

OPERATOR'S MANUAL

Patient Monitor M20

EU representative

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- The contents of this manual should be correct. If, for some reason, there are any questionable points, please do not hesitate to contact our service center.
- The manual will be replaced if any pages are missing or collation is incorrect.

Warranty

- Please contact your local distributor about the warranty period.
- Device failure or damage related to the following situations during the guarantee period is not covered by this warranty:
 - Installation, transfer installation, maintenance and repairs by any person other than an authorized Mediana. employee or technician specified by Mediana.
 - Damage sustained to the Mediana product(s) caused by product(s) from another company excluding products delivered by Mediana.
 - Damage – caused by mishandling and/or misuse – is the responsibility of the user.
 - Maintenance and repairs utilizing maintenance components that are not specified by Mediana.
 - Device modifications or use of accessories not recommended by Mediana.
 - Damage caused by accidents or natural disasters (earthquakes, flooding, etc.).
 - Damage resulting from usage where caution statements and operating instructions shown in this manual have not been followed.
 - Damage due to neglect of specified maintenance checks.
- This warranty only covers the hardware of the M20. The warranty does not cover the following selections:
 - Whatever damage or loss results from the attachment of accessories or their operation.
 - In the event of a defect in the product, contact our sales outlet or EU representative as noted on the back cover.
- The M20 conforms to the EMC standard IEC60601-1-2.
Note that mobile phones should not be used in the vicinity of the M20.

Note, however, any device not complying to the EMC standard that is used with the M20 renders the M20 as non-compliant to the EMC standard.

Trademark

Product brand names shown in this manual are likely to be the trademark or registered trademark of the company concerned.

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SAFETY INFORMATION

General Safety Information

This section contains important safety information related to general use of the M20 multi-parameter patient monitor. Other important safety information appears throughout the manual. The M20 will be referred to as the monitor throughout this manual.


Important! Before use, carefully read this manual, accessory directions for use, all precautionary information and specifications.


Warning





Warnings are identified by the WARNING symbol shown above.


Warnings alert you to potential serious outcomes (death, injury, or adverse events) to the patient or user.


-
-  **WARNING:** Do not take into or use the monitor in locations where highly combustible anesthetics or flammable gases are used or in high-pressure oxygen rooms or inside oxygen tents, as this may cause a flammable explosion.


 -  **WARNING:** When using the monitor with a commercial electric power source, use the monitor with an electric power wall socket with a grounding wire for medical use. Not doing so could cause electric shock.


 -  **WARNING:** Do not connect grounding wire to gas pipes. This could cause fire.


 -  **WARNING:** Only doctors and officially certified personnel should use this monitor. Do not allow patients to touch this monitor. Allowing patients to touch this monitor could cause accidents.


 -  **WARNING:** This monitor cannot be used when MRI is in progress. If MRI is in use, keep patient attachments away from patients to prevent accidents.


 -  **WARNING:** The monitor conforms to the requirements of the EMC standard (IEC60601-1-2), and may therefore be used simultaneously with pacemakers and other electrical simulators. It should, however, be noted that the M20 may be affected by electrical scalpels and microwave therapeutic apparatus. Please check operation of the monitor during and after use of such equipment.


 -  **WARNING:** Do not take mobile phones or transceivers into a room where this monitor is installed, as such devices may cause accidents.













 -  **WARNING:** In order to avoid accidents, do not use any unauthorized accessories or options.

 -  **WARNING:** Thoroughly read the instruction manuals supplied with accessories and options to ensure correct use. This instruction manual does not carry the caution selections for such equipment.

 -  **WARNING:** Do not open cover or disassemble this monitor. Doing so could cause electric shock or fire. It is prohibited by law to modify the monitor without authorization.

 -  **WARNING:** Do not use power source other than the specified voltage, (100-240V~50/60Hz) as this may cause fire or electric shock.

 -  **WARNING:** Pre-use inspection and preventive maintenance must be performed for safe use.
-






-
-  **WARNING:** The monitor may be used with electrical surgical equipment. Follow the instruction manuals for medical instruments – notably electrosurgical and diathermy instruments – when used, as their high-frequency energy units may cause burns to patients via attachments.
-
-  **WARNING:** This monitor is protected against the discharge of a defibrillator. However, do not touch the monitor when a defibrillator is being discharged (electrified), as doing so may cause electric shock.
-
-  **WARNING:** The following cautions apply when connecting the monitor with other equipment.
1. Ensure that the connected equipment is in accordance with the IEC60601-1 or IEC safety standards, so that the system complies with IEC60601-1.
 2. Employ additional protective measures (e.g. additional protective earthing) as necessary.
-
-  **WARNING:** Do not connect devices that do not meet medical safety standards (such as commercial PCs), as they may cause electric shock. This monitor meets the restricted level of leakage current required for medical devices. Therefore, this monitor cannot be connected to a device that would give a combined total of leakage current beyond the restricted level.
-
-  **WARNING:** Do not place anything on top of this monitor. If something is spilled over the monitor or gets into it, such spillage may cause fire or electric shock. If fluid spills on the monitor accidentally, disconnect power cord, wipe dry immediately, and have the monitor serviced to make sure that no hazard exists.
-
-  **WARNING:** Do not place heavy objects on the power cord, as doing so may cause fire or electric shock.
-
-  **WARNING:** Before conducting maintenance work, turn the power OFF and unplug the power cord from the wall socket to prevent electric shock.
-
-  **WARNING:** When the following occur, turn the power OFF immediately and unplug the power cord from the wall socket. Continued use in such situations may cause fire or electric shock.
- There is smoke or a strange odor leaking out of the device.
 - The device has been dropped or impacted by an object.
 - Liquid or foreign matter gets inside the device.
 - Device failure has occurred.
- Also, when any of the above occurs, promptly do the following:
1. Check to see that the power cord has been unplugged from the wall socket.
 2. Place an “Out of Order” sign on the device and do not use it.
-
-  **WARNING:** Do not connect more than one patient to the monitor. Do not connect more than one monitor to a patient.
-
-  **WARNING:** The patient monitor is a prescription device and is to be operated by qualified personnel only.
-
-  **WARNING:** As with any medical equipment, carefully route patient cabling to reduce the possibility of patient entanglement or strangulation.
-
-  **WARNING:** Never lift the monitor by the sensor cable, blood pressure hose, power cord, or any other accessory. Such accessories could detach, causing the monitor to fall on the patient.
-

Cautions



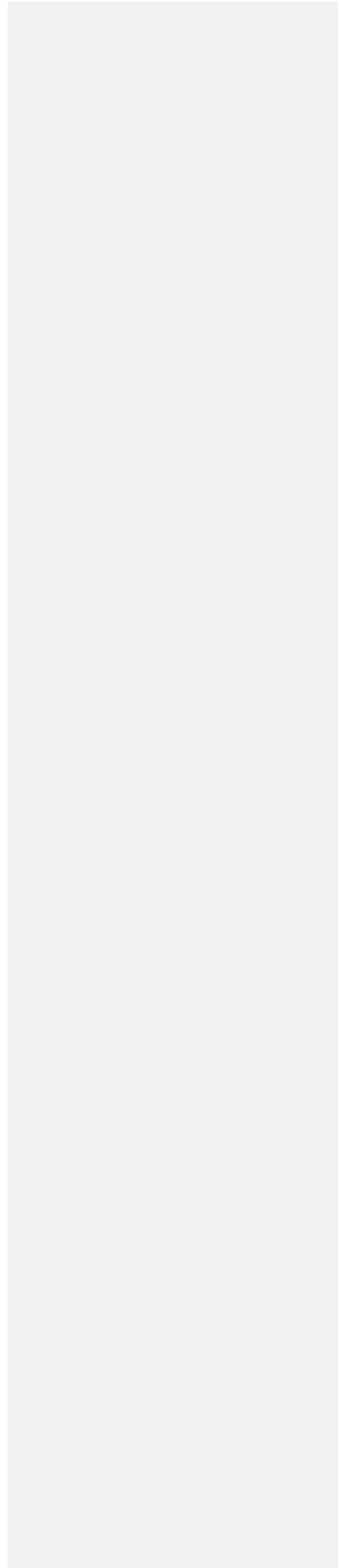
Cautions are identified by the CAUTION symbol shown above.

Caution statements identify conditions or practices that could result in damage to the equipment or other property.

-  **CAUTION:** The monitor may not operate properly if it is operated or stored at conditions outside the ranges stated in this manual, or subjected to excessive shock or dropping.
-  **CAUTION:** When connecting the patient monitor to any instrument, verify proper operation before clinical use. Both the monitor and the instrument connected to it must be connected to a grounded outlet.
-  **CAUTION:** Accessory equipment connected to the monitor's data interface must be certified according to IEC60950 for data-processing equipment or IEC60601-1 for electromedical equipment. All combinations of equipment must be in compliance with IEC60601-1-1 system requirements. Anyone who connects additional equipment to the signal input or signal output port configures a medical system and is therefore responsible that the system complies with the requirements of IEC 60601-1-1 and the electromagnetic compatibility system standard IEC60601-1-2. If in doubt, consult Mediana Technical Support Representative.
-  **CAUTION:** Risk of explosion if battery is replaced by an incorrect type.
-  **CAUTION:** Where the integrity of the external protective conductor in the installation or its arrangement is in doubt, equipment shall be operated from its internal electrical power source.



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INTRODUCTION



WARNING: Patient conditions may result in erroneous readings. If the measurements are suspect, verify the reading using another clinically accepted measurement method.

Intended Use for the M20

The M20 is intended to be used to monitor electrocardiography (ECG), heart rate (HR), noninvasive blood pressure (NIBP) - systolic, diastolic and mean arterial pressures, functional arterial oxygen saturation (SpO₂), pulse rate (PR), respiration (RR), temperature (Temp) for adult, pediatric and neonatal patients in all areas of a hospital and hospital-type facilities. Monitor users should be skilled at the level of a technician, doctor, nurse or medical specialist.

Note: Hospital use typically includes such areas as general care floors, operating rooms, special procedure areas, intensive and critical care area, within the hospital. Hospital-type facilities include physician office-based facilities, sleep labs, skilled nursing facilities, surgical centers, and sub acute care centers.

Note: The medically skilled and trained user can be clinicians like doctors and nurses who know how to take and interpret a patient's vital signs. These clinicians must take direct responsibility for the patient's life. This can include care-givers or medically trained interpreters who are authorized under the appropriate clinical facility procedures to support patient care. Any inappropriate setting, especially the alarm limit or alarm notification settings, can lead to a hazardous situation that injures the patient, harms the patient, or threatens the patient's life. This equipment should only be operated by trained users who can adjust the settings of the patient monitor.

About This Manual

This manual explains how to set up and use the M20 patient monitor.

Read the entire manual including the *Safety Information* section, before you operate the monitor.

Identifying the M20 Monitor Configurations

The following table identifies M20 monitor configurations and how they are indicated. The reference number and serial number are located on the back of the monitor.

All information in this manual, including the illustrations, is based on a monitor configured with the Battery, Mediana or Nellcor SpO₂ module, Printer module and TCP/IP module. If the relevant functions do not exist, please verify your unit configuration.

Reference no.	Description
M20M-0(A)	M20 Standard (ECG, NIBP, Respiration, Temperature) + Mediana SpO ₂
M20M-0P(A)	M20 Standard + Mediana SpO ₂ + Printer
M20M-0L(A)	M20 Standard + Mediana SpO ₂ + TCP/IP
M20M-0PL(A)	M20 Standard + Mediana SpO ₂ + Printer + TCP/IP
M20M-0N(A)	M20 Standard + Nellcor SpO ₂
M20M-0PN(A)	M20 Standard + Nellcor SpO ₂ + Printer
M20M-0LN(A)	M20 Standard + Nellcor SpO ₂ + TCP/IP
M20M-0PLN(A)	M20 Standard + Nellcor SpO ₂ + Printer + TCP/IP

Note: The numeric after dash can be changed to 1, 3 or 5 in accordance with the operating time of the installed battery. The numeric "0" represents that no battery is installed.

Note: The alphabet "A" can be added as the last digit of reference number in accordance with the region.

Features for the M20

Physical/Mechanical

The M20 is a multi-parameter patient monitor which can be battery-operated when AC power source is not available.

Electrical

The M20 is powered by an internal battery pack that typically provides 1, 3 or 5 hour(s) of monitoring from fully charged new batteries. The batteries are continuously recharged when the monitor is connected to AC power source. Refer to the **Battery Operation** section for details.

Display

The monitoring screen is a color LCD that shows all graphic and numeric patient information as well as status conditions and warning messages.

Jog dial

The jog dial provides user interaction with the display and the monitor functions. Rotating and pressing the jog dial allows the user to navigate and make changes to the display elements and monitor functions. Refer to the **Using the Monitor** section for details.

Auxiliary Input/Output(s)

The monitor provides LAN, USB and RJ11 ports.

DESCRIPTION OF THE MONITOR

Front Panel Components

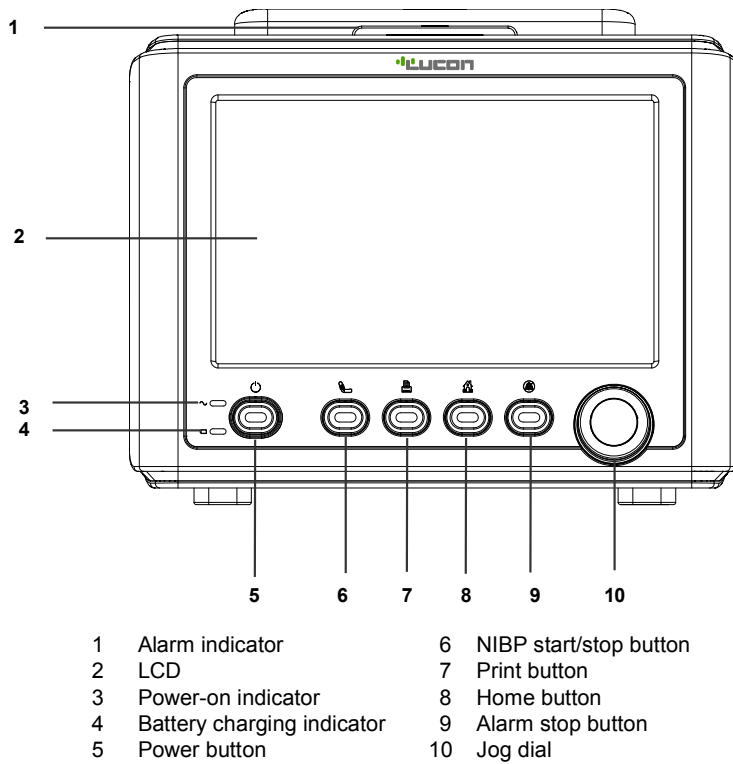






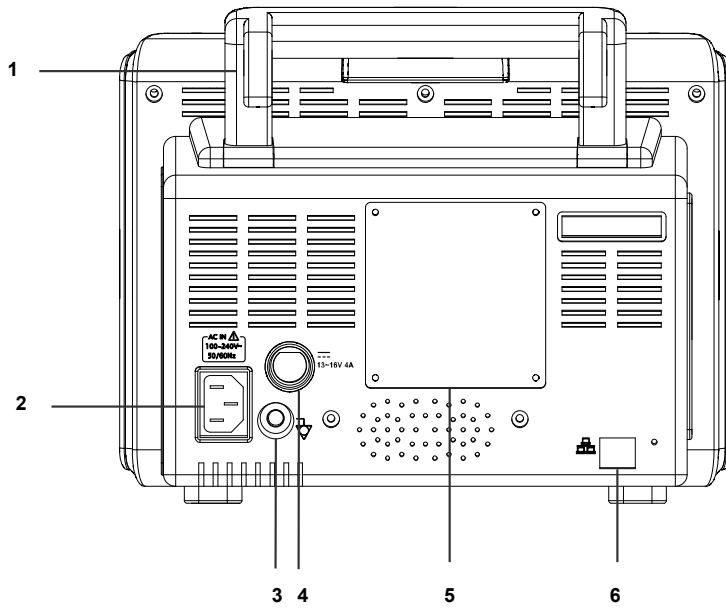


Figure 1. Front Panel Components

Table 1. M20 Controls

Symbols	Description
	Power Button turns the monitor on or off. Power On Indicator is lit while the monitor is turned on.
	NIBP Start/Stop Button toggles between starting and stopping NIBP measurements.
	Print Button prints measured data if an optional printer is installed.
	Home Button exits a menu displayed on the screen and goes to the main screen.
	Alarm Stop Button silences the audible alarm temporarily. suspends the audible alarm by pressing over 2 seconds.
	Jog Dial provides user interaction with the monitor to control the functions.

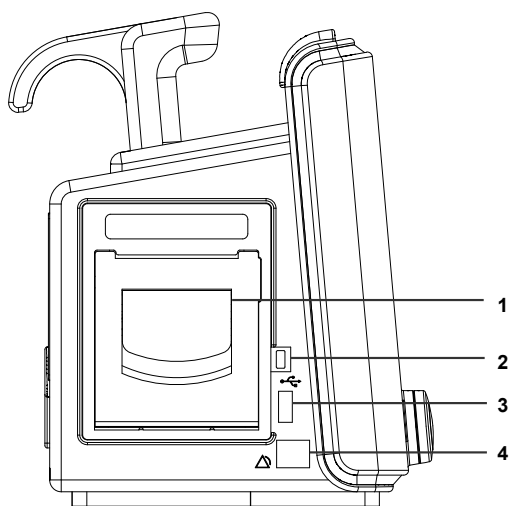
Rear Panel Components



- 1 Handle
- 2 AC power connector
- 3 Equipotential terminal
- 4 DC power connector
- 5 Battery pack
- 6 LAN port

Figure 2. Rear Panel Components

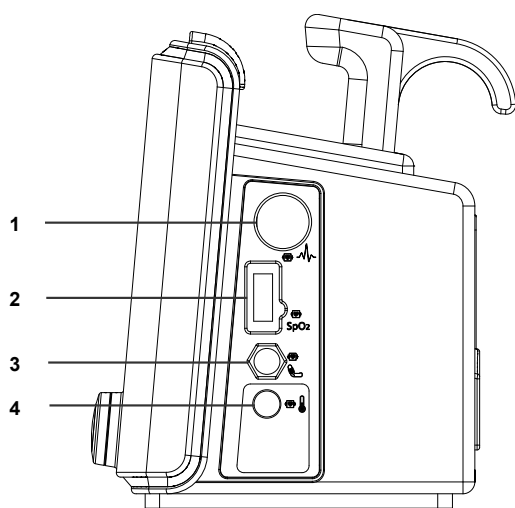
Left Panel Components



- 1 Printer (option)
- 2 USB port (mini USB B Type)
- 3 USB port (USB A Type)
- 4 RJ11 port

Figure 3. Left Panel Components





























Right Panel Components



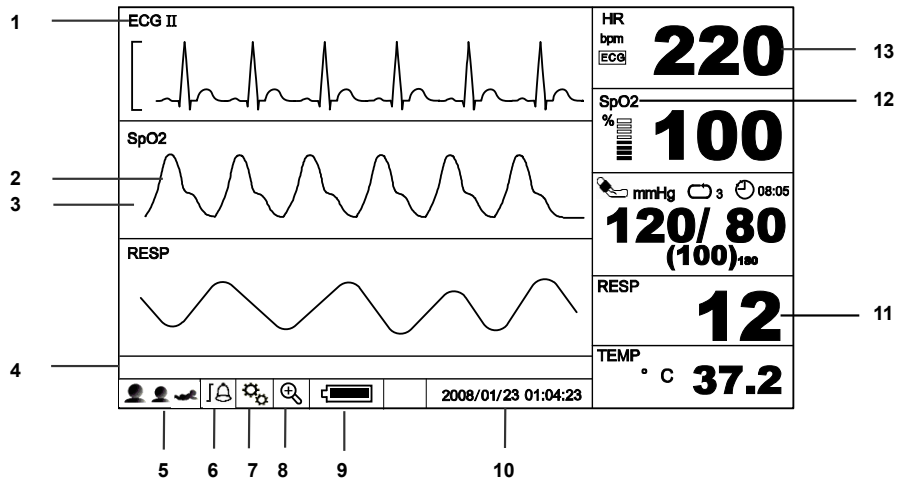
- 1 ECG connector
- 2 SpO₂ connector
- 3 NIBP connector
- 4 Temperature connector

Figure 4. Right Panel Components

Table 2. Panel and Label Symbols

Symbols	Description	Symbols	Description
	Battery charging indicator		Dust and water resistance
	Power on indicator		Attention, consult accompanying documents
	Type CF- Defibrillator proof		CE mark
	ECG connector		Disposal instructions
	Temperature connector		Manufacturer
	SpO ₂ connector		Date of manufacture
	NIBP connector		Reference number
	USB port		Serial number
	LAN port		Environmental shipping/storage altitude limitations
	Nurse call symbol		Environmental shipping/storage humidity limitations
	Equipotential terminal		Environmental shipping/storage temperature limitations
	AC power input rating		Fragile-handle with care
	DC power input rating		This way up
	EU representative		Keep dry

