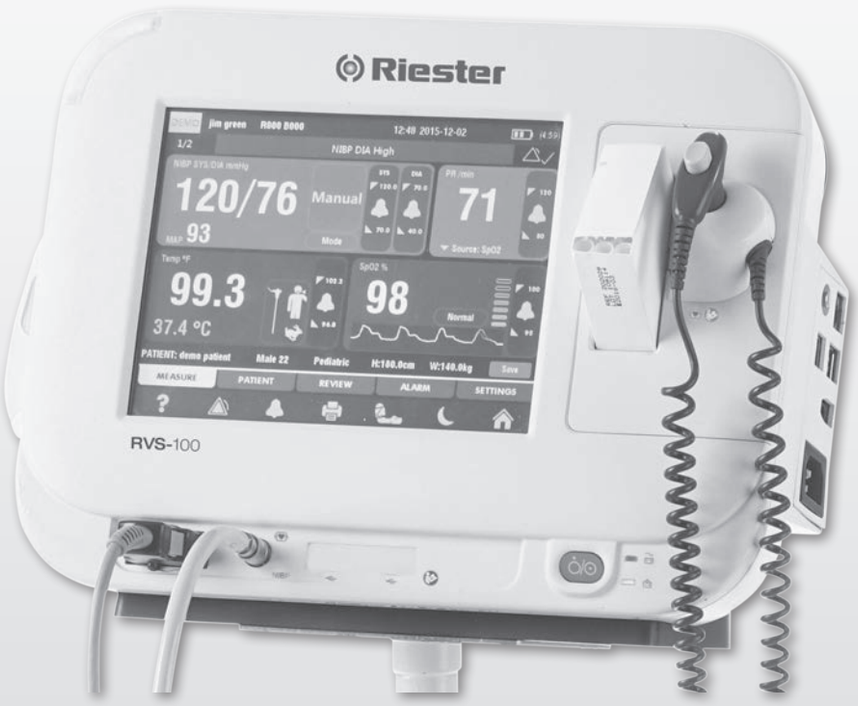

RVS-100 **Vital Signs Monitor**
User Manual

CE 0124

Riester

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The contents contained in this manual are subject to amendments without notification.

Manufacturer's Responsibility
Only under the following circumstances the manufacturer will be responsible for the safety, reliability and performance of the instrument:

- All the installation, expansion, readjustment, renovation or repairs are only meant to be conducted by personnel certified by the manufacturer.
- The storage condition, operation condition and electrical status of the instrument conform to the product specification.
- The instrument is used in accordance with the user's manual.

About this manual
This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.
This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any questions, please contact us.
This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.
The manual is geared for clinical professionals who are expected to have a working knowledge of medical procedures, practice and terminology as required for monitoring patients.
All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your product.

Conventions:
- ***Bold Italic*** text is used in this manual to quote the referenced chapter or sections.
- **[ ]** are used to enclose screen texts.
- → is used to indicate operational procedures.

Signs in this manual:

Warning: Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury.

Caution: Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

Note: Provides application tips or other useful information to ensure that you get the most from your product.

Welcome to the Riester RVS-100
Thank you for choosing the Riester RVS-100 for accurate monitoring of vital signs. The Riester RVS-100 is designed to be simple and efficient to use and the RVS-100 features:
automatic patient monitoring modes
averaging of multiple BP readings
user-programmable monitoring intervals
audible and visual patient alarms
connection to EMR system

Riester RVS-100 Description and Operation
The Riester RVS-100 vital signs monitor can perform automatic blood pressure, pulse oximetry and body temperature measurements for clinical professionals. For measuring blood pressure, a blood pressure cuff is placed around the patient's non-dominant upper arm. The cuff is inflated automatically and blood pressure is measured by the oscillometric method—which senses pressure waves in the artery when occluded by pressure in the cuff. Measurement of the frequency of the pressure waves enables heart rate to also be measured. The pulse oximetry function non-invasively measures the patient's percent oxygen saturation of arterial hemoglobin using principles of plethysmography via a SpO2 sensor placed on the patient's finger. Temperature can be measured using an oral/axillary/rectal temperature probe containing a thermistor that generates a voltage based on changes in temperature, and these voltages are recorded by the temperature circuitry. The RVS-100 is a portable device, approximately 350 x 245 x 115 mm in size and weighs approximately 3006 g without battery. A color touch screen allows the user to stop/start a BP measurement, save a set of measurements to memory, control patient alarm functions, print measurements, and return to the home screen. The touch screen can also be used to select many different device options. The backlit LCD display shows the user device status and measurement information. A set of multi-color LED's on the corner of the front enclosure alert users to visual alarms. The device uses a microprocessor with software, which is not accessible to the user. The unit is powered by a single rechargeable lithium-ion battery at the bottom of the device. Four USB-A port connections can be used to connect optional barcode scanner or Wi-Fi dongle. An optional internal thermal printer is available. There is also RJ45 Ethernet port for network connectivity and an RJ11 jack for nurse call connectivity.
Note: For purposes of this manual, the Riester RVS-100 may be referred to as "the Riester RVS-100", "the RVS-100," "the device" or "the monitor".

Contents

1. General Introduction

1.1 Intended Use

The RVS-100 vital signs monitor is intended to be used for monitoring, displaying, reviewing, storing and sending alarms regarding multiple physiological patient parameters, including Pulse Oxygen Saturation (SpO2), Pulse Rate (PR), Non-invasive Blood Pressure (NIBP), and Temperature (Temp).
The RVS-100 vital signs monitor is intended to be used in outpatient departments, emergency treatment rooms, and low-acuity areas of hospitals, community clinics, private clinics and other medical institutions. It is not intended for helicopter transport, hospital ambulance or home use.

Spot Check Profile: This profile is designed for taking a single set of vital signs measurements on a patient. Patient information can be entered and managed, and while technical alarms are still available, physiological alarms are disabled.

Warning: The monitor is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operations on it.

1.2 Restrictions for use

- **Do not use the monitor and the SpO2 sensor during magnetic resonance imaging (MRI). Induced current could cause burns.**
- **Operating high frequency electrosurgical equipment in the vicinity of the monitor may produce interference and cause incorrect measurements.**
- **The following factors may influence the accuracy of SPO2 measurements:**
  - ◊ **Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material);**
  - ◊ **Electromagnetic interference, such as from an MRI device;**
  - ◊ **Excessive patient movement;**
  - ◊ **Intravascular dyes such as indocyanine green or methylene blue;**
  - ◊ **Significant levels of dysfunctional hemoglobins (such as carboxyhemoglobin or methemoglobin);**
  - ◊ **Incorrect sensor application or use;**
  - ◊ **Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter or intravascular line;**
  - ◊ **Low perfusion;**
  - ◊ **Electrosurgical units.**
- **Do not use the SpO2 sensor on the same limb being used for NIBP measurement. This may result in inaccurate SpO2 reading due to blocked blood flow during cuff inflation.**
- **Do not measure SpO2 on a finger painted with nail polish. This may result in unreliable measurements.**
- **Do not measure NIBP on patients with sickle-cell disease or any condition in which skin damage has occurred or is expected.**
- **Use clinical judgment to decide whether to perform frequent Auto BP measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.**
- **Use clinical judgment to decide whether to perform Auto**

BP measurement on patients with thrombasthemia.

- **Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.**
- **NIBP Measurement Limitations: Accurate NIBP measurements cannot be taken when the heart rate is extremely low (less than 40 bpm) or extremely high (greater than 240 bpm) or if the patient is on a heart-lung machine. Accurate measurement also cannot be taken when the following conditions exist:**
  - ◊ **excessive and continuous patient movement such as shivering or convulsions;**
  - ◊ **difficulty detecting a regular arterial pressure pulse;**
  - ◊ **cardiac arrhythmias;**
  - ◊ **rapid blood pressure changes;**
  - ◊ **severe shock or hypothermia that reduces blood flow to the peripheries;**
  - ◊ **an edematous extremity.**
- **MRI may lead to vessel damage;**

1.3 Configurations

The monitor consists of main unit, NIBP cuff, SpO2 sensor, Temperature sensor (optional) and printer (optional). It can connect to the optional RVS-200 Wall Diagnostic Station through DC output. The connection details are provided the corresponding manual for the RVS-200 Wall Diagnostic Station.

1.4 Main Unit

1.4.1 Front View

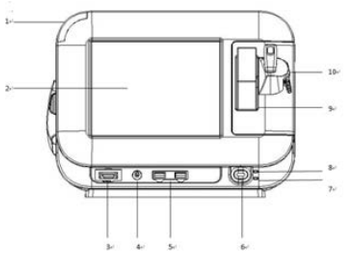


Fig.1-1

1) Physiological alarm visual indicator LED's. When a physiological alarm occurs, this lamp will light up as defined below:
   - High level alarm: the lamp quickly flashes red.
   - Medium level alarm: the lamp slowly flashes yellow.
   - Low level alarm: the lamp lights yellow without flashing.
2) LCD Touchscreen
3) SpO2 connector
4) NIBP connector
5) USB connector x 2
6) Power button
   - Press this button to turn on the monitor after AC power is connected or the battery is installed.
   - Press and hold for 3 seconds to turn the monitor off.
7) Battery charging indicator LED
   - On: When the battery is being charged.
   - Off: When the battery is fully charged or there is no battery in monitor.
8) Power indicator LED. Status of the LED is specified as follows:
   - Green: When the AC mains connected.
   - Orange: When the AC mains not connected and monitor is powered by battery.
   - Off: When the AC mains not connected.
9) Well for Temp Probe Cover box (20pcs)
10) Covidien Filac 3000 temp probe

1.4.2 Side View

Right side:

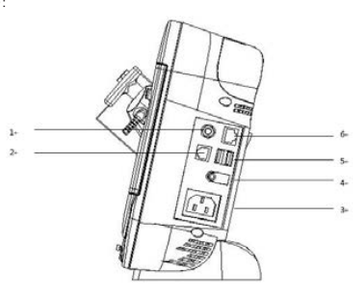


Fig.1-2

1) Grounding terminal
2) Nurse call connector
3) AC power connector (input)
4) DC power connector (output)
5) USB socket x 2
6) Ethernet LAN Network connector

Caution: Devices connected to this monitor must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard. Any personnel who connect devices to this monitor's signal input/output port is responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1. If you have any questions, please contact Riester. If it is not evident from the equipment specifications whether a particular device combination is hazardous--for example, due to summation of leakage currents—please consult the manufacturers or an expert in the field to ensure the necessary safety of patients and proper function of all connected devices.

Left side:

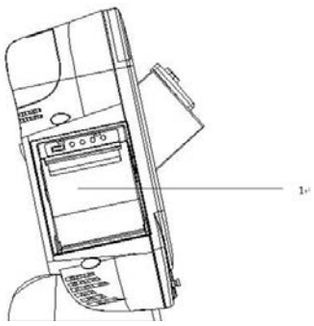


Fig.1-3

1) Integrated Thermal Printer

1.4.3 Rear View

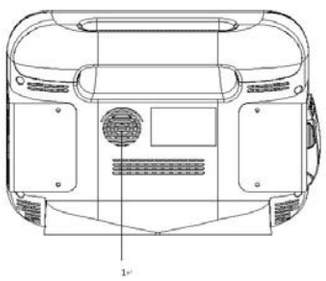
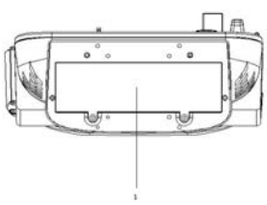


Fig.1-4

1) Speaker

1.4.4 Bottom View

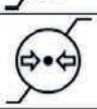


1. Battery compartment

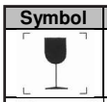
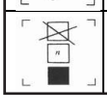
Fig.1-5

Caution: Clean the battery contacts regularly to ensure optimal electrical contact. Before cleaning, power down the unit and disconnect it from A/C power. To clean the contacts, rub with a cotton swab dampened (not dripping wet) with isopropyl alcohol.

1.5 Equipment Symbols

Symbol	Symbol Note
	Type CF applied part, defibrillation protected The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof.
	Refer to instruction manual/booklet.
	Non-ionizing radiation
	Dangerous voltage
	Equipotential grounding
	USB socket
	Network connector
	Nurse call connector
	Manufacture date
	Manufacturer
	Catalog Number
	Batch or Lot Code
	Serial number
	Temperature limitation
	Humidity limitation
	Pressure limitation
CE 0124	CE mark: Product meets the Medical Device Directive and is CE marked to indicate conformance.
IPX1	Degree of protection against ingress of liquid
SpO_2	Pulse Oxygen Saturation
NIBP	Non-Invasive Blood Pressure
Temp	Temperature
	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.

1.6 Packaging symbols

Symbol	Symbol Note
	Fragile. Handle with care.
	This Side Up.
	Keep dry.
	Stacking layer limit, where 'n' represents the maximum permissible number of layers. (N = 6).

2. Safety

2.1 Safety Information

Warning:

- Before putting the system into operation, verify that the RVS-100 and RVS-200 and accessories are in correct working order and operating condition.
- Do not use device if any electrical connections become damaged, bent, or misaligned.
- To avoid explosion hazard, do not use the monitor in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
- Do not open the monitor housings; electric shock hazard may exist. All servicing must be performed by personnel authorized by the manufacturer only.
- When using the monitor with electrosurgical units (ESU), make sure the patient is safe. And the ESU must not contact with patient cable.
- Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.
- Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off may result in a hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.
- The physiological data and alarm messages displayed on the monitor are for reference only and cannot be directly used for diagnostic interpretation.
- To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to avoid risk of entanglement or strangulation by patient or personnel.
- To avoid risk of electric shock, this equipment must only be connected to a grounded power supply.
- No modification of this equipment is allowed. Do not modify this equipment without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.
- There will be significant risks of reciprocal interference when the device is used in specific investigations or treatments.
- The device's connector (including USB, network and so on) can only be connected to the matched accessories and network server. The misuse of them may cause damage to the device.
- Operating high frequency electrosurgical equipment in the vicinity of the monitor may produce interference and cause incorrect measurements.

Caution:

- To ensure patient safety, use only parts and accessories specified in this manual.
- At the end of its service life, the monitor, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have any questions concerning disposal of the monitor, please contact the manufacturer.
- Magnetic and electrical fields are capable of interfering with the proper performance of the monitor. For this re-

ason make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.

- Before connecting the monitor to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the monitor's label or in this manual.
- Always install or carry the monitor properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.

Note:

- Put the monitor in a location where you can easily see the screen and access the operating controls.
- Keep this manual in the vicinity of the monitor so that it can be obtained conveniently when needed.
- The software was developed in compliance with IEC 62304. The possibility of hazards arising from software errors is minimized.
- This manual describes all features and options. Your monitor may not have all of them.

2.2 General Safety

Warning: This monitor is neither a therapeutic instrument nor a device that can be used at home.

1. Safety precautions for installation

- Connect the power cord to a properly grounded socket. Only connect device to A/C power sockets designated for use by medical equipment.
- Avoid putting the monitor in a location where it easily shakes or wobbles.
- Enough space shall be left around the monitor so as to guarantee normal ventilation.
- Make sure the ambient temperature and humidity are stable and avoid the occurrence of condensation in the operation process of the monitor.

