Operator's Manual

Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter®

Masimo

These operating instructions provide the necessary information for proper operation of all models of the rainbow SET® IntelliVue Module. There may be information provided in this manual that is not relevant for your system. General knowledge of pulse oximetry and an understanding of the features and functions of rainbow SET® IntelliVue Module are prerequisites for its proper use. Do not operate rainbow SET® IntelliVue Module without completely reading and understanding these instructions.

Notice: Purchase or possession of this device does not carry any express or implied license to use with replacement parts which would, alone or in combination with this device, fall within the scope of one of the relating patents.

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

Note: Cleared Use Only: The device and related accessories are cleared by the Food and Drug Administration (FDA) and are CE Marked for noninvasive patient monitoring and may not be used for any processes, procedures, experiments, or any other use for which the device is not intended or cleared by the applicable regulatory authorities, or in any manner inconsistent with the directions for use or labeling.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, and precautions.

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MEDICAL ELECTRICAL EQUIPMENT WITH RESPECT TO ELECTRIC SHOCK,FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH ANSI/AAMI ES 60601-1:2005,CAN/CSA C22.2 No. 60601-1:2008, and applicable Particular, (ISO 80601-2-61:2011) Standards for which the product has been found to comply by Intertek.

Patents: ***www.masimo.com/patents.htm***

Contents

About this Manual

This manual explains how to set up and use the rainbow SET® IntelliVue Module. Important safety information relating to general use of the rainbow SET® IntelliVue Module appears in this manual. Read and follow any warnings, cautions, and notes presented throughout this manual. The following are explanations of warnings, cautions, and notes.

A *warning* is given when actions may result in a serious outcome (for example, injury, serious adverse effect, death) to the patient or user.

WARNING: This is a sample of a warning statement.

A *caution* is given when any special care is to be exercised by the patient or user to avoid injury to the patient, damage to this device, or damage to other property. The following is an example of a caution:

CAUTION: This is a sample of a caution statement.

A *note* is given when additional general information is applicable. The following is an example of a note:

Note: This is a sample of a note.

Note: This manual contains information for the rainbow SET® IntelliVue Module as used with all available Masimo rainbow SET parameters and related settings/features. The availability of Masimo rainbow SET parameters may vary based on your particular module configuration. Consult the service manual for additional information regarding parameter upgrades.

Product Description, Features and Indications for Use

Product Description

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is a noninvasive monitor that measures arterial oxygen saturation (SpO_2), pulse rate (PR), and Perfusion Index (PI), along with optional measurements of hemoglobin (SpHb®), carboxyhemoglobin (SpCO®), total oxygen content (SpOC), methemoglobin (SpMet®), Pleth Variability Index (PVI®), and Acoustic Respiration Rate (RRa®)*. The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® features Masimo rainbow® technology in a Philips® single-width IntelliVue™-compatible module. The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is compatible with the following Philips IntelliVue Patient Monitoring Systems with software revision L.0 or later:

- IntelliVue MP40 in internal slots
- IntelliVue MP50 in internal slots
- IntelliVue MX500 in internal slots
- IntelliVue MX550 in internal slots
- IntelliVue MP60 via FMS-4 or FMS-8
- IntelliVue MP70 via FMS-4 or FMS-8
- IntelliVue MP80 via FMS-4 or FMS-8
- IntelliVue MP90 via FMS-4 or FMS-8
- IntelliVue MX600 via FMS-4 or FMS-8
- IntelliVue MX700 via FMS-4 or FMS-8
- IntelliVue MX800 via FMS-4 or FMS-8

All measurement information, as well as device status data, is displayed on the front panel of the Philips IntelliVue system.

All user input is handled by control buttons and/or touch screen on the front panel. The sensor cable connection is located on the front of the Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter®.

*RRa and RRac are used interchangeably in this manual to indicate Acoustic Respiration Rate. RRac is specific to the Philips acoustic respiration rate monitoring.

The following features are available for the Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter®. Some features are optional:

- Masimo rainbow technology uses 7+ wavelengths of light to continuously and noninvasively measure carboxyhemoglobin (SpCO), methemoglobin (SpMet), and total hemoglobin (SpHb), as well as providing a more reliable probe-off detection.
- Total arterial oxygen content (SpOC) provides a calculated measurement of the amount of oxygen in arterial blood, which may provide useful information about oxygen both dissolved in plasma and combined with hemoglobin.
- Perfusion Index (PI) with trending capability indicates arterial pulse signal strength and may be used as a diagnostic tool during low perfusion.

- Pleth Variability Index (PVI) may show changes that reflect physiological factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions. For more information, see ***General Description for Pleth Variability Index (PVI)*** on page 16.
- Respiration rate can be determined by the acoustic (RRa) waveform.
- FastSat tracks rapid changes in arterial O_2.

Indications for Use

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is intended to be used with compatible Philips IntelliVue Patient Monitors.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® 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 (RRa). The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is indicated for use during both no motion and motion conditions, and for patients who are well or poorly perfused.

The Masimo rainbow SET® IntelliVue Module Pulse CO-Oximeter® is not intended to be used as the sole basis for making diagnosis or treatment decisions related to suspected carbon monoxide poisoning; it is intended to be used in conjunction with additional methods of assessing clinical signs and symptoms.

Contraindications

The rainbow SET® IntelliVue Module Pulse CO-Oximeter is not intended for use as an apnea monitor.

Safety Information, Warnings, and Cautions

The rainbow SET® IntelliVue Module is to be operated by, or under the supervision of, qualified personnel only. The manual, accessories, directions for use, all precautionary information, and specifications should be read before use.

A complete reading of this manual by personnel in contact with the rainbow SET® IntelliVue Module prior to use is essential for safety. Improper setup, operation, maintenance, or parts replacement could result in injury to personnel and damage to the rainbow SET® IntelliVue Module components.

Always use the rainbow SET® IntelliVue Module precisely in accordance with the directions in this manual, including site selection, sensor placement, and subject behavior during testing. Failure to follow all of the directions in this manual could lead to inaccurate measurements.

Safety Warnings and Cautions

WARNING: Do not use the rainbow SET® IntelliVue Module if it appears or is suspected to be damaged.

WARNING: Do not start or operate the rainbow SET® IntelliVue Module unless the setup was verified to be correct.

WARNING: All sensors and cables are designed for use with specific devices. Verify the compatibility of the device, cable, and sensor before use; otherwise degraded performance and/or patient injury can result.

WARNING: Do not use the rainbow SET® IntelliVue Module during magnetic resonance imaging (MRI) or in an MRI environment.

WARNING: Explosion hazard: Do not use the rainbow SET® IntelliVue Module in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.

WARNING: Do not place the rainbow SET® IntelliVue Module or accessories in any position that might cause it to fall on the patient.

WARNING: To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.

WARNING: To protect against injury, follow the directions below:

- Avoid placing the device on surfaces with visible liquid spills.
- Do not soak or immerse the device in liquids.
- Do not attempt to sterilize the device.
- Use cleaning solutions only as instructed in this operator's manual.
- Do not attempt to clean the rainbow SET® IntelliVue Module while monitoring patient.

WARNING: To protect from electric shock, always remove the sensor and completely disconnect the rainbow SET® IntelliVue Module before bathing the patient.

WARNING: As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.

CAUTION: Do not place the rainbow SET® IntelliVue Module where the controls can be changed by the patient.

CAUTION: When patients are undergoing photodynamic therapy, they may be sensitive to light sources. Pulse oximetry may be used only under careful clinical supervision for short time periods to minimize interference with photodynamic therapy.

CAUTION: Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.

Performance Warnings and Cautions

WARNING: The rainbow SET® IntelliVue Module is not an apnea monitor.

WARNING: The rainbow SET® IntelliVue Module should not be used for arrhythmia analysis.

WARNING: The rainbow SET® IntelliVue Module may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.

WARNING: The rainbow SET® IntelliVue Module may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.

WARNING: Do not place containers with liquids on or near the rainbow SET® IntelliVue Module. Liquids spilled on the rainbow SET® IntelliVue Module may cause it to perform inaccurately or fail.

WARNING: The rainbow SET® IntelliVue Module should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.

WARNING: The rainbow SET® IntelliVue Module should not be used as the sole basis for diagnosis or treatment decisions related to suspected carbon monoxide poisoning. It is intended to be used in conjunction with other clinical tools including signs and symptoms and lab blood tests.

WARNING: A functional tester cannot be used to assess the accuracy of the rainbow SET® IntelliVue Module.

WARNING: Interfering Substances: Dyes, or any substance containing dyes, that change usual blood pigmentation may cause erroneous readings.

WARNING: SpO_2, SpCO, SpMet, and SpHb are empirically calibrated in healthy adult volunteers with normal levels of carboxyhemoglobin (COHb) and methemoglobin (MetHb).

WARNING: Inaccurate SpO_2 readings may be caused by:

- Improper sensor application.
- Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO_2. When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
- Intravascular dyes, such as indocyanine green or methylene blue.
- Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc.
- Elevated levels of bilirubin
- Severe anemia

- Low arterial perfusion
- Motion artifact

WARNING: Inaccurate SpHb and SpOC readings may be caused by:

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc.
- Elevated PaO_2 levels
- Elevated levels of bilirubin
- Low arterial perfusion
- Motion artifact
- Low arterial oxygen saturation levels
- Elevated carboxyhemoglobin levels
- Elevated methemoglobin levels
- Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc.
- Vasospastic diseases such as Raynaud's disease
- Elevated altitude
- Peripheral vascular disease
- Liver disease
- EMI radiation interference

WARNING: Inaccurate SpCO and SpMet readings can be caused by:

- Improper sensor application
- Intravascular dyes such as indocyanine green or methylene blue
- Abnormal hemoglobin levels
- Low arterial perfusion
- Low arterial oxygen saturation levels including altitude induced hypoxemia
- Elevated total bilirubin levels
- Motion artifact
- SpCO readings may not be provided if SpO_2 readings are less than 90%
- SpCO readings may not be provided if SpMet readings are greater than 2%

WARNING: SpCO readings may not be provided if there are low arterial saturation levels or elevated methemoglobin levels.

WARNING: If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the rainbow SET® IntelliVue Module for proper functioning.

WARNING: Inaccurate respiration rate measurements may be caused by:

- Improper sensor application
- Low arterial perfusion
- Motion artifact
- Low arterial oxygen saturation
- Excessive ambient or environmental noise

CAUTION: Do not place the rainbow SET® IntelliVue Module on electrical equipment that may affect the device, preventing it from working properly.

CAUTION: The device must be configured to match your local power line frequency to allow for the cancelation of noise introduced by fluorescent lights and other sources.

CAUTION: If using pulse oximetry during full body irradiation, keep the sensor out of the radiation field. If the sensor is exposed to the radiation, the reading might be inaccurate or the device might read zero for the duration of the active irradiation period.

CAUTION: Variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. Blood samples should be analyzed by laboratory devices prior to clinical decision making to completely understand the patient's condition.

CAUTION: If SpO_2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.

CAUTION: Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing the low SIQ troubleshooting steps listed in the troubleshooting section.

Note: Cables and sensors are provided with X-Cal™ technology to minimize the risk of inaccurate readings and unanticipated loss of patient monitoring. Refer to the Cable or Sensor DFU for the specified duration of patient monitoring time.

Note: Use the rainbow SET® IntelliVue Module in accordance with Environmental Specifications section in this manual.

Note: Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.

Note: Additional information specific to the Masimo sensors compatible with the rainbow SET® IntelliVue Module, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's Directions For Use (DFU).

Note: When monitoring acoustic respiration, Masimo recommends minimally monitoring both oxygenation (SpO_2) and respiration (RRa).

Note: High-intensity extreme lights (such as pulsating strobe lights) directed on the sensor, may not allow the Pulse CO-Oximeter to obtain vital sign readings.

Cleaning and Service Warnings and Cautions

WARNING: Do not adjust, repair, open, disassemble, or modify the rainbow SET® IntelliVue Module. Injury to personnel or equipment damage could occur. Return the rainbow SET® IntelliVue Module for servicing.

WARNING: Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the rainbow SET® IntelliVue Module. These substances affect the device's materials and device failure can result.

CAUTION: An operator may only perform maintenance procedures specifically described in the manual. Refer servicing to qualified service personnel trained in the repair of this equipment.

CAUTION: Do not submerge the rainbow SET® IntelliVue Module in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the rainbow SET® IntelliVue Module.

CAUTION: Electrical Shock Hazard: Carry out periodic tests to verify that leakage currents of patient-applied circuits and the system are within acceptable limits as specified by the applicable safety standards. The summation of leakage currents must be checked and in compliance with IEC 60601-1. The system leakage current must be checked when connecting external equipment to the system. When an event such as a component drop of approximately 1 meter or greater or a spillage of blood or other liquids occurs, retest before further use. Injury to personnel could occur.

