VS-600
Vital Signs Monitor

Operator's Manual

CE 0123

Release date: 2015-12
Revision: 3.0

Intellectual Property Statement

SHENZHEN MINDRAY BIO-MEDICAL ELECTRONICS CO., LTD. (hereinafter called Mindray) owns the intellectual property rights to this Mindray product and this manual. This manual may refer to information protected by copyrights or patents and does not convey any license under the patent rights of Mindray, nor the rights of others.

Mindray intends to maintain the contents of this manual as confidential information. Disclosure of the information in this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden.

Release, amendment, reproduction, distribution, rental, adaption and translation of this manual in any manner whatsoever without the written permission of Mindray is strictly forbidden.

mindray , MINDRAY, and MINDRAY are the registered trademarks or trademarks owned by Mindray in China and other countries. All other trademarks that appear in this manual are used only for editorial purposes without the intention of improperly using them. They are the property of their respective owners.

Responsibility on the Manufacturer Party

Contents of this manual are subject to changes without prior notice.

All information contained in this manual is believed to be correct. Mindray shall not be liable for errors contained herein nor for incidental or consequential damages in connection with the furnishing, performance, or use of this manual.

Mindray is responsible for the effects on safety, reliability and performance of this product, only if:

- all installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray authorized personnel;
- the electrical installation of the relevant room complies with the applicable national and local requirements;
- the product is used in accordance with the instructions for use.

WARNING

- **This equipment must be operated by skilled/trained clinical professionals.**
- **It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.**

Warranty

THIS WARRANTY IS EXCLUSIVE AND IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESSED OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR ANY PARTICULAR PURPOSE.

Exemptions

Mindray's obligation or liability under this warranty does not include any transportation or other charges or liability for direct, indirect or consequential damages or delay resulting from the improper use or application of the product or the use of parts or accessories not approved by Mindray or repairs by people other than Mindray authorized personnel.

This warranty shall not extend to

- Malfunction or damage caused by improper use or man-made failure.
- Malfunction or damage caused by unstable or out-of-range power input.
- Malfunction or damage caused by force majeure such as fire and earthquake.
- Malfunction or damage caused by improper operation or repair by unqualified or unauthorized service people.
- Malfunction of the instrument or part whose serial number is not legible enough.
- Others not caused by instrument or part itself.

Company Contact

Manufacturer:	Shenzhen Mindray Bio-Medical Electronics Co., Ltd.
Address	Mindray Building, Keji 12th Road South, High-tech industrial park, Nanshan, Shenzhen 518057, P.R.China
Website	www.mindray.com
E-mail Address:	service@mindray.com.cn
Tel:	+86 755 81888998
Fax:	+86 755 26582680
EC-Representative:	Shanghai International Holding Corp. GmbH (Europe)
Address:	Eiffestraβe 80, 20537 Hamburg, Germany
Tel:	0049-40-2513175
Fax:	0049-40-255726

Preface

Manual Purpose

This manual contains the instructions necessary to operate the product safely and in accordance with its function and intended use. Observance of this manual is a prerequisite for proper product performance and correct operation and ensures patient and operator safety.

This manual is based on the maximum configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be obtained conveniently when needed.

Intended Audience

This manual is geared for clinical professionals who are expected to have corresponding working knowledge of medical procedures, practices and terminology as required for the treatment of patients.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your equipment.

Conventions

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

Contents

FOR YOUR NOTES

1 Safety

1.1 Safety Information

⚠DANGER

- **Indicates an imminent hazard situation that, if not avoided, will result in death or serious injury.**

⚠WARNING

- **Indicates a potential hazard situation or unsafe practice that, if not avoided, could 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.**

1.1.1 Dangers

There are no dangers that refer to the product in general. Specific "Danger" statements may be given in the respective sections of this operation manual.

1.1.2 Warnings

WARNING

- **The monitor does not provide any alarms. Only the error codes are provided. It is not intended for continuous monitoring. Keep the patient under close surveillance during the use of this monitor.**
- **This equipment is used to one patient at a time.**
- **Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.**
- **To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. If the installation does not provide for a protective earth conductor, disconnect it from the power line and operate it on battery power, if possible.**
- **To avoid explosion hazard, do not use the equipment in the presence of oxygen –rich atmospheres, flammable anesthetics, or other flammable agents (such as gasoline).**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.**
- **Do not come into contact with patients during defibrillation. Otherwise serious injury or death could result.**
- **Do not touch the equipment's metal parts or connectors when in contact with the patient; otherwise patient injury may result.**
- **The physiological data and prompt information displayed on the equipment 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 reduce risk of entanglement or strangulation by patients or personnel.**
- **When disposing the package material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**
- **Ensure that the monitor is supplied with continuous electric power during work. Sudden power failure leads to the data loss.**

1.1.3 Cautions

CAUTION

- **Use only parts and accessories specified in this manual.**

⚠CAUTION

- **Take out the battery before the monitor is transported or will not be used for a long time.**
- **Carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.**
- **Disposable accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.**
- **At the end of its service life, the equipment, 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 equipment, please contact us.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason, make sure that all external devices operated in the vicinity of the equipment 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 equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or in this manual.**
- **Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**
- **If you spill liquid on the equipment or accessories, contact us or your service personnel.**

1.1.4 Notes

NOTE

- **Put the equipment in a location where you can easily view and operate the equipment.**
- **Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.**
- **The software was developed in compliance with IEC60601-1. The possibility of hazards arising from software errors is minimized.**
- **This manual describes all features and options. Your equipment may not have all of them.**
- **Only connect the specified device into RS-232 connector.**
- **During normal use, the operator is expected to face the front of the equipment.**

1.2 Equipment Symbols

Some symbols may not appear on your equipment.

	General warning sign		Neonate
	ON/OFF for a part of equipment		Pediatric
	Clear		Adult
	Alternating current		Equipotentiality
	Battery indicator		Input/Output
	DEFIBRILLATION –PROOF TYPE CF APPLIED PART		DATE OF MANUAFACTURE
	NIBP Start/Stop key		MANUFACTURER
IPX1	Protection against fluid ingress		Insertion Direction
SN	Serial number		No alarming system
	Refer to instruction manual/booklet		Humidity limitation
	Temperature limit		Atmospheric pressure limitation
EC REP	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		
CE 0123	The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive. Note: The product complies with the Council Directive 2011/65/EU.		

	The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it. * For system products, this label may be attached to the main unit only.

FOR YOUR NOTES

2 The Basics

2.1 Intended Use

The monitor is intended for spot-check monitoring physiologic parameters, including SpO_2, PR, NIBP and TEMP, on adult, pediatric, and neonatal patients in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

⚠WARNING

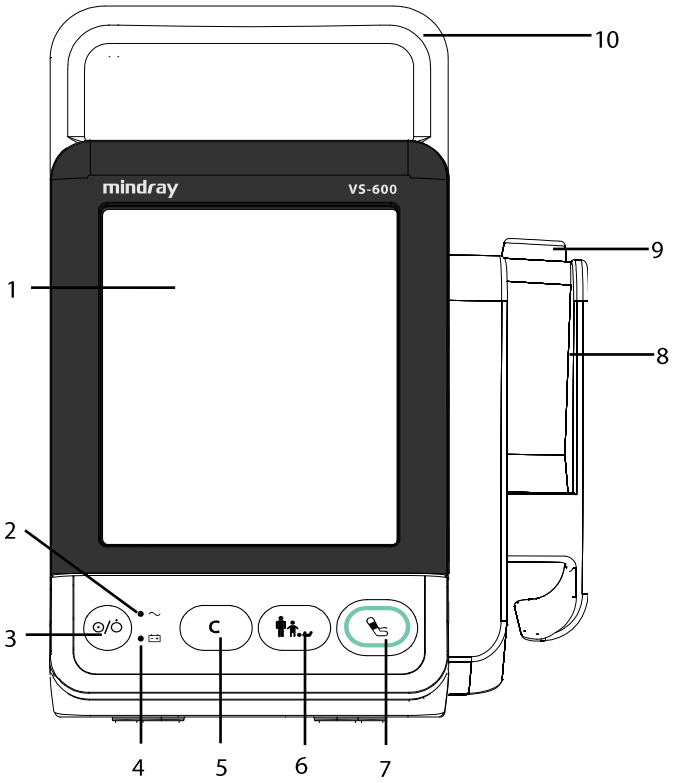
- **This equipment is intended for use only by clinical professionals or under their guidance. It must only be used by persons who have received adequate training in its use. Anyone unauthorized or untrained must not perform any operation on it.**

2.2 Applied Parts

The applied parts of the monitor are SpO_2 sensor and cable, NIBP tubing and cuff, and Temp probes and cable.

2.3 Main unit

2.3.1 Front View



1. Display screen
2. AC power indicator
   - On: indicates that the monitor is connected to the AC power.
   - Off: indicates that the monitor is not connected to the AC power.
3. Power ON/OFF switch
   - Press this key to turn the monitor on.
   - If no parameter is being measured, press this key to enter Standby mode.
   - When the monitor is on, press and hold this key for above 2 seconds to turn the monitor off.

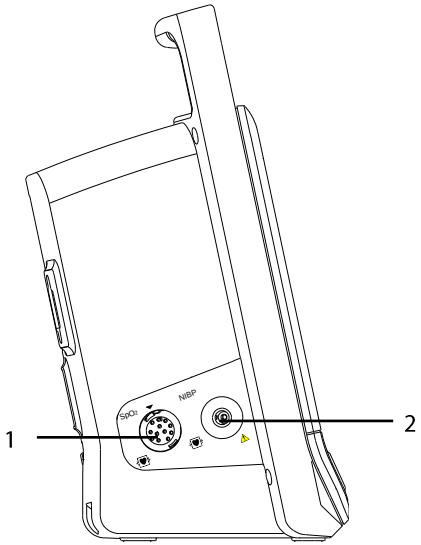
   An indicator is built in this switch. It turns green when the monitor is on, turns yellow when the monitor enters standby mode, and turns off when the monitor is off.