Warning: Never install the monitor in an environment where flammable anesthetic gas is present.

2. Monitor conforms to the safety requirements of IEC 60601-1. This monitor is protected against defibrillation effects.
3. Notes on symbols related to safety Type CF applied part, defibrillation protected.
   The unit displaying this symbol contains an F-Type isolated (floating) applied part providing a high degree of protection against shock, and is defibrillator-proof. The type CF applied parts provide a higher degree of protection against electric shock than that provided by type BF applied parts.

Attention! Please refer to the documents accompanying this monitor, such as the instruction manual.

4. When a defibrillator is applied on a patient, the monitor may have some disruption in its display of waveforms.

Warning: When conducting defibrillation, do not come into contact with the patient, the bed or the monitor. Otherwise serious injury or death could result.

5. To guarantee the safe operation of the monitor, the monitor is provided with various replaceable parts, accessories and consumables. Please use the products provided or designated by the manufacturer.
6. Safety and accuracy are assured only by the device and accessories provided or designated by the manufacturer. If the monitor is connected to other undesignated electrical equipment or devices, safety hazards and/or excessive leakage current may occur.
7. To guarantee the normal and safe operation of the monitor, a preventive check and maintenance should be conducted of the monitor and its parts every 6-12 months (including performance and safety check) to verify that the instrument can be operated safely, properly, and accurately.

Caution: The monitor does not contain any user-serviceable parts. The repair of the instrument must be conducted by technical personnel authorized by the manufacturer.

2.3 Important Notes for Safety

- **Patient Number**
  The monitor can only be applied to one patient at one time.
- **Interference**
  Do not use a mobile phone in the vicinity of the monitor. High level of electromagnetic radiation emitted from such devices may result in strong interference with the monitor performance.
- **Protection against ingress of liquid**
  To avoid electric shock or device malfunction, liquids must not be allowed to enter the device. If liquids have entered the device, take it out of service and have it checked by a service technician before it is used again.
- **Accuracy**
  If the accuracy of any value displayed on the monitor or printed on a printout paper is questionable, determine the patient's vital signs by alternative means. Verify that the equipment is working correctly.
- **Alarm**
  Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off during patient monitoring may result in a hazard to the patient. Remember that the most reliable method of patient monitoring combines close personal surveillance and correct operation of monitor. The functions of the alarm system for monitoring the patient must be verified at regular intervals.
- **Before Use**
  Before putting the system into operation, please visually inspect all connecting cables for signs of damage. Damaged cables and connectors must be replaced immediately. Before using the system, the operator must verify that it is in correct working order and operating condition. Periodically, and whenever the integrity of the product is in doubt, test all functions.
- **Cables**
  Route all cables away from patient's throat to avoid possible strangulation.
- **Disposal of package**
  When disposing of the packaging material, please observe the applicable waste control regulations and keep it out of children's reach.
- **Explosion hazard**
  Do not use this equipment in the presence of flammable anesthetics, vapors or liquids.
- **Leakage current test**
  When interfacing with other equipment, a test for leakage current must be performed by qualified biomedical engineering personnel before using with patients.
- **Battery**
  The device is equipped with a battery. The battery discharges even when the device is not in use. Store the device with a fully charged battery and take out the battery, so that the service life of the battery will not be shortened.
- **Disposal of accessories and device**
  Disposable accessories are intended for single use only. They should not be reused as performance could degrade or contamination could occur. The service life of this monitor is 5 years. At the end of its service life, the monitor, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products. If you have questions concerning disposal of products, please contact manufacturer or its representatives.
- **EMC**
  Magnetic and electrical fields are capable of interfering with the proper performance of the device. For this reason, make sure that all external devices operated in the vicinity of the monitor comply with the relevant EMC requirements. X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation. Also, keep mobile phones or other telecommunication equipment away from the monitor.
- **Instruction for use**
  For continuous safe use of the monitor, it is necessary that listed instructions are followed. However, instructions listed in this manual can in no way can supersede established medical practices concerning patient care.
- **Loss of data**
  Should the monitor at any time temporarily lose patient data, close patient observation or alternative monitoring devices should be used until monitor function is restored.
  If the monitor does not automatically resume operation within 60s, restart the monitor using the power switch. Once monitoring is restored, you should verify correct monitoring state and alarm function.

- **Intended for use in conjunction with other medical devices**
  The monitor can be used together with high-frequency electrosurgical units and defibrillators.
- **IT-NETWORK**
  Connection to IT-NETWORKS including other equipment could result in previously unidentified risks to patients, operators or third parties.
  The responsible organization operating the device should identify, analyse, evaluate and control these risks.
  Changes to the IT-NETWORK could introduce new risks that require additional analysis
  Changes to the IT-NETWORK include:
  - Changes In Network Configuration
  - Connection Of Additional Items
  - Disconnection Of Items
  - Update Of Equipment
  - Upgrade Of Equipment

2.4 Safe Operation Conditions

Methods of sterilization or disinfection recommended by the manufacturer	Sterilization: not applicable Disinfection: Refer to ***Maintenance and Cleaning*** Chapter
Electromagnetic interference	Not in proximity with mobile phones
Electrosurgical interference damage	No damage
Diathermy instruments influence	Displayed values and prints may be disturbed or erroneous during diathermy
Defibrillation shocks	The monitor specifications fulfill the requirements of IEC 60601-1, IEC 60601-2-49

3. Operations

3.1 Unpacking and Checking Contents

1. Unpacking
   Before unpacking the unit, examine the packing box carefully for signs of damage. If any damage is detected, contact the carrier.
2. Remove the device and accessories carefully.
3. Keep all the packaging materials for future use in transportation or storage.
4. Check the monitor and accessories according to the packing list. Check to see if the parts have any mechanical damage. In case of damaged items, please contact Rudolf Riester or a Rudolf Riester Authorized Service Center.

Warning: Keep packing materials out of the reach of children. Dispose of the packing materials according to applicable local waste control regulations.

Warning: The monitor might be damaged during storage and transport. Never use a damaged device or apply a damaged accessory to the patient.

Caution: Always place the monitor on a horizontal and stable supporting surface. Avoid putting the monitor in a location where it easily shakes or wobbles. Enough space should be left around the monitor to guarantee normal ventilation.

Warning: Always use the monitor within the conditions specified in Appendix A; otherwise, the technical specifications mentioned in this manual will not be met and could lead to damaged equipment, inaccurate readings and other unexpected results.

3.2 Getting Started

3.2.1 Powering the Monitor

1. Plug the included power cord into the A/C receptacle on the monitor. Ensure that it is fully seated in the socket.
2. Plug the power cord into A/C power source. When using a battery for the first time, the battery must be charged following the instructions given in ***Chapter 8: Battery.***

3.2.2 Monitor Startup

1. After pressing the power switch, the monitor will begin an automatic self-diagnostic and start-up. During this process, the visual alarm LED's will illuminate in sequence from red, to yellow, to cyan, and then turn off, after that the device will produce a sound and the Riester logo will also appear on the display.
2. After the Riester logo disappears, the monitor will enter the main interface. After a successful power up, the device will produce a sound.

Warning: If the startup characteristics are different from the description above, the monitor could be damaged.

Caution: The monitor does not have a mains power switch. The monitor is disconnected from A/C power only by unplugging the power cable from the A/C power source. If device accessories are placed near the heart, connect the monitor's equipotential grounding system. Connect a green/yellow equipotential grounding cable to the terminal labeled with the symbol :

Warning: The plug is used to break the power supply, it should not be placed in place bad for operation.

3.3 Connect Accessories

1. Decide which parameter should be monitored or measured.
2. Connect required cables or sensors to the monitor.
3. Connect appropriate cables or sensors to the patient.
4. Ensure the installation of cables or sensors is correct.
5. Ensure that device settings are correct.
6. Review instructions in Chapter 5 and start monitoring on a patient.

3.4 Shutting off the Monitor

There are two ways to shut off the monitor:

1. Press and hold the power switch for more than 1 second. A message box will appear asking for verification that power down is desired. Press 'Ok' to power down the device.
2. Press the power switch and hold it for 5 seconds to turn off the monitor without additional prompts.

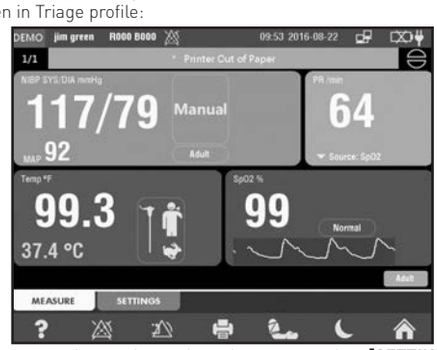
3.5 Operation Profiles

The device has three Operation Profiles for different clinical applications:

Monitor Profile: This profile is designed for monitoring patients over time, and includes physiological and technical alarms. Here is an example of the home screen in Monitor Profile:

Spot Check Profile: This profile is designed for taking a single set of vital signs measurements on a patient. Patient information can be entered and managed, and while technical alarms are still available, physiological alarms are disabled. Here is an example of the home screen in Spot Check profile:

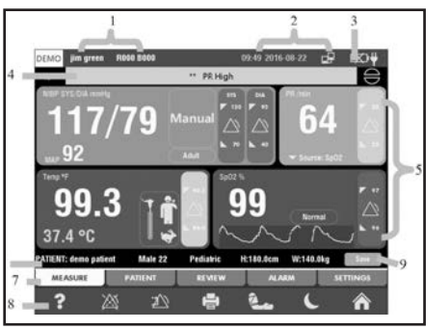
Triage profile: This profile is designed for rapidly taking vital signs measurements on many patients. Patient information is disabled, in addition to physiological alarms. Here is an example of the home screen in Triage profile:



If you want to change the work mode, you can select **[SETTINGS] → [Profile]**to select the work mode you want.

3.6 Using Menus

The main Home Screen can clearly display the basic patient information, time and date, physiological parameters, clinician information, and alarm information:



1. **Clinician Information:** Displays the clinician's Full Name, Department, and ID. Press anywhere in this area to open the Clinician Settings. Clinician Settings can also be accessed from the Settings tab: **[SETTING] → [Clinician]**
2. **System Time and Date and Network status:** Displays the current system time and date. Press anywhere in this area to open the Device Settings window where time and date can be set. Time and Date Settings can also be accessed from the Settings tab: **[SETTING] → [Device] → [Time]**. Network settings please refer to chapter 3.8.5
3. **Battery Status:** Displays the current charge status of the battery and whether or not the unit is connected to A/C power. See Chapter 9 for more details.
4. **Device Alarm Message Bar:** Entire area displays alarm messages when physiological and technical alarms are activated. If more than one alarm occurs, the highest level alarm will be displayed. Alarm settings can be changed by pressing the alarm areas in each measurement display window, or from the Alarm tab: **[ALARM]**
5. **Measurement Display Area:** Displays information about each vital sign parameter, including measurement values, and upper and lower alarm limits. Pressing on a measurement value will enlarge the information for that parameter. Pressing on the measurement again will shrink it. Pressing on an alarm limit box will open the Alarm Setting window for that parameter, where the alarm limits can be adjusted. This window can also be accessed from the Alarm tab: **[ALARM] → [NIBP]/ [PR] / [SpO2] / [Temp]**
6. **Patient Information:** Displays patient information such as Name, Location, and ID.
7. **Menu Tabs:** Used to access and navigate through the device Menu.
   a) **MEASURE:** The MEASURE tab is the default Home screen used to display vital sign parameter information.
   b) **PATIENT:** Used to enter, modify, and select patient information, review the patient list, and transmit patient information. NOTE: This tab does not appear in Triage Profile.
   c) **REVIEW:** Used to quickly review historical patient measurement information.
   d) **ALARM:** Used to adjust alarm limits for each parameter, change alarm volume settings, and review historical alarms. ***NOTE: This tab does not appear in either Spot Check profile or Triage profile.***
   e) **SETTINGS:** Used to adjust special settings for each vital sign parameter, enter and manage clinician information, and manage general device settings. General device settings include Date/Time, and selection of Operation Profile. Advanced settings are also accessed from the SETTINGS tab and include language settings, nurse call settings, and data / network setup and maintenance. *NOTE: A password is required to access Advanced settings.*
8. **Shortcut Icons:** Used to perform specific functions on the device.

a) : Help key;

b) : Alarm pause key;

c) : Shortcut key to reset the alarm;

d) : Shortcut key to print ;

e) : Shortcut key to start/stop NIBP measurement;

f) : Shortcut key to standby mode;

NOTE: In standby mode, the patient is not being monitored, but the monitor is still powered on. If no parameter is being measured, you can press the to enter the standby mode. A warning pops up, select ***[Yes]*** *to enter the standby mode. Click any area of the screen to exit standby mode. If no parameter is being measured for 5 minutes, the monitor will turn to standby mode automatically.*

g) : Shortcut key to the home screen ;

9. **Save button:** Press to save the current measurement data for the current patient.

3.7 Clinician Management

To enter information for a clinician:

1. Select **[SETTING] → [Clinician]** to set the clinician **[ID]**, **[First name]**, **[Last name]**, **[Department]**

2. Select **[SETTINGS] → [ADVANCED] → [DATA] → [Clinician Set]** to choose the clinician information as follows that can be displayed :**[Clinician ID]**, **[Clinician name]**, **[Clinician Icon]**

Note: * means this item must be input related information, or the settings will not be effective.

3.8 General Setup

3.8.1 Language settings

1. Select **[SETTINGS] → [ADVANCED] → [Language]** to access the language list.
2. Select the desired Language and press **[OK]** save the language setting.

3.8.2 Setting the Date and Time

Setting the current time:

1. Select **[SETTINGS] → [DEVICE] → [Settings] → [Time]**.
2. Set **[Year]**, **[Month]**, **[Day]**, **[Hour]**, **[Minute]** to the desired value.
3. Select **[OK]** to save settings.

Setting the date/time format:

1. Select **[SETTINGS] → [ADVANCED] → [GENERAL] → [DATE/TIME]**
2. Set the **[Date Format] to yyyy-mm-dd, mm-dd-yyyy or dd-mm-yyyy**;
3. Set the **[Time Zone]** to be GMT, GMT+1, GMT+2, GMT+3, etc.

3.8.3 DEMO Modes

1. Select **[SETTINGS] → [ADVANCED] → [GENERAL] → [DEMO]** to select demo type. There are three demo modes to choose from: Monitor profile demo, Spot check profile demo, or Triage profile demo.
2. Select **[Start]**to begin the demo.

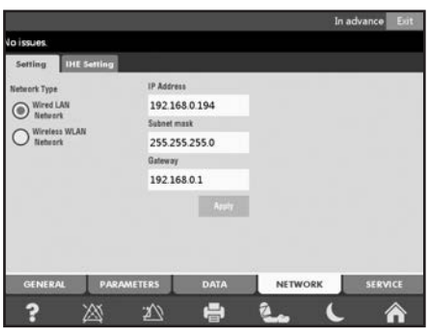
3.8.4 General Device Options

1. Select **[SETTINGS] → [ADVANCED] → [GENERAL] → [OPTIONAL]**to view the list of options available.
2. Choose the desired options.
3. Select **[OK]** to save settings.