Note: Excessive cleaning solution can flow into the rainbow SET® IntelliVue Module and cause damage to internal components.

Compliance Warnings and Cautions

WARNING: Changes or modifications not expressly approved by Masimo shall void the warranty for this equipment and could void the user's authority to operate the equipment.

CAUTION: Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.

CAUTION: To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the rainbow SET® IntelliVue Module.

Note: This equipment has been tested and found to comply with the Class B limits for medical devices according to the EN 60601-1-2, Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Note: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a

particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Note: This Class B digital apparatus complies with Canadian ICES-003.

Chapter 1: Technology

Successful SpO2 Monitoring

The following general points will aid in ensuring oximetry monitoring success.

- Place the sensor on a site that is not too thick, has sufficient perfusion, and provides proper alignment of the LEDs and photodetector.
- Place the sensor on a site that has unrestricted blood flow.
- Do not constrict the monitoring site when securing a sensor with tape.
- Do not select a site near potential electrical interference (electrosurgical unit, for example).
- Read the sensor's Directions for Use for proper sensor application.

Numeric Display: SpO2

Stability of the SpO_2 readings may be a good indicator of signal validity. Although stability is a relative term, experience will provide a good feeling for changes that are artifactual or physiological and the speed, timing, and behavior of each. The stability of the readings over time is affected by the averaging mode being used. The longer the averaging time, the more stable the readings tend to become. This is due to a dampened response as the signal is averaged over a longer period of time than during shorter averaging times. However, longer averaging times delay the response of the oximeter and reduce the measured variations of SpO_2 and PR.

Inaccurate measurements may be caused by:

- Significant levels of dysfunctional hemoglobin (e.g., carboxyhemoglobin or methemoglobin).
- Intravascular dyes such as indocyanine green or methylene blue.
- Venous pulsations at the frequency of the patient's arterial pulse.
- Very low hemoglobin levels.

Numeric Display: Pulse Rate

The Pulse Rate displayed from the rainbow SET® IntelliVue Module may differ slightly from the heart rate displayed from the ECG module due to differences in averaging times. There may also be a discrepancy between cardiac electrical activity and peripheral arterial pulsation. Significant differences may indicate a problem with the signal quality due to physiological changes in the patient or one of the devices or application of the sensor or patient cable. The pulsations from intra-aortic balloon support can be additive to the pulse rate displayed on the pulse oximeter.

General Description for Pleth Variability Index (PVI)

The Pleth Variability Index (PVI) is a measure of the dynamic changes in the perfusion index (PI) that occur during the respiratory cycle. The calculation is accomplished by measuring changes in PI over a time interval where one or more complete respiratory cycles have occurred. PVI is displayed as a percentage (0-100%).

Pleth Variability Index (PVI) may show changes that reflect physiologic factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions.

The utility of PVI has been evaluated in clinical studies [1-11]. Technical and clinical factors that may affect PVI include probe malposition, probe site, patient motion, skin incision, spontaneous breathing activity, lung compliance, open pericardium, use of vasopressors or vasodilators, low perfusion index, subject age, arrhythmias, left or right heart failure, and tidal volume [12-14].

Citations for Pleth Variability Index (PVI)

1. *Cannesson M., Desebbe O., Rosamel P., Delannoy B., Robin J., Bastien O., Lehot J.J. Pleth Variability Index to Monitor the Respiratory Variations in the Pulse Oximeter Plethysmographic Waveform Amplitude and Predict Fluid Responsiveness in the Operating Theatre. Br J Anaesth. 2008 Aug; 101(2):200-6.*
2. *Forget P, Lois F, de Kock M. Goal-Directed Fluid Management Based on the Pulse Oximeter-Derived Pleth Variability Index Reduces Lactate Levels and Improves Fluid Management. Anesth Analg. 2010 Oct; 111(4):910-4.*
3. *Zimmermann M., Feibicke T., Keyl C., Prasser C., Moritz S., Graf B.M., Wiesenack C. Accuracy of Stroke Volume Variation Compared with Pleth Variability Index to Predict Fluid Responsiveness in Mechanically Ventilated Patients Undergoing Major Surgery. Eur J Anaesthesiol. 2010 Jun; 27(6):555-61.*
4. *Desebbe O, Boucau C, Farhat F, Bastien O, Lehot JJ, Cannesson M. Anesth Analg. The Ability of Pleth Variability Index to Predict the Hemodynamic Effects of Positive End-Expiratory Pressure in Mechanically Ventilated Patients under General Anesthesia. 2010 Mar 1; 110(3):792-8.*
5. *Tsuchiya M., Yamada T., Asada A. Pleth Variability Index Predicts Hypotension During Anesthesia Induction. Acta Anesthesiol Scand. 2010 May; 54(5):596-602.*
6. *Loupec T., Nanadoumgar H., Frasca D., Petitpas F., Laksiri L., Baudouin D., Debaene B., Dahyot-Fizelier C., Mimoz O. Pleth Variability Index Predicts Fluid Responsiveness in Critically Ill Patients. Crit Care Med. 2011 Feb; 39(2):294-9.*
7. *Fu Q., Mi W.D., Zhang H. Stroke Volume Variation and Pleth Variability Index to Predict Fluid Responsiveness during Resection of Primary Retroperitoneal Tumors in Hans Chinese. Biosci Trends. 2012 Feb; 6(1):38-43.*
8. *Haas S., Trepte C., Hinteregger M., Fahje R., Sill B., Herich L., Reuter D.A. J. Prediction of Volume Responsiveness using Pleth Variability Index in Patients Undergoing Cardiac Surgery after Cardiopulmonary Bypass. Anesth. 2012 Oct; 26(5):696-701.*
9. *Byon H.J., Lim C.W., Lee J.H., Park Y. H., Kim H.S., Kim C.S., Kim J.T. Br. J. Prediction of fluid Responsiveness in Mechanically Ventilated Children Undergoing Neurosurgery. Anaesth 2013 Apr; 110(4):586-91.*
10. *Feissel M., Kalakhy R., Banwarth P., Badie J., Pavon A., Faller J.P., Quenot JP. Plethysmographic Variation Index Predicts Fluid Responsiveness in Ventilated*

Patients in the Early Phase of Septic Shock in the Emergency Department: A Pilot Study. J Crit Care. 2013 Oct; 28(5):634-9.

11. *Yu Y., Dong J., Xu Z., Shen H., Zheng J. Pleth Variability Index-Directed Fluid Management in Abdominal Surgery under Combined General and Epidural Anesthesia. J Clin Monit Comput. 2014 Feb 21.*
12. *Desgranges F.P., Desebbe O., Ghazouani A., Gilbert K., Keller G., Chiari P., Robin J.,Bastien O., Lehot J.J., Cannesson M. Br. J. Anaesth 2011 Sep; 107(3):329-35.*
13. *Cannesson M. Arterial pressure variation and goal-directed fluid therapy. J Cardiothorac Vasc Anesth. 2010 Jun; 24(3):487-97.*
14. *Takeyama M, Matsunaga A, Kakihana Y, Masuda M, Kuniyoshi T, Kanmura Y. Impact of Skin Incision on the Pleth Variability Index. J Clin Monit Comput 2011 Aug; 25(4):215-21.*

Signal Quality

The Philips IntelliVue Patient Monitoring system display (with the rainbow SET® IntelliVue Module), provides a plethysmogram signal and an alert when the displayed SpO_2 values are not based on adequate signal quality. When the Signal Quality is very low, a "SPO2 POOR SIGNAL" message is displayed. When this occurs, proceed with caution and do the following:

- Assess the patient.
- Check the sensor and ensure proper sensor application. The sensor must be well secured to the site for the rainbow SET® IntelliVue Module to maintain accurate readings. Also, misalignment of the sensor's emitter and detector can result in smaller signals.
- Determine if an extreme change in the patient's physiology and blood flow at the monitoring site occurred, (e.g. an inflated blood pressure cuff, a squeezing motion, sampling of an arterial blood specimen from the hand containing the pulse oximetry sensor, severe hypotension, peripheral vasoconstriction in response to hypothermia, medications, or a spell of Raynaud's syndrome.)
- With neonates or infants, check that the peripheral blood flow to the sensor site is not interrupted. For example, as may occur while lifting or crossing their legs, during a diaper change.

CAUTION: If the *SpO_2 Poor Signal* message is frequently displayed, find a better-perfused monitoring site. In the interim, assess the patient and, if indicated, verify oxygenation status through other means.

Low Perfusion Indicator

The Perfusion Index (PI) is the ratio of the pulsatile blood flow to the non-pulsatile or static blood in peripheral tissue. PI thus represents a noninvasive measure of peripheral perfusion that can be continuously and noninvasively obtained from a pulse oximeter.

The rainbow SET® IntelliVue Module indicates a numerical Perfusion Indicator. When the calculated Perfusion Indicator passes below a threshold (<0.3%), an "SpO2 LOWPERF" message will be displayed to alert to a low signal quality.

CAUTION: If the *SpO_2 Low Perf* message is frequently displayed, find a better-perfused monitoring site, in the interim, assess the patient and, if indicated, verify oxygenation status through other means.

Actions to Be Taken

If the SpO_2 readings show significant differences, do the following:

- Make sure the emitter and photodetector are aligned directly opposite each other.
- Select a site where the distance between the emitter and photodetector is minimized.
- Wipe the sensor site with a 70% isopropyl alcohol pad or rubefacient cream (10%-30% methyl salicylate and 2%-10% menthol) for 20-30 seconds. Strong vasodilator creams, such as nitroglycerin paste, are not recommended.
- If possible, remove electrical noise sources such as electrosurgical units or other electrical/electronic equipment.
- If artificial nails or excessive fingernail polish are present, select another site or remove the polish/artificial nails.
- If possible, ensure that the sensor is placed in a location with low ambient light. Although the rainbow SET® IntelliVue Module pulse oximeter with integrated Masimo SET® technology has significant immunity to ambient light, excessive ambient light may cause readings to be incorrect.

CAUTION: If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse oximeter for proper functioning.

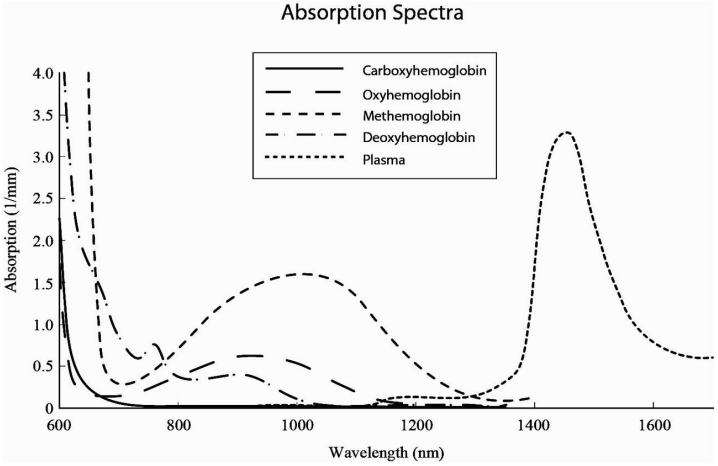
Default settings

Default settings are a function of the Philips IntelliVue monitor. Refer to the *Philips IntelliVue Patient Monitor Instructions for Use* for details.

rainbow Pulse CO-Oximetry Technology®

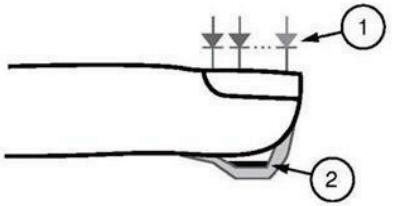
rainbow Pulse CO-Oximetry technology is governed by the following principles:

1. Oxyhemoglobin (oxygenated blood), deoxyhemoglobin (non-oxygenated blood), carboxyhemoglobin (blood with carbon monoxide content), methemoglobin (blood with oxidized hemoglobin) and blood plasma constituents differ in their absorption of visible and infrared light (using spectrophotometry).
2. The amount of arterial blood in tissue changes with pulse (photoplethysmography). Therefore, the amount of light absorbed by the varying quantities of arterial blood changes as well.



The rainbow SET® IntelliVue Module uses a multi-wavelength sensor to distinguish between oxygenated blood, deoxygenated blood, blood with carbon monoxide, oxidized blood and blood plasma.

The rainbow SET® IntelliVue Module utilizes a sensor with various light-emitting diodes (LEDs) that pass light through the site to a diode (detector). Signal data is obtained by passing various visible and infrared lights (LEDs, 500 to 1400nm) through a capillary bed (for example, a fingertip, a hand, a foot) and measuring changes in light absorption during the blood pulsatile cycle. This information may be useful to clinicians. The maximum radiant power of the strongest light is rated at ≤ 25 mW. The detector receives the light, converts it into an electronic signal and sends it to the rainbow SET® IntelliVue Module for calculation.



