BP+Vitals

SunTech® CT50™

BP + VITALS

Vital Signs Monitor

User Manual

Changes

This manual is identified as part number: 80-0078-00. The most recent is available for download from the SunTech Medical website. Should you notice errors or omissions in this manual, please notify us at:

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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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CE 0413

MD

Welcome to the SunTech CT50

Thank you for choosing the SunTech CT50 for accurate monitoring of vital signs. The SunTech CT50 is designed to be simple and efficient to use and features:

- automatic patient monitoring modes
- averaging of multiple BP readings
- user-programmable monitoring intervals
- audible and visual patient alarms
- connection to EMR system

SunTech CT50 Description and Operation

The SunTech CT50 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 CT50 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 alerts 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 SunTech CT50 (Model 270) may be referred to as "the SunTech CT50," "the CT50," "the device" or "the monitor."

Manufacturer's Responsibility

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

All of the installation, expansion, readjustment, renovation or repairs are conducted only by personnel certified by 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.

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:

【】are used to enclose screen texts.

→ is used to indicate operational procedures.

Symbols 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.*

Contents

1. General Introduction

1.1 Intended Use

The CT50 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 (SpO_2), pulse rate (PR), non-invasive blood pressure (NIBP), and temperature (Temp).

The CT50 vital signs monitor is intended to be used in outpatient departments, emergency treatment rooms, 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.

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 SpO_2 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 SPO_2 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);**
    - **the presence of an MRI device;**
    - **excessive patient movement;**
    - **intravascular dyes such as indocyanine green or methylene blue;**
    - **significant levels of dysfunctional hemoglobin (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; and**
    - **low perfusion.**
- **Do not use the SpO_2 sensor on the same limb being used for NIBP measurement. This may result in inaccurate SpO_2 reading due to blocked blood flow during cuff inflation.**
- **Do not measure SpO_2 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 measurements 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; and**
    - **an edematous extremity.**
- **Use of the monitor during MRI may lead to vessel damage.**

1.3 Configurations

The monitor consists of main unit, NIBP cuff, temperature sensor, and SpO_2 sensor.

1.4 Main Unit

1.4.1 Front View

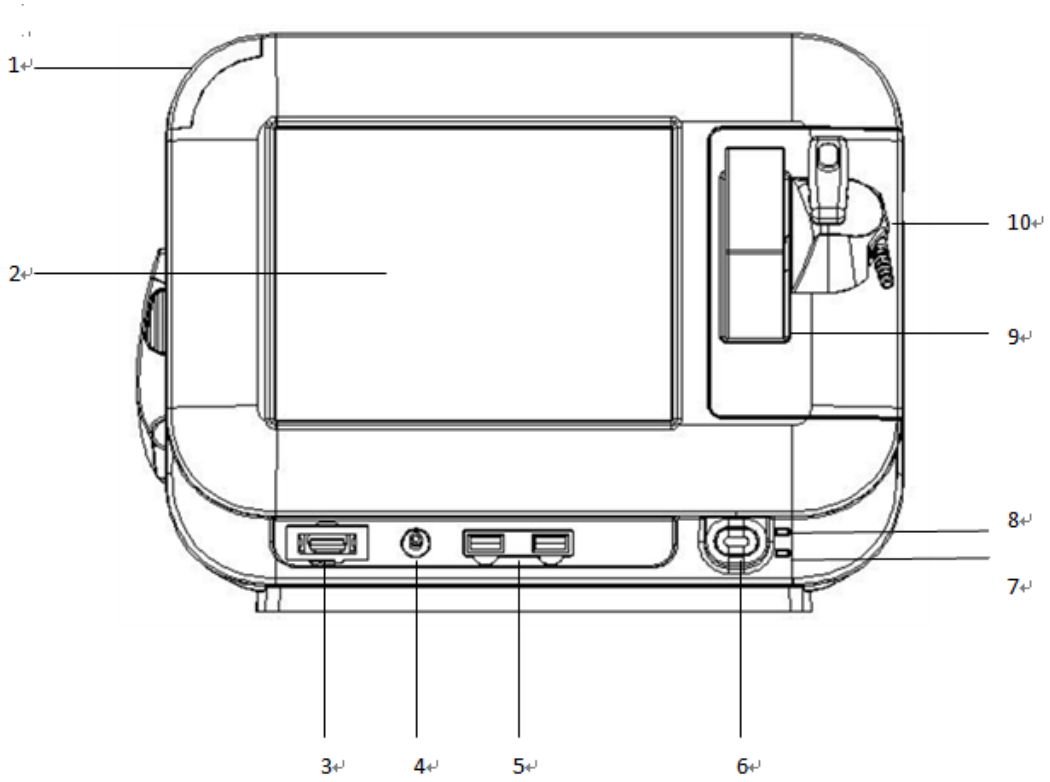


Fig.1-1

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 Touch screen

3) SpO_2 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 20-count Probe Cover box

10) Covidien Filac 3000 temperature probe

1.4.2 Side View

Right side:

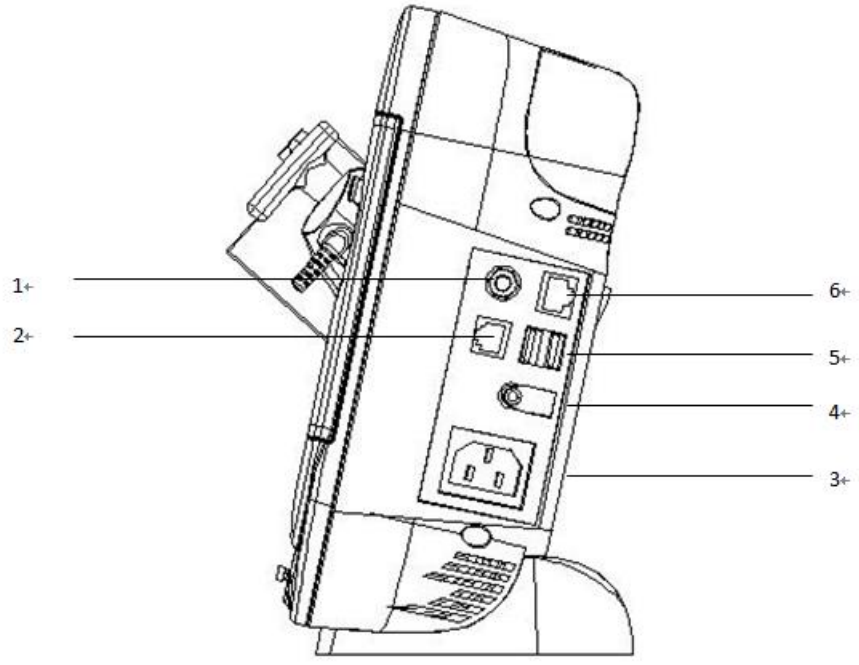


Fig.1-2

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 connects 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 SunTech. 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:

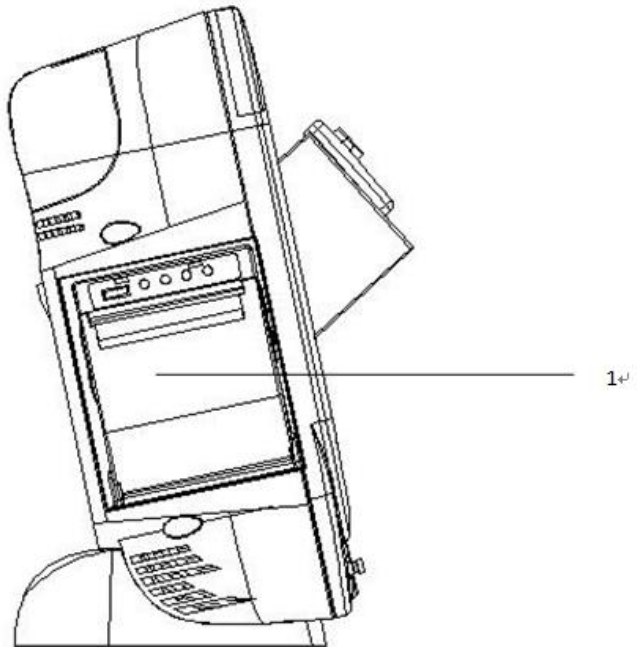


Fig.1-3

1) Print Recorder

1.4.3 Rear View

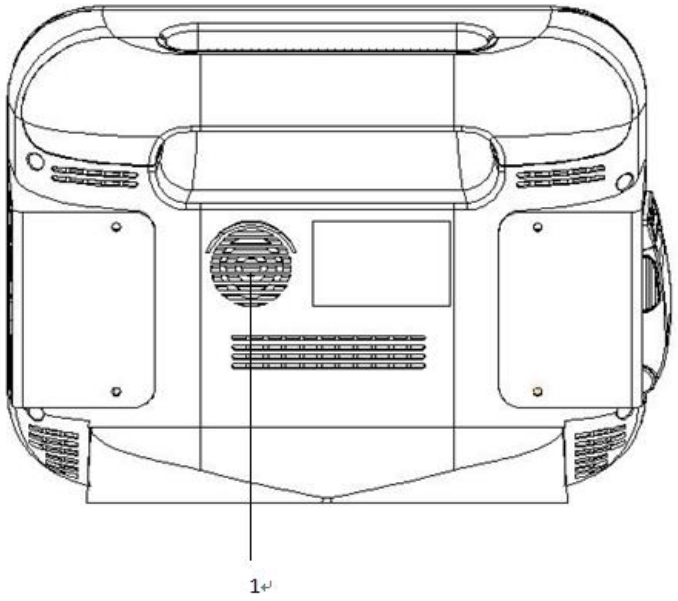


Fig.1-4

1) Speaker

1.4.4 Bottom View

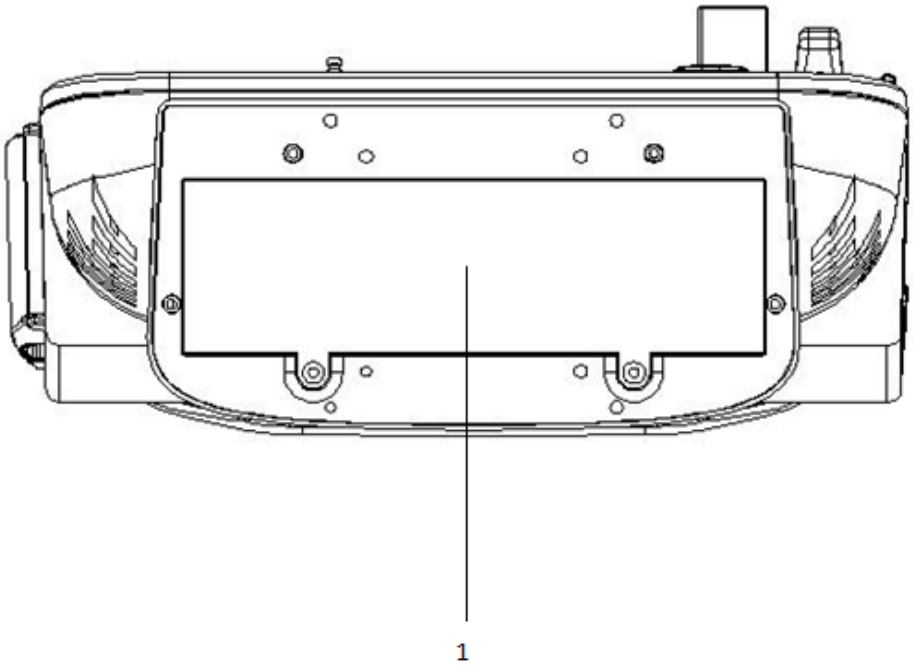


Fig.1-5

1. Battery compartment

⚠ ***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 Title	Symbol Description	Standard/ Source
	General Warning	Indicates a potential hazard or unsafe practice that, if not avoided, will result in death or serious injury	ISO 7010-W001
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 7000-0434A
	Defibrillation-proof type BF applied part	Identifies a defibrillation-proof type BF applied part complying with IEC 60601-1.	IEC 60417-5334
	Defibrillation-proof type CF applied part	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.	IEC 60417-5336
	Refer to instruction manual/booklet.	Signifies that the instruction manual/booklet must be read.	ISO 7010-M002
	Non-ionizing electromagnetic radiation	Indicates generally elevated, potentially hazardous, levels of nonionizing radiation, or to indicate equipment or systems e.g. in the medical electrical area that include RF transmitters or that intentionally apply RF electromagnetic energy for diagnosis or treatment.	IEC 60417-5140
	Dangerous voltage	Indicates hazards arising from dangerous voltages.	IEC 60417-5036
	Equipotential	Identifies the terminals which, when connected, bring the various parts of an equipment or of a system to the same potential, not necessarily being the earth (ground) potential, e.g. for local bonding.	IEC 60417-5021
	USB socket	Identifies a USB connection or socket.	Industry
	Network connector	Connection to a computer, mainframe system, or IT network	Industry
	Nurse call connector	Connection to a nurse monitoring system.	Industry

Symbol	Symbol Title	Symbol Description	Standard/ Source
	Date of Manufacture	Indicates the date when the medical device was manufactured.	ISO 7000-2497
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/ EEC, 93/42/EEC and 98/79/EC.	ISO 7000-3082
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 7000-2493
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 7000-2492
	Serial number	Serial number	ISO 7000-2498
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 7000-0632
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 7000-2620
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	ISO 7000-2621
	CE mark:	Product meets the Medical Device Directive and is CE marked to indicate conformance.	EU Directive
	Medical Device		
	Disposal	Symbol for the marking of electrical and electronics devices according to Directive 2002/96/EC.	WEEE Directive
	Authorized representative in the European Community	Indicates the authorized representative in the European Community.	EU Directive
	Alarm Pause	Indicates the alarm is paused.	IEC 60417-5319
	Alarm Reset	Identifies the control for alarm reset.	IEC 60417-5309

Symbol	Symbol Title	Symbol Description	Standard/ Source
	Active Alarm	Indicates an alarm condition.	IEC 60417-5307
	Bell cancel	Indicates the alarm audio is off.	IEC 60417-5576
	Acknowledgement	Identifies the control for acknowledge function.	ISO 7000-1326
	Print	Identifies the control for print.	SunTech Design
	Start/Stop NIBP measurement	Indicates the control for start/stop NIBP measurement.	SunTech Design
	Standby mode	Indicates the control for standby mode.	SunTech Design
	Home Screen	Indicates the control to the home screen.	SunTech Design
	Patient	Indicates patient category.	IEC 60417-5390
	Oral Measurement site	Indicates oral temperature measurement location.	SunTech Design
	Axillary Measurement site	Indicates axillary temperature measurement location.	SunTech Design
	Speed (Quick)	Indicates a setting for quick temperature measurement mode.	SunTech Design
	Cold	Indicates a setting for cold measurement mode.	SunTech Design
	Temperature Measurement Mode	Indicates a setting for monitor temperature measurement mode.	SunTech Design
	Rectal Measurement site	Indicates rectal temperature measurement location.	SunTech Design
	Temperature Probe Cover Indicator	Indicates (when flashing) that the temperature probe needs to have a probe cover installed or removed.	SunTech Design
	Temperature Timer	Indicates that a temperature measurement is completed (upon flashing).	IEC 60417-5417
	Battery charge status	Indicates battery charge status (fully charged).	SunTech Design
	Battery charge status	Indicates battery charge status (depleted battery, needs charged).	SunTech Design
	Battery charge status	Indicates battery charge status (battery is recharging).	SunTech Design

Symbol	Symbol Title	Symbol Description	Standard/ Source
	Battery status	Indicates battery condition (battery needs attention or replaced).	SunTech Design

1.6 Packaging symbols

Symbol	Symbol Title	Symbol Description	Standard/ Source
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.	ISO 7000-0621
	This Way Up	Indicates correct upright position of the transport package.	ISO 7000-0623
	Keep dry	Indicates a medical device that needs to be protected from moisture.	ISO 7000-0626
	Stacking limit by number	Stacking layer limit, where 'n' represents the maximum permissible number of layers. (N = 6).	ISO 7000-2403

1.7 Commonly Used Abbreviations

BP	Blood Pressure
BPM	Beats Per Minute
EMR	Electronic Medical Record system
K-sounds	Korotkoff sounds
MAP	Mean Arterial Pressure (not available in the U.S.)
DIA	Diastolic BP
NIBP	Non-Invasive Blood Pressure
OPD	One-Piece Durable
SpO_2	Percent Oxygen Saturation of Arterial Blood (hemoglobin)
SYS	Systolic BP
Temp	Temperature
IPX1	Degree of protection against ingress of liquid

2.Safety

2.1 Safety Information

Warning:

- Before putting the system into operation, verify that the monitor, connecting cables and accessories are in correct working order and operating condition.
- Do not use device if any electrical connections become damaged, bent, or mis-aligned.
- 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 does not contact the patient cable or any other cables. The patient should be isolated from touching any metal surfaces.
- Do not allow the device to 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 connections (including USB and network) 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 within 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 reason, 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 within 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 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: *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.*

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 allow the device to 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 for 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 packaging material out of children's reach.

- **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 any 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 in no way 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 60 seconds, 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.
  - 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 SunTech or a SunTech 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 of "Beep" and the SunTech logo will also appear on the display.
2. After the SunTech logo disappears, the monitor will enter the main interface. After a successful power up, the device will produce a single chime.

***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 power plug is used to remove power from the monitor. The monitor should be placed in a location where the plug is easily accessed if the need to remove power should arise.*

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, Spot Check Profile, and Triage Profile. Below is a chart outlining the different options available based on the profile chosen:

	Monitoring Profile	Triage Profile	Spot-check Profile
*Clinician Login**	✓	✗	✗
*Patient Selection**	✓	✗	✗
Set Alarms	✓	✗	✗
Adjust Patient Type	✗	✓	✓

Note: *In monitoring mode, you must login a clinician prior to selecting the patient.*

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:

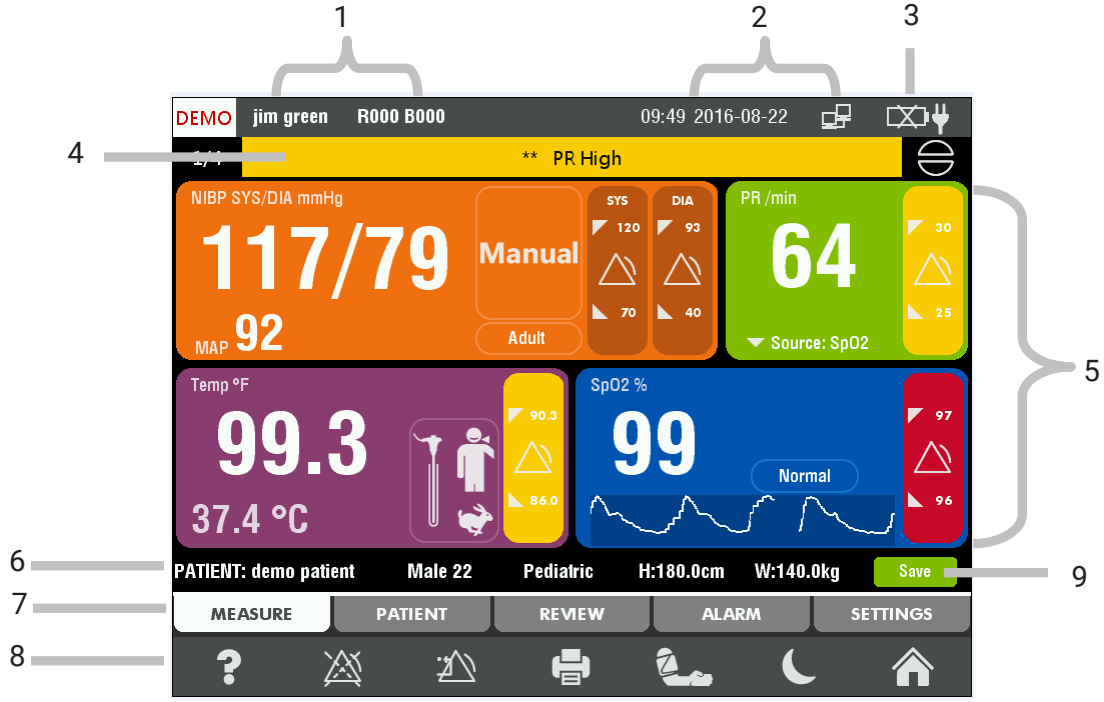
Spot Check Profile: This profile is designed for taking a single set of vital signs measurements on a patient. Patient information can be entered and managed, and while technical alarms are still available, physiological alarms are disabled. Here is an example of the home screen in Spot Check profile:

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**】

   Note: *In monitoring mode, you must login a clinician prior to selecting the patient.*

2. **System Time, Date, and Network status**: Displays the current system time, date, and network status. 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**】. For more information on 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 8*** 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**】

   Note: *See* ***Chapter 6*** *for more details*

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】/【SpO_2】/ 【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. To access the help feature, press the help key located at the bottom left of the screen. Once the help key is activated, press the area or object on the screen to reveal the help menu. To exit the help menu, press the help key again to turn off this feature.


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 【OK】 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.