3.8.5 Data Options

1. Select **[SETTINGS] → [ADVANCED] → [DATA]** to choose whether or not the full name or abbreviation is displayed for both the Patient and the Clinician. You can also choose to automatically send clinical information to the EMR when saving manually, and whether or not to delete the displayed readings after the data is sent to the EMR successfully.
2. Select **[OK]** to save settings

3.8.6 Network Settings



1. Select **[SETTINGS]** → **[ADVANCED]** → **[NETWORK]** to set the network to be **[Wired Network]** or the **[Wireless Network]**.
2. Select **[SETTINGS]** → **[ADVANCED]** → **[NETWORK]**→ **[IHE Setting]**, in this interface set the network server to be **[PCD Server]** / **[PDQ Server]**.
3. Select **[OK]** to save settings.

3.8.7 Service settings

1. Select **[SETTINGS]** → **[ADVANCED]** → **[SERVICE]** to reset factory default settings (not recommended), import and export the configure files by USB, or import configuration settings from a USB drive. In the **[SERVICE]** menu, you can also see the device logs and other information about the device.

3.8.8 Other settings

1. Select **[SETTINGS]** → **[ADVANCED]** → **[PARAM]** → **[OTHERS]** to set the **[Height Unit]** and the **[Weight Unit]**.
2. Select **[OK]** to save settings.

4. Patient Management

4.1 Adding a Patient

To add a patient,

1. Select **[PATIENT]** → **[Add]**. The patient information window will pop up.
2. Enter or select the patient information:
   Patient ID: The system can automatically produce an ID for the patient. The ID can also be manually entered.
   First Name: Enter the patient's first name.
   Last Name: Enter the patient's last name (family name).
   Age: Enter the patient's birthday.
   Gender: Choose **[Male]** or **[Female]**.
   Patient Type: Choose the patient category, either **[Adult]**, **[Pediatric]** or **[Neonate]**.
   Select **[OK]** to add the new patient.

Caution: The patient type determines which measurement algorithms, safety limits, and alarm limits the device will use during operation.

Caution: The number of patients who can be entered depends on the device's storage space.

4.2 Patient manage

When the patient is added, the patient information will automatically populate the patient interface (see the following picture):

You can conduct any of the following operations:
Select **[View All]**: Can view the last 1 day, last 7 days, or all the patients. Even you can choose the keyword search to find the exact one you need.
Select **[Delete]**: Select one or more pieces of patient information to delete it.
Select **[Modify]**: Select one piece of patient information to modify it **[except the patient ID]**.

Caution: Do not attempt to delete or modify that patient that is currently being monitored.

Select **[Select]**: Select one piece of patient information. The system automatically will go to the home screen. Monitoring of the selected patient will begin immediately.
Select **[Discharge]**: Discharges the current patient.
Select **[Print]**: Prints the patient information and measurement data about the selected one;
Select **[Last page]**: Checks the patient information of the last page;
Select **[Next page]**: Checks the patient information of the next page;

5. Patient Monitoring

5.1 NIBP Measurement

The monitor uses the oscillometric method for measuring NIBP. It is applicable for adult, pediatric and neonatal patients. It is not applicable for pregnant or pre-eclamptic patients.

The oscillometric method indirectly estimates the systolic and diastolic pressures within the blood vessels by measuring pressure change within the blood pressure cuff. The device senses pressure waves in the artery when occluded by pressure in the cuff and calculates the average pressure.

NIBP measurement is suitable for use during electrosurgery and during the discharge of a cardiac defibrillator according to IEC 80601-2-30.

A physician must determine the clinical significance of the NIBP measurement.

5.1.1 Safety Information

Warnings:

- Check the patient category before monitoring. Incorrect settings may result in some risk for patient safety. For example, higher alarm-level settings for adults are not suitable for pediatric and neonatal patients.
- Do not measure NIBP on patients with sickle-cell disease or any condition in which skin damage has occurred or is expected.
- Use clinical judgment to decide whether to perform frequent Auto BP measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.
- Use clinical judgment to decide whether to perform Auto BP measurement on patients with thrombasthemia.
- Do not use the NIBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.
- If you doubt the NIBP measurements, check the patient's vital signs using another device, and then check the monitor.
- The NIBP measurement function must be calibrated regularly for safe use.
- The performance of the automated sphygmomanometer can be affected by extremes of temperature, humidity and altitude.
- Avoid compression or restriction of the connection tubing, or the measurement result will be wrong, which may mislead the doctor to make wrong diagnosis, patient may be hurt.
- When patients cannot take care of themselves, there must be an operator standing by during auto mode measurement.
- The environmental or operational factors which can affect the performance of the NIBP module and its BP reading :
  - ◊ Avoid compression or restriction of pressure tubes. Air must pass unrestricted through the tubing.
  - ◊ The bladder of the cuff is not folded or twisted.
  - ◊ A wrong cuff size, and a folded or twisted bladder, can cause inaccurate measurements
  - ◊ Do not wrap the cuff too tightly around the limb.
- Continuously high cuff pressure due to compressed or bent tubing, may have the effect of blood flow interference and may result in harmful injury to the patient.
- Do not use the cuff over a wound, as this can cause further injury.
- A pressurized cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.
- Do not use the NIBP cuff on the arm of a mastectomy patient, we suggest measuring blood pressure on their legs.
- Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb.
- The application of the cuff and its pressurization on any limb where intravascular access, therapy, or an arteriovenous(A-V) shunt is present, temporary interference to blood flow and could result in injury to the patient.
- Check the operation of the automated sphygmomanometer regularly to make sure that it does not result in prolonged impairment of the circulation of the blood of the patient.

5.1.2 NIBP Measurement Limitations

Accurate NIBP measurements cannot be taken when the heart rate is extremely low (less than 40 bpm) or extremely high (greater than 240 bpm) or if the patient is on a heart-lung machine.

Accurate measurement also cannot be taken when the following conditions exist:

- excessive and continuous patient movement such as shivering or convulsions;
- difficulty detecting a regular arterial pressure pulse;
- cardiac arrhythmias;
- rapid blood pressure changes;
- severe shock or hypothermia that reduces blood flow to the peripheries;
- an edematous extremity.

5.1.3 NIBP Measurement Modes

There are four modes of measuring NIBP:

- **Manual:** a single measurement on demand.
- **Auto:** continuous repeated measurements with a set interval.
- **STAT:** rapid series of measurements over a five-minute period. For use only on supervised patients.
- **Averaging:** a set number of measurements taken and averaged.

5.1.4 NIBP Monitoring Procedure

Preparing to Measure NIBP

1. Encourage the patient to be still and quiet.
2. Check the patient category. If you want to change the patient category, select to enter the **[Patient Info]** menu. Select the desired patient category.
3. Select the appropriate cuff according to patient size.
   - Check the limb circumference of the patient. (Use the upper arm or thigh.)
   - Select the appropriate cuff. (The applicable limb circumference for the cuff is marked on the cuff). The width of the cuff should be about 40% of the limb circumference (50% for neonates), or 2/3 of the upper arm's length. The inflatable part of the cuff should be long enough to encircle 50% to 80% of the limb.

Note:

- BP measurement accuracy depends on a properly fitted cuff.
- The following steps should be taken to obtain accurate routine resting blood pressure measurements for the condition of hypertension , including:

  1) Comfortably seated
  2) Legs uncrossed
  3) Feet flat on the floor
  4) Back and arm supported
  5) Middle of the cuff at the level of the right atrium of the heart.
  6) The patient should relax as much as possible and not talk during the measurement procedure.
  7) 5 min should elapse before the first reading is taken;
  8) The operator is suggested standing on the right side of the monitor in normal use.

4. Confirm the cuff has been entirely deflated.
5. Connect one end of the BP cable to the cuff air tube and the other end to the monitor's NIBP connector. Gently push the tip of the BP cable over each socket to click the cable securely in place.
6. Wrap the cuff snugly around the upper arm or thigh of the patient. On the arm, the bottom of the cuff should be approximately 1 inch above the elbow joint. Ensure the Artery Marker

"Φ" on the cuff is positioned above artery and that there are no knots in the BP cable. When wrapped around the patient's arm, the Cuff Index Line should fall within the Range Markers printed on the cuff. If not, select another cuff size. The monitor is designed for use with standard neonatal, pediatric and adult cuffs (including arm and thigh cuffs).

Note: The cuff should be at heart level to avoid measurement errors. If you cannot position the cuff on a limb at heart level, you may need to make manual adjustments to measurements as follows:

- If the limb/cuff position is higher than heart level, the BP reading will be lower. Add 0.75mmHg (0.1kPa) to the measurement result for each centimeter of distance between the limb/cuff and the heart.
- If the limb/cuff position is lower than heart level, the BP reading will be higher. Subtract 0.75mmHg (0.1kPa) for each centimeter of distance between the limb/cuff and the heart.

Starting/Stopping Measuring
Press on the device display to start NIBP measurement.

Press again to stop measurement.

Auto Measurement
1. Select **[SETTING] → [NIBP Mode] → [Long-Term Automatic]** to start an automatic measurement cycle.
2. Select **[Minute]** to set the duration of time you want to automatically measure BP. Select a time period from **[5 min]** to **[240 min]** .
3. Select to begin the cycle.

Warning: Prolonged NIBP measurement in Auto Measurement mode can be associated with purpura, ischemia and neuropathy in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop NIBP measurement immediately.

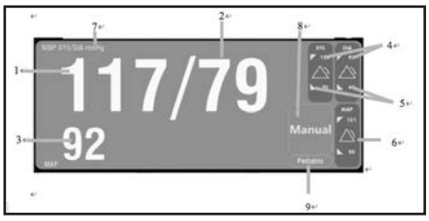
STAT Measurement
1. Select **[SETTING] → [NIBP Mode] → [STAT]**to start a quick measurement cycle. BP measurements will be taken for about 5 minutes.
2. Select to begin the cycle.

Note: STAT measurement mode will return to manual mode when one STAT measurement is finished.

Averaging Mode
1. Select **[SETTING] → [NIBP Mode] → [Averaging]** to start an averaging mode measurement cycle.
2. To include the first measurement in the average, check the box beside "Include the first measurement in averaging calculation." If you do not wish to include the first measurement in the average, and the box is checked, touch the check box to uncheck it.
3. Select the total number of measurements to be taken and averaged. Select between 2 and 5 measurements.
4. Select the number of minutes before the first measurement begins. Select between 0 minutes and 5 minutes. If you select 0, measurement will begin immediately after you begin the cycle by touching . If you select 1, measurement will begin 1 minute after you touch , etc.
5. Select the number of seconds between each discreet measurement. Select an interval between 15 seconds and 120 seconds.
6. Select OK to apply your settings and then select to begin the cycle.

Warning: Operator is in continual attendance during the series of measurements.

5.1.5 NIBP Display
There is no waveform displayed for NIBP measurement. NIBP readings are displayed in the BP section of the measurement display. The following figure shows the NIBP display screen. The display on your monitor may look slightly different.



1. Systolic blood pressure
2. Diastolic blood pressure
3. Mean arterial blood pressure
4. Upper alarm limits
5. Lower alarm limits
6. Alarm switch
7. Pressure unit
8. Measurement mode
9. Patient type

Note: In Triage profile, click the patient type area (see the above picture area 9) in order to change the patient type. In monitor and spot check Profile, the patient type is just displayed in this area.

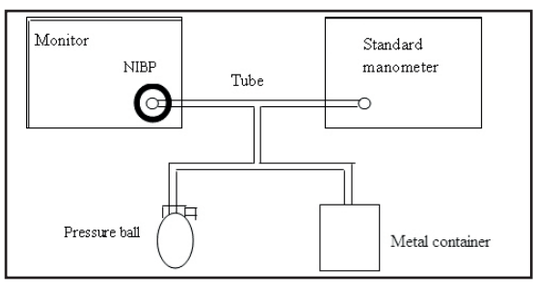
5.1.6 Setting NIBP
You can setup the NIBP measurement information as follows:
1. Select **[SETTING] → [ADVANCED] → [PARAMETERS] → [NIBP] → [Default patient type]** to choose the patient category. Choose either **[Adult]**, **[Pediatric]** or **[Neonate]**.
2. Select **[SETTING] → [ADVANCED] → [PARAMETERS] → [NIBP]** to set the **[Unit]** to **[mmHg]** or **[kPa]**.

Note: This setup is only available in Triage profile.

5.1.7 NIBP Calibration
EU countries except Germany:
Legal regulations for monitoring instruments apply to all EU countries except Germany.

Countries outside the EU:
For any countries where no legal regulations exist for monitoring instruments, it is recommended to examine the accuracy of measuring instruments in 2-year intervals. If you need to do NIBP maintenance, please contact professional service personnel.

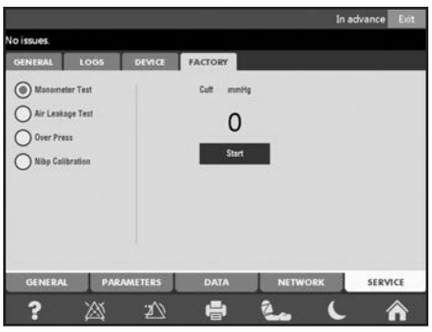
Calibration tools: 3 way connector, pipe, pressure ball, metal container (500±25 ml), standard manometer (already calibrated, precision over 1 mmHg)
1. Connect monitor, manometer, pressure ball and metal container as follows.



2. Reading of manometer should be 0 before deflation, if not, cut the connection until it returns to zero.
3. Select **[Main Menu]** - **[Settings]** – **[Advanced]** - input password → **[Factory]** – input password **[Factory]** → **[NIBP Calibration]**.
4. Select e.g. 250 mmHg as calibration level. Push [**Start]** button. Manually pump up standard manometer to 250 mm Hg. Consult pressure level shown on device. Deviation +-can't be over 3 mmHg. If correct, push **[Set]** button to confirm pressure calibration level.

5.1.8 Manometer Test

When the NIBP value measured is inaccurate, you can select **[SETTINGS] → [ADVANCED]** input password **→ [Factory],** after enter the correct password to go to **[Factory]** to select the following tests: Manometer test , air leakage test ,over press test, NIBP Calibration. After the selection, you can actually conduct these tests.



Note: Only qualified clinical professionals or specified personnel of the manufacturer can perform the above operation.

5.2 SpO2 measurement

5.2.1 Introduction

The measurement of oxygen saturation of arterial blood (also known as pulse oxygen saturation, or SpO2) adopts the principles of light spectra and volume tracing. The LED emits lights with two specific wavelengths, which are selectively absorbed by oxygenated hemoglobin and deoxyhemoglobin. The optical receptor measures the changes in the light intensity after the light passes the capillary network and estimates the ratio of oxygenated hemoglobin and the total hemoglobin.

$$SpO_2\ \% = \frac{\text{Oxygenated hemoglobin}}{\text{Oxyhemoglobin + deoxyhemoglobin}} \times 100\%$$

Wavelengths of the light emitted by the pulse oximeter probe are nominally 660nm for red LED and 940nm for infrared LED.