1. Light Emitting Diodes (LEDs) (7 + wavelengths)
2. Detector

Once the rainbow SET® IntelliVue Module receives the signal from the sensor, it utilizes proprietary algorithms to calculate the patient's functional oxygen saturation (SpO_2 [%]), blood levels of carboxyhemoglobin saturation (SpCO [%]), methemoglobin saturation (SpMet [%]), total hemoglobin concentration (SpHb [g/dL]) and pulse rate (PR). The SpCO, SpMet and SpHb measurements rely on a multi-wavelength calibration equation to quantify the percentage of carbon monoxide and methemoglobin and the concentration of total hemoglobin in arterial blood. Maximum skin-sensor interface temperature was tested to be less than 41° C (106° F) in a minimum ambient temperature of 35° C (95° F). The tests were conducted with sensors operating at reasonable worst case power.

Pulse CO-Oximetry vs. Drawn Whole Blood Measurements

When SpO_2, SpCO, SpMet, and SpHb measurements obtained from the rainbow SET® IntelliVue Module (noninvasive) are compared to drawn whole blood (invasive) measurements by blood gas and/or laboratory CO-Oximetry methods, caution should be taken when evaluating and interpreting the results.

The blood gas and/or laboratory CO-Oximetry measurements may differ from the SpO_2, SpCO, SpMet, SpHb, and SpOC measurements of the rainbow SET® IntelliVue Module. Any comparisons should be simultaneous, meaning the measurement on the device should be noted at the exact time that blood is drawn.

In the case of SpO_2, different results are usually obtained from the arterial blood gas sample if the calculated measurement is not appropriately corrected for the effects of variables that shift the relationship between the partial pressure of oxygen (pO_2) and saturation, such as: pH,temperature, the partial pressure of carbon dioxide (pCO_2), 2,3-DPG, and fetal hemoglobin.

In the case of SpCO, different results are also expected if the level of methemoglobin (MetHb) in the blood gas sample is abnormal (greater than 2% for MetHb).

In the case of SpHb, variation in hemoglobin measurements may be profound and may be affected by sampling technique as well as the patient's physiological conditions. Any results

exhibiting inconsistency with the patient's clinical status should be repeated and/or supplemented with additional test data. As with most hemoglobin tests, a laboratory blood sample should be analyzed prior to clinical decision making.

High levels of bilirubin may cause erroneous SpO_2, SpMet, SpCO, and SpHb readings. As blood samples are usually taken over a period of 20 seconds (the time it takes to draw the blood) a meaningful comparison can only be achieved if the oxygen saturation (SaO_2), levels of carboxyhemoglobin (COHb), and MetHb of the patient are stable and not changing over the period of time that the blood gas sample is taken. Subsequently, blood gas and laboratory CO-Oximetry measurements of SpO_2, SpCO, SpMet, SpHb, and SpOC may vary with the rapid administration of fluids and in procedures such as dialysis. Additionally, drawn whole blood testing can be affected by sample handling methods and time elapsed between blood draw and sample testing.

Measurements with Low Signal IQ should not be compared to laboratory measurements.

General Description for Total Hemoglobin (SpHb)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of total hemoglobin (SpHb) in arterial blood. It relies on the same principles of pulse oximetry to make its SpHb measurement. The measurement is taken by a sensor capable of measuring SpHb, usually on the fingertip for adults and pediatric patients.

The sensor connects directly to the Pulse CO-Oximeter or with a patient cable. The sensor collects signal data from the patient and sends it to the device. The device displays the calculated data as measurement of total hemoglobin concentration.

Successful Monitoring for SpHb

A stable SpHb reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion at the measurement site. Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration, and perfusion. See ***Safety Information, Warnings, and Cautions*** on page 9 and ***Chapter 5: Troubleshooting*** on page 47.

General Description for Total Arterial Oxygen Content (CaO2)

Oxygen (O_2) is carried in the blood in two forms, either dissolved in plasma or combined with hemoglobin. The amount of oxygen in the arterial blood is termed the oxygen content (CaO_2) and is measured in units of ml O_2/dL blood. One gram of hemoglobin (Hb) can carry 1.34 ml of oxygen, whereas 100 ml of blood plasma may carry approximately 0.3 ml of oxygen.* The oxygen content is determined mathematically as:

$$CaO_2 = 1.34\ (ml\ O_2/g) \times Hb\ (g/dL) \times HbO_2 + PaO_2\ (mmHg) \times 0.003\ (ml\ O_2/dL/mmHg)$$

Where HbO_2 is the fractional arterial oxygen saturation and PaO_2 is the partial pressure of arterial oxygen.

For typical PaO_2 values, the second part of the above equation is approximately 0.3 ml O_2/dL based on PaO_2 being approximately 100 mmHg. Furthermore, for typical carboxyhemoglobin and methemoglobin levels, the functional saturation (SpO_2) as measured by a pulse oximeter is given by:

$$SpO_2 = 1.02 \times HbO_2$$

**Martin, Laurence. All You Really Need to Know to Interpret Arterial Blood Gases, Second Edition. New York: Lippincott Williams & Wilkins, 1999.*

General Description for SpOC

The above approximations result in the following reduced equation for oxygen content via the Pulse CO-Oximeter:

$$SpOC\ (ml/dL^*) = 1.31\ (ml\ O_2/g) \times SpHb\ (g/dL) \times SpO_2 + 0.3\ (ml\ O_2/dL)$$

*When ml O_2/g Hb is multiplied by g/dL of SpHb, the gram unit in the denominator of ml/g cancels the gram unit in the numerator of g/dL resulting in ml/dL (ml of oxygen in one dL of blood) as the unit of measure for SpOC. See ***Safety Information, Warnings, and Cautions** on page 9.

General Description for Carboxyhemoglobin (SpCO)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of carboxyhemoglobin saturation (SpCO) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpCO measurement.

The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry device or through a device patient cable.

The sensor collects signal data from the patient and sends it to the device. The device displays the calculated data as percentage value for the SpCO, which reflect blood levels of carbon monoxide bound to hemoglobin.

Successful Monitoring for SpCO

A stable SpCO reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (measurement site). Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. See ***Safety Information, Warnings, and Cautions*** on page 9.

General Description for Methemoglobin (SpMet)

Pulse CO-Oximetry is a continuous and noninvasive method of measuring the levels of methemoglobin saturation (SpMet) in arterial blood. It relies on the same basic principles of pulse oximetry (spectrophotometry) to make its SpMet measurement.

The measurement is obtained by placing a sensor on a patient, usually on the fingertip for adults and the hand or foot for infants. The sensor connects either directly to the Pulse CO-Oximetry device or through a patient cable.

The sensor collects signal data from the patient and sends it to the device. The device displays the calculated data as percentage value for the SpMet.

Successful Monitoring for SpMet

A stable SpMet reading is associated with correct sensor placement, small physiological changes during the measurement and acceptable levels of arterial perfusion in the patient's fingertip (measurement site).

Physiological changes at the measurement site are mainly caused by fluctuations in the oxygen saturation, blood concentration and perfusion. See ***Safety Information, Warnings, and Cautions*** on page 9.

SpCO, SpMet, and SpHb Measurements During Patient Motion

The rainbow SET® IntelliVue Module displays measurements of SpCO, SpMet, and SpHb during patient motion. However, because of the changes in the physiological parameters such as blood volume, arterial-venous coupling, etc. that occur during patient motion, the accuracy of such measurements may not be reliable during excessive motion. In this case, the measurement value for SpCO, SpMet, or SpHb displays as dashes (---) and a message (*Low SpCO SIQ*, *Low SpMet SIQ*, or *Low SpHb SIQ*) displays to alert the clinician that the device does not have confidence in the value due to poor signal quality caused by excessive motion or other signal interference.

rainbow Acoustic Monitoring (RAM) Technology

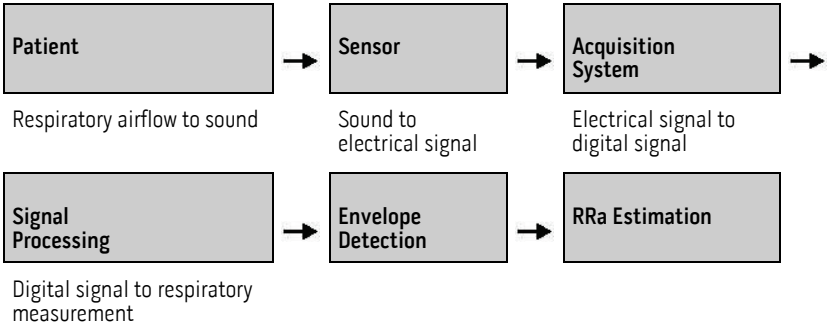
rainbow Acoustic Monitoring™ (RAM™) continuously measures a patient's respiration rate based on airflow sounds generated in the upper airway. The Acoustic Sensor, which is applied on the patient's neck, translates airflow sounds generated in the upper airway to an electrical signal that can be processed to produce a respiration rate, measured as breaths per minute.

Respiratory sounds include sounds related to respiration such as breath sounds (during inspiration and expiration), adventitious sounds, cough sounds, snoring sounds, sneezing sounds, and sounds from the respiratory muscles [1].

These respiratory sounds often have different characteristics depending on the location of recording [2] and they originate in the large airways where air velocity and air turbulence induce vibration in the airway wall. These vibrations are transmitted, for example, through the lung tissue, thoracic wall and trachea to the surface where they may be heard with the aid of a stethoscope, a microphone or more sophisticated devices.

rainbow Acoustic Monitoring Architecture

The following figure illustrates how a respiratory sound produced by a patient can be turned into a numerical measurement that corresponds to a respiratory parameter.



Patient

The generation of respiratory sounds is primarily related to turbulent respiratory airflow in upper airways. Sound pressure waves within the airway gas and airway wall motion contribute to the vibrations that reach the body surface and are recorded as respiratory sounds.

Although the spectral shape of respiratory sounds varies widely from person to person, it is often reproducible within the same person, likely reflecting the strong influence of individual airway anatomy [2-6].

Sensor

The sensor captures respiratory sounds (and other biological sounds) much like a microphone does. When subjected to a mechanical strain, (e.g., surface vibrations generated during breathing), the sensor becomes electrically polarized.

The degree of polarization is proportional to the applied strain. The output of the sensor is an electric signal that includes a sound signal that is modulated by inspiratory and expiratory phases of the respiratory cycle.

Acquisition System

The acquisition system converts the electric signal provided by the sensor into a digital signal. This format allows the signal to be processed by a computing device.

Signal Processing

The digital signal produced by the acquisition system is converted into a measurement that corresponds to the respiratory parameter of interest. As shown in the previous figure, this can be performed by, for example, determining the digital signal envelope or outline which in turn may be utilized to determine the respiratory rate. In this way, a real-time, continuous breath rate parameter can be obtained and displayed on a monitor which, in many cases, may be real-time and continuous.

The respiratory cycle envelope signal processing principle is similar to methods that sample airway gasses and subsequently determine a respiratory rate.

Citations

[1] A.R.A. Sovijärvi, F. Dalmasso, J. Vanderschool, L.P. Malmberg, G. Righini, S.A.T. Stoneman. Definition of terms for applications of respiratory sounds. Eur Respir Rev 2000; 10:77, 597-610.

[2] Z. Moussavi. Fundamentals of respiratory sounds analysis. Synthesis lectures on biomedical engineering #8. Morgan & Claypool Publishers, 2006.

[3] Olsen, et al. Mechanisms of lung sound generation. Semin Respir Med 1985; 6: 171-179.

[4] Pastercamp H, Kraman SS, Wodicka GR. Respiratory sounds – Advances beyond the stethoscope. Am J Respir Crit Care Med 1977; 156: 974-987.

[5] Gavriely N, Cugell DW. Airflow effects on amplitude and spectral content of normal breath sounds. J Appl Physiol 1996; 80: 5-13.

[6] Gavrieli N, Palti Y, Alroy G. Spectral characteristics of normal breath sounds. J Appl Physiol 1981; 50: 307-314.

Chapter 2: Description

General System Description

The rainbow SET® IntelliVue Module system includes the following:

- rainbow SET® IntelliVue Module Device

Sensor Compatibility

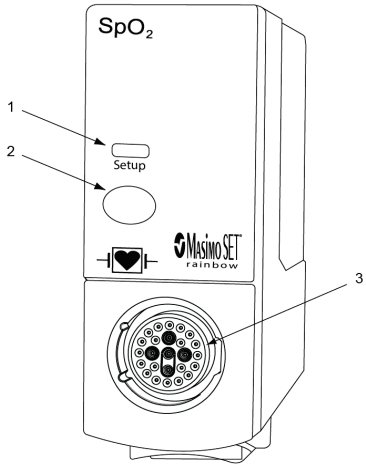
The rainbow SET® IntelliVue Module is compatible with clinically validated Masimo sensors. The compatible sensor product families are as follows:

- LNOP, LNCS, M-LNCS and RD SET product family of sensors and cables.
- Rainbow SET product family of sensors and cables.
- RAM product family of sensors and cables.

