SERVICE MANUAL

Patient Monitor M30

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Directive

- Copyright law allows no part of this instruction manual to be reproduced without permission.
- The content of this manual are subject to change without notice.
- 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 M30. 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 M30 conforms to the EMC standard IEC60601-1-2.
  Note that mobile phones should not be used in the vicinity of the M30.

Note, however, any device not complying to the EMC standard that is used with the M30 renders the M30 as non-compliable 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 M30 monitor. Other important safety information appears throughout the manual. The M30 may be referred to as the monitor throughout this manual.

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

Warnings

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: Explosion hazard. Do not use the monitor in the presence of flammable anesthetics or gases.**
	**WARNING: Do not spray, pour, or spill any liquid on the monitor, its accessories, connectors, switches, or openings in the chassis.**
	**WARNING: Do not immerse the monitor or its accessories in liquid or clean with caustic or abrasive cleaners.**
	**WARNING: Ensure that conductive portions of the electrodes, leads, and cable do not come into contact with any other conductive parts.**
	**WARNING: Before attempting to open or disassemble the monitor, disconnect the power cord from the monitor.**
	**WARNING: Chemicals from a broken LCD display panel are toxic when ingested. Use caution when handling a monitor with a broken display panel.**
	**WARNING: The use of accessories, transducers, and cables other than those specified may result in increased emission and/or decreased immunity of the monitor.**
	**WARNING: Do not silence the monitor audible alarm or decrease its volume if patient safety could be compromised.**
	**WARNING: During the safety test, AC power voltage will be present on the applied part terminals. Exercise caution to avoid electrical shock hazard.**
	**WARNING: Do not place the monitor into operation after repair or maintenance has been performed until all Performance Tests and Safety Tests listed in the Performance Verification section of this service manual have been performed. Failure to perform all tests could result in erroneous monitor readings.**
	**WARNING: High voltage is generated by the LCD backlight driver. Exercise caution when operating the monitor with covers open.**
	**WARNING: Extreme care must be taken in modifying default or other settings to ensure they are appropriate to the intended use.**

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: Observe ESD (electrostatic discharge) precautions when working within the unit and/or when disassembling and reassembling the monitor and when handling any of the components of the monitor.**
- **CAUTION: When reassembling the monitor, over-tightening screws could strip the screw holes in the cases, rendering it unusable.**
- **CAUTION: If there is a problem with the optional printer, check to make sure the printer door is closed properly.**
- **CAUTION: If the internal battery cable has been disconnected, pay particular attention to polarity of the cable before reattaching. If the battery cable polarity is reversed, it is likely that circuit damage will occur.**
- **CAUTION: Ferrite Cores are used for electromagnetic compatibility. Please do not remove Ferrite Cores while disassembling or reassembling, otherwise the monitor can be affected by electromagnetic interference and cause inaccurate data to be displayed or stored.**
- **CAUTION: For continued protection against risk of fire, replace the fuse only with the same type and rating of fuse.**

Manual Overview

This manual contains information for servicing the M30 monitor.
The monitor is subsequently referred to as the monitor throughout this manual. Only qualified service personnel should service this product. Before servicing the monitor, read the operation manual carefully for a thorough understanding of safe operation.

Read and understand all safety warnings and service notes printed in this service manual and the operation manual.

Related Documents

To perform tests and troubleshooting procedures, and to understand the principles of operation and circuit analysis sections of this manual, you must know how to operate the monitor. Refer to the monitor operation manual.
To understand the various SpO_2 sensors, ECG leads, blood pressure cuffs, CO_2 sensors and temperature probes that work with the monitor, refer to the individual directions for use that accompany these accessories.

Intended Use for the M30 Monitor

The M30 is intended to be used to monitor electrocardiography (ECG), heart rate (HR), noninvasive blood pressure (systolic, diastolic and mean arterial pressures) (NIBP) functional arterial oxygen saturation (SpO_2), pulse rate (PR), respiration (RR), capnography ($EtCO_2$ and $InCO_2$) and 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 areas such as general care floors, operating rooms, special procedure areas, intensive and critical care areas 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.

Identifying the M30 Monitor Configurations

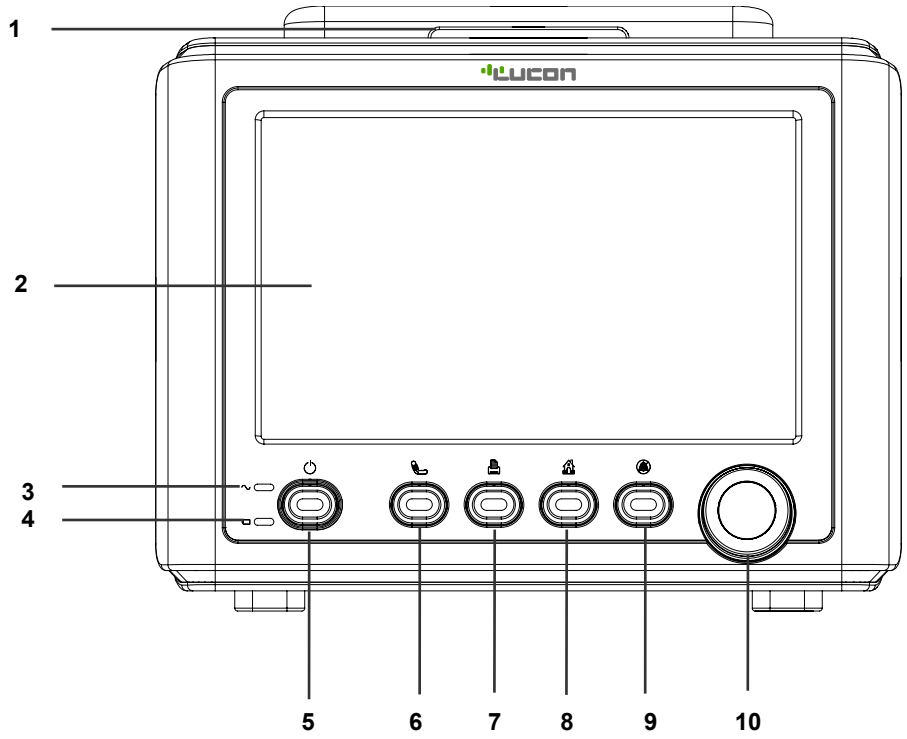
The following table identifies M30 monitor configurations and how they are indicated. The model-option number and serial number are located on the back of the monitor. All information in this manual, including the illustrations, is based on a monitor configured with the Battery, Mediana and Nellcor SpO_2 module, Printer module, TCP/IP module and Capnography ($EtCO_2$ and $InCO_2$). If the relevant functions do not exist, please verify your unit configuration.

Reference no.	Description
M30M-0(A)	M30 Standard (ECG, NIBP, Respiration, Temperature) + Mediana SpO_2
M30M-0P(A)	M30 Standard + Mediana SpO_2 + Printer
M30M-0L(A)	M30 Standard + Mediana SpO_2 + TCP/IP
M30M-0E(A)	M30 Standard + Mediana SpO_2 + Capnography
M30M-0PL(A)	M30 Standard + Mediana SpO_2 + Printer + TCP/IP
M30M-0PE(A)	M30 Standard + Mediana SpO_2 + Printer + Capnography
M30M-0LE(A)	M30 Standard + Mediana SpO_2 + TCP/IP + Capnography
M30M-0PLE(A)	M30 Standard + Mediana SpO_2 + Printer + TCP/IP + Capnpgraphy
M30M-0N(A)	M30 Standard + Nellcor SpO_2
M30M-0PN(A)	M30 Standard + Nellcor SpO_2 + Printer
M30M-0LN(A)	M30 Standard + Nellcor SpO_2 + TCP/IP
M30M-0NE(A)	M30 Standard + Nellcor SpO_2 + Capnography
M30M-0PLN(A)	M30 Standard + Nellcor SpO_2 + Printer + TCP/IP
M30M-0PNE(A)	M30 Standard + Nellcor SpO_2 + Printer + Capnography
M30M-0LNE(A)	M30 Standard + Nellcor SpO_2 + TCP/IP + Capnography
M30M-0PLNE(A)	M30 Standard + Nellcor SpO_2 + Printer + TCP/IP + Capnpgraphy

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.

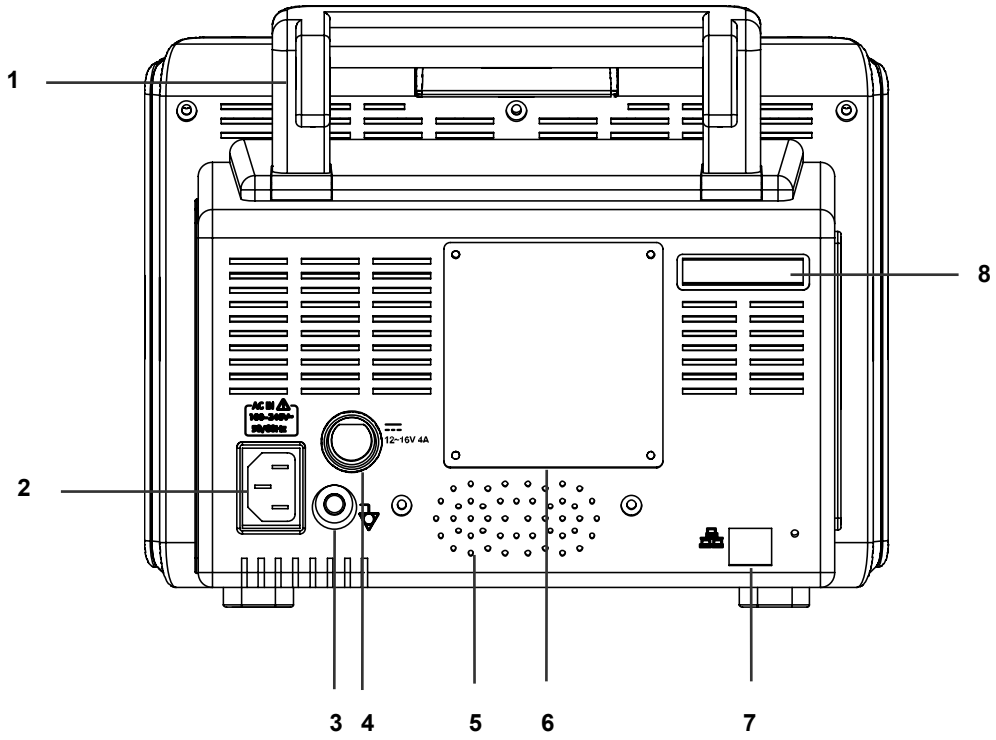
Front Panel Components



1	Alarm indicator	6	NIBP start/stop button
2	LCD	7	Print button
3	AC indicator	8	Home button
4	Battery charging indicator	9	Alarm stop button
5	Power button	10	Jog dial

Figure 1. Front Panel Components

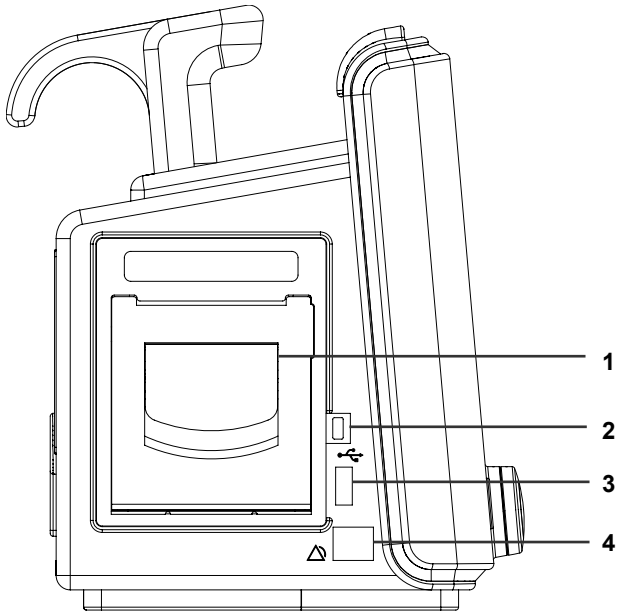
Rear Panel Components



1 Handle
2 AC power connector
3 Equipotential terminal
4 DC power connector
5 Speaker
6 Battery cover
7 LAN port
8 Vent Cover

Figure 2. Rear Panel Components

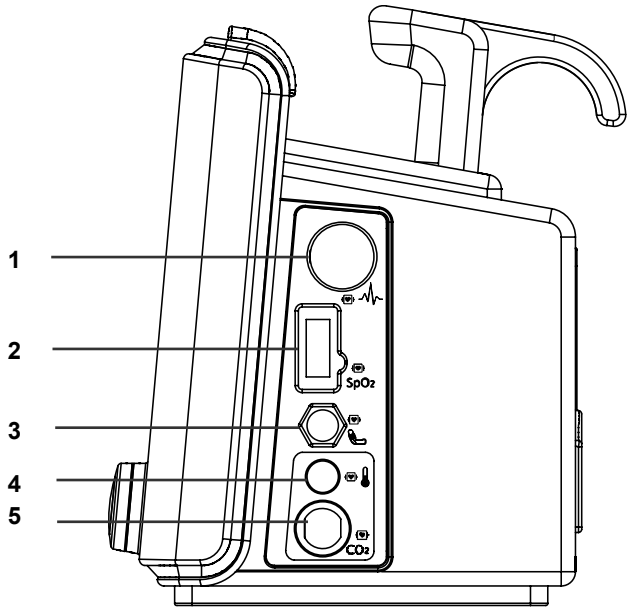
Left Panel Components



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 SpO_2 connector
3 NIBP connector
4 Temperature connector
5 CO_2 connector (Option)

Figure 4. Right Panel Components

ROUTINE MAINTENANCE

WARNING: Do not spray or pour any liquid on the monitor or its accessories. Do not immerse the monitor or its accessories in liquid or clean with caustic or abrasive cleaners.