5.2.2 Safety Information

Warnings:

- Only use SpO2 sensors specified in this manual. Follow the SpO2 sensor's instructions for use and adhere to all warnings and cautions.
- When using Covidien Nellcor SpO2 sensors/cables, please use the enclosed Covidien Nellcor SpO2 sensors/cables instruction manuals.
- When a trend toward patient deoxygenation is indicated, blood samples should be analyzed by a laboratory co-oximeter to completely understand the patient's conditions.
- Do not use the monitor and the SpO2 sensor during magnetic resonance imaging (MRI). Induced current could cause burns.
- Prolonged continuous monitoring may increase the risk of unexpected changes in skin characteristics, such as irritation, reddening, blistering or burns. Inspect the sensor site every two hours and move the sensor if the skin quality changes. For neonates, or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.
- Check the SpO2 sensor and its package for any sign of damage before use. Do not use the sensor if any damage is detected. Contact the manufacturer.
- Use only SpO2 sensors and extension cables approved for use with this monitor. Do not use damaged sensors or cables. Incompatible or damaged sensors or cables could pose patient burn risk.
- Do not soak the sensor in water. Avoid contact with moisture to prevent damage.
- When disposing of any SpO2 probes, please observe all local, state, and federal regulations that relate to the disposal of this product or similar products.
- Pulse rate measurement is based on the optical detection of a peripheral flow pulse and therefore may not detect certain arrhythmias. The pulse oximeter should not be used as a replacement or substitute for ECG-based arrhythmia analysis.

Caution: If it is necessary to clip the SpO2 device to the patient, always clip the cable, not the sensor itself. Never use force to pull the sensor cable.

Note:

- During SpO2 measurement, a pleth wave will show in the SpO2 display area. This wave does not equal the intensity of the PR signal.
- The production divergence and drive current of LED influence the range of the peak wavelength of the emitted light by the oxygen probe.
- The monitor does not provide an automatic self-examination alarm signal. An SpO2 simulator can be used to verify alarm limit functions.
- Functional test cannot be used to assess the accuracy of the monitor.
- When the displayed SpO2 or pulse rate value is potentially incorrect, the system will show a "?" in the value position.

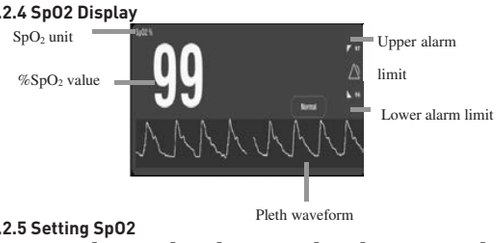
5.2.3 SpO2 Monitoring Procedure

1. Selecting SpO2 Sensor: Select a SpO2 sensor that is appropriate for the patient category, weight and application site.
2. Connecting SpO2 Sensor: Plug the SpO2 sensor cable into the SpO2 connector on the device. (See device diagram in Chapter 1.4.)
3. Applying SpO2 Sensor: Clean the application site, remove any colored nail polish, and apply the sensor to the patient. Typically, the sensor should be used on the middle or ring finger of the non-dominant hand. The fingernail should face the side with the red light.

Warnings:

- Do not use the SpO2 sensor on the same limb being used for NIBP measurement. This may result in inaccurate SpO2 reading due to blocked blood flow during cuff inflation.
- Do not measureSpO2 on a finger painted with nail polish. This may result in unreliable measurements.
- When using a finger sensor, make sure the fingernail faces the red light.
- If "Weak Signal" is indicated, check the patient's condition and move the probe to another position to try to obtain a better signal.

5.2.4 SpO2 Display



5.2.5 Setting SpO2

1. Select **[SETTING] → [ADVANCED] → [PARAMETERS] → [SPO2] → [Default response]** to choose the response to be**[Normal: 16 seconds]** or **[Fast : 4 seconds]**. (Not applicable to Masimo)
2. Select **[SETTING] → [ADVANCED] → [PARAMETERS] → [SPO2] → [Sweep speed]** to setup the speed to be **[6.25mm/s]** or **[25 mm/s]**.

5.2.6 SpO2 Measurement Limitations (Riester and Nellcor SpO2)

If you doubt the SpO2 measurements, check the patient and move the probe to a different finger. The following factors may influence the accuracy of measurements:

- Exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps or direct sunlight (exposure to excessive illumination can be corrected by covering the sensor with a dark or opaque material);
- Electromagnetic interference, such as from an MRI device;
- Excessive patient movement;
- Intravascular dyes such as indocyanine green or methylene blue;
- Significant levels of dysfunctional hemoglobins (such ascarboxyhemoglobin or methemoglobin);
- Incorrect sensor application or use;

- Placement of a sensor on an extremity with a blood pressure cuff, arterial catheter or intravascular line;
- Low perfusion;
- Electrosurgical units.

The monitor can be used during defibrillation, but the readings may be inaccurate for a short time.

5.2.7 Riester / SpO2 Sensors and Extension cables

a) Sensors

Model: 15-100-0013, 15-100-0015

Intended use:

Intended use of the non-invasive pulse oximeter probe is during continuous non-invasive arterial oxygen or hemoglobin saturation measurement or during pulse rate monitoring. The probes may be used in co-ordination with a variety of other equipment of the non-invasive pulse oximeter.

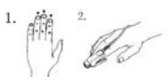
Contraindications:

The probe may be used on the same location for a maximum of 4 hours, provided the location is inspected routinely to ensure skin integrity and correct positioning. Because individual skin condition affects the ability of the skin to tolerate probe placement, it may be necessary to change the probe location more frequently with some patients.

Instruction:

a) Select a suitable location for the probe. The patient's index finger is the preferred location, alternative recommended locations are middle or ring finger.

b) As shown on figure 2 , place the index finger over the sensor window into the probe with the fingertip against the stop. The probe should be positioned with the cable showing above the finger and hand.



Note:

If the probe doesn't track the pulse reliably, it may be positioned incorrectly. It is possible that the diameter of the finger might be too thick, too thin, or deeply pigmented. Otherwise it might also be too deeply coloured (for example, as a result of externally applied coloring such as nail polish, dye, or pigmented cream) to permit appropriated light transmission . . If any of these situations occurs, reposition the probe or choose an alternate probe to be used at a different location.

Warning:

The operator or user is responsible for checking compatibility of monitor, probe and cable before use. Otherwise, incompatible components can result in patient injury or inferior performance.

Failure to apply the probe properly may cause incorrect measurements.

Using in the presence of bright light may result in inaccurate measurements. In such cases, cover the probe location with an opaque material.

Intravascular dyes or externally applied coloring such as nail polish, dye, or pigmented cream, may lead to inaccurate measurements.

Heavily moving fingers of active patients affect and/or may compromise the performance of the probe. The use of the probe is not recommended for such patients.

Do not use any tape to secure positioning of the probe or on any fingers directly. Strong venous pulsations may result in inaccurate saturation measurements.

As with other medical devices likewise, do carefully position cables in order to reduce possible patient entanglement or strangulation.

Do not use the probe during MRI scanning. Conducted current may cause burns. The probe may as well affect the MRI image, , and the MRI unit may affect the accuracy of oximeter measurement.

Do not assess the probe's accuracy only by testing it on a oximetry simulation device.

Do not do NIBP measurement or use other instruments on the same arm as the SpO2 probe. Interruption of flow of blood by an NIBP cuff or special circulatory condition of the patient may result in no pulse found or a loss of pulse.

Do not reprocess or modify the probes. Performance or accuracy of probes may otherwise be affected. .

Do not disassemble or repair probes, as it may result in product damage of operator injury. Such wrongdoings will be regarded as severe product misuse and a breach of warranty and thus result in a complete loss of all warranty claims thereafter.

Disposal of the pulse oximeter probe and extension cable shall comply with laws of the local government. Please contact your local government authorities regarding such relative local rules. .

Specifications:

Peak wavelength: Red 660-666nm, IR 895-920nm
Maximum optical output power: 2mW
Measurement Range: SpO2 0% ~ 100%
Arms: 70% ~ 100% SpO2: ±2%
0 ~ 69% SpO2: unspecified

Notes:

The accuracy can be reached only in normal working conditions.

Required working conditions:

Range of temperature: 10°C ~ 40°C
Relative humidity: 30% ~ 75%
Required transport and storage conditions:
Range of temperature: -40°C ~ +70°C
Relative humidity: ≤ 93%

Cleaning and disinfection:

Use a clean, soft cloth to wipe the probe with 70% isopropyl alcohol. Do not use undiluted bleach (5%~5.25% sodium hypochlorite) or any cleaning solution other than those recommended here because permanent damage to the probe may occur.

Clean and disinfect the probe after use.

Saturate a clean, soft cloth with 70% isopropyl alcohol. Wring out excess isopropyl alcohol and wipe all surfaces of the probe and cable.

Dry all surfaces of the probe and cable with a clean, soft cloth.

Caution: Do not sterilize by irradiation, steam, or ethylene oxide. These sterilization methods may damage the probe.

b) Extension cables

1. Introduction

Description of function

The SpO2 extension cable is a type of cable connecting the pulse oximeter sensor cable with the SpO2 main board thus prolonging the signal transmission distance. .

2. Required working and storage conditions:

Range of working temperature 1°C ~ +40°C
Range of storage temperature -20°C ~ +60°C (inside box), -20°C ~ +50°C (outside of box)
Humidity: 30% – 75%

c) Transportation

The packaged product may be transported by any means of transport. However, during transport collision, severe vibrations or any exposure to severe weather conditions such as rain, snow, flooding, etc. must be avoided by any means.

Storing goods in any kind of open-air warehouse may severely damage the product and may lead to loss of performance.

d) Storage

The product shall be stored in a dry and ventilated environment, free of any acid, alkali or other corrosive gases. The temperature and humidity conditions in such warehouse shall be within -20°C - +60°C, and in between of 30% -70% relative humidity.

e) Cleaning and disinfection

Please use the following materials for cleaning and disinfection:

- green soap, green soap (USP) or non-alcoholic hand soap;
- 2% Glutaraldehyde solution (such as Cidex)
- 10% Aqueous sodium hypochlorite solution (Bleach).

f) Life requirements

If the product is used in normal environment conditions, correctly operated, cleaned and disinfected, the working life is minimum two years. Maximum shelf life: 4 years

g) Using Steps:

1) Check the product in order to make sure it is not damaged.
2) Clean the product.
3) Connect the 12P plug to the appropriate connector on the instrument.

4) Connect the DB9P plug to the corresponding SpO2 probe socket
5) Start the test.
6) After the detection, take down SpO2 probe, and then remove the SpO2 extension cable.
7) Clean and dry thoroughly after use.

Warning:

- This product is intended to be used by the physician only our under the instructions of a physician.
- Avoid using on imaging equipment such as magnetic resonance imaging equipment (MRI) and electronic computer tomography (CT).
- In order to avoid damage to the cable code sensor, hold the plug of the medical signal specific cable in our hand when disconnecting.
- Incorrect connection will cause the device data display to be discontinued or not displayed.

5.2.8 Nellcor Information

COVIDIEN

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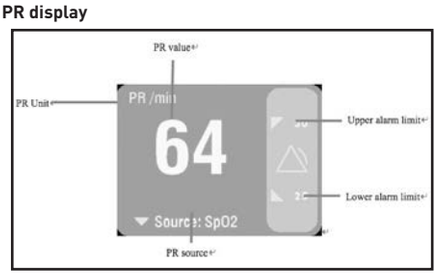
5.3 PR Measurement
5.3.1 PR display



5.3.2 Selecting PR Source
Select **[SETTING] → [ADVANCED] → [PARAMETERS] → [PR] → [Source]** SpO2 or NIBP.

5.4 Temperature Measurement

Contraindications:

a) There is a possible danger of inflammation of gases if the instrument is operated in the presence of inflammatory mixtures or mixtures of pharmaceuticals and air or oxygen or laughing gas!
b) Never attempt to take the instrument apart!
c) Unplug the instrument before cleaning or when disinfecting.
d) RVS-100 thermometer probe and probe cover are designed for use with this thermometer.
e) Do not use this thermometer without first installing a new RVS-100 thermometer probe cover.
f) Use only RVS-100 thermometer probe covers with this device.
g) Use of any other probe cover will result in erroneous temperature readings.
h) The device and probe covers are non-sterile. Do not use on abraded tissue.
i) To limit cross contamination, only use blue devices for taking oral and axillary temperatures.
j) Use red devices only for rectal temperatures.
k) Thoroughly dry all electrical contacts on both probe and thermometer after washing or device may fail to function properly.
l) For re-calibration, service or integrity checks refer to a qualified biomedical technician or return to manufacturer.
m) Do not open unit. No user-serviceable parts inside. Opening device may affect calibration and voids warranty.
n) Disposal of used probe covers must be performed in accordance with current medical practices or local regulations regarding disposal of infectious, biological medical waste.
o) Cleaning frequency and practices must be consistent with institutional policy for cleaning of non-sterile devices.
p) Device to be used by trained personnel.

Intended use / Indications for use
The RVS-100 thermometer module is used for measuring body temperature in the mouth (oral), the anus (rectal) and the armpit (axillary) and thus aids the detection, diagnosis and monitoring of vital body functions.

5.4.1 Introduction
This monitor is equipped with fast temperature measurement capability. Fast temperature measurement uses a pre-heating mode to reach the patient's body temperature rapidly. It then converts the temperature into electrical signals, which are processed by the monitor and quickly displayed as measurements.
Information about body temperature
It is a common misconception that 37 °C is the 'normal' body temperature. It is actually the case that 37 °C is the average body temperature. Normal body temperature are in a range that varies with age, gender and measuring point.
Furthermore, body temperature fluctuates over the course of the day. It is usually lower in the morning, higher in the afternoon and goes down a little again in the evening. Other factors that affect body temperature include the patient's particular activity, metabolic rate or medications taken. The normal body temperature also tends to drop with increasing age.
Normal temperatures are listed in the following table according to the age of the patient and measuring point. Temperatures measured at different parts of the body, even if they are measured at the same time, must not be directly compared with one another as body temperature differs between measuring points.