Additional information specific to the Masimo sensors and patient cables that are compatible with rainbow SET® IntelliVue Module, including information about parameter/measurement performance during motion and low perfusion, site selection, and sensor placement, may be found in the *Directions for Use* for the sensor or cable.

Front and Rear Panels

Front



1. Setup Indicator

This indicator is illuminated when the Setup menu for this Module is displayed on the monitor screen.

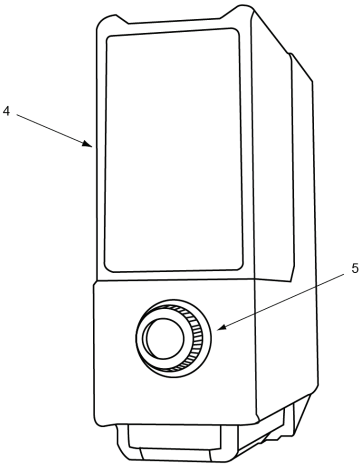
2. Setup Key

Press the Setup key to display the measurement's setup menu on the monitor screen.

3. Patient Cable Connector Socket

Connects to the Masimo patient cable.

Rear



4. Label

Serial number and certification label.

5. Power Connector

Connects into the mating connector within the internal slots of Philips IntelliVue Patient Monitoring System or the Flexible Measurement Server.

Chapter 3: Setting Up

Introduction

Before the rainbow SET® IntelliVue Module can be used in a clinical setting, it needs to be inspected, installed into an internal slot or rack (see ***Product Description*** on page 7), and properly set up.

Unpacking and Inspection

1. Remove the rainbow SET® IntelliVue Module from the shipping carton and examine for signs of shipping damage. Check all materials against the packing list. Save all packing materials, invoice and bill of lading. These may be required to process a claim with the carrier.
2. If anything is missing or damaged, contact the Technical Service Department. The contact address and phone numbers are listed in ***Service and Repair*** on page 79.
3. The rainbow SET® IntelliVue Module may be plugged and unplugged during monitoring. Insert the module until the lever on the module clicks into place. Remove the module by pressing the lever upwards and pulling the module out. Reconnecting a module to the same monitor restores its label and measurement settings, such as alarm limits. If you insert the module into a different monitor, the module remembers only its label.

Preparation for Monitoring

The following sections of the manual describe the preparation, setup, and initial installation of the rainbow SET® IntelliVue Module.

Power Requirements

All necessary power is provided by the Philips IntelliVue system.

Monitor Setup

Prior to initial setup:

1. Inspect the rainbow SET® IntelliVue Module for damage.
2. Install the rainbow SET® IntelliVue Module into an empty slot in a compatible Philips IntelliVue Patient Monitoring System. For a list of compatible monitors, see ***Product Description*** on page 7.

   Cautions:

- Only one rainbow SET® IntelliVue Module per FMS/integrated rack is supported.
- The rainbow SET® IntelliVue Module and Philips Anesthetic Gas Module (AGM) cannot be combined in one system.

3. Insert the module until the lever on the module clicks into place.
4. Press the Setup key on the front of the rainbow SET® IntelliVue Module to display the measurement's setup menu on the monitor screen. When the setup menu is open, a light appears above the key.
5. Connect the patient cable to the connector socket on the front of the rainbow SET® IntelliVue Module.

   Caution: Ensure that you are using a Masimo patient cable. There are a number of similar connectors with different colors and different mechanical keying. Never force a patient cable connector into the rainbow SET® IntelliVue Module. Failure to use a Masimo patient cable may result in damage to the module, inaccurate readings, or no readings.

For additional steps to verify proper functioning of the unit, see ***General Setup and Use*** on page 31.

For information on supported sensors and selection criteria, see the sensor's Directions for Use.

Chapter 4: Operation

Introduction

To effectively utilize the SpO_2, pulse rate, and rainbow parameter information on the IntelliVue screen, the device must be properly set up, and the operator must:

- Know how the rainbow SET® IntelliVue Module derives its readings.
- Be familiar with its controls and operation.
- Understand its status and alarm messages. For more information, see ***Alarms*** on page 39 and ***Chapter 5: Troubleshooting*** on page 47.

Basic Operation

General Setup and Use

1. Inspect the oximeter case for damage.
2. Connect a Masimo patient cable to the patient cable socket of the rainbow SET® IntelliVue Module.
3. Make sure it is a firm connection and the cable is not twisted, sliced, or frayed.
4. Connect sensor to appropriate patient cable. If using a single patient adhesive or disposable sensor, check that the emitter (red light) and the photodetector are properly aligned. If using a reusable sensor, make sure it opens and closes smoothly. Remove any substances that may interfere with the transmission of light between the sensor's light source and photo detector.
5. Attach the sensor to the patient. Refer to the sensor's Directions for Use for appropriate sensor application.
6. Connect the sensor to the patient cable; make sure it is a firm connection.
7. Verify the display on the Philips IntelliVue Patient Monitor is free of alarm and system failure messages. See ***Chapter 5: Troubleshooting*** on page 47.
8. On the display, verify the readings for SpO_2 and pulse rate.

   Note: *"?" will be on the numeric display until the SpO_2 and pulse rate readings have stabilized (approximately 10 seconds).*

9. Verify that the patient alarms are functional by setting the high and low SpO_2 and pulse rate alarm limits beyond the patient readings.
   - An alarm tone sounds.
   - The violated alarm limit and reading flash on the display.
10. Verify the sensor alarms are functional by removing the sensor from the sensor site.
    - *SpO2 SENSOR OFF* message appears on the display.
    - The alarm tone sounds.
    - Disconnect the sensor from the patient cable or the rainbow SET® IntelliVue Module.
    - Confirm that either a *SpO2 NO SENSOR* message appears on the display or the SpO_2 display box goes away.

    Note: Refer to the *Philips IntelliVue Patient Monitor Instructions for Use* for specific information on alarm options and behavior. See ***Alarms*** on page 39, for additional rainbow alarm information.
11. To begin patient monitoring, refer to the *Philips IntelliVue Patient Monitor Instructions for Use*.
12. Verify the sensor is applied correctly and that the measured data is appropriate. See ***Successful SpO2 Monitoring*** on page 15.
13. Monitor the patient.
14. After monitoring is complete, remove the sensor from the patient and store or dispose of the sensor according to governing rules. See the sensor's Directions for Use.

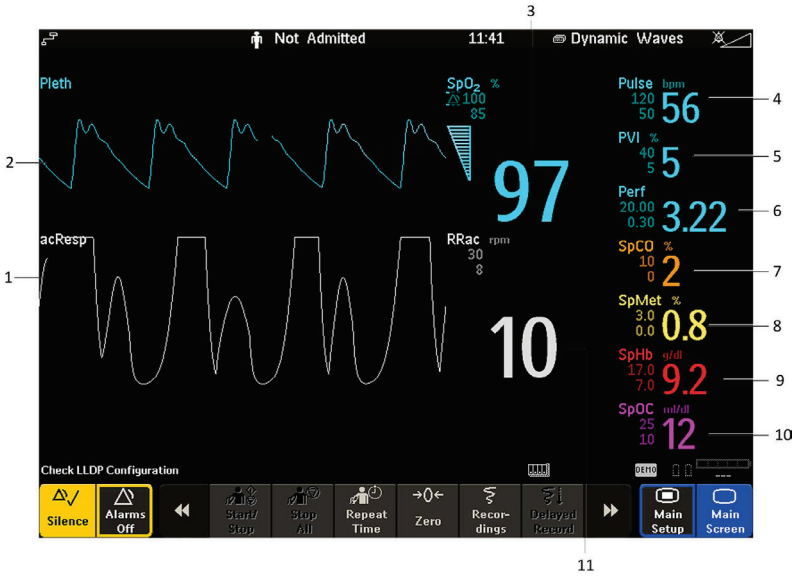
    Note: The feature NBP Alarm Suppression that can be configured in the IntelliVue system is not supported by the rainbow SET® IntelliVue Module and its setting has no effect to the operation nor the performance of the rainbow SET® IntelliVue Module.

Masimo rainbow SET Measurements

To enable the rainbow SET measurements, the label for SpO_2 has to be set to the standard SpO_2 and not to an alternative label e.g. SpO_2po.

To use the measurements SpCO, SpHb/SpOC, or SpMet, connect a sensor to the patient monitor that supports those measurements and enable the measurement in the SpO_2 menu.

Screen Layout Example



No.	Description	No.	Description
1	Respiration wave	7	SpCO label with alarm limits and numeric
2	Pleth wave	8	SpMet label with alarm limits and numeric
3	SpO_2 label with alarm limits and numeric	9	SpHb label with alarm limits and numeric
4	Pulse label with alarm limits and numeric	10	SpOC label with alarm limits and numeric
5	PVI label with alarm limits and numeric	11	RRac label with alarm limits and numeric
6	Perfusion (Perf) label with alarm limits and numeric	--	--

The rainbow SET measurements can be set up and customized in Configuration and Monitoring Mode. Refer to the *Philips IntelliVue Patient Monitor Instructions for Use* for additional instructions.

SpO2 Sensitivity

Sensitivity settings allow you to adapt the SpO_2 measurement sensitivity to the strength and quality of the SpO_2 signal at the measurement site.

Normal Sensitivity

Normal Sensitivity is the recommended sensitivity mode for patients who are experiencing some compromise in blood flow or perfusion. It is advisable for care areas where patients are observed frequently, such as an intensive care unit (ICU).

Adaptive Probe Off Detection (APOD) Sensitivity

APOD (Adaptive Probe Off Detection Sensitivity) APOD is the recommended sensitivity mode where there is a high probability of the sensor becoming detached. It is also the suggested mode for care areas where patients are not visually monitored continuously. This mode delivers enhanced protection against erroneous pulse rate and arterial oxygen saturation readings when a sensor becomes inadvertently detached from a patient due to excessive movement.

1. Select the **Setup SpO2** menu.
2. Select **Sensitivity** from the menu.
3. Switch between **APOD** and **Normal**.

Maximum Sensitivity (MAX)

This is a temporary setting recommended for use on patients with weak signals (e.g. high ambient noise and/or patients with very low perfusion) and for use during procedures, or when you have continuous patient contact, such as in higher-acuity settings.

1. Select the **Setup SpO2** menu.
2. Select **Max. Sensitivity** from the menu.
3. Switch between **On** and **Off**.
4. When you select **On**, the following message displays:
   Select Confirm to enable maximum sensitivity. Sensor off detection is compromised, attended monitoring recommended.
5. Select **Confirm**.

Sensitivity will fall back to the configured sensitivity (APOD or Normal) after a patient is discharged. Also if the Sensitivity Mode is manually set to APOD or Normal, the MAX Sensitivity will fall back to Off. Maximum Sensitivity will survive a short power interruption.

FastSat

FastSat enables rapid tracking of arterial oxygen saturation changes. Arterial oxygen saturation data is averaged using pulse oximeter averaging algorithms to smooth the trend. When FastSat is ON, the averaging algorithm evaluates all the saturation values providing an averaged saturation value that is a better representation of the patient's current oxygenation status. With FastSat, the averaging time is dependent on the input signal.

1. Select the **Setup SpO2** menu.
2. Select **FastSat Algor.** from the menu.
3. Switch between **No** and **Yes**.

Masimo rainbow Parameter Setup

General setup information for Masimo rainbow features are defined below. Refer to the *Philips IntelliVue Patient Monitor Instructions for Use* for additional instructions.

Perfusion (Perf)

1. Select the **Setup SpO2** menu.
2. Select **Perf** from the menu.
3. Select if the Perf measurement should be **On** or **Off**.
4. Select if Alarms should be **On** or **Off**.
5. Enter values for the **High Limit** and **Low Limit**.

Setting up Perfusion Baseline

Select **Set Baseline** to update the perfusion baseline. Setting the perfusion baseline also turns on the 3D Perf Delta Alarm. Whenever the perfusion baseline is set, the 3D Perf Delta duration is started automatically with the configured value. See 3D Perf Delta instructions for further information.

Perfusion Index 3D Alarm (3D Perf Delta)

1. Select **3D Perf Delta** from the menu.
2. Select if the 3D Perf Delta should be **On** or **Off**.
3. Enter a value for the **% Decrease** parameter.
4. Enter a value for the **Duration** the alarm should be active.