4. Battery indicator
   - On: indicates that the battery is installed and AC power is connected.
   - Off: indicates that the battery is not installed.
   - Flash: indicates that the monitor is powered by battery.
5. Clear key
   - In Measurement mode, press this key to clear current parameter value and error code.
   - In Measurement mode, press and hold this key for above 2 seconds to access Parameter Setup mode.
   - When the monitor is starting up and a beep is heard, press and hold this key within 10 seconds to access Maintenance mode.
6. Patient Category key

   In Measurement mode, press this key to toggle among adult, pediatric and neonate.
7. NIBP Start/Stop key

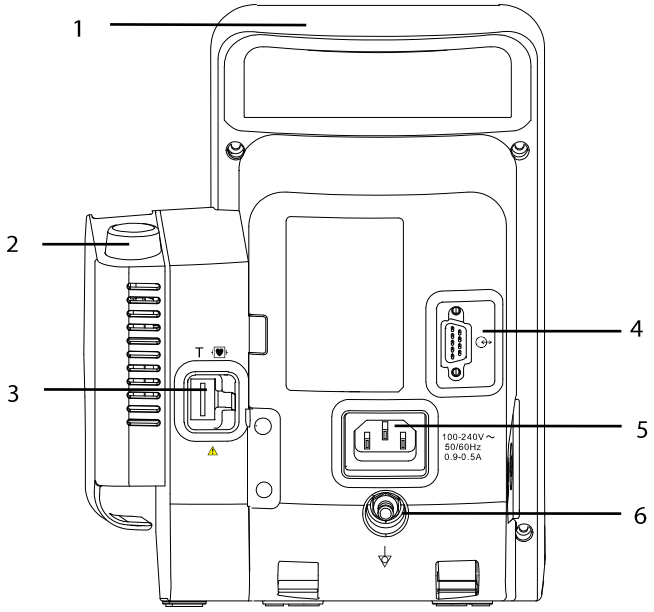
   In Measurement mode, press this key to start or stop NIBP measurement.
8. Probe cover pack holder
9. Temperature probe well
10. Handle

2.3.2 Side View



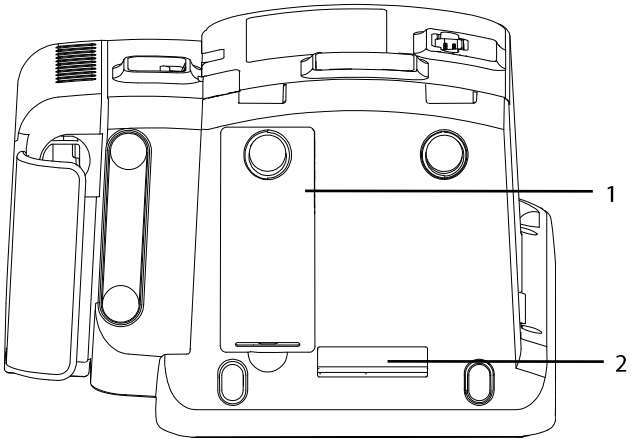
1. Connector for SpO_2 cable
2. Connector for NIBP cuff

2.3.3 Rear View



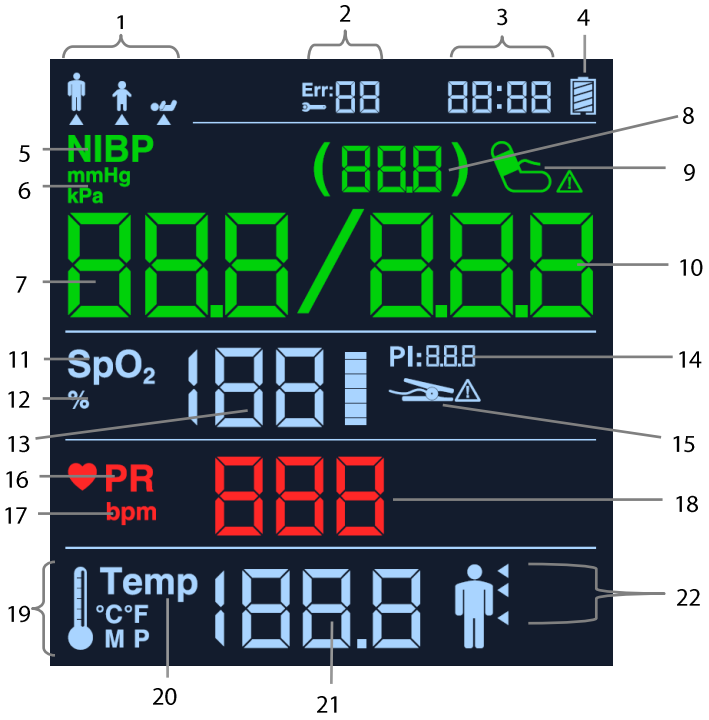
1. Handle
2. Temperature probe well
3. Connector for temperature probe
4. Input/Output connector (RS-232 connector)
   This connector can be used for software upgrade and DIAP communication.
5 AC power input
6. Equipotential grounding terminal
   When using the monitor together with other devices, connect their equipotential grounding terminals together to eliminate the potential differences between them.

2.3.4 Bottom View



1. Battery compartment door
2. Hole for installing a support

2.4 Display Screen



1. Patient category (Adult, Pediatric, Neonate)
2. Error code

   Refer to ***C Error Codes*** for additional information.
3. System time
4. Battery charge
5. NIBP label
6. NIBP unit
7. Systolic pressure
8. Mean pressure
9. NIBP cuff indicator

   When there is an error with the cuff, such as air leakage, a wrong air pressure, a weak signal, overpressure, a wrong cuff type, or patient's excessive motion, the cuff indicator displays.
10. Diastolic pressure
11 SpO_2 label
12. SpO_2 unit
13. SpO_2 value

14. Perfusion index
15. SpO_2 sensor indicator
    - Flash for 5 seconds indicates the SpO_2 sensor is off.
    - Persistently flash: indicates a weak SpO_2 signal, no pulse or too much light.
    - On: indicates SpO_2 sensor error or no sensor.
16. PR label
17. PR unit
18. PR value
19. Temperature unit (°F, °C) and measurement mode (M or P. M for Monitor, P for Predictive)
20. Temperature label
21. Temperature value
22. Temperature measurement site (Oral, Axillary, Rectal)

FOR YOUR NOTES

3 Basic Operations

3.1 Installation

⚠WARNING

- **The equipment shall be installed by personnel authorized by us.**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.**
- **The software copyright of the equipment is solely owned by us. No organization or individual shall resort to juggling, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.**
- **Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard. Any personnel who connect devices to the equipment'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 question, please contact us.**
- **If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturers or else an expert in the field, to ensure the necessary safety of patients and all devices concerned will not be impaired by the proposed combination.**

3.1.1 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or us.

If the packing case is intact, open the package and remove the equipment and accessories carefully. Check all materials against the packing list and check for any mechanical damage. Contact us in case of any problem.

WARNING

- **When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.**
- **The equipment might be contaminated during storage and transport. Before use, please verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.**

NOTE

- **Save the packing case and packaging material as they can be used if the equipment must be reshipped.**

3.1.2 Environmental Requirements

The equipment is suitable for use within the patient environment.

The operating environment of the equipment must meet the requirements specified in this manual.

The environment where the equipment is used shall be reasonably free from noises, vibration, dust, corrosive, flammable and explosive substances. If the equipment is installed in a cabinet, sufficient space in front and behind shall be left for convenient operation, maintenance and repair. Moreover, to maintain good ventilation, the equipment shall be at least 2 inches (5cm) away from around the cabinet.

When the equipment is moved from one place to another, condensation may occur as a result of temperature or humidity difference. In this case, never start the system before the condensation disappears.

WARNING

- **Make sure that the operating environment of the equipment meets the specific requirements. Otherwise unexpected consequences, e.g. damage to the equipment, could result.**

NOTE

- **The equipment uses a mains plug as a means of isolation to the mains power supply. Do not position the equipment in a place difficult to access the mains plug.**

3.2 General Operation

Read this operator's manual carefully before the use of this monitor. Familiarize yourself with the equipment's function and operation, and observe the warnings and cautions included in the manual.

3.2.1 Connection to AC Power

This monitor can be powered by AC power or battery. Connect the power cord to the AC input on the back of the monitor, and connect the other end of the power cord to the power outlet.

⚠WARNING

- **Always use the accompanying power cord with the monitor.**
- **Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, the equipment shall be operated from the battery.**

3.2.2 Using a Battery

This monitor can be equipped with rechargeable Lithium-ion battery. If a battery is installed, the monitor system will automatically switch to battery for power supply if AC power is interrupted.

Installing a Battery

Battery compartment cover is at the bottom of monitor. Refer to ***7.3 Replace a Battery*** for additional information of battery installation.

NOTE

- **When a battery has been stored for a long time, or the battery is depleted, recharge the battery at once. Otherwise, the low battery may not support to power up the monitor if the AC power is unavailable.**

Charging a Battery

The battery is charged whenever the monitor is connected to an AC power source regardless of whether the monitor is currently on or not.

When the battery is charging, the battery indicator is On. The battery charge icon on the screen dynamically displays the charging status when the monitor is powered on.

3.2.3 Connecting Accessories

Insert the hose of NIBP cuff into the cuff connector on the side of monitor; insert the SpO_2 cable into the SpO_2 cable connector on the side of monitor; insert the temperature probe cable into the TEMP probe connector on the back of monitor.

3.3 Turning On/Off Power

3.3.1 Check before Power On

It is recommended to check the followings before power on the monitor:

- Environment

  If other electric devices, such as electrosurgical unit, ultrasound, X-ray machine, are around the monitor, power off those devices if the measurement is interfered.

- Power Supply

  Check that power supply specification is met and the power cord is securely connected if mains power is used. Use only power socket that is properly grounded.

  Check that a battery is installed and fully charged if battery is used.

- Connecting Accessories

  Verify that the connection of all accessories to monitor is secured.

3.3.2 Turning Power On

Once the monitor is installed, you can get ready for measurement.

1. Check the monitor for any mechanic damage and make sure that all external cables, plug-ins and accessories are properly connected.
2. Check the power supply specification is met if mains power is used. Only use a power outlet that is properly grounded.
3. Plug the power cord into the AC power source. If you run the monitor on battery power, ensure that the battery is sufficiently charged.
4. Press the power on/off switch on the monitor's front.

After press power button, all contents on the display are lit up (refer to the figure in ***2.4 Display Screen***), and then the system gives a beep after self-test finishes. The monitor enters the normal monitoring screen.

⚠ WARNING

- **Do not use the monitor on a patient if you suspect it is not working properly, or if it is mechanically damaged. Contact your service personnel or us.**

NOTE

- **Carefully check if the system performs the self-test as described above. Contact your service personnel or us if the self-test is abnormal.**
- **If you are not sure about the displayed contents during system self-test, you can check them again in brightness adjustment screen. Refer to *3.7.7 Adjusting the Screen Brightness*.**

3.3.3 Turning off the Monitor

Before turning off the monitor:

1. Confirm that the monitoring is finished.
2. Disconnect patient cables and sensors from the patient.

Press and hold the power on/off switch for above 2 seconds to turn off monitor.

⚠ **CAUTION**

- **Although not recommended, you can press and hold the power on/off switch for 10 seconds to forcibly shut down the monitor when it could not be shut down normally or under some special situations. This may cause data loss of the monitor.**
- **When a power failure occurs, the monitor restores the latest configuration after restarts.**

NOTE

- **To completely disconnect the power supply, unplug the power cord.**

3.4 Standby

3.4.1 Entering Standby Mode

If no parameter is being measured, you can press the power switch to enter Standby mode.

The monitor will automatically enter Standby mode if there is no key operation within 10 minutes.

NOTE

- **When the monitor enters Standby mode, all the previous messages and values are cleared up.**
- **In Standby mode, the display automatically shuts down and the built-in indicator on power switch turns to yellow. When the monitor exits Standby mode, the display restores the brightness prior to entering Standby mode.**

3.4.2 Exiting Standby Mode

To exit Standby mode, you can take any one of the following ways:

- Press any hardkey.
- Connect SpO_2 sensor, and let the monitor receive SpO_2 signal for above 5 seconds.
- Remove the temperature probe from the probe well.

NOTE

- **A low battery (when  displays) will cause the monitor to automatically exit Standby mode.**

3.5 Using Keys

In different modes, the key functions vary:

Mode	Keys and Functions
Measurement Mode	 : Change patient category.  : Start/stop NIBP measurements.  : Press to: ■ Clear the parameter value displayed on the screen (such as NIBP, Temp value). ■ Clear the error code. ■ Clear NIBP cuff indicator. ■ Clear the flashing SpO_2 sensor indicator. ■ When a parameter label flashes due to the module failure, stop the flashing. ■ Remove the reminder tone of low battery.  : Press and hold for above 2 seconds to enter Parameter Setup mode.
Parameter Setup Mode	 :

Mode		Keys and Functions
		■ Press and hold for above 2 seconds to return to Measurement mode. ■ Press to toggle among the parameters.  : Switch on/off pulse tone; toggle among Temp measurement sites.
Maintenance Mode		C: Press to toggle among maintenance items.
Maintenance Items	NIBP Unit Setup	 : Toggle between mmHg and kPa.
	Temp Unit Setup	 : Toggle between °C and °F.
	System Time Setup	 : Toggle among hour and minute digits.  : Add one number based on current value.
	NIBP Leakage Test (PR parameter area displays "550")	 : Start/Stop leakage test.
	NIBP Accuracy Test (PR parameter area displays "555")	 : Start/Stop accuracy test.
	NIBP Cuff Overpressure test (PR parameter area displays "520")	 : Start NIBP cuff overpressure calibration.
	Software Version	 : View the version of each module.
	Factory Default Configuration (PR parameter area displays "000")	 : Toggle between ON and OFF: ON: Restore the factory default configuration OFF: Keep current configuration
	Working Time	/
	Brightness Setup	 : Decrease screen brightness.  : Increase screen brightness.
	DIAP Communication Setup (PR parameter area displays "001")	 : Toggle between 9600 and 19200 bps.