Displays



- | | | | |
|---|-----------------------------|----|----------------------------|
| 1 | Title of waveform parameter | 8 | Main screen select icon |
| 2 | Waveform | 9 | Battery status icon |
| 3 | Waveform area | 10 | Time display |
| 4 | Informative message area | 11 | Numerical area |
| 5 | Patient mode icon | 12 | Title of numeric parameter |
| 6 | Alarm limits menu icon | 13 | Numeric value |
| 7 | Setup menu icon | | |

Figure 5. Displays

Table 3. Display Symbols





















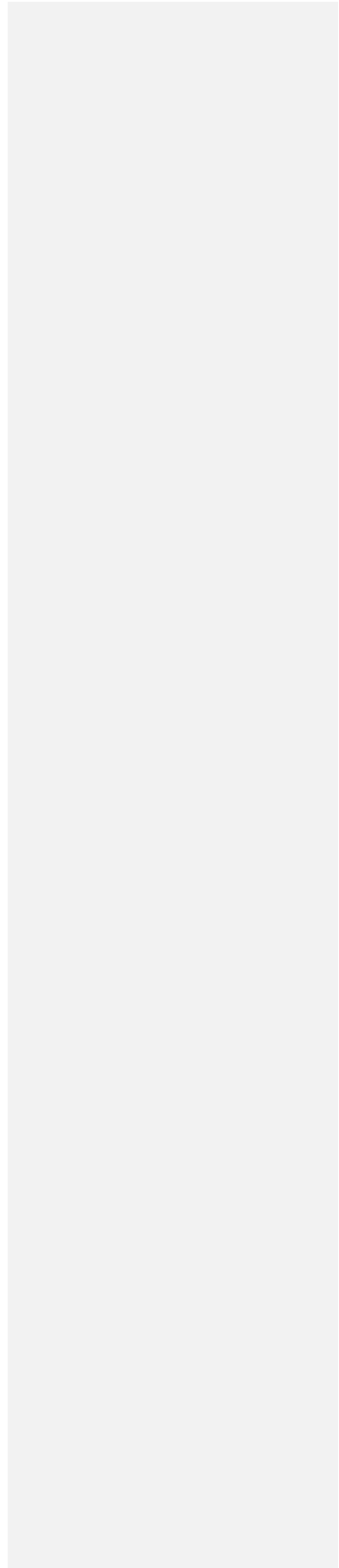
Symbols	Description	Symbols	Description
ECG	ECG waveform icon	°C	Temperature unit: Celsius
II	ECG lead pair	°F	Temperature unit: Fahrenheit
[ECG size bar		Audible Alarm Active icon
SpO2	SpO ₂ waveform icon		Audible Alarm silence icon
RESP	Impedance respiration waveform icon		Audible Alarm suspend icon
bpm	HR/PR icon & unit		Audible Alarm inhibition icon
	HR source icon: ECG		Patient mode: Adult
	PR source icon: SpO ₂		Patient mode: Pediatric
	PR source icon: NIBP		Patient mode: Neonatal
	NIBP icon		Setup menu icon
mmHg	NIBP unit: mmHg		Alarm limits menu icon
kPa	NIBP unit: kPa		Main screen: Big number screen
	NIBP auto mode Interval		Main screen: 3-ch wave screen
	NIBP elapsed time		Battery status icon
	Pulse amplitude indicator	2008/01/23 01:04:23	Time display
TEMP	Temperature icon		NIBP graphical trend icon

Table 4. Display Colors

Function	Color
ECG Waveform	Green
SpO ₂ Waveform	Cyan
Respiration Waveform	Yellow
ECG	Green
NIBP	Orange
SpO ₂	Cyan
Respiration Rate	Yellow
Temperature	Dark blue
General background	Black
Informative message	Black background, Green font
Low priority alarm message	Black background, Yellow font
Medium priority alarm message	Black background, Yellow font
High priority alarm message	Black background, Red font
Battery status icon (normal)	Green
Battery status icon (low battery)	Yellow or Red (refer to Table 8)



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SETTING UP THE MONITOR



WARNING: To ensure accurate performance and prevent device failure, do not expose the monitor to extreme moisture, including direct exposure to rain. Such exposure may cause inaccurate performance or device failure. Refer to *Specification* section.



WARNING: The monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the monitor should be observed to verify normal operation in the configuration it is to be used.



WARNING: Make sure that the monitor speaker is not obstructed. Failure to do so could result in an inaudible alarm tone.



CAUTION: Recharging the battery is strongly recommended when the battery has not been recharged for 2 or more months.



CAUTION: Follow local government ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.

Unpacking and Inspection

The monitor is shipped in one carton. Examine the carton carefully for evidence of damage. Contact Mediana Technical Support Representative immediately if any damage is discovered. Refer to the **Maintenance** section for instructions on returning damaged items.

Note: Refer to the **Performance Verification** section in the service manual for detailed information.

Set the monitor to the user's intended position where the user can easily recognize the visual and audible monitoring conditions. Normally it is recommended to set at a distance of 1m from the user. Also the viewpoint is at any point within the base of a cone by an angle of 30° to the center of the monitoring display.

List of Components

The following items are standard in the package.

Table 5. Standard Accessories

Items	Qty
M20 monitor	1
Operation manual (English)	1
AC power cord	1
Printer paper *Only when Printer option is installed.	1
Cuff/Bladder set medium HEM-CS23 (13-22cm)	1
Cuff/Bladder set medium HEM-CR23 (22-32cm)	1
Cuff hose No.1 (3.5m)	1
ECG trunk cable for 3 leads	1
ECG 3 leads wire pack (SNAP)	1
SpO ₂ reusable sensor YM-1 (for Mediana module) or DS-100A (for Nellcor module)	1
SpO ₂ extension cable RCP058 (for Mediana module) or DOC-10 (for Nellcor module)	1

Optional items may be ordered if needed. Contact your local supplier for pricing and ordering information.

Table 6. Optional Accessories

Items	Qty
Cuff/Bladder set medium HEM-CL23 (32-42cm)	-
Cuff/Bladder set medium HEM-CX23 (42-50cm)	-
Cuff for neonatal	-
Cuff hose No.3 (1.5m)	-
ECG trunk cable for 5 leads	-
ECG 5 leads wire pack (SNAP)	-
ECG 3 leads wire pack (GRAB)	-
ECG 5 leads wire pack (GRAB)	-
SpO ₂ disposable sensor	-
Service manual (English)	-
Li-ion battery (1 hour type)	-
Li-ion battery (3 hours type)	-
Li-ion battery (5 hours type)	-
DC input cable	-

Power Cable Connections



WARNING: Do not connect to an electrical outlet controlled by a wall switch because the device may be accidentally turned off.



CAUTION: If the integrity of the AC power source is in doubt, the monitor must be operated from its internal battery.

AC Power

Make sure that the AC outlet is properly grounded and supplies the specified voltage and frequency (100-240V~ 50-60 Hz).

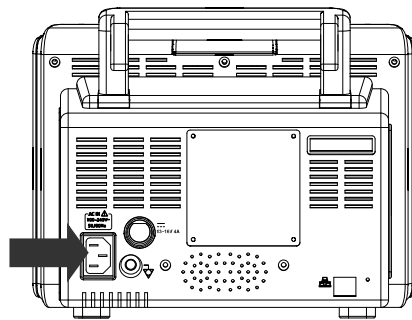


Figure 6. AC Power Connection

1. Connect the female connector end of the AC power cord to mains connector on the monitor's rear panel.
2. Plug the male connector end of the AC power cord into a properly grounded mains outlet.
3. If necessary, connect grounding wire. Connect the grounding wire connector to the equipotential terminal on the rear panel. Now attach the clip end of the grounding wire to the medical equipment grounding terminal on the wall.
4. Verify that the **Battery Charging Indicator** on the monitor's front panel is lit.

Note: Even if the monitor is not turned on, the **Battery Charging Indicator** is lit when the AC power cord is connected into a mains outlet.

Note: If the **Battery Charging Indicator** is not lit, check:

- the power cord
- the AC power inlet
- the power/ mains outlet
- No Battery

If the **Battery Charging Indicator** still is not lit although no problem is found, contact qualified service personnel or your local supplier for assistance.

Measurement Cable Connections



WARNING: For best product performance and measurement accuracy, use only accessories supplied or recommended by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards. Use only accessories that have passed the recommended biocompatibility testing in compliance with ISO10993-1.

Note: Both frequent checks by the operator on a daily basis and more comprehensive technical checks less frequently are covered by this requirement in order to detect mechanical damage and damage to cables, etc.

ECG Cables and Leads

1. Connect an ECG cable to the "ECG" connector making sure that the connector arrow is pointing panel.
2. Attach the ECG lead wire to the end of the cable. (see Figure 3)

NIBP Hoses and Cuffs

1. Select an appropriate size cuff for the patient. (Refer to the **NIBP Monitoring** section.)
2. Connect the hose to the "CUFF" connector making sure to tighten the connector in the clockwise direction.
3. Attach the cuff to the end of the hose. (see Figure 3)

SpO₂ Cables and Sensors

1. Select an appropriate sensor for the patient and desired application. (Refer to the **SpO₂ Monitoring** section.)
2. Connect the extension cable to the "SpO₂" connector on the monitor's right panel.
3. Attach the sensor to the end of the cable. (see Figure 3)

Temperature Probes

1. Select the appropriate probe(s) for the desired application. (YSI 400 and 700 Series)
2. Connect the temperature probes to the Temperature connector on the monitor's right panel. (see Figure 3)

BATTERY OPERATION

CAUTION: Recharging the battery is strongly recommended when it has not been fully recharged for 2 or more months.

CAUTION: When the voltage of the battery is very low, it is a possibility of not operating.

Note: It is recommended that the monitor remain connected to AC power source when not in use. This will ensure a fully charged battery whenever it is needed.

Note: As the battery is used and recharged over a period of time, the amount of time between the onset of the low battery alarm and the instrument shut-off may become shorter. It is recommended for service personnel to check periodically or replace the internal battery if necessary.

Operating the Monitor on Battery Power

The monitor has an internal battery that can be used to power the monitor when AC power source is not available. The battery status icon appears on the screen when the monitor is on battery power.

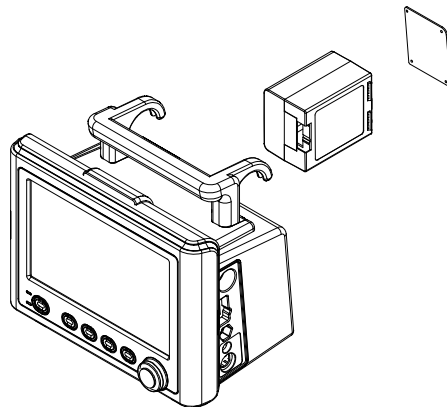


Figure 7. Battery Placement

1. Turn off the monitor.
2. Remove the battery cover.
3. Insert the battery into the main unit carefully.

Table 7. Front Panel Indications for Power Source

Power Connections	Front Panel Indications
AC source	Battery status icon disappears on the screen.
Battery	Battery status icon appears on the screen.

The monitor cannot operate with a fully discharged battery. Before turning on the monitor with a battery that has been completely discharged, first plug the monitor into an AC outlet to charge the battery for a minimum of 3 minutes. The monitor may then be powered on.

A new, fully charged optional battery will provide 1, 3 or 5 hour(s) monitoring operation under the following conditions:




- Operation of ECG, Respiration, SpO₂, and Temperature
- NIBP automatic measurement per 15 minutes
- No audible alarm condition
- No external communication operating
- No printing
- Ambient temperature at 25°C

Note: Three types of battery are available as the optional items.

Battery Status Indication

When operating on batteries, the battery status icon in the lower part of the display indicates the battery charge condition. See Table 8.

Table 8. The Monitor Battery Status Icon

Battery Status Icons	Battery Status Icon Color
	Green (constant)
	Yellow (constant) ≤ 15 minutes
	Red (flashing) ≤ 5 minutes

A low priority alarm occurs when the remaining battery power is only enough for 15 minutes of operation. The alarm message '**Low Battery**' appears on the screen and the visual alarm indicator is lit with yellow.

This alarm cannot be silenced while running on battery power. Connecting the monitor to AC power will silence the alarm.

A high priority alarm occurs for about 5 minutes before the monitor shuts off. The alarm message '**Critically Low-Battery Condition**' will appear and the visual alarm indicator will flash with red. After that, the monitor will automatically shut down. Connect the monitor to an AC power source to avoid any loss of trend data or settings.

Charging a Low Battery

1. Connect the monitor to AC power source to charge a low or depleted battery (see the **Setting up the Monitor** section).
2. Verify that the **Battery Charging Indicator** is lit with orange.





Table 9. Front Panel Indications for Battery Status

Battery status	Battery charging indicator
Full charged	Green
Charging	Orange
Not installed	OFF

Note: Even if the monitor is turned off, the **Battery Charging Indicator** is lit while the battery is recharged.


Note: A full charge of a depleted battery takes over 4, 8 or 12 hours per battery.

USING THE MONITOR

-  **WARNING:** If the Power On Self-Test is not completed successfully, do not try to use the monitor.
-  **WARNING:** Each time the monitor is used, check alarm limits to make sure that they are appropriate for the patient being monitored.
-  **WARNING:** If different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room, a potential hazard can exist.
-  **WARNING:** Keep patients under close surveillance when monitoring. It is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and the monitor can cause inaccurate measurement readings. Do not rely entirely on the monitor readings for patient assessment.

Turning On the Monitor

Before using the monitor, confirm that the monitor is working properly and is safe to use as described below.

-  **CAUTION:** When power is applied, the monitor automatically starts the Power-On Self-Test (POST), which tests the monitor circuitry and functions. During POST, confirm that the monitor screen turns on. If the monitor screen does not function properly, do not use the monitor. Instead, contact qualified service personnel or your local supplier.

Note: The post pass tone sounds when the monitor completes the Power-On Self-Test (POST). This functions as an audible confirmation that the speaker is performing properly. If the speaker does not function, the alarm warning sounds cannot be heard.

Note: If unusable sound like buzzer can be heard, do not use the monitor. Instead, please contact qualified service personnel or your local supplier.

1. Turn on the monitor by pressing the **Power Button**. Confirm that the **Power On Indicator** on the monitor's front panel is lit.
2. The monitor performs POST and the checksum. The initial screen appears during POST. The initial screen displays the company logo, the version of system and the current time.
3. If there is no error, all indicators are lit for at least 2 seconds and the post pass tone sounds during POST. Confirm that the post pass tone sounds and all indicators are lit during POST.

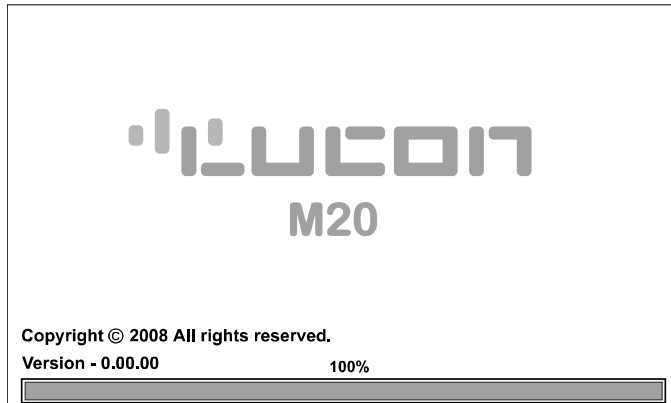


Figure 8. Initial Screen

Note: The system version shown above is only an example.

4. After power-up diagnostics are successfully completed, the monitor is ready for operation.

Note: If the monitor detects an internal problem during POST, the monitor will display an error code and will not display the monitoring screen. If an error code is displayed during POST, contact qualified service personnel or your local supplier for assistance.

Setting Date and Time

You may set the date and time displayed on the screen and printed on the reports.

1. Rotate the jog dial to highlight **Time Display**, and then press the jog dial to select **Date/Time Menu**.
2. Rotate the jog dial to display the desired number for year, month, day, hour or minute, and then press the jog dial to select the desired number.

Note: The time format is 24 hours only.

Table 10. Date/Time Menu

Level 1 Menu	Level 2 Menu or Response
DATE/TIME MENU	
Set Date	Year
	Month
	Day
	Return
Set Time	Hour
	Minute
	Second
	Return
Date Format	mm/dd/yy
	dd/mm/yy
	yy/mm/dd
	Return

Setting Basic Setup Parameters

This procedure will allow you to set Patient Mode, Trend Clear, Alarm Volume, Key Beep Volume, QRS Volume, Service Menu.

Rotate the jog dial to highlight the **Setup Menu Icon**. Press the jog dial to display the setup menu.

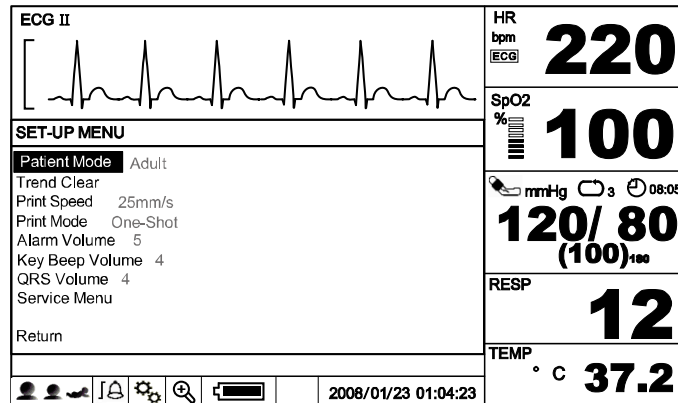


Figure 9. Setup Menu

Table 11. Setup Menu

Level 1 Menu	Level 2 Menu or Response
SET-UP MENU	
Patient Mode	Adult, Pediatric, Neonatal
Trend Clear	-
Print Speed*	25, 50 mm/s
Print Mode*	One-Shot, Continuous
Alarm Volume	1, 2, 3, 4, 5, 6, 7, 8
Key Beep Volume	Off, 1, 2, 3, 4, 5, 6, 7
QRS Volume	Off, 1, 2, 3, 4, 5, 6, 7
Service Menu	(Pass code)
Return	

Note: If there is no activity for 20 seconds, the monitor will return to main screen.

Note: The menu options followed by an asterisk (*) are only displayed with as optional printer installed.

Patient Mode

To select Patient Mode rotate the jog dial to highlight **Patient Mode**, and then press the jog dial to select an appropriate mode: Adult, Pediatric or Neonatal.

Trend Clear

When **Trend Clear** is selected, trend data in the trend memory is cleared.

Setting Print

If an optional printer is installed, this menu will allow you to set **Print Speed**, **Print Mode**. Refer to the **Printing** section for details.

Setting Volume

Setting Volume allows you to adjust the audible Alarm Volume, QRS volume and Key beep volume. **Alarm Volume** can be set to level 1 to 8 and **QRS Volume** and **Key Beep Volume** can be set to level 1 to 7 or Off (see Alarms and Limits section).

1. Rotate the jog dial to highlight **Alarm Volume**, **QRS Volume** or **Key Beep Volume**.
2. Press the jog dial. Levels of **Alarm Volume**, **QRS Volume** or **Key Beep Volume** will appear.
3. Rotate the jog dial to select a volume level (see each volume level in the Table [1144](#)).
4. Press the jog dial to enter the desired volume into the monitor.

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Service Menu

This menu includes Save Current Values as Power-On Default, Save Factory Default Setting as Power-On Default, Alarm Suspension Period, Alarm Silence Period, Alarm Reminder Tone, Audible Alarm Type, Language, NIBP TEST MODE, System Information. Only authorized personnel is allowed to change the **Service Menu** settings. A pass code is required for access. Refer to the service manual for instructions.

Setting the Main Screen

You may select the main screen to be displayed; **3-ch Wave Screen** or **Big Number Screen**.

1. Rotate the jog dial to highlight the **Big Number Screen Icon**, and then press the jog dial to display the **Big Number Screen**.
2. To return the **3-ch Wave Screen**, rotate the jog dial to highlight the **3-ch Wave Screen Icon**, and then press the jog dial to display the **3-ch Wave Screen**.