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, transducers and probes, follow 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.

Periodic Safety and Functional Checks

The following performance verification tests may be used following repair or during routine maintenance (if required by your local institution). The following checks should be performed at least every year by qualified service personnel.

1. Inspect labels for legibility. If the labels are not legible, contact Mediana Technical Service Department.
2. If the monitor has been visibly damaged or subjected to mechanical shock (for example, if dropped), perform the performance tests as described in the **Performance Verification** section. If the unit fails these performance tests, refer to the **Troubleshooting** section.
3. Perform the electrical safety tests described in the **Performance Verification** section. If the unit fails these electrical safety tests, do not attempt to repair. Contact Mediana Technical Service Department.
4. Inspect the fuses for proper value and rating.
   Qty 2, 3.15 A, 250 volts for AC mains

Batteries

If the monitor has not been used for a long period of time, more than 6 months, the battery will need charging. To charge the battery, connect the monitor to an AC outlet as described in the **Battery Charge** paragraph in this service manual or the **Battery Operation** section of the operation manual.

Note: Storing the monitor for a long period without charging the battery may degrade the battery capacity. The battery may require a full charge/discharge cycle to restore normal capacity. Mediana recommends that the monitor's sealed, Li-ion batteries be replaced at 2 year intervals. Refer to the **Disassembly Guide** section.

Note: Due to the physical dimensions of the battery compartment, only batteries supplied by Mediana should be used. Using other types of replacement batteries may result in damage to the monitor and void the limited warranty.

CAUTION: If the monitor is to be stored for a period of 2 months or longer, it is recommended to notify service personnel to remove the battery from the monitor prior to storage. To replace or remove the battery, refer to the Disassembly Guide section. Recharging the battery is strongly recommended when the battery has not been recharged for 6 or more months.

CAUTION: If the battery shows any signs of damage, leakage, or cracking, it must be replaced immediately.

CAUTION: Discarded batteries may explode during incineration. Recycle used batteries properly. Do not dispose of batteries in refuse containers.

Environmental Protection

Follow local governing ordinances and recycling plans regarding disposal or recycling of batteries and other device components.

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.

PERFORMANCE VERIFICATION

General

This section discusses the tests used to verify performance following repairs or during routine maintenance. All tests can be performed without removing the monitor covers. All tests except the battery charge and battery discharge tests must be performed as the last operation before the monitor is returned to the user.
If the monitor fails to perform as specified in any test, repairs must be made to correct the problem before the monitor is returned to the user.

Required Equipment

Table 1 lists the equipment required for performance verifications.

Table 1. Required Equipment

Equipment	Description
Digital multimeter (DMM)	Fluke Model 87 or equivalent
ECG cable for 3 leads	ECG trunk cable for 3 leads
ECG cable for 5 leads (option)	ECG trunk cable for 5 leads
ECG 3 lead wires	ECG 3 leads wire pack (SNAP)
ECG 5 lead wires (option)	ECG 5 leads wire pack (SNAP)
NIBP cuff hose	Omron cuff hose No.1
NIBP cuff	Omron cuff HEM series
Dummy can	Dummy can-large
Dummy can	Dummy can-small
SpO_2 extension cable	Nellcor DOC-10 or RCP058
SpO_2 sensor (durable)	Nellcor DS-100A or YM-1
Temperature probes	YSI-400 series
Mainstream CO_2 sensor (option)	Capnostat 5 mainstream CO_2 sensor
Mainstream CO_2 monitoring airway adapter (option)	TruLink adult reusable airway adapter
Sidestream CO_2 sensor (option)	LoFlo sidestream CO_2 sensor
Sidestream CO_2 airway adapter and sampling line (option)	TruLink adult/pediatric airway adapter and sampling line
ECG simulator	Metron PS-420 or equivalent
SpO_2 simulator	Nellcor SRC-MAX simulator (for Nellcor module)
SpO_2 simulator	ITEC Engineering LLC 8010 oximetry simulator (for Mediana module)
NIBP simulator	Bio-Tek BP Pump 2 or equivalent
Temperature simulator	medSim 300 or equivalent
Respiration simulator	Metron PS-420 or equivalent
CO_2 gas flow meter	STEC SEF-21A or equivalent
CO_2 gas cylinder	10% CO_2 gas cylinder
Safety analyzer	Metron QA-90 or equivalent
Stopwatch	Manual or electronic

Note: The sphygmomanometer must be calibrated periodically. The correct value can not be found if the sphygmomanometer has not been calibrated.

Note: Contact Mediana Technical Service Department for pricing and ordering information of the required equipment.

Performance Tests

The battery charge and battery discharge test should be performed before monitor repairs whenever the battery is suspected as being a source of problems. All other tests may be used following repairs or during routine maintenance (if required by your local institution). Before performing the battery discharge test, ensure that the battery is fully charged. This section is written using **factory defaults** as power-up. Please refer to the **Service Menu and Factory Default Settings** section to set the factory defaults. If your institution has preconfigured custom defaults, those values will be displayed.

Power

1. Connect the monitor to AC power source using the proper power cord.
2. Verify that the ***AC Indicator*** and ***Battery Charging Indicator*** are lit.
3. Press the ***Power Button***.
4. Verify that the monitor is turned on.
5. After the monitor operates in normal mode, disconnect the power cord.
6. Verify that the ***Battery Status Icon*** appears on the screen instead of lighting the ***Battery Charging Indicator***.
7. Press the ***Power Button*** over 2 seconds, and then verify that the monitor is turned off.

Battery Charge

1. Connect the monitor to AC power source using the proper power cord.
2. Verify that the ***Battery Charging Indicator*** is lit with red.
3. Charge the battery fully until the ***Battery Charging Indicator*** is changed to green. It will take about 4, 8 or 12 hours per battery.
4. To check for a full charge, perform the procedure in the section "**Battery Discharge**".

Note: The battery may require a complete charge/discharge cycle to restore its normal capacity, depending on its previous usage.

Battery Discharge

1. Disconnect the power cord from the monitor with a fully charged battery.
2. Turn on the monitor by pressing the ***Power Button.***
3. Verify that the ***Battery Status Icon*** appears at the bottom of the screen after power-on self-test is completed. The bar in the battery status icon should be filled, indicating that the battery is charged.
4. Connect the SpO_2 simulator to the monitor via the SpO_2 extension cable.
5. Connect the NIBP simulator to the monitor via NIBP cuff hose.
6. Set the SpO_2 simulator as follows: SpO_2 of 95% and pulse rate of 60bpm.
7. Set the NIBP simulator to simulate pressure setting of 120/80mmHg and heart rate of 80bpm.
8. Set the ***NIBP auto mode interval*** to 15 minutes.
9. The monitor must operate for 1, 3 or 5 hour(s) with a fully charged optional battery. The monitor must operate for at least 15 minutes after the alarm message "Low Battery" appears before the monitor powers down due to the low battery condition.
10. Verify that the low priority alarm occurs and the alarm message "***Low Battery***" is

displayed about 15 minutes before battery fully discharges.

11. Allow the monitor to operate until it automatically powers down due to the low battery condition. Verify that the high priority alarm occurs and the alarm message "***Critically Low-Battery condition***" is displayed about 5 minutes before the monitor automatically shuts down.
12. If the monitor passes this test, immediately recharge the battery. (see "**Battery Charge.**")

Power-On Self-Test (POST)

1. Connect the monitor to AC power source and verify that the ***AC Indicator*** and ***Battery Charging Indicator*** are lit.
2. Observe the monitor's LCD screen. With the monitor off, press the ***Power Button***. The monitor must perform the following sequence:
    a. The monitor performs the power-on self-test (POST) and the checksum for the flash memory and displays a status bar while the checksum is proceeding.
    b. During the POST, the copyright screen appears and alarm indicator is lit for a few seconds. The copyright screen displays the company logo, the version of system and the current time.
    c. Upon successful completion of the POST, the POST pass tone sounds and the monitor will be in normal monitoring screen.

Note: Power-on self-test (POST) including the checksum for the flash memory takes approximately 13 seconds to complete.

Note: If an error condition occurs during the POST, the monitor will display an error message.

Note: During the POST, the integrity of all programming is checked first. If software testing is successful, hardware tests are initiated. If all testing is successful, the monitor is ready for use. If an error message is displayed during the POST, please refer to the **Troubleshooting** section.

Date and Time Setting

1. Rotate the jog dial to highlight the ***Time Display***, and then press the jog dial to select the ***Date/Time Menu***.
2. Rotate the jog dial to display the desired number for ***Year***, ***Month***, ***Day***, ***Hour, Minute***, or ***Second*** and then press the jog dial to select the desired number.
3. Press the jog dial to apply the desired data and return to the monitoring screen. Verify that the selected time setting is indicated on the ***Time Display*** correctly.
4. If an optional printer is installed in the monitor, press the ***Print Button*** on the monitor's front panel. Verify that the selected time setting is indicated on the printed paper correctly.

General Operation Tests

Alarms and Alarm Silence

1. Connect the monitor to an AC power source.
2. Press the ***Power Button*** to turn on the monitor.
3. Connect the SpO_2 simulator to the SpO_2 extension cable and connect the cable to the monitor.
4. Set the SpO_2 simulator as follows: SpO_2 of 75% and pulse rate of 60bpm.
5. Verify the following monitor reaction:
    a. The pulse amplitude indicator begins to track artificial pulse signal from the SpO_2 simulator.
    b. After about 10 to 20 seconds, the monitor displays oxygen saturation and pulse rate as specified by the simulator. Verify values are within the following tolerances:
        - Tolerance of Oxygen Saturation : ±2%
        - Tolerance of Pulse Rate : ±3bpm
    c. Audible alarm sounds and "***Low SpO_2 limits violated***" message will be displayed and %SpO_2 numerical area will flash, indicating the parameter has violated default alarm limits (medium priority alarm).
6. Press the ***Alarm Stop Button*** on the monitor's front panel. The audible alarm will be temporarily silenced.
7. Verify the following:
    a. The audible alarm remains silenced.
    b. The ***Alarm Silence Icon*** appears in the SpO_2 numerical area on the screen.
    c. The %SpO_2 display continues flashing.
    d. The audible alarm returns in approximately 60 seconds.

QRS Volume Control

1. Press the ***Power Button*** to turn on the monitor.
2. Connect the SpO_2 simulator to the SpO_2 extension cable and connect the cable to the monitor.
3. Set the SpO_2 simulator as follows: SpO_2 of 75% and pulse rate of 60bpm.
4. Verify %SpO_2 and pulse rate values are correctly displayed.
5. Press the ***Alarm Stop Button*** on the front panel of the monitor to temporarily silence the audible alarm.
6. Select the ***Setup Icon*** to display the ***Setup Menu***.
7. Select ***QRS Volume*** in the ***Setup Menu***.
8. Set QRS volume level 1 to level 7 and return to the monitoring screen. Verify beeping pulse rate tone increases.
9. Set QRS volume level 7 to level 1 and return to the monitoring screen. Verify beeping

pulse rate tone decreases.