3.6 Parameter Setup Mode

1. In Measurement mode, press and hold C hardkey for above 2 seconds to enter Parameter Setup mode.
2. Press C hardkey in turn to switch to Temp measurement site setup, pulse tone setup.
3. Press and hold C hardkey for above 2 seconds to return to Measurement mode.

3.7 Maintenance Mode

1. Start the monitor. Within 10 seconds after you hear a beep, press and hold C hardkey to enter Maintenance mode.
2. Press C hardkey to toggle among maintenance items.
3. Power off the monitor. The settings take effect after the monitor restarts.

3.7.1 Setting NIBP Unit

1. Enter Maintenance mode.
2. Press C hardkey to switch to NIBP unit setup screen.

3. Press hardkey to toggle between mmHg and kPa.

3.7.2 Setting Temp Unit

1. Enter Maintenance mode.
2. Press C hardkey to switch to Temp unit setup screen.

3. Press hardkey to toggle between ℃ and ℉.

3.7.3 Setting System Time

1. Enter Maintenance mode.
2. Press C hardkey to switch to time setup screen.

The system time format is "00 : 00".

3. Press  hardkey to switch to the digit to be modified. The selected digit flashes.
4. Press  hardkey to modify the value.
5. After all the digits are properly set, press C hardkey to exit time setup.

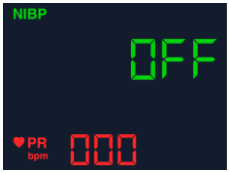
3.7.4 Viewing Software Version

1. Enter Maintenance mode.
2. Press C hardkey to switch to system software version screen.
3. Press  hardkey to view the version of each module.

The monitor will in turn display system software version, NIBP module version, SpO_2 module version, Temp module version and power management software version.

3.7.5 Loading Factory Default Configuration

1. Enter Maintenance mode.
2. Press C hardkey to switch to the screen of loading default factory setup. PR parameter area displays "000".



3. Press  hardkey to set up. Select  to load the factory default configurations. Select  to remain current configurations.

You can not change factory default configurations. You can choose to load the factory default configurations if necessary.

The factory default configurations are:

- NIBP unit setup: mmHg
- Temp unit setup: ℃
- Patient Category: Adult

- Pulse tone: On
- Temp measurement site: Oral
- Brightness: 5

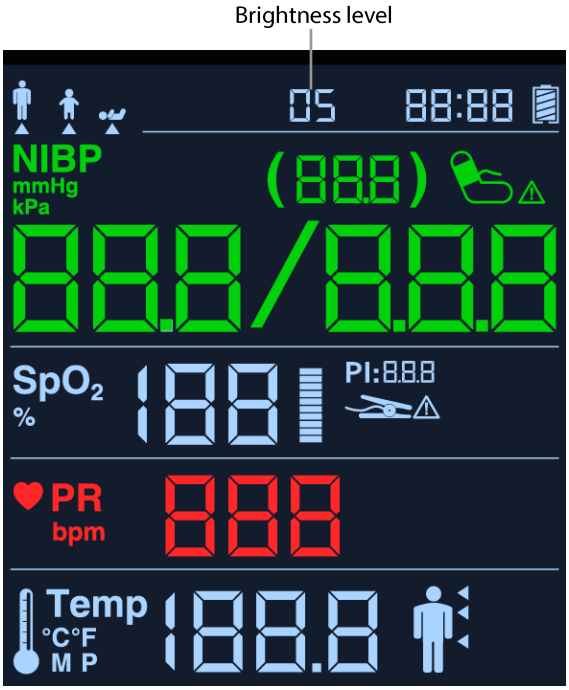
3.7.6 Viewing Working Time

1. Enter Maintenance mode.
2. Press C hardkey to switch to working time screen.

The system time area displays the total working days of the monitor. For example, "00 10" represents that the monitor has totally worked for 10 days (240 hours).

3.7.7 Adjusting the Screen Brightness

1. Enter Maintenance mode.
2. Press C hardkey to switch to brightness setup screen.
   In brightness setup, all the fields and icons are lit up. The error code area displays current brightness value.

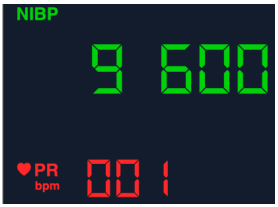


3. Press  to decrease screen brightness, or  hardkey to increase screen brightness.

The screen brightness range is 1~10. The default brightness is 5. The brightness setting takes into effect immediately.

3.7.8 DIAP Communication Setup

1. Enter Maintenance mode.
2. Press  hardkey to switch to the screen of loading default factory setup. PR parameter area displays "001".



3. Press  hardkey to toggle between 9600 bps and 19200 bps.

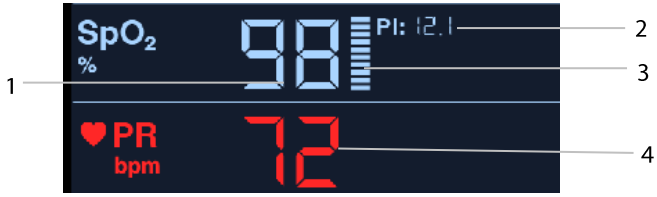
FOR YOUR NOTES

4 Monitoring SpO_2

4.1 Overview

SpO_2 monitoring is a non-invasive technique used to measure the amount of oxygenated haemoglobin and pulse rate by measuring the absorption of selected wavelengths of light. The light generated in the probe passes through the tissue and is converted into electrical signals by the photodetector in the probe. The SpO_2 module processes the electrical signal and displays a waveform and digital values for SpO_2 and pulse rate.

This device is calibrated to display functional oxygen saturation. It provides following measurements.



1. Oxygen saturation of arterial blood (SpO_2): percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin.
2. Perfusion index (PI): gives the numerical value for the pulsatile portion of the measured signal caused by arterial pulsation. PI is an indicator of the pulsatile strength. You can also use it to assess the quality of SpO_2 measurement.
   - Above 1 is optimal.
   - between 0.3 and 1 is acceptable.
   - Below 0.3 indicates low perfusion.Reposition the SpO_2 sensor or find a better site. If low perfusion persists, choose another method to measure oxygen saturation if possible.

   PI is available for Mindray SpO_2 module and Masimo SpO_2 module.
3. Perfusion indicator: the pulsatile portion of the measured signal caused by arterial pulsation.
4. Pulse rate (PR): Detected pulsations per minute. PR can be obtained through SpO_2 or NIBP measurement. When NIBP and SpO_2 are measured at the same time, the PR source is from SpO_2.

NOTE

- **A function tester or SpO_2 simulator can be used to verify the sensor functions.**
- **A functional tester or SpO_2 simulator cannot be used to assess the accuracy of a SpO_2 module or a SpO_2 sensor.**
- **A functional tester or SpO_2 simulator can be used to determine the pulse rate accuracy.**

4.2 Safety

⚠WARNING

- **Use only 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 condition.**
- **Do not use SpO_2 sensors during magnetic resonance imaging (MRI). Induced current could potentially cause burns. The sensor may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.**
- **Prolonged continuous monitoring may increase the risk of undesirable 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. Change the application site every four hours. For neonates, or patients with poor peripheral blood circulation or sensitive skin, inspect the sensor site more frequently.**

NOTE

- **Do not perform SpO_2 monitoring and NIBP measurements on the same limb simultaneously. Obstruction of blood flow during NIBP measurements may adversely affect the SpO_2 reading.**

4.3 Identifying SpO_2 Module

To identify which SpO_2 module is incorporated into your monitor, see the company logo located at the side panel. The color of the cable connector matches the company as shown below:

- Mindray SpO_2 module: a blue connector without logo.

- Masimo SpO_2 module: a purple connector with a logo of Masimo SET.
- Nellcor SpO_2 module: a grey connector with a logo of Nellcor.

The connectors for these three SpO_2 sensors are mutually exclusive.

4.4 Applying the Sensor

⚠WARNING

- **If the sensor is too tight because the application site is too large or becomes too large due to edema, excessive pressure for prolonged periods may result in venous congestion distal from the application site, leading to interstitial edema and tissue ischemia.**

NOTE

- **Place the SpO_2 sensor so that the light source is against the application site.**
- **Check if the sensor is in normal condition before monitoring. Do not use the SpO_2 sensor if the package or the sensor is found damaged.**
- **Do not apply the sensor on a limb with an intravenous infusion or arterial catheter in place.**

1. Select an appropriate sensor according to the module type, patient category and weight.
2. Clean the application site. For example, remove colored nail polish.
3. Apply the sensor to the patient.
4. Select an appropriate adapter cable according to the connector type and plug this cable into the SpO_2 connector.
5. Connect the sensor cable to the adapter cable.

4.5 Switching On/Off Pulse Tone

To switch on/off pulse tone, follow this procedure:

1. In Measurement mode, press and hold C hardkey for above 2 seconds to enter Parameter Setup mode.
2. Press C hardkey to switch to pulse tone setup.

3. Press hardkey to switch on/off pulse tone.

- When PR parameter area displays  , it indicates that pulse tone is switched off.
- When PR parameter area displays  , it indicates that pulse tone is switched on.

4. The settings take effect after you exit Measurement mode.

NOTE

- **If pulse tone is set to  , the monitor will give a beep at each pulse beat during SpO2 measurement.**

4.6 Measurement Limitations

If you doubt the measured SpO_2, check patient vital signs first. Then check the equipment and SpO_2 sensor. The following factors may influence the accuracy of measurement:

- Ambient light
- Physical movement (patient and imposed motion)
- Diagnostic testing
- Low perfusion
- Electromagnetic interference, such as MRI environment
- Electrosurgical units
- Dysfunctional haemoglobin, such as carboxyhemoglobin (COHb) and methemoglobin (MetHb)
- Presence of certain dyes, such as methylene and indigo carmine
- Inappropriate positioning of the SpO_2 sensor, or use of incorrect SpO_2 sensor
- Drop of arterial blood flow to immeasurable level caused by shock, anemia, low temperature or vasoconstrictor.

4.7 Masimo Information

- Masimo Patents

This device is covered under one or more the following U.S.A. patents: 5,758,644, 6,011,986, 6,699,194, 7,215,986, 7,254,433, 7,530,955 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.

4.8 Nellcor Information

- Nellcor Patents

This device may be covered by one or more of the following US patents and foreign equivalents: 5,485,847, 5,676,141, 5,743,263, 6,035,223, 6,226,539, 6,411,833, 6,463,310, 6,591,123, 6,708,049, 7,016,715, 7,039,538, 7,120,479, 7,120,480, 7,142,142, 7,162,288, 7,190,985, 7,194,293, 7,209,774, 7,212,847, 7,400,919.

- No Implied License

Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized replacement parts which would, alone, or in combination with this device, fall within the scope of one or more of the patents relating to this device.

FOR YOUR NOTES

5 Monitoring NIBP

5.1 Overview

The monitor uses the oscillometric method for measuring the non-invasive blood pressure (NIBP). This measurement can be used for adults, pediatrics and neonates.

