full-page report, in the same format as they are printed out. Only electronic strip reports are displayed differently - in the form of a recording strip. The electronic strip report opens with the section of the

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1. EASI/Hexad-derived 12-lead ECGs and their measurements are approximations to conventional 12-lead ECGs. As the 12-lead ECG derived with EASI/Hexad is not exactly identical to the 12-lead conventional ECG obtained from an electrocardiograph, it should not be used for diagnostic purposes.

2. Not available in the USA and territories relying on FDA market clearance.

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3. Refer to the Product Information Sheet: https://www.corning.com/content/dam/corning/microsites/csm/gorillaglass/PI_Sheets/CGG_PI_Sheet_Anitimicrobia_Gorilla_Glass.pdf

wave from the time the report was triggered. You can scroll to see the rest of the strip. When an electronic strip is printed out, it will be in the standard page format. When the X3 is used in companion mode, that is, connected to a host monitor, the strips can be reviewed on, and printed from the host monitor.

Alarms

The alarm system can be configured to present either the traditional HP/Agilent/Philips alarm sounds or sounds compliant with the IEC 60601-1-8 Standard.

Dependent on the screen layout, alarm limits are permanently visible on the main screen. When an alarm limit is exceeded, it is signaled by the monitor in the following ways:
- An alarm tone sounds, graded according to severity.
- An alarm message is shown on the screen, color-coded according to severity.
- The numeric of the alarming measurement flashes on the screen.
- Alarm lamps flash for red and yellow alarms and are illuminated for technical INOPs.

The alarm-limit review page offers an overview of alarm limit settings and the possibility to modify these settings for all parameters.

A Smart Alarm Delay feature helps to reduce the number of pulse oximetry nuisance alarms.

If the monitor is connected via a network to a central station, alarming is simultaneous at the monitor and at the Information Center.

Alarms are graded and prioritized according to severity:
  - **Red Alarms***** identify a potentially life-threatening situation for a patient.
  - **Yellow Alarms**** indicate conditions violating preset vital-signs limits.
  - **Yellow Alarms*** indicate arrhythmia alarms.
  - **Technical Alarms (INOPs)** are triggered by signal quality problems, equipment malfunction, or equipment disconnect.
- The Silence function allows you to switch off alarm tones with one touch while retaining visual alarm messages.
- Holding the Silence button opens a window which lets you pause alarms. All alarms can be paused indefinitely, or for one, two, three, five, or 10 minutes depending on their configuration.
- Electronic strip recording allows alarm-triggered and manually started electronic strips to be captured in the monitor database and printed in the form of reports when a printer is available. The strips can be sent to an Information Center or to the XDS Printing Service that is part of the IntelliVue XDS Application. The reports can then be printed to a standard off-the-shelf printer and can also be stored as files on the Information Center or the PC hosting the XDS Printing Service. For printing the X3 must be connected to a host monitor, an M8023A external power supply, or a 867043 IntelliVue Dock.
- Patented "AutoLimits" help caregivers to manage alarms more effectively, automatically adapting the alarm limits to the patient's currently measured vital signs within a safe margin defined individually for each patient.
- Visual and/or audible latching and non-latching alarm handling is available.

Profiles

Profiles are predefined configuration settings for screens, measurement settings, and monitor properties. Each Profile can be designed for a specific application area and patient category, for example OR adult, or ICU neonatal. Profiles enable a quick reaction to patient and care location changes: activating a Profile with a particular patient category (adult, pediatric, or neonatal) automatically applies suitable alarm and safety limits and saves time usually spent carrying out a complete set-up procedure.

A selection of Profiles for common monitoring situations is provided with the monitor. Profiles can also be created directly on the monitor or remotely on a PC and transferred to the monitor using the IntelliVue Support Tool.

Networking Capabilities

Network Interface

The network interface provides the system with networking capability via a wired connection (LAN) when connected to the 867043 IntelliVue Dock (option E50), or the M8023A external power supply (option E27), or via a wireless network connection as described below.

Wireless Network

The monitor can function within a wireless infrastructure based on an IEEE 802.11a/b/g/n network in the 2.4 GHz/5 GHz bands (ISM).). Also, the monitor can function within the proprietary Philips IntelliVue Smart Hopping Network in the WMTS[1] band.

Additional components are required to complete the system. Refer to the IntelliVue Smart Hopping Network (865346) documentation for further information.

Optional Networking Capabilities

The monitor can operate as part of a networked system (wired/wireless) using the Philips IntelliVue Clinical Network interface.

This includes:
- DHCP/BootP
- QoS Tagging
- WMM on wireless networks.
- 802.11 WLAN, or Smart Hopping Interface (1.4 GHz – USA only)

Device Connections

The monitor can be connected to:
- Measurement extensions[2] (867039, 867040, 867041).
- Measurement extensions[3] (M3012A, M3014A, M3015A/B).
- A compatible host monitor of the IntelliVue family[4].
- An IntelliVue Dock (867043).
- An external power supply (M8023A)
- IntelliVue Battery Extension (865297).
- A Central Station/Information Center (for example, PIIC iX[5]).
- A PC running the IntelliVue XDS Solution.

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1. USA only.

2. The measurement extensions 867039, 867040, and 867041 are powered from the X3 internal battery during transport.

3. The measurement extensions M3012A, M3014A, and M3015A/B will only function when they are connected to the IntelliVue Battery Extension, or the monitor is connected to either an external power supply or a host monitor.

4. The host monitor requires software J.x, K.x, L.0, or M.0.

5. Requires PIIC release N.00.26 or later, or PIIC iX.

Compatibility

1.1.6.4. Compatible host monitors for the X3 are:
- IntelliVue MP20/30, MP40/50, MP60/70, MP80/90
- IntelliVue MX400, MX430, MX450, MX500, MX550, MX600, MX700, MX800

Service Features

A password-protected service mode ensures that only trained staff can access service tests and tasks.

A password-protected configuration mode allows trained users to customize the monitor configuration.

Upgradability

The monitor allows new capabilities to be added in the future as your monitoring requirements evolve. This upgradability gives the security of knowing that the monitors can be enhanced and updated as practices and technologies advance, and it protects long-term investments.

IntelliVue Support Tool

The IntelliVue Support Tool helps technical personnel to:
- Carry out configuration, upgrades, and troubleshooting via the network, or on an individual monitor
- Share configuration settings between monitors
- Back up the monitor settings

Care and Cleaning

The X3 deploys chemically-resistant surface materials, designed to resist deterioration from cleaning and disinfection agents. Even against very aggressive disinfectants, the X3's housing materials have been tested, and found to resist deterioration about 60 times longer than the housing material used for its predecessor. Refer to the list of tested agents in the monitor's Instructions for Use.

Monitor Specifications

For measurement extensions, see the respective Data Sheets.