10. Set QRS volume to ***Off*** and return to the monitoring screen. Verify beeping pulse rate tone is no longer audible.
11. Return QRS volume to a comfortable level.

Sensor LED Test

This procedure uses normal system components to test circuit operation. An SpO_2 sensor, *DS-100A* is used to examine LED intensity control. The red LED is used to verify intensity modulation caused by the LED intensity control circuit.

1. Connect the monitor to an AC power source.
2. Press the ***Power Button*** to turn on the monitor.
3. Connect the SpO_2 extension cable to the monitor.
4. Connect the SpO_2 sensor to the SpO_2 extension cable.
5. Leave the sensor open with the LEDs and photodetector visible.
6. After the monitor completes its normal power-up sequence, verify that the sensor LED is brightly lit.
7. Slowly move the sensor LED in proximity of the photodetector element of the sensor (close the sensor slowly). Verify as the LED approaches the optical sensor, the LED intensity decreases.
8. Open the sensor and notice that the LED intensity increases.
9. Repeat step 7 and intensity will again decrease. This variation is an indication that the microprocessor is in proper control of LED intensity.
10. Press the ***Power Button*** to turn off the monitor.

Restoring Power-On Default Settings

The following test procedures will verify that alarms are activated at the level of factory default alarm limits and that any changed settings are saved and in effect when the user changes alarm limit settings and saves the current settings as a power default.

Table 2. Parameter Alarm Limit Factory Defaults

Alarm Conditions	Adult	Pediatric	Neonatal
HR/PR Upper Alarm Limits	120 bpm (beats per minute)	160 bpm	200 bpm
HR/PR Lower Alarm Limits	50 bpm	75 bpm	100 bpm
ST Level (1 to 5) High Alarm Limits	0.50mV	0.50mV	0.50mV
ST Level (1 to 5) Low Alarm Limits	-0.50mV	-0.50mV	-0.50mV
Arrhythmia High Alarm Limits	5 /min	5 /min	5 /min
NIBP SYS Upper Alarm Limits	160mmHg	120 mmHg	90 mmHg
NIBP SYS Lower Alarm Limits	90 mmHg	70 mmHg	40 mmHg
NIBP DIA Upper Alarm Limits	90 mmHg	70 mmHg	60 mmHg
NIBP DIA Lower Alarm Limits	50 mmHg	40 mmHg	20 mmHg
NIBP MAP Upper Alarm Limits	110 mmHg	90 mmHg	70 mmHg
NIBP MAP Lower Alarm Limits	60 mmHg	50 mmHg	30 mmHg
%SpO_2 Upper Alarm Limits	100 %	100 %	100 %
%SpO_2 Lower Alarm Limits	90 %	90 %	85 %
RESP Upper Alarm Limits	30 bpm (breaths per minute)	30 bpm	100 bpm
RESP Lower Alarm Limits	8 bpm	8 bpm	30 bpm

Alarm Conditions	Adult	Pediatric	Neonatal
TEMP Upper Alarm Limits	39.0°C (102.2°F)	39.0°C (102.2°F)	39.0°C (102.2°F)
TEMP Lower Alarm Limits	36.0 °F (96.8 °F)	36.0 °F (96.8 °F)	36.0 °F (96.8 °F)
$EtCO_2$ Upper Alarm Limits	80 mmHg	80mmHg	80mmHg
$EtCO_2$ Lower Alarm Limits	0 mmHg	0mmHg	0 mmHg
$InCO_2$ Upper Alarm Limits	20 mmHg	20 mmHg	20 mmHg
$InCO_2$ Upper Alarm Limits	0 mmHg	0 mmHg	0 mmHg

1. Turn on the monitor under ***Factory default settings***.
2. Select the ***Alarm Limits Icon*** to display the ***Alarm Limits Menu***.
3. Verify that alarm limits are set as shown in Table 2.
4. Change Patient mode in the setup menu from Adult to Pediatric or Neonatal, then verify that alarm limits are set as shown in Table 2.
5. Change alarm limit value via ***Alarm Limits Menu***.
6. Save the current changed alarm limit values as a power on default setting via the service menu (see Service Menu and Factory Defaults section).
7. Select “Done” to turn off the monitor.
8. Press ***Power Button*** to turn on the monitor.
9. Verify alarm limits are set to the current changed alarm limit values.

Printer Test (Option)

If an optional printer is installed in the monitor, the following test procedures will verify the printer performance.

1. Connect the monitor to an AC power source.
2. Press the ***Power Button*** to turn on the monitor.
3. Connect all necessary simulators to the monitor.
4. Select the ***Setup Icon*** to display the ***Setup Menu***.
5. Test #1: One-Shot printing
    a. Set Print Mode to ***One-Shot*** via the Setup Menu.
    b. Press the ***Print Button*** when all the parameter signals display normally.
    c. Verify that the parameter values and waveforms are printed out for 20 seconds.
6. Test #2: Continuous printing
    a. Set Print Mode to ***Continuous*** via the Setup Menu.
    b. Press the ***Print Button*** when all the parameter signals display normally.
    c. Verify the parameter values and waveforms are printed out continuously.
    d. Verify printing stops when the ***Print Button*** is pressed again.
7. Test #3: Print Speed
    a. Set ***Print Speed*** to 25 mm/s.

b. Press the ***Print Button*** when all the parameter signals display normally.

c. Verify the parameter values and waveforms are printed out with 25 mm/s.

d. Set ***Print Speed*** to 50 mm/s.

e. Press the ***Print Button*** when all the parameter signals display normally.

f. Verify that the parameter values and waveforms are printed out with 50 mm/s.

g. Verify the two ECG waveforms are printed out.

h. Repeat this test for other selections.

8. Test #5: Print-On-Alarm

a. Set Print-On-Alarm to ***ON*** via the Alarm Limits Menu.

b. Set the Heart Rate of your ECG simulator to 30bpm.

c. Verify "***Low Heart Rate/Pulse Rate limits violated***" alarm is activated and the parameter values and waveforms are printed out.

Note: If no printer is installed in the monitor, Print Mode, Print Speed and Print On Alarm will not display.

Note: If there is no printer paper left or printer paper feeds improperly, the monitor will display an alarm message.

Measurement Parameter Operation Tests

ECG Operation

1. Press the ***Power Button*** to turn on the monitor.
2. Connect the ECG 3 lead wires to appropriate terminals on the ECG simulator.
3. Connect lead wires to the ECG cable.
4. Connect the ECG cable to the ECG connector on the monitor's right panel.
5. Set the ECG simulator as follows:
   - Heart rate: 30bpm
   - Amplitude: 1millivolt
   - Lead select: II
   - Normal sinus rhythm
   - Adult mode
6. After normal power-up sequence, verify the following monitor reactions:
   a. After about 15 seconds, the monitor displays a heart rate of 30±1bpm.
   b. Verify that the audible alarm sounds and that "***Low Heart Rate/Pulse Rate limits violated***" message displays on the message area.
   c. Verify that the HR/PR numerical area flashes and that the heart rate is below the default lower alarm limit (medium priority alarm).
7. Increase the heart rate setting on the ECG simulator to 240bpm.
   a. After about 15 seconds, verify that the monitor displays heart rate of 240±1bpm.
   b. Verify that the audible alarm sounds and that "***High Heart Rate/Pulse Rate limits violated***" message displays on the message area.
   c. Verify that the HR/PR numerical area flashes and that the heart rate is above the default upper alarm limit (medium priority alarm).
8. Decrease the heart rate setting on the ECG simulator to 120bpm.
   a. After about 15 seconds, verify the monitor displays heart rate of 120±1bpm.
9. Disconnect the LL lead from the ECG simulator.
   a. Verify that the "***ECG Leads Off***" message appears, that three dashes are displayed in the HR/PR numerical area, and that the medium priority alarm sounds.
   b. Reconnect the LL lead to the ECG simulator. Verify that "***ECG Leads Off***" message no longer appears and that the audible alarm is stopped.
   c. Repeat this test for the LA and the RA leads.
10. Connect all the leads to the ECG simulator.
    a. Select the ***ECG Waveform Menu*** and set ***Lead Select*** to Lead I.
    b. Verify that the lead selection is displayed on the ECG waveform area.
    c. Repeat step 10-a for all the ECG Lead selections.
11. Set ECG Lead selection to Lead II.
12. Change ECG waveform size to all the selectable sizes and verify that an appropriate size is displayed on the ECG waveform area.
13. Disconnect 3 ECG leads and connect 5 ECG leads.

14. Repeat step 9 to 12.

15. Turn off the monitor.

Note: The accuracy of the monitor's ECG measurements is ±1bpm. In the procedure, add the tolerance of the simulator to the acceptable range of readings.

NIBP Operation

These tests verify the functionality of the M30 pneumatic system. The Bio-Tek simulator or any equivalent NIBP simulator is required to perform these tests. Each of the tests must be performed to verify pneumatic system functionality.

Over-Pressure Test

1. Connect the cuff hose for adult to the NIBP connector on the monitor's right panel.
2. Connect the other end of the cuff hose to the NIBP simulator.
3. Set the NIBP simulator to Pressure Relief or Overpressure Test mode.
4. Press the Start Test Button on the NIBP simulator. The simulator will pressurize the system until the monitor's over pressure relief system activates.
5. Verify that the peak point displayed on the NIBP simulator (point of protection pressure) is within 330mmHg. Also, this point of protection pressure may be verified at the moment of the monitor's NIBP relief system activation.

The monitor must be placed in the Service Menu to perform the following tests. For a detailed explanation of how to access the Service Menu, refer to the **Service Menu and Factory Default Settings** section**.**

1. Rotate the jog dial to select ***NIBP TEST MODE*** in the Service Menu, and then press the jog dial.

Note: Before accessing the NIBP Test mode, ensure that current patient mode is proper for the Pneumatic system to test. You can set Patient mode; Adult/Pediatric or Neonatal via Setup Menu.

Note: In the NIBP Test Mode, no function button will have no effect except the jog dial. All tests will start to be performed by pressing or rotating the jog dial. If you would like to stop the test during test progressing, press the jog dial.

Pressure Sensor Accuracy Test

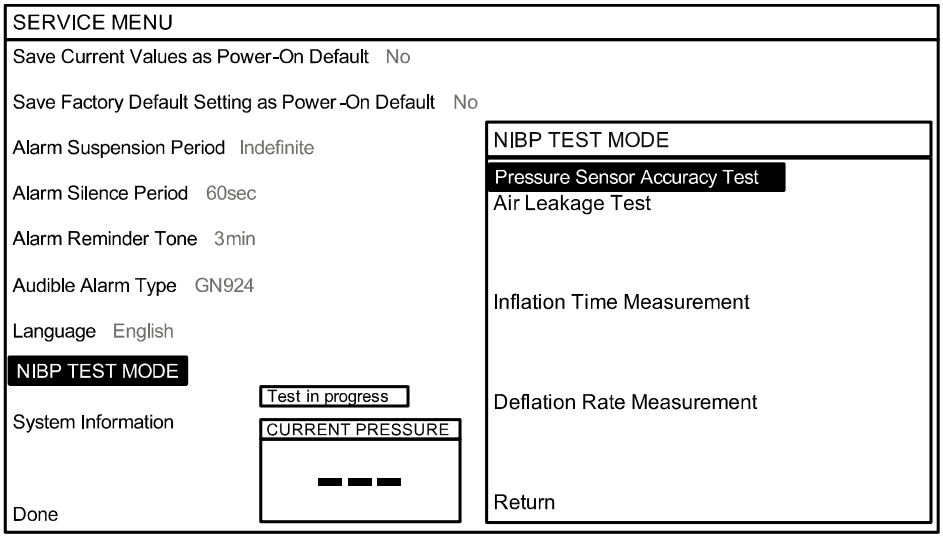


Figure 5. Pressure Sensor Accuracy Test

1. Ensure Bio-Tek simulator is in the static pressure test mode.
2. The NIBP test screen is active on the monitor, then select Pressure Sensor Accuracy Test by the jog dial.
3. Press Select button on the simulator until simulator displays “Pressure Source Set Test Pressure”. Adjust the pressure on the simulator for 250, 150, 50 and 0 mmHg.
4. Press Start Pump button on the simulator. The simulator will begin to pressurize. Allow 15-20 seconds for pressure to stabilize.
5. The current pressure in mmHg will be displayed on both of the simulator and the monitor displays. Ensure the monitor pressure sensor accuracy meets the performance standard of ANSI/AAMI SP-10:2002+A1:2003 (within the specification by more than ±3 mmHg or 2 percent of reading, whichever is greater) to successfully complete the test.