- ✓ 3-ch Wave Screen: ECG + SpO₂ + RESP

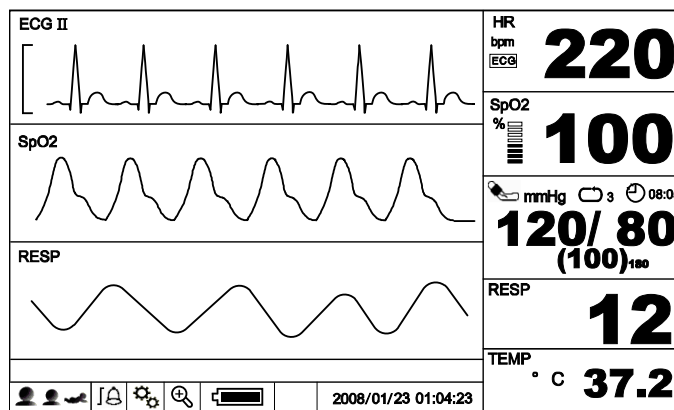


Figure 10. 3-ch Wave Screen

- ✓ Big Number Screen

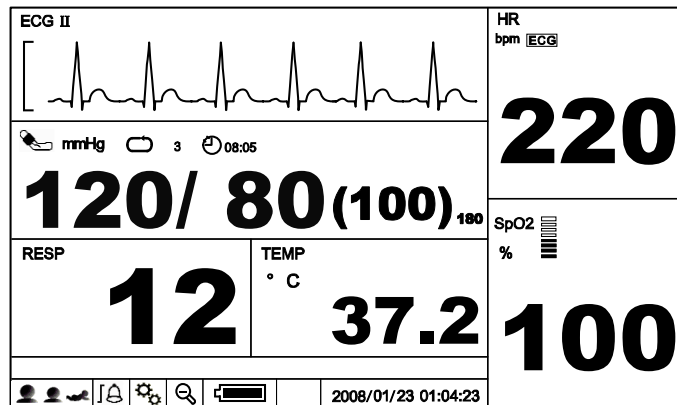


Figure 11. Big Number Screen

ALARMS AND LIMITS



WARNING: Each time the monitor is used, check alarm limits to make sure that they are appropriate for the patient being monitored.



WARNING: If different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room, a potential hazard can exist.

General

When the monitor detects certain conditions that require user attention, the monitor enters an alarm state. The monitor response is indicated by:

- Visual alarm indication
- Audible alarm indication
- Physiological alarms including identification of out-of-limit vital signs
- Technical alarms

Note: The audible and visual alarms on the monitor, used in conjunction with clinical signs and symptoms, are the primary source for notifying medical personnel that a patient alarm condition exists.

Changing Alarm Volume

You can select an alarm volume level of 1 to 8. Refer to the **Using the Monitor** section (see Figure 9, Table 11).

Alarm Priority and Messages

There are three possible priorities for visual and audible alarms: High, Medium, and Low. The high, medium and low priority messages are displayed in the alarm message area, and the informative messages are displayed in the informative message area. A message is displayed alternatively every 2 seconds when the monitor is in multiple alarm conditions. Refer to the **Troubleshooting** section for the recommended actions.

High Priority

Table 12. High Priority Alarm

Condition	Messages
Asystole	Asystole
Loss of Pulse from SpO ₂ no valid ECG and no motion artifact	SpO ₂ Loss of Pulse
Critically Low-Battery condition	Critically Low-Battery condition

Medium Priority

Table 13. Medium Priority Alarm

Technical Alarm Message		
Parameter	Condition	Messages
HR	High Heart Rate limits violated	High Heart Rate/Pulse Rate limits violated
	Low Heart Rate limits violated	Low Heart Rate/Pulse Rate limits violated
%SpO ₂	High SpO ₂ limits violated	High SpO ₂ limits violated
	Low SpO ₂ limits violated	Low SpO ₂ limits violated
NIBP	High Systolic blood pressure limits violated	NIBP-High Systolic blood pressure limits violated
	High Diastolic blood pressure limits violated	NIBP-High Diastolic blood pressure limits violated
	High MAP blood pressure limits violated	NIBP-High MAP blood pressure limits violated
	Low Systolic blood pressure limits violated	NIBP-Low Systolic blood pressure limits violated
	Low Diastolic blood pressure limits violated	NIBP-Low Diastolic blood pressure limits violated
	Low MAP blood pressure limits violated	NIBP-Low MAP blood pressure limits violated
Resp	High Respiration Rate limits violated	High Respiration Rate limits violated
	Low Respiration Rate limits violated	Low Respiration Rate limits violated
	Loss of Respiration Signal	Loss of Respiration Signal
Temp	High Temperature limits violated	High Temperature limits violated
	Low Temperature limits violated	Low Temperature limits violated

Low Priority

Table 14. Low Priority Alarm

Technical Alarm Message		
Parameter	Condition	Messages
ECG	ECG Leads Off	ECG Leads Off
	Chest Lead off	Chest Lead Off
	ECG Signal Saturation	ECG Signal Saturation
Temp	Temperature Probe Disconnect	Temperature Probe Disconnect
	Temperature – Out of range	Temperature – Out of range
NIBP	NIBP – Abnormal Cuff	NIBP – Abnormal Cuff / EEE 11
	NIBP – Abnormal Cuff	NIBP – Abnormal Cuff / EEE 21
	NIBP – Measurement Fail	NIBP – Measurement Fail / EEE 12
	NIBP – Measurement Fail	NIBP – Measurement Fail / EEE 14
	NIBP – Measurement Fail	NIBP – Measurement Fail / EEE 15
	NIBP – Measurement Fail	NIBP – Measurement Fail / EEE 18
	NIBP – Measurement Fail	NIBP – Measurement Fail / EEE 20
	NIBP – Overpressure	NIBP – Overpressure / EEE 19
	NIBP – Artifact	NIBP – Artifact / EEE 13
	NIBP – Artifact	NIBP – Artifact / EEE 16
NIBP - Time-Out	NIBP – Time-Out / EEE 17	
%SpO ₂	SpO ₂ – Technical Error Messages #All SpO ₂ Error Codes have corresponding recovery code. Errors will be handled by its recovery code. The following messages are the results of all recovery codes.	SpO ₂ Error - EEE001
		~ SpO ₂ Error - EEE511
		SpO ₂ Module Reset
		Reconnect / Replace SpO ₂ sensor
		Reposition / Replace SpO ₂ sensor
		Replace SpO ₂ sensor
Loss of Pulse from SpO ₂ with valid ECG or with motion artifact	Loss of Pulse from SpO ₂	
Resp	SpO ₂ Cable/Sensor Disconnect	SpO ₂ Cable/Sensor Disconnect
	Sensor Off from SpO ₂ Sensor	SpO ₂ Sensor Off
System	Respiration Leads Off	Respiration Leads Off
	Low Battery	Low Battery
	Technical System Error	EEE 700 ~

Informative Messages

Informative messages indicate a system condition that needs to be corrected.

Table 15. Informative Messages

Parameter	Condition	Messages
%SpO ₂	SpO ₂ Sensor Adjust Condition	SpO ₂ Weak pulse
	SpO ₂ Sensor Adjust Condition	SpO ₂ Weak signal
	SpO ₂ Sensor Adjust Condition	SpO ₂ Motion Interference
	SpO ₂ Sensor Adjust Condition	SpO ₂ Excess Infrared light
	SpO ₂ Sensor Adjust Condition	SpO ₂ Electrical/Optical Interference
	SpO ₂ Sensor Adjust Condition	High Pulse Amplitude
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Alternate site?
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Cover sensor site?
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Ear/Forehead sensor?
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Nasal/Ear sensor?
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: OxiMax adhesive sensor?
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Secure cable
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Headband
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Warm site
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Bandage assembly
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Nail polish
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Sensor too tight?
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Reposition sensor
	SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Isolate interference source.
SpO ₂ Sensor Adjust Messages	SpO ₂ Sensor: Clean sensor site.	
SpO ₂ Pulse search	SpO ₂ Pulse search	
Other	The sensor is not for In-Sensor trend	Not applicable sensor type
	Abnormally shut down last time <i>Note: When power is lost for less than 30 seconds, the monitor will preserve the current settings and trend data restored automatically before the power loss. However, if the power loss is over 30 seconds, the monitor will be back to the previous user settings (or the factory default settings) as per the 'save settings on power off' in the service menu.</i>	Abnormally shut down last time.
	Record switch pressed when no optional printer installed	Printer is not available.
	Exit Scrolling in Trend Screens	Press Knob to Exit Scroll.
	Exit Graphical Trend Screen	Press Home switch to Exit Graphical trend.
	Exit Tabular Trend Screen	Press Home switch to Exit Tabular trend.
	Alarm suspend	Alarm suspend
	Alarm inhibition	Alarm inhibition
Demo Mode	Demo Mode	
Freeze	Freeze	

Note: There may be other informative messages that are not listed above.

Visual Alarm Indication

Table 16. Visual Alarm Characteristics

Alarm Category	Color	Alarm Indicator Flashing Rate
High priority	Red	5 flashes in 3 seconds (approximately 1.7Hz)
Medium priority	Yellow	5 flashes in 8 seconds (approximately 0.6Hz)
Low priority	Yellow	Always on (non-flashing)

Note: **Alarm Indicator** on the center top of the front panel respond with the flashing rates described in Table 16 when an alarm occurs.

When a **high priority alarm** is activated, a non-flashing alarm message is displayed. The numerical area will flash red.

When a **medium priority alarm** is activated, a non-flashing alarm message is displayed. The numerical area will flash yellow.

When a **low priority alarm** activated, a non-flashing alarm message is displayed. The numerical area will change to yellow.

Audible Alarm Indication



WARNING: Do not silence the audible alarm or decrease its volume if patient safety could be compromised.



WARNING: Make sure that the monitor speaker is not obstructed. Failure to do so could result in an inaudible alarm tone.

Table 17. Audible Alarm Characteristics

Alarm Category	Tone Pitch		Beep Rate	
	GN924	IEC60601-1-8	GN924	IEC60601-1-8
High priority	~976 Hz	~976 Hz	7 beeps in 2 sec	10 beeps in 15 sec
Medium priority	~697 Hz	~697 Hz	2 beeps in 1 sec	3 beeps in 15 sec
Low priority	~488 Hz	~488 Hz	1 beeps in 15 sec	1 beeps in 30 sec

Note: Audible alarms may be decreased in volume as described in Table 11 or temporarily silenced.

Verifying Visual and Audible Alarm Indication

If the monitor fails to perform as specified in this test, contact qualified service personnel or your local supplier for assistance.

You can verify the alarm operation for all parameters like ECG, SpO₂, NIBP, Temp, and Resp by following the below procedures.

1. Connect the monitor to an AC power source.
2. Press the **Power Button** to turn on the monitor.
3. Connect the simulator to the sensor input cable and connect cable to monitor.
4. Set the simulator to a smaller value than the lower alarm limit on the monitor.
5. Verify the following monitor reaction:
 - a. The monitor begins to track the physiological signal from the simulator.

- b. After about 10 to 20 seconds, the monitor displays the value measured as specified by the simulator. Verify values are within the tolerances specified in the **Specification** section for each parameter (ECG, SpO₂, NIBP, Temp, Resp).
- c. Audible alarm sounds.
- d. Alarm Indicator flashes.
- e. “**Low limits violated**” message is displayed.
- f. The numerical area flashes, indicating the parameter has violated default alarm limits.

Note: The maximum mean time of the alarm delay is less than 10 seconds unless otherwise specified in this manual.

Changing Alarm Limits



WARNING: Each time the monitor is used, check alarm limits to make sure that they are appropriate for the patient being monitored.



WARNING: If different alarm presets are used for the same or similar equipment in any single area, e.g. an intensive care unit or cardiac operating room, a potential hazard can exist.



CAUTION: Do not set the alarm limits to extreme values that can cause the alarm to become useless.

You can change alarm limits from default values, if necessary.

Alarm limits or alarm inhibition for each parameter may be set in two ways:

- Via interaction with **HR/PR, SpO₂, NIBP, Respiration** and **Temperature menus** or
- Via interaction with the **Alarm Limits Menu** that presents the limits in all the parameters at one time

Setting Alarm Limits via Alarm Limits Menu

1. Rotate the jog dial to highlight the **Alarm Limits Icon** on the lower of the screen, then press the jog dial to display the **Alarm Limits Menu**.
2. Press the jog dial to select **Alarm Limits**. The monitor will display all alarm limits that are currently in effect for all monitored parameters. Select the alarm limits to set.

Table 18. Alarm Limits Menu

Level 1 Menu	Level 2 Menu or Response
ALARM LIMITS MENU	
Record on Alarm*	On, Off
Alarm Limits	HR/PR, SpO ₂ , RESP, TEMP, NIBP (SYS, DIA, MAP) Alarm Inhibition for each parameter
Return	

Note: The menu options followed by an asterisk (*) are only displayed with as optional printer installed.

Alarm Limits Ranges

Table 19 describes the possible alarm limits. The monitor is shipped with factory default settings.

Note: Authorized personnel can define the way to save the power default: user setting, backup and factory default. The detailed information is described in the service manual.

Table 19. Alarm Limits Ranges

Parameters	Upper Limit, Default	Lower Limit, Default	Resolution
HR/PR (BPM)			
Adult	25 ~ 300 BPM, 120 BPM	20 ~ 295 BPM, 50 BPM	5 BPM
Pediatric	25 ~ 300 BPM, 160 BPM	20 ~ 295 BPM, 75 BPM	5 BPM
Neonatal	25 ~ 300 BPM, 200 BPM	20 ~ 295 BPM, 100 BPM	5 BPM
NIBP Systolic (mmHg, kPa)			
Adult	35 ~ 270 mmHg, 160 mmHg (4.6 ~ 356.0 kPa, 21.3 kPa)	30 ~ 265 mmHg, 90 mmHg (4.0 ~ 35.3 kPa, 12.0 kPa)	5 mmHg (0.6 or 0.7 kPa)
Pediatric	35 ~ 270 mmHg, 260 mmHg (4.6 ~ 356.0 kPa, 16.0 kPa)	30 ~ 265 mmHg, 70 mmHg (4.0 ~ 35.3 kPa, 9.3 kPa)	5 mmHg (0.6 or 0.7 kPa)
Neonatal	35 ~ 270 mmHg, 90 mmHg (4.6 ~ 356.0 kPa, 12.0 kPa)	30 ~ 265 mmHg, 40 mmHg (4.0 ~ 35.3 kPa, 5.3 kPa)	5 mmHg (0.6 or 0.7 kPa)
NIBP Diastolic (mmHg, kPa)			
Adult	15 ~ 250 mmHg, 90 mmHg (2.0 ~ 33.3 kPa, 12.0 kPa)	20 ~ 245 mmHg, 50 mmHg (2.6 ~ 32.6 kPa, 6.6 kPa)	5 mmHg (0.6 or 0.7 kPa)
Pediatric	15 ~ 250 mmHg, 70 mmHg (2.0 ~ 33.3 kPa, 9.3 kPa)	20 ~ 245 mmHg, 40 mmHg (2.6 ~ 32.6 kPa, 5.3 kPa)	5 mmHg (0.6 or 0.7 kPa)
Neonatal	15 ~ 250 mmHg, 60 mmHg (2.0 ~ 33.3 kPa, 8.0 kPa)	20 ~ 245 mmHg, 20 mmHg (2.6 ~ 32.6 kPa, 2.6 kPa)	5 mmHg (0.6 or 0.7 kPa)
NIBP MAP (mmHg, kPa)			
Adult	25 ~ 260 mmHg, 110 mmHg (3.3 ~ 34.6 kPa, 14.6 kPa)	20 ~ 255 mmHg, 60 mmHg (2.6 ~ 34.0 kPa, 8.0 kPa)	5 mmHg (0.6 or 0.7 kPa)
Pediatric	25 ~ 260 mmHg, 90 mmHg (3.3 ~ 34.6 kPa, 12.0 kPa)	20 ~ 255 mmHg, 50 mmHg (2.6 ~ 34.0 kPa, 6.6 kPa)	5 mmHg (0.6 or 0.7 kPa)
Neonatal	25 ~ 260 mmHg, 70 mmHg (3.3 ~ 34.6 kPa, 9.3 kPa)	20 ~ 255 mmHg, 30 mmHg (2.6 ~ 34.0 kPa, 4.0 kPa)	5 mmHg (0.6 or 0.7 kPa)
SpO₂ (%)			
Adult	21 ~ 100 %, 100 %	20 ~ 99 %, 90 %	1 %
Pediatric	21 ~ 100 %, 100 %	20 ~ 99 %, 90 %	1 %
Neonatal	21 ~ 100 %, 100 %	20 ~ 99 %, 85 %	1 %
Respiration (BPM)			
Adult	4 ~ 150 BPM, 30 BPM	3 ~ 149 BPM, 8 BPM	1 BPM
Pediatric	4 ~ 150 BPM, 30 BPM	3 ~ 149 BPM, 8 BPM	1 BPM
Neonatal	4 ~ 150 BPM, 100 BPM	3 ~ 149 BPM, 30 BPM	1 BPM
Temperature (°C, °F)			
Adult	15.1 ~ 45.0°C, 39.0 °C (59.1 ~ 113.0°F, 102.2°F)	15.0 ~ 44.9 °C, 36.0 °C (59.0 ~ 112.8°F, 96.8°F)	0.1°C (0.1°F or 0.2°F)
Pediatric	15.1 ~ 45.0°C, 39.0 °C (59.1 ~ 113.0°F, 102.2°F)	15.0 ~ 44.9 °C, 36.0 °C (59.0 ~ 112.8°F, 96.8°F)	0.1°C (0.1°F or 0.2°F)
Neonatal	15.1 ~ 45.0°C, 39.0 °C (59.1 ~ 113.0°F, 102.2°F)	15.0 ~ 44.9 °C, 36.0 °C (59.0 ~ 112.8°F, 96.8°F)	0.1°C (0.1°F or 0.2°F)

Audible Alarm Silence



WARNING: Do not silence the audible alarm or decrease its volume if patient safety could be compromised.

When an alarm occurs, you can silence the audible alarm for the audible alarm silence period (30, 60, 90 or 120 seconds) selected via service menu. However, visual alarms continue during this time. The factory default for audible alarm silence period is 60 seconds.

To silence an audible alarm:

1. Press the **Alarm Stop Button** to immediately silence the alarm tone. The alarm resumes after the audible alarm silence period if the alarm condition has not been corrected.
2. Check the patient and provide appropriate care.

During the audible alarm silence period, you can press the **Alarm Stop Button** again to re-enable the audible alarm tones. Also, if another alarm occurs during the audible alarm silence period, the audible alarm tones will be automatically re-enabled.

Note: The audible alarms caused by some technical errors may be canceled by pressing the **Alarm Stop Button**. However, battery failure and physiological alarms cannot be canceled until the alarm condition is corrected.

Audible Alarm Suspend/Inhibition



WARNING: If an alarm condition occurs while in the Alarm Suspend state, the only alarm indication on the monitor will be visual displays related to the alarm condition.

There are two modes to disable the audible alarm.

1. Audible Alarm Suspend Mode
2. Audible Alarm Inhibition Mode

To initiate an audible alarm suspend or inhibition:

1. To initiate an audible alarm suspend or inhibition, press the **Alarm Stop Button** and hold it for at least 2 seconds.
2. To cancel an audible alarm suspend or inhibition condition, press the **Alarm Stop Button** for 2 seconds again.

Note: You may disable limit violation alarms of each vital sign via the **HR/PR, SpO₂, NIBP, Respiration, Temperature or Alarm Limits menus**.

This action disables audible alarms for a user-defined **Alarm Suspension Period** (10, 20, 30 or 60 minutes) selected via the Service Menu.

If Alarm Suspension Period is set to **10, 20, 30** or **60** minutes, the audible alarm is not activated for the specified time interval and the message "**Audible alarm suspended**" is displayed.

If **OFF** is selected, the audible alarm suspend or inhibition is not allowed to activate.

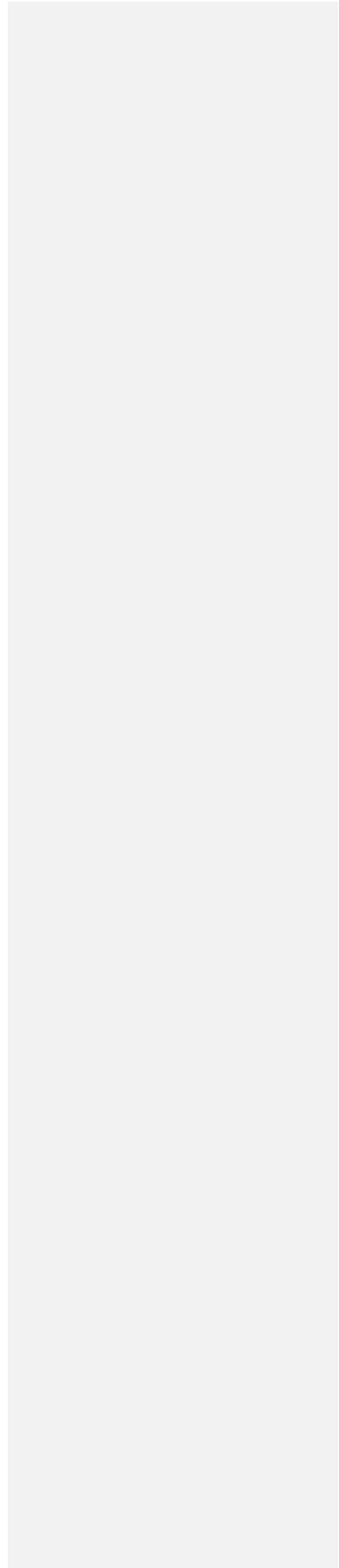
If **Indefinite** is selected, the audible alarm is inhibited and the message "**Audible alarm inhibited**" is displayed. The alarm inhibition state will be terminated by pressing the **Alarm Stop Button** for at least 2 seconds.