Temperature measuring points	Normal body temperatures according to patient age			
	0-2 years	3-10 years	11-65 years	> 65 years
Oreille	97,5° - 100,4 °F 36,4° - 38,0 °C	97,0° - 100,0 °F 36,1° - 37,8 °C	96,6° - 99,7 °F 35,9° - 37,6 °C	96,4° - 99,5 °F 35,8° - 37,5 °C
Mouth	- -	95,9° - 99,5 °F 35,5° - 37,5 °C	97,6° - 99,6 °F 36,4° - 37,6 °C	96,4° - 98,5 °F 35,8° - 36,9 °C
Heart	97,5° - 100,0 °F 36,4° - 37,8 °C	97,5° - 100,4 °F 36,4° - 37,8 °C	98,2° - 100,2 °F 36,8° - 37,9 °C	96,6° - 98,8 °F 35,9° - 37,1 °C
Rectum	97,9° - 100,4 °F 36,6° - 38,0 °C	97,9° - 100,4 °F 36,6° - 38,0 °C	98,6° - 100,6 °F 37,0° - 38,1 °C	97,1° - 99,2 °F 36,2° - 37,3 °C
Armpit	94,5° - 99,1 °F 34,7° - 37,3 °C	96,6° - 98,0 °F 35,9° - 36,7 °C	95,3° - 98,4 °F 35,2° - 36,9 °C	96,0° - 97,4 °F 35,6° - 36,3 °C

5.4.2 Temperature Monitoring Procedure

1. Select the appropriate measurement sites. Choose between Oral , Axillary or Rectal .
2. Select the measurement mode. Choose between quick , Cold, or Monitor . For Oral site measurement, only Quick or Cold modes are available. For Axillary or Rectal site measurement, all three modes are available.

Note:

- Quick mode is suitable for patients whose body temperature is expected to be in the normal range of between 96.8 degrees F to 100.4 degrees F(36 degrees C to 38 degrees C).
- Cold Preheat mode is suitable for patients whose temperature is expected to be lower than normal (i.e., 91.4 degrees F, or 33 degrees C), such as those coming out of surgery.
- Monitor mode is suitable for continuous temperature monitoring. The minimum measuring time of this mode is recommend to be 60s.

3. Remove the temp probe rapidly from the probe well on the front of the monitor. This temp probe symbol will begin flashing as a reminder to apply a probe cover.
4. Place the disposable probe cover and position the probe on the patient (see guidance below on proper positioning). The temperature timer symbol will flash while the measurement is completed.

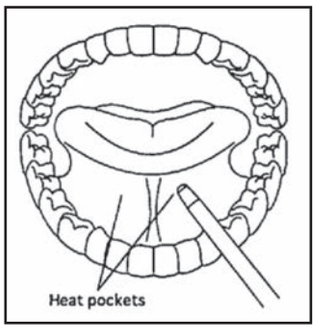
   If using Direct mode, real-time measurement data will appear on the screen continuously.
5. When the measurement is completed, this probe symbol will flash as a reminder to eject the used disposable probe cover. Eject the probe cover and insert the probe back into the probe well.

Warnings:
a.) Never make a body temperature measurement without new probe covers.
Body temperature measurement without probe covers can give incorrect readings. To avoid infection always use a new probe cover.
b.) Probe
To avoid infection use only the blue probe for taking oral and axillary temperatures. The red probe must only be used for taking rectal temperatures.

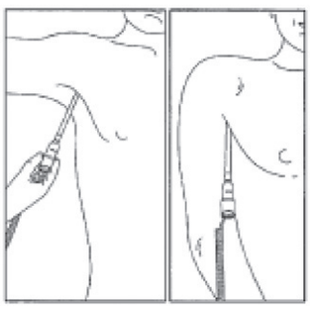
Proper Temperature Probe Positioning

Oral Temperature Taking

Insert the probe tip under the tongue on one side or the other. Ask the patient to close their mouth. Hold the probe in place until there is a long beep and the temperature reading is displayed.



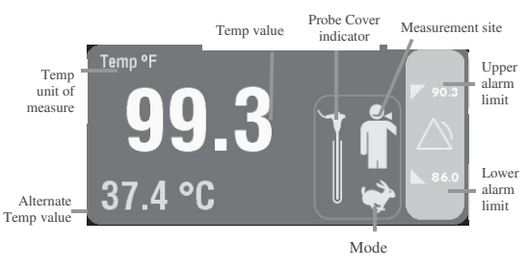
Axillary Temperature Taking
With the patient's arm uplifted, place the probe tip into the patient's armpit, directly on the skin. Ask the patient to lower their arm and hold still. Hold the probe perpendicular to the arm until there is a long beep and the temperature reading is displayed.



Rectal Temperature Taking
Apply lubricant to the probe cover and insert it gently into the patient's rectum only one-half inch to three-fourth inch (12 mm to 19 mm) for adults or one-fourth to one-half inch (6 mm to 13 mm) for children. Hold the probe still until there is a long beep and the temperature reading displays.

Caution: If the monitor cannot take the temperature in quick temp mode, it will automatically change modes and output the results. The temperature measurement site and mode can only be changed when the probe is stored in its holding receptacle on the monitor. These settings cannot be changed when the probe is out.

5.4.3 Temperature Display



5.4.4 Temperature Settings

1. Select **[SETTING] → [ADVANCED] → [PARAMETERS] → [Temp]** to enter the temperature setup menu.
2. Set **[Unit]** to **[Celsius]** or **[Fahrenheit]**. The selected measurement unit will be effective during the next measurement.

5.4.5 Safety Information

- EU countries except Germany:
  Legal regulations for monitoring instruments apply to all EU countries except Germany.
- Countries outside the EU:
  For any countries where no legal regulations exist for monitoring instruments, it is recommended to examine the accuracy of measuring instruments in 2-year intervals
- If the temperature exceeds the measurement range, the alarm will be activated. Check whether the temperature probe is placed on the patient's appropriate site.
- Damaged or outdated probes should be repaired or replaced immediately.

5.5 Nurse Call

The Nurse Call function will send a signal to the nurse call system when a patient's vital signs exceed a pre-set alarm limit. To activate this function, the monitor must be connected to the hospital's nurse call system. Please use the provided the nurse-call connection cable.
The Nurse Call function will only operate under these concurrent conditions:

- The Nurse Call function is active;
- An alarm condition is occurring; and
- Alarms have not been paused or silenced.

To set up Nurse Call:

1. Select **[SETTINGS] → [ADVANCED] → [GENERAL] → [OPTIONAL]** and then **[Enable Nurse Call]**
2. Select **[SETTINGS] → [ADVANCED] → [GENERAL] → [ALARM] → [Nurse Call threshold]** to set the alarm level at which the nurse will be called (i.e., low, middle or high).
3. Select **[SETTINGS] → [ADVANCED] → [GENERAL] → [ALARM] → [Nurse Call relay type]** to set the relay type to be **[Normally close]** or **[Normally open]**.
4. Select**[SETTINGS] → [ADVANCED] → [GENERAL] → [ALARM] → [Nurse Call trigger mode]** to set the trigger mode to be **[continual]** or **[1s pause]**.

Warning: The Nurse Call function should not be used as the primary means of patient monitoring. The care team should evaluate alarms in combination with observations of the patient's symptoms and overall physiological condition.

6. Alarms

Alarms are prompts given by the monitor for medical personnel through visual, audible and other means when either a vital sign appears to be abnormal or a technical problem occurs.

Note:

- The monitor generates all audible and visual alarms through a speaker, LED lights and the display. When the monitor powers on, the alarm LEDs will light once and the speaker will beep, which indicates that the alarm system is working properly.
- Alarm settings are saved in real time, and then stored in the memory of the device. After a loss of power, the last stored settings will be shown after restarting the monitor.

Warning: Do not set the alarm limits to extreme values that can render the alarm system useless. Vital signs alarm limits are pre-set by the manufacturer, but be sure to choose clinically appropriate limits for the patient. Only when the selected patient type is different from the last one, the alarm limits will return to factory defaults.

6.1 Alarm Categories

The monitor's alarms can be classified into three categories: physiologic alarms, technical alarms and prompt messages.

Physiologic alarms: Physiologic alarms are triggered by a monitored parameter value (i.e., the DIA blood pressure value) that violates set alarm limits. Physiologic alarm messages are displayed in the physiologic alarm area.

Technical alarms: Technical alarms are triggered by a device malfunction due to improper operation or system problems. The problems may result in system abnormal operation. Technical alarm messages are displayed in the technical alarm area.

Prompt messages: As a matter of fact, prompt messages are not alarm messages. Apart from the physiological and technical alarm messages, the monitor will show some message to indicate the system status.

6.2 Alarm Levels
The monitor's physiologic alarms are classified into three categories according to the severity of the alarm issue.

High level alarms: Indicate that the patient is in a life-threatening situation and an emergency treatment is necessary. This is the highest level alarm.

Medium level alarms: Indicate that the patient's vital signs appear abnormal and an immediate treatment is required.

Low level alarms: Indicate that the patient's vital signs appear abnormal and an immediate treatment may be required.

The monitor's technical alarms are classified into three categories: high level, medium level and low level. Technical alarm levels are predefined at the factory and can't be changed by users.

The alarm levels are as follows:

Physiological alarm	Alarm level
SpO_2 lower alarm limit exceeded	High
NIBP SYS high /low	Medium
NIBP DIA high /low	Medium
NIBP MAP high /low	Medium
PR high /low	Medium
SpO_2 high /low	High
TEMP high /low	Low
Search timeout	High

Technical alarm	Alarm level
Battery Low	High
NIBP	
Self-Test Error	Low
System Failure	Low
Loose Cuff	Low
Air Leak	Low
Air Pressure Error	Low
Weak Signal	Low
Range Exceeded	Low
Excessive Motion	Low
Overpressure Detected	Low
Signal Saturated	Low
Time Out	Low
Cuff Type Error	Low
Zero Calibration Error	Low
Calibration Failure	Low
Hardware overpressure: Zero Calibration Error	Low
Hardware overpressure: Calibration Failure	Low
SpO_2	
Sensor off	Medium
SpO2 Searching for pulse...	Low
TEMP	
Upper alarm limit exceeded	Low
Lower alarm limit exceeded	Low
TEMP Module Failure	Low

All alarm levels, including physiological and technical alarms, cannot be changed by users.

6.3 Alarm Indicators
When an alarm occurs, the monitor will indicate it through the following means:
Alarm tone: According to the alarm level, alarm sounds of different tones will emit from the speaker.
Alarm Light: According to the alarm level, the alarm LED light on the monitor will flash in a different color and speed.
Alarm message: Alarm messages will be displayed on the screen.

Caution: The exact nature of the alarm depends on the specific alarm level.

6.3.1 Alarm Tones
The device will make the following sounds for different level alarms:

Alarm level	Audible prompt
High	"DO-DO-DO------DO-DO, DO-DO-DO-----DO-DO"
Medium	"DO-DO-DO"
Low	"DO-"

6.3.2 Alarm Lamp
The device has two alarm lamps; one flashes as red/yellow, and the other flashes as cyan. When a physiologic alarm occurs, the alarm levels are indicated in the following visual ways:

Alarm level	Visual prompt
High	Alarm LED flashes red at 2 Hz intervals.
Medium	Alarm LED flashes yellow with 0.5 Hz intervals.
Low	Alarm LED lights up yellow without flashing.

When a technical alarm occurs, the alarm levels are indicated in following visual ways:

Alarm level	Visual prompt
High	Alarm LED flashes red at 2 Hz intervals.
Medium	Alarm LED flashes yellow with 0.5 Hz intervals.
Low	Alarm LED lights up cyan without flashing.

Caution: When multiple alarms of different levels occur at the same time, the monitor will issue visual and audible alarm indicators for the highest-level issues. If both the low level technical alarm and the low level physiologic alarm occur simultaneously, both of the two corresponding LED lights will be lit, one continuous yellow and the other continuous cyan.

6.3.3 Alarm Messages

The system uses different background colors to distinguish alarm level messages. The background color for different alarm message levels is as follows:

High level alarms: red

Medium level alarms: yellow

Low level alarms: yellow (Physiologic alarm), cyan (technical alarm)

The number of * will indicate the relative alarm level in the message area as follows:
High level alarms: ***
Medium level alarms: **
Low level alarms: *.

Caution: If several alarms occur, the highest-level alarm message will be displayed first. The latest alarm message will display first when the alarm level of two alarm messages is the same. You can manually change the displayed message in the alarm area to see other alarm messages.

6.4 Alarm Icons


The alarm is off.


The alarm is active.


The alarm sound is off.


The alarm is paused

6.5 Setting Alarm Volume

1. Select **[Alarm]** → **[General]**.
2. Select **[Alarm Volume]** and choose a desired value from **[Low]**, **[Medium]**, **[High]**;
3. At the same time, you can select **[SETTINGS]** → **[ADANCED]** → **[General]** → **[Alarm]** to set the Minimum Alarm Volume to be **[Low]**, **[Medium]**, **[High]**.

Warning:
- Ensure that alarm volume is always higher than ambient noise which may occur.
- If not, it may impede operator recognition of actual alarm and evtl. put patient in danger.

6.6 Alarm Parameters

All alarm limits are adjustable. When the physical measurement value exceeds the alarm limit value, the alarm will be triggered.

6.6.1 Alarm Switches

To turn alarm limits on or off, select **[SETTINGS]** → **[ADVANCED]**→ **[PARAMETERS]** → **[Alarm limits status]** and then choose the measurement type (i.e., NIBP, PR, SpO2 or Temp). To set the alarm to be **[Alarm limits on]** or **[Alarm limits off]**. When you select **[Alarm limits off]**, the symbol will display in the status bar of the related parameter.

6.6.2 Setting Alarm Limits

1. Go to **[Settings]** → **[Profile]** and select **[Monitor]** to make sure the device is in this profile. This profile must be selected in order to access alarms settings and set alarm limits.
2. From the main measurement display, press anywhere in the Alarm Settings Area to access alarm limit settings. You can then set the upper and lower alarm limits.
3. The alarm limits can also be set up by selecting **[Alarm]** on the main measurement display and then selecting the tab for the alarm limits you wish to set (i.e., alarm limits for NIBP, PR, etc.).

Warning: Medical personnel should set alarm limits based on industry protocols, the clinical environment and their clinical experience. Before monitoring, please confirm whether alarm settings are suitable for the monitored patient.

6.7 Pausing Alarms

Press the button on the front panel of monitor to temporarily suspend all alarm indicators. The icon will appear in the status area; press the button again to exit alarm pause status, the icon will disappear. When you pause alarms, the following will occur:
- All the physiological alarms will be closed.
- Only alarm messages in the technical alarm area will still be displayed. The light and volume of the technical alarm will be closed.
- A 30-second countdown for the alarm pause period will appear in top right in a red bar across the top of the screen.

After the alarm pause time has elapsed, the monitor will automatically cancel the alarm pause and return to normal status. If alarm conditions remain active, alarms will be active. To manually cancel the alarm pause at any time, select .

6.8 Acknowledging Alarms

By selecting on the front panel of the monitor; you can acknowledge active physiological and technical alarms one by one. After you perform this action, the following occurs:
- Visual alarms are open, but audible alarms are shut off.
- "Acknowledged" will appear in front of the acknowledged physiologic alarm message.
- Other remaining physiological and technical alarms will remain.

If a new technical or physiological alarm occurs, the acknowledged alarms will not be influenced, and the system will produce audible alarms according to the level of the new alarms.

6.9 Alarm Reset

Press the button on the front panel of the monitor, you can reset all active physiological and technical alarms:
- The auditory alarms are all shut off.
- The visual alarm signals for any existing alarm conditions will continue as long as those alarm conditions exist.
- Technical alarms about lead-off/sensor-off will be deleted.
- After resetting the alarms, if a new technical alarm or physiological alarm occurs, the monitor will enable the audible alarms once again.