Safety Specifications

The monitor complies with the Medical Device Directive 93/42/EEC and, among other standards, with:
- IEC 60601-1, Ed. 3.1:2012-08 (cons.)
- EN 60601-1:2006 + AC:2010 + A1:2013, Ed. 3
- ANSI/AAMI ES60601-1:2005/(R)2012, Ed. 3 (cons.)
- CAN/CSA-C22.2 No. 60601-1:14, Ed. 3 (cons.)
- IEC 60601-1-2:2007, Ed. 3
- EN 60601-1-2:2007 + AC:2010, Ed. 3
- IEC 60601-1-2:2014, Ed. 4
- EN 60601-1-2:2015, Ed. 4
- IEC 60601-1-6:2010 + A1:2013
- EN 60601-1-6:2010
- IEC 60601-1-8:2006 + A1:2012
- EN 60601-1-8:2007 + A1:2013
- IEC 60601-2-49:2011
- EN 60601-2-49:2015

All applied parts are Type CF unless otherwise specified. They are protected against damage from defibrillation and electrosurgery.

The possibility of hazards arising from software errors was minimized in compliance with:
- ISO 14971:2007
- EN ISO 14971:2012
- ANSI/AAMI ISO 14971:2010
- IEC 62304:2006
- EN 62304:2006 +AC:2008

This ISM device complies with Canadian ICES-001. Cet appareil ISM est conforme à la norme NMB-001 du Canada.

The monitor fulfills the following additional mechanical requirements:
- Shock Tests according to IEC TR 6072-4-7, Class 7M3. Test procedure according to IEC/EN 60068-2-27.
- Random Vibration according to IEC TR 60721-4-7, Class 7M3. Test procedure according to IEC/EN 60068-2-64.
- Sinusoidal Vibration according to IEC TR 60721-4-7, Class 7M3. Test procedure according to IEC/EN 60068-2-6.
- Bump Test according to IEC/EN 60068-2-27 (peak acceleration 15 g, 1000 bumps).
- Free Fall Test covers IEC TR 60721-4-7 and Class 7M3. Test procedure according to EN 60068-2-32.

Physical Specifications

Product	Max. Weight	WxHxD
IntelliVue X3	1.4 kg (3.1 lb) (incl. options, battery pack and handle)	Without handle: 194 x 97 x 85 mm (7.6 x 3.8 x 3.3 in) With handle: 249 x 97 x 111 mm (9.8 x 3.8 x 4.4 in)

Environmental Specifications

Item	Condition	Range
Temperature range	Operating	0–40°C (32–104°F) or, 0–35°C (32–95°F) – when charging the battery, or – when using a Smart Hopping Interface or WLAN, or – when mounted on the back of a host monitor.
	Storage	–20–60°C (–4–140°F)
Humidity range	Operating	15–95% RH non-condensing
	Storage	5–90% RH non-condensing
Altitude range	Operating	–500–3000 m (–1640–9842 ft)
	Storage	–500–4600 m (–1640–15091 ft)
Ingress protection	Monitor	IP32 (when in the horizontal position)

Item	Condition	Range
	External Power Supply (M8023A, or 867043)	• M8023A: – IP31 when rested on its rubber feet on a flat, level surface. – IP32 when mounted with the connectors facing downwards. • 867043: IP32

Performance Specifications

X3 patient monitor

Power

Power consumption	• <12 W average • <20 W when on IntelliVue Dock
Operating voltage	36–60 V dc floating
Current	1.3–0.7 A
Frequency	50/60 Hz

Display — *Aktyvios matricos spalvotas LCD tūrinis monitorius su daugiafunkcinio lietimo ekranu.*	Active matrix color LCD display with capacitive multi-touch screen
	1.2.2.1.
Sweep speeds	6.25, 12.5, 25, and 50 mm/s
Resolution — *Ekrano raiška*	1024 x 480
	1.2.2.3.
Useful screen	140 x 65 mm (5.5 x 2.6 in)
Pixel pitch	0.14 x 0.14

Indicators

Alarms off	Red or yellow LED with crossed out alarms symbol
Alarms	Red/yellow/light blue (cyan) LED
On/Standby/Error	Green/red LED integrated in power switch
External power	Green LED
Battery	Green (full), yellow (charging), red blinking (empty) LED

Sounds

• Audible feedback for user input

• Prompt tone

• QRS tone, or SpO$_2$ modulation tone

Sounds

• Four different alarm sounds

Display Wave Speeds

Available for standard waves	6.25 mm/s, 12.5 mm/s, 25 mm/s, 50 mm/s with ±5% accuracy (guaranteed only for integrated displays)

Trends

Resolution	12 or 16 numerics @ 12 seconds, 1 minute, 5 minute resolution.
Information	Multiple choices of number of numerics, resolution, and duration depending on trend option and application area.

Alarm Signal

System delay	<4 seconds. The system alarm delay is the processing time the system requires for any alarm to be indicated on the monitor, after the measurement has triggered the alarm.
Delay for alarm availability on the network	<5 seconds This is the time required after an alarm indication on the monitor, until the alarm signal is available on the network, to the Patient Information Center, or for transmission to other systems.
Pause duration	1, 2, 3 minutes or infinite, depending on configuration
Extended alarm pause	5 or 10 minutes
Sound pressure range	Minimum 0 dB(A) Maximum 45–85 dB(A)

Review Alarms

Information	All alarms/INOPs, main alarms on/off, alarm silence, and time of occurrence
Capacity	300 items

Real Time Clock

Range	From: January 1, 1997, 00:00 to: December 31, 2080, 23:59
Accuracy	Better than 4 seconds per day

Real Time Clock

Hold Time when switched off	· If powered by AC: Infinite · With battery: time is stored but a hold time is not specified, as storing a battery in an unused device for a longer period of time is not recommended. · Without power or battery: at least 48 hours.

Buffered Memory

Contents	Active settings, trends, patient data, realtime reports, events, review alarms
Hold Time when switched off	· If powered by AC: Infinite · With battery: memory is buffered but a hold time is not specified, as storing a battery in an unused device for a longer period of time is not recommended. · Without power: at least 4 hours.

Internal Battery (453564526811)

The battery is required for the operation of the monitor. The battery lifetime is 3 years from manufacturing date or 500 charge/discharge cycles.

Operating time (with a new, fully charged battery at 25°C)	Basic Mode 1: >5 hours. · ECG/Resp · FAST SpO_2 · NBP every 15 minutes · Brightness (auto mode off) set to optimum (4) Extended Mode 2: >3 hours. · ECG/Resp · FAST SpO_2 · Dual Pressure · Temperature · NBP every 15 minutes · CO_2 · Wireless radio · Brightness (auto mode off) set to optimum (4)
Charge time	· When monitor is off: 3 hours approx. · When monitor is in use and connected to an IntelliVue Dock, without measurement extensions: 2.5 hours approx. · When monitor is in use and connected to the external power supply (M8023A) without measurement extensions: 4 hours approx.

Restart Time

	After a power interruption, an ECG wave will be shown on the display after a maximum of 30 seconds.