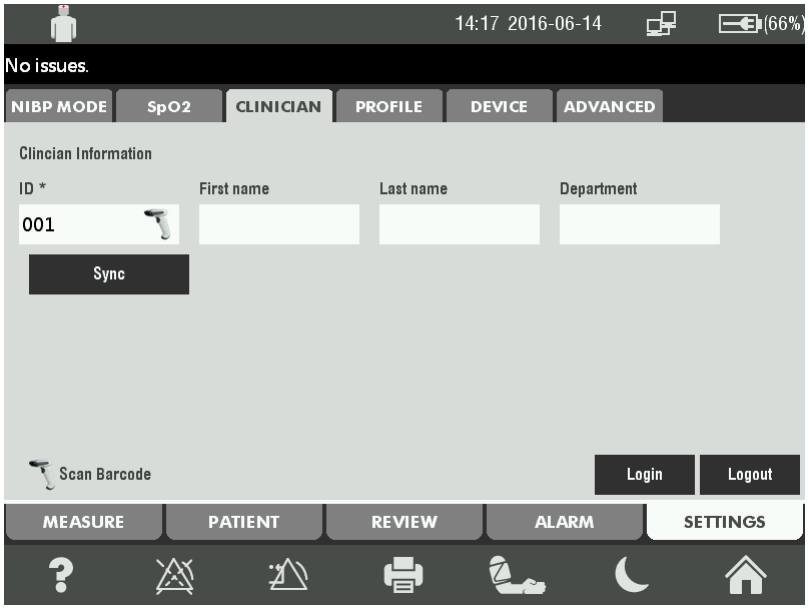
9. 

Save Icon: Press to save the current measurement data for the current patient.

3.7 Clinician Management

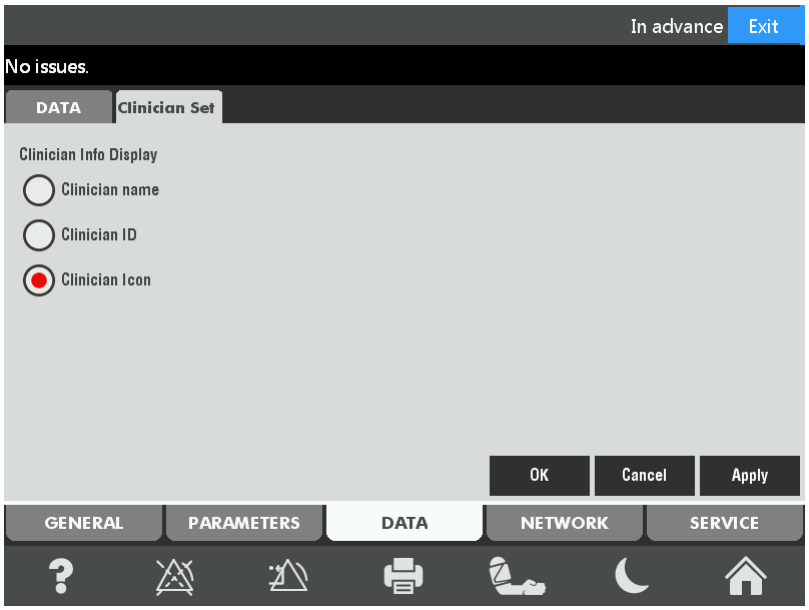
To enter information for a clinician:

1. Select【**SETTINGS**】→【**Clinician**】to set the clinician【**ID**】,【**First name**】,【**Last name**】,【**Department**】



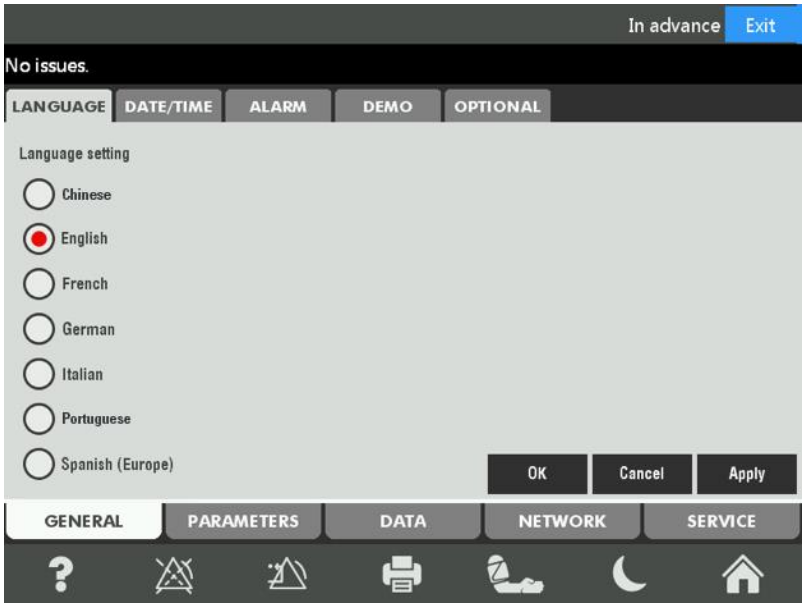
2. Select【**SETTINGS**】→【**ADVANCED**】→【**DATA**】→【**Clinician Set**】to choose the clinician information as follows that can be displayed:【**Clinician ID**】,【**Clinician name**】,【**Clinician Icon**】

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



3.8 General Setup

3.8.1 Setting the Language

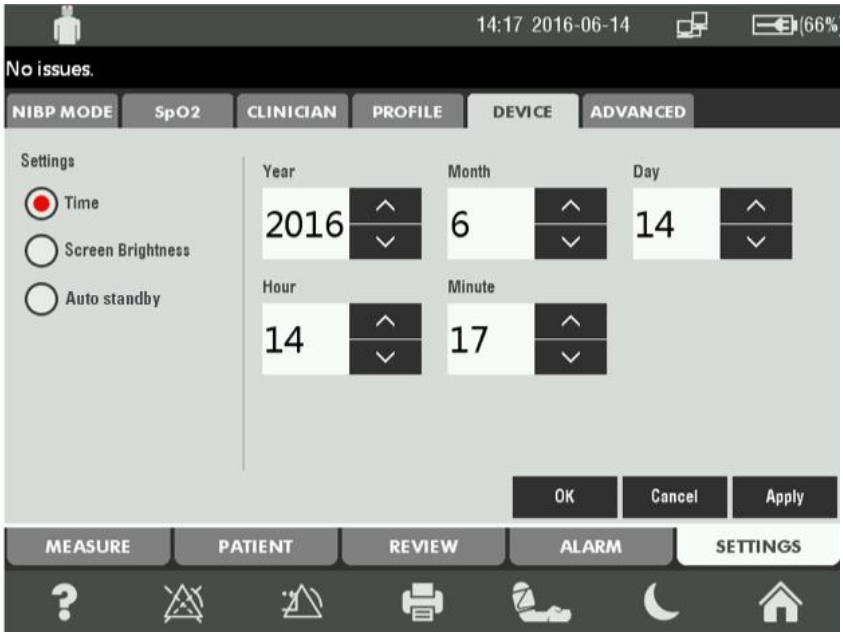


1. Select【**SETTINGS**】→【**ADVANCED**】→【**General**】 →【**Language**】 to access the language list.
2. Select the desired Language and press【**OK**】save the language setting.

3.8.2 Setting the Date and Time

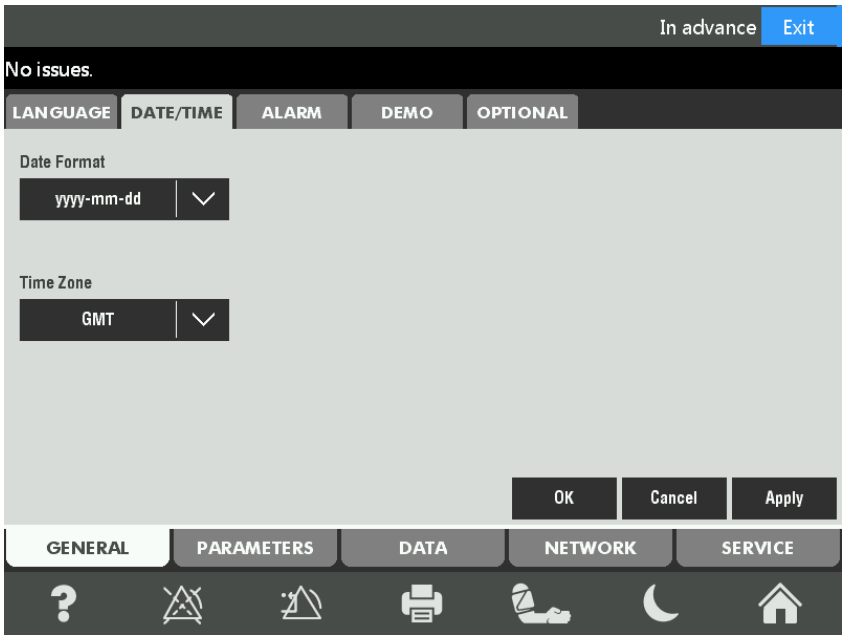
Setting the current time:

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

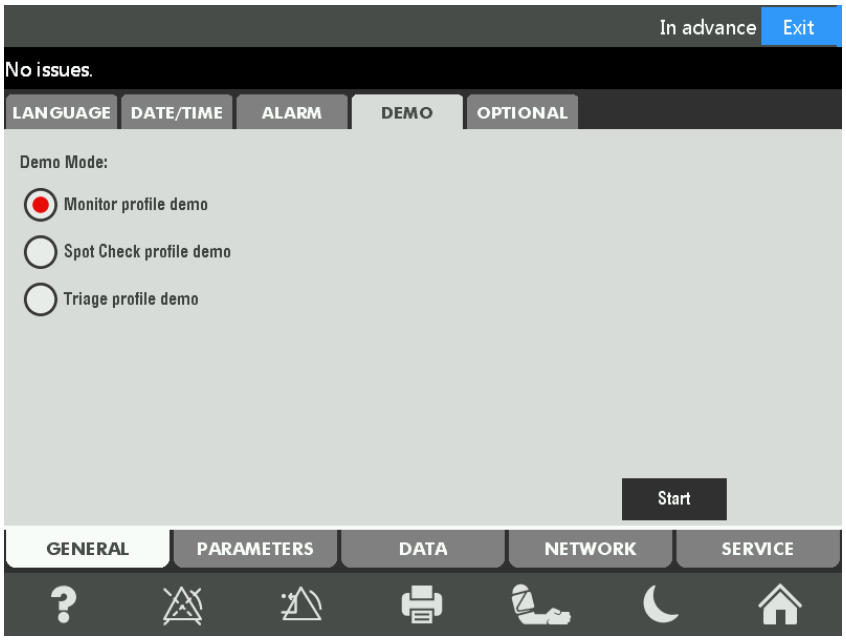


Setting the date/time format:

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.