In the alarm inhibition state, an **Alarm Reminder Tone** will sound at the preset interval to remind the user that the audible alarm is inhibited. The preset interval for an **Alarm Reminder Tone** can be set to **OFF, 3** or **10 minutes** via the Service Menu. If **OFF** is selected, the **Reminder Tone** will be disabled.









Note: The periods can only be changed by authorized personnel via the *Service Menu*.



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ECG MONITORING

-  **WARNING:** For best product performance and measurement accuracy, use only accessories supplied or recommended by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards.
-  **WARNING:** Line isolation monitor transients may resemble actual cardiac waveforms and thus inhibit heart rate alarms. Such transients may be minimized by proper electrode and cable placement, as specified in this manual and electrode directions for use.
-  **WARNING:** Do not use damaged ECG leads. Do not immerse ECG leads completely in water, solvents, or cleaning solutions. Do not sterilize ECG leads by irradiation, steam, or ethylene oxide. Follow the manufacturer's directions for use.
-  **WARNING:** Do not use ECG electrodes with expired dates. Do not use defective ECG electrodes. These might cause improper performance.
-  **WARNING:** ECG cables may be damaged if they are connected to a patient during defibrillation. Cables that have been connected to a patient during defibrillation should be checked for functionality before using again.
-  **WARNING:** It is possible for the patient to receive a burn due to an improperly connected electrosurgical unit. Additionally, the monitor could be damaged or measurement errors could occur. Place the ECG cable and leads as far as possible from the site of the electrosurgical unit and from the electrosurgical cables. This will minimize interference and the risk of burns to the patient.
-  **WARNING:** For pacemaker patients, the monitor may continue to count pacemaker rate during occurrences of cardiac arrest or some arrhythmias. To reduce the likelihood of this, ensure that the Pacer Detect setting is ON in the ECG waveform menu when monitoring such patients. Do not rely entirely upon the monitor alarms. Keep pacemaker patients under close surveillance.
-  **WARNING:** To ensure patient safety, the conductive parts of the ECG electrodes (including associated connectors) and other patient-applied parts should not contact other conductive parts, including earth ground, at any time.

General

The process of depolarization and repolarization of the myocardium generates electric potentials that are sensed by ECG electrodes on the skin surface. These electrodes are typically attached to the patient's right arm, left arm, and left leg. The monitor processes and amplifies these signals and presents the ECG waveform on the screen. Also, the monitor computes the minute heart rate at least every second by moving average. In addition to the acquisition of the QRS complex, the circuitry performs a number of other functions. The monitor can display:

- Heart rate in beats per minute
- Detection of a "lead off" condition if an electrode is disconnected or poorly connected
- Detection of the presence of pacemaker signals within the ECG waveform complex

Note: Occasionally, electromagnetic interference beyond the range guaranteed from the manufacturer's declaration may cause the monitor to display a "Check ECG Leads & Electrodes" alarm. This occurrence is rare, and duration should be short. When the interference ceases, the monitor removes the "Check ECG Leads & Electrodes" alarm. Refer to the **Specification** section

Setup Connections

Note: Mediana recommends the use of silver/silver chloride electrodes (Ag/AgCl). When dissimilar metals are used for different electrodes, the electrodes may be subject to large offset potentials due to polarization, which may be severe enough to prevent obtaining an ECG trace. Using dissimilar metals may also increase recovery time after defibrillation.

1. Select the electrodes to be used. Use only one type of electrode on the same patient to avoid variations in electrical resistance. Prepare the electrode sites according to the electrode manufacturer's instructions. See Figure [12](#) and [13](#) for electrode placement configurations.

서식 있음: 글꼴 색: 자동, 맞춤법 및 문법 검사

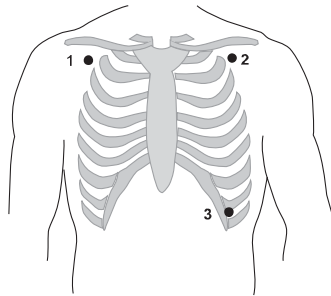


Figure 12. Standard 3 Electrode Placement

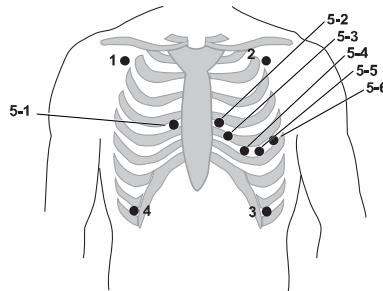


Figure 13. 5 Electrode Placement

Note: One of 5-1 to 5-6 Lead electrode placement sites for the fifth lead.

2. Connect the ECG lead wires and ECG cable.
3. Connect the ECG cable to the ECG connector on the monitor's right panel.

4. Attach the leads to the electrodes, and then apply the electrodes to the patient, using the color-code guide in Table 20. Verify that the desired Lead Selection is active in the ECG waveform area. Refer to Table 21. Lead II is best suited for most monitoring situations.

Table 20. ECG Lead Colors

Lead	AAMI	IEC
1. Right arm	White (RA)	Red (R)
2. Left arm	Black (LA)	Yellow (L)
3. Left leg	Red (LL)	Green (F)
4. Right leg	Green (RL)	Black (N)
5-1 to 5-6. V (Chest)	Brown (V)	White (C)

Table 21. ECG Lead Pairs

Lead-Selection	Electrode Differential (AAMI)	Electrode Differential (IEC)
I	RA LA	R L
II	RA LL	R F
III	LA LL	L F
V (Chest)	(RA+LA+LL)/3 Chest (V)	(R+L+F)/3 Chest (C)
aVR	$-(\text{Lead I} + \text{Lead III})/2$	$-(\text{Lead I} + \text{Lead III})/2$
aVL	$(\text{Lead I} - \text{Lead III})/2$	$(\text{Lead I} - \text{Lead III})/2$
aVF	$(\text{Lead II} + \text{Lead III})/2$	$(\text{Lead II} + \text{Lead III})/2$

Description of HR/PR Menu Functions

The calculated Heart Rate/Pulse Rate may be derived from different sources (ECG, SpO₂ or NIBP) as shown by the icon in the HR/PR numerical area.

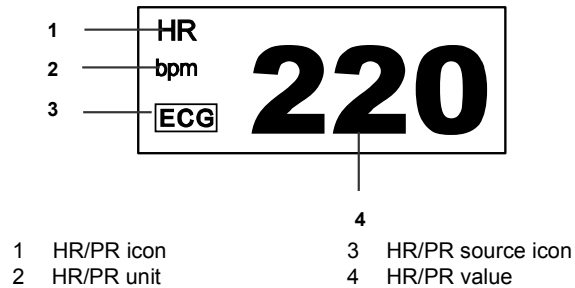


Figure 14. HR/PR Display

Table 22. HR/PR Menu

Level 1 Menu	Level 2 Menu or Response
HR/PR MENU	
HR/PR Source	Auto (ECG > SpO ₂ PR > NIBP PR), ECG, SpO ₂ , NIBP
(Alarm Limits Adjustment)	
▲	Upper Alarm Limit
▼	Lower Alarm Limit
(HR/PR Alarm Inhibition)	On, Off
Return	

HR/PR Source

You may select **Auto**, **ECG**, **SpO₂** or **NIBP** to decide the source of the heart rate or pulse rate. If you select **Auto**, the monitor automatically derives the heart rate or pulse rate from one of the monitoring parameters in this order of priority: ECG, SpO₂ or NIBP. When **ECG** is selected, the heart rate is measured from ECG. When **SpO₂** or **NIBP** is selected, the pulse rate is measured from SpO₂ or NIBP. The color of the HR/PR icon and HR/PR source icon will be changed according to the current source. If the pulse rate is derived from NIBP, the value will be displayed for only 180 minutes after the NIBP measurement, then the value will be removed from the display. The HR/PR tone volume can be adjusted in the **Setup Menu**. Refer to the **Using the Monitor** section. (See Figure 9, Table 11.)

HR/PR Alarm Inhibition

When the HR/PR alarm inhibition is set to **On**, the audible alarm for HR/PR limit violation is inhibited.

Description of ECG Waveform Menu Functions

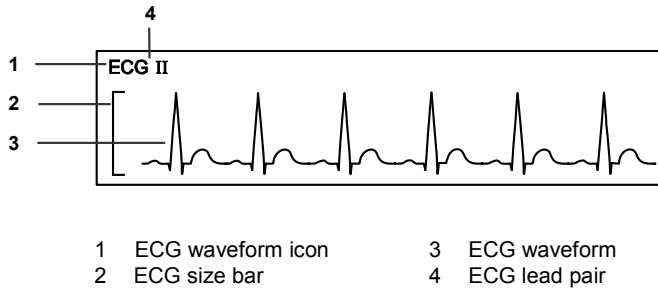


Figure 15. ECG Waveform Display

Table 23. ECG Waveform Menu

Level 1 Menu	Level 2 Menu or Response
ECG WAVEFORM MENU	
Lead Select	Lead I, II, III, aVR, aVL, aVF, V (Chest Lead)
Sweep Speed	12.5 mm/s, 25.0 mm/s, 50.0 mm/s
Size (<i>mm per 1mV</i>)	Auto, 1.25 mm/mV, 1.7 mm/mV, 2.5mm/mV, 5.0 mm/mV, 7.5 mm/mV , 10.0 mm/mV, 15.0 mm/mV, 20.0 mm/mV
Pacer Detect	On, Off
Filter Mode	Monitor, Low Extend, Filter
Large Numeric NIBP	-
Waveform Menu	ECG waveform, SpO ₂ waveform, Respiration waveform
Trend Menu	Tabular trend, Graphical trend
Return	

ECG Cable Select

The monitor detects ECG 3 lead wire or 5 lead wire automatically.

Lead Select

The monitor automatically detects the attached lead and the available ECG lead selection is displayed when the lead select menu is selected. For example, Lead Select shows only Lead I, II and III when 3 leads are attached. You can select the desired ECG lead. For more information about the lead selection, refer to Table [2121](#).

Sweep Speed

The user-selectable sweep speed determines the speed at which the ECG waveform trace moves across the screen. **Sweep Speed** can be selected from 12.5 mm/s, 25.0 mm/s and 50.0 mm/s, and ECG waveform is synchronized with Pleth waveform.

Size

The user-selectable ECG waveform size allows you to adjust the amplitude of an ECG waveform. The size can be selected from Auto, 1.25mm/mV, 1.7mm/mV, 2.5mm/mV, 5.0 mm/mV, 7.5 mm/mV, 10.0 mm/mV, 15.0 mm/mV, 20.0 mm/mV. When the size is set to Auto, The monitor automatically determines the optimal size of the ECG waveform to fit the space.

서식 있음: 글꼴: 굵게 없음, 글꼴 색: 검정

Pacer Detect

Pacer detect should always be **On** for patients with pacemakers (refer to the warning in this section). When **Pacer detect** is **On**, the monitor detects and filters pacemaker-generated signals so that they will not be calculated in determining a patient's heart rate. When monitoring patients without pacemakers, Pacer detect should be set to **Off** to avoid misdiagnosis.

Filter Mode

The monitor can filter ECG waveform noise with different ranges of frequency response:

Low Extend (0.05 Hz to 40 Hz): Expands the range to display very low frequencies down to 0.05 Hz.













Filter (0.5 Hz to 30 Hz): Generally called a filter mode, it reduces ECG waveform noise.

Monitor (0.5 Hz to 40 Hz): Choose this mode to see just the ECG waveform monitoring.

Large Numeric NIBP

When **Large Numeric NIBP** is selected, Large Numeric NIBP is displayed on the waveform area.

NIBP MONITORING

-  **WARNING:** For best product performance and measurement accuracy, use only accessories supplied or recommended by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards.
-  **WARNING:** Inaccurate measurements may be caused by incorrect cuff application or use. This can include placing the cuff too loosely on the patient, using the incorrect cuff size, or not placing the cuff at the same level as the heart, leaky cuff or hose or excessive patient motion.
-  **WARNING:** In some cases, rapid, prolonged cycling of an oscillometric, noninvasive blood pressure monitor cuff has been associated with any or all of the following: ischemia, purpura, or neuropathy. Periodically observe the patient's limb to make sure that the circulation is not impaired for a prolonged period of time. Also make sure the cuff is placed according to directions in this manual and the cuff directions for use.
-  **WARNING:** Do not place the cuff, the catheter or SpO₂ sensor on an extremity being used for intravenous infusion or any area where circulation is compromised or has the potential to be compromised.
-  **WARNING:** As with all automatically inflatable blood pressure devices, continual cuff measurements can cause injury to the patient being monitored. Weigh the advantages of frequent measurement and/or use of CONT mode against the risk of injury.
-  **WARNING:** Ensure the patient is quiet with minimal movement during NIBP readings; minimize the patient's shivering.
-  **WARNING:** Never place the cuff on an extremity being used for intravenous infusion or any area where circulation is compromised or has the potential to be compromised. Never fit NIBP system with Luer Lock adapters.
-  **WARNING:** Never use an adult monitor setting or cuff for an NIBP measurement on a neonatal patient. Adult inflation limits can be excessive for neonatal patients, even if a neonatal cuff is used.
-  **CAUTION:** In the automatic mode, the monitor displays results of the last blood pressure measurement until another measurement starts. If a patient's condition changes during the time interval between measurements, the monitor will not detect the change or indicate an alarm condition.
-  **CAUTION:** Any excessive patient motion may cause inaccurate measurements of non-invasive blood pressure. Minimize motion to improve blood pressure measurements.
-  **CAUTION:** Do not apply the blood pressure cuff to the same extremity as the one to which the SpO₂ sensor is attached. Cuff inflation can disrupt SpO₂ monitoring and lead to nuisance alarms.
-  **CAUTION:** Make sure that heavy objects are not placed on the cuff hose. Avoid crimping or undue bending, twisting, or entanglement of the hose.

Note: Blood pressure measurements can be affected by the position of the patient, the patient's physiological condition and other factors.

Note: Blood pressure measurements determined with the M20 monitor are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard for manual, electronic, and automated sphygmomanometers.

General

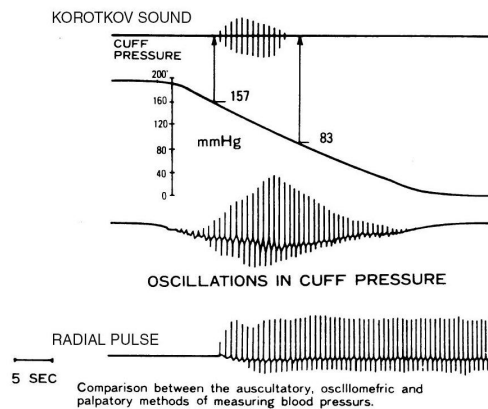
The monitor performs Non-Invasive Blood Pressure measurements using the oscillometric measuring technique. A motorized pump inflates the cuff to initially blocking the flow of blood in the extremity. Then, under monitor control, the pressure in the cuff is gradually reduced, while a pressure transducer detects air pressure and transmits a signal to the NIBP circuitry.

When the cuff pressure is still above systolic pressure, small pulses or oscillations in the cuff pressure begin to be sensed by the transducer. As the cuff continues to deflate, oscillation amplitude increases to a maximum and then decreases. When maximum oscillation amplitude occurs, the cuff pressure at that time is measured as mean arterial pressure (MAP). The systolic and diastolic pressures are calculated based on analysis of the oscillation amplitude profile.

Oscillometric Method

The blood pressure values are determined by measuring the small oscillations (changes) in the cuff pressure caused by the heart's contractions as the pressure in the cuff is released. Mediana's measurement technology utilizes a unique deflation technique, Dynamic Linear Deflation. This cuff deflation technique allows the Mediana monitor to measure each small change in the cuff pressure oscillations that directly correspond to the measurement's systolic, mean and diastolic blood pressure values.

The cuff is first increased in pressure until it reaches a pressure above arterial occlusion. As the cuff starts to deflate, the pulse rate of the patient is determined and the deflation speed of the cuff is modified to create a patient specific deflation speed. As the pressure decreases, small cuff pressure oscillations are recorded that correspond to the applied pressure of the blood under the cuff as the heart contracts. These oscillations increase in strength as the cuff pressure approaches the systolic blood pressure value. A sudden increase in oscillation amplitude indicates that the patient's systolic blood pressure is now able to push blood completely through beneath the cuff. The oscillation amplitude continues to increase as the pressure in the cuff is decreases until the mean blood pressure value is reached. The oscillation strength then starts to diminish and finally drop off as the diastolic blood pressure value is reached.



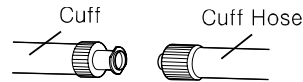
<< From MEASUREMENT OF BLOOD PRESSURE by L.A.GEDDES >>

The oscillometric method does not determine an instantaneous blood pressure reading like the auscultatory method employing a microphone-type auto blood pressure monitor but, as described above, determines blood pressure from an uninterrupted changing curve, which means that the oscillometric method is not easily effected by external noise and electro-surgical instruments.

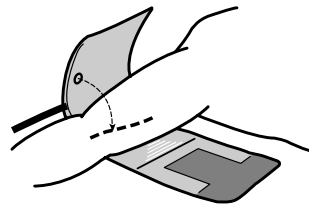
Note: This equipment is suitable for use in the presence of electro-surgery.

Setup Connections

1. Measure the patient's limb and select a proper size cuff. As a general rule, cuff width should span approximately two-thirds of the distance between the patient's elbow and shoulder.
2. Connect the cuff hose to the connector on the monitor's right panel and turn to right to lock (see Figure 3).
3. Connect a cuff to the cuff hose and turn the connector to right to lock the hoses together. Firm connection must be made.



4. Wrap the cuff around a bare arm or around an arm covered in thin clothing. Thick clothing or a rolled up sleeve will cause a major discrepancy in the blood pressure reading.
5. Wrap the cuff around the patient's arm so that the center of the cuff's rubber bladder sits on the artery of the upper arm. The hose should be brought out from the peripheral side without bending (The Brachial artery is located on the inside of the patient's upper arm.) At this time, check that the index line on the edge of the cuff sits inside the range. Use a different sized cuff if the index line is outside of the range because this will cause a major discrepancy in blood pressure reading.



CAUTION: The adult cuff should be wrapped around the arm tightly enough so that only two fingers can be inserted under it, above and below the cuff.

6. Maintain the height of the cuff-wrapped upper arm artery to that of the heart's right ventricle during measurement.
7. Follow the cuff directions for use when applying the cuff to the arm.

Note: Obtaining NIBP readings can be more difficult in patients with arrhythmias. These arrhythmias increase the beat-to-beat pressure fluctuations, which increases the variability of the NIBP readings. Temporarily verify pressure using another method if it becomes difficult to obtain readings in the presence of arrhythmias.

Table 24. Cuff Size

	Model Number	Arm circumference (cm)
Neonate	Cuff No.10	3.5 to 6
	Cuff No.11	5.0 to 7.5
	Cuff No.12	7.5 to 10.5
	Cuff No.13	8.5 to 13
Pediatric	HEM-CS23	13 to 22
Adult	HEM-CR23	22 to 32
	HEM-CL23	32 to 42
	HEM-CX23	42 to 50

NIBP Measurement Modes

Blood pressure measurements can be made in three modes:

- **MANUAL mode:** Single measurement of systolic/diastolic/mean arterial pressure.
- **Automatic (AUTO) mode:** Measurements at preset intervals.
- **Continuous (CONT) mode:** As many measurements as possible within a 5-minute period

To Initiate MANUAL Measurement Mode

1. Press the **NIBP Start/Stop Button**.

A single blood pressure measurement will be made. The measurement will be displayed for 180 minutes unless another measurement is initiated. A manual NIBP reading can be obtained in AUTO mode by pressing **NIBP Start/Stop Button** between two AUTO measurements without the cancellation of AUTO mode.

To Initiate Automatic (AUTO) Measurement Mode

1. Select the desired automatic mode interval from **NIBP Menu**, accessed via the NIBP numerical area (see Table [2525](#)). The initial measurement will start automatically in a selected interval.
2. An NIBP reading can be cancelled by pressing the **NIBP Start/Stop Button** during the AUTO measurements.