Air Leakage Test

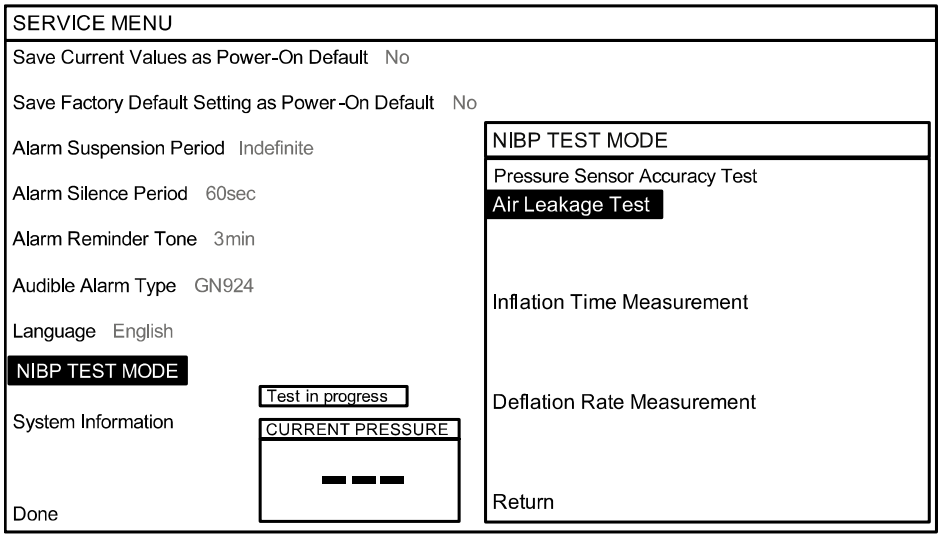


Figure 6. Air Leakage Test

1. Ensure the monitor is set up with dummy can-large.
2. Ensure NIBP Test Mode screen is active on the monitor, then select Air Leakage Test by the jog dial.
3. The monitor displays the pressure of approximately 290 mmHg automatically.
4. The test result displays at the test completion. The initial pressure value at 1 minute is displayed after the test start and the air leakage value at further 3 minutes after the 1 minute elapsed.

Note: The test will have been successfully completed if the pressure has dropped by 6 mmHg, or less, during the 1-minute period.

Inflation Time Measurement

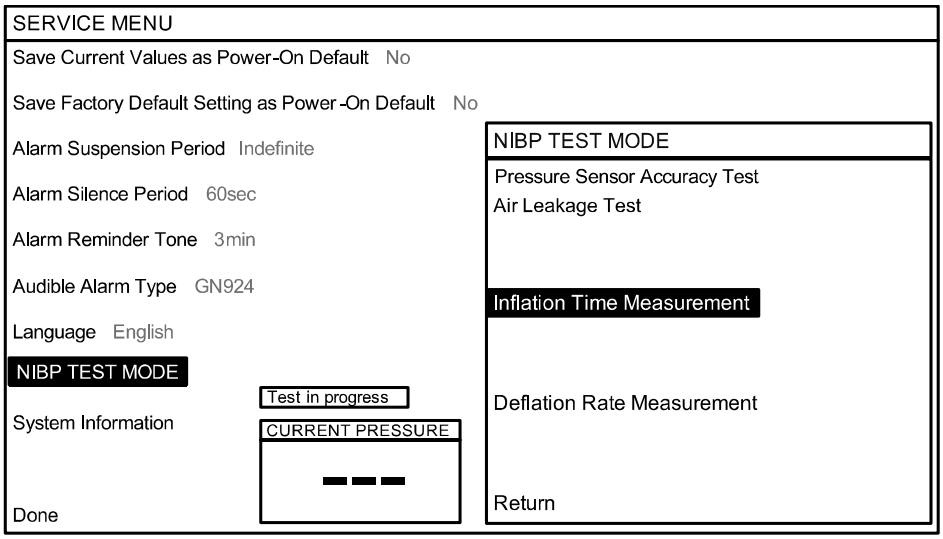


Figure 7. Inflation Time Measurement

1. Ensure the monitor is set up with the dummy can-large.
2. Ensure NIBP Test screen is active on the monitor, then select “Inflation Time Measurement” by the jog dial.
3. The monitor displays the pressure of approximately 290 mmHg automatically and measures the inflation time in seconds.
4. The test result displays at the test completion.

Note: The test will have been successfully completed if the inflation time is 4.0 to 7.5 seconds (to 250 mmHg).

Deflation Rate Measurement

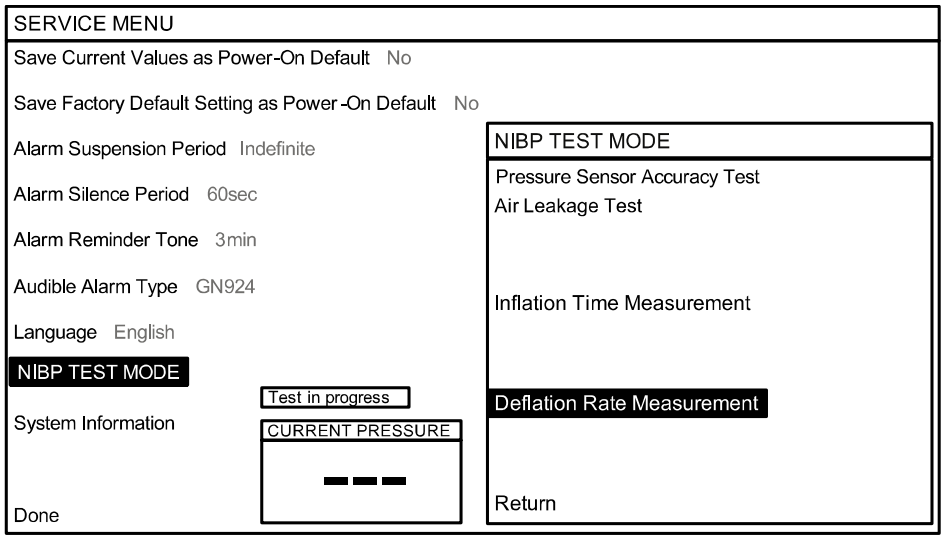


Figure 8. Deflation Rate Measurement

1. Ensure the monitor is set up with the dummy can-small.
2. Ensure NIBP Test screen is active on the monitor, then select “Deflation Rate Measurement” by the jog dial.
3. The monitor displays the pressure of approximately 290 mmHg automatically, then measures the deflation rate during reducing the pressure.
4. The test result displays 4 parts (from 260-180mmHg, 180-100mmHg, 100-60mmHg and 60-30 mmHg) at the test completion.
5. Confirm the result is within the specification.
   - 260-180mmHg : 4.8 ~ 6.0 mmHg/s
   - 180-100mmHg : 4.8 ~ 6.0 mmHg/s
   - 100-60mmHg: 3.5 ~ 5.0 mmHg/s
   - 60-30 mmHg : 2.8 ~ 4.2 mmHg/s

Pulse Oximetry Operation

1. Connect the monitor to an AC power source.
2. Turn on the monitor by pressing the ***Power Button***.
3. Connect the SpO_2 extension cable to the SpO_2 connector on the monitor's right panel after the monitor completes POST.
4. Connect the SpO_2 simulator to the other end of the SpO_2 extension cable.
5. Test #1: SpO_2

   - For Nellcor module

   a. Press the $\%SpO_2$ selection button on the SpO_2 simulator. The $\%SpO_2$ 90 LED will light:

   b. The monitor will display three dashes until the SpO_2 simulator stabilizes at $90\%SpO_2$. The test pass criteria is 88 to $92\%SpO_2$.

   c. The monitor will display: - $90\%SpO_2$
   - 60 bpm
   - no alarm

   - For Mediana module

   a. Press the $\%SpO_2$ selection button on the SpO_2 simulator. The $\%SpO_2$ 92 LED will light:

   b. The monitor will display three dashes until the SpO_2 simulator stabilizes at $92\%SpO_2$. The test pass criteria is 90 to $94\%SpO_2$.

   c. The monitor will display: - $92\%SpO_2$
   - 60 bpm
   - no alarm

6. Test #2: Pulse rate (bpm)

   - For Nellcor module

   a. Press the PULSE RATE selection button on the SpO_2 simulator. The PULSE RATE 200 LED will light.

   b. The pulse rate will increase to 200 bpm. The test pass criteria is 197 to 203 bpm.

   c. The monitor will display:
   - $90\%SpO_2$
   - 200 bpm
   - alarm: "High SpO_2 limits violated" message will display and the HR/PR area will flash, indicating pulse rate is above default upper alarm limit (medium priority alarm).

   d. Press the PULSE RATE selection button on the SpO_2 simulator. The PULSE RATE 60 LED will light.

   e. The pulse rate will decrease to 60 and stabilize at 60 bpm. The test pass criteria is 57 to 63 bpm.

   f. The monitor will display:
   - $90\%SpO_2$
   - 60 bpm
   - no alarm
   - low level modulation

- For Mediana module

g. Press the PULSE RATE selection button on the SpO_2 simulator. The PULSE RATE 240 LED will light.

h. The pulse rate will increase to 240 bpm. The test pass criteria is 238 to 242 bpm.

i. The monitor will display:
- 92%SpO_2
- 240 bpm
- alarm: "High SpO_2 limits violated" message will display and the HR/PR area will flash, indicating pulse rate is above default upper alarm limit (medium priority alarm).

j. Press the PULSE RATE selection button on the SpO_2 simulator. The PULSE RATE 60 LED will light.

k. The pulse rate will decrease to 60 and stabilize at 60 bpm. The test pass criteria is 58 to 62 bpm.

l. The monitor will display:
- 92%SpO_2
- 60 bpm
- no alarm
- low level modulation

7. Test #3: Modulation Level (for Nellcor module only)

a. Press the %MODULATION selection button on the SpO_2 simulator. The %MODULATION LED will light.

b. The monitor's waveform area will spike and stabilize at a higher modulation level.

c. The monitor will display:
- 90% SpO_2
- 60 bpm
- no alarm

d. Disconnect all equipment and turn off the monitor.

Respiration Operation

1. Press the ***Power Button*** to turn on the monitor.
2. Connect ECG lead wires to an appropriate terminal on the respiration simulator.
3. Connect ECG lead wires to the ECG cable.
4. Connect the ECG cable to the ECG connector on the monitor's right panel.
5. Set the respiration simulator lead selection to lead I.
6. Set the respiration simulator to 120 breaths per minute.
7. After the normal power-up sequence, verify the following reactions:

a. The monitor displays respiration rate of 120 ±3 breaths per minute.

b. Audible alarm will sound, "***High Respiration Rate limits violated***" message will display and the Respiration numerical area will flash, indicating the respiration rate is above default upper alarm limits (medium priority alarm).

8. Decrease the respiration rate setting on the respiration simulator to 20 breaths per minute.
    a. Verify that the monitor displays the respiration rate of 20 ±3 breaths per minute.

Note: The accuracy of Respiration measurements is ±3 breaths per minute. In the procedure above, add the tolerance of the simulator to the acceptable range of readings.

Temperature Operation

1. Press the ***Power Button*** to turn on the monitor.
2. Connect the temperature probe (supplied with the temperature simulator) to an appropriate terminal on the temperature simulator.
3. Connect the temperature probe to the temperature connector on the monitor's right panel.
4. Set the temperature simulator as follows:
    - Temperature: 37°C (98.0°F)
    - Probe type: YSI-400 series Temperature Probes (Probe accuracy: ±0.1°C)
5. After the normal power-up sequence, verify that the temperature reads 37°C ±0.1°C (98.6°F ±0.2°F if Fahrenheit is selected for the temperature unit).
6. Turn off the monitor.

Note: The accuracy of temperature measurements is ±0.1°C (±0.2°F). In the procedure above, add the tolerance of the simulator and the probe to the acceptable range of readings.

CO_2 Operation

1. Connect the monitor to an AC power source.
2. Turn on the monitor by pressing the ***Power Button***.
3. Test #1: Display Accuracy
    - For Mainstream
    a. Connect the mainstream CO_2 sensor into the CO_2 connector on the monitor's right panel.
    b. Place a mainstream CO_2 airway adapter into the transducer head.
    c. Verify that the "***CO_2 - Sensor Warming-up***" message displays and wait until the message clears.
    d. Breathe through the CO_2 airway adapter for five slow breaths. Verify that the waveform displayed rises and falls accordingly.
    e. Connect a gas cylinder containing 10% CO_2 to a flow meter and then to the CO2 airway adapter.
    f. Turn the gas ON and verify that the flow through the airway adapter is 200 to 300 ml/min
    g. Allow the reading to stabilize for 15 seconds.
    h. Verify that the monitor displays 76 ± 2 mmHg (10 ± 0.2%) in CO_2 numerical area.