Note: The 3D Perf Delta is cleared/disabled when the sensor is unplugged, or when a Sensor off condition occurs, or when a patient is discharged. It will not be re-enabled automatically. The extended alarm text contains the maximum exceeded Perf Delta value.

Desat Index 3D Alarm (3D Desat Index)

The configurable 3D Desat Index alarm is issued when a patient experiences a specified number of desaturations that exceed a specified threshold over a specific period of time.

1. Select the **Setup SpO2** menu.
2. Select **3D Desat Index** from the menu.
3. Select if the 3D Desat Index should be **On** or **Off**.
4. Set the **Delta Threshold** for the alarm between minimum 2% and maximum 10%, in steps of 1%.
5. Set the **Count** for the alarm between minimum 1 and maximum 25, in steps of 1.
6. Set the **Period** for which the alarm should be active, with a minimum of 1 hour to a maximum of 4 hours, and in a step size of 1 hour.

Note: The 3D Desat Index restarts counting when power is removed from the measurement device (e.g. MMS is moved to different monitor), the sensor or patient cable is disconnected, or in the event of a Sensor off condition.

PVI

The Pleth Variability Index (PVI) numeric may reflect physiologic factors such as vascular tone, circulating blood volume, and intrathoracic pressure excursions.

1. Select the **Setup SpO2** menu.
2. Select **PVI** from the menu.
3. Select if the PVI measurement should be **On** or **Off**.
4. Select if Alarms should be **On** or **Off** for the measurement.
5. Enter values for the **High Limit** and **Low Limit**.

SpCO

The SpCO numeric reflects the carboxyhemoglobin saturation at the measurement location.

1. Select the **Setup SpO2** menu.
2. Select **SpCO** from the menu.
3. Select if the SpCO measurement should be **Enabled** or **Disabled**.
4. Select if Alarms should be **On** or **Off** for the measurement.
5. Enter values for the **High Limit** and **Low Limit**.

SpMet

The SpMet numeric reflects the methemoglobin saturation at the measurement location.

1. Select the **Setup SpO2** menu.
2. Select **SpMet** from the menu.
3. Select if the SpMet measurement should be **Enabled** or **Disabled**.
4. Select if Alarms should be **On** or **Off** for the measurement.
5. Enter values for the **High Limit** and **Low Limit**.

SpHb/SpOC

The SpHb numeric reflects the total hemoglobin concentration at the measurement location.

1. Select the **Setup SpO2** menu.
2. Select **SpHb/SpOC** from the menu.
3. Select if the SpHb measurement should be **Enabled** or **Disabled**.
4. Select if Alarms should be **On** or **Off** for the measurement.
5. Enter values for the **High Limit** and **Low Limit**.

The SpOC numeric reflects the total oxygen content at the measurement location. The SpOC numeric requires the SpHb measurement to be enabled. SpOC is calculated from SpO2 and SpHb values.

1. Select the **Setup SpO2** menu.
2. Select **SpHb/SpOC** from the menu.
3. Select if the SpHb measurement should be **Enabled** or **Disabled**.
4. Select if SpOC Alarms should be **On** or **Off** for the measurement.
5. Enter values for the **High Limit** and **Low Limit**.

SpHb Averaging

Depending on the configuration, the user may be able to select the averaging period for SpHb in Monitoring Mode. The choices are **Short**, **Medium**, or **Long**. This setting adjusts the responsiveness of the SpHb measurement to make rapid variations of SpHb values more visible.

SpHb Mode

Depending on your configuration, you may be able to select the SpHb monitoring mode in the Monitoring Mode. The choices are **Arterial** or **Venous**. This setting adjusts the source of the SpHb reading to arterial or venous.

Note: When in Venous mode, the SpHb label will display as **SpHbv**.

RRac

The RRac numeric reflects the respiration rate at the measurement location. SpO_2 monitoring is required when monitoring RRac.

1. Select the **Setup SpO2** menu.
2. Select **RRac** from the menu.
3. Select if the RRac measurement should be **On** or **Off**.
4. Select if Alarms should be **On** or **Off** for the measurement.
5. Enter values for the **High Limit** and **Low Limit**.
6. Set the **Pause Time** from minimum 15 sec to maximum 40 sec, in steps of 5 sec.
7. Set the **Max.Extd. Update** choosing from 0, 1, 5, 10, or 15 minutes.

The **Max.Extd. Update** value determines the maximum amount of time the measurement will display the last known RRac value before the value becomes invalid. If it is set to a value other than 0 and the measurement cannot detect a respiration signal, there is no immediate indication (INOP issued) that the displayed status is an older one, and that currently no measurement is possible. If you do change the value, you are prompted to confirm your choice.

RRac Averaging

Depending on the configuration, the user may be able to select the averaging period for RRac in Monitoring Mode. The choices are **None**, **Fast**, **Medium**, **Slow**, and **Trending**. This setting adjusts the responsiveness of the RRac measurement.

Alarms

The following tables show typical alarm limits and default settings for the rainbow IntelliVue Module. Refer to the *Philips IntelliVue Patient Monitor Instructions for Use* for additional instructions on setting alarm limits.

Alarm Limits

Item	Profile	High Range	Low Range	Desat Range	Adjustment Steps
SpO_2	Adult	51-100%	50-99%	50-99%	1%
	Neonate/Pediatric	31-100%	30-99%	30-99%	1%

Item	Profile	High Range	Low Range	Adjustment Steps
SpMet	Adult/Pediatric/ Neonate	0.1-100.0%	0.0-99.0%	0.1% (0.0-9.9%) 1% (10.0-100.0%)
SpCO	Adult/Pediatric/ Neonate	1-100%	0-99%	1%
SpHb	Adult/Pediatric/ Neonate	0.1-25.0 g/dl 0.1-15.5 mmol/l	0.0-24.5 g/dl 0.0-15.0 mmol/l	0.1g/dl (0.0-9.9 g/dl) 0.1g/dl (0.0-9.9 mmol/l) 0.5 mmol/l (10.0-25.0 g/dl) 0.5 mmol/l (10.0-15.5 mmol/l)
Pulse Rate	Adult	31-300 bpm	30-295 bpm	1 bpm (30-40 bpm) 5 bpm (40-300 bpm)
	Neonate/Pediatric	31-300 bpm	30-295 bpm	1 bpm (30-50 bpm) 5 bpm (50-300 bpm)
PVI	Adult/Pediatric/ Neonate	1-100%	0-99%	1%
RRac	Adult/Pediatric	1-100 rpm	0-95 rpm	1 rpm steps below 20 rpm 5 rpm steps above 20 rpm
	Neonate	30-150 rpm	0-145 rpm	1 rpm steps below 20 rpm 5 rpm steps above 20 rpm
Perf	Adult/Pediatric/ Neonate	0.10-20.00	0.02-19.00	0.01 (0.02-0.10) 0.10 (0.10-1.00) 1.00 (1.00-20.00)

Item	% Decrease	Adjustment Steps	Duration	Adjustment Steps
3D Perf Delta PI Delta 3D Alarm	10-100%	2%	1 min - 48 hr, Infinite	1 min, 5 min, 30 min, 1 hr, 4 hr, 8 hr, 12 hr, 24 hr, 36 hr, 48 hr, Infinite

Item	3D Desat Index Settings	Range	Adjustment Steps
3D Desat Index – Desat Index 3D Alarm	Delta Threshold	2-10%	1%
	Count	25-Jan	1
	Period	1-4 hr	1 hr

Check alarm limits each time the pulse oximeter is used in order to ensure that they are appropriate for the patient being monitored. An audible alarm and an alarm icon and a flashing indicator light will occur when an alarm limit is exceeded.

If the monitor is having a problem picking up the signal from the sensor, it will display one of two alarm messages:

- *SpO2 SENSOR OFF:* The sensor is not properly attached to the patient.
- *SpO2 NO SENSOR* or SpO_2 parameters are not displayed: The sensor is not properly attached to the patient cable or the patient cable is not properly attached to the monitor.

See ***Technical Alarm Messages (INOPs)*** on page 48 for more information regarding Philips technical alarm messages (INOPs).

Alarm Delays

Alarm Specifications	Standard Delay	Smart Alarm Delay		
		Short Mode	Medium Mode	Long Mode
SpO_2 high and low limit alarms	0-30 seconds (adjustable in 1 second steps) + system alarm delay	10-25 seconds + system alarm delay	10-50 seconds + system alarm delay	10-100 seconds + system alarm delay

Alarm Specifications	Standard Delay
Desat	0-30 seconds (adjustable in 1 second steps) + system alarm delay
Pulse	10 seconds + system alarm delay
RRac	0, 10, 15, 30, 60 seconds + system alarm delay
PVI	system alarm delay
Perf	system alarm delay
SpCO	system alarm delay
SpHb	system alarm delay
SpMet	system alarm delay
SpOC	system alarm delay

Alarm Default Settings

SpO_2

Setting	Adult	Pediatric	Neonate
Desat Limit	80	80	80
Low Limit	90	90	85
High Limit	100	100	95
Desat Delay	20 sec	20 sec	20 sec
High Alarm Delay	10 sec	10 sec	10 sec
Low Alarm Delay	10 sec	10 sec	10 sec
SpO_2 Alarms	On	On	On

Setting	Adult	Pediatric	Neonate
Perfusion	On	On	On
Color	Cyan	Cyan	Cyan
Extd. Auto OnOff	Disabled	Disabled	Disabled
Average in Mon.	No	No	No
Signal Quality (Also available with rainbow SET, but not supported from the existing Masimo SET)	On	On	On
SmartAlarmDelay **(SAD)** (If set to On, the High/Low Alarm Limit Delay (SAD) settings are valid; if set to Off, the Standard SpO_2 High/Low Alarm limit delay setting (0-30 sec) is valid)	Off	Off	Off
High Alarm Delay **(SAD)**	Short	Short	Short
Low Alarm Delay **(SAD)**	Short	Short	Short

SpO_2 rainbow

Setting	Adult	Pediatric	Neonate
Averaging Time	8 sec	8 sec	8 sec
Algorithm Sensitivity	APOD	APOD	APOD
FastSat Algorithm	Off	Off	Off
Smart Tone	Off	Off	Off
3D Desat Index	Off	Off	Off
3D Desat Index Threshold	4%	4%	4%
3D Desat Index Count	5	5	5
3D Desat Index Period	1 hr	1 hr	1 hr

Pulse Rate

Setting*	Adult	Pediatric	Neonate
Pulse (SpO_2)	On	On	On
Pulse Alarms	On	On	On
High Limit	120 bpm	160 bpm	200 bpm
Low Limit	50 bpm	75 bpm	100 bpm

*Dependent on HR/Pulse Source SpO_2 Setting

Perfusion

Setting	Adult	Pediatric	Neonate
High Limit	20	20	10
Low Limit	0.3	0.3	0.3
Alarms	Off	Off	Off
3D Perf Delta % Decrease	50%	50%	50%
3D Perf Delta Period Duration	Infinite	Infinite	Infinite

PVI (Pleth Variability Index)

Note: The PVI numeric has the same color that is configured for the SpO_2 numeric

Setting	Adult	Pediatric	Neonate
High Limit	40	40	40
Low Limit	5	5	5
PVI Alarms	Off	Off	Off
PVI	Enabled	Enabled	Enabled

SpMet

Settings	Adult	Pediatric	Neonate
High Limit	3.00%	3.00%	3.00%
Low Limit	0.00%	0.00%	0.00%
SpMet Alarms	On	On	On
SpMet	Enabled	Enabled	Enabled
Color	Yellow	Yellow	Yellow

SpCO

Setting	Adult	Pediatric	Neonate
High Limit	10%	10%	10%
Low Limit	0%	0%	0%
SpCO Alarms	On	On	On
SpCO	Enabled	Enabled	Enabled
Color	Orange	Orange	Orange

SpHb/SpOC

Setting	Adult	Pediatric	Neonate
SpHb	Enabled	Enabled	Enabled
SpHb High Limit	17.0 g/dl	17.0 g/dl	17.0 g/dl
SpHb Low Limit	7.0 g/dl	7.0 g/dl	7.0 g/dl
SpHb Alarms	On	On	On

Setting	Adult	Pediatric	Neonate
SpHb Unit	g/dl	g/dl	g/dl
Average	Medium	Medium	Medium
SpHb Precision	0.1	0.1	0.1
SpHb Cal	Arterial	Arterial	Arterial
SpHb Color	Red	Red	Red
SpOC	Enabled	Enabled	Enabled
SpOC High Limit	25 ml/dl	25 ml/dl	25 ml/dl
SpOC Low Limit	10 ml/dl	10 ml/dl	10 ml/dl
SpOC Alarms	Off	Off	Off
SpOC Color	Magenta	Magenta	Magenta

RRac

Setting	Adult	Pediatric	Neonate
High Limit	30 rpm	30 rpm	100 rpm
Low Limit	8 rpm	8 rpm	30 rpm
Alarms	On	On	On
Alarm Delay	30 seconds	30 seconds	30 seconds
Average	Slow	Slow	Slow
Pause Time	30 seconds	30 seconds	30 seconds
Max.Extd. Update	0 min	0 min	0 min
Color	White	White	White

Chapter 5: Troubleshooting

rainbow SET® IntelliVue Module Troubleshooting

The following chart describes what to do if the rainbow SET® IntelliVue Module does not operate properly or fails.