6.10 Alarm Volume off and on

Only when the following setting steps are performed, function of the alarm volume off or on can be achieved.
Select **[SETTINGS]** → **[ADVANCED]**, input the correct password to enter the alarm control interface. In this interface, select **[Allow control alarm audio]**. Then go back to the main interface, select**: [ALARM]** to choose **[Alarm audio on]** or **[Alarm audio off]**.

Note: After selecting **[Alarm audio off]**, the icon will appear on the interface.

6.11 Reminder signal

When the active alarm audio is off, the alarm system would provide a periodical audible reminder signal sound like "Ding, Ding, Ding". **[SETTINGS] → [ADVANCED]**, input the correct password to enter the alarm control interface. In this interface, you can select or deselect **[Active reminder signal]** to open or close the reminder signal. You also can adjust the intervals between the reminder signal to be 30s, 60s, 90s, and 120s in this interface.

6.12 Resetting Alarm Limit

To reset all alarm limits to factory default levels, select **[Alarm] → [General] → [Reset alarm limits]**. Limits will be reset to the following defaults:

Parameter			Upper limit	Lower limit
NIBP (mmHg)	Adult	SYS	160	90
		DIA	150	50
		MAP	110	60
	Pediatric	SYS	120	70
		DIA	70	40
		MAP	90	50
	Neonatal	SYS	90	40
		DIA	60	25
		MAP	70	35
SpO_2			100	95
PR			120	50
TEMP (℃)			39	36

Warning: A potential hazard can exist if different alarm pre-sets are used for the same or similar equipment in any single area.

6.13 Alarm History

Select the **[ALARM]** on the main measurement display and then select the **[HISTORY]** tab to see the alarm time, alarm level, alarm message, alarm duration time and so on of all the alarms as shown in the next image:

Note:

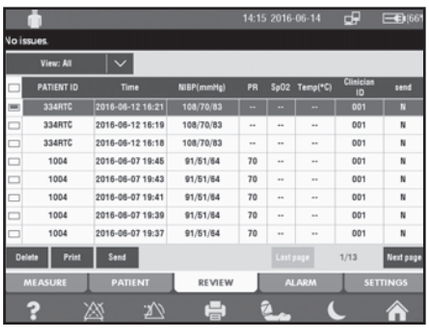
- The recorded number of the alarm logs depends on the storage space.
- The alarm system generates a technical alarm condition when the storage space is insufficient. When storage is less than 10MB, a low level technical alarm occurs, and a prompt information will pop up as "Insufficient storage space". When the storage space is less than 5MB, the other low level technical alarm occurs, and a prompt information will pop up as "Critical shortage of storage space".
- When the alarm system is powered down, the log is maintained, but the time of powering down will not be captured in a log.
- The contents of the log is maintained after the alarm system has experienced a total loss of power (mains adapter and internal electrical power source) for a finite duration.
- When the log reaches capacity, the system will automatically delete the earliest log.

7. Reviewing

You can use the Review feature to access any patient information saved by the monitor.

7.1 Reviewing patient measurements

Select **[REVIEW]** on the home screen to access saved patient measurement data.



7.2 Deleting patient data

Select the blank box ☐ to the left of the Patient ID and then select **[DELETE]** to delete the patient's measurement data.

7.3 Print patient data

Select the blank box ☐ to the left of the Patient ID and then select **[PRINT]** to print the selected patient's measurement data.

8. Battery

8.1 Introduction

The monitor can be fitted with a rechargeable battery to ensure continuous operation in the event of a power outage. The battery requires no special maintenance under normal conditions. While the monitor is connected to an external power source, the battery will charge, regardless of whether the device is turned on. In the case of a sudden power outage, the monitor will automatically switch to battery power without interruption of measurement.

Battery status can be found at the top right corner of the touch screen.

indicates that the battery is fully charged.

indicates the battery is depleted and needs recharging.

indicates the battery is recharging.

indicates the battery is abnormal.

Battery power lasts for a limited time. When battery power is very low, the monitor will issue a monitor technical alarm. The user should immediately connect the device to a power supply to charge the battery.

Caution: If the monitor is unlikely to be used for an extended time period, remove the battery prior to shipping or storage.

Warnings:

- Use only batteries specified in this manual.
- Keep the batteries out of reach of children.
- Check the battery regularly to guarantee its normal function.
- Replace the battery at the end of its service life.
- The battery can only be replaced, maintained by professional personnel specified by Rudolf Riester GmbH. Or the device may not be started up.

8.2 Installing a Battery

The battery compartment is located on the bottom of the monitor. Follow these steps when installing the battery.

1. Turn off the monitor and disconnect the power cable and other connected wires and cables.
2. Open the battery door in the direction indicated on the door label.

3. Take out the old battery.
4. Insert the new battery in the direction indicated.
5. Close the battery door.

8.3 Optimizing Battery Performance

A battery needs at least two optimizing cycles when it is put into use for the first time. A battery cycle is one complete, uninterrupted charge of the battery, followed by a complete, uninterrupted discharge of the battery. A battery should be conditioned in this way regularly to maintain its useful life. In addition to the initial use, ideal times to condition a battery are when it is used or stored for two months or when the battery run time becomes noticeably shorter.

To optimize a battery, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
2. Place the battery in need of optimizing into the battery compartment.
3. Place the monitor in the charger stand and connect it to AC power supply. Allow the battery to charge uninterrupted for at least 6 hours.
4. Disconnect the monitor from the AC power supply and allow the monitor to run on battery power until the battery is depleted and the device shuts off.
5. Return the monitor to the charger stand and connect it to the AC power supply. Allow the battery to charge uninterrupted for at least 6 hours.

8.4 Checking Battery Performance

The performance of a battery may deteriorate over time. To check battery performance, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring and measuring procedures.
2. Place the monitor in the charger stand and connect it to an AC power supply. Allow the battery to charge uninterrupted for at least 6 hours.
3. Disconnect AC power and allow the monitor to run on battery power until it shuts off.
4. Make note of the monitor operating time on battery power. Operating time is a direct indicator of battery performance. If you notice a decline in battery operating time span, you may need to run it through an optimizing cycle or replace it.

Caution: Battery operating time depends on the configuration and operation of the monitor. For example, continuous monitoring of NIBP and SpO2 will deplete the battery faster than occasional vital signs spot checks.

8.5 Disposing of Batteries

Batteries that are damaged or depleted should be replaced and discarded properly. Dispose of used batteries according to local regulations.

Caution: Battery service life depends on how often the monitor is used and how many features are used. The battery typically can be charged and discharged 300 times.

Warning: Do not disassemble batteries or dispose of them in fire, or cause them to short circuit. They may ignite, explode or leak, causing personal injury.

9. Maintenance and Cleaning

9.1 Introduction

Keep your equipment and accessories free of dust and dirt. To avoid damage to the equipment, follow these rules:

1. Always dilute cleaners according the manufacturer's lowest-possible concentration.
2. Do not immerse any part of the equipment in liquid.
3. Do not pour liquid onto the equipment or accessories.
4. Do not allow liquid to enter the case.
5. Never use abrasive materials (such as steel wool or silver polish) or erosive cleaners (such as acetone or acetone-based cleaners).

Warning: For optimal performance, product service should be performed only by qualified service personnel.

Note: To ensure equipment performance and safety, the monitor should be evaluated by a qualified service technician after 1 year of use. Contact the device manufacturer to schedule a service appointment.

9.2 Cleaning the Monitor

1. Common detergents and non-corrosive disinfectants commonly used in hospitals can be applied to clean the monitor. Many of these cleaners must be diluted prior to use. Please use them according to the instructions of the detergent manufacturer.
2. Avoid the use of alcohols, amino or acetonyl detergents.
3. The monitor's enclosure casing and touch screen should be kept free of dust. They can be wiped with a lint-free soft cloth or moistened sponge. While cleaning, be careful and do not spill liquid onto the monitor. Be especially careful to keep water and liquid out of all cable outlets and USB ports.
4. Do not use abrasive materials, including wire brushes or metal brighteners, during cleaning. They will damage the panel and monitor screen.
5. Do not submerge the monitor in liquid.
6. If a cable or other attachment accidentally gets wet with cleanser, please rinse it with distilled water or deionized water and dry it at 40 degrees C to 80 degrees C for at least one hour.

9.3 Cleaning and Disinfection of Accessories

9.3.1 SpO2 Sensor

Isopropyl alcohol 70% or 10% bleach solution can be used for sterilization. Do not use undiluted bleach (5% ~ 5.25% sodium hypochlorite) or other non-recommended disinfectants to avoid damaging the sensor.

Caution:

- Do not sterilize the sensor by radiation, steam or ethylene oxide (ETO).
- Do not directly submerge sensor in liquid.
- To avoid long-time harm to sensor, sterilization should only be conducted when necessary according to your facility's regulations.

9.3.2 NIBP Cuff

a. Please regularly clean the product;
b. Remove the cuff from the connector and pull out cuff bladder form the cover.
c. Submerge a clean and soft medical gauze pad or other soft cleaning tools into fresh water or neutral soapy water. Wring out surplus water from the submerged gauze then wipe the bladder and the tube;
d. Wash the cuff sheath in clean neutral soapy water;
e. After the intensive drying of the sheath and airbag, place the bladder into the cuff cover and put into operation.

Caution:

- Excessive or frequent cleaning may damage cuff.
- Do not dry cuff at high temperatures.
- If a high level of sterilization is required, please choose a disposable cuff.
- Be careful to keep water and cleaning solutions out of the connecting parts of the cuff and monitor.

9.3.3 Temp probe

Dampen a cloth or sponge with a 10:1 water/bleach mixture or 70% isopropyl alcohol. Use this to wipe the sensor occasionally. During cleaning, shake the probe handle to drain out any excess liquid thoroughly.

Caution: Probe covers are only for single use. Reuse may cause damage and contamination.

9.4 Maintenance and replacement of accessories

The device should be checked and maintained regularly by professional personnel to identify whether it is operating properly. Do not use the device if it is operating abnormally.

Caution:

- Always unplug the device from the power source before changing any accessories.
- Service personnel should use caution when repairing broken power cables.

Note: The device's electric schematic and element list should only be supplied to an eligible service center or qualified personnel.

10. Accessories

Warnings:

- Use only accessories specified in this manual. Using other accessories may cause damage to the monitor.
- Disposable accessories are designed for single-patient use only. Reusing them may cause a risk of contamination and affect measurement accuracy.
- Check the accessories and their packaging for any sign of damage. Do not use them if any damage is detected.

10.1 SpO_2

SpO_2 Sensors

Nellcor SpO_2			
Type	Model	Patient category	PN
Disposable	MAXA/MAXAL	Adult finger (patient size>30kg)	
	MAXN	Adult finger or neonatal foot/hand (patient size >40 kg or <3 kg)	
Reusable	DS-100A	Adult finger	13305
Riester / Biolight SpO_2			
Type	Patient category	PN	
Reusable	Adult SpO_2 Sensor (Model: Biolight 15-100-0013)	13302	
	Neonate SpO_2 Sensor (Model: Biolight 15-100-0015)	13300	

SpO_2 Extension cable

Nellcor SpO_2 Accessories	**PN**
Extension cable (Model: Nellcor Pulse Oximetry Interface Cable DOC-10)	13319

SpO_2 Extension cable

Riester / Biolight SpO_2 Accessories	**PN**
Extension cable (Model: Biolight, R-RUI Pulse Oximeter adaptor RCT006)	13320

10.2 Riester / Biolight NIBP

Reusable cuffs

Cuff Size	Part Number
Adult	M5124
Adult XL	M5125
Neonate	M5121
Child	M5123

10.3 Temp

Part Number	Description	Details
12669	Oral/Axillary Temp Probe, 9’	1 unit
12668	Rectal Temp Probe, 9’	1 unit
12688	Disposable Temp Probe Covers (25 boxes/pack, 20 covers/box)	1 pack

10.4 Miscellaneous

Part Number	Description	Details
	Patient BP Hose	1 unit
	AC Power Cord, Americas	1 unit
	AC Power Cord, Europe	1 unit
	AC Power Cord, UK	1 unit
	AC Power Cord, Australia	1 unit
13317	Mobile Stand	1 unit
13315	RVS-100 Barcode Scanner (USB) with Scanner Mount	1 unit
13316	RVS-100 WiFi Dual Band USB Dongle	1 unit
	RVS-100 Rechargeable Lithium Ion Battery (custom battery, only purchase from Rudolf Riester GmbH)	1 unit

Appendix A Product Specifications

A.1 Safety Specifications

According to the MDD 93/42/EEC, the monitor is Type Ⅱb equipment. Classified according to the IEC 60601-1 is as follows:

Parts	Classification of protection against electric shock	Degree of protection against electric shock	Degree of protection against ingress of liquid	Degree of protection against hazards of explosion	Mode of operation
Mainframe	I	No mark	IPX1	Not suitable	Continuous
Temp Module	NA	Type CF applied part defibrillation proof			
NIBP Module					
SpO_2 Module					

Note:

I: Class I, internally and externally powered equipment.
If there is doubt about protecting earth integrality or protecting the earth lead of the equipment, change the equipment to internally powered equipment.
NA: Not applicable.

CF: Type CF applied part, defibrillation proof.

Not suitable: Equipment is not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide.

A.2 Environmental Specifications

Operating temperature	+5℃ to +40℃
Operating humidity	15% to 85%（non condensing）
Operating atmospheric pressure	700hPa to 1060hPa
Transportation and storage temperature	-20℃ to +55℃
Transportation and storage humidity	10% to 93%（non condensing）
Transportation and storage atmospheric pressure	500hPa to 1060hPa

A.3 Physical Specifications

Parts	Weight（kg）	Size(W×H×D)(mm)	Remarks
Mainframe	<4kg	314mm × 132mm × 239mm	Including screen, stationary parameter module, a lithium battery, without accessories.

A.4 Power Specifications

Input voltage	100V-240V AC
Frequency	50Hz/60Hz

Earth leakage current	<0.3 mA
Input current	0.7A-1.5A
Standard requirement	According to IEC 60601-1 and IEC 60601-1-2
Fuse	T 2A/250V, integrated in the power module

A.5 Hardware Specifications

A.5.1 Display

Mainframe display	
Type	Color TFT LCD
Size（diagonal）	8 inch
Resolution	800×600 pixels

A.5.2 Printer

Model	BTR50
Type	Thermal dot array
Horizontal resolution	16 dots/mm（at 25 mm/s paper speed）
Vertical resolution	8 dots/mm
Paper width	50 mm
Paper length	15 m
Recording speed	12.5 mm/s, 25 mm/s, 50 mm/s
Recording waveform	Maximum 3 tracks
Recording way	Real-time recording, periodic recording, alarm recording

A.5.3 Battery

Type	Rechargeable lithium ion battery
Model	DVAUS-BLT-001
Size	200mm×57mm×24mm
Weight	<360 g
Quantity	1
Rated voltage	10.8 VDC
Capability	6600 mAh
Operating time	Approx. 11 hours; One new and fully charged battery at 25℃ ambient temperature, using SpO_2, ECG, Temp, and NIBP on AUTO mode for 15 minute interval.