Note: When the time interval is set to **1 minute**, the initial measurement will automatically start after 5 seconds or it can be activated by pressing the **NIBP Start/Stop Button** after selecting **1 minute**. Then the measurement interval will be automatically converted to *Off* after 12 minutes elapsed.

The NIBP numerical area will display the **NIBP Auto Mode Interval** and **NIBP Elapsed Time Icon**. The interval is the time from when one measurement starts to when the next measurement starts. The measurement value will be displayed until another measurement starts. When AUTO mode is cancelled, the last measurement will be displayed for 180 minutes.

In AUTO mode, the monitor attempts to meet the requirement of SVRP (Safe Venous Return Pressure) as long as starting a new reading does not violate the requirement of being 30 seconds below SVRP between readings. A new blood pressure reading will not start until the 30 second period has elapsed. When CONT or 1 minute are selected in the **NIBP Menu**, this SVRP can be shortened over 2 seconds since CONT is the intensive measurement during the short term which is 5 minutes and 1 minute is the auto measurement during the short term which is 12 minutes.

To Initiate Continuous (CONT) Measurement Mode

You may press the **NIBP Start/Stop Button** and hold it for at least 2 seconds to activate the continuous measurement. The initial measurement will automatically starts after 5 seconds, or it can be also activated by pressing the **NIBP Start/Stop Button** after initiating **Cont**. The measurement interval will automatically be converted to *Off* after 5 minutes elapsed. Also, if the **NIBP Start/Stop Button** is pressed during CONT mode, the measurement will be canceled and the interval will be converted to *Off*.

To Stop Blood Pressure Measurements

You may press the **NIBP Start/Stop Button** at any time to stop the current measurement and deflate the cuff. If an automatic measurement is underway, the next measurement will start at the next interval after the current measurement stops.

서식 있음: 맞춤법 및 문법 검사

Description of NIBP Menu Functions

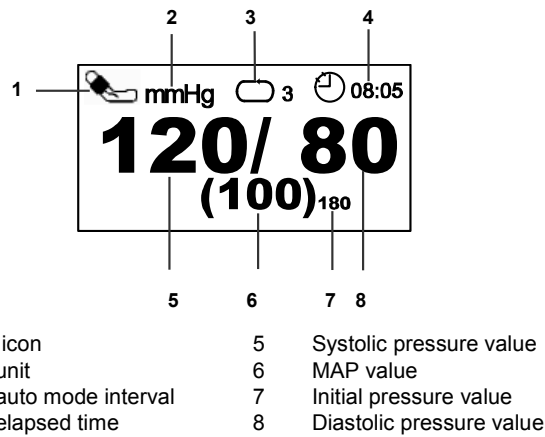


Figure 16. NIBP Display

Table 25. NIBP Menu

Level 1 Menu	Level 2 Menu or Response
NIBP MENU	
Automatic Mode Interval	Off, 1 min, 2.5 min, 3 min, 5 min, 10 min, 15 min, 30 min, 60 min, 90 min
Initial Inflate Pressure	120, 140, 160, 180, 200, 220, 240, 260, 280 (mmHg) (Adult/pediatric) 80, 90, 100, 110, 120, 130, 140 (mmHg) (Neonatal)
NIBP Unit	mmHg, kPa
(SYS Alarm Limits Adjustment)	
▲	Upper Alarm Limit
▼	Lower Alarm Limit
(MAP Alarm Limits Adjustment)	
▲	Upper Alarm Limit
▼	Lower Alarm Limit
(DIA Alarm Limits Adjustment)	
▲	Upper Alarm Limit
▼	Lower Alarm Limit
(NIBP Alarm Inhibition)	On, Off
Return	

Note: Initial Inflate Pressures shown above are for Adult patient mode. In order to set alarm limits to Neonatal mode, change Patient mode via the **Setup Menu**.

Note: The NIBP unit can only be changed by authorized personnel via the **Service Menu**.

Initial Inflate Pressure

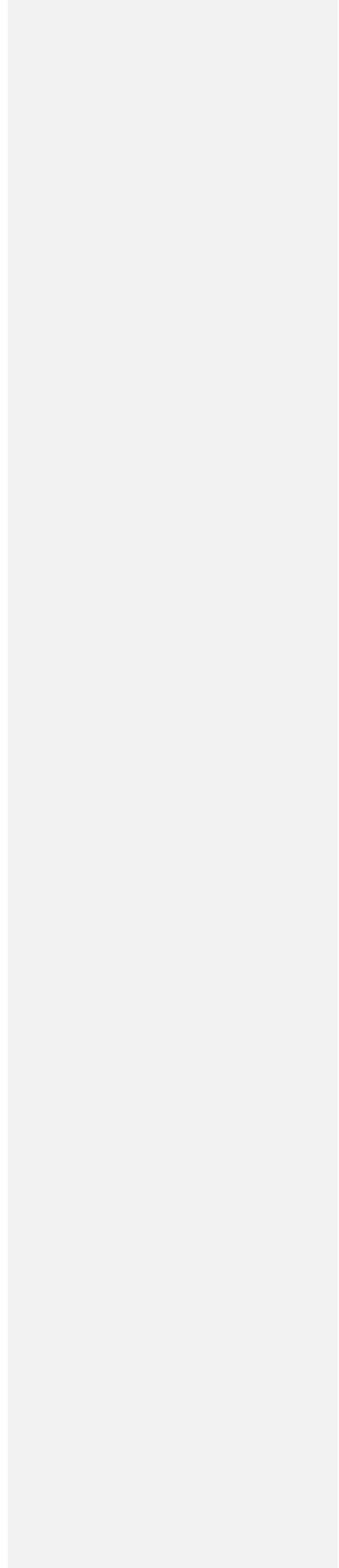
The inflating pressure can be set from 120 to 280 mmHg for adult and pediatric, or from 80 to 140 mmHg for neonatal.

NIBP Alarm Inhibition

When the NIBP alarm inhibition is set to **On**, the audible alarm for NIBP systolic, MAP and diastolic limit violation is inhibited.



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SpO₂ MONITORING



WARNING: For best product performance and measurement accuracy, use only accessories manufactured by Tyco Healthcare Inc. or supplied by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards.



WARNING: Tissue damage can be caused by incorrect application or use of an SpO₂ sensor. Harm can be caused, for example, by wrapping the sensor too tightly, by applying supplemental tape, or by leaving a sensor on too long in one place. Inspect the sensor site as directed in the sensor directions for use to ensure skin integrity, correct positioning, and adhesion of the sensor.



WARNING: Do not use damaged SpO₂ sensors. Do not use an SpO₂ sensor with exposed optical components. Do not immerse sensor completely in water, solvents, or cleaning solutions because the sensor and connectors are not waterproof. Do not sterilize SpO₂ sensors by irradiation, steam or ethylene oxide. Refer to the cleaning instructions in the directions for use for reusable SpO₂ sensors.



WARNING: Inaccurate measurements may be caused by:

- incorrect sensor application or use
- significant levels of dysfunctional hemoglobin (such as carboxyhemoglobin or methemoglobin)
- intravascular dyes such as indocyanine green or methylene blue
- exposure to excessive illumination, such as surgical lamps (especially ones with a xenon light source), bilirubin lamps, fluorescent lights, infrared heating lamps, or direct sunlight
- excessive patient movement
- high-frequency electrosurgical interference and defibrillators
- venous pulsations
- placement of a sensor on an extremity with a blood pressure cuff, arterial catheter, or intravascular line
- patient conditions such as hypotension, severe vasoconstriction, severe anemia, hypothermia, cardiac arrest, or shock
- arterial occlusion proximal to the sensor
- environmental conditions
- unspecified length of the extension cable



WARNING: Do not attach any cable to the sensor port connector that is intended for computer use.



CAUTION: The sensor disconnect error message and associated alarm indicate the sensor is either disconnected or the wiring is faulty. Check the sensor connection and, if necessary, replace the sensor, extension cable or both.



CAUTION: Reusable sensors may be used on the same site for a maximum of 4 hours, provided the site is inspected routinely to ensure skin integrity and correct positioning.

General

The monitor uses pulse oximetry to measure functional oxygen saturation in the blood. Because a measurement of SpO₂ is dependent upon light from the SpO₂ sensor, excessive ambient light can interfere with this measurement. SpO₂ and Pulse rate are updated every second. This monitor measures functional saturation - oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin.

Functional versus Fractional Saturation

This monitor measures functional saturation — oxygenated hemoglobin expressed as a percentage of the hemoglobin that can transport oxygen. It does not detect significant amounts of dysfunctional hemoglobin, such as carboxyhemoglobin or methemoglobin. In contrast, hemoximeters such as the IL482 report fractional saturation — oxygenated hemoglobin expressed as a percentage of all measured hemoglobin, including measured dysfunctional hemoglobin. To compare functional saturation measurements to those from an instrument that measures fractional saturation, fractional measurements must be converted as follows:

$$\text{functional saturation} = \frac{\text{fractional saturation}}{100 - (\% \text{carboxyhemoglobin} + \% \text{methemoglobin})} \times 100$$

Measured versus Calculated Saturation

When saturation is calculated from a blood gas partial pressure of oxygen (PO₂), the calculated value may differ from the SpO₂ measurement of the monitor. This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO₂ and pH, temperature, the partial pressure of carbon dioxide (PCO₂), 2, 3-DPG, and fetal hemoglobin.

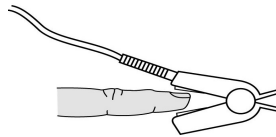
Automatic Calibration

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the OXIMAX sensor's red LED to accurately measure SpO₂. The wavelength range of the light emitted are near 660 nm and 890 nm with the energy not exceeding 15 mW. During monitoring, the instrument's software selects coefficients that are appropriate for the wavelength of that individual sensor's red LED; these coefficients are then used to determine SpO₂. Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is adjusted automatically.

Setup Connections

When selecting a sensor, consider the patient's weight and activity, adequacy of perfusion, availability of sensor sites, need for sterility, and anticipated duration of monitoring. Refer to Table 26, or contact Tyco Healthcare Inc. or Mediana sales department for ordering information.

1. Select the proper sensor for the patient.
2. Connect the extension cable to the SpO₂ connector on the monitor's right panel and lock it (see Figure 3).
3. Connect the sensor to the extension cable and lock it.
4. Carefully apply the sensor to the patient, as described in the sensor directions for use. Observe all warnings and cautions in the directions for use.



Note: Refer to directions for use to ensure the proper placement for various types of SpO₂ sensors.

Note: Periodically check to see that the sensor remains properly positioned on the patient and that skin integrity is acceptable. Refer to the sensor directions for use.

Table 26. SpO₂ Sensors

	Sensor	Model	Patient Size	
For Mediana Module	SpO ₂ reusable sensor YM-1	YM-1	>40 kg	
	SpO ₂ disposable sensor YM-2	YM-2	<3 kg or >40 kg	
	SpO ₂ disposable sensor YM-3	YM-3	>30 kg	
	SpO ₂ disposable sensor YM-4	YM-4	10 to 30 kg	
	SpO ₂ disposable sensor YM-5	YM-5	10 to 30 kg	
For Nellcor Module	OXIMAX oxygen transducer (Sterile, single-use only)	MAX-N MAX-I MAX-P MAX-A MAX-AL MAX-R	<3 or >40 kg 3 to 20 kg 10 to 50 kg >30 kg >30 kg >50 kg	
	OXIMAX Oxiband® oxygen transducer (Reusable with disposable non-sterile adhesive)	OXI-A/N OXI-P/I	<3 or >40 kg 3 to 40 kg	
	OXIMAX Durasensor® Oxygen transducer (Reusable, non-sterile)	DS-100A	>40 kg	
	OXIMAX OxiCliq® oxygen transducers (Sterile, single-use only)	P	10 to 50 kg	
		N	<3 or >40 kg	
		I	3 to 20 kg	
		A	>30 kg	
	OXIMAX Dura-Y® multisite oxygen transducer (Reusable, non-sterile) For use with the Dura-Y sensor:	D-YS	>1 kg	
		Ear clip (Reusable, non-sterile)	D-YSE	>30 kg
		Pedi-Check™ pediatric spot-check clip (Reusable, non-sterile)	D-YSPD	3 to 40 kg
OXIMAX MAX-FAST® adhesive reflectance oxygen transducer	MAX-FAST	>40 kg		

Description of SpO₂ Menu Functions

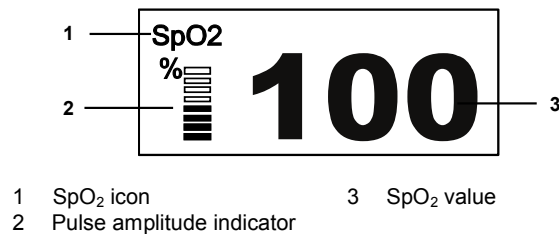


Figure 17. SpO₂ Display

Pulse Amplitude Indicator

The pulse amplitude indicator is the segmented display within the SpO₂ numerical area that shows the relative strength of the detected pulse. A stronger pulse causes a larger amplitude indicator.

Table 27. SpO₂ Menu

Level 1 Menu	Level 2 Menu or Response
SpO₂ MENU	
C-Lock	On, Off
(Alarm Limits Adjustment)	
▲	Upper Alarm Limit
▼	Lower Alarm Limit
(SpO ₂ Alarm Inhibition)	On, Off
Return	

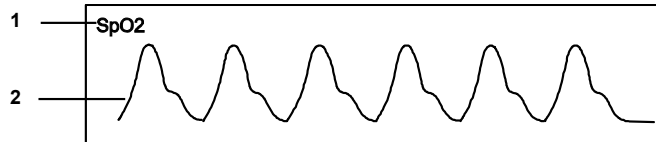
C-Lock

When C-Lock is turned on in the SpO₂ menu, C-Lock automatically becomes operational any time a valid ECG signal is detected by the monitor. It is not necessary to turn C-Lock off if an ECG signal is not available; the monitor handles this function automatically. If the ECG signal is noisy, or of poor quality, SpO₂ performance may be improved by turning C-Lock off. C-Lock provides ECG synchronization for more reliable saturation measurements. An ECG (R-wave) signal can be used as a time reference to identify the pulse and synchronize saturation measurements. C-Lock enhances performance while maintaining rapid response time.

SpO₂ Alarm Inhibition

When the SpO₂ alarm inhibition is set to **On**, the audible alarm for SpO₂ limit violation is inhibited.

Description of Pleth Waveform Menu Functions



1 SpO₂ waveform icon 2 SpO₂ waveform

Figure 18. SpO₂ Waveform Display

Table 28. SpO₂ Waveform Menu

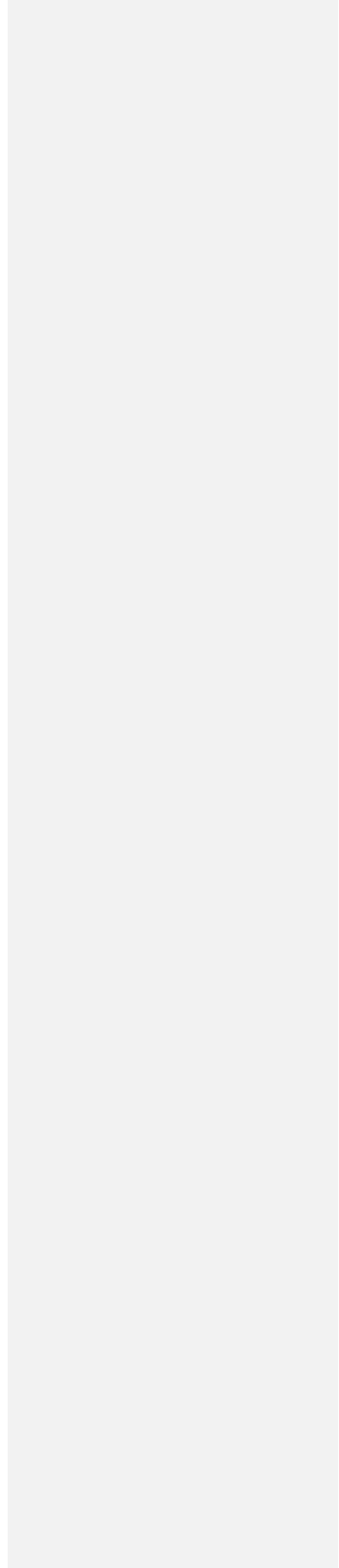
Level 1 Menu	Level 2 Menu or Response
SpO₂ WAVEFORM MENU	
Sweep Speed	12.5 mm/s, 25.0 mm/s, 50.0 mm/s
Large Numeric NIBP	-
Waveform Menu	ECG waveform, SpO ₂ waveform, Respiration waveform
Trend Menu	Tabular Trend, Graphical Trend
Return	

Sweep Speed

The user-selectable Sweep Speed determines the speed at which the SpO₂ waveform trace moves across the screen. **Sweep Speed** can be selected from 12.5 mm/s, 25.0 mm/s and 50.0 mm/s, and the SpO₂ waveform is synchronized with the ECG waveform.



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RESPIRATION MONITORING



WARNING: For best product performance and measurement accuracy, use only accessories supplied or recommended by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards.



WARNINGS: The monitor does not detect apnea when the respiration signal is measured by trans-thoracic impedance.



WARNING: Keep patients under close surveillance when monitoring respiration. Respiration signals are relatively more sensitive to interference from radiated electromagnetic signals. Thus, it is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and monitor can cause inaccurate respiration readings. Do not rely entirely on the monitor respiration readings for patient assessment. If measured waveforms are not appropriate readings, check external conditions to ensure there is no equipment causing electromagnetic interference.

General

The impedance respiration measurement uses the impedance between ECG electrodes. Human respiration takes place by chest expansion by the respiratory muscle. As the chest expands in the inspiratory movement, the impedance between the ECG electrodes will change. The monitor detects respiration rate by putting high-frequency current between RA and LA of the ECG electrodes.

Setup Connections

Refer to the **ECG Monitoring** section for how to acquire the respiration signal by patient impedance using the ECG electrodes, leads and cable.

The performance of impedance respiration can be improved by the particular placement of the Left arm (LA) and Right arm (RA) electrodes. (See **Standard ECG electrode placement** in Figure 12.)

Description of Respiration Menu Functions



1 Respiration icon 2 Respiration value

Figure 19. Respiration Display

Table 29. Respiration Menu

Level 1 Menu	Level 2 Menu or Response
RESPIRATION MENU	
Respiration	On, Off
(Alarm Limits Adjustment)	
▲	Upper Alarm Limit
▼	Lower Alarm Limit
(Respiration Alarm Inhibition)	On, Off
Return	

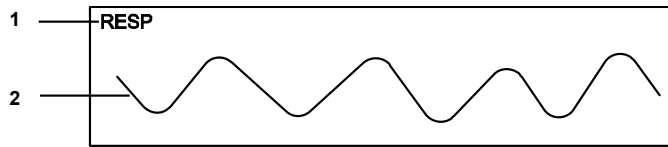
Respiration

When respiration is set to **On**, The measurement value for respiration rate and respiration waveform are displayed on the screen. And when the respiration is set to **Off**, respiration rate is not measured and respiration value is displayed with “---”. Respiration icon is only displayed when the respiration is set to **On**.

Respiration Alarm Inhibition

When respiration alarm inhibition is set to **On**, the audible alarm for respiration rate limit violation is inhibited.

Description of Respiration Waveform Menu Functions



1 Impedance respiration waveform icon 2 Respiration waveform

Figure 20. Respiration Waveform Display

Table 30. Respiration Waveform Menu

Level 1 Menu	Level 2 Menu or Response
RESPIRATION WAVEFORM MENU	
Sweep Speed	6.25 mm/s, 12.5 mm/s, 25.0 mm/s
Size	Auto, 1, 2, 3, 4, 5, 6, 7, 8
Large Numeric NIBP	-
Waveform Menu	ECG waveform, SpO ₂ waveform, Respiration waveform
Trend Menu	Tabular trend, Graphical Trend
Return	

Sweep Speed

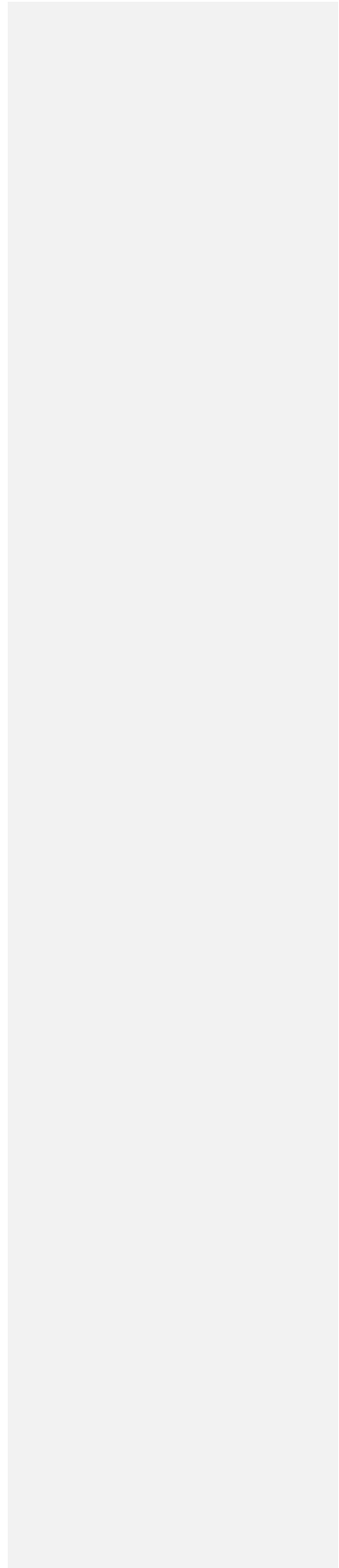
The user-selectable sweep speed determines the speed at which the respiration waveform trace moves across the screen. **Sweep Speed** can be selected from 6.25 mm/s, 12.5 mm/s and 25.0 mm/s.