Issue	Possible Cause	Recommendation
The rainbow SET® IntelliVue Module does not power on	The rainbow SET® IntelliVue Module is not properly installed into the Philips IntelliVue Patient Monitor.	Confirm the rainbow SET® IntelliVue Module is fully inserted. Remove and re-insert the rainbow SET® IntelliVue Module. Listen for 'click' as locking lever snaps into place. Remove and re-insert the rainbow SET® IntelliVue Module into a different slot. Listen for 'click' as locking lever snaps into place.
	The rainbow SET® IntelliVue Module may not be installed in the recommended slot.	See ***Product Description*** on page 7 and confirm that it has been installed in the recommended slot.
	Philips IntelliVue Patient Monitor may not support the rainbow SET® IntelliVue Module.	See ***Product Description*** on page 7 and confirm the IntelliVue monitor software version.
No SpO_2 display on monitor screen	Philips IntelliVue Patient Monitor not properly configured.	Refer to the *Philips IntelliVue Patient Monitor Instructions for Use* for details on installing and configuring modules.
	Philips IntelliVue system not at proper software revision.	Upgrade Philips IntelliVue Patient Monitor and FMS (if applicable) to the software revision indicated in the ***Product Description*** on page 7.
	The rainbow SET® IntelliVue Module is not supported by the monitoring system.	Confirm the rainbow SET® IntelliVue Module is installed in a supported patient monitoring system.
	Sensor or cable not properly attached to the rainbow SET® IntelliVue Module.	Inspect connection of patient cable to the rainbow SET® IntelliVue Module. Inspect connection of sensor to patient cable. Replace cable or sensor if indicated.

Issue	Possible Cause	Recommendation
	The rainbow SET® IntelliVue Module is not properly installed into the Philips IntelliVue Patient Monitor.	See *The rainbow SET® IntelliVue Module does not power on* section above.
No speaker tone	Alarm Silence Enabled	Inspect Alarm Silence Indicator. *See Philips IntelliVue Patient Monitor Instructions for Use*, for specific details.
SpO2 Equip Malf error message	Internal Failure of Module	Return for service.
Setup button does not work when pressed	Internal Failure of Module	Return for service.
A rainbow parameter is not active	The rainbow parameter is not enabled.	Ensure that the rainbow parameter is enabled. Refer to the service manual for further instruction.
	The sensor does not support the rainbow parameter.	Confirm that the sensor supports the specific rainbow parameter.

Refer to the *Philips IntelliVue Patient Monitor Instructions for Use* for additional troubleshooting information.

Technical Alarm Messages (INOPs)

SpO_2 INOPs

INOP Message, Indication	What to do
No 3D Desat Index INOP tone	The 3D Desat Index is "On", but currently no 3D Desat Index alarming is possible, wait until the values are re-calculated.
No 3D Perf Delta INOP tone	The 3D Perfusion Delta is "On", but currently no 3D Perf Delta alarming is possible. Check the Perf settings and set the Perf baseline.

INOP Message, Indication	What to do
SpO2 Only SpO2 Numerics that are unavailable are replaced by -?-, INOP tone	If Only SpO_2 is displayed, rainbow measurements will not be available. To reinitialize rainbow parameters, remove and re-apply the sensor.
SpO2 ReplaceSensr Numeric is displayed with a small -?-	If issued without a tone, the lifetime of the cable, sensor, or adhesive has expired, but you still have a grace period for monitoring. Replace the cable, sensor, or adhesive part before monitoring is no longer possible.
SpO2 ReplaceSensr Numeric is replaced by -?- INOP tone	The lifetime of the connected cable, sensor, or adhesive has expired. No more monitoring is possible. Replace the cable, sensor, or adhesive sensor part.
SpO2 Sensor Malf Numeric is replaced by -?- INOP tone	Make sure the adhesive part of the sensor is connected. If the INOP persists, try another adhesive sensor, or exchange the adhesive part.
	The cable, sensor, or adhesive sensor part type are unknown, or not supported by your software revision. Replace the cable, sensor, or adhesive sensor part using only approved Masimo sensors and patient cables.
	The connected adhesive sensor part is defective.

SpCO INOPs

INOP Message, Indication	What to do
SpCO Cannot Meas Numeric is replaced by -?- INOP tone	The SpCO value is invalid/unavailable for more than 60 seconds, or cannot be measured with the connected accessories. Check the sensor placement. Try another adapter cable and sensor. If the INOP persists, contact your service personnel.
SpCO Low Perf Numeric is displayed with a small -?-	The perfusion is low and SpCO accuracy may be compromised. Stimulate the circulation at the sensor site. If the INOP persists, change the measurement site.
SpCO Poor Signal Numeric is displayed with a small-?-	The signal of the SpCO measurement is poor and measurement accuracy may be compromised. If the INOP persists, consider changing the application site or using another sensor.

SpMet INOPs

INOP Message, Indication	What to do
SpMet Cannot Meas Numeric is replaced by -?- INOP tone	The SpMet value is invalid/unavailable for more than 60 seconds, or cannot be measured with connected accessories. Check the sensor placement. Try another adapter cable and sensor. If the INOP persists, contact your service personnel.
SpMet Low Perf Numeric is displayed with a small -?-	The perfusion is low and SpMet accuracy may be compromised. Stimulate the circulation at the sensor site. If INOP persists, change the measurement site.
SpMet Poor Signal Numeric is displayed with a small -?-	The signal of the SpMet measurement is poor and measurement accuracy may be compromised. If the INOP persists, consider changing the application site, or using another sensor.

SpHb INOPs

INOP Message, Indication	What to do
SpHb Cannot Meas Numeric is replaced by -?- INOP tone	The SpHb value is invalid/unavailable for more than 60 seconds, or cannot be measured with the connected accessories. Check the sensor placement. Try another adapter cable and sensor. If the INOP persists, contact your service personnel.
SpHb Low Perf Numeric is displayed with a small -?-	The perfusion is low and SpHb accuracy may be compromised. Stimulate the circulation at the sensor site. If the INOP persists, change the measurement site.
SpHb Poor Signal Numeric is displayed with a small -?-	The signal of the SpHb measurement is poor and measurement accuracy may be compromised. If the INOP persists, consider changing the application site or using another sensor.

SpOC INOPs

INOP Message, Indication	What to do
SpOC Cannot Meas Numeric is replaced by -?- INOP tone	The SpOC value is invalid/unavailable for more than 60 seconds, or cannot be measured with connected accessories. Check the sensor placement. Try another adapter cable and sensor. If the INOP persists, contact your service personnel.
SpOC Low Perf Numeric is displayed with a small -?-	The perfusion is low and SpOC accuracy may be compromised. Stimulate the circulation at the sensor site. If the INOP persists, change the measurement site.
SpOC Poor Signal Numeric is displayed with a small -?-	The signal of the SpOC measurement is poor and measurement accuracy may be compromised. If the INOP persists, consider changing the application site or using another sensor.

PVI INOPs

INOP Message, Indication	What to do
PVI Cannot Meas Numeric is replaced by -?- INOP tone	The PVI value is invalid/unavailable for more than 160 seconds, or cannot be measured with connected accessories. Check the sensor placement. Try another adapter cable and sensor. If the INOP persists, contact your service personnel.
PVI Poor Signal Numeric is displayed with a small -?-	The signal of the PVI measurement is poor and measurement accuracy may be compromised. If the INOP persists, consider changing the application site, or using another sensor.

RRac INOPs

INOP Message, Indication	What to do
RRac Cannot Meas Numeric is replaced by -?- INOP tone	The RRac numerics are not displayed after the start-up phase. Check if the connected accessories are compatible for the RRac measurement. Check if the sensor is placed correctly.
RRac Chk Sensor Numeric is displayed with a small -?-	RRac Monitoring is still possible but accuracy may be compromised. Check sensor, cable, and connections. If the INOP persists replace the sensor or the cable
RRac Chk Sensor Numeric is replaced by -?- INOP tone	No RRac monitoring is possible. Check sensor, cable, and connections. If the INOP persists replace the sensor or the cable.
RRac Extd.Update Numeric is displayed with a small -?-	The RRac update period is extended due to bad signal conditions. Check the proper fit of the sensor, and reduce environmental noise level.
RRac Interference Numeric is displayed with a small -?-	The signal of the RRac measurement is affected by interference or noise, and accuracy may be compromised. If the INOP persists, check if the sensor is placed correctly or use another sensor.

INOP Message, Indication	What to do
RRac Interference Numeric is replaced by -?- INOP tone	RRac cannot be derived, because of interference or noise. Check that the sensor is applied according to instructions. Try to reduce background noise, and check that nothing comes into contact with the sensor.
RRac No Sensor Numeric is replaced by -?- INOP tone	Make sure the cable and the sensor are connected. If the INOP persists, try another adapter cable and sensor. If you silence this INOP, the RRac measurement will be switched off.
RRac No SpO2 Numeric is replaced by -?- INOP tone	An SpO_2 measurement has to be enabled for the RRac measurement to work. Connect an SpO_2 sensor and enable an SpO_2 measurement.
RRac Poor Signal Numeric is displayed with a small -?-	The signal of the RRac measurement is poor and measurement accuracy may be compromised. If the INOP persists, check if the sensor is placed correctly. If INOP still persists, use another sensor.
RRac ReplaceSensr Numeric is displayed with a small -?-	The lifetime of the connected sensor or cable has almost expired. Replace the sensor or cable before monitoring is no longer possible.
RRac ReplaceSensr Numeric is replaced by -?- INOP tone	The lifetime of the connected cable, sensor, or adhesive has expired. No more monitoring is possible. Replace the cable, sensor, or adhesive sensor part.
RRac Sensor Malf Numeric is replaced by -?- INOP tone	The cable and sensor are unknown, or not supported by your software revision. Replace the cable and sensor using only Philips supported sensors listed in the "Accessories" section.
RRac Sensor Off Numeric is replaced by -?- INOP tone	The sensor is not properly applied to the patient. Apply the sensor following the instructions supplied by the manufacturer.
RRac Unkn.Sensor Numeric is replaced by -?- INOP tone	The connected adapter cable or sensor is not supported by the measurement. Use only specified adapter cables and sensors.

Patient Alarm Messages

The following is a list of patient alarm messages/indications, and the conditions under which they can become active.

Alarm Message	From	Condition	Indication
**** 3D Desat Index**	Oxygen Saturation	The Desat index has exceeded the specified number of desaturations in the specified time.	SpO2 numeric flashes, yellow alarm lamp, alarm tone
**** 3D Perf Delta**	Perfusion Delta	The perfusion has decreased by a specified value over a specific period.	SpO2 numeric flashes, yellow alarm lamp, alarm tone
**** Perf High**	Perfusion	The perfusion has exceeded the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm lamp, alarm tone
**** Perf Low**	Perfusion	The perfusion has dropped below the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm lamp, alarm tone
**** PVI High**	Pleth Variability Index	The pleth variability index has exceeded the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm lamp, alarm tone
**** PVI Low**	Pleth Variability Index	The pleth variability index has dropped below the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm lamp, alarm tone
**** RRac High**	Acoustic Respiration Rate	The acoustic respiration rate has exceeded the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm lamp, alarm tone
**** RRac Low**	Acoustic Respiration Rate	The acoustic respiration rate has dropped below the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm lamp, alarm

Alarm Message	From	Condition	Indication
			tone
***** RRac Pause**	Acoustic Respiration Rate	No breath detected for a configured time period.	Numeric flashes, red alarm lamp, alarm tone
**** SpCO High**	Carboxyhemoglobin Saturation	The carboxyhemoglobin saturation has exceeded the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm lamp, alarm tone
**** SpCO Low**	Carboxyhemoglobin Saturation	The carboxyhemoglobin saturation has dropped below the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm lamp, alarm tone
**** SpHb High**	Total Hemoglobin Concentration	The total hemoglobin concentration has exceeded the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm lamp, alarm tone
**** SpHb Low**	Total Hemoglobin Concentration	The total hemoglobin concentration has dropped below the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm lamp, alarm tone
**** SpMet High**	Methemoglobin Saturation	The methemoglobin saturation has exceeded the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm lamp, alarm tone
**** SpMet Low**	Methemoglobin Saturation	The methemoglobin saturation has dropped below the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm lamp, alarm tone
**** SpOC High**	Total Oxygen Content	The total oxygen content has exceeded the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm lamp, alarm tone

Alarm Message	From	Condition	Indication
** SpOC Low	Total Oxygen Content	The total oxygen content has dropped below the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm lamp, alarm tone

Desat Index 3D Alarm (3D Desat Index)

The 3D Desat Index alarm provides an alert to an increasing number of smaller desaturations that may not exceed the low SpO2 alarm threshold. The smaller desaturations provide an early indication that the patient's respiratory status is declining.