Charge time	6h to 100%（Standby）
Turn off delay	5 min -15 min after the low battery alarm first occurs.
Indicator of battery capability	Yes

A.5.4 Mainframe LED

Physiologic alarm indication **LED**	1 (Yellow/Red)
Technical alarm indication LED	1 (Cyan)
Power indication LED	1 (Green/Orange)
Battery charging indicator LED	1 (Orange)

A.5.5 Audio indication

Speaker	Gives audible alarm (sound description: DO, DO,DO) Supports Pitch Tone (sound description: DE, DE,DE) Alarm tones meet the requirement of IEC 60601-1-8.
Alarm pressure	45 dB to 85 dB. Test distance is 1 meter from the tone.

A.5.6 Input device

Keys	
Key Numbers	1 power button
Touch screen	
Touch screen input	Yes
Others	
Mouse input	Supported
Keyboard input	Supported

A.5.7 Connectors

Power	1 x AC power inlet
Wired network	1 x standard RJ45 interfaces.10-100 BASE-TX, IEEE 802.3
USB	4 x standard USB socket (for the connections to peripherals)
Equipotential grounding point	1
Nurse call	1 x RJ11 connector for nurse call
DC output	15V/1.2A

A.5.8 Signal Output

Nurse call output	
Drive mode	Relay
Electric specification	≤60W, ≤2A, ≤36VDC, ≤25VAC
Isolated voltage	1500 VAC
Signal type	N.C., N.O.

A.5.9 Data Storage

Patient numbers	＞1000
Parameter measurement event	＞5000 items
alarm event	＞100000 items
Log event	＞10000 items

A.6 Measurement Specifications

A.6.1 Riester / Biolight NIBP

Standard	IEC 80601-2-30		
Measurement method	Oscillometry		
Measurement types	Systolic, Diastolic, MAP, Pulse Rate		
Range of measurement（mmHg)	Adult	Sys	30~270 mmHg
		Dia	10~220 mmHg
		Map	20~235 mmHg
	Pediatric	Sys	30~235 mmHg
		Dia	10~220 mmHg
		Map	20~225 mmHg
	Neonatal	Sys	30~135 mmHg
		Dia	10~110 mmHg
		Map	20~125 mmHg
Cuff pressure range	0 mmHg to 300 mmHg		
Resolution	1 mmHg		
Pressure accuracy Static: Clinical:	 ±3 mmHg Average error: ±5 mmHg, standard deviation: ≤8 mmHg		
Unit	mmHg, kPa		

Auto pressure zeroing	The device will automatically zero itself as soon as it is turned on.	
Cuff auto deflation	The cuff will deflate automatically when power is off or the time of measurement exceeds 120 seconds (90 seconds for neonate) or the cuff pressure exceeds the overpressure protection levels, set by software and hardware.	
Inflation time for cuff	＜40s (standard adult cuff)	
Measurement time	Normally, it is 20s～45s (depending on HR and interference from movement)	
Initial inflation pressure	Adult default: 160 mmHg Pediatric default: 130 mmHg Neonatal default: 75 mmHg	
Software overpressure protection	Double hardware, software overpressure protection Adult: (297±3) mmHg Pediatric: (252± 3) mmHg Neonatal: (147±3) mmHg	
Intervals for AUTO measurement time	5min-240min	
Alarm range	Sys	0 mmHg to 300 mmHg, high/low limit can be adjusted continuously.
	Dia	0 mmHg to 300 mmHg, high/low limit can be adjusted continuously.
	Map	0 mmHg to 300 mmHg, high/low limit can be adjusted continuously.
Alarm Indication	Three levels of alarms: sound-light alarms, color changes in alarm limits area; and alarms with text prompts.	
Measure mode	Adult	Single, Cycle, STAT, Average
	Pediatric	Single, Cycle, STAT, Average
	Neonatal:	Single, Cycle, Average
PR		
PR range	40 bpm to 240 bpm	
Resolution	1 bpm	
Accuracy	±3 bpm	
Recovery time after defibrillation	<5s	

A.6.2 SpO_2

Riester / Biolight SpO_2

SpO_2	
Measurement technique	Riester / Biolight SpO_2 technique
Measurement range	0% to 100%
Resolution	1%
Accuracy	70% to 100%: ±2% 40~69%：± 3% 0% to 39%: unspecified
Alarm range	0% to 100%, high/low limit can be adjusted continuously.
Average time	Normal: 8s, slow: 16s，fast: 4s
Update Period	<30s
Anti-interference ability	Anti-interference of electrocautery unit
PR modulation tone （Pitch Tone）	Yes
SpO_2 alarm range	0% to 100%, high/low limit can be adjusted continuously.
PR	
Reference method for the computation of PR accuracy	Electronic pulse simulator
Measurement range	20bpm to 250 bpm
Resolution	1 bpm
Average time	8s
Accuracy	±1% or ±1 bpm, whichever is greater
Alarm range	0 bpm～300 bpm, high/low limit can be adjusted continuously.
PR alarm range	0 bpm to 300 bpm, high/low limit can be adjusted continuously.
Recovery time after defibrillation	<5s

Nellcor SpO_2

SpO_2	
Measurement range	0% to 100%
Resolution	1%
Accuracy	70% to 100%: ±2%（adult/pediatric） 70% to 100%: ±3%（neonate） 0% to 69%, unspecified

Alarm range	0% to 100%, high/low limit can be adjusted continuously.
Average time	8s, 16s
Update Period	<30s
PR	
Reference method for the computation of PR accuracy	Electronic pulse simulator
Measurement range	20 bpm to 300 bpm
Accuracy	20 bpm to 250 bpm: ±3 bpm 251 bpm to 300 bpm: unspecified
Resolution	1 bpm
Alarm range	0bpm～300bpm, high/low limit can be adjusted continuously.
Recovery time after defibrillation	<5s

A.6.3 Fast Temp

Sensor type	Thermosensitive sensor
Measurement range	30.0°C~43.0°C
Measurement part	Oral, Axillary, Rectal
Measurement modes	Direct mode: Monitor modes Adjusted mode: Quick modes and Cold modes
Unit	℃, ℉
Resolution	0.1℃ / ℉
Accuracy	Accuracy of Laboratory (Constant temperature water tank): All Mode (All Sites): ±0.1°C (±0.2°F)
Measurement time	Adjusted mode: Oral 6-10 seconds Axillary Mode10-14 seconds Rectal Mode14-18 seconds Direct Mode (All Sites): 60-120 seconds
Transient response time	＜25s(Only Monitor mode)
Preheat time	About 800 ms
Self-checking	Every 3s
Alarm range	30.0~43.0℃, up-low range can be adjustable
Alarm indication	Three levels of alarms: sound-light alarms, color change in alarm limits area; and alarms with text prompts.

Appendix B: Factory Defaults

This chapter is about factory defaults setup. The user can't change the factory defaults. Qualified personnel must input a password through【SETTINGS】→【ADVANCED】 to change the factory defaults.

B.1 Date /Time

Date /Time general setting	Factory Defaults
Date type	Year/month/day
Time zone	GMT +8

B.2 Alarm

Alarm setup	Factory defaults
ALM Volume	Low
Allow closing of general alarm	No selection
Alarm pause time	2 min
Allow control alarm audio	No selection
Alarm control	Alarm audio on
Active reminder signal	Yes
Remind signal interval	30 sec

B.3 Display

Display general setup	Factory defaults
Battery working time	10min

B.4 Others

Others general setup	Factory defaults
Power supply frequency	50Hz

B.5 SpO_2

SpO2 setup	Factory defaults
SPO2 display	SPO_2 value
Wave Speed	25mm/s

B.6 NIBP

NIBP setup	Factory defaults
NIBP display	Display as SYS/DIA
Default patient type	Adult
Unit	mmHg
Inflation pressure	Adult170 mmHg Pediatric 130 mmHg Neonatal 90 mmHg

B.7 Temp

Temp setup	Factory defaults
Unit	℃

Appendix C: Guidance and Manufacturer's Declaration of EMC

Guidance and manufacturer's declaration – electromagnetic emissions

-for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The monitor 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 emission CISPR 11	Class A	The monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity			
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the monitor 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 wooden, concrete or ceramic tile. If the floor is covered with synthetic material, the relative humidity should be at least 30%. Users must eliminate static in their hands before use.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	± 2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
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)	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the monitor requires continued operation during power mains interruptions, it is recommended that the monitor be powered from an uninterruptible power supply or a battery.

	for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	
Power frequency (50Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the A.C. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

–for all EQUIPMENT and SYSTEMS

Guidance and manufacturer's declaration – electromagnetic immunity

–for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity			
The monitor is intended for use in the electromagnetic environment specified below. The customer or the user of monitor should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the monitor including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1{,}2\sqrt{P}$ $d = 1{,}2\sqrt{P}$ 80 MHz to 800 MHz $d = 2{,}3\sqrt{P}$ 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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. 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 monitor is used exceeds the applicable RF compliance level above, the monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the monitor			
b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

Recommended separation distances between **portable and mobile RF communications equipment and the Q3 monitor**			
The monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the monitor as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter **(W)**	**Separation distance according to frequency of transmitter** **(m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 separation distance for 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.			

Warning:

- This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided. This unit can be affected by portable and mobile RF communications equipment.
- Do not use a mobile phone or other devices that emit electromagnetic fields near the unit. This may result in incorrect operation of the unit.

Caution:

- This unit has been thoroughly tested and inspected to assure proper performance and operation.
- This machine should not be used adjacent to or stacked with other equipment. If such positioning is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Appendix D: Troubleshooting

Normal trouble

Possible Trouble	Possible Reason	Trouble Shooting
Startup failure	1. The device is not turned on 2. External power supply failure 3. No battery or the power cable is not connected 4. The battery charge is not strong enough to power the device	1. Open the device 2. Make sure the external power supply system works normally. 3. Connect the power cable or insert the battery 4. Connect the device to AC power supply, recharge the battery
Blank screen	1. The device is not turned on 2. The device is in standby mode	1.Turn on the device 2. Press the touchscreen of the device to illuminate the screen
Printer doesn't work	1. The paper is not loaded 2. The printer cover is not fully closed. 3. The printer is too hot.	1. Load paper according to the user manual 2. Ensure the printer cover is fully closed. 3. Start the operation again after the printer has a chance to cool.
Printer paper does not fit	1. Specified paper is not used 2. The paper is installed improperly. 3. Software failure	1. Use the correct paper (width 48 mm length 15m) 2. Install the paper according to the user manual or product diagram. 3. Turn off the device then start it again
Printer paper jam	1. Specified paper is not used 2. The paper is installed improperly	1. Use the correct paper (width 48 mm length 15m) 2. Install the paper according to the user's manual or product diagram.
The scanner doesn't work	1. The scanner is not connected to the device or they have poor contact. 2. Scanner breakdown	1. Connect the scanner to the main USB port. Ensure the connection is secure. 2. Change the scanner to one that functions properly.
The device has automatically shutdown	The battery charge is not strong enough to power the device.	Connect the device to AC power supply to recharge the battery.

Prompt Information

Prompt Information	Possible Reason
Printer Out of Paper	Printer paper is not installed or paper is used up
Battery Low	Medium level alarm means the battery life is less than 30min; high level alarm means the battery life is less than 5min.
DEMO	The system is in demonstration mode.
Insufficient storage space	The storage space is less than 10MB.
Critical shortage of storage space	The storage space is less than 5MB.
There are too many log entries.	Over 5000 items have been logged.
Critical shortage of space for log entries.	Over 7000 items have been logged.
SpO_2 Sensor off	The SPO_2 sensor is not on a finger or it is not placed correctly.
SpO_2 No sensor	There is no SPO_2 sensor on the device.

SpO_2 Searching for pulse...	The SPO_2 module is searching for pulse.
SpO_2 Replace Cable	The cable of the Masimo SPO_2 module must be changed.
SpO_2 Incompatible Cable	The cable of the Masimo SPO_2 module is incompatible.
SpO_2 Unrecognized Cable	The cable of the Masimo SPO_2 module can't be recognized.
SpO_2 No Sensor	The sensor of the Masimo SPO2 module can't be detected.
SpO_2 Invalid Sensor	The sensor of the Masimo SPO2 module is invalid.
SpO_2 Replace Sensor	The sensor of the Masimo SPO2 module needs to be changed.
SpO_2 Calibrate Sensor	The Masimo SPO2 module is calibrating.
SpO_2 Motion Interference	The patient's finger is moving too much during SPO2 measurement.
SpO_2 Low perfusion	The signal of the patient's finger is too low during SPO2 measurement.
NIBP Cuff Type Error	The cuff type is wrong.
NIBP Air Leak Or Loose Cuff	An internal valve, air hose, or the cuff is leaking air. The cuff is not wrapped properly around the patient's limb. An adult cuff is used in neonate mode.
NIBP Air Pressure Error	The system can't maintain a stable air pressure.
NIBP Weak Signal	The cuff is wrapped too loosely, leading to a low patient signal. The pulse of the patient is very weak.
NIBP Range Exceeded	The NIBP value exceeds the measurement range (275mmHg)
NIBP Excessive Motion	The patient is moving too much. The signal noise is too loud during deflation to detect the patient's pulse pressure. The patient's pulse is random.
NIBP Overpressure Detected	There is too much cuff pressure. Pressure exceeds the set safe range (adult mode is 325mmHg，neonate mode is 165mmHg)
NIBP Signal Saturated	Too much patient movement has impacted the NIBP signal amplifier.
NIBP Time Out	The time exceeds 120s in adult mode; The time exceeds 90s in neonate mode;
TEMP No Probe	The fast temp probe is not connected.
TEMP too high/ too low	The temp value exceeds the measurement range

Appendix E Applicable Standards

MDD 93/42/EEC	Council Directive 93/42/EEC
IEC 60601-1:2005 + A1:2012	Medical electrical equipment -- Part 1: General requirements for safety
IEC 60601-1-2:2007	Medical electrical equipment –Part 1-2:General requirements for basic safety and essential performance –Collateral standard: Electromagnetic compatibility – Requirements and tests
IEC 60601-1-6:2010	Medical electrical equipment –Part 1-6: General requirements for basic safety and essential performance –Collateral standard: Usability
IEC60601-1-8:2006+A1:2012	Medical electrical equipment –Part 1-8:General requirements for basic safety and essential performance –Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
IEC 62366:2007	Medical devices – Application of usability engineering to medical devices
IEC 62304:2006	Medical device software –Software life cycle processes
EN ISO 14971: 2012	Medical devices - Application of risk management to medical devices
ISO 10993-1:2009	Biological evaluation of medical devices— Part 1：Evaluation and testing
IEC 60601-2-49: 2011	Part 2-49: Particular requirements for the safety of multifunction patient monitoring equipment
IEC 80601-2-30:2013	Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
ISO 80601-2-56:2009	Medical electrical equipment —Part 2-56:Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement
ISO 80601-2-61:2011	Medical electrical equipment —Part 2-61:Particular requirements for basic safety and essential performance of pulse oximeter equipment
ISO 15223.1:2012	Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied
EN 1041:2008	Information Supplied by the Manufacturer with Medical Device.
IEC 60825-1:2007	Safety of laser products –Part 1:Equipment classification and requirements

Appendix F RVS-100
with Masimo SpO2

5.2.5 Setting SpO2
Select **[SETTING] → [ADVANCED] → [PARAMETERS] → [SpO2] → [Default response]** to choose the response to be **[Normal: 16 seconds]** or **[Fast: 4 seconds]**. (Not applicable to Masimo)

5.2.7 General statements, warnings, cautions, and notes for Masimo SpO2
General:
The pulse co-oximeter 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.
Warnings:
As with all medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
Do not place the pulse co-oximeter or accessories in any position that might cause it to fall on the patient.
Do not start or operate the pulse co-oximeter unless the setup was verified to be correct.
Do not use the pulse co-oximeter during magnetic resonance imaging (MRI) or in an MRI environment.
Do not use the pulse co-oximeter if it appears or is suspected to be damaged.
Explosion hazard: Do not use the pulse co-oximeter in the presence of flammable anesthetics or other flammable substance in combination with air, oxygen-enriched environments, or nitrous oxide.
To ensure safety, avoid stacking multiple devices or placing anything on the device during operation.
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 device while monitoring a patient.