External Power Supply M8023A Performance Specifications

Power

Power consumption	· <12 W average · <30 W peak
Line voltage	100−240 V ~
Current	1.3−0.7 A
Frequency	50/60 Hz ~

Indicators

AC power	Green LED

Interface Specifications

X3 patient monitor

Measurement Link (MSL)

Connectors	Female MSL (proprietary)
Power	36−60 V input
Power sync	Unused
LAN signals	IEEE 802.3 10Base-T and 100Base-TX compliant
Serial signals	RS-422 compliant
Local signals	Provided for connecting measurement extensions
Local voltage	9−12.3 V - provided to power the measurement extensions: 867039, 867040, and 867041

Smart Hopping IF 1.4 GHz (USA only)

Type	Internal WMTS adapter
Technology	Compatible with Philips Cellular Telemetry System (CTS), cellular infrastructure

Smart Hopping IF 1.4 GHz (USA only)

Frequency band	WMTS, 1395–1400 MHz and 1427–1432 MHz
Modulation technique	GFSK
Effective isotropically radiated power (EIRP)	Below 22 dBm (164 mW)

802.11 Wireless IF (Wireless Network Adapter)

Type	Internal wireless adapter
Technology	IEEE 802.11a/b/g/n
Frequency band	2.4 GHz and 5 GHz ISM
USA	• 2.400–2.483 GHz • 5.15–5.35 GHz • 5.72–5.825 GHz
Europe	• 2.400–2.483 GHz • 5.15–5.35 GHz, • 5.470–5.725 GHz
Japan	• 2.400–2.483 GHz • 5.15–5.25 GHz • 5.25–5.35 GHz • 5.470–5.725 GHz
China	• 2.400–2.483 GHz • 5.725–5.85 GHz
Modulation technique 802.11b/g/n	• DSSS (CCK, DQPSK, DBPSK) • OFDM (BPSK, QPSK, 16-QAM, 64-QAM)
Modulation technique 802.11a/n	OFDM (BPSK, QPSK, 16-QAM, 64-QAM)
Bandwidth	20 MHz (nominal)
Effective isotropically radiated power (EIRP)	Below 20 dBm (100 mW)

M8023A External Power Supply Interface Specifications

Measurement Link (MSL)

Connectors	Male MSL (proprietary)
Power	48 V output
Power sync.	RS-422 compliant output 78.125 kHz (typical)
LAN signals	IEEE 802.3 10Base-T compliant

Battery Specifications

45364526811 Battery

Physical Specifications

WxHxD	69.6 x 72.3 x 21.6 mm (2.7 x 2.8 x 0.8 in)
Weight	0.2 kg (0.4 lb)

Performance Specifications

Nominal voltage	10.8 V
Rated capacity at discharge C/5	2000 mAh (typically)
Continuous discharge capability	4 A

Environmental Specifications

Temperature range	• Discharge 0–60°C (32–140°F) • Charge 0–60°C (32–140°F) • Storage and Transport: -20–65°C (-4–149°F)
Humidity range	• Operating: 15–90% Relative Humidity (RH) • Storage and Transport: 5–95% Relative Humidity (RH)
Battery type	Lithium-ion, 10.8 V, 2000 mAh
Safety	Complies with: UL 62133/IEC 62133
Electromagnetic compatibility	Complies with the requirements for FCC Type B computing device, and EN 61000-4-2, and EN 61000-4-3
Communication standard	Complies with the SMBus specification v1.1

Measurement Specifications

ECG/Arrhythmia/ST/QT

Complies with:
- IEC 60601-2-25:2011
- ANSI/AAMI/IEC 60601-2-25:2012
- IEC 60601-2-27:2011
- ANSI/AAMI/IEC 60601-2-27:2011 + Err:2012

ECG/Arrhythmia/ST Performance Specifications

Cardiotach

Range	• Adult/pedi: 15–300 bpm • Neo: 15–350 bpm
Accuracy	±1% of range
Resolution	1 bpm
Sensitivity	≥200 μV_{peak}

PVC Rate

Range	0–300 bpm
Resolution	1 bpm

ST Numeric

Range	-20–20 mm
Accuracy	±0.5 mm or 15% whichever is greater
Resolution	0.1 mm

QT Numeric

Range	200–800 ms
Accuracy	±30 ms
Resolution	8 ms

QTc Numeric

Range	200–800 ms
Resolution	1 ms

ΔQTc Numeric

Range	-600–600 ms
Resolution	1 ms

QT-HR Numeric

Range – Adult	15–150 bpm
Range – Pedi/neo	15–180 bpm
Resolution	1 bpm

Sinus and SV Rhythm Ranges

Brady	• Adult: 15–59 bpm • Pedi: 15–79 bpm • Neo: 15–89 bpm
Normal	• Adult: 60–100 bpm • Pedi: 80–160 bpm • Neo: 90–180 bpm
Tachy	• Adult: >100 bpm • Pedi: >160 bpm • Neo: >180 bpm

Bandwidth

Diagnostic mode	Adult/neo/pedi: 0.05–150 Hz
Extended monitoring mode	Neo/pedi: 0.5–150 Hz
Monitoring mode	• Adult: 0.5–40 Hz • Neo/pedi: 0.5–55 Hz
Filter mode	Adult/neo/pedi: 0.5–20 Hz

Bandwidth – when ECG is transmitted from a telemetry device via a short-range radio

Diagnostic mode	Adult/neo/pedi: 0.05–40 Hz
Extended monitoring mode	Adult/neo/pedi: 0.5–40 Hz
Monitoring mode	• Adult: 0.5–40 Hz • Neo/pedi: 0.5–40 Hz
Filter mode	Adult/neo/pedi: 0.5–20 Hz

Differential Input Impedance

- >2 MΩ RA-LL leads (Resp)
- >5 MΩ at all other leads (at 10 Hz including patient cable)

Common Mode Rejection Ratio

- Diagnostic mode: >86 dB (with a 51 kΩ/47 nF imbalance)
- Filter mode: >106 dB (with a 51 kΩ/47 nF imbalance)

Electrode Offset Potential Tolerance

±500 mV

Auxiliary Current (Leads off Detection)

· Active electrode: <100 nA
· Reference electrode: <900 nA

Input Signal range

±5 mV

ECG/Arrhythmia/ST Supplemental Information as required by IEC 60601-2-27

Respiration Excitation Waveform

Sinusoidal signal, <260 µA @ 40.5 kHz

Noise Suppression

RL drive gain 44 dB maximum, maximum voltage 1.8 Vrms

Time to Alarm for Tachycardia

Vent Tachycardia 1 mV$_{pp}$, 206 bpm	· Gain 0.5, Range 6.5–8.4 seconds, Average 7.2 seconds · Gain 1.0 Range 6.1–6.9 seconds, Average 6.5 seconds · Gain 2.0, Range 5.9–6.7 seconds, Average 6.3 seconds
Vent Tachycardia 2 mV$_{pp}$, 195 bpm	· Gain 0.5, Range 5.4–6.2 seconds, Average 5.8 seconds · Gain 1.0, Range 5.7–6.5 seconds, Average 6.1 seconds · Gain 2.0, Range 5.3–6.1 seconds, Average 5.7 seconds

Tall T–Wave Rejection Capability

1.2 mV T–Wave amplitude according to IEC 60601-2-27, clause 201.12.1.101.17.

Heart Rate Averaging Method

Three different methods are used:
· Normally, heart rate is computed by averaging the 12 most recent RR intervals.
· For runs of PVCs, up to eight RR intervals are averaged to compute the HR.
· If each of three consecutive RR intervals is >1200 ms (that is, rate <50 bpm), then the four most recent RR intervals are averaged to compute the HR.