Automatic non-invasive blood pressure monitoring uses the oscillometric method of measurement. To understand how this method works, we'll compare it to the auscultative method.

With auscultation, the clinician listens to the blood pressure and determines the systolic and diastolic pressures. The mean pressure can then be calculated with reference to these pressures as long as the arterial pressure curve is normal.

Since the monitor cannot hear the blood pressure, it measures cuff pressure oscillation amplitudes. Oscillations are caused by blood pressure pulses against the cuff. The oscillation with the greatest amplitude is the mean pressure. This is the most accurate parameter measured by the oscillometric method. Once the mean pressure is determined, the systolic and diastolic pressures are calculated with reference to the mean.

Simply stated, auscultation measures systolic and diastolic pressures and the mean pressure is calculated. The oscillometric method measures the mean pressure and determines the systolic and diastolic pressures.

As specified by IEC 80601-2-30, NIBP measurement can be performed during electro-surgery and discharge of defibrillator.

NIBP diagnostic significance must be decided by the doctor who performs the measurement.

NOTE

- **Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method or an intra-arterial blood pressure measurement device, within the limits prescribed by the American National Standard, Manual, electronic, or automated sphygmomanometers.**

5.2 Safety

⚠WARNING

- **During NIBP measuring, the inflated cuff will apply pressure on the application site. The clinician shall determine if NIBP measuring is suitable for the patient.**
- **Be sure to select the correct patient category setting for your patient before measurement. Do not apply the higher adult settings for pediatric or neonatal patients. Otherwise it may present a safety hazard.**
- **Do not measure NIBP on patients with sickle-cell disease or on the limb where skin damage has occurred or is expected.**
- **Use clinical judgement to determine whether to perform frequent unattended blood pressure measurements on patients with severe blood clotting disorders because of the risk of hematoma in the limb fitted with the cuff.**
- **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 measurements can be affected by the measurement site, the position of the patient, patient movement, or the patient's physiologic condition. If the NIBP measurement seems out of range or inaccurate, determine the patient's vital signs by alternative means and then verify that the monitor is working correctly.**
- **Make sure the air hose connecting the NIBP cuff and the monitor is not blocked, twisted, or tangled.**
- **Do not apply the cuff on the arm on the side of a mastectomy.**
- **Continuous cuff pressure due to connection tubing kinking may cause blood flow interference and resulting harmful injury to the patient.**

5.3 Measurement Limitations

Measurements are impossible with heart rate extremes of less than 40bpm or greater than 240bpm, or if the patient is on a heart-lung machine.

The measurement may be inaccurate or impossible:

- If arterial pressure pulses are hard to detect
- In the presence of excessive and continuous patient movement such as shivering or convulsions
- During cetrain cardiac arrhythmias
- Rapid blood pressure changes

- Severe shock or hypothermia that reduces blood flow to the peripheries
- Obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery

5.4 Measuring NIBP

5.4.1 Preparing the Patient

In order to minimize NIBP measurement errors, whenever possible check that the patient:

- Is comfortably seated
- Has legs uncrossed
- Has feet flat on the floor
- Has back and arm supported, and
- The middle of the cuff at the level of the right atrium of the heart.

NOTE

- **It is recommended that the patient relax as much as possible before the NIBP measurement is performed and that the patient does not talk during measurement.**
- **It is recommended that the patient sit still for 5 min before the first measurement is taken.**
- **The operator should not touch the cuff and tubing during the NIBP measurement.**

5.4.2 Prepare to Measure NIBP

1 Power on the monitor.

2. Verify that the patient category is correct. If not, change the patient category by pressing the hard key  in measurement mode. Refer to ***3.5 Using Keys*** for details.
3. Connect the NIBP hose to the monitor.
4. Select the appropriate sized cuff by referring to the limb circumference marked on the cuff.

   The width of the cuff should be 40% (50% for neonates) of the limb circumference, or 2/3 of the upper arm's length. The inflatable part of the cuff should be long enough to encircle at least 50% to 80% of the limb.
5. Apply the cuff to an upper arm or thigh of the patient and make sure the Φ marking on the cuff matches the artery location. Do not wrap the cuff too tightly around the limb. It may cause discoloration, and ischemia of the extremities. Make sure that the cuff edge falls within the marked range. If it does not, use a cuff that fits better.

6. Connect the cuff to the air tubing and make sure that the bladder inside the cover is not folded and twisted. Air must pass unrestricted through the tubing.

⚠WARNING

- **Continuous cuff pressure due to connection tubing kinking may cause blood flow interference and resulting harmful injury to the patient.**

NOTE

- **The use of the equipment is restricted to one patient at a time.**
- **For known hypertensive patients, you need to set initial cuff pressure to a higher value to reduce the measurement time.**

5.4.3 Starting and Stopping Measurements

Press  hardkey on the monitor's front panel to start or stop a NIBP measurement.

⚠WARNING

- **Long-term non-invasive blood pressure measurements may cause purpura, ischemia and neuropathy in the limb with the cuff. Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth and sensitivity. If any abnormity occurs, move the cuff to another site or stop the blood pressure measurements immediately.**

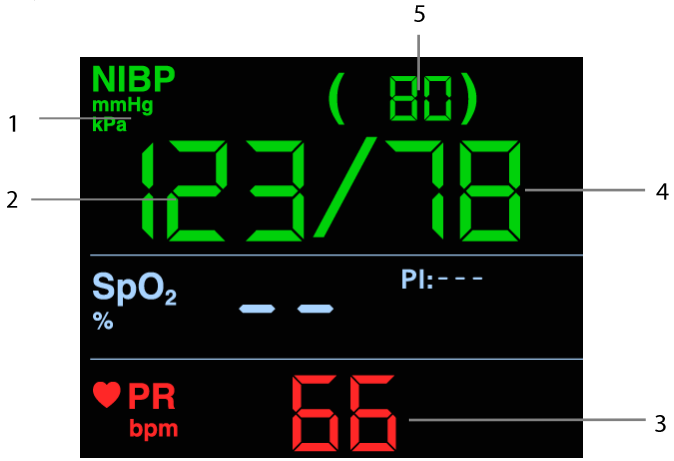
5.4.4 Correcting the Measurement if Limb is not at Heart Level

The cuff should be applied to a limb at the same level as the patient's heart. If the limb is not at the heart level, to the displayed value:

- Add 0.75 mmHg (0.10 kPa) for each centimetre higher, or
- Deduct 0.75 mmHg (0.10 kPa) for each centimeter lower.

5.5 Understanding the NIBP Numerics

The NIBP display shows numerics only as below. Your display may be configured to look slightly different.



1. Unit of pressure: mmHg or kPa. Refer to ***3.7.1 Setting NIBP Unit*** to set the unit to [**mmHg**] or [**kPa**].
2. Systolic pressure
3. Pulse rate (PR): detected pulsations per minute. PR can be obtained through SpO_2 or NIBP measurement. The PR source is from SpO_2 if SpO_2 and NIBP are measured simultaneously.
4. Diastolic pressure
5. Mean pressure

FOR YOUR NOTES

6 Monitoring Temp

6.1 Overview

The SmarTemp™ Temp module is intended for monitoring oral, axillary and rectal temperature of adult and pediatric patients and axillary temperature of neonatal patients.

Temperature can be measured in either Predictive mode or Monitor mode. The default is Predictive mode.

⚠ WARNING

- **Do not take oral temperature on the infant (0-3 years).**
- **Do not take rectal temperature on the neonate (0-28 days).**
- **Use only the specified temperature probe and probe cover. Using other probe or probe cover, or not using probe cover may cause damage to the monitor or failure to meet the declared specifications in this manual.**
- **The temperature probe cover is disposable. Re-use of probe cover may result in patient cross-contamination.**
- **Use disposable probe covers for temperature measurement. Failure to use a probe cover can cause inaccurate temperature readings, and patient cross-contamination.**
- **Check the disposable probe cover for damage before using. Never use any probe cover for temperature measurement in case of damage or contamination.**
- **Be careful to avoid damaging the temperature probe. Place the temperature probe in the probe well if not in use.**
- **Prior to taking a temperature, instruct the patient not to bite down on the probe, as patient injury and damage to the probe may result.**
- **In the rectal mode, incorrect probe placement may result in bowel perforation.**
- **Wash hands after temperature is taken. This will significantly reduce the risk of cross contamination and nosocomial contamination.**
- **Ensure that probe covers are disposed of according to local regulations or hospital's requirements.**
- **Accuracy verification of the temperature module is required every two years or according to your hospital's policy. Please contact our Customer Service if accuracy verification is needed.**

NOTE

- **Patient actions may interfere with oral temperature readings. Ingesting hot or cold liquids, eating food, chewing gum, brushing teeth, smoking, or performing strenuous activities may affect temperature readings for up to 20 minutes after the activity has ended.**
- **In the axillary mode, the probe shall directly contact with patient's skin. Measuring through patient's clothes or long-term exposure of patient's armpit to the air may result in inaccurate temperature reading.**
- **Choose appropriate probe according to patient type and measurement site. Using the incorrect probe may cause patient's discomfort and inaccurate measurements.**
- **Improper use of probe may also cause patient's discomfort and inaccurate measurements.**

6.2 Setting Temp

Selecting Measurement Site

The temperature module can be configured with 2 types of temperature probe:

- oral/axillary probe (blue), and
- rectal probe (red)

The blue oral/axillary probe shall only be used with blue probe well, while the red rectal probe shall only be used with red well.

Be sure to select correct probe according to the measurement site.

- Oral/Axillary probe: This type of probe is intended for taking oral or axillary temperature of adult and pediatric patients, or axillary temperature of neonatal patient.
- Rectal probe: This type of probe is intended for taking rectal temperature of adult and pediatric patient.

1. In Measurement mode, press and hold C hardkey for above 2 seconds to enter Parameter Setup mode.

2. Press C hardkey to switch to Temp parameter setup.
3. Press hardkey to toggle between measurement sites.
4. Press and hold C hardkey for above 2 seconds to return to Measurement mode, and then the settings take effect; or press and hold

 hardkey for above 2 seconds to shut down, restart the monitor, and then the settings take effect.

Only when the probe is in the probe well, you can select the measurement site.

Setting Temp Unit

Refer to ***3.7.2 Setting Temp Unit***.

6.3 Taking a Temperature

6.3.1 Entering Predictive Mode and Monitor Mode

After power-on, the monitor automatically enters Predictive mode (P).

In Predictive mode, when neither measurement is taken nor is the probe replaced in the probe well in 60 seconds after the probe is withdrawn from the well, the monitor enters Monitor mode (M).

Replace the probe in the well, the monitor mode restores to Predictive mode (P).

6.3.2 Taking a Temperature in the Predictive Mode

In Predictive mode, when a temperature value is obtained. The value always displays on the screen.

1. Verify that the probe is placed in the probe well.
2. Verify that the temperature measurement site is correct.
3. Unplug the probe from the probe well and insert it into a cover in the probe cover pack. Press the probe handle down firmly until the cover engages with the probe.

   The temperature module starts to warm up when the probe is taken out. The warming up time is about 2 seconds in room temperature. The monitor issues two beeps and Temp parameter area displays "- -"when warm-up is complete. Then you can place the probe at measurement site.
4. Place the probe at measurement site and wait till the measurement stabilizes. When the segment moves clockwise, it indicates that the monitor is taking the measurement.
   - When taking an oral temperature, apply the probe under the patient's tongue from either side of the mouth. Verify that the probe reaches the rear sublingual pocket. Have the patient close his/her lips to hold the probe. Hold the probe in place. Make sure that the probe contacts with the patient's oral tissue throughout the measurement.
   - When taking an axillary temperature, lift the patient's arm to expose the entire armpit. Apply the probe as high as possible in the armpit. Check that

the probe tip is completely surrounded by the axillary tissue. Lower the patient's arm so that it is tightly placed at the patient side. Keep the patient's arm and the probe in place throughout the measurement.