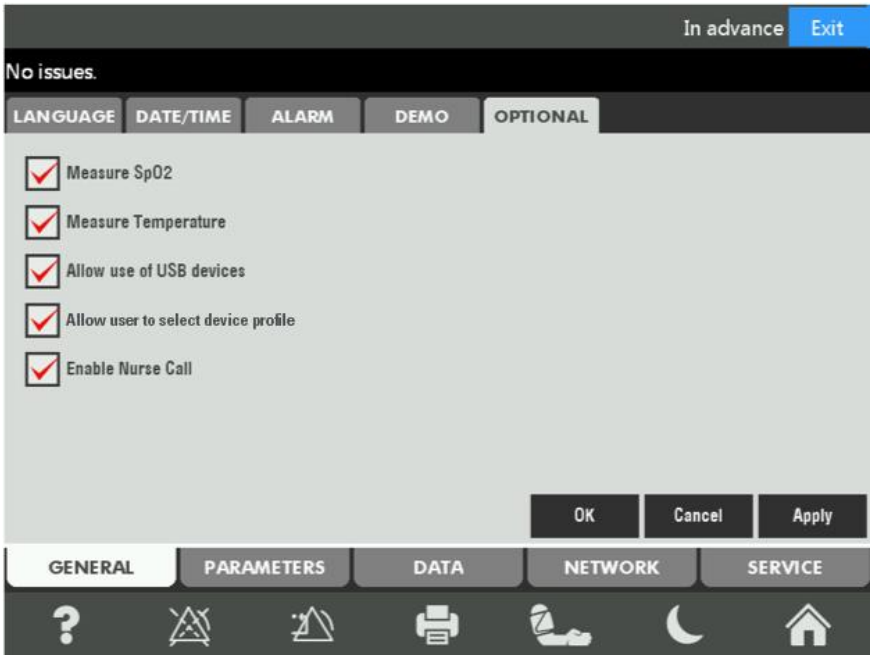
3.8.2 DEMO Modes



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.

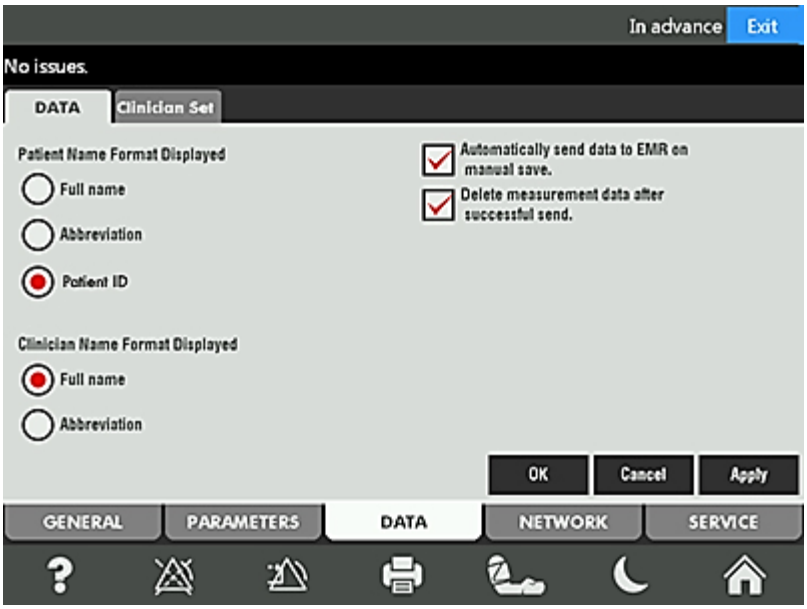
2. Select【**Start**】to begin the demo.

3.8.3 General Device Options



1. Select【**SETTING**】→【**ADVANCED**】→【**GENERAL**】→【**OPTIONAL**】to view the list of options available.
2. Choose the desired options.
3. Select 【**OK**】to save settings.

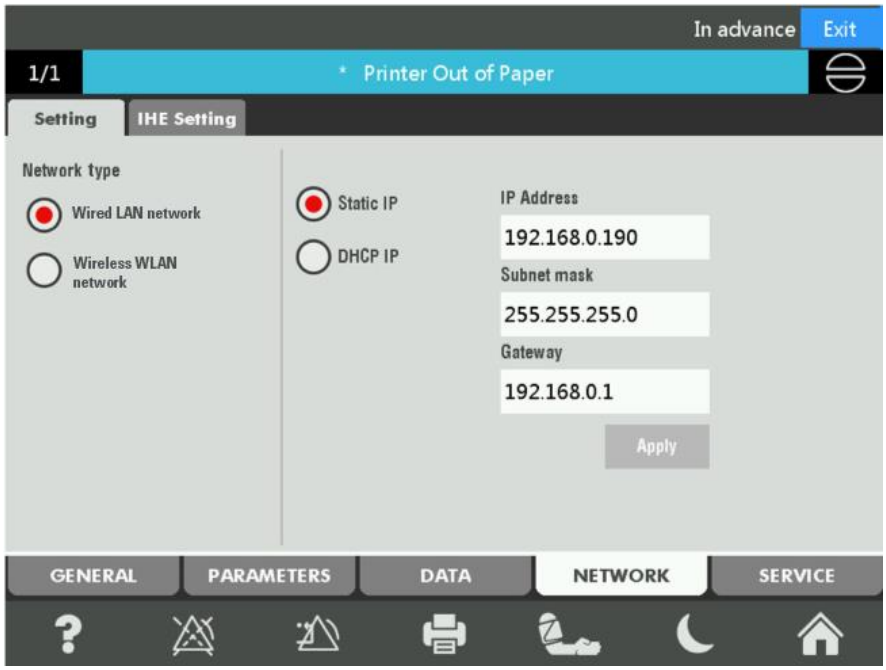
3.8.4 Data Options



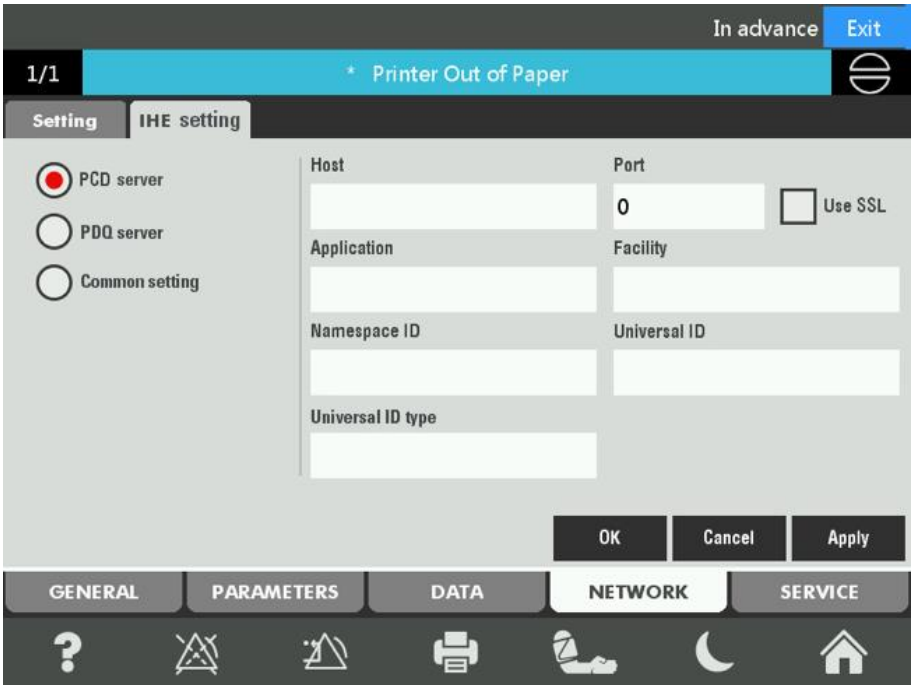
1. Select 【**SETTINGS**】→【**ADVANCED**】→【**DATA**】to choose whether or not the full name or abbreviation is displayed for both the Patient and the Clinician. You can also choose to automatically send clinical information

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.

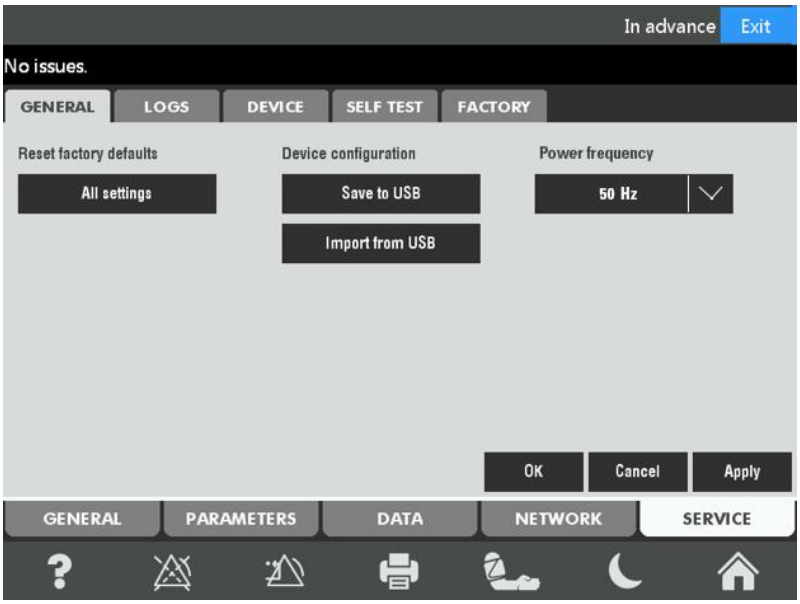


3.8.5 Network Settings



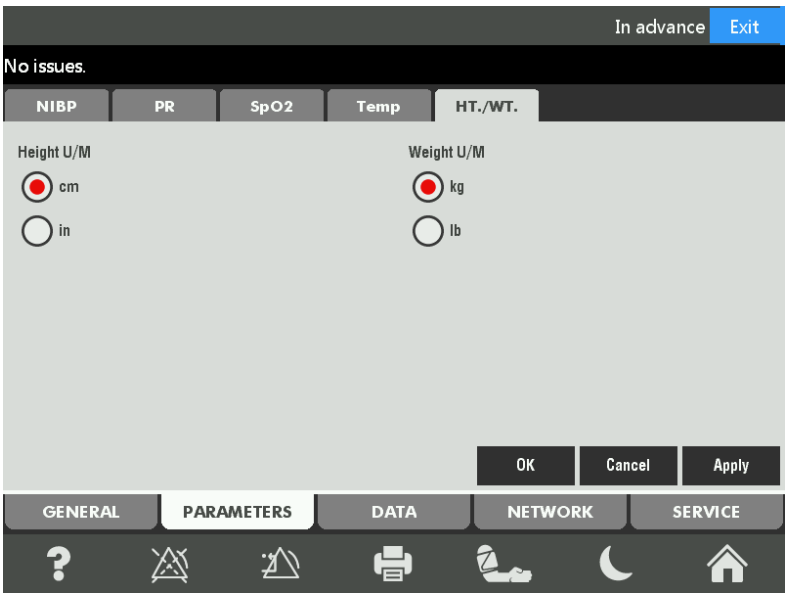
1. Select【**SETTINGS**】→【**ADVANCED**】→【**NETWORK**】to set the network to be【**Wired Network**】or the【**Wireless Network**】.
2. Select【**SETTING**】→【**ADVANCED**】→【**NETWORK**】→【**IHE Setting**】. In this interface set the network server to be【**PCD Server**】/【**PDQ Server**】.
3. Select【**OK**】to save settings.