Response Time of Heart Rate Meter to Change in Heart Rate

HR change from 80–120 bpm:	· Range: 6.4–7.2 seconds · Average: 6.8 seconds
HR change from 80–40 bpm:	· Range: 5.6–6.4 seconds · Average: 6.0 seconds

Heart Rate Meter Accuracy and Response to Irregular Rhythm

· Ventricular bigeminy: 80 bpm
· Slow alternating ventricular bigeminy: 60 bpm
· Rapid alternating ventricular bigeminy: 120 bpm
· Bidirectional systoles: 90 bpm

Accuracy of Input Signal Reproduction

Methods A and D (according to IEC 60601-2-25, clause 201.12.4.107.1.1.1) were used to establish overall system error and frequency response.

Pacemaker Pulse Rejection Performance

Rejection of pacemaker pulses with amplitudes from ±2 mV to ±700 mV and widths from 0.1 ms to 2.0 ms (Method B)

Pacemaker Pulse Rejection of Fast ECG Signals

2.2 V/s RTI (Paced Mode)

Minimum Input Slew Rate

2.2 V/s RTI

ECG/Arrhythmia/ST Alarm Specifications

HR

Range	15–300 bpm maximum delay: 10 seconds according to IEC 60601-2-27
Adjustment	Adult: · 1 bpm steps (15–40 bpm) · 5 bpm steps (40–300 bpm) Pedi/neo: · 1 bpm steps (15–50 bpm) · 5 bpm steps (50–300 bpm)

Extreme Tachy

Range	· Difference to high limit 0–50 bpm · Clamping at 150–300 bpm
Adjustment	· 5 bpm steps

Extreme Brady

Range	· Difference to low limit 0–50 bpm · Clamping at 15–100 bpm
Adjustment	· 5 bpm steps

Run PVCs

Range	None, fixed setting of 2 PVCs
Adjustment	Not adjustable by user

PVCs Rate

Range	1–99 PVCs/minute
Adjustment	1 PVC

Vent Tach HR

Range	20–300 bpm
Adjustment	5 bpm

Vent Tach Run

Range	3–99 PVCs/minute
Adjustment	1 PVC

Vent Rhythm Run

Range	3–99 PVCs/minute
Adjustment	1 PVC

SVT HR

Range	120–300 bpm
Adjustment	5 bpm

SVT Run

Range	3–99 SV beats
Adjustment	1 SV beat

ST High

Range	-19.8–20 mm
Adjustment	0.2 mm

ST Low

Range	-20–19.8 mm
Adjustment	0.2 mm

QTc High

Range	200–800 ms

QTc High

Adjustment	10 ms steps

ΔQTc High

Range	30–200 ms
Adjustment	10 ms steps

Respiration

Respiration Performance Specifications

Respiration Rate

Range	• Adult/pedi: 0–120 rpm • Neo: 0–170 rpm
Accuracy	• At 0–120 rpm ±1 rpm • At 120–170 rpm ±2 rpm
Resolution	1 rpm

Bandwidth

0.3–2.5 Hz (-6 dB)

Noise

<25 mΩ (rms) referred to the input

Respiration Alarm Specifications

High

Range	• Adult/pedi: 10–100 rpm • Neo: 30–150 rpm
Adjustment	• <20 rpm: 1 rpm steps • ≥20 rpm: 5 rpm steps
Delay	Maximum 14 seconds

Low

Range	• Adult/pedi: 0–95 rpm • Neo: 0–145 rpm
Adjustment	• <20 rpm: 1 rpm steps • ≥20 rpm: 5 rpm steps
Delay	• For limits from 0 to 20 rpm: maximum 4 seconds • For limits above 20 rpm: maximum 14 seconds

Apnea Alarm

Range	10–40 seconds
Adjustment	5 second steps

FAST SpO$_2$ (867030 #SP1)

Complies with:
· ISO 80601-2-61:2011
· EN ISO 80601-2-61:2011

Measurement Validation

The SpO$_2$ accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements.

The specified accuracy is the root-mean-square (RMS) difference between the measured values and the reference values.

Philips FAST SpO$_2$ Performance Specifications

Range and Resolution

Range	0–100%
Resolution	1%

With Philips Reusable Sensors

Accuracy 2% (70–100%)	· M1191A · M1191AL · M1191B · M1191BL · M1192A
Accuracy 3% (70–100%)	· M1193A · M1194A · M1195A · M1196A/S

With Philips Reusable Sensors with M1943A(L) adapter cable

Accuracy 3% (70–100%)	· M1191T · M1192T · M1193T (Adult) · M1196T
Accuracy 4% (70–100%)	· M1193T (Neonate)

With Philips Disposable Sensors with M1943A(L) adapter cable

Accuracy 2% (70–100%)	· M1132A · M1133A · M1134A (Adult/infant)

With Philips Disposable Sensors with M1943A(L) adapter cable

Accuracy 3% (70–100%)	· M1131A · M1133A · M1134A (Neonate) · M1901B · M1902B · M1903B · M1904B

With Nellcor Sensors with M1943A(L) adapter cable

Accuracy 3% (70–100%)	· MAXA · MAXAL · MAXP · MAXI · MAXN · D-25 · D-20 · I-20 · N-25 · OxiCliq[a] A, P, I, N

a. requires additional Nellcor OC3 adapter cable

With Masimo Reusable Sensors with LNC MP10 adapter cable

Accuracy 2% (70–100%)	· LNCS DCI · LNCS DCIP · LNCS YI (Adult/pedi/infant)
Accuracy 3% (70–100%)	· LNCS YI (Neonate)
Accuracy 3.5% (70–100%)	· LNCS TC-I

With Masimo Disposable Sensors with LNC MP10 adapter cable

Accuracy 2% (70–100%)	· LNCS Adtx · LNCS Adtx-3 · LNCS Pdtx · LNCS Pdtx-3 · LNCS Inf · LNCS Inf-3 · LNCS Neo (Adult) · LNCS Neo-3 (Adult)
Accuracy 3% (70–100%)	· LNCS Neo (Neonate) · LNCS Neo-3 (Neonate) · LNCS NeoPt · LNCS NeoPt-3

Pulse

Range	30–300 bpm
Accuracy	±2% or 1 bpm, whichever is greater
Resolution	1 bpm

Sensors

Wavelength range	500–1000 nm
Emitted light energy	≤15 mW

Numeric update rate

Typical	1 second
Maximum	30 seconds Maximum with noninvasive blood pressure INOP suppression on: 60 seconds

Pulse Oximeter Calibration Range

70–100%

Nellcor OxiMax SpO$_2$ (867030 #SP6)

Complies with:
· ISO 80601-2-61:2011
· EN ISO 80601-2-61:2011

Measurement Validation

The SpO$_2$ accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements.

The specified accuracy is the root-mean-square (RMS) difference between the measured values and the reference values.