- When taking a rectal temperature, separate patient's buttocks with one hand, and the probe 1.5 cm inside the rectum with the other hand. For pediatric patient, depth of insertion shall be less. Tilt the probe so that it always contacts with patient's tissue. Lubricant can be used in rectal mode.

The monitor will give a beep as the temperature measurement is complete. The temperature reading displays continuously until the probe is taken out from the probe well.

5. Withdraw the probe. Press firmly the ejection button on the top of the probe to eject the probe cover. Replace the probe into the probe well.

NOTE

- **In Predictive mode, temperature probe shall be placed to the measurement site as soon as probe warmup is complete; otherwise, inaccurate temperature reading may result.**
- **In Predictive mode, if the probe has a high temperature due to the environmental temperature or other causes, cool the probe and then measure the patient's temperature.**

6.3.3 Taking a Temperature in Monitor Mode

To measure a temperature in Monitor mode,

1. Verify that the temperature measurement site is correct.
2. Unplug the probe from the probe well and hold it for 60 seconds till the monitor automatically enters Monitor mode.
3. Insert the probe into a cover in the probe cover pack. Press the probe handle down firmly until the cover engages with the probe.
4. Place the probe to the measurement site and then start measuring. Refer to Step 4 in ***6.3.2 Taking a Temperature in the Predictive Mode*** for how to place a probe.
5. Withdraw the probe. Press firmly the ejection button on the top of the probe to eject the probe cover. Replace the probe into the probe well.

NOTE

- **In Monitor mode, record the measured value prior to taking away the probe from measurement site. The monitor will automatically stop measuring temperature after 10 minutes from the start of the measurement.**

6.4 Disinfecting Temperature Probe

The recommended disinfectants include: ethanol 70%, isopropanol 70%, glutaraldehyde-type 2% liquid disinfectants.

To disinfect the temperature probe:

1. Disconnect the temperature probe from Temp connector.
2. Disinfect the probe with a soft cloth dampened with the recommended disinfectant.
3. Wipe off all the remaining disinfectants from the probe with a soft cloth dampen with water.
4. Dry the probe in a cool place.

⚠ WARNING

- **Perform the decontamination or cleaning process with the monitor powered down and power cord removed.**
- **The used soft cloth shall be properly disposed of.**

FOR YOUR NOTES

7 Battery

7.1 Overview

The monitor is designed to operate from battery power when AC power supply is not available. In case of power failure, the equipment will automatically run power from battery. So we recommend you always install a fully charged battery in the equipment.

Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, the equipment shall be operated from the battery.

CAUTION

- **Remove the battery before transporting the equipment or if the equipment will not be used for a long time.**

NOTE

- **It is recommended to always install a fully charged battery in the monitor to ensure normal monitoring in case of accidental power failure.**

The on-screen battery symbol indicate the battery status as follows:

-  Indicates that battery works correctly. The solid portion represents the current charge level of the battery in proportion to its maximum charge level.
-  Indicates that the battery has low charge level and needs to be charged.
-  Indicates that the battery is almost depleted and need to be charged immediately. Otherwise, the monitor will shut down automatically.

The capacity of the internal battery is limited. When the battery is low, symbol  persistently flashes, and the monitor gives a beep every 10 seconds to remind you to charge the battery. Press C hardkey to switch off the reminder tone.

If the battery is depleted, the battery symbol  on the screen starts to flash, and the monitor gives a beep every 5 seconds to remind you to charge the battery. The reminder tone can not be switched off.

7.2 Charging a Battery

The battery is charged whenever the monitor is connected to an AC power source regardless of whether or not the monitor is currently on. When battery is charging, the AC power indicator and battery indicator are both On. The battery status symbol on the monitor screen displays  when the charging is complete.

7.3 Replace a Battery

1. Power off the monitor.
2. Open the battery compartment door.
3. Push aside the latch fixing the battery to be replaced and remove the battery.
4. Place a new battery into the slot with its contact point inward.
5. Close the battery compartment door.

7.4 Battery Guidelines

Life expectancy of a battery depends on how frequent and how long it is used. For a properly maintained and stored lithium ion battery, its life expectancy is about 3 years. For more aggressive use models, life expectancy can be less. We recommend replacing lithium ion batteries every 3 years.

To get the most out of the battery, observe the following guidelines:

- The battery performance test must be performed once a year, before monitor repairs, or whenever the battery is suspected as being the source of the problems.
- Condition the batteries once when they are used or stored for three months, or when their run time becomes noticeably shorter.
- Take out the battery before the monitor is transported or will not be used for more than 3 months.
- Remove the battery from the monitor if it is not being used regularly. (Leaving the battery in a monitor that is not in regular use will shorten the life of the battery).
- The shelf life of a Lithium Ion battery is about 6 months when the battery is stored with the battery power being 50% of the total power. In 6 months the battery power must be depleted before the Lithium Ion battery is fully charged. Then run the monitor on this fully charged battery. When its battery power becomes 50% of the total power, take out the battery from the monitor and store it.
- When storing batteries, make sure that the battery terminals do not come into contact with metallic objects. If batteries are stored for an extended period of time, they should be placed in a cool place with a partial charge of 40% to 60% capacity. Storing batteries at high temperature for an extended period of time will significantly shorten the life expectancy of a battery. Do not store the battery at a temperature beyond -20°C-60°C.

⚠ WARNING

- **Keep the battery out of children's reach.**
- **Use only specified batteries.**
- **If the battery shows signs of damage or signs of leakage, replace it immediately. Do not use a faulty battery in the monitor.**

7.5 Battery Maintenance

7.5.1 Conditioning a Battery

A battery should be conditioned before it is used for the first time. A battery conditioning cycle is one complete, uninterrupted charge of the battery, followed by an uninterrupted battery discharge and charge. Batteries should be conditioned regularly to maintain their useful life.

To condition a battery, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring or measuring.
2. Insert the battery in need of conditioning in the battery slot of the monitor.
3. Connect the monitor to AC power. Allow the battery to be charged uninterrupted till the battery is full and the battery indicator is off.
4. Remove AC power and allow the monitor to run from the battery until it shuts off.
5. Again connect the monitor to AC power. Allow the battery to be charged uninterruptedly till the battery is full and the battery indicator is off.

NOTE

- **The actual battery capacity will decrease over time with use of batteries. For old batteries, the full capacity battery symbol does not indicate the capacity and operating time of this battery can still fulfill battery specifications in the operator's manual. Please replace the battery if its operating time is significantly lower than the specified time.**

7.5.2 Checking a Battery

The performance of a rechargeable battery may deteriorate over time. The battery performance test must be performed once a year, before monitor repairs, or whenever the battery is suspected as being the source of the problems.

To check the performance of a battery, follow this procedure:

1. Disconnect the monitor from the patient and stop all monitoring or measuring.

2. Install the battery.
3. Connect the monitor to AC power. Allow the battery to be charged uninterrupted till the battery is full and the battery indicator is off.
4. Remove AC power and allow the monitor to run from the battery until it shuts off.

The operating time of a battery reflects their performance directly. If the operating time of a battery is noticeably shorter than that stated in the specifications, contact your service personnel.

NOTE

- **The battery might be damaged or malfunctioned if its operating time is too short after being fully charged. The operating time depends on the configuration and operation. For example, measuring NIBP more frequently will also shorten the operating time.**
- **When a battery has visual signs of damage, or no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly.**

7.6 Recycling a Battery

When a battery has visual signs of damage, or no longer holds a charge, it should be replaced. Remove the old battery from the monitor and recycle it properly. To dispose of the batteries, follow local laws for proper disposal.

⚠ WARNING

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

8 Care and Maintenance

The monitor should be maintained and cleaned on a regular basis. This chapter describes the basic cleaning, disinfection and test method.

WARNING

- **Failure for the responsible individual, hospital or institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.**
- **The safety checks or maintenance involving any disassembly of the equipment should be performed by professional servicing personnel. Otherwise, undue equipment failure and possible health hazards could result.**
- **If you discover a problem with any of the equipment, contact your service personnel or us.**
- **The responsible hospital or institution shall carry out all cleaning and disinfection procedure specified in this chapter.**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by the personnel trained and authorized by our company only.**
- **No modification of this equipment is allowed.**
- **The service personnel must be properly qualified and thoroughly familiar with the operation of the equipment.**

8.1 Cleaning and Disinfection

In this chapter we only describe cleaning and disinfection of the main unit. For the cleaning and disinfection of other reusable accessories, refer to instructions for use of corresponding accessories.

Keep you equipment and accessories clean. To avoid damage to the equipment, follow these rules:

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

WARNING

- **Be sure to shut down the system and disconnect all power cables from the outlets before cleaning the equipment.**
- **Use only the substances approved by us and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by unapproved substances or methods.**
- **We make no claims regarding the efficacy of the listed chemicals or methods as a means for controlling infection. For the method to control infection, consult your hospital's Infection Control Officer or Epidemiologist.**

CAUTION

- **If you spill liquid on the equipment or accessories, contact us or your service personnel.**

8.1.1 Cleaning

Your equipment should be cleaned on a regular basis. If there is heavy pollution or lots of dust and sand in your place, the equipment should be cleaned more frequently. Before cleaning the equipment, consult your hospital's regulations for cleaning the equipment.

Recommended cleaning agents are:

- Sodium hypochlorite bleach (diluted)
- Hydrogen peroxide (3%)
- Ethanol (70%)
- Isopropanol (70%)

To clean your equipment, follow these rules:

1. Shut down the monitor and disconnect it from the power line.
2. Clean the display screen using a soft, clean cloth dampened with a glass cleaner.
3. Clean the exterior surface of the equipment using a soft cloth dampened with the cleaner.
4. Wipe off all the cleaning solution with a dry cloth after cleaning if necessary.
5. Dry your equipment in a ventilated, cool place.

8.1.2 Disinfecting

Disinfection may cause damage to the equipment and is therefore not recommended

for this monitor unless otherwise indicated in your hospital's servicing schedule. Cleaning equipment before disinfecting is recommended.

The recommended disinfectants include: ethanol 70%, isopropanol 70%, Perform® classic concentrate OXY.

8.2 General Inspection

Before every first use, after your equipment has been used for 6 to 12 months, or whenever your equipment is repaired or upgraded, a thorough inspection should be performed by qualified service personnel to ensure the reliability.

Follow these guidelines when inspecting the equipment:

- Make sure that the environment and power supply meet the requirements.
- Inspect the equipment and its accessories for mechanical damage.
- Inspect all power cords for damage, and make sure that their insulation is in good condition.
- Make sure that only specified accessories are applied.
- Make sure that the battery meets the performance requirements.
- Make sure that the monitor is in good working condition.

In case of any damage or abnormity, do not use the equipment. Contact the hospital's biomedical engineers or your service personnel immediately.

8.3 Maintenance and Testing Schedule

The following maintenance and tests, except for visual inspection, power on test, and battery check, shall be carried out by the service personnel only. Contact your service personnel if any maintenance is required. Make sure to clean and disinfect the equipment before any test and maintenance.

CAUTION

- **Service personnel should acquaint themselves with the test tools and make sure that test tools and cables are applicable.**

Check/Maintenance Item		Recommended Frequency
Preventive Maintenance		
Visual inspection		When first installed or after reinstalled.
NIBP Tests	Pressure check	1. If the user suspects that the measurement is incorrect.
	Leakage Test	

	Calibration	2. Following any repairs or replacement of the module. 3. At least once a year.
Performance Test		
SpO_2 Test		1. If the user suspects that the measurement is incorrect. 2. Following any repairs or replacement of the module. 3. At least once every two years. Note: At least once a year is recommended for NIBP.
NIBP test and calibration	Pressure check	
	Leakage test	
	Calibration	
Temp test		
Electrical safety tests		
Electrical safety tests		At least once every two years, or as required.
Other tests		
Power on test		1. When first installed or after reinstalled. 2. Following any maintenance or the replacement of any main unit parts.
Battery check	Functionality test	1. When first installed. 2. Whenever a battery is replaced.
	Performance test	Once a year or if the battery run time reduced significantly.