Size

Size allows you to adjust the waveform size. When the size is set to **Auto**, The monitor automatically determines the optimal size of the respiration waveform to fit the space.



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TEMPERATURE MONITORING



WARNING: For best product performance and measurement accuracy, use only YSI 400 and 700 series temperature probes recommended by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards.

General

Measurement of patient temperature is accomplished by processing the signal from a probe containing a resistance element whose impedance is temperature dependent. These devices are called thermistors. The measuring time required to obtain accurate readings at the specific body site is about 10 seconds.

Setup Connections

The monitor is designed to accept signals from the temperature probes, YSI 400 series and 700 series for skin, rectal or etc. Refer to the temperature probe directions for use for details

1. Insert a body temperature probe into the temperature connector on the monitor's right panel (see Figure 3).
2. Follow the directions for use accompanying the temperature probe.

Description of Temperature Menu Functions

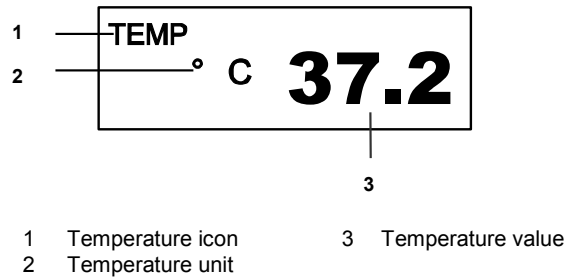


Figure 21. Temperature Display

Table 31. Temperature Menu

Level 1 Menu	Level 2 Menu or Response
TEMPERATURE MENU	
Temp Unit	°C, °F
(Alarm Limits Adjustment)	
▲	Upper Alarm Limit
▼	Lower Alarm Limit
(Temperature Alarm Inhibition)	On, Off
Return	

Note: The temperature unit of measure can only be changed by authorized personnel via the **Service Menu**.

Temperature Alarm Inhibition

When the temperature alarm inhibition is set to **On**, the audible alarm for Temperature limit violation is inhibited.

TRENDS

General

Trend data in either graphical or tabular format may be displayed or printed if a printer module is installed (see **Printing** section).

1. Rotate the jog dial to highlight the **Trend Select Icon**.
2. Press the jog dial to display the trend screen.
3. Select the trend screen by rotating and pressing the jog dial.

The trend data is stored in memory. When the monitor turns on and starts to measure vital signs, the monitor saves data at a selected interval. Also, the monitor saves all physiological alarm conditions, NIBP measurements and error events. The data remains even if the monitor is powered off. After the monitor has stored 20480 trend data, the monitor begins to store the new data over the oldest data.

Tabular Trend Data

The monitor presents trend information in tabular format for all monitored parameters. The newest data appears at the bottom of tabular trends. The gray bar at the right side of the trend screen presents the memory saved. The red point indicates the location of current scrolling location.

For the NIBP trends, the data may display the latest measurement.

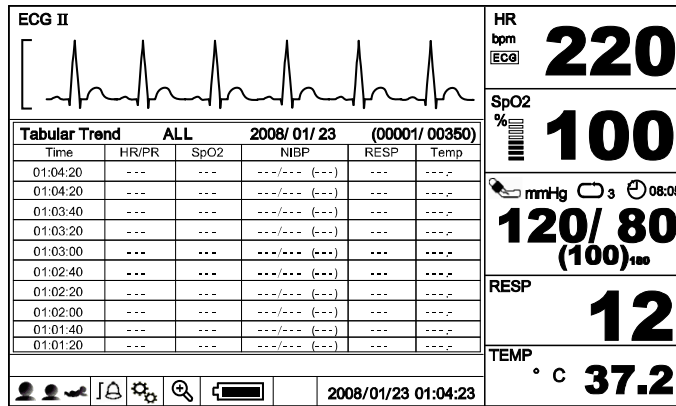


Figure 22. Tabular Trend Screen

To scroll or change viewing options, push the jog dial on the tabular trend screen when the tabular trend screen is highlighted. The monitor displays the **Tabular Trend Menu**.

Table 32. Tabular Trend Menu

Level 1 Menu	Level 2 Menu or Response
TABULAR TREND MENU	
Scroll	The jog dial is activated for scrolling. Note: Press the Home Button to exit.
Display Time Interval	20sec, 1, 2, 3, 5, 10, 20 minutes
Trend Display Select	Normal, NIBP, Alarm, Normal + NIBP, Normal + Alarm, NIBP + Alarm, All
Tabular Trend Off	-
Return	<i>Exits Tabular Trend Menu immediately, returns to Tabular Trend Screen.</i>

Scrolling Tabular Trend Data

1. Rotate the jog dial to highlight **Scroll**.
2. Press the jog dial to activate scrolling.
3. Rotate the jog dial to scroll through the trend data.
Clockwise rotation moves forward to newer data. Counterclockwise rotation moves backward to older data.
4. After viewing the trends, press the jog dial to exit the scrolling.

Display Time Interval

The display time interval can be selected from 20 sec, 1, 2, 3, 5, 10, 20 minutes. The tabular trend will be displayed in a selected interval.

Trend Display Select

The monitor displays the trends selected by the user.

- Normal
- NIBP
- Alarm
- Normal + NIBP
- Normal + Alarm
- NIBP + Alarm
- All

Tabular Trend Off

To exit tabular trend display, select **Tabular Trend Off**.

Graphical Trend Data

Trend information in graphical format for all monitored parameters is displayed in one graph. The user can select each parameter to display via interaction with **Graphical Trend Menu**.

The graphical trend data of each parameter is indicated by the symbols specified in table 25. The vertical range of a graphical trend is presented with fixed value, and the horizontal range is 90 minutes. The newest data appears at the right of graphical trend. Use the scroll function to view more data.

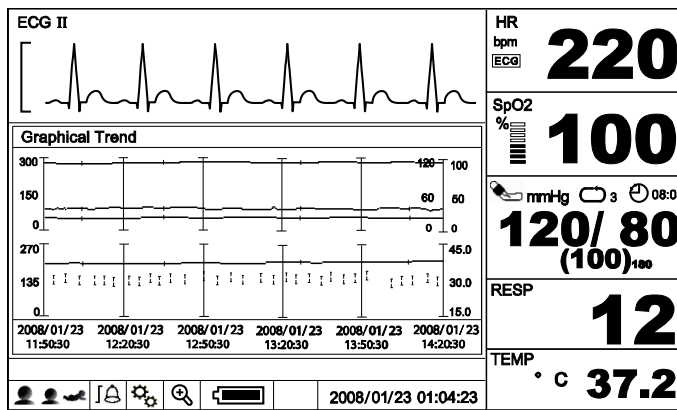


Figure 23. Graphical Trend Screen

To scroll or change viewing options, push the jog dial on the tabular trend screen when the tabular trend screen is highlighted. The monitor displays the **Graphical Trend Menu**.

Table 33. Graphical Trend Menu

Level 1 Menu	Level 2 Menu or Response
GRAPHICAL TREND MENU	
Scroll	The jog dial is activated for scrolling. Note: Press the Home Button to exit.
HR/PR Graphical Trend	On, Off
SpO ₂ Graphical Trend	On, Off
NIBP Graphical Trend	On, Off
RESP Graphical Trend	On, Off
TEMP Graphical Trend	On, Off
Graphical Trend Off	-
Return	<i>Exits Graphical Trend Menu immediately, returns to Graphical Trend Screen.</i>

Scrolling Graphical Trend Data

1. Rotate the jog dial to highlight **Scroll**.
2. Press the jog dial to activate scrolling.
3. Rotate the jog dial to scroll through the trend data.
Clockwise rotation moves forward to newer data. Counterclockwise rotation moves backward to older data.
4. After viewing the trends, press the jog dial to exit the scrolling.

Selecting Graphical Trend Data

1. Rotate the jog dial to select **HR/PR, NIBP, SpO₂, RESP or TEMP**.
2. Press the jog dial to set to **On**.
3. Rotate the jog dial to highlight **Return**, then press the jog dial to return to the graphical trend screen. Only parameters set to **On** will be displayed in the graphical trend screen.

Note: Setting **Off** will not display the trends of the selected parameter.

Graphical Trend Off

To exit graphical trend display, select **Graphical Trend Off**.

MENU STRUCTURE

ECG WAVEFORM MENU

- Lead Select
 - I
 - II
 - III
 - aVR
 - aVL
 - aVF
 - V (Chest Lead)
 - Return
- Sweep Speed
 - 12.5 mm/s
 - 25.0 mm/s
 - 50.0 mm/s
 - Return
- Size
 - Auto
 - 1.25 mm/mV
 - 1.7 mm/mV
 - 2.5 mm/mV
 - 5.0 mm/mV
 - 7.5 mm/mV
 - 10.0 mm/mV
 - 15.0 mm/mV
 - 20.0 mm/mV
 - Return
- Pacer Detect
 - On
 - Off
- Filter Mode
 - Monitor
 - Low Extend
 - Filter
 - Return
- Large Numeric NIBP
- Waveform Menu
 - ECG waveform
 - SpO₂ waveform
 - Respiration waveform
 - Return
- Trend Menu
 - Tabular Trend
 - Graphical Trend
 - Return
- Return

SpO₂ WAVEFORM MENU

- Sweep Speed
 - 12.5 mm/s
 - 25.0 mm/s
 - 50.0 mm/s
 - Return
- Large Numeric NIBP Waveform Menu
 - ECG waveform
 - SpO₂ waveform
 - Respiration waveform
 - Return
- Trend Menu
 - Tabular Trend
 - Graphical Trend
 - Return
- Return

RESPIRATION WAVEFORM MENU

- Sweep Speed
 - 6.25 mm/s
 - 12.5 mm/s
 - 25.0 mm/s
 - Return
- Size
 - Auto
 - 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
 - Return
- Large Numeric NIBP Waveform Menu
 - ECG waveform
 - SpO₂ waveform
 - Respiration waveform
 - Return
- Trend Menu
 - Tabular Trend
 - Graphical Trend
 - Return
- Return

Note: You can select the same waveform to display in two consecutive waveform areas.

HR/PR MENU

- **HR/PR Source**
- - **AUTO** *"HR > SpO₂ PR > NIBP PR"*
- - **ECG**
- - **SpO₂**
- - **NIBP**
- - **Return**



"Alarm limits adjustment"



180

40

"HR/PR alarm inhibition"

- -  **On**
- -  **Off**
- - **Return**

NIBP MENU

- **Automatic Mode Interval**
- - Off
- - 1 min
- - 2.5 min
- - 3 min
- - 5 min
- - 10 min
- - 15 min
- - 30 min
- - 60 min
- - 90 min
- - Return







- **Initial Inflate Pressure**
- - *"Adult/Pediatric"*
- - 120 mmHg
- - 140 mmHg
- - 160 mmHg
- - 180 mmHg
- - 200 mmHg
- - 220 mmHg
- - 240 mmHg
- - 260 mmHg
- - 280 mmHg
- - Return
- - *"Neonatal"*
- - 80 mmHg
- - 90 mmHg
- - 100 mmHg
- - 110 mmHg
- - 120 mmHg
- - 130 mmHg
- - 140 mmHg
- - Return

- **NIBP Unit**
- - mmHg
- - kPa



"Alarm limits adjustment (mmHg)"

	SYS	MAP	DIA
▲	200	180	160
▼	70	40	30



"NIBP alarm inhibition"

-   
- On On On
-   
- Off Off Off
- **Return**



SpO₂ MENU

- C-Lock
- - On
- - Off
- *"Alarm limits adjustment"*
- 100
- 90
- *"SpO₂ alarm inhibition"*
- 
- On
- 
- Off
- Return

RESPIRATION MENU

- Respiration
- - On
- - Off
- *"Alarm limits adjustment"*
- 30
- 0
- *"Respiration alarm inhibition"*
- 
- On
- 
- Off
- Return

TEMPERATURE MENU

- Temp Unit
- - °C
- - °F
- *"Alarm limits adjustment (°C)"*
- 38.0
- 14.5
- *"Temperature alarm inhibition"*
- 
- On
- 
- Off
- Return

TABULAR TREND MENU

- Scroll
- Display Time Interval
 - 20 sec
 - 1 min
 - 2 min
 - 3 min
 - 5 min
 - 10 min
 - 20 min
 - Return
- Trend Display Select
 - Normal
 - NIBP
 - Normal + NIBP
 - Normal + Alarm
 - All
 - Return
- Tabular Trend Off
- Return

GRAPHICAL TREND MENU

- Scroll
- HR/PR Graphical Trend
 - On
 - Off
- SpO₂ Graphical Trend
 - On
 - Off
- NIBP Graphical Trend
 - On
 - Off
- RESP Graphical Trend
 - On
 - Off
- TEMP Graphical Trend
 - On
 - Off
- Graphical Trend Off
- Return

SET-UP MENU

- Patient Mode
 - Adult
 - Pediatric
 - Neonatal
 - Return
- Trend Clear
- Print Speed
 - 25 mm/s
 - 50 mm/s
- Print Mode
 - One-Shot
 - Continuous
- Alarm Volume
 - 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - 8
- Key Beep Volume
 - 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - Off
- QRS Beep Volume
 - 1
 - 2
 - 3
 - 4
 - 5
 - 6
 - 7
 - Off
- Service Menu
 - (Pass code)
 - Return
- Return

ALARM LIMITS MENU

- Record On Alarm
 - On
 - Off
- Alarm Limits *"Alarm limits adjustment/Alarm inhibition for each parameter"*

	HR/PR	SpO ₂	RESP	TEMP	SYS	NIBP	
	120	100	30	39.0	160	MAP	DIA
	50	90	8	36.0	90	110	90
	▲	▲	▲	▲		▲	▲
	On	On	On	On		On	
	▲	▲	▲	▲		▲	
	Off	Off	Off	Off		Off	
- Return

Note: Alarm limits shown above are for Adult patient mode. In order to set alarm limits to Pediatric or Neonatal patient mode, change Patient mode via the **Setup Menu**.

DATE/TIME MENU

- Date
 - Year
 - Month
 - Day
 - Return
- Set Time
 - Hour *"24 hours only"*
 - Minute
 - Second
 - Return
- Date Format
 - mm/dd/yy
 - dd/mm/yy
 - yy/mm/dd
 - Return

PRINTING

General

The monitor can print real-time measurement and trend data as follows.

1. Set **Print Speed, Print Mode** via the **Setup Menu** and **Record On Alarm** via the **Alarm Limits Menu**.
2. To start printing, press the **Print Button**.
3. To stop printing during print out, press the **Print Button** again.

Print Speed

The print speed for is user-selectable: either 25.0 or 50.0mm/s. When 50.0mm/s is selected, the Print Mode is fixed to one-shot.

Print Mode

One-Shot

A one-shot print, recording real-time graphical and numeric information beginning 10 seconds before the print initiation and ending 10 seconds after that event.

Continuous

A print of real-time graphical and numeric information, beginning 10 seconds before initiating the action and continuing until stopped.

Record On Alarm

If **Record On Alarm** is set to **On** in Alarm Limits menu, the monitor will automatically print out whenever a physiological alarm condition occurs.

Print-Out Configuration

One-Shot Print-Out

If **Print Mode** is set to **One-Shot**, the monitor will print out numeric data and waveforms by pressing the **Print Button** as shown Figure 2424.

서식 있음: 글꼴 색: 자동, 맞춤법 및 문법 검사

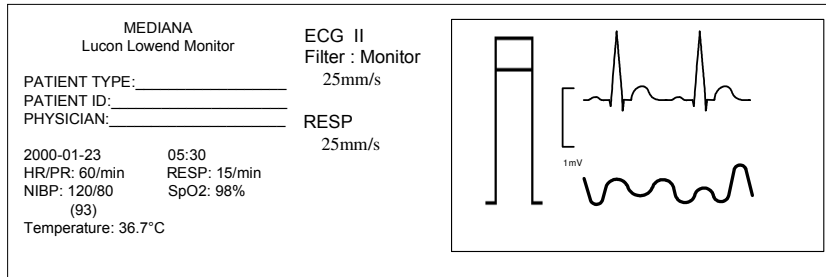


Figure 24. One-Shot Printing

Continuous Print-Out

If **Print Mode** is set to **Continuous**, the monitor will print out numeric data every minute and waveforms continuously by pressing the **Print Button** as shown in Figure 25.

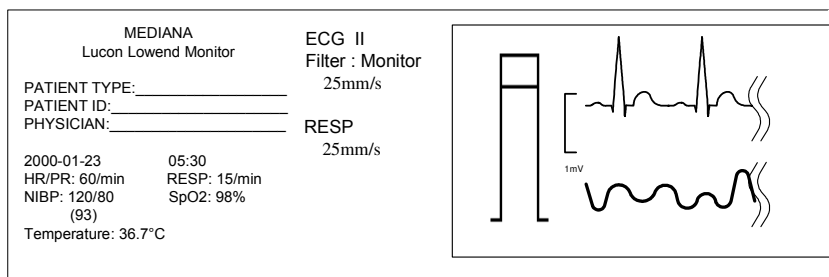


Figure 25. Continuous Printing

Tabular Trend Data Print Out

When tabular trend data is displayed on the screen, the monitor will print out the displayed data by pressing the **Print Button** as shown in Figure 2626.

서식 있음: 글꼴 색: 자동, 맞춤법 및 문법 검사

TIME	HR/PR	SpO ₂	RESP	SYS	MAP	DIA	TEMP
05:30:00	60	99↑	12	---	---	---	30.2 ↓
05:30:00	60	99↑	12	---	---	---	30.2 ↓
05:30:00	60	99↑	12	---	---	---	30.2 ↓
05:30:00	60	99↑	12	---	---	---	30.2 ↓
05:30:00	60	99↑	12	---	---	---	30.2 ↓
05:30:00	60	99↑	12	---	---	---	30.2 ↓
05:30:00	60	99↑	12	---	---	---	30.2 ↓
05:30:00	60	99↑	12	---	---	---	30.2 ↓
05:30:00	60	99↑	12	---	---	---	30.2 ↓

Figure 26. Tabular Trend Printing

Setting Information Print-Out

The monitor can print out all internal settings by selecting **Print value of configuration** in the **Service Menu** as shown in Figure 2727. Refer to the service manual for the detailed instructions.

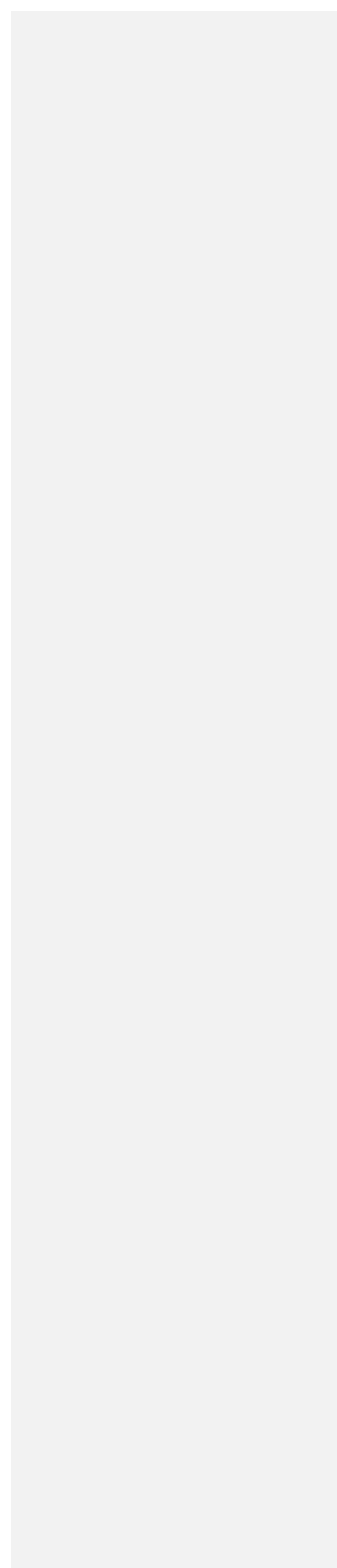
서식 있음: 글꼴 색: 자동, 맞춤법 및 문법 검사

MEDIANA	HR/PR MENU-----
Lucon Lowend Monitor	HR/PR Source : AUTO
2008-01-23 05:30	HR/PR High Alarm (BPM) : 120
	HR/PR Low Alarm (BPM) : 50
ECG WAVE MENU-----	SPO2 MENU-----
Sweep Speed 25.0mm/s	C-Lock: Off
Pacer Detect OFF	SPO2 High Alarm (%) : 100
Filter Mode Monitor	SPO2 Low Alarm (%) : 90
SPO2 WAVE MENU-----	-NIBP MENU-----
Sweep Speed 25.0mm/s	Automatic Interval Off
RESPIRATION WAVE MENU-----	Initial Inflate Pressure 180mmHg
Sweep Speed 12.5mm/s	NIBP Unit : mmHg
	SYS High Alarm (mmHg) : 160

Figure 27. Setting Information Printing



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EXTERNAL INTERFACE

General

The monitor provides external connectors on the right panel to support communication with external equipment and functions such as a nurse call, software upgrades or PC connection.