Pulse Oximetry Performance Specifications

SpO$_2$

Measurement range	1–100%
Resolution	1%
Accuracy	See the Pulse Oximetry Accuracy Table
Low perfusion accuracy [a]	2% (70–100%)

Pulse

Range	25–300 bpm
Resolution	1 bpm
Accuracy	±3 bpm (20–250 bpm)
Low perfusion accuracy [a]	±3 bpm (20–250 bpm)

Sensors – with M1943NL adapter cable

Wavelength range [b]	500–1000 nm
Emitted light energy	≤15 mW

Numeric update rate

Typical	1 second
Maximum	≤60 seconds

[a] Specification applies to the performance of the device. Reading accuracy in the presence of low perfusion (detected IR pulse modulation amplitude 0.03–1.5%) was validated using signals supplied by a patient simulator. SpO$_2$ and pulse rate values were varied across the monitoring range over a range of weak signal conditions and compared to the known true saturation and pulse rate of the input signals.

[b] Information about the wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).

Pulse Oximetry Accuracy Table

	SaO$_2$ Range: 70–100%		SaO$_2$ Range: 60–80%
Sensor	Adult/Infant	Neonate	Adult
MAXA, MAXAL	2%	n/a	3%
MAXN [a]	2%	2%	3%
MAXP	2%	n/a	3%
MAXI	2%	n/a	3%
MAXFAST	2%	n/a	3%
MAXR [b]	3.5%	n/a	n/a
SC-A	2%	n/a	n/a
SC-PR [c]	n/a	2%	n/a
SC-NEO [c]	n/a	2%	n/a
OxiCliq A	2.5%	n/a	n/a
OxiCliq P	2.5%	n/a	n/a
OxiCliq N [d]	2.5%	3.5%	n/a
OxiCliq I	2.5%	n/a	n/a
D-YS [d]	3%	4%	n/a
D-YS & D-YSE	3.5%	n/a	n/a
D-YSPD	3.5%	n/a	n/a
DS100A	3%	n/a	n/a

	SaO$_2$ Range: 70–100%		SaO$_2$ Range: 60–80%
Sensor	**Adult/Infant**	**Neonate**	**Adult**
OXI-A/N [d]	3%	4%	n/a
OXI-P/I	3%	n/a	n/a
M1901B [a]	Identical to OxiMax MAXN		
M1902B	Identical to OxiMax MAXI		
M1903B	Identical to OxiMax MAXP		
M1904B	Identical to OxiMax MAXA		

[a] M1901B/MAXN: Clinical functionality has been demonstrated on a population of hospitalized neonate patients. The observed SpO$_2$ accuracy was 2.5% in a study of 42 patients with ages of 1 to 23 days, weight from 750–4100 grams, and 63 observations made spanning a range of 85–99% SaO$_2$ while monitored with Nellcor OxiMax N-595 pulse oximeters.

[b] The accuracy specification has been determined between saturations of 80–100%.

[c] SoftCare SC-PR-I, SC-NEO-I: Clinical functionality has been demonstrated on a population of hospitalized neonate and infant patients. The observed SpO$_2$ accuracy was 3.0% in a study of 57 patients with ages of 24 to 40 weeks, weight from 710–5000 grams, and 185 observations made spanning a range of 63–100% SaO$_2$ while monitored with Nellcor OxiMax N-595 pulse oximeters.

[d] Neonatal accuracy: When sensors are used on neonatal subjects as recommended, the specified accuracy range is increased by ±1 digit, as compared to adult usage, to account for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood. For example, OxiCliq N accuracy on neonates is ±3.5 digits, rather than ±2.5.

Alarm Specifications for Philips FAST SpO$_2$ and Nellcor OxiMax SpO$_2$

SpO$_2$

Range	• Adult: 50–100% • Pedi/neo: 30–100%
Adjustment	1% steps
Delay	0–30 seconds (0, 1, 2, 3,... 30) + 4 seconds

Desat

Range	• Adult: 50% to low alarm limit • Pedi/neo: 30% to low alarm limit
Adjustment	1% steps
Delay	0–30 seconds (0, 1, 2, 3,... 30) + 4 seconds

Pulse

Range	30–300 bpm
Adjustment	Adult: • 1 bpm steps (30–40 bpm) • 5 bpm steps (40–300 bpm) Pedi/neo: • 1 bpm steps (30–50 bpm) • 5 bpm steps (50–300 bpm)
Delay	Maximum 14 seconds

Tachycardia

Range	• Difference to high limit: 0–50 bpm • Clamping at 150–300 bpm
Adjustment	5 bpm steps
Delay	Maximum 14 seconds

Bradycardia

Range	• Difference to low limit: 0–50 bpm • Clamping at 30–100 bpm
Adjustment	5 bpm steps
Delay	Maximum 14 seconds

Masimo rainbow SET SpO$_2$ (867030 #SP5)

Complies with:
• ISO 80601-2-61:2011
• EN ISO 80601-2-61:2011

General Performance Specifications SpO$_2$

Numeric update rate for SpO$_2$, Pulse Rate, and Perf	• Typical: 1 second • Maximum: 30 seconds
Sensors	• Emitted Light Energy ≤25 mW • Wavelength Range [a] 500–1400 nm

[a] Information about wavelength range can be especially useful to clinicians (for instance when photodynamic therapy is performed).

Indications for Use

The Masimo rainbow SET measurement is indicated for the noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO$_2$), pulse rate, carboxyhemoglobin saturation (SpCO), methemoglobin saturation (SpMet), total hemoglobin concentration (SpHb), and/or respiratory rate (RRac). The Masimo rainbow SET measurement is indicated for use with adult, pediatric, and neonatal patients during both no motion and motion conditions, and for patients who are well or poorly perfused.

Operating Conditions

In addition to the general specifications for operating conditions for the X3 portable patient monitor, the following additional environmental limitations apply for the Masimo rainbow SET measurement:

Environmental Limitations

Incandescent Light Intensity	≤100 klx
Fluorescent Light Intensity	≤10 klx
Fluorescent Light Frequency	• 50 Hz or 60 Hz ±1.0 Hz (LNCS sensors) • 50 Hz or 60 Hz ±0.5 Hz (rainbow sensors)
Ambient Noise Level (Sound Pressure Level) (applies to acoustic respiration measurement only)	≤65 dB, Alarm tolerant

Measurement Accuracy

The following accuracy specifications represent only the device's portion of the integrated Masimo rainbow SET technology performance. The actual measurement performance and accuracy depends on the accessory used and can be limited by the accessory as specified in the sensor's Directions For Use.

Ensure that you only use accessories that are specified and provide accuracy specifications applicable for your device.