3.8.6 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.

3.8.7 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.

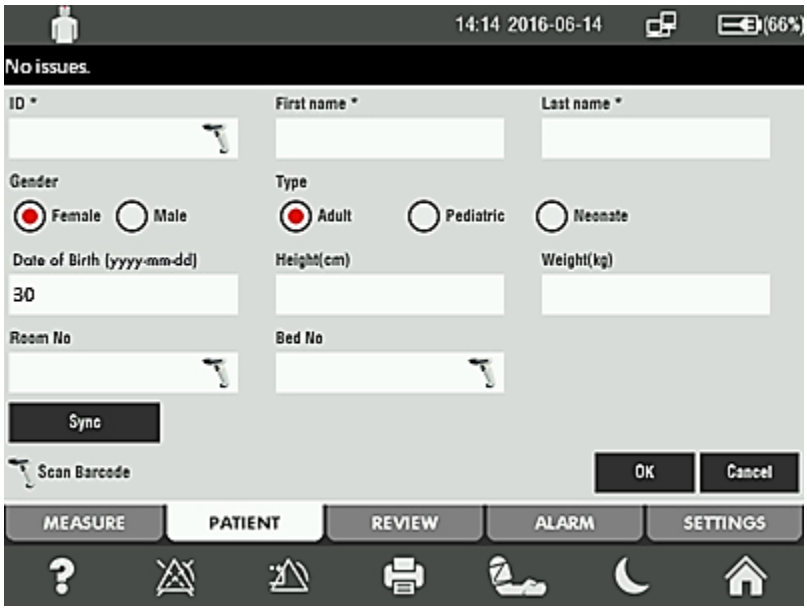
——**Last Name**: Enter the patient's last name (family name).

——**Date of Birth**: 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.

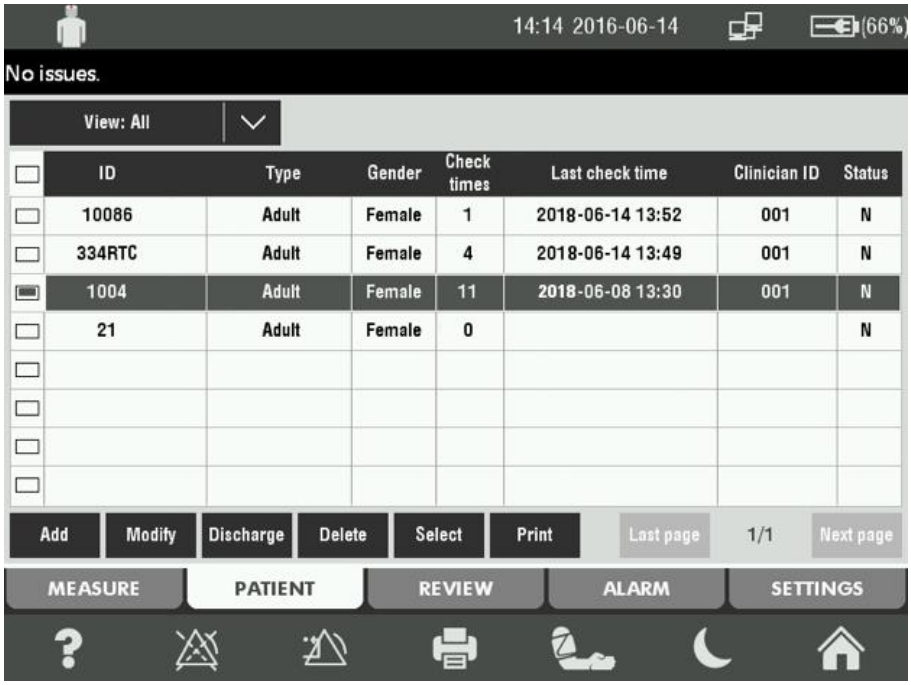


Caution: *The patient type determines which measurement algorithms, safety limits, and alarm limits the device will use during operation.*

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

4.2 Patient Tab

In order to select a patient, a clinician must first be logged in. Please see S***ection 3.7*** for instructions on how to login a clinician. When the patient is added, the patient information will automatically populate the patient interface (see the following picture):



Any of the following operations may be selected:

Select **【View All】: V**iew the last 1 day, last 7 days, or all the patients. A keyword search is available to find a specific patient.

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 the 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】**： Discharge the current patient.

Select **【Print】**： Print the patient information and measurement data.

Select **【Last page】**： View the last page of patient information.

Select **【Next page】**： View the next page of patient information.

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 the 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 to 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 monitor can be affected by extremes of temperature, humidity and altitude.
- Avoid compression or restriction of the connection tubing. This can result is incorrect measurements, which cause an incorrect diagnosis, potentially leading to patient harm.
- When the patients cannot take care of themselves, there must be an operator standing by during auto mode measurement.
- Environmental or operational factors which can affect the performance of the NIBP module and its BP reading are:
    - Compression or restriction of the air hose. Avoid compression or restriction of pressure tubes. Air must pass unrestricted through the tubing.
    - Folding or twisting of the cuff bladder. The bladder of the cuff should not be folded or twisted.
    - A wrong cuff size, and a folded or twisted bladder. Incorrect cuff size or a folded or twisted bladder can cause inaccurate measurements.
    - Cuff wrapped too tightly on the limb. Do not wrap the cuff too tightly around the limb.

- Continuous high cuff pressure due to connection tubing kinking may cause 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.
- That pressurization of the cuff can temporarily cause loss of function of monitoring ME equipment simultaneously used on the same limb.
- Do not use the NIBP cuff on the arm of a mastectomy patient. Blood pressure may be measured on the thigh.
- The application of the cuff and its pressurization on any limb where intravascular access or therapy or an arterio-venous(A-V) shunt is present, may cause temporary interference to blood flow and could result in injury to the patient.
- Check the operation of the monitor 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.

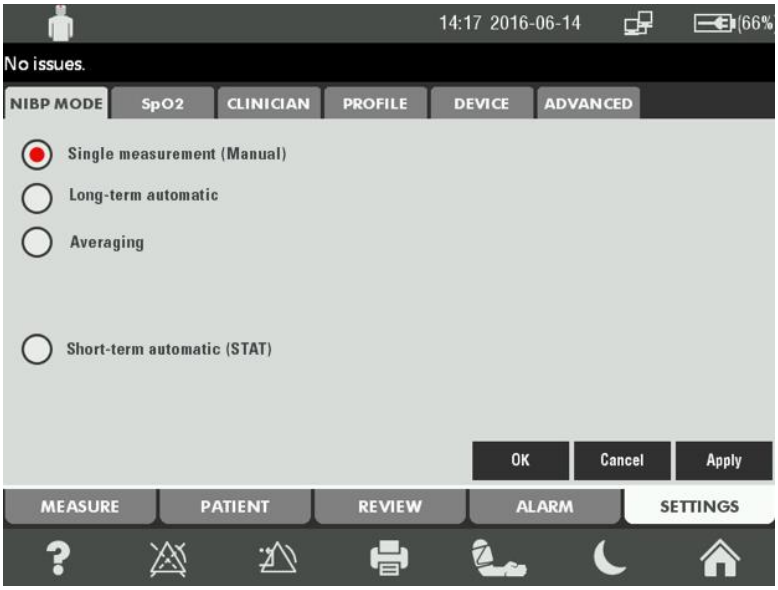
Accurate measurement also cannot be taken when the following conditions exist:

- 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 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 BP measurements for the condition of hypertension , including:
  1. Ensure patient is comfortably seated.
  2. Ensure legs are uncrossed.
  3. Ensure feet are flat on the floor.
  4. Ensure the back and arm are supported.
  5. Check that the middle of the cuff is 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 minutes should elapse before the first reading is taken.
  8. The operator is recommended to stand 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 the artery and that there are no knots or kinks 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 【**SETTINGS**】→【**NIBP**】→【**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.*

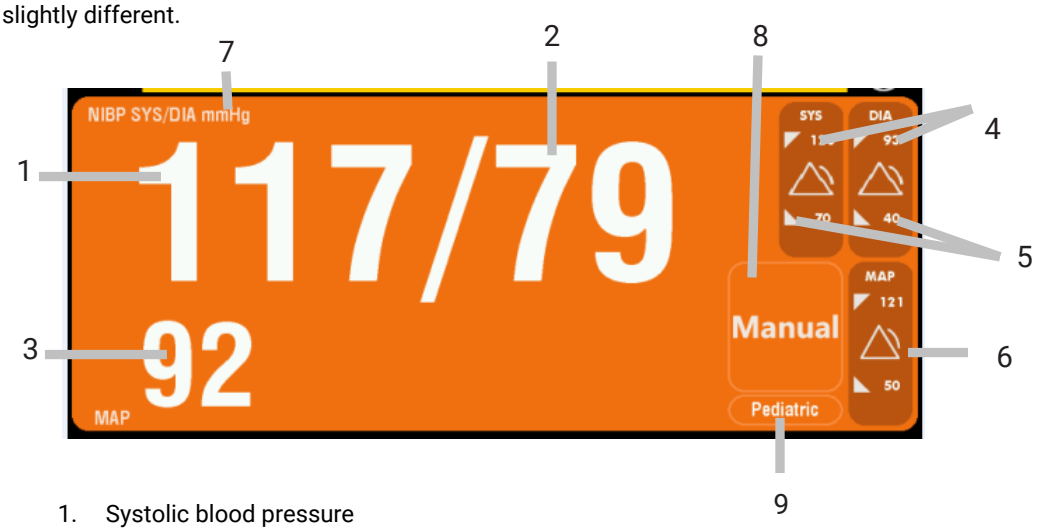
Averaging Mode

1. Select 【**SETTINGS**】→【**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 once you begin the cycle by touching  . If you select 1, measurement will begin 1 minute after you touch  .
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 determinations.

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) to change the patient type. In Monitor and Spot Check Profile, the patient type is displayed in this area.*

5.1.6 Setting NIBP

You can setup the NIBP measurement information as follows:

1. Select **【SETTINGS】→【ADVANCED】→【PARAMETERS】→【NIBP】→【Default patient type】** to choose the patient category. Choose either **【Adult】**, **【Pediatric】** or **【Neonate】**.
2. Select **【SETTINGS】→【ADVANCED】→【PARAMETERS】→【NIBP】** to set the **【Unit】** to **【mmHg】** or 【kPa】.