8.4 Checking Monitor Information

1. Enter Maintenance mode. Refer to ***3.7 Maintenance Mode***.
2. Press C hardkey to switch to system software version screen.
3. Press hardkey to display the version of each module.

8.5 NIBP Leakage Test

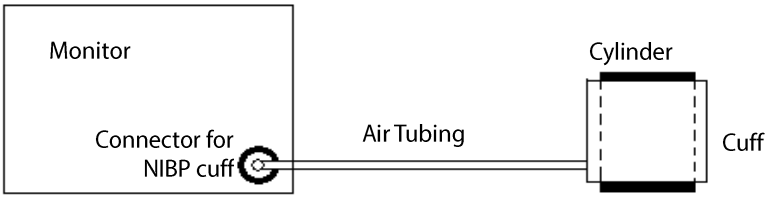
The NIBP leakage test checks the integrity of the system and of the valve. It is required at least once a year or when you doubt the measured NIBP. If the test failed, corresponding prompt messages will be given. If no message is displayed, it means no leakage is detected.

Tools required:

- An adult cuff
- An air tubing
- A correct sized cylinder

Follow this procedure to perform the leakage test:

1. In Measurement mode, press  hardkey set the patient category to  .
2. Connect the cuff to the NIBP cuff connector on the monitor.
3. Wrap the cuff around the cylinder as shown below.



4. Enter Maintenance mode. Refer to ***3.7 Maintenance Mode***. Press  hardkey to switch to NIBP Leakage Test screen. In the PR parameter area, the code "550" is displayed.

6. Press  hardkey to start leakage test. The real-time pressure is displayed in the mean pressure area.

   In the process, you can press  hardkey to terminate the current leakage test.
7. When the leakage test is completed, the cuff releases gas automatically.

If  is displayed in the error code area, it indicates the leakage test is passed and that the system has no leakage. If  is displayed, it indicates that the NIBP airway may have leakages. Check the tubing and connections for leakages. If you ensure that the tubing and connections are all correct, perform a leakage test again. If the problem persists, contact your service personnel.

NOTE

- **The leakage test is intended for use to simply determine whether there are leakages in the NIBP airway.**

8.6 NIBP Accuracy Test

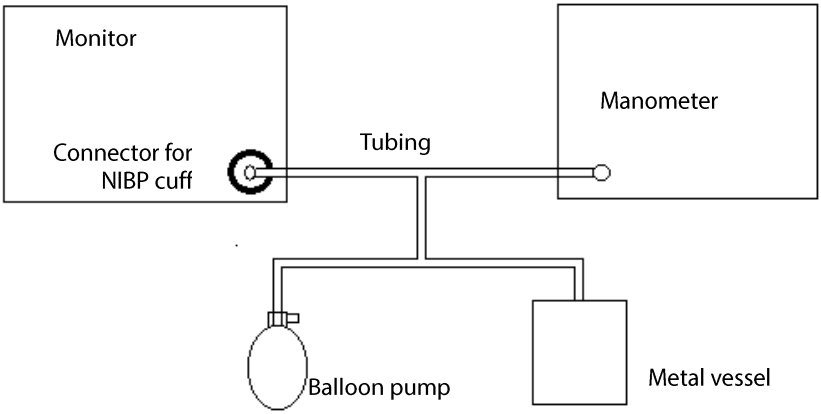
The NIBP accuracy test is required at least once a year or when you doubt the measured NIBP.

Tools required:

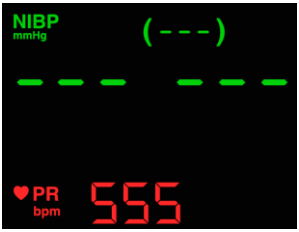
- T-shape connector
- Tubing
- Balloon pump
- Metal Vessel (volume 500±25 ml)
- Reference manometer (calibrated with accuracy equal to or better than 0.75 mmHg)

Follow this procedure to perform the accuracy test:

1. Connect the equipment as shown.



2. Before inflation, check that the reading of the manometer should be 0. If not, open the valve of the balloon pump to let the whole airway open to the atmosphere. Close the valve of the balloon pump after the reading is 0.
3. Enter Maintenance mode. Refer to ***3.7 Maintenance Mode***. Then press C hardkey to display the NIBP accuracy test screen. In the PR parameter area, the code "555" is displayed.



4. Press  hardkey to start accuracy test. The real-time pressure is displayed in the mean pressure area.

   In this process, you can press  hardkey to terminate the current accuracy test. An invalid value is displayed in the mean pressure area.
5. Check the manometer values and the monitor reading. Both should be 0mmHg.
6. Raise the pressure in the metal vessel to 50 mmHg with the balloon pump. Then wait for 10 seconds until the measured values become stable.
7. Compare the manometer values with the displayed values. The difference between the manometer and displayed values should be within ± 3 mmHg.
8. Raise the pressure in the metal vessel to 200 mmHg with the balloon pump. Then wait for 10 seconds until the measured values become stable. Repeat step 7.

If the difference between the manometer and displayed values is greater than 3 mmHg, contact your service personnel.

8.7 Calibrating NIBP

NIBP is not user-calibrated. Cuff-pressure transducers must be verified and calibrated once a year by a qualified service professional. Contact your service personnel when a calibration is necessary.

FOR YOUR NOTES

9 Accessories

WARNING

- **Use accessories specified in this chapter. Using other accessories may cause damage to the equipment or not meet the claimed specifications.**
- **Disposable accessories are not designed to be reused. Reuse may cause a risk of contamination and affect the measurement accuracy.**
- **Check the accessories and their packages for any sign of damage. Do not use them if any damage is detected.**
- **The disposable accessories shall be disposed of according to hospital's regulations.**
- **The accessory material that contacts the patients or other staff has undertaken the bio-compatibility test and is verified to be in compliance with ISO 10993-1.**
- **Use the accessories before the expiry date if their expiry date is indicated.**

9.1 SpO_2 Accessories

Extension Cable

Module Type	Remarks	Part No.
Mindray SpO_2 Module	7 pins, 2.5 m	0010-20-42710
	7 pins, 1.2 m	040-001443-00
Masimo SpO_2 Module	8 pins, 2.1 m	040-000332-00
Nellcor SpO_2 Module	8 pins, 2.5 m	0010-20-42712

SpO_2 Sensors

Mindray SpO_2 module				
Type	**Model**	**Patient Category**	**Application Site**	**Part No.**
Disposable	MAX-AI	Adult (>30Kg)	Finger	0010-10-12202
	MAX-PI	Pediatric (10 to 50Kg)	Finger	0010-10-12203
	MAX-II	Infant (3 to 20Kg)	Toe	0010-10-12204
	MAX-NI	Neonate (<3Kg), Adult (>40Kg))	Foot, Finger	0010-10-12205
	520A	Adult (non-adhesive)	Finger	520A-30-64101

Mindray SpO_2 module				
Type	**Model**	**Patient Category**	**Application Site**	**Part No.**
	520P	Pediatric (non-adhesive)	Finger	520P-30-64201
	520I	Infant (non-adhesive)	Toe	520I-30-64301
	520N	Neonate (non-adhesive)	Foot	520N-30-64401
Reusable	DS-100A	Adult (Finger)	Finger	9000-10-05161
	OXI-P/I	Pediatric, infant	Finger, Foot	9000-10-07308
	OXI-A/N	Adult, neonate	Finger, Foot	9000-10-07336
	ES-3212-9	Adult	Finger	0010-10-12392
	518B	Neonate	Foot	518B-30-72107
	518C	Neonate	Foot	040-000330-00
	512E	Adult	Finger	512E-30-90390
	512F	Adult (Split type)	Finger	512F-30-28263
	512F	Adult (Integrated type)	Finger	115-012807-00
	512G	Pediatric	Finger	512G-30-90607
	512H			512H-30-79061

Masimo SpO_2 module				
Type	**Model**	**Patient Category**	**Application Site**	**Part No.**
Disposable	LNCS NeoPt-L	Pediatric, neonate	Foot	0010-10-42626
	LNCS Neo-L	Neonate	Foot	0010-10-42627
	LNCS Inf-L	Infant	Toe	0010-10-42628
	LNCS Pdtx	Pediatric	Finger	0010-10-42629
	LNCS Adtx	Adult	Finger	0010-10-42630
	LNCS NeoPt	Neonate (<1 kg)	Toe	040-000295-00
	LNCS Neo	Adult and pediatric (>40 Kg), neonate(<3 Kg)	Finger	040-000296-00
	LNCS Inf	Pediatric and neonate (3 to 20 Kg)	Finger	040-000297-00
Reusable	LNCS DCI	Adult	Finger	0010-10-42600
	LNCS DCIP	Pediatric	Finger	0010-10-42634
	LNCS YI	Adult, pediatric,	Finger, Foot	0010-10-43016

Masimo SpO_2 module				
Type	**Model**	**Patient Category**	**Application Site**	**Part No.**
		neonate		

Nellcor SpO_2 Module				
Type	**Model**	**Patient Category**	**Application Site**	**Part No.**
Disposable	MAX-AI	Adult (>30Kg)	Finger	0010-10-12202
	MAX-PI	Pediatric (10 to 50Kg)	Finger	0010-10-12203
	MAX-II	Infant (3 to 20Kg)	Toe	0010-10-12204
	MAX-NI	Neonate (<3Kg), Adult (>40Kg)	Finger, Foot	0010-10-12205
Reusable	DS-100A	Adult	Finger	9000-10-05161
	OXI-P/I	Pediatric, infant	Finger, Foot	9000-10-07308
	OXI-A/N	Adult, neonate	Finger, Foot	9000-10-07336
	D-YS	Adult, Pediatric, infant, neonate	Finger, Foot	0010-10-12476

Wavelength emited by the sensors is between 600 nm and 1000 nm.

The maximum photic output consumption of the sensor is less than 18 mW.

The information about the wavelength range and maximum photic output consumption can be especially useful to clinicians (for example, when photodynamic therapy is performed).