Measurement	Accuracy
SpO_2, no motion	• 60–80 ±3%, Adult/pedi/infant • 70–100 ±2%, Adult/pedi/infant, ±3% Neo
SpO_2, motion	70–100 ±3%, Adult/pedi/infant/neo
SpO_2, low perfusion	70–100 ±2%, Adult/pedi/infant/neo
Pulse Rate, no motion	25–240 ±3 bpm, Adult/pedi/infant/neo
Pulse Rate, motion	25–240 ±5 bpm, Adult/pedi/infant/neo
Pulse Rate, low perfusion	25–240 ±3 bpm, Adult/pedi/infant/neo
SpCO	1–40 ±3%, Adults/pedi/infant
SpMet	1–15 ±1%, Adult/pedi/infant/neo
SpHb	8–17 ±1 g/dl (arterial or venous), Adult/pedi

Measurement	Accuracy
RRac	4–70 ±1 breath per minute, Adult/pedi (>10 kg)

Measurement Range and Resolution

SpO_2

Range	0–100%
Resolution	1%

Perf

Range	• 0.02–20 for disposable sensors • 0.05–20 for reusable sensors
Resolution	0.01

PVI

Range	0–100%
Resolution	1%

Pulse

Range	25–240 bpm
Resolution	1 bpm

SpCO

Range	0–100%
Resolution	1%

SpMet

Range	0–100%
Resolution	0.1%

SpHb

Range	0–25 g/dl (0–15.5 mmol/l)
Resolution	0.1 g/dl (0.1 mmol/l)

SpOC

Range	0–35 ml/dl
Resolution	1 ml/dl

RRac

Range	4–70 rpm
Resolution	1 rpm

Alarm Specifications

SpO$_2$

Range	· Adult: 50–100% · Pedi/neo: 30–100%
Adjustment	1% steps
Delay	0–30 seconds (0, 1, 2, 3,... 30) + 4 seconds

Desat

Range	· Adult: 50–99% · Pedi/neo: 30–99%
Adjustment	1% steps
Delay	0–30 seconds (0, 1, 2, 3,... 30) + 4 seconds

SpMet

Range	Adult/pedi/neo: 0–100%
Adjustment	· 0.1% steps (0–9.9%) · 1% steps (10–100%)
Delay	Maximum 4 seconds

SpCO

Range	Adult/pedi/neo: 0–100%
Adjustment	1%
Delay	Maximum 4 seconds

SpHb

Range	Adult/pedi/neo: 0–25 g/dl (0–15.5 mmol/l)

Adjustment	· 0.1 g/dl steps (0–9.9 g/dl)
	  0.1 mmol/l (0–9.9 mmol/l)
	· 0.5 g/dl steps (10–25 g/dl)
	  0.5 mmol/l (10–15.5 mmol/l)

Delay	Maximum 4 seconds

SpOC

Range	Adult/pedi/neo: 0–35 ml/dl

SpOC

Adjustment	1 ml/dl steps
Delay	Maximum 4 seconds

Pulse [a]

Range	Adult/pedi/neo: 30–300 bpm
Adjustment	Adult: · 1 bpm steps (30–40 bpm) · 5 bpm steps (40–300 bpm) Pedi/neo: · 1 bpm steps (30–50 bpm) · 5 bpm steps (50–300 bpm)
Delay	Maximum 14 seconds

Tachycardia

Range	· Difference to high limit: 0–50 bpm · Clamping at 150–300 bpm
Adjustment	5 bpm steps
Delay	Maximum 14 seconds

Bradycardia

Range	· Difference to low limit: 0–50 bpm · Clamping at 30–100 bpm
Adjustment	5 bpm steps
Delay	Maximum 14 seconds

PVI

Range	Adult/pedi/neo: 0–100%
Adjustment	1%
Delay	Maximum 4 seconds

RRac [b]

Range	· Adult/pedi: 0–100 rpm · Neo: 0–150 rpm
Adjustment	· 1 rpm steps below 20 rpm · 5 rpm steps above 20 rpm
Delay	0–60 seconds (0, 10, 15, 30, 60) + 4 seconds

RRac Pause Time

	15, 20, 25, 30, 35, 40 seconds.

Perf

Range	Adult/pedi/neo: 0.02–20
Adjustment	· 0.01 steps (0.02–0.10) · 0.10 steps (0.10–1) · 1 steps (1–20)
Delay	Maximum 4 seconds

[a] The Masimo rainbow SET technology only provides pulse rate values up to 240 bpm. To get pulse rate alarms, set the high alarm limit below 240 bpm.

[b] The Masimo rainbow SET technology only provides respiration rate values from 4 rpm to 70 rpm. For respiration rate alarms, set the high alarm limit below 70 rpm and the low alarm limit above 4 rpm.

3D Perf Delta

% Decrease	Adjustment	Duration	Adjustment
10–100%	2%	1 min to 48 hr, infinite	1 min, 5 min, 30 min, 1 hr, 4 hr, 8 hr, 12 hr, 24 hr, 36 hr, 48 hr, infinite

3D Desat Index

Delta Threshold

Range	2–10%
Adjustment	1%

Count

Range	1–25
Adjustment	1 step

Period

Range	1–4 hours
Adjustment	1 hour steps

Noninvasive blood pressure (NBP)

Complies with:
· IEC 80601-2-30:2010 + A1:2013
· EN 80601-2-30:2010 + A1:2015

NBP Performance Specifications

Systolic

Range	· Adult: 30–270 mmHg (4–36 kPa) · Pedi: 30–180 mmHg (4–24 kPa) · Neo: 30–130 mmHg (4–17 kPa)

Diastolic

Range	· Adult: 10–245 mmHg (1.5–32 kPa) · Pedi: 10–150 mmHg (1.5–20 kPa) · Neo: 10–100 mmHg (1.5–13 kPa)

Mean

Range	· Adult: 20–255 mmHg (2.5–34 kPa) · Pedi: 20–160 mmHg (2.5–21 kPa) · Neo: 20–120 mmHg (2.5–16 kPa)

Pulse Rate

Range	· Adult: 40–300 · Pedi: 40–300 · Neo: 40–300

Accuracy

Max. Std. Deviation	8 mmHg (1.1 kPa)
Max. Mean Error	±5 mmHg (±0.7 kPa)

Pulse Rate Measurement

Accuracy	· 40–100 bpm: ±5 bpm · 101–200 bpm: ±5% of reading · 201–300 bpm: ±10% of reading (average over NBP measurement cycle)

Measurement Time

Typical at HR >60 bpm

Auto/manual	· Adult: 30 seconds · Neo: 25 seconds · Stat: 20 seconds
Maximum time	· Adult/pedi: 180 seconds · Neo: 90 seconds

Cuff Inflation Time

Typical for normal adult cuff	<10 seconds
Typical for neonatal cuff	<2 seconds

Initial Cuff Inflation Pressure

	· Adult: 165 ±15 mmHg · Pedi: 130 ±15 mmHg · Neo: 100 ±15 mmHg

Maximum Cuff Pressure

- Adult/pedi: 300 mmHg
- Neo: 150 mmHg

Auto Mode Repetition Times

1, 2, 2.5, 3, 5, 10, 15, 20, 30,
45 minutes, or 1, 2, 4, 8, 12, 24 hours

STAT Mode Cycle Time

5 minutes

Venipuncture Mode Inflation

Inflation pressure	• Adult: 20–120 mmHg (3–16 kPa) • Pedi: 20–80 mmHg (3–11 kPa) • Neo: 20–50 mmHg (3–7 kPa)
Automatic deflation	• Adult/pedi: after 170 seconds • Neo: after 85 seconds

Measurement Validation:

Clinical investigation according to ISO 81060-2:2013 with the auscultatory reference method:
- The 5th Korotkoff sound (K5) was used in adult/adolescent subjects and the 4th Korotkoff sound (K4) was used in pediatric subjects to determine the diastolic reference pressures.
- The approximation MAP = (2*DIA + SYS) / 3 was used to calculate reference MAP (mean arterial pressure) values from the systolic and diastolic reference pressures.