- For Sidestream

a. Connect the sidestream sampling line to the inlet port located on the metal container on the front of the CO_2 module. You will hear a click when properly inserted.

b. A "***CO_2 - Sensor Warming-up***" message displays for up to 2 minutes, depending on the temperature of the environment, the temperature of the module, and the temperature of the sensor.

c. Breathe through the CO_2 airway adapter for five slow breaths. Verify that the displayed waveform rises and falls accordingly.

d. Connect a gas cylinder containing 10% CO_2 to a flow meter and then to the CO_2 airway adapter.

e. Turn the gas On and verify that the flow through the airway adapter is 200 to 300 ml/min

f. Allow the reading to stabilize for 15 seconds.

g. Verify that the monitor displays 76 ± 2 mmHg (10 ± 0.2 %) in CO_2 numerical area.

4. Test #2: Flow Rate Accuracy

a. Connect the sidestream CO_2 module into the CO_2 connector on the monitor's right panel.

b. Attach the sidestream sampling lime to the inlet port located on the metal container on the front of the CO_2 module. You will hear a click when properly inserted.

c. Connect the calibrated flow meter to the exhaust port of the module after the monitor is warmed up and all messages have cleared.

d. Verify that the flow rate is 50 ml/min ±10ml. If the measured flow rate is outside the specified limits, remove the CO_2 module form use and contact a Mediana Technical Service Department.

5. Test #3: Occlusion

a. Block the exhaust port while the sidestream CO_2 sensor module is runing.

b. Verify that the "***CO_2 - Occlusion or leak***" message displays.

Safety Tests

The monitor safety tests meet the standards of, and are performed in accordance with, IEC 60601-1, Clause 19 (Second Edition, 1988; Amendment 1, 1991-11, Amendment 2, 1995-03), EN60601-1 for instruments classified as Class I and Type CF.

Protective Earth Continuity

This test checks the integrity of the power cord ground wire from the AC plug to the instrument chassis ground. The current used for this test is less than or equal to 4 Volts RMS, 50 to 60 Hz, and 25 Amperes.

1. Connect the monitor AC power plug to the analyzer as recommended by the analyzer operating instructions.
2. Connect the analyzer resistance input lead to the equipotential terminal (ground lug) on the rear of the instrument. Verify that the analyzer indicates 100 milliohms or less.

Electrical Leakage

Earth Leakage Current

This test is in compliance with IEC60601-1 earth leakage current. The applied voltage for IEC60601-1 is 264 Volts AC, 50 to 60 Hz. All measurements shall be made with the power switch in both “On” and “Off” positions.

1. Connect the monitor AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions.
2. Perform the test as recommended by the analyzer operating instructions.

Table 3. Earth Leakage Current Values

Test Condition	Allowable Leakage Current (microamps)
Normal Condition (NC)	500
SFC Open Supply (SFC OS)	1000
Normal Condition RM (NCRM)	500
SFC Open Supply RM (SFC OSRM)	1000

SFC: Single Fault Condition / RM: Reverse Mains/Lines Voltage

Note: Earth leakage current is measured under various conditions of the AC power and protective earth conductor. For each condition, the measured leakage current must not exceed that indicated in Table 8.

Enclosure Leakage Current

This test is in compliance with IEC60601-1 enclosure leakage current. This test is for ungrounded enclosure current, measured between enclosure parts and earth. The applied voltage for IEC60601-1 is 264 Volts AC at 50 to 60 Hz.

1. Connect the monitor AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions.
2. Place a 200cm^2 foil in contact with the instrument case making sure the foil is not in contact with any metal parts of the enclosure that may be grounded.
3. Measure the leakage current between the foil and earth.

Note: The analyzer leakage current indication must not exceed the values listed in Table 4.

Table 4. Enclosure Leakage Current

Test Condition	Allowable Leakage Current (microamps)
Normal Condition (NC)	100
SFC Open Supply (OS)	500
SFC Open Earth (SFC OE)	500
Normal Condition RM (NCRM)	100
SFC Open Supply RM (SFC OSRM)	500
SFC Open Earth RM (SFC OERM)	500

Patient Leakage Current

This test measures patient leakage current in accordance with IEC60601-1, clause 19, for Class I, Type CF equipment. Patient leakage current in this test is measured from any individual patient connection to earth (power ground).

1. Configure the electrical safety analyzer as recommended by the analyzer operating instructions.
2. Connect the monitor's AC power cord to the analyzer as recommended by the analyzer operating instructions.
3. Connect the ECG test cable between the ECG connector on the monitor and the appropriate input connector on the analyzer.
4. Turn on the monitor.
5. Perform the patient leakage current test as recommended by the analyzer operating instructions.
6. Repeat the patient leakage current test for the SpO_2 and temperature patient connections, using the appropriate test cables.

Note: Patient leakage current is measured under various conditions of the AC power and protective earth conductor. For each condition, the measured leakage current must not exceed that indicated in Table 5.

Note: This test requires a test cable for each patient connector. For example, the ECG test cable consists of the ECG cable connector, with all conductors shorted together, connected to a test lead from the electrical safety analyzer. Test cables for SpO_2 and temperature can be configured in a similar manner, by wrapping each sensor end individually with aluminum foil filled with conductive gel (only enough gel to ensure conductivity). Attach a wire to the foil that is connected to a test lead from the electrical safety analyzer.

Table 5. Patient Leakage Current Values

Test Condition	Allowable Leakage Current (microamps)
Normal Condition (NC)	10
SFC Open Supply (OS)	50
SFC Open Earth (SFC OE)	50
Normal Condition RM (NCRM)	10
SFC Open Supply RM (SFC OSRM)	50
SFC Open Earth RM (SFC OERM)	50

Patient Leakage Current - Mains Voltage on the Applied Part

WARNING: AC power voltage will be present on the applied part terminals during this test. Exercise caution to avoid electrical shock hazard.

WARNING: Do not touch the patient leads clips or the simulator parts connected to patient leads during this test as an electrical shock will occur.

This test measures patient leakage current in accordance with IEC60601-1, clause 19, for Class I, type CF equipment. In this test, 110% of mains voltage is applied between each patient connection and earth (power ground). Patient leakage current is then measured from any individual patient connection to earth.

Note: Keep the patient test cable length as short as possible during the leakage test.

Note: This test requires the same test cables for each patient connector as described in the section **Patient Leakage Current**.

1. Configure the electrical safety analyzer as recommended by analyzer operating instructions.
2. Connect the monitor's AC power cord to the analyzer as recommended by the analyzer operating instructions.
3. Connect the ECG test cable between the ECG connector on the monitor and the appropriate input connector on the analyzer.
4. Turn on the monitor.
5. Perform the test as recommended by the analyzer operating instructions.
6. Repeat the test for SpO_2 and temperature patient connections, using the appropriate test cables.

Note: Patient leakage current is measured with normal and reverse mains polarity. For each condition, the measured leakage current must not exceed that indicated in Table 6.

Table 6. Patient Leakage Current Values - Mains Voltage on Applied Part

Test Condition	Allowable Leakage Current (microamps)
Normal polarity (SFC)	50
Reverse polarity (SFCRM)	50

Patient Auxiliary Current

This test measures patient auxiliary current in accordance with IEC60601-1, clause 19, for Class I, type CF equipment. The applied voltage for IEC60601-1 is 264 volts, 50 to 60 Hz. Patient auxiliary current is measured between each ECG test lead and between each sensor connection for all possible connections.

Note: Keep the patient test cable length as short as possible during the leakage test.

Note: This test requires the same test cables for each patient connector as described in the section "**Patient Leakage Current**".

1. Configure the electrical safety analyzer as recommended by the electrical analyzer's operating instructions.
2. Connect the monitor's AC power cord to the electrical analyzer as recommended by the electrical analyzer's operating instructions.
3. Connect the patient test lead combination in Table 7 to the appropriate input connector on the electrical analyzer.
4. Turn on the monitor.
5. Perform patient auxiliary current test per Table 8 as recommended by the electrical analyzer's operating instructions.
6. Repeat the patient auxiliary current test for each test lead combination as listed in Table 7 and measure each patient auxiliary current.

Table 7. Test Lead Combinations

First Test Lead	Second Test Lead
ECG #1 (LA)	ECG #2 (LL)
ECG #1 (LA)	ECG # 3 (RA)
ECG #2 (LL)	ECG #3 (RA)
ECG #1 (LA)	Temperature
ECG #2 (LL)	Temperature
ECG #3 (RA)	Temperature
ECG #1 (LA)	SpO_2
ECG #2 (LL)	SpO_2
ECG #3 (RA)	SpO_2
Temperature	SpO_2

Table 8. Allowable Leakage Current

Test Condition	Allowable Leakage Current (microamps)
Normal Condition (NC)	10
SFC Open Supply (OS)	50
SFC Open Earth (SFC OE)	50
Normal Condition RM (NCRM)	10
SFC Open Supply RM (SFC OSRM)	50
SFC Open Earth RM (SFC OERM)	50

Verification Check Sheet

Record the results of the performance verification on this sheet.

Model Name		Serial No.		Software Version		Date		Tester	

ITEMS	RESULTS	REMARKS
PERFORMANCE TEST		
Power	Pass / Fail	
Battery charge	Pass / Fail	
Battery discharge	Pass / Fail	
Power-on self-test (POST)	Pass / Fail	
Date and Time setting	Pass / Fail	
Alarms and alarm silence	Pass / Fail	
QRS volume control	Pass / Fail	
Sensor LED test	Pass / Fail	
Restoring power-on default settings	Pass / Fail	
Printer test (option)	-	
- One-Shot printing	Pass / Fail	
- Continuous printing	Pass / Fail	
- Print speed	Pass / Fail	
- Print-On-Alarm	Pass / Fail	
ECG operation	-	
- 30 ±1bpm (High priority alarm condition)	Pass / Fail	Value: bpm
- 240 ±1bpm (High priority alarm condition)	Pass / Fail	Value: bpm
- 120 ±1bpm (Normal condition)	Pass / Fail	Value: bpm
- ECG lead off (LL) for 3 leads	Pass / Fail	
- ECG lead off (LA) for 3 leads	Pass / Fail	
- ECG lead off (RA) for 3 leads	Pass / Fail	
- Lead selection for 3 leads	Pass / Fail	
- Waveform size selection for 3 leads	Pass / Fail	
- ECG lead off (LL) for 5 leads	Pass / Fail	
- ECG lead off (LA) for 5 leads	Pass / Fail	
- ECG lead off (RA) for 5 leads	Pass / Fail	
- Lead selection for 5 leads	Pass / Fail	
- Waveform size selection for 5 leads	Pass / Fail	
NIBP operation	-	
- Over pressure test (within 330mmHg)	Pass / Fail	Value: mmHg
- Pressure sensor accuracy test 0 mmHg	Pass / Fail	Value: mmHg
- Pressure sensor accuracy test 50 mmHg	Pass / Fail	Value: mmHg
- Pressure sensor accuracy test 150 mmHg	Pass / Fail	Value: mmHg
- Pressure sensor accuracy test 250 mmHg	Pass / Fail	Value: mmHg
- Air leakage test 12mmHg / 3minutes	Pass / Fail	Value: mmHg
- Inflation time measurement	Pass / Fail	
- Deflation rate measurement	Pass / Fail	
Pulse oximetry operation	-	
- SpO_2 90 ± 2% (for Nellcor module) - SpO_2 92 ± 2% (for Mediana module)	Pass / Fail	Value: %
- Pulse rate 200 ± 3bpm (High priority alarm condition) (for Nellcor module) - Pulse rate 240 ± 2bpm (High priority alarm condition) (for Mediana module)	Pass / Fail	Value: bpm
- Pulse rate 60 ± 3bpm (for Nellcor module) - Pulse rate 60 ± 2bpm (for Mediana module)	Pass / Fail	Value: bpm
- Modulation level (for Nellcor module only)	Pass / Fail	
Respiration operation	Pass / Fail	
Temperature operation	Pass / Fail	
CO2 operation	-	
- Display accuracy 76 ± 2mmHg (for Mainstream) - Display accuracy 76 ± 2mmHg (for Sidestream)	Pass / Fail	Value: mmHg
- Flow rate	Pass / Fail	
- Occlusion	Pass / Fail	