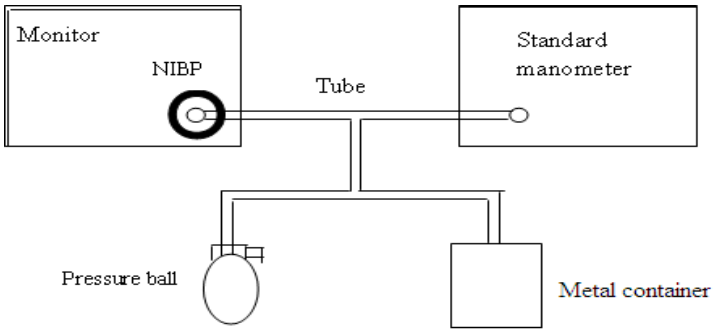
Note: *This setup is only available in Triage Profile.*

5.1.7 NIBP Calibration

Annual maintenance and calibration of NIBP measurement is necessary. If you need to maintain NIBP, please contact the professional service personnel.

Calibration tools: 3 way connector, pipe, hand inflation pump, metal container (500±25 ml), standard calibrated manometer (with precision over 1 mmHg)

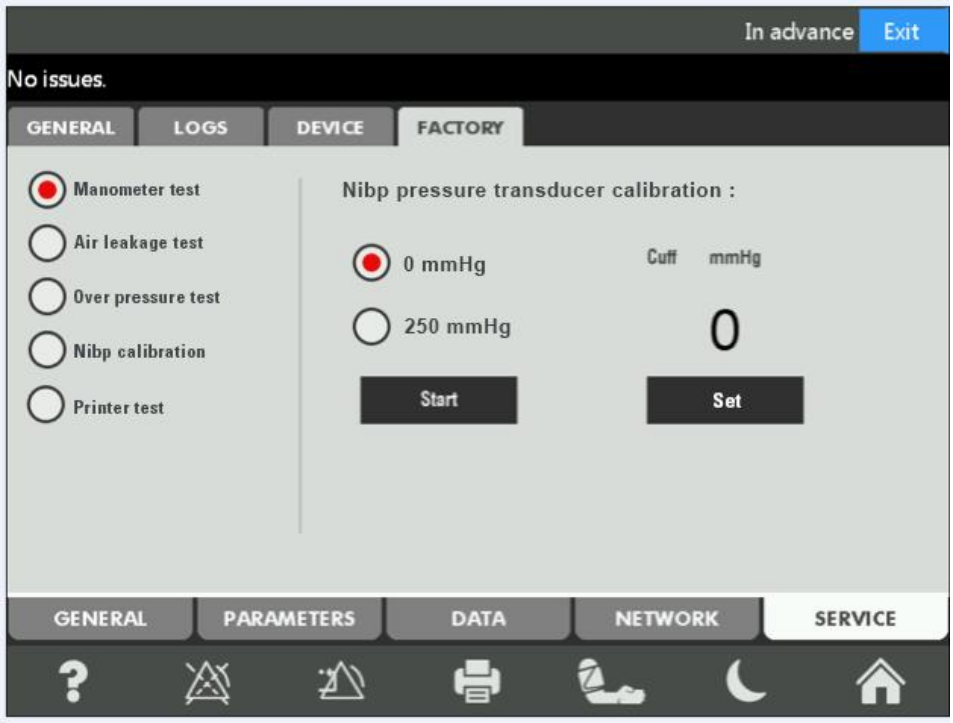
1. Connect monitor, manometer, inflation pump and metal container as follows.



2. Reading of manometer should be 0 before deflation, if not, cut the connection until it returns to zero.
3. Select **【Maintenance】** →input password→ **【Main Menu】→【Maintenance】→【Machine Maintenance】→【NIBP Maintenance】→【Adult】→【NIBP Calibration】**.
4. Turn up pump output pressure to 150 mmHg. The difference pressure showed by monitor and consult manometer must be less than 3 mmHg. If not, select setting **【Press Calibration】** for 150 mmHg and select【Ok】key in right of the menu.

5.1.8 NIBP Test

When the NIBP value measured is inaccurate, you can select 【**SETTINGS**】→【**ADVANCED**】→【**SERVICE**】. After entering the correct password to go to【**FACTORY**】to select the following test : manometer test, air leakage test, over pressure test, NIBP Calibration. Selecting a test will allow you to perform that test.



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

5.2 SpO_2 measurement

5.2.1 Introduction

The measurement of oxygen saturation of arterial blood (also known as pulse oxygen saturation, or SpO_2) 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:

- Use only the SpO_2 sensors specified in this manual. Follow the SpO_2 sensor's instructions for use and adhere to all warnings and cautions.
- 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 SpO_2 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 SpO_2 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 SpO_2 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 SpO_2 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 SpO_2 device to the patient, always clip the cable, not the sensor itself. Never use force to pull the sensor cable.*

Note:

- During SpO_2 measurement, a photoplethysmosgraphic waveform will be displayed in the SpO_2 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. The operator must use an SpO_2 simulator for self-test of the device.
- Functional test cannot be used to assess the accuracy of the monitor.
- When the displayed SpO_2 or pulse rate value is potentially incorrect, the system will show a "？" in the value position.

5.2.3 SpO_2 Monitoring Procedure

1. Selecting SpO_2 Sensor: Select an SpO_2 sensor that is appropriate for the patient category, weight, and application site.

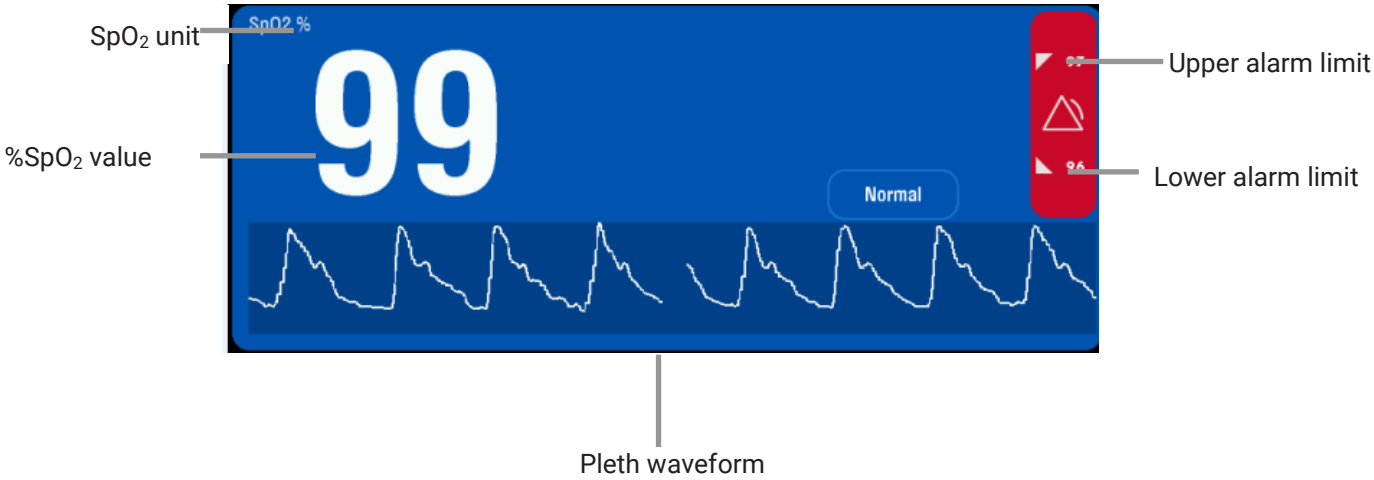
2. Connecting SpO_2 Sensor: Plug the SpO_2 sensor cable into the SpO_2 connector on the device (see device diagram in ***Chapter 1.4***).

3. Applying SpO_2 Sensor: Clean the application site, removing any colored nail polish, and apply the sensor to the patient. Typically, the sensor should be used on the index, middle or ring finger. The fingernail should face the side with the red light.

Warnings:

- Do not use the SpO_2 sensor on the same limb being used for NIBP measurement. This may result in inaccurate SpO_2 reading due to blocked blood flow during cuff inflation.
- Do not measureSpO_2 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 SpO_2 Display



5.2.5 Setting SpO_2

1. Select 【**SETTINGS**】→【**ADVANCED**】→【**PARAMETERS**】→【**SPO_2**】→【**Default response**】to choose the response to be【**Normal : 16 seconds**】or 【**Fast : 4 seconds**】.
2. Select 【**SETTINGS**】→【**ADVANCED**】→【**PARAMETERS**】→【**SPO_2**】→【**Sweep speed**】to setup the speed to be【**6.25mm/s**】or【**25 mm/s**】.

5.2.6 SpO_2 Measurement Limitations

If you doubt the SpO_2 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 hemoglobin (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.

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

5.2.7 Masimo Information

Masimo Patents:

This device is covered under one or more of the following U.S.A. patents: 5,758,644, 5,823,950, 6,011,986, 6,157,850, 6,263,222, 6,501,975 and other applicable patents listed at: www.masimo.com/patents.htm.

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.

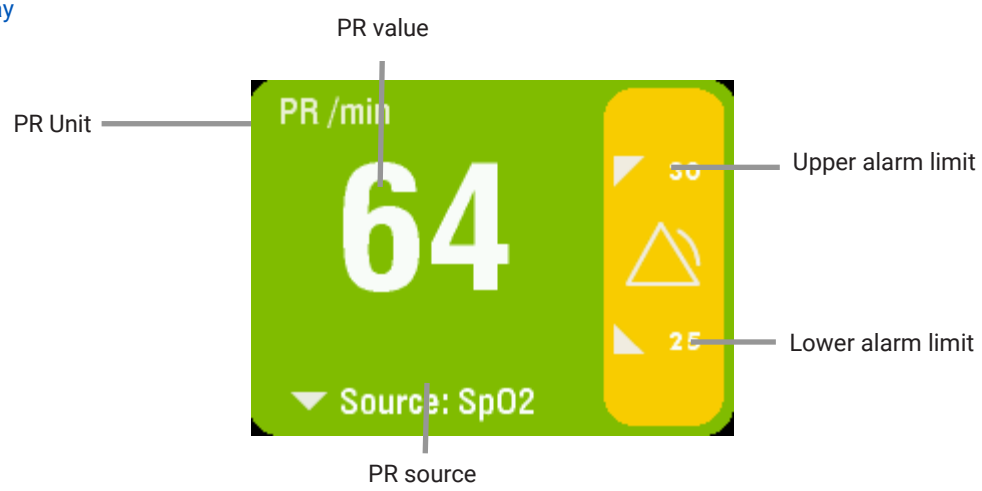
5.2.8 Nellcor Information

COVIDIEN

This is the trademark of Covidien plc.

5.3 PR Measurement

5.3.1 PR display



5.3.2 Selecting PR Source

Select **【SETTINGS】→【ADVANCED】→【PARAMETERS】→【PR】→【Source】：** SpO_2 or NIBP.

5.4 Temperature Measurement

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.

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 recommended to be 60s.

3. Remove the temp probe 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 on the probe 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.