Clinical investigation according to ISO 81060-2:2013 with the intra-arterial reference method:
- The radial artery was used for the intra-arterial reference measurement.
- The MAP values displayed by the reference invasive blood pressure monitor were used as MAP reference values.

Blood pressure recordings with any arrhythmias were excluded.

NBP Alarm Specifications

Systolic

Range	• Adult: 30–270 mmHg (4–36 kPa) • Pedi: 30–180 mmHg (4–24 kPa) • Neo: 30–130 mmHg (4–17 kPa)
Adjustment	• 10–30 mmHg (1.5–4 kPa): 2 mmHg (0.5 kPa) • >30 mmHg (>4 kPa): 5 mmHg (1 kPa)

Diastolic

Range	• Adult: 10–245 mmHg (1.5–32 kPa) • Pedi: 10–150 mmHg (1.5–20 kPa) • Neo: 10–100 mmHg (1.5–13 kPa)

Diastolic

Adjustment	• 10–30 mmHg (1.5–4 kPa): 2 mmHg (0.5 kPa) • >30 mmHg (>4 kPa): 5 mmHg (1 kPa)

Mean

Range	• Adult: 20–255 mmHg (2.5–34 kPa) • Pedi: 20–160 mmHg (2.5–21 kPa) • Neo: 20–120 mmHg (2.5–16 kPa)
Adjustment	• 10–30 mmHg (1.5–4 kPa): 2 mmHg (0.5 kPa) • >30 mmHg (>4 kPa): 5 mmHg (1 kPa)

NBP Overpressure Settings (Not user adjustable)

Adult	>300 mmHg (40 kPa) >2 seconds
Pedi	>300 mmHg (40 kPa) >2 seconds
Neo	>150 mmHg (20 kPa) >2 seconds

Invasive Pressure and Pulse

Supports up to two pressure transducers via one connector and one Y-cable.

Complies with:
- IEC 60601-2-34:2011
- EN 60601-2-34:2014

Invasive Pressure Performance Specifications

Measurement Range

–40–360 mmHg

Pulse Rate

Range	25–350 bpm
Accuracy	±1% full range
Resolution	1 bpm

Input Sensitivity

Sensitivity	5 µV/V/mmHg (37.5 µV/V/kPa)
Adjustment range	±10%

Transducers (compliant with ANSI/AAMI BP22)

Load impedance	200–2000 Ω (resistive)

Transducers (compliant with ANSI/AAMI BP22)

Output impedance	≤3000 Ω (resistive)

Frequency Response

	DC to 12 Hz or 40 Hz

Zero Adjustment

Range	±200 mmHg (±26 kPa)
Accuracy	±1 mmHg (±0.1 kPa)
Drift	<0.1 mmHg/°C (0.013 kPa/°C)

Gain Accuracy

Accuracy	±1%
Drift	<0.05%/°C
Non linearity and Hysteresis	Error of ≤ 0.4% FS (@CAL 200 mmHg)

Overall Accuracy (including transducer)

	±4% of reading or ±4 mmHg (±0.5 kPa), whichever is greater

Volume displacement of CPJ840J6

	0.1 mm³/100 mmHg

Invasive Pressure Alarm Specifications

Pressure

Range	-40–360 mmHg (-5.0–48 kPa)
Adjustment	· -40–50 mmHg (-5–4 kPa): 2 mmHg (0.5 kPa) · >50 mmHg (>4 kPa): 5 mmHg (1 kPa)
Delay	Maximum 12 seconds

Extreme High

Range	Difference to high limit 0–25 mmHg (0–3.5 kPa)
Adjustment	5 mmHg steps (0.5 kPa)
Range	Clamping at -35–360 mmHg (-4–48 kPa)
Adjustment	5 mmHg steps (1.0 kPa)

Extreme High

Delay	Maximum 12 seconds

Extreme Low

Range	Difference to low limit 0–25 mmHg (0–3.5 kPa)
Adjustment	5 mmHg steps (0.5 kPa)
Range	Clamping at -40–355 mmHg (-5–47 kPa)
Adjustment	5 mmHg steps (1.0 kPa)
Delay	Maximum 12 seconds

Pulse

Range	25–300 bpm
Adjustment	Adult: · 1 bpm steps (25–40 bpm) · 5 bpm steps (40–300 bpm) Pedi/neo: · 1 bpm steps (25–50 bpm) · 5 bpm steps (50–300 bpm)
Delay	Maximum 12 seconds

Tachycardia

Range	· Difference to high limit 0–50 bpm · Clamping at 150–300 bpm
Adjustment	5 bpm steps
Delay	Maximum 14 seconds

Bradycardia

Range	· Difference to low limit 0–50 bpm · Clamping at 25–100 bpm
Adjustment	5 bpm steps
Delay	Maximum 14 seconds

Temperature

Complies with:
· ISO 80601-2-56:2009
· EN ISO 80601-2-56:2012

Temperature Performance Specifications

Temperature

Range (absolute)	-1–45°C (30–113°F)
Range (differential)	±46°C (±115°F)

Temperature

Resolution	0.1°C (0.1°F)
Accuracy	±0.1°C (±0.2°F)

Average Time Constant

<10 seconds

Temperature Alarm Specifications

Temperature High/Low Alarms

Range	−1–45°C (30–113°F)
Adjustment	• −1–30°C (30–86°F), 0.5°C (1.0°F) steps • 30–45°C (86–113°F), 0.1°C (0.2°F) steps

CO$_2$

Complies with:
• ISO 80601-2-55:2011
• EN ISO 80601-2-55:2011

Mainstream CO$_2$ Performance Specifications

CO$_2$

Range	0–150 mmHg (0–20 kPa)
Accuracy	After 2 minutes warm-up: • For values between 0 and 40 mmHg (0 and 5,3 kPa): ±2.0 mmHg (±0.29 kPa). • For values from 41–70 mmHg (5.4–9.3 kPa): ±5% of reading. • For values from 71–100 mmHg (9.4–13.3 kPa) ±8% of reading. • For values from 101–150 mmHg (13.4–20 kPa): ±10 % of reading the specifications are valid for standard gas mixtures, balance air, fully hydrated at 35°C, Pabs = 760 mmHg (101.3 kPa), flow rate = 2 l/min
Resolution	• Numeric: 1.0 mmHg (0.1 kPa) • Wave: 0.1 mmHg (0.01 kPa)

Stability:

Short-term drift	±0.8 mmHg (0.11 kPa) over four hours.
Long-term drift	Accuracy specification is maintained over a 120-hour period

awRR

Range	2–150 rpm

awRR

Accuracy	±1 rpm

Warm-up Time

2 minutes with CO$_2$ transducer attached for full accuracy specification

Response Time

<60 ms (with adult or infant reusable or disposable adapter)