SAFETY TEST			
TEST CONDITIONS	**LIMIT (uA)**	**RESULTS**	**REMARKS**
Earth leakage current (NC)	500	Pass / Fail	Value: uA
Earth leakage current (SFC OS)	1000	Pass / Fail	Value: uA
Earth leakage current (NCRM)	500	Pass / Fail	Value: uA
Earth leakage current (SFC OSRM)	1000	Pass / Fail	Value: uA
Enclosure leakage current (NC)	100	Pass / Fail	Value: uA
Enclosure leakage current (OS)	500	Pass / Fail	Value: uA
Enclosure leakage current (SFC OE)	500	Pass / Fail	Value: uA
Enclosure leakage current (NCRM)	100	Pass / Fail	Value: uA
Enclosure leakage current (SFC OSRM)	500	Pass / Fail	Value: uA
Enclosure leakage current (SFC OERM)	500	Pass / Fail	Value: uA
Patient leakage current (NC)	10	Pass / Fail	Value: uA
Patient leakage current (OS)	50	Pass / Fail	Value: uA
Patient leakage current (SFC OE)	50	Pass / Fail	Value: uA
Patient leakage current (NCRM)	10	Pass / Fail	Value: uA
Patient leakage current (SFC OSRM)	50	Pass / Fail	Value: uA
Patient leakage current (SFC OERM)	50	Pass / Fail	Value: uA
Mains voltage on applied part (SFC)	50	Pass / Fail	Value: uA
Mains voltage on applied part (SFCRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG LL (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG LL (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG LL (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG LL (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG LL (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG LL (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG RA (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG RA (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG RA (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG RA (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG RA (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-ECG RA (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-ECG RA (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-ECG RA (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-ECG RA (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-ECG RA (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-ECG RA (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-ECG RA (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-TEMP (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-TEMP (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-TEMP (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-TEMP (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-TEMP (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-TEMP (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-TEMP (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-TEMP (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-SpO_2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-SpO_2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-SpO_2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-SpO_2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-SpO_2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LA-SpO_2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-SpO_2 (NC)	10	Pass / Fail	Value: uA

SAFETY TEST			
TEST CONDITIONS	**LIMIT (uA)**	**RESULTS**	**REMARKS**
Patient auxiliary current ECG LL-SpO_2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-SpO_2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-SpO_2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-SpO_2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG LL-SpO_2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-SpO_2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-SpO_2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-SpO_2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-SpO_2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-SpO_2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current ECG RA-SpO_2 (SFC OERM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP-SpO_2 (NC)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP-SpO_2 (OS)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP-SpO_2 (SFC OE)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP-SpO_2 (NCRM)	10	Pass / Fail	Value: uA
Patient auxiliary current TEMP-SpO_2 (SFC OSRM)	50	Pass / Fail	Value: uA
Patient auxiliary current TEMP-SpO_2 (SFC OERM)	50	Pass / Fail	Value: uA

Remarks

NC: Normal Condition
NCRM: Normal Condition Reverse
SFC: Single Fault Condition
OS: Single Fault Condition (Open Line/Neutral)
OSRM: Single Fault Condition (Open Line/Neutral) Reverse
OE: Single Fault Condition (Open Earth)
OERM: Single Fault Condition (Open Earth) Reverse

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SERVICE MENU AND FACTORY DEFAULT

General

This section discusses use of the Service menu to configure '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' and 'System Information'. Also, this section explains briefly the factory default settings.

Service Menu

The purpose of the Service menu is to allow the authorized user to create a Power-On Default for the settings in effect each time the monitor is powered on. Once the Service Menu is entered, physiological monitoring is terminated. The screen layouts do not display any information associated with normal monitoring operation. Use the following procedure to configure the Service Menu for the monitor (also see the **Using the Monitor** section of the operation manual):

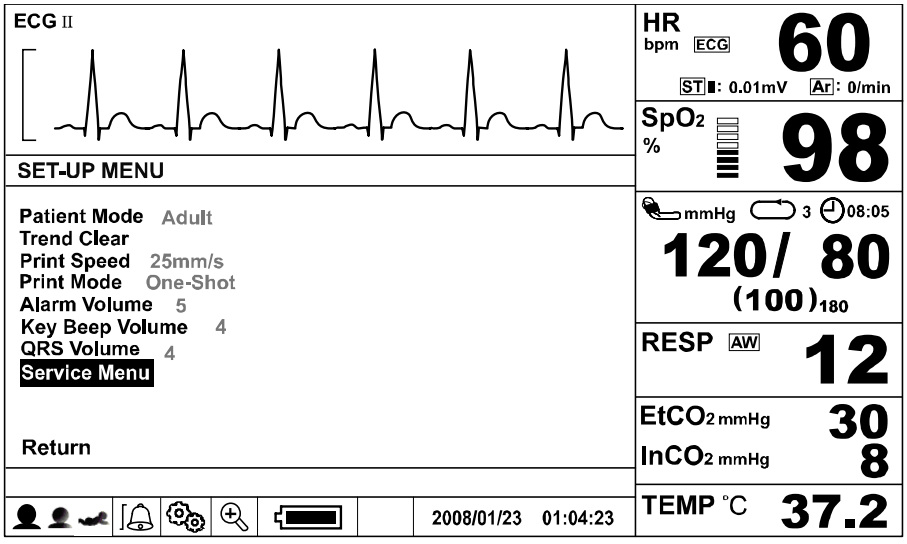

Figure 9. The access of Service Menu via Setup Menu

1. Set the monitor to normal monitoring mode.
2. Rotate the jog dial to highlight the ***Setup icon*** located on the bottom of the screen and then press the jog dial. ***Setup Menu*** displays.
3. Rotate the jog dial to highlight ***Service Menu*** in ***Setup Menu***, and then press the jog dial to access the ***Service Menu***.
4. Three digits are displayed in the Level 2 Menu as shown in Figure 10.

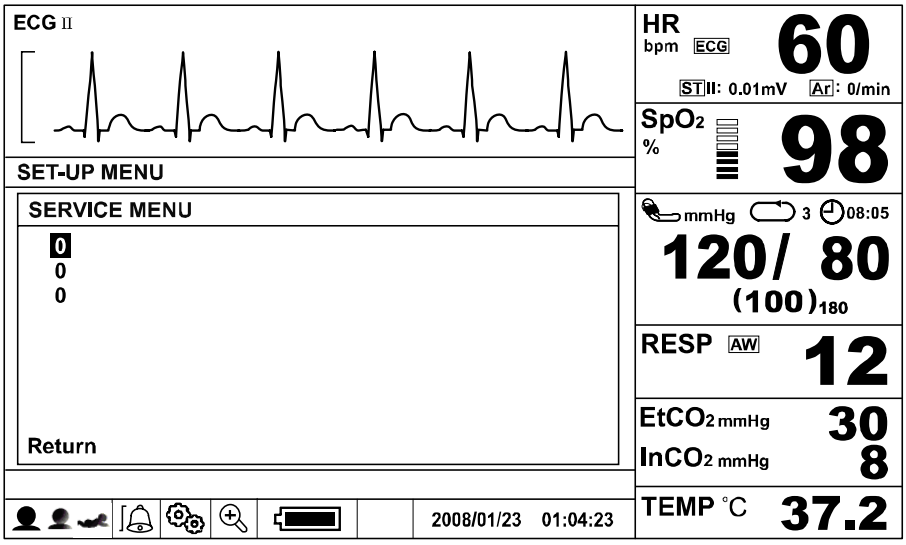

Figure 10. The access of Service Menu via Setup Menu

Note: The access code is **4, 0, 2**. It is set at the factory and can not be changed.

5. Rotate the jog dial to highlight the top of the digits. Press the jog dial to enter the ***Pass Code***.
6. Rotate the jog dial until "6" appears, then press the jog dial.
7. Repeat step 5-6 to enter the access code "**4**" "**0**" "**2**".

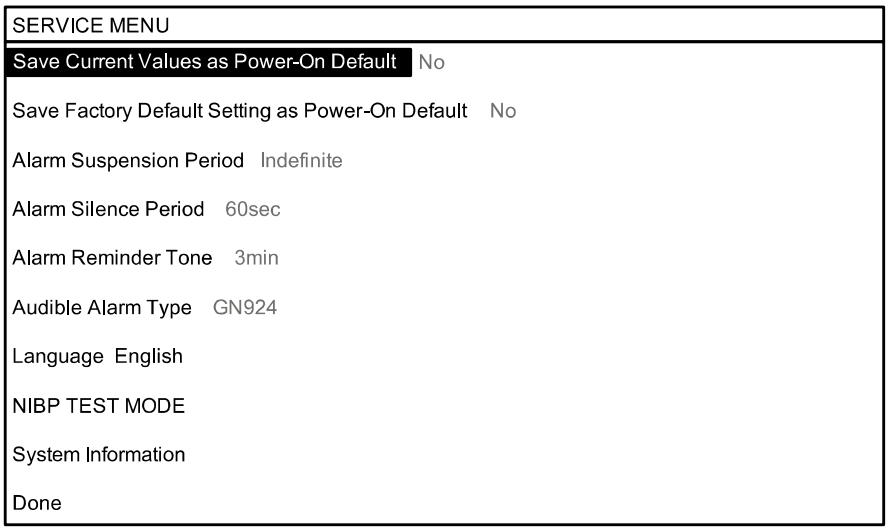

Figure 11. Service Menu

8. The Service Menu will now be present. The available Service Menu items are explained in Figure 11 and Table 9. Make changes to these menu items as desired by rotating and pressing the jog dial.
9. Select "Done". The monitor will present the message "All changes made to the power-up defaults will be in effect the next time the monitor is turned on." Before turned off.
10. Wait for the monitor to turn off, and then turn on the monitor again.

Note: The monitor is powered off upon selecting “Done” to save any changes in the service menu, and then the changes made to the Power On Defaults will be in effect next time the monitor is powered up.

Table 9. Service Menu

Level 1 Menu	Level 2 Menu	Level 3 Menu
Save Current Values as Power-On Default	Yes, No	
Save Factory Default Setting as Power-On Default	Yes, No	
Alarm Suspension Period	OFF, 1, 3, 5, 10, 20, 30, 60 min, Indefinite (Alarm Inhibition)	
Alarm Silence Period	30, 60, 90, 120 sec	
Alarm Reminder Tone	OFF, 3, 10 min	
Audible Alarm Type	GN924, IEC60601-1-8	
Language	한국어 (Korean), 中文 (Chinese), English, Français (French), Deutsch (German), Italiano (Italian), 日本語 (Japanese), Português (Portuguese), Dansk (Danish), Nederlands (Dutch), Suomi (Finnish), Ελληνικά (Greek), Norsk (Norwegian), Polski (Polish), Русский (Russian), Castellano (Spanish), Svenska (Swedish)	
NIBP TEST MODE	Pressure Sensor Accuracy Test	
	Air Leakage Test	
	Inflation Time Measurement	
	Deflation Rate Measurement	
System Information	Monitor On Time	
	Recorder On Time	
	Battery Deep Discharge	
	System Software Version	
	Sub CPU	
	ECG	
	SpO_2	
	NIBP	
	Temperature	
	$EtCO_2$	
Done	The monitor will be powered off upon selecting “Done” if any changes are made to save as Power-On defaults.	

Save Current Values as Power-On Default

The current settings become the power-up defaults next time the unit is powered up.

Save Factory Default Setting as Power-On Default

The factory default settings become the power-up defaults next time the unit us powered up. See Table 12.

Alarm Suspension Period

If the ***Alarm Suspension Period*** is set to anything other than ***OFF*** or ***Indefinite***, the audible alarm is not activated for the specified time interval by pressing and holding the ***Alarm Stop Button*** for 2 seconds. If ***OFF*** is selected, the audible alarm suspension is not allowed to activate. If ***Indefinite*** is selected, the audible alarm suspension continues until canceled.

Audible Alarm Silence Period

Pressing the ***Alarm Stop Button*** temporarily silences alarms for the period selected in the Service Menu. The factory default alarm silence period is 60 seconds.

Alarm Reminder Tone

The ***Alarm Reminder Tone*** menu is activated with the user-selectable period in the Service Menu. The interval can be set to ***OFF***, ***3*** or ***10 minutes***. If ***OFF*** is selected, the reminder tone will be disabled.