WARNING: Any connections between this monitor and other devices must comply with applicable medical systems safety standards such as IEC 60601-1. Failure to do so could result in unsafe leakage current and grounding conditions.

Note: This equipment is to be used on a network and the communication wirings (LAN or RJ11 Nurse call Interface) are limited to inside of the building.

Cable Connection

RJ11 Nurse Call Interface

The Pin layouts of 6-pin Nurse call interface are illustrated below.

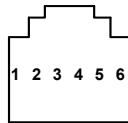


Figure 28. Nurse Call Interface Pin Layout

Table 34. Nurse Call Interface Connections

Pin #	Signal
1	Nurse call normally closed
2	Nurse call common
3	Nurse call normally open
4	12V
5	NC
6	GND

Nurse Call Interface



WARNING: The nurse call feature should not be used as the primary source of alarm notification. The audible alarms of the monitor, used in conjunction with clinical signs and symptoms, are the primary sources for notifying medical personnel that an alarm condition exists.



CAUTION: The nurse call feature is not functional whenever the monitor alarms are silenced.



CAUTION: The nurse call function needs to be tested after it has been set up in your facility. The nurse call feature should be tested whenever setting up the M20 in a location that uses nurse call. One way to test the nurse call function is to create an alarm condition (for example, sensor disconnect) and verify that your facility's nurse call system is activated.

The nurse call feature of the monitor is operational when the monitor is powered by AC power or battery power. The nurse call feature of the monitor works in conjunction with the nurse call system of your institution when the monitor sounds an audible alarm.

The monitor provides the nurse call interface of relay closure type. The interface functions when the monitor is operating either on AC power or battery power.

The remote location is signaled anytime there is an audible alarm. If the audible alarm has been turned off or silenced, the nurse call function is also turned off.

Nurse Call Relays Normally Open/Closed

Pins 2 and 3 provide a relay that closes when an alarm is sounding on the monitor. Pins 1 and 2 provide a relay that opens when an alarm is sounding. Pin 2 is a common lead for both relays.

MAINTENANCE



WARNING: The cover should be removed only by qualified service personnel. There are no internal user-serviceable parts except for the battery.



WARNING: Do not spray, pour, or spill any liquid on the monitor, its accessories, connectors, switches or openings in the chassis.



WARNING: Unplug the power cord from the monitor before cleaning the monitor.

Recycling and Disposal

When the monitor, battery, or accessories reach the end of useful life, recycle or dispose of the equipment according to appropriate local and regional regulations.

Note: The monitor should be disposed of separately from the municipal waste stream via designated collection facilities appointed by the government or the local authorities.

Note: The correct disposal of your old appliance will help prevent potential negative consequences for the environment and human health.

Note: For more detailed information about disposal of your old appliance, please contact your city office, waste disposal service or the shop where you purchased the monitor.

Returning the Monitor and System Components

Pack the monitor with sensors, cable or other accessory items in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect the monitor during shipping.

Service

The monitor requires no routine service other than cleaning, battery maintenance, and service activity which is mandated by the user's institution. For more information, refer to the monitor service manual. Qualified service personnel in the user's institution should perform periodic inspections of the monitor. If service is necessary, contact qualified service personnel or your local supplier.

Periodic Safety Checks

It is recommended that the following checks be performed every year.

- Inspect the equipment for mechanical and functional damage.
- Inspect the external safety labels for legibility.

Cleaning

The monitor may be surface-cleaned by using a soft cloth dampened with either a commercial, nonabrasive cleaner or one of the solutions listed below. Lightly wipe the top, bottom and front surfaces of the monitor.

- 70% Isopropyl alcohol
- 10% Chlorine bleach solution

For cables, sensors, cuffs, and probes, follow the cleaning instructions in the directions for use shipped with those components.

Avoid spilling liquid on the monitor, especially in connector areas. If liquid is accidentally spilled on the monitor, clean and dry thoroughly before reuse. If in doubt about monitor safety, refer the unit to qualified service personnel for checking.

Battery Maintenance

- ◆ **CAUTION: Recharging the battery is strongly recommended when the battery has not been recharged for 2 or more months.**
- ◆ **CAUTION: Follow local government ordinances and recycling instructions regarding disposal or recycling of device components, including batteries.**
- ◆ **CAUTION: Do not short-circuit the battery, as it may generate heat. To avoid short-circuiting, do not let the battery come in contact with metal objects at any time, especially when transporting.**
- ◆ **CAUTION: Do not solder the battery directly. Heat applied during soldering may damage the safety vent in the battery's positive cover.**
- ◆ **CAUTION: Do not deform the battery by applying pressure. Do not throw, hit, drop, fold or impact the battery.**
- ◆ **CAUTION: Do not connect the battery reversed in positive (+) and negative (-) terminals. Do not charge the battery with polarities reversed, as it may swell or explode.**
- ◆ **CAUTION: Do not use any chargers not specified by Mediana.**
- ◆ **CAUTION: Do not use the battery with other maker's batteries, different types or models of batteries such as dry batteries, nickel-metal hydride batteries, or Li-ion batteries together, as they might leak electrolyte heat or explode.**
- ◆ **CAUTION: Do not mistreat the battery, or use the battery in applications not recommended by Mediana.**
- ◆ **CAUTION: Keep the battery out of reach of babies and children to avoid any accidents.**
- ◆ **CAUTION: If there are any problems with the battery, immediately put the battery in a safe place and contact qualified service personnel.**

If the monitor has not been used for 2 months, the Li-ion battery will need charging. To charge the battery, connect the monitor to an AC power source as described in the **Battery Operation** section.

Note: Storing the monitor for a long period without charging the battery may degrade the battery capacity. A full charge of a depleted battery takes over 6 hours.

Note: The service menu displays the number of deep discharge cycles seen by the battery. The monitor records a deep discharge cycle when the battery reaches the voltage at which a "Critically low battery" alarm is issued. Refer to the service manual for details.

Note: The battery should be removed from the monitor if placed in storage or if it will not be used for a long period.

It is recommended strongly that the monitor's Li-ion battery be replaced every 6 months. Refer to the service manual for battery replacement and general service instructions.

Loading Printer Paper



CAUTION: Use only printer paper specified by Mediana.

Note: The paper roll is easier to load if it is held horizontally with your thumb on top and your forefinger and/or index finger underneath it.

Load printer paper as follows:

1. Open the printer door by pulling the latch on the printer slightly and carefully. The door should tilt open. Gently pull the door open if necessary.
2. Reach in and remove the empty paper core by pulling it over gently with your thumb and index finger.
3. Insert a new paper roll oriented properly.
4. Pull the paper out towards you until approximately 2 inches (5 cm) of paper have been unrolled.
5. Align the paper with the pinch roller attached to the printer door.
6. Close the printer door.

Note: To make sure that the paper is aligned in the slot and has not been pinched in the door, pull the loose edge until a few inches of paper is showing. If the paper will not move, open the door and return to step 4.

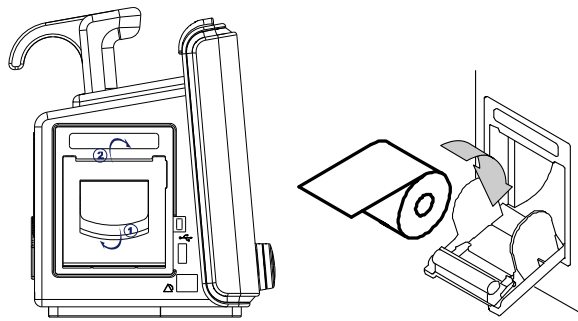


Figure 29. Printer Paper Replacement

TROUBLESHOOTING



WARNING: If you are uncertain about the accuracy of any measurement, check the patient's vital signs by alternate means; then make sure the monitor is functioning correctly.



WARNING: The cover should be removed only by qualified service personnel. There are no user-serviceable parts inside except for the battery.

General

If the monitor detects an error, it can display an error code. The error codes are listed in the monitor service manual. If an error code is displayed, write down the code and contact your service department. Before calling your local supplier, make sure that the battery is charged and that all power connections are in place.

Corrective Action

If you experience a problem while using the monitor and are unable to correct it, contact qualified service personnel or your local supplier. The service manual provides additional troubleshooting information for qualified personnel.

Following is a list of possible errors and suggestions for corrective action.

1. There is no response to the Power Button.

- A fuse may be blown. Notify service personnel to check and replace the fuse.
- If operating on battery power, the battery may be missing or discharged. If the battery is discharged, charge the battery (see **Battery Operation** section).

2. The monitor screen does not function properly and the power-on beep tones do not sound during the power-on self test.

- Do not use the monitor; contact qualified service personnel or your local supplier.

3. The monitor is operating on battery power, even though it is connected to AC.

- Make sure that the power cord is properly connected to the monitor.
- Check to see if power is available to other equipment on the same AC circuit.
- The monitor operates from its internal battery if there is no AC power source.

EMI (Electromagnetic Interference)



WARNING: Keep patients under close surveillance when monitoring. It is possible, although unlikely, that radiated electromagnetic signals from sources external to the patient and monitor can cause inaccurate measurement readings. Do not rely entirely on the monitor readings for patient assessment.



WARNING: It is possible that any radio frequency transmitting equipment and other nearby sources of electrical noise may result in disruption in the monitor operation.



WARNING: It is possible, although unlikely, that large equipment using a switching relay for its power on/off may affect monitor operation. Do not operate the monitor in such environments.

This device has been tested and found to comply with the limits for medical devices to the IEC60601-1-2, and the Medical Device Directive 93/42/EEC. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

However, because of the proliferation of radio-frequency transmitting equipment and other sources of electrical noise in health care environments (such as electrosurgical equipment, defibrillator, cellular phones, mobile two-way radios, electrical appliances, and high-definition television), it is possible that high levels of such interference due to close proximity or strength of a source may affect monitor operation.



WARNING: The monitor is designed for use in environments in which the signal can be obscured by electromagnetic interference. During such interference, measurements may seem inappropriate or the monitor may not seem to operate correctly.

Monitor disruption may be indicated by erratic readings, cessation of operation, or other incorrect functioning. If this occurs, survey the site to determine the source of this disruption. Try the following actions to see if they eliminate the disruption:

- Turn equipment in the vicinity off and on to isolate the offending equipment.
- Reorient or relocate the interfering equipment.
- Increase the separation between the interfering equipment and this equipment.

The monitor generates, uses, and can radiate radio frequency energy. If the monitor is not installed and used in accordance with these instructions, the monitor may cause harmful interference with other devices in the vicinity.

If assistance is required, contact your local supplier.

Obtaining Technical Assistance

For technical information and assistance, or to order a monitor service manual, call your local supplier. The service manual provides information required by qualified service personnel when servicing the monitor.

When calling your local supplier, you may be asked to provide the software version number of your monitor. The software version is displayed when monitor power is activated.

FACTORY DEFAULTS

General

The monitor is shipped with factory default settings. Authorized personnel can use the procedures described in the service manual to change default settings.

Parameter Ranges and Default Settings

Table 35. Parameter Ranges and Factory Defaults

Parameter	Ranges/Selections	Factory Defaults		
		Adult	Pediatric	Neonatal
ECG				
ECG Lead Select	I, II, III, aVR, aVL, aVF, V(Chest Lead)	II	II	II
ECG Size (mm/mV)	Auto, 1.25, 1.7, 2.5, 5.0, 7.5, 10.0, 15.0, 20.0 mm/mV	10.0 mm/mV	10.0 m/mV	10.0 m/mV
ECG Filter Mode	Monitor, Low Extend, Filter	Monitor	Monitor	Monitor
ECG Pacer Detect	On, Off	Off	Off	Off
ECG Sweep Speed	12.5, 25.0, 50.0 mm/s	25.0 mm/s	25.0 mm/s	25.0 mm/s
HR/PR Source	AUTO, ECG, PR	AUTO	AUTO	AUTO
HR/PR Alarm Inhibition	On, Off	Off	Off	Off
HR/PR Upper Alarm Limits	25 to 300 BPM (Adult/Pedi/Neo) (5 BPM steps)	120 BPM	160 BPM	200 BPM
HR/PR Lower Alarm Limits	20 to 295 BPM (Adult/Pedi/Neo) (5 BPM steps)	50 BPM	75 BPM	100 BPM
NIBP				
Automatic Mode Interval	Off, 1, 2.5, 3, 5, 10, 15, 30, 60, 90 min	Off	Off	Off
NIBP Initial Cuff Inflation	120, 140, 160, 180, 200, 220, 240, 260, 280 mmHg (Adult/Pediatric) (16.0, 18.7, 21.3, 24.0, 26.7, 29.3, 32.0, 34.7, 37.3 kPa kPa) 80, 90, 100, 110, 120, 130, 140 mmHg (Neonatal) (10.7, 12.0, 13.3, 14.7, 16.0, 17.3, 18.7 kPa)	180 mmHg 24.0 kPa	180 mmHg 24.0 kPa	120 mmHg 16.0 kPa
NIBP Unit	mmHg, kPa	mmHg	mmHg	mmHg
NIBP Alarm Inhibition	On, Off	Off	Off	Off
NIBP Automatic Mode Interval	Off, 1, 2.5, 3, 5, 10, 15, 30, 60, 90, minutes	Off	Off	Off
NIBP SYS Upper Alarm Limits	35 to 270 mmHg (Adult/Pedi/Neo) 4.6 to 36.0 kPa (Adult/Pedi/Neo) (5 mmHg / 0.6 or 0.7 kPa steps)	160 mmHg 21.3 kPa	120 mmHg 16.0 kPa	90 mmHg 12.0 kPa
NIBP SYS Lower Alarm Limits	30 to 265 mmHg (Adult/Pedi/Neo) 4.0 to 35.3 kPa (Adult/Pedi/Neo) (5 mmHg / 0.6 or 0.7 kPa steps)	90 mmHg 12.0 kPa	70 mmHg 9.3 kPa	40 mmHg 5.3 kPa
NIBP DIA Upper Alarm Limits	15 to 250 mmHg (Adult/Pedi/Neo) 2.0 to 33.3 kPa (Adult/Pedi/Neo) (5 mmHg / 0.6 or 0.7 kPa steps)	90 mmHg 12.0 kPa	70 mmHg 9.3 kPa	60 mmHg 8.0 kPa
NIBP DIA Lower Alarm Limits	20 to 245 mmHg (Adult/Pedi/Neo) 2.6 to 32.6 kPa (Adult/Pedi/Neo)	50 mmHg 6.6 kPa	40 mmHg 5.3 kPa	20 mmHg 2.6 kPa

Parameter	Ranges/Selections	Factory Defaults		
		Adult	Pediatric	Neonatal
	(5 mmHg / 0.6 or 0.7 kPa steps)			
NIBP MAP Upper Alarm Limits	25 to 260 mmHg (Adult/Pedi/Neo) 3.3 to 34.6 kPa (Adult/Pedi/Neo) (5 mmHg / 0.6 or 0.7 kPa steps)	110 mmHg 14.6 kPa	90 mmHg 12.0 kPa	70 mmHg 9.3 kPa
NIBP MAP Lower Alarm Limits	20 to 255 mmHg (Adult/Pedi/Neo) 2.6 to 34.0 kPa (Adult/Pedi/Neo) (5 mmHg / 0.6 or 0.7 kPa steps)	60 mmHg 8.0 kPa	50 mmHg 6.6 kPa	30 mmHg 4.0 kPa
SpO₂				
C-Lock	On, Off	Off	Off	Off
%SpO ₂ Alarm Inhibition	On, Off	Off	Off	Off
%SpO ₂ Upper Alarm Limits	21 to 100 % (Adult/Pedi/Neo) (1 % steps)	100 %	100 %	100 %
%SpO ₂ Lower Alarm Limits	20 to 99 % (Adult/Pedi/Neo) (1 % steps)	90 %	90 %	85 %
Respiration				
Respiration	On, Off	On	On	On
Respiration Alarm Inhibition	On, Off	Off	Off	Off
RR Upper Alarm Limits	4 to 150 BPM (1 BPM steps)	30 BPM	30 BPM	100 BPM
RR Lower Alarm Limits	3 to 149 BPM (1 BPM steps)	8 BPM	8 BPM	30 BPM
Temperature				
Temp Unit	°C, °F	°C	°C	°C
Temp Alarm Inhibition	On, Off	Off	Off	Off
Temp Upper Alarm Limits	15.1 to 45.0 °C (Adult/Pedi/Neo) (0.1° C steps) 59.1 to 113.0 °F (Adult/Pedi/Neo) (0.1°F or 0.2°F steps)	39.0 °C (102.2 °F)	39.0 °C (102.2 °F)	39.0 °C (102.2 °F)
Temp Lower Alarm Limits	15.1 to 44.9 °C (Adult/Pedi/Neo) (0.1° C steps) 59.0 to 112.8 °F (Adult/Pedi/Neo) (0.1°F or 0.2°F steps)	36.0 °F (96.8 °F)	36.0 °F (96.8 °F)	36.0 °F (96.8 °F)
Others				
Patient Mode	Adult, Neonatal	Adult		
Print Speed**	25mm/s, 50mm/s	25mm/s		
Print Mode**	One-Shot, Continuous	One-Shot		
Record On Alarm**	On, Off	Off		
Display Time Interval	20 sec, 1, 2, 3, 5, 10, 20 min	20 sec		
Trend Display Select	Normal, NIBP, Alarm, Normal + NIBP, Normal + Alarm, NIBP + Alarm, ALL	ALL		
Alarm Volume	1, 2, 3, 4, 5, 6, 7, 8	5		
QRS Volume	Off, 1, 2, 3, 4, 5, 6, 7	4		
Key Beep Volume	Off, 1, 2, 3, 4, 5, 6, 7	4		
Save Current Values as Power-On Default*	Yes, No	No		
Save Factory Default Setting as Power-On Default*	Yes, No	No		
Alarm Suspension Period*	Off, 1, 3, 5, 10, 20, 30, 60 min, Indefinite (Alarm Inhibition)	Indefinite		
Alarm Silence Period*	30, 60, 90, 120 sec	60 sec		
Alarm Reminder Tone*	Off, 3, 10 min	3 min		
Audible Alarm Type*	GN924, IEC60601-1-8	GN924		
Language*	한국어 (Korean), 中文 (Chinese), English, Français (French), Deutsch (German), Italiano (Italian), 日本語 (Japanese), Português (Portuguese), Dansk (Danish), Nederlands (Dutch),	English		

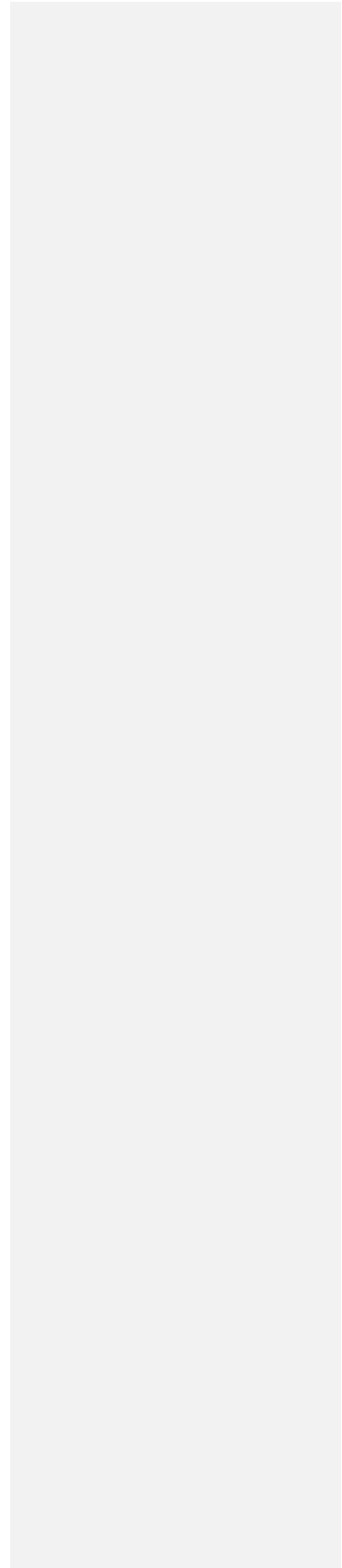
Parameter	Ranges/Selections	Factory Defaults		
		Adult	Pediatric	Neonatal
	Suomi (Finnish), Ελληνικά (Greek), Norsk (Norwegian), Polski (Polish), Русский (Russian), Castellano (Spanish), Svenska (Swedish)			

Note: An asterisk (*) by a parameter in the above table indicates that the parameter can only be changed by authorized personnel as described in the service manual.