9.2 NIBP Accessories

Tubing

Type	Patient Category	Part No.
Reusable	Adult, pediatric, infant	6200-30-09688
	Neonate	6200-30-11560

Reusable Cuff

Model	Patient Category	Measurement Site	Limb Circumference (cm)	Part No.
CM1200	Small Infant	Arm	7 to 13	115-002480-00
CM1201	Infant		10 to 19	0010-30-12157
CM1202	Pediatric		18 to 26	0010-30-12158
CM1203	Adult		24 to 35	0010-30-12159
CM1204	Large adult		33 to 47	0010-30-12160
CM1205	Adult	Thigh	44 to 66	0010-30-12161
CM1300	Small infant	Arm	7 to 13	040-000968-00
CM1301	Infant		10 to 19	040-000973-00
CM1302	Pediatric		18 to 26	040-000978-00
CM1303	Adult		24 to 35	040-000983-00
CM1304	Large adult		33 to 47	040-000988-00
CM1305	Adult	Thigh	46 to 66	040-000993-00

Disposable Cuff

Model	Patient Category	Measurement Site	Limb Circumference (cm)	Part No.
CM1500A	Neonate	Arm	3.1 to 5.7	001B-30-70692
CM1500B			4.3 to 8.0	001B-30-70693
CM1500C			5.8 to 10.9	001B-30-70694
CM1500D			7.1 to 13.1	001B-30-70695
CM1500E			8 to 15	001B-30-70681
CM1501	Infant		10 to 19	001B-30-70697
CM1502	Pediatric		18 to 26	001B-30-70698
CM1503	Adult		24 to 35	001B-30-70699
CM1504	Large adult		33 to 47	001B-30-70700
CM1505	Adult	Thigh	46 to 66	001B-30-70701

9.3 Temp Accessories

Probe Well

Type	Description	Part No.
Reusable	Blue, oral /axillary	M09A-20-62062
	Red, Rectal	M09A-20-62062-51

Temp Probes

Type	Patient Category	Measurement Site	Part No.
Reusable	Adult, Pediatric, Neonate	Oral/ Axillary	6006-30-39598
	Adult, Pediatric	Rectal	6006-30-39599

Probe Cover

Type	Patient Category	Description	Part No.
Disposable	Adult, Pediatric, Neonate	Cover, 20 pcs/pack	M09A-20-62124
	Adult, Pediatric, Neonate	Cover, 200 pcs/pack	M09A-30-62126
	Adult, Pediatric, Neonate	Cover, 2000 pcs/pack	M09A-30-62128

FOR YOUR NOTES

A Product Specifications

A.1 Classifications

The equipment is classified, according to IEC60601-1:

Type of protection against electrical shock	CLASS I EQUIPMENT, equipment energized from an external and internal electrical power source.
Degree of protection against electrical shock	DEFIBRILLATION-PROOF TYPE CF APPLIED PART for SpO_2, NIBP, and TEMP
Mode of operation	Continuous
Degree of protection against harmful ingress of water	IPX 1 (Protection against vertically falling water drops)
Degree of safety of application in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE	EQUIPMENT not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR or WITH OXYGEN OR NITROUS OXIDE
Degree of mobility	Portable

A.2 Environmental Specifications

Main Unit

Item	Operating conditions	Storage conditions
Temperature (°C)	0 to 40 (without Temp module) 5 to 40 (with Temp module)	-20 to 60
Relative humidity (noncondensing)	15% to 95%	10% to 95%
Barometric (kPa)	57.0 to 107.4	16.0 to 107.4

WARNING

- **The equipment may not meet the performance specifications if stored or used outside the specified temperature and humidity ranges.**

NOTE

- **The environmental specifications of unspecified parameters are the same as those of the main unit.**

A.3 Power Supply Specifications

AC Power

Line voltage	100 to 240 VAC ~ (±10%)
Current	0.9 to 0.5A
Frequency	50/60 Hz (±3Hz)
Fuse	T2AL-250V

Battery

Battery (Standard)	
Battery Type	LI13I001A, Chargeable Lithium-Ion
Voltage	11.1 VDC
Capacity	2600 mAh
Run time	At least 11 hours when powered by a new fully-charged battery at 25°C±5°C with SpO_2 cable connected, and auto NIBP measurements at an interval of 15 minutes.
Charge time	Monitor power off: less than 3 hours to 90%; less than 4 hours to 100% Monitor power on: less than 6 hours to 90%; less than 7.5 hours to 100%
Shutdown delay	At least 20 minutes (after a low battery prompt first occurs)
Battery (Optional)	
Battery Type	LI23S002A, Chargeable Lithium-Ion
Voltage	11.1 VDC
Capacity	4500 mAh
Run time	At least 22 hours when powered by a new fully-charged battery at 25°C±5°C with SpO_2 cable connected, and auto NIBP measurements at an interval of 15 minutes.
Charge time	Monitor power off: less than 5.5 hours to 90%; less than 6.5 hours to 100% Monitor power on: less than 10.5 hours to 90%; less than 11.5 hours to 100%
Shutdown delay	At least 20 minutes (after a low battery prompt first occurs)

A.4 Physical Specifications

Size	134mm×120mm×243mm
Weight	≤1.9 kg (with SpO_2 module, NIBP module and a battery) ≤1.7 kg (with NIBP module and a battery)

A.5 Hardware Specifications

A.5.1 Display

Screen type	Segment display
Screen Size	90mm X 99mm

A.5.2 LEDs

Power on LED	1 (two color: yellow/green)
AC power LED	1 (green)
Battery LED	1 (green)

A.5.3 Audio Indicator

Buzzer	Give pulse tone, power-on self check tone.

A.5.4 Monitor Interface Specifications

Power	1 AC power input connector
RS 232 connector	1
Equipotential Grounding Terminal	1

A.6 Measurement Specifications

A.6.1 SpO_2

Mindray SpO_2 Module

Standards	Meet standards of ISO 80601-2-61
*Measurement accuracy verification: The SpO_2 accuracy has been verified in human experiments by comparing with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurement are statistically distributed and about two-thirds of the measurements are expected to come within the specified accuracy range compared to CO-oximeter measurements.	
SpO_2 Measurement range	0 to 100%
PI measurement range	0.05% to 20%
SpO_2 Resolution	1%
Accuracy	70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured without motion in neonate mode) 0% to 69%: Not specified.

*Studies were performed to validate the accuracy of Pulse Oximeter with neonatal SpO_2 sensors by contrast with a CO-Oximeter. Some neonates aged from 1 day to 30 days with a gestation age of 22 weeks to full term were involved in this study. The statistical analysis of data of this study shows the accuracy (Arms) is within the stated accuracy specification. Please see the following table.

Sensor type	Totally neonates	Data	Arms
518B	97 (51 male & 46 female)	200 pairs	2.38%
520N	122 (65 male & 57 female)	200 pairs	2.88%
The Pulse Oximeter with neonatal SpO_2 sensors was also validated on adult subjects.			
Refreshing rate	1 s		

Masimo SpO_2 Module

Standards	Meet standards of ISO 80601-2-61
SpO_2 Measurement range	1 to 100%
PI measurement range	0.02% to 20%
SpO_2 Resolution	1%
Accuracy[1]	70 to 100%: ±2% (measured without motion in adult/pediatric mode) 70 to 100%: ±3% (measured without motion in neonate mode) 70 to 100%: ±3% (measured with motion) 1% to 69%: Not specified.
Refreshing rate	1 s
Low perfusion conditions	Pulse amplitude: >0.02% Light penetration: >5%
Low perfusion SpO_2 accuracy[2]	±2%

[1] The Masimo pulse oximeter with sensors have been validated for no motion accuracy in human blood studies on healthy adult volunteers in induced hypoxia studies in the range of 70% to 100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

The Masimo pulse oximeter with sensors 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 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% to 100% SpO2 against a laboratory co-oximeter and ECG monitor. This variation equals plus or minus one standard deviation. Plus or minus one standard deviation encompasses 68% of the population.

[2] The Masimo pulse oximeter has been validated for low perfusion accuracy in bench top testing against a Biotek Index 2 simulator and Masimo's simulator with signal strengths of greater then 0.02% and a % transmission of greater than 5% for saturations ranging from 70 to 100%. This variation equals plus or minus one standard deviation. Plus or minus one

standard deviation encompasses 68% of the population.

Nellcor SpO_2 Module

Standards	Meet standards of ISO 80601-2-61
Measurement range	0 to 100%
Resolution	1%
Accuracy	70 to 100%: ±2% (adult/pediatric) 70 to 100%: ±3% (neonate) 0% to 69%: Not specified.
Refreshing rate	1 s
*: When the SpO_2 sensor is applied for neonatal patients as indicated, the specified accuracy range is increased by ±1%, to compensate for the theoretical effect on oximeter measurements of fetal hemoglobin in neonatal blood.	

Information of the Test Subjects of the Clinical Study Report

Skin color	Gender	Number	Age (years)	Health
Black	Male	1	28.2±9.19	Healthy
	Female	1		
Yellow	Male	3		
	Female	9		

A.6.2 PR

PR from Mindray SpO_2 Module

Measurement range	20 to 254 bpm
Resolution	1 bpm
Accuracy	±3 bpm (without motion)
Refreshing rate	1 s

PR from Masimo SpO_2 Module

Measurement range	25 to 240 bpm
Resolution	1 bpm
Accuracy	±3 bpm (without motion) ±5 bpm (with motion)
Refreshing rate	1 s

PR from Nellcor SpO_2 Module

Measurement range	20 to 300 bpm
Resolution	1 bpm
Accuracy	20 to 250 bpm: ±3 bpm 251 to 300 bpm, not specified
Refreshing rate	1 s

PR from NIBP Module

Measurement range	40 to 240 bpm
Resolution	1 bpm
Accuracy	±3bpm or ±3%, whichever is greater

A.6.3 NIBP

Standards	Meet standards of IEC80601-2-30, ISO 81060-2			
Technique	Oscillometry			
Max measurement time	Adult, pediatric: 180 s Neonate: 90 s			
Measurement ranges (mmHg)		**Adult**	**Pediatric**	**Neonate**
	Systolic:	40 to 270	40 to 200	40 to 135
	Diastolic:	10 to 210	10 to 150	10 to 100

	Mean:	20 to 230	20 to 165	20 to 110
Accuracy	Max mean error: ±5 mmHg Max standard deviation: 8 mmHg			
Static pressure measurement range	0mmHg to 300mmHg			
Static pressure measurement accuracy	±3 mmHg			
Resolution	1mmHg			
Default initial cuff inflation pressure (mmHg)	Adult: 160 Pediatric: 140 Neonate: 90			
Software overpressure protection	Adult: 297±3 mmHg Pediatric: 240±3 mmHg Neonate: 147±3 mmHg			
Hardware overpressure protection	Adult: ≤330 mmHg Pediatric: ≤330 mmHg Neonate: ≤165 mmHg			

* Measurement accuracy verification: In adult and pediatric modes, the blood pressure measurements measured with this device are in compliance with the American National Standard for Electronic or Automated Sphymomanometers (ANSI/AAMI SP10) in terms of mean error and standard deviation by comparing with intra-arterial or auscultatory measurements (depending on the configuration) in a typical patient population. For auscultatory reference, the 5th Korotkoff sound was used to determine the diastolic pressure.

In neonatal mode, the blood pressure measurements measured with this device are in compliance with the American National Standard for Electronic or Automated Sphymomanometers (ANSI/AAMI SP10) in terms of mean error and standard deviation by comparing with intra-arterial measurements (depending on the configuration) in a typical patient population.

A.6.4 Temp

Standards	Meets standards of ISO 80601-2-56
Technique	Thermal resistance (use thermistor to measure temperature)
Operating mode	Adjusted mode (predictive mode) Direct mode (monitor mode)
Measurement range	Monitor mode: 25 to 44°C (77 to 111.2°F) Predictive mode: 35 to 43°C (95 to 109.4°F)
Accuracy (Monitor mode)	25 to 32°C (not include 32°C): ± 0.2°C 32 to 44°C (include 32°C): ±0.1°C or 77 to 89.6°F (not include 89.6°F): ± 0.4°F 89.6 to 111.2°F (include 89.6°F): ± 0.2°F
Resolution	±0.1°C or ± 0.2°F
Minimum measurement time for accurate readings	Monitor mode: <60 s Predictive mode: <20 s (typical test: < 12s)

Statistical Results of Clinical Investigation Data

	Clinical BIAS (Δcb)	**Limits of Agreement (LA)**	**Clinical Repeatability (σr)**
Oral	0.02	0.33	0.1
Axilla	0.06	0.38	0.13
Rectum	-0.05	0.48	0.14

B EMC

The device meets the requirements of IEC 60601-1-2.