Audible Alarm Type

GN924 or IEC60601-1-8
The M30 has two different audible alarm types, called GN924 and IEC60601-1-8. They have different tone pitch and on-off beep patterns. (Refer to Alarms and Limits section in the operator's manual)

Language

The selected language will be used for all the text shown on the display; and it will be effective from the next time the monitor is powered up.

NIBP TEST MODE

These menus facilitate performing verification testing for the NIBP subsystem.
For a detailed procedure, refer to the **Performance Verification** section**.**

Table 10. NIBP Test

Tests	Description
Pressure Sensor Accuracy Test	Verifies that the pneumatic pressure sensor accuracy is within the specification.
Air Leakage Test	Verifies that the pneumatic pressure air leakage is within a pressure drop of 6 mmHg/min.
Inflation Speed Test	Verifies that the pneumatic pressure inflation is at the time of 4.0 to 7.5 seconds (to 250 mmHg).
Deflation Speed Test	Verifies that the proportional valve will open and bleed off pressure at the rate of 2.8 to 6.0 mmHg/second (260mmHg – 30mmHg).
Return	Returns to Service Menu.

System Information

The screen displays several system-related items**.**

Table 11. System Information

Tests	Description
Monitor On Time	Displays the number of hours, rounded to the nearest hour, that the monitor has been operational.
Recorder On Time	Displays the number of hours, rounded to the nearest hour, that the Recorder has been operational.
Battery Deep Discharges	Displays the number of deep-discharge cycles seen by the battery. The monitor records a deep discharge cycle when the battery voltage reaches the voltage at which a "Critically Low Battery" alarm is issued.
System Software Version	Displays the revision level of the system software. The revision level is also shown on the LCD as part of the Copyright screen.
Module Version (Sub CPU, ECG, SpO_2, NIBP, Temperature, $EtCO_2$)	Displays information for each module or board version.

Note: The values of Monitor On Time, Recorder On Time and Battery Deep Discharges may not be reset, but they will be reset to zero when a new CPU module is installed.

Done

The monitor will be powered off upon selecting "Done", then any changes will be in effect the next time the unit is powered up.

Factory Default Settings

Factory default settings are divided into adult, pediatric and neonatal as described in Table 12.

The patient mode is preset to “Adult” mode. Alarm limits will be automatically changed to the default settings for each patient mode as the mode is changed to Adult, Pediatric or Neonatal mode.

Table 12. Factory Default Settings

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
ST Level (1 to 5) High Alarm Limits	-1.99 to 2.00 mV (Adult/Pedi/Neo)	0.50 mV	0.50 mV	0.50 mV
ST Level (1 to 5) Low Alarm Limits	-2.00 to 1.99 mV (Adult/Pedi/Neo)	-0.50 mV	-0.50 mV	-0.50 mV
Arrhythmia High Alarm Limits	0 to 300 /min (Adult/Pedi/Neo)	5 /min	5 /min	5 /min
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) 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 SYS Upper Alarm Limits	35 to 270 mmHg (Adult/Pedi) 4.6 to 36.0 kPa (Adult/Pedi) 45 to 130 mmHg(Neo) 6.0 to 17.3 kPa (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) 4.0 to 35.3 kPa (Adult/Pedi) 40 to 125 mmHg (Neo) 5.3 to 16.6 kPa (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

Parameter	Ranges/Selections	Factory Defaults		
		Adult	Pediatric	Neonatal
NIBP DIA Upper Alarm Limits	15 to 250 mmHg (Adult/Pedi) 2.0 to 33.3 kPa (Adult/Pedi) 25 to 90 mmHg (Neo) 3.3 to 12.0 kPa (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	10 to 245 mmHg (Adult/Pedi) 1.3 to 32.6 kPa (Adult/Pedi) 20 ~85 mmHg (Neo) 2.6 to 11.3 kPa (Neo) (5 mmHg / 0.6 or 0.7 kPa steps)	50 mmHg 6.6 kPa	40 mmHg 5.3 kPa	20 mmHg 2.6 kPa
NIBP MAP Upper Alarm Limits	25 to 260 mmHg (Adult/Pedi) 3.3 to 34.6 kPa (Adult/Pedi) 35 to 110 mmHg (Neo) 4.6 to 14.6 kPa (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) 2.6 to 34.0 kPa (Adult/Pedi) 30 to 105 mmHg (Neo) 4.0 to 14.0 kPa (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
SpO_2				
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 source	AUTO, AW, IM	AUTO	AUTO	AUTO
Respiration Alarm Inhibition	On, Off	Off	Off	Off
RR Upper Alarm Limits	4 to 120 BPM (1 BPM steps)	30 BPM	30 BPM	100 BPM
RR Lower Alarm Limits	3 to 119 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	0.1 to 50.0 °C (Adult/Pedi/Neo) (0.1° C steps) 32.2 to 122.0 °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	0.0 to 49.9 °C (Adult/Pedi/Neo) (0.1° C steps) 32.0 to 122.8 °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)
$EtCO_2$				
$EtCO_2$ Unit	mmHg, kPa, %	mmHg	mmHg	mmHg
APNEA Alarm	Off, 15, 20, 25, 30, 35, 40 sec	20 sec	20 sec	20 sec
Zero Calibration	Yes, No	No	No	No
$EtCO_2$ Alarm Inhibition	On, Off	Off	Off	Off
$InCO_2$ Alarm linhibition	On, Off	Off	Off	Off

Parameter	Ranges/Selections	Factory Defaults		
		Adult	Pediatric	Neonatal
$EtCO_2$ Upper Alarm Limits	1 to 80 mmHg (Adult/Pedi/Neo) (1 mmHg steps) 0.13 to 10.7 kPa (Adult/Pedi/Neo) (0.13 kPa steps) 0.13 to 10.5 % (Adult/Pedi/Neo) (o.13 % steps)	80 mmHg 10.7 kPa 10.5 %	80 mmHg 10.7 kPa 10.5 %	80 mmHg 10.7 kPa 10.5 %
$EtCO_2$ Lower Alarm Limits	0 to 79 mmHg (Adult/Pedi/Neo) (1 mmHg steps) 0 to 10.5 kPa (Adult/Pedi/Neo) (0.13 kPa steps) 0 to 10.4 % (Adult/Pedi/Neo) (o.13 % steps)	0 mmHg 0 kPa 0 %	0 mmHg 0 kPa 0 %	0 mmHg 0 kPa 0 %
$InCO_2$ Upper Alarm Limits	1 to 20 mmHg (Adult/Pedi/Neo) (1 mmHg steps) 0.13 to 2.7 kPa (Adult/Pedi/Neo) (0.13 kPa steps) 0.13 to 2.6 % (Adult/Pedi/Neo) (0.13 % steps)	20 mmHg 2.7 kPa 2.6 %	20 mmHg 2.7 kPa 2.6 %	20 mmHg 2.7 kPa 2.6 %
$InCO_2$ Lower Alarm Limits	0 to 19 mmHg (Adult/Pedi/Neo) (1 mmHg steps) 0 to 2.5 kPa (Adult/Pedi/Neo) (0.13 kPa steps) 0 to 2.5 % (Adult/Pedi/Neo) (0.13 % steps)	0 mmHg 0 kPa 0 %	0 mmHg 0 kPa 0 %	0 mmHg 0 kPa 0 %
Others				
Patient Mode	Adult, Pediatric, Neonatal	Adult		
Trend Clear	Yes, No	No		
Print Speed**	25mm/s, 50mm/s	25mm/s		
Print Mode**	One-Shot, Continuous	One-Shot		
Print-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 Alram 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), Suomi (Finnish), Ελληνικά (Greek), Norsk (Norwegian), Polski (Polish), Русский (Russian), Castellano (Spanish), Svenska (Swedish)	English		

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.

FIRMWARE DOWNLOAD

General

This section is for the purpose of reloading Firmware into the monitor when the possibility of corrupted Firmware exists, or updating Firmware with a new system revision (system/device version). Call Mediana Technical Service Department for the latest version of Firmware utility required.

Note: The firmware download can be performed via USB or TCP/IP. If the USB and TCP/IP are connected to the monitor simultaneously, the firmware downloading would be performed by the method detected first.

Equipment Needed

Table 13 lists the equipment required for Firmware download.

Table 13. Required Equipment for Firmware Download

Equipment	Description
USB	
Firmware Download Tool	USB Memory with M30 Field Utility (firmware downloading software)
TCP/IP	
Firmware Downloading Cable	LAN Cable
Firmware Downloading Software	M30 Field Utility
Personal Computer (PC)	With TCP/IP Port

How to Download

1. Turn off the monitor.
2. Turn on the monitor by pressing the ***Home Button*** and ***NIBP Start/Stop Button*** simultaneously.
3. The monitor will display the firmware upgrade screen as shown in Figure 12.

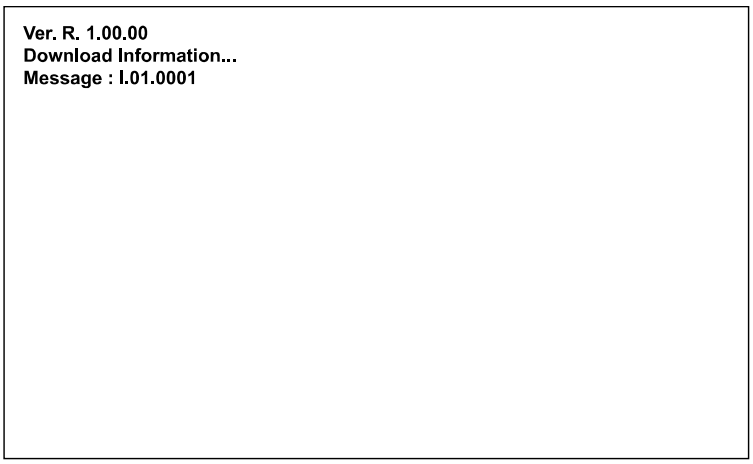

Figure 12. Firmware Downloading Display

USB download

a. Connect a USB memory drive containing the firmware to the USB port on the left panel of the monitor.

b. The monitor will automatically run the firmware download once the USB memory is detected.

TCP/IP download

a. Connect a LAN cable to the LAN port on the rear panel of the monitor.

b. Run the downloading software on the PC.

c. Perform the firmware download according to the software instructions.

4. When Firmware downloading is completed, the completion code will be displayed on the message line as shown in Figure 13. Refer to Table 14 for descriptions of the completion codes.

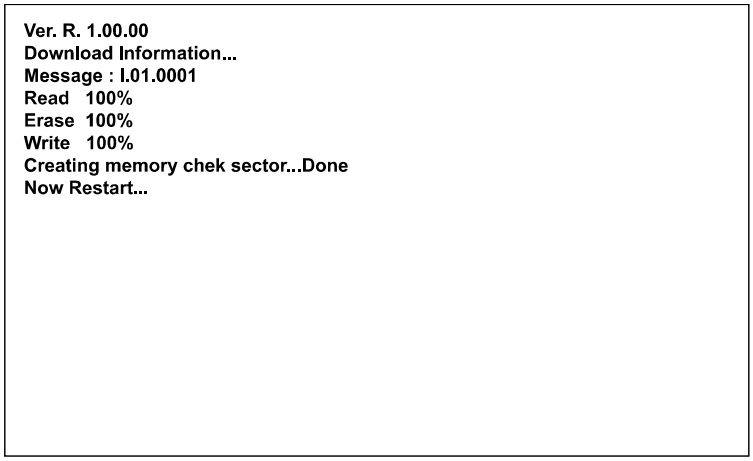

Figure 13. Firmware Downloading Completion

Table 14. Completion Codes

Code	Description
I.00.0001	USB is not connected
I.01.0001	USB initializing is completed
I.01.0003	Bad connection for boot download
I.02.0003	Bad connection for main download
S.00.0001	Detected USB
S.01.0001	Boot download & fusing are completed
S.02.0001	Main download & fusing are completed

Note: If there is any problem during Firmware downloading, the error code will be displayed on the message line. Refer to Firmware Download in the **Troubleshooting** section.

5. After completion of downloading, turn off the monitor.
6. Disconnect the USB memory or LAN cable from the monitor.
7. After a few seconds, turn on the monitor again.
8. Check the system version indicated on the copyright screen.
9. Perform the tests specified in the **Performance Verification** section.

Note: When new firmware downloading is completed, the monitor still keeps the previous settings.