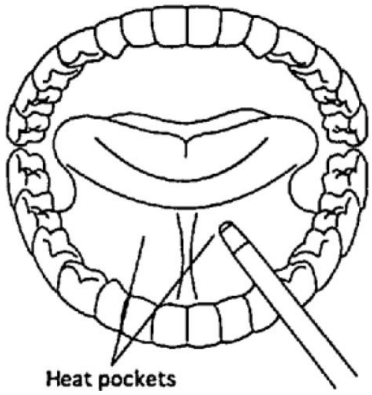
5. When the measurement is completed, this probe symbol  will flash as a reminder to eject the used disposable probe cover. Eject the probe cover and insert the probe back into the probe well.

Warnings: If measurement is made without the probe cover, the measurement result may be inaccurate**.**

Proper Temperature Probe Positioning

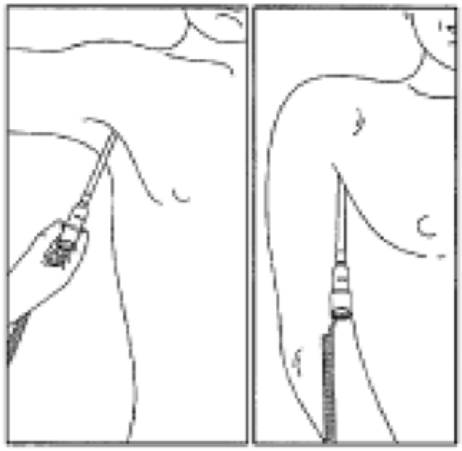
Oral Temperature Taking

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



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 his arm and hold still. Hold the probe perpendicular to the arm until there is a long beep and the temperature reading displays.

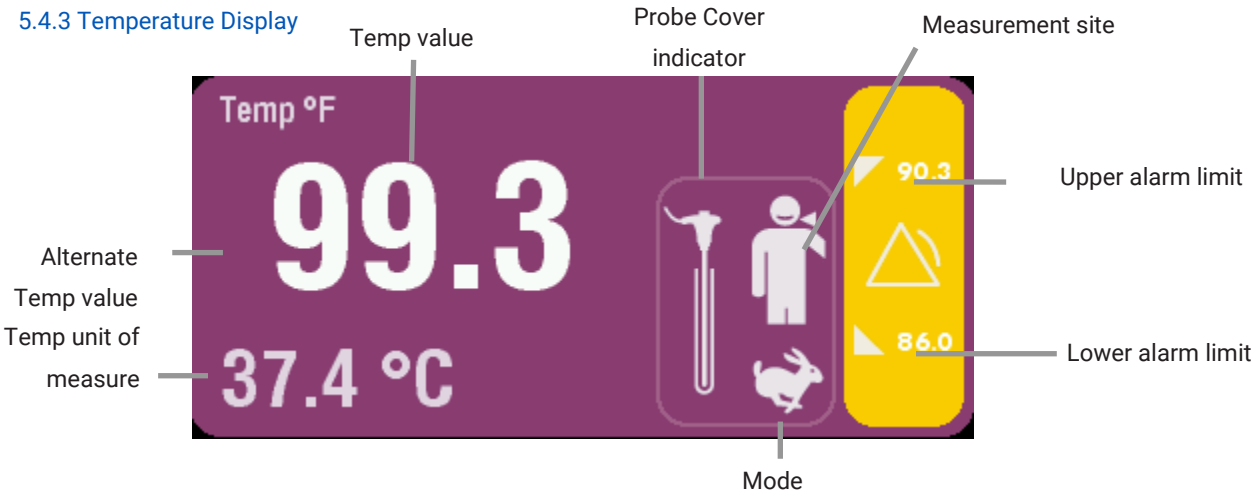


Rectal Temperature Taking

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



5.4.4Temperature Settings

1.Select 【**SETTINGS**】→【**ADVANCED**】→【**PARAMETERS**】→【**Temp**】to enter the temperature setup menu.

2. Set【**Unit**】to【**Celsius**】or【**Farhenheit**】. The selected measurement unit will be effective during the next measurement.

5.4.5 Safety Information

Warning

- Calibrate the device's temperature measurement function every six months to one year or according to your facility's regulations.
- If the temperature exceeds the measurement range, the alarm will be activated. Check whether the temperature probe is placed in the appropriate site on the patient.
- 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. Once a setting is finished, it is saved simultaneously. After a loss of power, the alarm settings prior to the power loss will recover automatically when the monitor is restarted.

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. When the selected patient 's 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.

	Monitoring Profile	Triage Profile	Spot-check Profile
Set Alarms	✓	✗	✗

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

Prompt messages: Prompt messages are not alarm messages. Prompt messages on the monitor are shown 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 the alarm levels, including physiologic alarms 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 in 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. When the low level technical and physiologic alarms occur at the same time, the two alarm lamps will be illuminated simultaneously: one flashes yellow and one is 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）or cyan (technical alarm）

The number of * will indicate the 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. When two alarm messages are the same alarm level, the latest alarm message will be displayed first. The display message may be manually changed by the user to display the other alarm messages occurring.*

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】;

At the same time , you can select【**SETTINGS**】→【**ADANCED**】→【General】→【Alarm】to set the minimum alarm volume to be 【Low】,【Medium】,【High】.

Warning:

- Auditory alarm signal sound pressure levels, when set to less than ambient levels, can impede operator recognition of alarm conditions and the alarm system.
- When setting the alarm volume, the volume should be louder than the noise of the environment.

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**】→【**ADANCED**】→【**PARAMETERS**】→【**Alarm limits status**】 and then choose the measurement type (i.e., NIBP, PR, SpO_2 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 the Monitor 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 and 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 occur in the status area. Press the button  again to exit alarm pause status, the icon  will disappear.

When alarms are paused, the following will occur:

- All the physiological alarms will be suspended.
- Only alarm messages in the technical alarm area will still be displayed. The lamp and volume of the technical alarm will be suspended.
- A 30-second countdown for the alarm pause period will appear at 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. When alarms are acknowledged, the following occurs:

- Visual alarms remain open, but audible alarms are turned off.
- "Acknowledged" will appear in front of the acknowledged physiologic alarm message.
- Other remaining physiologic and technical alarms will remain active.

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

6.9 Alarm Reset

Press the button on the front panel of the monitor to reset all active physiologic and technical alarms. When alarms are reset, the following occurs:

- All auditory alarms are turned off.
- The visual alarm signals for any existing alarm conditions will continue as long as those alarm conditions exist.
- Any technical alarms related to lead-off/sensor-off will be deleted.
- After alarms are reset, if a new technical alarm or physiologic alarm occurs, the monitor will enable the audible alarm once again.

6.10 Alarm Audio Control

The following steps can turn the alarm audio function on or off.

Select **【SETTINGS】→【ADVANCED】**, input the correct password to enter the alarm control interface. In this interface, select **【Allow control alarm audio】**. Return to the main interface and select **【ALARM】** to choose **【Alarm audio on 】** or **【Alarm audio off】.**

Note: *After selecting【Alarm audio off】, the following icon will appear:* 

6.11 Reminder Signal

When alarm audio is turned off, the alarm system may be set to provide a periodic audible reminder signal sound consisting of three chimes. Enter **【SETTINGS】→【ADVANCED】**and input the correct password to enter the alarm control interface. In this interface, select or deselect**【Active reminder signal】** to turn on or off the reminder signal. The intervals between the reminder signals may be adjusted to be 30s, 60s, 90s, or 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:

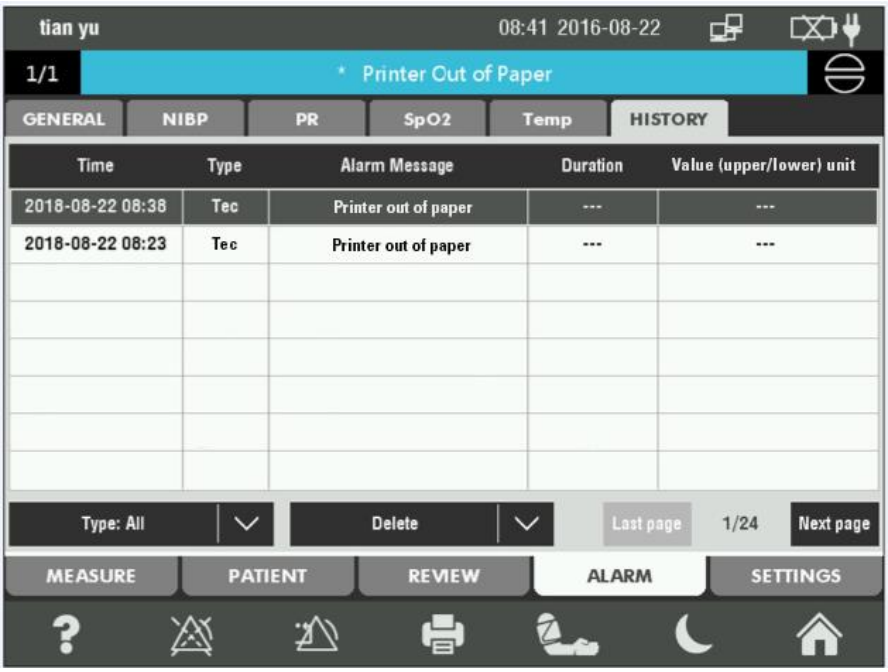
Parameter			Upper limit	Lower limit
NIBP (mmHg)	Adult	SYS	160	90
		DIA	150	50
		MAP	110	60
	Pediatric	SYS	120	70
		DIA	70	40
		MAP	90	50
	Neonatal	SYS	90	40

		DIA	60	25
		MAP	70	35
SpO_2			100	95
PR			120	50
TEMP（℃）			39	36

Warnings: *A potential hazard can exist if different alarm pre-sets are used for the same or similar equipment in any single area. If different settings are used, the operator may be confused by the different device pre-set alarms in the area and thus could harm the patient.*

6.13 Alarm History

Select【**ALARM**】on the main measurement display and then select the【**HISTORY**】tab to see all the alarm times, alarm levels, alarm messages, and alarm duration times as the following picture shows:



Note:

- The record number of the alarm log depends on the storage space.
- The alarm system generates a technical alarm condition when the storage space is insufficient. When the storage space is less than 10M, a low level technical alarm occurs and a prompt message will pop up with the message: “Insufficient storage space". When the storage space is less than 5M, another low level technical alarm occurs and a prompt message will pop up with the message: “Critical shortage of storage space".
- When the alarm system is powered down, the log is maintained, but the time that the alarm system was powered down will not be captured in the log.