Note

- **Using accessories, transducers and cables other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.**
- **The device or its components should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device or its components should be observed to verify normal operation in the configuration in which it will be used.**
- **The device needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided below.**
- **Other devices may interfere with this monitor even though they meet the requirements of CISPR.**
- **When the inputted signal is below the minimum amplitude provided in technical specifications, erroneous measurements could result.**
- **Portable and mobile communication equipment may affect the performance of this monitor.**
- **Other devices that have RF transmitter or source may affect this device (e.g. cell phones, PDAs, and PCs with wireless function).**
- **If the device is operated within the electromagnetic environment listed in Table Guidance and declaration - electromagnetic immunity, it will remain safe and provide the accuracy as essential performance.**

Guidance and Declaration - Electromagnetic Emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emission tests	**Compliance**	**Electromagnetic environment - guidance**
Radio frequency (RF) emissions CISPR 11	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The device is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC 61000-3-3	Complies	

WARNING

- **This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM] or shielding the location.**

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0.5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of our product requires continued operation during power mains interruptions, it is recommended that our product be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 HZ) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC mains voltage prior to application of the test level.			

Guidance and Declaration - Electromagnetic Immunity			
The device is intended for use in the specified electromagnetic environment. The customer or the user of the device should assure that it is used in such an environment as described below.			
Immunity test	**IEC60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conduced RF IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances: $d = 1.2\sqrt{P}$
Radiated RF IEC61000-4-3	3V/m 80MHz to 2.5GHz	3V/m	Recommended separation distances: 80 MHz - 800 MHz $d = 1.2\sqrt{P}$ 800MHz-2.5GHz $d = 2.3\sqrt{P}$ Where, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] 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 to 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.			
[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV			

broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the [ME EQUIPMENT or ME SYSTEM] is used exceeds the applicable RF compliance level above, the [ME EQUIPMENT or ME SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the [ME EQUIPMENT or ME SYSTEM].

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the device

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance in meters (m) according to frequency of the transmitter**		
	150 kHz - 80 MHz $d = 1.2\sqrt{P}$	80 MHz - 800 MHz $d = 1.2\sqrt{P}$	800 MHz - 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	1.20	1.20	2.30
10	3.80	3.80	7.30
100	12.00	12.00	23.00

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.

FOR YOUR NOTES

C Error Codes

This chapter lists all the error codes that may appear on your monitor. In the "Solution" column, corresponding solutions are given instructing you to troubleshoot problems. If the problem persists, contact your service personnel.

When an error occurs, the Error Code area on the screen displays the code. If the error is related with parameter module, the corresponding parameter label flashes as well. Some error codes can be cleared, but some cannot be deleted. In Measurement mode, you can press C hardkey to remove the clearable code in Error Code area and stop parameter label flashing.

When multiple errors occur, the error codes are displayed circularly.

Error Code	Description	Clearable? (Yes/No)	Causes	Solution
01	NIBP overrange	Yes	The measured NIBP value exceeds the measurement range.	Contact your service personnel.
02	NIBP module error	No	1. Self-test failure. 2. NIBP module error, or communication error between NIBP and main unit. 3. System error. After startup, pump, A/D sampling or pressure transducer error, or pointer error during software running.	Restart the monitor. If the error remains, contact our service personnel.
03	NIBP communication error	No	NIBP module error, or communication error between NIBP and main unit.	
04	NIBP air pressure error	No	The NIBP airway may be occluded, or the cuff is squeezed during deflation.	Check the air pressure. Restart the monitor and retry. If the error remains, contact your service personnel.
05	NIBP weak signal	Yes	The patient's pulse is weak or the cuff is loose.	Check the patient's condition and change the cuff application

Error Code	Description	Clearable? (Yes/No)	Causes	Solution
				site. If the error persists, replace the cuff.
06	NIBP excessive motion	Yes	Patient's arm moves too much.	Check the patient's condition and reduce the patient motion.
07	NIBP cuff overpressure	Yes	The NIBP airway may be occluded.	Check the airway and measure again.
08	NIBP illegally reset	Yes	An illegal reset occurred during NIBP measurement.	Check if the airway is occluded.
09	NIBP timeout	Yes	Time is out. In Adult/Pediatric mode, the measurement time is over 120 seconds; in neonate mode, the time is over 90 seconds.	Check the patient's condition and NIBP connections, or replace the cuff.
10	NIBP cuff type wrong	Yes	The cuff type applied mismatches the patient category.	Verify the patient category and replace the cuff.
11	NIBP air leak	Yes	The cuff is not properly applied or connected, or the airway leaks air.	Correctly apply and use the cuff. If the problem still exists, contact your service personnel.
17	SpO_2 board fault (Masimo)	No	There is a problem with the SpO_2 measurement board.	Do not use the module and contact your service personnel.
18	SpO_2 module error	No	SpO_2 module error or communication error between SpO_2 module and main unit.	Restart the monitor. If the error remains, contact our service personnel.
19	PR overrange	No	The measured PR value exceeds the measurement range.	Contact your service personnel.
20	SpO_2 low perfusion (Mindray, Masimo, Nellcor)	No	The SpO_2 signal is too weak.	Move the sensor to a site with better perfusion.
26	Temp module error	No	Temp initialization	Restart the monitor. If

Error Code	Description	Clearable? (Yes/No)	Causes	Solution
			error, or communication error between Temp module and main unit; too high or too low power voltage; no Temp module or Temp module error.	the error remains, contact our service personnel.
27	Temp probe error	No	Temp probe can not work; or the probe is not, or incorrectly, inserted into the probe well	Verify that the probe is in the probe well, or cool the probe and re-insert into the probe well.
28	Ambient temp overrange	No	The environmental temperature is out the range of the monitor's measurement.	Change an environment and retry.
29	Temp overrange	No	The measured Temp value exceeds the measurement range.	Contact your service personnel.
35	Battery charging error	No	The battery can not be charged.	Replace the battery.
36	12V too high	No	There is a problem with the system power supply.	Restart the monitor. If the problem still exists, contact your service personnel.
37	12V too low	No		
38	5V too high	No		
39	5V too low	No		
40	Power board communication error	No	No data from power module has been received for 10 seconds.	Restart the monitor. If the problem still exists, contact your service personnel.

FOR YOUR NOTES

D Electrical Safety Inspection

The following electrical safety tests are recommended as part of a comprehensive preventive maintenance program. They are a proven means of detecting abnormalities that, if undetected, could prove dangerous to either the patient or the operator. Additional tests may be required according to local regulations.

All tests can be performed using commercially available safety analyzer test equipment. These procedures assume the use of a 601PROXL International Safety Analyzer or equivalent safety analyzer. Other popular testers complying with IEC 60601-1 used in Europe such as Fluke, Metron, or Gerb may require modifications to the procedure. Follow the instructions of the analyzer manufacturer.

The electrical safety inspection should be periodically performed every two years .The safety analyzer also proves to be an excellent troubleshooting tool to detect abnormalities of line voltage and grounding, as well as total current loads.

D.1 Power Cord Plug

D.1.1 The Power Plug

Test Item		Acceptance Criteria
The power plug	The power plug pins	No broken or bent pin. No discolored pins.
	The plug body	No physical damage to the plug body.
	The strain relief	No physical damage to the strain relief. No plug warmth for device in use.
	The power plug	No loose connections.
The power cord		No physical damage to the cord. No deterioration to the cord.
		For devices with detachable power cords, inspect the connection at the device.
		For devices with non-detachable power cords, inspect the strain relief at the device.

D.2 Device Enclosure and Accessories

D.2.1 Visual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No physical damage to the enclosure and accessories.
	No physical damage to meters, switches, connectors, etc.
	No residue of fluid spillage (e.g., water, coffee, chemicals, etc.).
	No loose or missing parts (e.g., knobs, dials, terminals, etc.).

D.2.2 Contextual Inspection

Test Item	Acceptance Criteria
The enclosure and accessories	No unusual noises (e.g., a rattle inside the case).
	No unusual smells (e.g., burning or smoky smells, particularly from ventilation holes).
	No taped notes that may suggest device deficiencies or operator concerns.

D.3 Device Labeling

Check the labels provided by the manufacturer or the healthcare facility are present and legible.

- Main unit label
- Integrated warning labels

D.4 Protective Earth Resistance

1. Plug the probes of the analyzer into the device's protective earth terminal and protective earth terminal of the AC power cord.
2. Test the earth resistance with a current of 25 A.
3. Verify the resistance is less than limits.

LIMITS

ALL COUNTRIES R = 0.2 Ω Maximum

D.5 Earth Leakage Test

Run an Earth Leakage test on the device being tested before performing any other leakage tests.

The following outlet conditions apply when performing the Earth Leakage test:

- normal polarity (Normal Condition),
- reverse polarity (Normal Condition),

- normal polarity with open neutral (Single Fault Condition),
- reverse polarity with open neutral (Single Fault Condition)

LIMITS

For UL60601-1,

- 300 µA in Normal Condition
- 1000 µA in Single Fault Condition

For IEC60601-1,

- 500 µA in Normal Condition
- 1000 µA in Single Fault Condition

D.6 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements have a true RMS only

The following outlet conditions apply when performing the Patient Leakage Current test.

- normal polarity (Normal Condition);
- reverse polarity (Normal Condition),
- normal polarity with open neutral (Single Fault Condition);
- reverse polarity with open neutral (Single Fault Condition).
- normal polarity with open earth (Single Fault Condition);
- reverse polarity with open earth (Single Fault Condition).

LIMITS

For CF  applied parts

- 10µA in Normal Condition
- 50µA in Single Fault Condition

For BF  applied parts

- 100µA in Normal Condition
- 500µA in Single Fault Condition

D.7 Mains on Applied Part Leakage

The Mains on Applied Part test applies a test voltage, which is 110% of the mains voltage, through a limiting resistance, to selected applied part terminals. Current measurements are then taken between the selected applied part and earth. Measurements are taken with the test voltage (110% of mains) to applied parts in the normal and reverse polarity conditions

The following outlet conditions apply when performing the Mains on Applied Part test.

- Normal Polarity;
- Reversed Polarity

LIMITS

- For CF  applied parts: 50 µA
- For BF  applied parts: 5000 µA

NOTE

- **Make sure the safety analyzer is authorized comply with requirement of IEC 60601-1.**
- **Follow the instructions of the analyzer manufacturer.**

E Symbols and Abbreviations

E.1 Symbols

µA	microampere
µV	microvolt
µs	Microsecond
A	ampere
Ah	ampere hour
bpm	beat per minute
bps	bit per second
°C	centigrade
cm	centimeter
dB	decibel
DS	dyne second
°F	fahrenheit
g	gram
GHz	gigahertz
h	hour
Hz	hertz
in	inch
k	kilo
kg	kilogram
kPa	kilopascal
L	litre
lb	pound
m	meter
mAh	milliampere hour
Mb	mega byte
mg	milligram
min	minute
ml	milliliter
mm	millimeter
mmHg	millimeters of mercury
ms	millisecond
mV	millivolt
mW	milliwatt
MΩ	megaohm

nm	nanometer
rpm	breaths per minute
s	second
V	volt
VA	volt ampere
Ω	ohm
W	watt
−	minus
-	negative
%	percent
/	per; divide; or
~	to
+	plus
=	equal to
<	less than
>	greater than
≤	less than or equal to
≥	greater than or equal to
±	plus or minus
×	multiply
©	copyright

E.2 Abbreviations

AC	altenating current
CE	Conformité Européenne
DC	direct current
EMC	electromagnetic compatibility
Err	error
IEC	International Electrotechnical Commission
ISO	International organization for standardization
M	Monitoring
MDD	Medical Device Directive
MRI	magnetic resonance imaging
NIBP	noninvasive blood pressure
P	power
P	Predictive
PR	pulse rate

SpO2	arterial oxygen saturation from pulse oximetry
TEMP	temperature

FOR YOUR NOTES

P/N: 046-004925-00 (3.0)