Note: Asterisks (**) by a parameter in the above table indicate the settings only when an optional printer is installed in the monitor.



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SPECIFICATION

Display

Screen Size	7" measured diagonally across the TFT-LCD screen
Screen Type/Color	Liquid Crystal Display (LCD) Color, Cold Cathode Fluorescent Backlit
Resolution	800 × 480 pixel
Number of Traces	3 waveforms

Controls

Standard	Jog dial control; 5 soft buttons (Alarm Stop, NIBP Start/Stop, Home, Print, Power)
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Alarms

Categories	Patient Status and System Status
Priorities	Low, Medium and High Priorities
Notification	Audible and Visual
Setting	Default and Individual
Alarm Volume Level	45 to 85 dB

Physical Characteristics and Printer

Instrument	
Dimensions	250 × 210 × 170 (mm) (W×H×D) including a handle and excluding options and accessories
Weight	Approx. 3.2 kg excluding optional configurations and accessories
Degree of Protection against Electric Shock	ECC: Type CF with defibrillator protection NIBP: Type CF with defibrillator protection SpO ₂ : Type CF with defibrillator protection Temperature: Type CF with defibrillator protection
Mode of Operation	Continuous
Classification	Class IIb (MDD Annex IX Rule10: MEDDEV 2.4/1 Rev.8)

Printer (Optional)	
Type	Thermal
Weight	150 g
Resolution	8 dot/mm
Number of Channels	1 to 2 channels
Paper Type	Thermal
Paper Width	50 mm
Paper Speeds	25.0 mm/s and 50.0 mm/s

Electrical

Instrument	
Power Requirements	AC Mains 100 to 240V~, 50/60 Hz, 110 VA
Fuses	q'ty 2, T3.15 A, 250 volts / T5.0A, 250 volts
Battery (option)	
Type	Li-ion battery
Operating time	1 hour (2200mAh), 3 hours (4400mAh), 5 hours (6600mAh) <i>At the following condition:</i> <i>no printing</i> <i>no external communication</i> <i>no audible alarm sound</i> <i>one NIBP measurement per 15 minutes at 25°C</i>
Voltage/Capacity	11.1 V / 2200 mAh (1 hour type) 11.1 V / 4400 mAh (3 hours type) 11.1 V / 6600 mAh (5 hours type)
Recharge	Over 4, 8 or 12 hours with monitor turned on/off 6 months, new battery fully-charged
Life Cycle	After 2 months storage the M20 would run for 50% of stated battery life.
Compliance	91/157/EEC

Environmental Conditions

Operation	
Temperature	5 to 40°C (41 to 104°F)
Humidity	30 to 85% RH, non-condensing
Altitude	700 to 1060 hPa
Transport and Storage (in shipping container)	
Temperature	-20°C to 60°C (-4°F to 140°F)
Humidity	10 to 95% RH, non-condensing
Altitude	500 to 1060 hPa
Note: The system may not meet its performance specifications if stored or used outside the specified temperature and humidity range.	

Tone Definition

High Priority Alarm Tone	
Volume level	Adjustable (level 1~8)
Pitch (± 20Hz)	976 Hz
Pulse width (± 20msec)	240 msec (IEC60601-1-8), 250 msec (GN924)
Number of pulses	10 pulses per 4 sec, 10 sec inter burst (IEC60601-1-8) 7 pulses per 2 sec (GN924)
Repetitions	Continually
Medium Priority Alarm Tone	
Volume level	Adjustable (level 1~8)
Pitch (± 20Hz)	697 Hz
Pulse width (± 20msec)	250 msec (IEC60601-1-8), 350 msec (GN924)
Number of pulses	3 pulses per 1 sec, 15 sec inter burst (IEC60601-1-8) 2 pulses per 1 sec (GN924)
Repetitions	Continually
Low Priority Alarm Tone	
Volume level	Adjustable (level 1~8)
Pitch (± 20Hz)	488 Hz
Pulse width (± 20msec)	250 msec (IEC60601-1-8), 500 msec (GN924)
Number of pulses	1 pulse per 1 sec, 30 sec inter burst (IEC60601-1-8) 1 pulse per 1 sec, 15 sec inter burst (GN924)
Alarm Reminder Tone	
Volume level	Not changeable
Pitch (± 20Hz)	800 Hz
Pulse width (± 20msec)	200 msec
Number of pulses	1 pulse per 1 second, 3 min ~ 10 min inter burst
Repetitions	Continually
HR/PR Tone	
Volume level	Adjustable (level 0~8)
Pitch (± 20Hz)	650 Hz (ECG) (162 + 5*SpO ₂) Hz (SpO ₂ 80% to 100%) (562 * (0.992 ^(80 - SpO₂))) Hz (SpO ₂ below 80%)
Pulse width (± 20msec)	100 msec
Number of pulses	N/A
Repetitions	No repeat
Key Beep	
Volume level	Adjustable (level 0~7)
Pitch (± 20Hz)	440 Hz (valid) 168 Hz (invalid)
Pulse width (± 20msec)	110 msec
Number of pulses	N/A
Repetitions	No repeat
POST Pass Tone	
Volume level	Not changeable
Pitch (± 20Hz)	810 Hz + 1.15 kHz (Complex)
Pulse width (± 20msec)	1500 msec
Number of pulses	N/A
Repetitions	No repeat

Measurement Parameters

ECG

Heart Rate	
Measurement Range	0, 30 to 300 BPM
Accuracy	± 1 BPM or $\pm 1\%$ whichever is greater
Average Response Time	5 seconds (from 80 to 120 BPM) 9 seconds (from 80 to 40 BPM)
Tall T-wave Rejection	maximum T-wave amplitude 1.8 mV
ECG (Electrocardiograph)	
Leads	3 / 5 Lead Lead I, II, III, aVR, aVL, aVF, V (Chest Lead)
Lead Off Detection	Detected and displayed
Pacer Detection	Detect pacer pulses of ± 2 mV to ± 700 mV with pulse widths of 0.25 to 2msec and rise times 10% of width not to exceed 100msec
Input	
Input Impedance	5 M ohm or more
Input Dynamic Range	± 5 mV AC, ± 300 mV DC
Voltage Range	± 0.5 mV ~ ± 5 mV
Signal Width	40 to 120 ms (Q to S)
Output	
Frequency Response (Bandwidth)	
Low Extend	0.05 to 40 Hz
Filter	0.5 to 30 Hz
Monitor	0.5 to 40 Hz
Hum filter	50 Hz and 60 Hz
ECG Size	Auto, 1.25, 1.7, 2.5, 5.0, 7.5, 10.0, 15.0, 20.0 mm/mV
Display Sweep Speeds	12.5 mm/sec, 25.0 mm/sec, and 50.0 mm/sec
Display Sensitivity	10 mm/mV ($\times 1$)
Pacing Pulse Detection	On, Off
Electrode Disconnect Alarm	Display and/or sound
CMRR	80 dB or more
Defibrillator Discharge Recovery	<5 sec per IEC60601-2-27
Defibrillator Protection	Protected

Respiration

Respiration	
Technique	Impedance Pneumography
Range	0, 3 to 120 breaths/min
Accuracy	±3 breaths/min
Leads	RA to LA
Display Sweep Speeds	6.25 mm/s, 12.5 mm/s, 25.0 mm/s
Lead Off Condition	Detected and displayed
Display Size	10 mm/ohm (×1)
Wave Size	Auto, Level 1~8
Defibrillator Protection	Protected

NIBP

Pulse Rate	
Pulse Rate Range	Adult/Pediatric 40 to 200 BPM
	Neonatal 40 to 240 BPM
Pulse Rate Accuracy	±2 BPM or ±2%, whichever is greater
NIBP (Non-Invasive Blood Pressure)	
Technique	Oscillometric Measurement
Measurement Modes	MANUAL, AUTO and CONT
NIBP AUTO Mode Intervals	Off, 1, 2.5, 3, 5, 10, 15, 30, 60, 90 minutes
Measurement Range	Adult/Pediatric
	SYS 60 to 250 mmHg
	MAP 45 to 235 mmHg
	DIA 40 to 200 mmHg
	Neonatal
	SYS 40 to 120 mmHg
MAP 30 to 100 mmHg	
DIA 20 to 90 mmHg	
NIBP Accuracy	Mean error and standard deviation per ANSI/AAMI SP10:2002+A1:2003
Pressure Display Range	Adult/Pediatric 0 to 300 mmHg
	Neonatal 0 to 150 mmHg
Pressure Display Accuracy	Within ±3mmHg
Initial Cuff Inflation	Adult/Pediatric 120, 140, 160, 180, 200, 220, 240, 260, 280 mmHg (16.0, 18.7, 21.3, 24.0, 26.7, 29.3, 32.0, 34.7, 37.3 kPa)
	Neonatal 80, 90, 100, 110, 120, 130, 140 mmHg (10.7, 12.0, 13.3, 14.7, 16.0, 17.3, 18.7 kPa)
Automatic Cuff Deflation	Measurement time exceeding 180s in adult/pediatric (90s in neonatal) or maximum pressure value exceeding 300 mmHg in adult (150 mmHg in neonatal).
Overpressure Protector	300 ±10 mmHg for Adult 150 ± 5 mmHg for Neonatal
Defibrillator Protection	Protected

Measurement Speed	About 20 seconds At the following condition: Adult Cuff size 12 cm SYS 120 mmHg MAP 90 mmHg DIA 80 mmHg/ PR 80 BPM Manual Measurements (180 mmHg)
Measurement Noise Level	45dB (The distance from the microphone is 30 cm.)

SpO₂

Pulse Rate	
Range	<i>Nellcor module:</i> 20 to 300 BPM <i>Mediana module:</i> 30 to 254 BPM
Accuracy	<i>Nellcor module:</i> ±3 BPM <i>Mediana module:</i> ±2 % or 2 BPM, whichever is greater
SpO ₂	
Range	<i>Nellcor module:</i> 1 to 100 % <i>Mediana module:</i> 0 to 99 %
Low Perfusion (Nellcor module only)	0.03 to 20 %
Accuracy	<i>Nellcor module:</i> Without Interference-Adult/Pediatric 70 to 100 % ±2 digits 1 to 69 % unspecified Without Interference-Neonatal 70 to 100 % ±3 digits 1 to 69 % unspecified Low Perfusion 70 to 100 % ±2 digits 1 to 69 % unspecified <i>Mediana module:</i> Adult/Pediatric/Neonatal 70 to 99 % ±2 digits 0 to 69 % unspecified
Display Update	Within 30 seconds
Display Sweep Speeds	12.5 mm/sec, 25.0 mm/sec and 50.0 mm/sec
Defibrillator Protection	Protected

Neonatal specifications are shown for neonatal sensors with the monitor. Saturation accuracy will vary by sensor type as specified by the manufacturer.

Note: The wavelength range of the light emitted are near 660 nm and 890 nm with the energy not exceeding 15mW.

Temperature

Thermistor Temp	
Probe Type	Thermistor probe YSI 400 series and 700 series
Measurement Method	Thermistor
Range	15 to 45°C (59 to 113°F)
Display Accuracy	±0.1°C
Probe Accuracy	±0.1°C (YSI 400 series)
Defibrillator Protection	Protected

Trends

Types	Graphical and Tabular
Memory	saves total 20480 data saves every 20 seconds saves alarm condition saves NIBP Measurements
Graphical Format	Total 2 graphs <ul style="list-style-type: none">• a graph for HR/PR, Resp, SpO₂ parameters• a graph for NIBP, Temp parameters User-selectable each parameter to be desired
Tabular Format	One table for all parameters
Display	10 lists
Display Time Interval	20 sec, 1, 2, 3, 5, 10, 20 minutes

Compliance

Item	Compliant with
Classification	Class I (on AC power) Internally powered (on battery power)
Type of protection	Type CF – Applied part
Mode of operation	Continuous
Degree of protection	IPX1 (provided by enclosures)
General	93/42/EEC Directives for medical devices 21CFR820 Code of federal regulations 2002/96/EC Waste electrical and electronic equipment directive (WEEE) 91/157/EEC Battery declaration directive 93/86/EEC Battery disposal directive 2006/66/EC Battery directive ISO13485:2003 Quality systems - Medical Devices - Requirements for regulating purposes ISO14971:2000+A1:2003 Risk analysis managements – medical devices IEC60601-1:1988+A1:1991+A2:1995 General requirements for safety of medical electrical equipment IEC60529:2001 Degree of protection provided by enclosures (IPX1) EN ISO14155-1:2003 Clinical investigation of medical devices for human subjects – part 1: General requirements AAMI HE48:1993 Human factors engineering guidelines and preferred practices for the design of medical devices IEC60601-1-1:2000 Collateral standard for medical electrical systems IEC60601-1-4:2000 Collateral standard for programmable medical systems IEC60601-1-6:2004 Collateral standard for usability ISO10993-1:2003 Biological evaluation of medical devices – Part 1: Evaluation and testing ISO10993-5:1999 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity ISO10993-10:2002 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed-type hypersensitivity IEC60601-2-49:2001 Particular requirements for multifunction patient monitoring equipment
Alarms	IEC60601-1-8:2003 Alarm systems requirements, tests and guidances in medical electrical equipments systems
Electrocardiograph	IEC60601-2-27:2005 Particular requirements for the safety of Electrocardiographic monitoring equipment AAMI EC13:2002 Cardiac monitors, heart rate meters and alarms AAMI EC53:1995+A1:1998 ECG cable and leads
Non-invasive blood pressure	AAMI SP10:2002+A1:2003 Electronic or automated sphygmomanometers EN1060-1:1995+A1:2002 Non-invasive sphygmomanometers EN1060-3:1997 Supplementary requirements for electrical-mechanical blood pressure measuring systems EN1060-4:2004 Non-invasive sphygmomanometers - Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers IEC60601-2-30:1999 Particular requirements for the safety, including essential performance, of automatic cycling indirect blood pressure monitoring equipment

Item	Compliant with
Oxygen saturation	ISO9919:2005 Basic safety & essential performance of pulse oximeter for medical use
Temperature monitoring	EN12470-4:2000 Performance of electrical thermometers for continuous Measurement
Electromagnetic compatibility	IEC60601-1, sub clause 36, and IEC60601-1-2:2001+A1:2004 Electromagnetic compatibility-requirements & test IEC61000-3-2:2005 Harmonic emission Ed 3.0 IEC61000-3-3:2005 Voltage fluctuations/Flicker emission Ed 1.2 IEC61000-4-2:2001 Electrostatic discharge Ed 1.2 IEC61000-4-3:2006 Radiated RF electromagnetic field Ed 2.1 IEC61000-4-4:2004 Electrical fast transient/burst Ed 2.0 IEC61000-4-5:2005 Surge current Ed 2.0 IEC61000-4-6:2006 Conducted disturbances, induced by RF field Ed 2.2 IEC61000-4-8:2001 Power frequency (50/60Hz) magnetic field Ed 1.1 IEC61000-4-11:2004 Voltage dips, short interruption and voltage variation on power supply input lines Ed 2.0 CISPR 11:1997 (EN55011:1998) Limits and methods of measurement of radio disturbance characteristics of industrial scientific and medical (ISM) radio-frequency equipment RF Emissions Group 1, Class B
Package	ISTA (Procedure 1A, 2001) Pre-shipment test procedures (Package) ASTM D4169:2005 Standard practice for performance testing of shipping containers and system IEC60068-1:1988 Environmental testing, Part1: General guidelines
Reliability	IEC60068-2-27:1987 Environmental testing – Shock IEC60068-2-6:1995 Environmental testing – Vibration IEC60068-2-64:1993 Environmental testing: vibration, broad-band random (digital control) and guidance
Labeling	EN1041:1998 Information supplied by the manufacturer with medical devices
Marking	IEC /TR60878:2003 Graphical symbols for electrical equipment in medical practice EN980:2003 Graphical symbols for use in the labeling of medical devices ISO7000:2004 Graphical symbols for use on equipment-index and synopsis EN60417-1:1999 Graphical symbols for use on equipment-overview and application EN60417-2:1999 Graphical symbols for use on equipment-symbol originals EN50419:2005 Marking of electrical and electronic equipment in accordance with article II (2) of directive 2002/96/EC (WEEE)

Manufacturer's Declaration



WARNING: For best product performance and measurement accuracy, use only accessories supplied or recommended by Mediana. Use accessories according to the manufacturer's directions for use and your facility's standards. The use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the M20.

The M20 is suitable for use in the specified electromagnetic environment. The customer and/or user of the M20 should assure that it is used in an electromagnetic environment as described below;

Table 36. Electromagnetic Emissions (IEC60601-1-2)

Emission Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1	The M20 must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class B	The M20 is suitable for use in all establishments.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emission IEC 61000-3-3	Complies	


Table 37. Electromagnetic Immunity (IEC60601-1-2)

Immunity Test	IEC 60601-1-2 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	Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electric 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 and/or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment
Voltage dips, short interruptions and voltage variations on power supply	<5 % U T (>95 % dip in UT) for 0.5 cycle	<5 % U T (>95 % dip in U T) for 0.5 cycle	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the M20 requires continued operation during power mains interruption, it is recommended that the M20 be powered from an uninterruptible power supply or battery.
IEC 61000-4-11	40 % U T (60 % dip in UT) for 5 cycles	40 % U T (60 % dip in U T) for 5 cycles	
	70 % U T (30 % dip in UT) for 25 cycles	70 % U T (30 % dip in UT) for 25 cycles	

Immunity Test	IEC 60601-1-2 Test Level	Compliance Level	Electromagnetic Environment Guidance
	<5 % U T (95 % dip in UT) for 5 sec.	<5 % U T (95 % dip in UT) for 5 sec.	
Power frequency (50/ 60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	It may be necessary to position the M20 further from the sources of power frequency magnetic fields or to install magnetic shielding. The power frequency magnetic field should be measured in the intended installation location to assure that it is sufficiently low.

Note: UT is the AC mains voltage prior to application of the test level.

Table 38. Electromagnetic Immunity (IEC60601-1-2)

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
The M20 is intended for use in the electromagnetic environment specified below. The customer or the user of the M20 should assure that it is used in such an environment.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the M20 including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter. Recommend separation distance $d = 1.2 \sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 800 MHz	3 V/m	$d = 1.2 \sqrt{P}$ 80 MHz to 800 MHz
	3 V/m 800 MHz to 2.5 GHz	3 V/m	$d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range. ^b Interference may occur in the vicinity of equipment marked with the following symbol: 

Note: At 80 MHz and 800 MHz, the higher frequency range applies.
Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
<p>^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile 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 M20 is used exceeds the applicable RF compliance level above, the M20 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the M20.</p> <p>^b Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m</p>			

Table 39. Recommended Separation Distances

Recommended separation distance between portable and mobile RF communications equipment and the M20			
The M20 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the M20 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the M20 as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter in watt	Separation distance according to frequency of transmitter in meter		
	150 kHz to MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5GHz $d = 2.3 \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. Note: At 80MHz and 800MHz, the separation distance for the higher frequency range applies Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			

Table 40. Cables (IEC60601-1-2)

Cables and Sensors	Maximum Length	Complies with
Power Cable	1.8 m	-RF emissions, CISPR 11, Class B/ Group 1 -Harmonic emissions, IEC 61000-3-2 -Voltage fluctuations/flicker emission, IEC 61000-3-3 -Electrostatic discharge (ESD), IEC 61000-4-2 -Electric fast transient/burst, IEC 61000-4-4 -Surge, IEC 61000-4-5 -Conducted RF, IEC 61000-4-6 -Radiated RF, IEC 61000-4-3
Power Cable	1.5 m	
NIBP Hose	4.0 m	
Trunk Cable	3.0 m	
ECG Lead Cable	1.0 m	
SpO ₂ Cable	3.0 m	
Finger Probe Cable	0.5 m	
LAN Cable	20.0 m	
Temperature Cable	3.0 m	
Cuff Hose	0.3 m	
Nurse Call Cable	1.8 m	
ITE Power Supply DC Cable	1.5 m	