To protect from electric shock, always remove the sensor and completely disconnect the pulse co-oximeter before bathing the patient.
If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the pulse co-oximeter for proper functioning.
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

Inaccurate SpCO and SpMet readings can be caused by:
Improper sensor application, Intravascular dyes such as indocyanine green or me¬thylene blue, Abnormal hemoglobin levels, Low arterial perfusion, Low arterial oxygen saturation levels including altitude induced hypoxemia, Elevated total bilirubin levels, Motion artifact

Inaccurate SpHb and SpOC readings may be caused by:
Improper sensor application, Intravascular dyes such as indocyanine green or me¬thylene blue, Externally applied coloring and texture such as nail polish, acrylic nails, glitter, etc., Elevated PaO2 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 disease such as Raynaud's, Elevated altitude, Peripheral vascular disease, Liver disease, EMI radiation interference

Inaccurate SpO2 readings may be caused by: Improper sensor application and placement
Elevated levels of COHb or MetHb: High levels of COHb or MetHb may occur with a seemingly normal SpO2.
When elevated levels of COHb or MetHb are suspected, laboratory analysis (CO-Oximetry) of a blood sample should be performed.
Elevated levels of bilirubin
Elevated levels of dyshemoglobin
Vasospastic disease, such as Raynaud's, and periphe¬ral vascular disease
Hemoglobinopathies and synthesis disorders such as thalassemias, Hb s, Hb c, sickle cell, etc., Hypocapnic or hypercapnic conditions, Severe anemia, Very low arterial perfusion, Extreme motion artifact, Abnormal venous pulsation or venous constriction, Severe vasoconstriction or hypothermia, Arterial catheters and intra-aortic balloon, Intravascular dyes, such as indocyanine green or methylene blue, Externally applied coloring and texture, such as nail polish, acrylic nails, glitter, etc., Birthmark(s), tattoos, skin discolorations, moisture on skin, deformed or abnormal fingers. etc., Skin color disorders

Interfering Substances: Dyes or any substance containing dyes that change usual blood pigmentation may cause erroneous readings.
The pulse co-oximeter should not be used as the sole basis for diagnosis or therapy decisions. It must be used in conjunction with clinical signs and symptoms.
The pulse co-oximeter is not an apnea monitor.
The pulse co-oximeter may be used during defibrillation, but this may affect the accuracy or availability of the parameters and measurements.
The pulse co-oximeter may be used during electrocautery, but this may affect the accuracy or availability of the parameters and measurements.
The pulse co-oximeter should not be used for arrhythmia analysis.
SpCO readings may not be provided if there are low arterial saturation levels or elevated methemoglobin levels.*
SpO2, SpCO*, SpMet*, and SpHb* are empirically calibrated in healthy adult volunteers with normal levels of
carboxyhemoglobin (COHb) and methemoglobin (MetHb).
Do not adjust, repair, open, disassemble, or modify the pulse co-oximeter or accessories. Injury to personnel or equipment damage could occur. Return the pulse co-oxi¬meter for servicing if necessary.

Cautions:
Do not place the pulse co-oximeter where the controls can be changed by the patient.
Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.
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.
Do not place the pulse co-oximeter on electrical equip¬ment that may affect the device, preventing it from working properly.
If SpO2 values indicate hypoxemia, a laboratory blood sample should be taken to confirm the patient's condition.
If the Low Perfusion 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.
Change the application site or replace the sensor and/or patient cable when a "Replace sensor" and/or "Replace patient cable", or a persistent poor signal quality message (such as "Low SIQ") is displayed on the host monitor. These messages may indicate that patient monitoring time is exhausted on the patient cable or sensor.

- 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.
- 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.
- To ensure that alarm limits are appropriate for the patient being monitored, check the limits each time the pulse cooximeter is used.
- 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.
- Do not submerge the pulse co-oximeter in any cleaning solution or attempt to sterilize by autoclave, irradiation, steam, gas, ethylene oxide or any other method. This will seriously damage the pulse co-oximeter.
- 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 and UL60601-1. 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.
- Disposal of product - Comply with local laws in the disposal of the device and/or its accessories.
- To minimize radio interference, other electrical equipment that emits radio frequency transmissions should not be in close proximity to the pulse co-oximeter.
- Replace the cable or sensor when a replace sensor or when a low SIQ message is consistently displayed while monitoring consecutive patients after completing troubleshooting steps listed in this manual.

Notes:
A functional tester cannot be used to assess the accuracy of the pulse co-oximeter.
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.
The Desat Index alarm is intended as an adjunct alarm rather than in place of the Low SpO2 alarm.*
When monitoring acoustic respiration, Masimo recommends minimally monitoring both oxygenation (SpO2) and respiration (RRa).*
When using the Maximum Sensitivity setting, performance of the „Sensor Off" detection may be compromised. If the device is in this setting and the sensor becomes dislodged from the patient, the potential for false readings may occur due to environmental „noise" such as light, vibration, and excessive air movement.
Do not loop the patient cabling into a tight coil or wrap around the device, as this can damage the patient cabling.
Additional information specific to the Masimo sensors compatible with the pulse oximeter, including information about parameter/measurement performance during motion and low perfusion, may be found in the sensor's directions for use (DFU).
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 the patient monitoring time.

5.2.9 Masimo Information

No Implied License: Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

10.1 SpO2

Masimo SpO2 Sensor

Type	Model / PN	Patient category	PN
Disposable	4000 RD SET Adult SpO2 Adhesive Sensor Single Patient Use	Adult use weight >30kg	13339
	4001 RD SET Pediatric SpO2 Adhesive Sensor Single Patient Use	Pediatric use weight 10kg – 50kg	13340
	4002 RD SET Infant SpO2 Adhesive Sensor Single Patient Use	Infant use weight 3kg – 20kg	13341
	4003 RD SET Neo Adult / Neonatal SpO2 Adhesive Sensor Single Patient Use	Neo Use weight <3kg or >40kg	13342
Reusable	4050 RD SET DCI Adult Reusable Sensor 3ft non-sterile	Adult weight >30kg	13343
	4051 RD SET DCI-P Pediatric/Slender Digit Reusable Sensor, 3ft non-sterile	Pediatric/Slender Weight 10-50kg	13344
	4054 RD SEET YI Multi-Site Reusable Sensor, 3ft non-sterile multiple foam and adhesive wraps	Weight >1kg	13345
Patient cable	4104 RD SET MD20-12RD SET 20-pin SpO2 patient cable, 12 ft.	SpO2 patient cable	13346

Masimo SpO2

Measurement range	0% to 100%
Resolution	1%
Accuracy	70% to 100%: ±2% (adult/pediatric, non-motion conditions) 70% to 100%:±3%（neonate, non-motion conditions） 70% to 100%:±3%（motion conditions） 1 The Masimo 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% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 2 The Masimo SET technology with Masimo sensors has been validated for motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation, which encompasses 68% of the population. 3 The Masimo SET technology has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2™ simulator and Masimo's simulator with signal strengths of greater than 0.02% and transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 4 The Masimo SET Technology with Masimo Neo sensors has been validated for neonatal motion accuracy in human blood studies on healthy adult male and female volunteers with light to dark skin pigmentation in induced hypoxia studies while performing rubbing and tapping motions, at 2 to 4 Hz at an amplitude of 1 to 2 cm and a non-repetitive motion between 1 to 5 Hz at an amplitude of 2 to 3 cm in induced hypoxia studies in the range of 70-100% SpO2 against a laboratory CO-Oximeter and ECG monitor. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 1% has been added to the results to account for the effects of fetal hemoglobin present in neonates. 5 The Masimo 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 2™ simulator. This variation equals ±1 standard deviation. Plus or minus one standard deviation encompasses 68% of the population. 6 See sensor directions for use (DFU) for complete application information. Unless otherwise indicated, reposition reusable sensors at least every 4 hours and adhesive sensors at least every 8 hours. 7 Sensor accuracy specified when used with Masimo technology using a Masimo patient cable for LNOP sensors, RD SET sensors, the LNCS sensors, or the M-LNCS sensors. Numbers represent Arms (RMS error compared to the reference). Because pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within a range of ± Arms compared to the reference value. Unless otherwise noted, SpO2 accuracy is specified from 70% to 100%. Pulse Rate accuracy is specified from 25 to 240 bpm. 8 Masimo M-LNCS, LNOP, RD SET, and LNCS sensors types have the same optical and electrical properties and may differ only in application type (adhesive/non-adhesive/hook & loop), cable lengths, optical component locations (top or bottom of sensor as aligned with cable), adhesive material type/size, and connector type (LNOP 8 pin modular plug, RD 15 pin modular plug, LNCS 9 pin, cable based, and M-LNCS 15 pin, cable based). All sensor accuracy information and sensor application instructions are provided with the associated sensor directions for use.
Average time	2-4s, 4-6s, 8s, 10s, 12s, 14s, 16s
Update Period	<30s
Recovery time after defibrillation	<5s
PR	
Reference method for the computation of PR accuracy	Electronic pulse simulator
Measurement range	25 bpm to 240 bpm
Resolution	1bpm
PI	
Measurement range	0.02% - 20%
Low perfusion performance	>0.02% Pulse Amplitude and % Transmission > 5% Saturation (SpO2%) +/- 2 digits Pulse rate +/- 3 digits

Appendix G RVS-10
with EWS and Optional Bluetooth Thermometer Functionality

1. EWS User Manual
This document provides a step-by-step description how the Early Warning Score Feature can be used.

1.1. Using Menus
The Measure/home screen includes an EWS tab which must display the four primary vital sign EWS's within separate scoring tiles.

When the EWS tab is selected the NIBP, Pulse Rate, Temp and SpO2 tabs will be minimized and display the previous results displayed on the measure/home page.

The individual scoring tile for the secondary parameters respond to touch. In response to touch of the secondary parameter scoring tile the relevant data input tab appear to the right of the name and within the increased EWS tab.

In response to touch of the "View History" tab, the individual parameters of the EWS score is no longer visible. A graph of Total score against recording will be displayed, which show the previous ten scores to visualize the trend.

The EWS settings tab shall display the available EWS options. The EWS options will include the NEWS and MEWS along with five customizable options. It is only possible to select one EWS option.

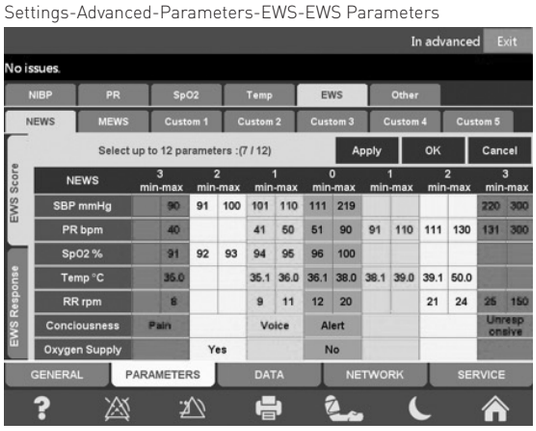
1.2. EWS Management
Following steps to use the Early Warning Score Feature:

1. Enter the information for a clinician (see 3.7 Clinician Management in the RVS-100 Vital Signs Monitor User Manual).
[SETTING] → [CLINICIAN] to set the clinician **[ID], [First name], [Last name], [Department]**
or
[SETTINGS] → [ADVANCED] → [DATA] → [Clinician Set]
2. Adding or Selecting a Patient (see 4. Patient Management in the RVS-100 Vital Signs Monitor User Manual).
[PATIENT] → [Add]
3. Selecting the EWS type. There are two predefined EWS options ("NEWS", "MEWS") and five customizable options.
[SETTINGS] → [EWS]

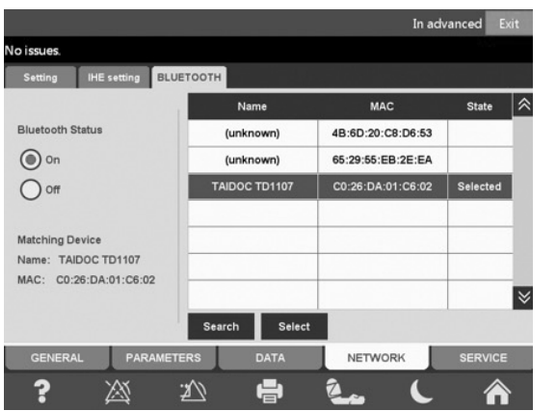
Settings - EWS

4. EWS advanced settings
In advanced mode the parameters of the EWS system is accessible via Parameters and then through an additional tab "EWS".
[SETTINGS] → [ADVANCED] → [PARAMETERS] → [EWS] → [EWS PARAMETERS]

Settings-Advanced-Parameters-EWS-EWS Parameters



2. Bluetooth Temperature module User Manual
1. Activate Bluetooth® and add Bluetooth® Thermometer to RVS-100/200
Make sure that the optional Bluetooth® dongle is plugged into one of the USB ports.
Caution: Use only the original Bluetooth® dongle supplied by Riester.
The thermometer can be paired in the settings menu.
[SETTINGS] → [ADVANCED] → [NETWORK] → [BLUETOOTH]
Turn Bluetooth status "On". A list of potential devices will be shown, select the one you intend to pair (Riester tympanic or non-contact thermometer).



2. The Riester Bluetooth® thermometer is activated and indicated on the TEMP screen of RVS-100/200. After taking a measurement the result is automatically transferred to the vital signs monitor.
The correct use of the Riester Bluetooth® thermometers is described in the manual of the respective thermometer.

Product Information
- Product Model: RVS-100 Vital Signs Monitor
- Product Name: RVS-100 Vital Signs Monitor
- Manufacturer: Rudolf Riester
- After Service Contact Information:

Revision History
This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior notice.

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