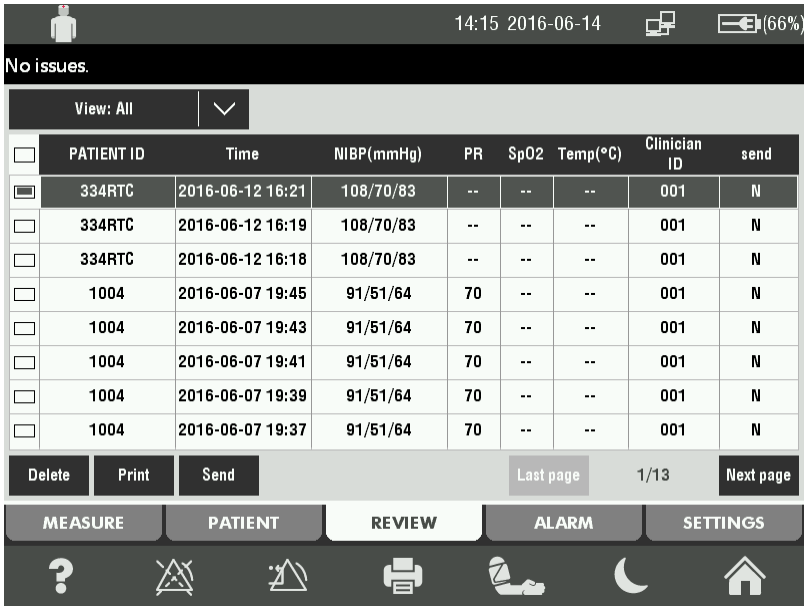
- The contents of the log are maintained after the alarm system has experienced a total loss of power (supply mains and internal electrical power source) for a finite duration.
- When the log reaches capacity, the system will automatically delete the earliest log.

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 on or off. In the case of a sudden power outage, the monitor will automatically switch to battery power without any 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 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 the battery specified in this manual.
- Keep the batteries out of children's reach.
- 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 or maintained by professional personnel specified by SunTech Medical, or the device may not be operational.

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 initial use, condition a battery when it is unused or stored for two months or when its 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. Connect the monitor 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 declining 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 SpO_2 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, dispose of them in fire, or cause them to short circuit. They may ignite, explode, or leak, potentially 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 to 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 a room temperature 40 degrees C to 80 degrees C for at least one hour.

9.3 Cleaning and Disinfection of Accessories

9.3.1 SpO_2 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 (EtO2).
- Do not directly submerge sensor in liquid.
- To avoid long-term harm to the 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) Clean cuffs according to the instruction leaflet included with the cuff.

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 replace of the 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

Warning:

- 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. Reuse of them may cause a risk of contamination and affect measurement accuracy.
- Check the accessories and their packages 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	MAX-A	Adult finger (patient size>30kg)	52-0017-00
	MAX-P	Pediatric foot/hand(patient size 10-50kg)	52-0017-01
	MAX-I	Infant foot/hand (patient size 3-20kg)	52-0017-02

	MAX-N	Adult finger or neonatal foot/hand (patient size >40 kg or <3 kg)	52-0017-03
Reusable	DS-100A	Adult finger	52-0018-00
	OXI-A/N	Adult / neonatal finger	52-0018-01
	OXI-P/I	Pediatric / infant finger	52-0018-02

Generic (Nellcor compatible) SpO_2		
Type	Patient category	PN
Reusable	Adult finger	52-0014-03
	Pediatric finger	52-0014-00
	Neonatal finger	52-0014-01

SpO_2 Extension cable

Accessories	**PN**
Extension cable	52-0014-02

Masimo SpO_2 Sensor (Must order directly from Masimo)

Type	**Model**	**Patient category**
Reusable	DCI / 2501	Adult finger
	DCIP / 2502	Pediatric finger
Disposable	Neo / 2514	Infant foot/hand

Masimo SpO_2 Extension cable (Must order directly from Masimo)

Accessories	**Model**
Extension cable	2525

10.2 NIBP

Disposable cuffs (Boxes of 20 cuffs)

Cuff Size	**Limb Circ. (cm)**	**Part Number**
Infant	8-13	98-0400-40
Child	12-19	98-0400-41

Small Adult	17-25	98-0400-43
Adult	23-33	98-0400-45
Adult Plus	28-40	98-0400-4A
Large Adult	31-40	98-0400-47
Large Adult Plus	40-55	98-0400-4C
Thigh	38-50	98-0400-49

Reusable cuffs

Cuff Size	Limb Circ. (cm)	Part Number
Infant	8-13	98-0600-40
Child	12-19	98-0600-41
Small Adult	17-25	98-0600-43
Adult	23-33	98-0600-45
Adult Plus	28-40	98-0600-4A
Large Adult	31-40	98-0600-47
Large Adult Plus	40-55	98-0600-4C
Thigh	38-50	98-0600-49

10.3 Temp

Part Number	Description	Details
52-0009-00	F3000 Oral/Axillary Temp Probe, 9’	Each
45-0006-00	F3000 Oral/Axillary Isolation Chamber, Blue	Each
52-0009-01	F3000 Rectal Temp Probe, 9’	Each
45-0006-01	F3000 Rectal Isolation Chamber, Red	Each
98-0131-01	F3000 Disposable Temp Probe Covers (25 boxes/tray, 20 covers/box)	1 tray
98-0130-01	F3000 Disposable Temp Probe Covers (25 boxes/tray, 20 covers/box)	10 trays
52-0011-00	F3000 Calibration Plug	Each

10.4 Miscellaneous

Part Number	Description	Details
91-0028-16	10'/3.0m Patient BP Hose, Bayonet to Bayonet	Each
91-0003-00	AC Power Cord, Americas	Each

91-0003-05	AC Power Cord, Europe	Each
91-0003-06	AC Power Cord, UK	Each
46-0040-00	Deluxe Mobile Stand	Each
99-0184-00	CT40/CT50 Barcode Scanner (USB) with Scanner Mount	Each
45-0005-00	CT40/CT50 WiFi Dual Band USB Dongle	Each
17-0027-00	CT50 Rechargeable Lithium Ion Battery (custom battery, only purchase from SunTech Medical, Inc.)	Each

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 IEC60601-1 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 the protecting earth integrality or protecting earth lead of the equipment, switch the equipment to internally powered.

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	70 kPa to 106 kPa
Transportation and storage temperature	-20℃ to +55℃
Transportation and storage humidity	10% to 93%（non condensing）
Transportation and storage atmospheric pressure	50 kPa to 106 kPa

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	48 mm
Paper length	15 m
Recording speed	12.5 mm/s, 25 mm/s, 50 mm/s
Recording waveform	Maximum 3 tracks
Recording method	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	Over 8 hours: One new and fully charged battery at 25℃ ambient temperature, using SpO_2, Temp, and NIBP on AUTO mode for 15 minute intervals.
Charge time	6 h to 100%（Standby）
Turn off delay	5 min -15 min after the low battery alarm first occurs.
Indicator of battery capability	With

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 indicating

Speaker	Gives audible alarm (sounds as DO, DO, DO) Supports Pitch Tone (sounds as 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	With
Others	
Mouse input	Support
Keyboard input	Support

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	＞100000items
Log event	＞10000 items

A.6 Measurement Specifications

A.6.1 SunTech NIBP

Measurement method	Oscillometry

Measurement types	Sys, Dia, MAP,PR		
Range of measurement	Adult	SYS	40~260 mmHg
		DIA	20~200 mmHg
		MEAN	26~220 mmHg
	Child	SYS	40~160 mmHg
		DIA	20~120 mmHg
		MEAN	26~133 mmHg
Range of measurement	Neonate	SYS	40~130 mmHg
		DIA	20~100 mmHg
		MEAN	26~110mmHg
Pressure Accuracy Static Clinical	±3 mmHg ±5 mmHg average error 8 mmHg standard deviation		
Unit	mmHg, kPa		
Recovery time after defibrillation	<5s		
Pulse rate range	30 ~ 220 bpm		
Pulse veracity	2bpm or3%, whichever is greater		
Inflation time for cuff	<75s		
Measurement protection time	Adult: <180s		
	Child: <180s		
	Neonate: <90s		
Initial inflation pressure	Adult: 120~280mmHg，default 160mmHg		
	Child: 80~280mmHg，default 140mmHg		
	Neonate: 60~140mmHg，default 90mmHg		
Intervals for AUTO measurement time	5min-240min		
Overpressure Protection Adult Child Neonatal	Hardware and software double protections <300 mmHg <300 mmHg <150 mmHg		
Alarm indication	Three levels of alarms: sound-light alarms, color change in alarm limits area, and alarms with text prompts.		
Measurement Mode	Adult	Manual, Auto and STAT, Average	
	Child	Manual, Auto and STAT , Average	
	Neonatal	Manual, Auto	

A.6.2 SpO_2

Generic (Nellcor compatible) SpO_2

SpO_2	
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	ESU
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	0bpm～300bpm, 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

Masimo SpO_2

SpO_2	
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） ***Note : The Masimo SPO_2 sensor for adult/pediatric/ neonate has been validated for motion accuracy in human blood studies on healthy adult volunteers 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. 1% has been added to the results to account for the effect of fetal hemoglobin. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.*** 0% to 69%,unspecified

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
Accuracy	±3 bpm（non-motion conditions） ±5 bpm（motion conditions）
Resolution	1 bpm
PI	
Measurement range	0.05% to 20%

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 Mode 10-14 seconds Rectal Mode 14-18 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 appendix is about factory defaults setup. Factory defaults cannot be changed by the user. 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 close general alarm	No selection
Alarm paused time	2min
Allow control alarm audio	No selection
Alarm control	Alarm audio on
Active reminder signal	√
Remind signal interval	30sec

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

SpO_2 setup	Factory defaults
SPO_2 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

This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.
- Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

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.

Use of accessories, transducers, and cables other than those specified may result in increased emissions or decreased immunity of the monitor.

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.

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. This equipment has been tested and found to comply with the limits for medical devices to IEC60601-1-2: 2007.		
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 manufacturer's declaration – electromagnetic immunity

–for all EQUIPMENT and SYSTEMS

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**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%. Users must eliminate static in their hands before use it.
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) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for 5 sec	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.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/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 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,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

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

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

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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 theQ3monitor

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.

Appendix D: Troubleshooting

Basic Troubleshooting

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 wire 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 wire or install 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 any button on the device to illuminate the screen

Printer doesn't work	1.The paper is not loaded 2.The printer door is not fully closed. 3. The printer is too hot.	1.Load paper according to the user's manual 2.Ensure the printer door is fully closed. 3.Start the operation again after the printer as 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. 2. Install the paper according to the user's 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 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 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 remaining 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 off the 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 SpO_2 module can't be detected.
SpO_2 Invalid Sensor	The sensor of the Masimo SpO_2 module is invalid.
SpO_2 Replace Sensor	The sensor of the Masimo SpO_2 module needs to be changed.
SpO_2 Calibrate Sensor	The Masimo SpO_2 module is calibrating.
SpO_2 Motion Interference	The patient's finger is moving too much during SpO_2 measurement.
SpO_2 Low perfusion	The signal of the patient's finger is too low during SpO_2 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 when use 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

Product name: CT50/Model 270

Product type: Vital Signs Monitor

Manufacturer: SunTech Medical, Inc.

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