Sidestream CO$_2$ Performance Specifications

CO$_2$

Range	0–150 mmHg (0–20 kPa)
Accuracy	After 2 minutes warm-up: • For values between 0 and 40 mmHg (0 and 5,3 kPa): ±2.0 mmHg (±0.29 kPa). • For values from 41–70 mmHg (5.4–9.3 kPa): ±5% of reading. • For values from 71–100 mmHg (9.4–13.3 kPa) ±8% of reading. • For values from 101–150 mmHg (13.4–20 kPa): ±10% of reading. At respiration rates above 80 rpm, all ranges are ±12% of reading. The specifications are valid for gas mixtures of CO$_2$, balance N$_2$, dry gas at 760 mmHg (101.3 kPa) within specified operating temperature range.
Resolution	• Numeric: 1.0 mmHg (0.1 kPa) • Wave: 0.1 mmHg (0.01 kPa)

Stability:

Short-term drift	±0.8 mmHg (0.11 kPa) over four hours.
Long-term drift	Accuracy specification is maintained over a 120-hour period

awRR

Range	2–150 rpm
Accuracy	±1 rpm

Warm-up Time

2 minutes with CO$_2$ sensor attached for full accuracy specification

Sample Flow Rate

50 ±10 ml/minute

Total System Response Time

3 seconds

CO$_2$ Alarm Specifications

etCO$_2$ High

Range	20–95 mmHg (2–13 kPa)
Adjustment	1 mmHg (0.1 kPa) steps
Delay	<14 seconds

etCO$_2$ Low

Range	10–90 mmHg (1–12 kPa)
Adjustment	1 mmHg (0.1 kPa) steps
Delay	<14 seconds

imCO$_2$ High

Range	2–20 mmHg (0.3–3 kPa)
Adjustment	1 mmHg (0.1 kPa) steps
Delay	<14 seconds

awRR High

Range	· Adult/pedi: 10–100 rpm · Neo: 30–150 rpm
Adjustment	· <20 rpm: 1 rpm steps · >20 rpm: 5 rpm steps
Delay	<14 seconds

awRR Low

Range	· Adult/pedi: 0–95 rpm · Neo: 0–145 rpm
Adjustment	· <20 rpm: 1 rpm steps · >20 rpm: 5 rpm steps
Delay	· Settings <20 rpm: <4 seconds · Settings >20 rpm: <14 seconds

Apnea Delay

Range	10–40 seconds
Adjustment	5 second steps
Delay	Set apnea delay time + 4 seconds

Ordering Information

Base Unit

Philips 867030 including:
  – 1 x Lithium-ion battery

Mandatory Options

Application Areas

Critical Care Transport Software, includes: – Full Arrhythmia Capability – ST/STE Map – Full Networking – Timers – Alarm Visualization – Smart Alarm Delay – QT Analysis – Hexad derived 12-lead ECG – Full Customization	H72

Waves   3 kreivių vaizdavimo konfigūracija

3-wave capability	A03 1.2.2.4.
4-wave capability	A04
5-wave capability	A05

SpO$_2$ Technology

FAST SpO$_2$	SP1
Masimo rainbow SET SpO$_2$	SP5
Nellcor OxiMax SpO$_2$	SP6

Add-On Options

Measurement Options

Dual SpO$_2$	B02 [a]
Respironics CO$_2$ ready	B03 [a]
Dual Press and Temp	B06 [b]

a. Only available with Philips FAST SpO2
b. Requires the use of Dual IBP Adapter (option K14), or Transpac IV
   Dual IBP Cable (option K16)

Clinical Applications

Parameter Histograms	C09
Conventional 12-Lead ECG	C12

XDS Options

XDS Connectivity	X00

XDS Options

XDS Clinical Workstation	X30
XDS Database	X40

Pulse Oximetry Options

Masimo rainbow SpHb + SpOC	R01
Masimo rainbow SpCO	R02
Masimo rainbow SpMet	R03
Masimo rainbow PVI	R04

SpHb + SpOC + PVI, includes:
  – Masimo rainbow SpHb + SpOC – R01
  – Masimo rainbow PVI – R04
	R11

SpHb + SpOC + PVI + SpMet + SpCO, includes:
  – Masimo rainbow SpHb + SpOC – R01
  – Masimo rainbow SpCO – R02
  – Masimo rainbow SpMet – R03
  – Masimo rainbow PVI – R04
	R12

Masimo rainbow Acoustic Monitoring	R21

Wireless Interfaces   Išmanus belaidis medicininių duomenų perdavimas 1,4 GHz dažniu

802.11 Wireless IF	J35
Smart Hopping IF 1.4 GHz	J45 [a]

[a] Check availability in your country.

Hardware Add-Ons

Fix Clamp Mount	E20
Bedhanger Mount	E21
Add 1 Lithium-ion Battery (includes battery charger adapter)	E24
Rotatable Quick Claw Mount	E29
Carrying Handle	E31
IntelliVue Dock	E50
Sync Signal Cable	SN3

Sensors and Disposables Options

Starter Kits

12-lead Accessories Bundle ICU–AAMI	G01
12-lead Accessories Bundle ICU–IEC	G02
12-lead Accessories Bundle OR–AAMI	G03
12-lead Accessories Bundle OR–IEC	G04

Starter Kits

5-lead Accessories Bundle ICU–AAMI	G06
5-lead Accessories Bundle ICU–IEC	G07
5-lead Accessories Bundle OR–AAMI	G08
5-lead Accessories Bundle OR–IEC	G09
Accessories Bundle Neonatal–AAMI	G14
Accessories Bundle Neonatal–IEC	G15
3-lead Accessories Bundle ICU–AAMI	G16
3-lead Accessories Bundle ICU–IEC	G17
3-lead Accessories Bundle OR–AAMI	G18
3-lead Accessories Bundle OR–IEC	G19

Invasive Pressure Accessories

Dual IBP Adapter – for use with existing Philips–compatible invasive pressure cables	K14
Transpac IV Dual IBP Cable – for use with compatible ICU Medical pressure transducers	K16

Respironics CO_2

CO_2 Mainstream Sensor	N01
Reusable Adult/Pediatric Airway Adapter	N02
Reusable Infant Airway Adapter	N03
Single-Use Adult Airway Adapter	N04
Single-Use Infant Airway Adapter	N05
LoFlo Sidestream CO_2 Sensor	N11
Non-intubated Adult Airway Adapter (Sidestream)	N12
Non-intubated Pediatric Airway Adapter (Sidestream)	N13
Intubated Adult Airway Adapter (Sidestream)	N14
Intubated Pediatric Airway Adapter (Sidestream)	N15

Supplies and Accessories

For information about supplies and accessories, refer to the separate "Philips IntelliVue Accessories" technical data sheet.

Related Products

M3086A IntelliVue Support Tool. Available on DVD and via InCenter. For more information, see: www3.medical.philips.com/resources/hsg/docs/en-us/custom/Intellivue_order.asp

Documentation

All documentation is available in .pdf format on a documentation DVD that is shipped with the product. Additionally, a predefined number of printed Instructions for Use ships with each order.

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CE0123

867030 complies with the requirements of the Council Directive 93/42/EEC of 14 June 1993 (Medical Device Directive) as amended.