The SpO2 alarm has to be on to set the 3D Desat Index. The 3D Desat Index alarm is issued when a patient experiences a specified number of desaturations that exceed a specified threshold over a specific period of time. The baseline to determine the desaturations is calculated automatically. The extended alarm text contains the maximum exceeded count.

PI Delta 3D Alarm (3D Perfusion Delta)

Changes in the peripheral perfusion are a valuable indicator of a patient's condition worsening, but they are difficult to identify and often missed. The 3D Perfusion Delta helps you to notice early changes in peripheral perfusion.

A 3D Perfusion Delta alarm indicates that a patient's perfusion is deteriorating. The Perfusion alarms have to be on, to set the 3D Perfusion Delta. Set a perfusion baseline as a reference for the current perfusion value. Set the Delta % Decrease to a configurable value. The Delta % Decrease determines the delta from the set baseline to the point where a 3D Perfusion Delta alarm is issued. Set the Duration to configure the time span in which you want to monitor the Delta % Decrease from the set perfusion baseline. The 3D Perfusion Delta is only enabled during the configured Duration.

The extended alarm text contains the maximum exceeded perfusion delta value.

Chapter 6: Specifications

Performance Specifications

SpO2 Accuracy*			
Condition	**Range**	**Population**	**A_{RMS}****
No Motion [1]	60% to 80%	Adults, Pediatrics, Infants	3%
No Motion [2]	70% to 100%	Adults, Pediatrics, Infants	2%
No Motion [2]	70% to 100%	Neonates	3%
Motion [3]	70% to 100%	All patient populations	3%
Low perfusion [4]	70% to 100%	All patient populations	2%

*See the ***ARMS Performance Specifications*** on page 59 section for additional SpO2 accuracy information.

** A_{RMS} accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fell within +/- A_{RMS} of the reference measurements in a controlled study.

Pulse Rate (PR)			
Condition	**Range**	**Population**	**A_{RMS}**
No Motion [5]	25 bpm to 240 bpm	All patient populations	3 bpm
Motion [5]	25 bpm to 240 bpm	All patient populations	5 bpm
Low perfusion [5]	25 bpm to 240 bpm	All patient populations	3 bpm

Carboxyhemoglobin Level (SpCO) [1]		
Range	**Population**	**A_{RMS}**
1% to 40%	Adults, Pediatrics, Infants	3%

Methemoglobin Level (SpMet) [1]		
Range	**Population**	**A_{RMS}**
1% to 15%	All patient populations	1%

Total Hemoglobin SpHb [6]		
Range	**Population**	**A_{RMS}**
8 g/dL to 17 g/dL	Adults, Pediatrics	1 g/dL

Respiratory Rate (RRa) [7]		
Range	**Population**	**A_{RMS}**
4 to 70 bpm	Adults, Pediatrics	1 bpm

Display Ranges

Parameter	Display Range
SpO2 (Oxygen Saturation)	0% to 100%
SpMet (Methemoglobin)	0% to 99.9%
SpCO (Carboxyhemoglobin)	0% to 99%
SpHb (Hemoglobin)	0 g/dL to 25.0 g/dL
SpOC (Oxygen Content)	0 ml of O2/dL to 35 ml of O2/dL of blood
PR (Pulse Rate) [5]	25 bpm to 240 bpm
PI (Perfusion Index)	0.02% to 20%

Parameter	Display Range
PVI (Pleth Variability Index)	0% to 100%
RRac (Respiration Rate)	0 breaths per minute to 70 breaths per minute
Display Update Rate	Once per second [9]

ARMS Performance Specifications

Accuracy testing for SpO_2 was performed on healthy adult subjects. The tables below provides Arms (Accuracy Root Mean Square) values measured using the Masimo Rainbow SET Technology, which is included in the Rainbow IVM, with Masimo Rainbow sensors in clinical studies under no motion conditions. The Bland-Altman plots provided in the operator's manual are for the sensors identified in the respective plots. Bland-Altman plots for sensors not listed in the tables below are available in the Directions for Use (DFU) for those sensors. See the sensor DFU for the Bland-Altman plots for the respective compatible sensor.

The below Bland-Altman plot represents the correlation of the (SpO_2 + SaO_2)/2 versus (SpO_2 - SaO_2) under no motion with an upper 95% and lower 95% limits of agreement.

Measurement A_{RMS} Values for rainbow Reusable (DCI) Sensors	
SpO_2 Accuracy Range (%)	A_{RMS} (%)
60% – 70%	2.00%
70% – 80%	1.61%
60% – 80%	1.83%

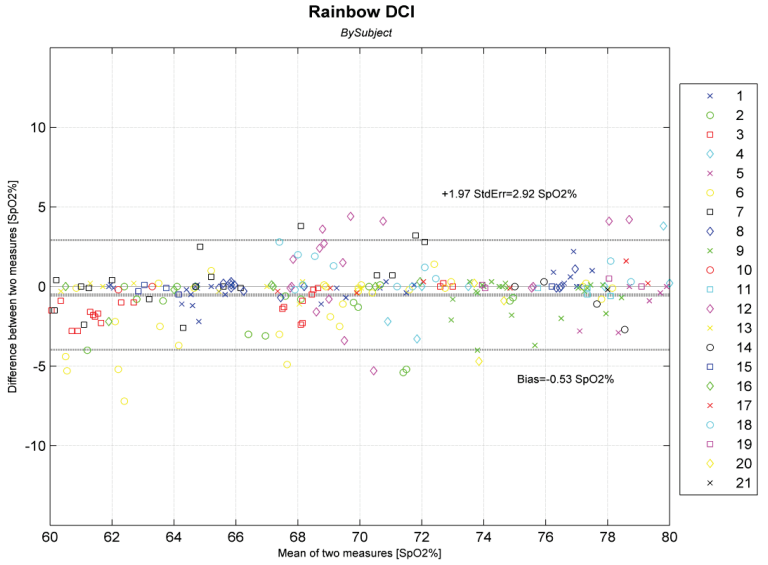


Figure 1: rainbow Reusable (DCI) Sensors (Arms 60-80%)

Measurement A_{RMS} Values for rainbow Reusable (DCI) Sensors	
SpO_2 Accuracy Range (%)	A_{RMS} (%)
70% – 80%	1.88%
80% – 90%	1.72%
90% – 100%	1.21%
70% – 100%	1.63%

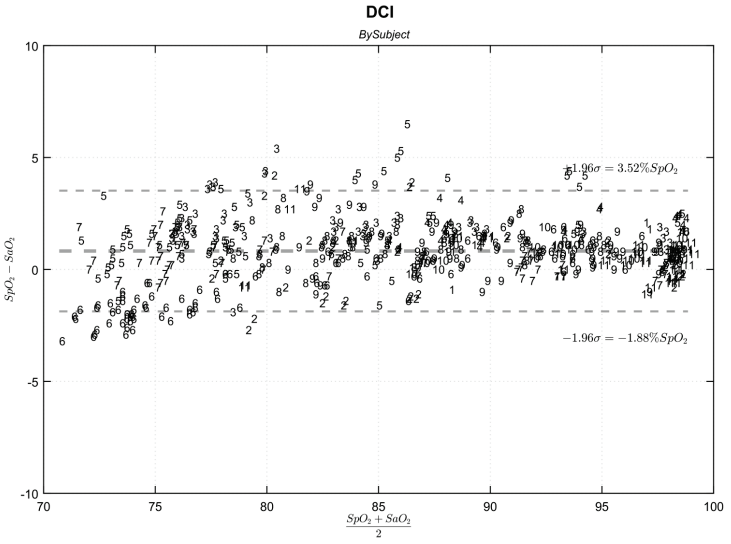


Figure 2: rainbow Reusable (DCI) Sensors (Arms 70-100%)

Measurement A_{RMS} Values for rainbow Adhesive (R1 Series) Sensors	
SpO_2 Accuracy Range (%)	A_{RMS} (%)
60% – 70%	3.42%
70% – 80%	2.49%
60% – 80%	2.99%

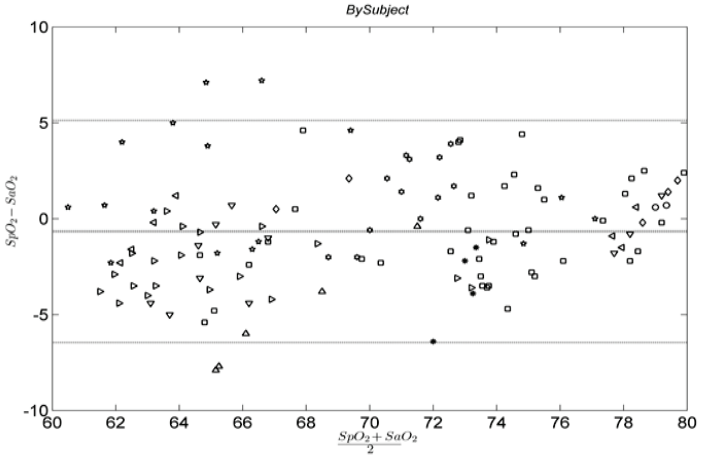


Figure 3: rainbow Adhesive (R1 Series) Sensors (Arms 60-80%)

Measurement A_{RMS} Values for rainbow Adhesive (R1 Series) Sensors	
SpO_2 Accuracy Range (%)	A_{RMS} (%)
70% – 80%	2.47%
80% – 90%	1.80%
90% – 100%	1.57%
70% – 100%	1.98%

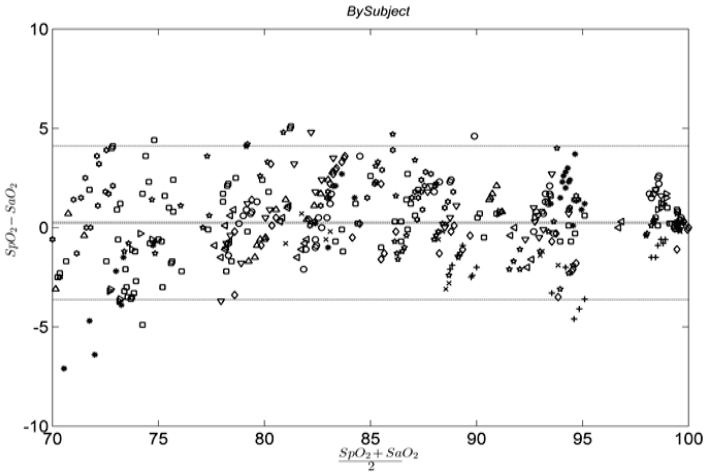


Figure 4: rainbow Adhesive (R1 Series) Sensors (Arms 70-100%)

Resolution

Parameter	Resolution
%SpO2	1%
%SpCO	1%
%SpMet	0.1%
SpHb g/dL	0.1 g/dL
Pulse Rate	1 beat per minute
Respiration Rate	1 breath per minute

Environmental

Item	Description
Operating Temperature	+0° C to +55° C, ambient humidity (+32° F to 131° F)
Transport/Storage Temperature	-40° C to + 70° C, ambient humidity (-40° F to +158° F)
Operating Humidity	95% RH max. at 40° C
Transport/Storage Humidity	95%, RH max. at 65° C
Operating Altitude	Up to 4,600 m. (15,000 ft.)
Transport/Storage Altitude	-380 m to +5,560 m (-1,250 ft. to +18250 ft.)
Vibration	Per IEC 60068-2-6, IEC 60068-2-64
Shock	Per IEC 60068-2-27

Physical Characteristics

Item	Description
Dimensions	102.5 x 99.6 x 36 mm (4.0 x 3.9 x 1.4 in.)
Weight	195g (7.0 oz.)
Host Interface connector	Philips IntelliVue standard 12-pin circular connector
Patient Cable connector	Masimo 25-pin receptacle
Indicators	1 LED indicator (above button); Color: Green
Controls	1 momentary push button switch; function determined by host device

Modes

Refer to the *Philips IntelliVue Patient Monitor Instructions for Use* for access to the following modes of operation.

Item	Description
SpO_2 Averaging mode	2, 4, 8, 10, 12, 14, and 16 seconds
Sensitivity mode	Normal, Maximum, and APOD
SpHb Averaging mode	Long, Medium, Short
SpHb Monitoring Mode	Arterial or Venous
SpHb Units	g/dL or mmol/L
SpHb Precision Mode	1, 0.5, 0.1 (g/dL or mmol/L)
Perfusion Index Averaging (Smooth PI)	Automatically set based on SpO_2 averaging mode SpO_2 Averaging mode: 2-8 seconds = Short SpO_2 Averaging mode: 10-16 seconds = Long
Pleth Variability Averaging (PVI)	Automatically set based on SpO_2 averaging mode SpO_2 averaging mode: 2-6 seconds = Short SpO_2 averaging mode: 10-16 seconds = Long
Acoustic Respiration Rate Averaging	None, Fast, Medium, Slow, Trending
Acoustic Respiration Rate Pause Time	15, 20, 25, 30, 35, and 40 seconds
Acoustic Respiration Rate Freshness Timeout	0, 1, 5, 10, and 15 minutes
Line Frequency	50/60Hz
SmartTone	On/Off
Desaturation Index Alarm (Desat Index)	%Threshold: 2-10%, in 1% increments Occurrence Count: 1-25 in 1 step increments Period: 1-4 hours in 1 hour increments

Item	Description
Perfusion Index Delta Alarm (PI Delta)	%Delta: 10-100%, in 2% increments Duration Period: 1, 5, or 30 minutes, 1 hour, 4-48 hours (4 hour increments), Infinite.

Display / Indicators

Item	Description
Data display	SpO_2%, pulse rate, alarm status, alarm silenced status, perfusion index, carboxyhemoglobin (SpCO%), methemoglobin (SpMet%), total hemoglobin (SpHb g/dL or mmol/l), SpOC, Pleth Variability Index (PVI), Acoustic respiration rate, (RRac), total oxygen content (SpOC)

Sensor LED Wavelengths / Intensity [8]

Item	Description
Wavelength	500 to 1400nm
Intensity	15 mW max. non-rainbow sensors 25mW max. rainbow sensors

Compliance

Safety Standards Compliance
ANSI/AAMI ES60601-1: 2005
UL 60601-1: 2003
CAN/CSA C22.2 No. 60601-1:2008
CAN/CSA C22.2 No. 601.1-M90
IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
IEC 60601-1: 1988 + A1: 1991 + A2: 1995
EN 60601-1: 1990 +A2:1995 + A11: 1993 + A12: 1998 + A13: 1996

EN 60601-1: 2006
IEC 60601-1-4: 2000
ISO 9919: 2005
ISO 80601-2-61: 2011

Equipment Classification per IEC 60601-1	
Degree of Protection against Electrical Shock	Defibrillation Proof Type CF-Applied Part
Mode of Operation	Continuous
Environment	Not suitable for use in the presence of flammable anesthetics

Guidance and Manufacturer's Declaration-Electromagnetic Emissions

Guidance and Manufacturer's Declarations - Electromagnetic Emissions		
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	ME Equipment uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	ME Equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	N/A	

Guidance and Manufacturer's Declaration-Electromagnetic Immunity

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
The ME Equipment is intended for use in the electromagnetic environment specified below. The customer or the user of the ME Equipment should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	+6 kV contact +8 kV air	+6 kV contact +8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	+/- 2 kV for power lines +/- 1 kV for input/ output lines	+/- 2 kV for power lines +/- 1 kV for input/ output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	+/-1 kV line(s) to line(s) +/- 2 kV line(s) to earth	+/-1 kV line(s) to line(s) +/- 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5s	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the [ME EQUIPMENT or ME SYSTEM] requires continued operation during power mains interruptions, it is recommended that the [ME EQUIPMENT or ME SYSTEM] be powered from an uninterruptible power supply or a battery.
Power frequency (50 / 60 Hz) magnetic field. IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ME Equipment, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$ 150 kHz to 80 MHz

Guidance and Manufacturer's Declaration - Electromagnetic Immunity			
Radiated RF IEC 61000-4-3	3 V/m 80 MHZ to 2.5 GHz	3 V/m	$d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey *a*, should be less than the compliance level in each frequency range *b*. Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

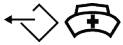
Recommended Separation Distances

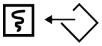
Recommended Separation Distance Between Portable and Mobile RF Communication Equipment and the ME Equipment			
The ME Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ME Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ME Equipment as recommended below, according to the maximum output power of the communication equipment.			
Rated maximum output power of transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150 K Hz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2.5GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.7	3.7	7.37
100	11.7	11.7	23.3
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
Note 1: At 80 MHz and 800 MHz, the higher frequency range applies. **Note 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Symbols

The following symbols may appear on the product or product labeling:

Symbol	Description	Symbol	Description
	Follow instructions for use		Consult instructions for use
CE 0123	Mark of conformity to European medical device directive 93/42/EEC	c UL us	UL LLC certification
	Non-Sterile		Defibrillation-proof. Type CF applied part
	Recyclable	EC REP	Authorized representative in the European community
	Separate collection for electrical and electronic equipment (WEEE)	FCC ID:	Identifies unit has been registered as a radio device
Rx ONLY	**Caution:** Federal (USA) law restricts this device to sale by or on the order of a physician	IC Model:	Industry Canada Identification
FC	Federal Communications Commission (FCC) Licensing		Biohazardous Waste
	Non-ionizing electromagnetic radiation	 SpO_2	Not for continuous monitoring (No alarm for SpO_2)
	Warning, electricity		Product contains no PVC (polyvinyl chloride) material
	Electrostatic		Not made with natural rubber latex

Symbol	Description	Symbol	Description
	No parameter alarms		Catalog number (model number)
	Caution		Masimo reference number
	Manufacturer		Serial number
	Date of manufacture YYYY-MM-DD		Fragile, handle with care
	Storage temperature range		Do not use if package is damaged
	Keep dry		Equipotential Ground Terminal
	Storage humidity limitation		Nurse Call Interface
	Atmospheric pressure limitation		SatShare Interface
	AC current		Wireless Symbol level
	Fuse		Wireless features can be used in member states with the restriction of indoor use in France -Class 2 wireless device
	Stand-By		Iris Connection
	RS-232 Interface		Ethernet

Symbol	Description	Symbol	Description
	Analog Out Interface		USB port
<	Less than	>	Greater than
	China Restriction of Hazardous Substances		The names and content of the toxic and hazardous substances or elements shall be provided in the product instruction manual
	Instructions/Directions for Use/Manuals are available in electronic format @http://www.Masimo.com/TechDocs **Note: eIFU is not available for CE mark countries.**		

Citations

[1] SpO_2, SpCO, and SpMet accuracy was determined by testing on healthy adult volunteers in the range 60% to 100% SpO_2, 0% to 40% SpCO, and 0% to 15% SpMet against a laboratory CO-Oximeter. SpO_2 and SpMet accuracy was determined on 16 neonatal NICU patients ranging in age from 7 days to 135 days old and weighing between 0.5 kg and 4.25 kg. Seventy-nine (79) data samples were collected over a range of 70% to 100% SaO_2 and 0.5% to 2.5% HbMet with a resultant accuracy of 2.9% SpO_2 and 0.9% SpMet. Contact Masimo for testing specifications.

[2] The Masimo rainbow SET technology with Masimo sensors has been validated for no motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies in the range of 70%-100% SpO_2 against a laboratory CO-Oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population weight.

[3] Unless otherwise stated in the sensor Directions for Use, Masimo SET® technology and sensors have been validated for neonatal motion accuracy in human blood studies on neonates while moving the neonate's foot at 2 to 4 Hz at an amplitude of 1 to 2 cm against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation which encompasses 68% of the population.

[4] The Masimo SET® technology has been validated for low perfusion accuracy in bench-top testing against a Biotek Index 2TM simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70%-100%. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.*

[5] Masimo rainbow SET technology with Masimo sensors has been validated for pulse rate accuracy for the range of 25-240 bpm in bench top testing against a Biotek Index 2TM simulator. This variation equals plus or minus one standard deviation which encompasses 68% of the population.*

[6] SpHb accuracy has been validated on healthy adult male and female volunteers and on surgical patients with light to dark skin pigmentation in the range of 8 g/dL to 17 g/dL SpHb against a Coulter Counter. The variation equals plus or minus one standard deviation which encompasses 68% of the population. The SpHb accuracy has not been validated with motion or low perfusion.

[7] Respiration rate accuracy for the Masimo Acoustic Respiration Sensor and Instrument has been validated for the range of 4 to 70 breaths per minute in bench top testing. Clinical validation for up to 30 breaths per minute was also performed with the Masimo Acoustic Respiration Sensor and Instrument.

[8] Information about wavelength range may be useful to clinicians.

[9] Values are sent to the display device once per second. Actual display update rate is a function of the Philips IntelliVue system.

**Registered trademark of Fluke Biomedical Corporation, Everett, Washington.*

Chapter 7: Service and Maintenance

Introduction

This chapter covers how to test the operation of the rainbow SET® IntelliVue Module, how to properly clean the rainbow SET® IntelliVue Module, and how to obtain service.

Under normal operation, no internal adjustment or recalibration is required.

Cleaning

Warning: Before cleaning the rainbow SET® IntelliVue Module, always remove it from the IntelliVue monitor.

- To clean the rainbow SET® IntelliVue Module, use a cotton swab moistened with 70% isopropyl alcohol and gently wipe the panel.
- To clean the outer surface of the rainbow SET® IntelliVue Module, use a soft cloth dampened with a mild soap and water. Do not allow liquids to enter the interior of the device.

Cautions:

- Do not autoclave, pressure sterilize, or gas sterilize the rainbow SET® IntelliVue Module.
- Do not soak or immerse the rainbow SET® IntelliVue Module in any liquid.
- Use the cleaning solution sparingly. Excessive solution can flow into the monitor and cause damage to internal components.
- Do not touch, press, or rub the rainbow SET® IntelliVue Module with abrasive cleaning compounds, instruments, brushes, rough-surface materials, or bring them into contact with anything that could cause scratches.
- Do not use petroleum-based or acetone solutions, or other harsh solvents, to clean the rainbow SET® IntelliVue Module. These substances attack the device's materials and device failure can result.

Service and Repair

Masimo or an authorized service department must perform warranty repair and service. Do not use malfunctioning equipment. Have the device repaired.

Clean contaminated and/or dirty equipment before returning, following the cleaning procedure described in ***Cleaning*** on page 79. Make sure the equipment fully dry before packing.

To return the device for service, follow the Return Procedure.

Return Procedure

Clean contaminated/dirty equipment before returning and make sure it is fully dry before packing the equipment. Package the equipment securely–in the original shipping container if possible–and enclose the following information and items:

- Call Masimo at 800-326-4890 and select Technical Support. Ask for an RMA number.
- A letter describing in detail any difficulties experienced with the device. Include the RMA number in the letter.
- Warranty information–a copy of the invoice or other applicable documentation must be included.
- Purchase order number to cover repair if the device is not under warranty, or for tracking purposes if it is.
- Ship-to and bill-to information.
- Person (name, telephone/Telex/fax number, and country) to contact for any questions about the repairs.
- A certificate stating the device has been decontaminated for bloodborne pathogens.
- Return the rainbow SET® IntelliVue Module to the shipping address listed in ***Contacting Masimo*** on page 80 below.

Contacting Masimo

Masimo Corporation
40 Parker
Irvine, California 92618

Tel:+1 949 297 7000
Fax:+1 949 297 7001

Limited Warranty

Masimo warrants to the original end-user purchaser the Masimo-branded hardware product rainbow SET® IntelliVue Module and any software media contained in the original packaging against defects in material and workmanship when used in accordance with Masimo's user manuals, technical specifications, and other Masimo published guidelines for a period of 12 months from the original date the Product was obtained by the end-user purchaser.

Masimo's sole obligation under this warranty is the repair or replacement, at its option, of any defective Product or software media that is covered under the warranty.

To request a replacement under warranty, Purchaser must contact Masimo and obtain a returned goods authorization number so that Masimo can track the Product. If Masimo determines that a Product must be replaced under warranty, it will be replaced and the cost of shipment covered. All other shipping costs must be paid by purchaser.

Exclusions

The warranty does not apply to any non-Masimo branded product or any software, even if packaged with the Product, or any Product that was: (a) not new or in its original packaging when supplied to purchaser; (b) modified without Masimo's written permission; (c) supplies, devices, or systems external to the Product; (d) disassembled, reassembled, or repaired by anyone other than a person authorized by Masimo; (e) used with other products, like new sensors, reprocessed sensors, or other accessories, not intended by Masimo to be used with the Product; (f) not used or maintained as provided in the operator's manual or as otherwise provided in its labeling; (g) reprocessed, reconditioned, or recycled; and (h) damaged by accident, abuse, misuse, liquid contact, fire, earthquake or other external cause.

No warranty applies to any Product provided to Purchaser for which Masimo, or its authorized distributor, is not paid; and these Products are provided AS-IS without warranty.

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