Note: If any problem occurs during Firmware downloading, refer to Firmware Download in the **Troubleshooting** section.

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TROUBLESHOOTING

General

This section provides information that can be helpful in troubleshooting the M30 monitor.

How to Use This Section

If the Unit is not functioning properly, please check on the following items before calling for repair service. Use this section in conjunction with the **Performance Verification** section and the **Spare Parts** section. To remove and replace a part suspected to be trouble, follow the instructions in the **Disassembly Guide** section.

Who Should Perform Repairs

Only qualified service personnel should open the monitor housing, remove and replace components, or make adjustments in accordance with this service manual. If your medical facility does not have qualified service personnel, contact Mediana Technical Service Department.

Replacement Level Supported

The replacement level supported for this product is to the printed circuit board (PCB assembly) and major subassembly level. Once you isolate a suspected PCB assembly, follow the procedures in the **Disassembly Guide** section to replace the PCB assembly with a known good PCB assembly. Check to see if the trouble symptom disappears and that the monitor passes all performance tests.
If the trouble symptom persists, swap back the replacement PCB assembly with the suspected malfunctioning PCB assembly (the original PCB assembly that was installed when you started troubleshooting) and continue troubleshooting as directed in this section.

Obtaining Replacement Parts
Mediana provides technical assistance information and replacement parts. To obtain replacement parts, contact Mediana Technical Service Department. Refer to the part names and part numbers listed in the **Spare Parts** section.

Troubleshooting Guide

Problems with the monitor are separated into categories for further troubleshooting instructions.

Note: Taking the recommended actions discussed in this section will correct the majority of problems you will encounter. However, problems not covered here can be resolved by calling Mediana Technical Service Department.

Table 15. Problem Categories

Categories	Symptoms
1. Power	1.1 : Monitor will not turn on though the Power button is pressed. 1.2 : Monitor does not power on with battery.
2. Display	2.1 : Display is blacked out after normal POST. 2.2 : Display is deformed. 2.3 : Some pixels or lines are gone.
3. Sound	3.1 : Audible alarm does not operate. 3.2 : Alarm is not silenced. 3.3 : Buzzer Alarm goes off during the POST.
4. Button/Jog Dial	4.1 : Cannot push the jog dial. 4.2 : No response from the display against jog dial operation. 4.3 : Button does not work.
5. NIBP	5.1 : Cuff does not inflate.
6. SpO_2	6.1 : SpO_2 sensor does not light. 6.2 : No display on the numeric window though sensor is lighting.
7. Temperature	7.1 : Temperature value does not display.
8. Respiration	8.1 : Respiration value is inaccurate.
9. CO_2	9.1 : Flow rates fall and module is not working properly.
10. ECG	10.1 : Rapid, large and erratic detections. 10.2 : Occasional noise or artifact in the waveform for one or more leads. 10.3 : No display on the ECG waveform menu.

1. Power

Power problems are related to AC and/or Battery as follows. If the action requires replacement of the components, refer to the **Disassembly Guide** section.

CAUTION: Electrical shock hazard. Disconnect the power cord from the monitor before attempting to open or disassemble the monitor.

Symptom 1.1: Monitor will not turn on though the power button is pressed.

Cause or Checkpoint	Action	Remark
- AC line power cord is disconnected. - Battery is depleted or defective.	Connect the AC power cord to the outlet or install the battery.	
Charge light illumination - Battery missing or not properly seated - Failed charger	1. No : Replace the key assembly board → Replace the SMPS → Replace the Main Board 2. Yes : Replace the SMPS → Replace the Main Board.	

Symptom 1.2: Monitor does not power on with battery.

Cause or Checkpoint	Action	Remark
Battery is not installed.	Check the battery installation.	
Battery is totally discharged.	Recharge the battery for 4, 8 or 12 hours or if it persists, replace the battery.	
SMPS does not charge the battery.	Replace the SMPS.	
Main board is malfunctioning.	Replace the Main Board.	

2. Display

Symptom 2.1: The LCD display is blacked out after normal POST.

Cause or Checkpoint	Action	Remark
LCD cable is disconnected.	Reconnect the cable or replace the cable.	
Inverter wire is disconnected or inverter is broken.	Reconnect the wire or replace the inverter.	
LCD is damaged.	Replace the LCD.	

Symptom 2.2: Display is deformed.

Cause or Checkpoint	Action	Remark
LCD cable is not connected properly.	Reconnect the cable.	
CPU module is broken.	Replace the CPU module.	
Main Board is broken.	Replace the main board.	

Symptom 2.3: Some pixels or lines are gone.

Cause or Checkpoint	Action	Remark
LCD is broken.	Replace the LCD.	

3. Sound

Symptom 3.1: No sound during the POST.

Cause or Checkpoint	Action	Remark
Speaker is broken or speaker wire is loose/disconnected.	Reconnect the wire or replace the speaker.	
Main Board is malfunctioning.	Replace the Main Board.	

Symptom 3.2: Alarm is not silenced.

Cause or Checkpoint	Action	Remark
Key assembly board is broken.	Replace the key assembly board.	
Main Board is broken.	Replace the Main Board.	

Symptom 3.3:Buzzer Alarm goes off during the POST.

Cause or Checkpoint	Action	Remark
CPU is dead or Sub CPU is not communicating with the CPU.	Replace the CPU. If the problem persists, replace the Main Board.	

4. Button/Jog Dial

Symptom 4.1: Cannot push the Jog Dial.

Cause or Checkpoint	Action	Remark
Encoder is broken.	Replace the key assembly board.	

Symptom 4.2: No response from the display in response to Jog Dial operation.

Cause or Checkpoint	Action	Remark
Jog dial is broken or the jog dial wire is loose.	Replace the key assembly board or check the wire connection.	
Main Board is broken.	Replace the Main Board.	

Symptom 4.3: Button does not work.

Cause or Checkpoint	Action	Remark
Wire is disconnected or key assembly board is broken.	Replace the key assembly board or check the wire connection. If the problem persists, replace the Main Board.	

5. NIBP

Symptom 5.1: The cuff does not inflate.

Cause or Checkpoint	Action	Remark
Cuff or Cuff hose is folded.	Unfold the cuff or cuff hose.	
NIBP tube inside of the monitor is blocked or kinked.	Check the tube assembly between NIBP module and hose fitting.	
NIBP module is broken.	Replace the NIBP module.	
Main board is broken.	Replace the Main Board.	

6. SpO_2

Symptom 6.1: The SpO_2 sensor does not light.

Cause or Checkpoint	Action	Remark
The connection between SpO_2 sensor and extension cable is loose.	Reconnect sensor and extension cable.	
SpO_2 sensor is broken.	Replace the SpO_2 sensor.	
SpO_2 module is broken.	Replace the SpO_2 module.	
Main Board is broken.	Replace the Main Board.	

Symptom 6.2: No display on the numeric window though sensor is fine.

Cause or Checkpoint	Action	Remark
SpO_2 module is broken.	Replace the SpO_2 module.	

7. Temperature

Symptom 7.1: Temperature value does not display.

Cause or Checkpoint	Action	Remark
Sensor is not properly located.	Check the connection of Temperature sensor to the skin.	
Temperature module is broken.	Replace the Temperature module.	
Main Board is broken.	Replace the Main Board.	

8. Respiration

Symptom 8.1: Respiration value is inaccurate.

Cause or Checkpoint	Action	Remark
Gain is too low.	Select appropriate gain from the Respiration menu.	
Electrodes are not attached tightly.	Check the electrodes.	

9. CO_2

Symptom 9.1: Flow rates fall and module is not working properly.

Cause or Checkpoint	Action	Remark
Pump is not working properly	Check CO_2 module	
The Flow rates fall outside of the normal operating range Message "CO2 - Sampling Line Disconnected"	Sampling line is crimped or pinched. Sampling line is damaged. Check exhaust port. Remove the connector for inspection.	

10. ECG

Symptom 10.1: Rapid, large and erratic detections.

Cause or Checkpoint	Action	Remark
A broken wire in the patient lead A poorly applied sensor	Replace wire and electrode Check artifact occurred.	
ECG module is broken.	Replace the ECG module.	
Main board is broken.	Replace the main board.	

Symptom 10.2: Occasional noise or artifact in the waveform for one or more leads.

Cause or Checkpoint	Action	Remark
Improperly applied sensors and poor sensor contact with skin Electrical interference Ineffective baseline filter setting	Re-position ECG cables Keep the power code away from cable leads. Connect the unit to a properly grounded wall outlet. Check line filter setting in the menu.	
ECG module is broken.	Replace the ECG module.	
Main Board is broken.	Replace the Main Board.	

Symptom 10.3: No display on the ECG waveform menu though ECG accessories are connected to patient.

Cause or Checkpoint	Action	Remark
Check the ECG accessories and electrode connection.	- Re-position ECG cables. - Replace Accessories and Eletrode.	
ECG module is broken.	Replace the ECG module.	
Main Board is broken.	Replace the Main Board.	

11. Firmware Download

If an error code appears during the firmware downloading, take the action specified in Table 16.

Note: If the alarm message still appears, take monitor out of service and contact Mediana Technical Service Department for advice on remedial action.

Table 16. Firmware Downloading Error Codes

Code	Description	Action
E.00.0001	USB is not used.	Check your USB memory.
E.00.0002	Section.muf file not found or break.	Check your USB memory.
E.00.0003	Ver.muf file not found or break.	Check your USB memory.
E.00.0004	Update.muf file not found or break.	Check your USB memory.
E.00.0005	Binary file not found or break.	Check your USB memory.
E.01.0003	Boot download failed.	Try downloading again.
E.02.0003	Main download failed.	Try downloading again.
E.01.0005	Burn boot failed.	Try downloading again.
E.02.0005	Burn main failed.	Try downloading again.
E.01.0007	Boot data between SDRAM and FLASH are not matched.	Try downloading again. / Contact Mediana Technical Service Department.
E.02.0007	Main data between SDRAM and FLASH are not matched.	Try downloading again.

12. Technical Alarm Condition

When the monitor detects an error condition, the monitor will attempt to show an error code on the display screen.

If such an error occurs during monitoring operation, the monitor will sound a low-priority alarm. Audible alarm can be terminated by pressing Alarm silence/suspend switch, but it depends on error codes and conditions.

Table 17 provides a complete list of error codes and problem identification.

If an error code occurs, take the following actions:

1. Turn monitor off, then on again.

Note: If error code still appears, take monitor out of service and contact Mediana Technical Service Department or your local representative for advice on remedial action.

Table 17. Technical Error Codes

Error codes	Conditions
EEE001	SpO_2 module RAM error
EEE002	SpO_2 module ROM/code integrity error
EEE003	SpO_2 module bad CRC in communications
EEE004	SpO_2 module bad communication message
EEE005	SpO_2 module communication error, incorrect value
EEE006	SpO_2 module calibration (offset) failure
EEE009	SpO_2 module syntax communication error
EEE010	SpO_2 module sensor error
EEE012	SpO_2 module other hardware problem
EEE017	SpO_2 module indicator that sensor appears defective
EEE050	SpO_2 module intermittent error

Error codes	Conditions
EEE051	SpO_2 module DigiCAL communication error
EEE255	SpO_2 module invalid jumper selection
EEE256	SpO_2 module beginning of packet missing
EEE257	SpO_2 module packet start (SID) missing
EEE258	SpO_2 module packet length error
EEE259	SpO_2 module message length error
EEE260	SpO_2 module packet contains unsupported key
EEE261	SpO_2 module packet CRC error
EEE262	SpO_2 module end of packet missing
EEE263	SpO_2 module packet contains undefined key
EEE264	SpO_2 module corrupted variable
EEE265	SpO_2 module memory overflow
EEE266	SpO_2 module bad pointer
EEE267	SpO_2 module parameter value out-of-range
EEE268	SpO_2 module reset detected
EEE269	SpO_2 module unexpected value
EEE270	SpO_2 module time out
EEE271	SpO_2 module not ready/not initialized
EEE272	SpO_2 module double fault
EEE273	SpO_2 module data out of range error
EEE274	SpO_2 module incompatible digical sensor
EEE275	SpO_2 module incorrect registration number
EEE276	SpO_2 module sensor read failure
EEE277	SpO_2 module sensor signature verification fails
EEE281	SpO_2 module overflow/underflow
EEE282	SpO_2 module sensor activation failure
EEE283	SpO_2 module sensor write failure
EEE284	SpO_2 module both HW and SW ECG triggers received
EEE285	SpO_2 module host attempted read or close of sensor trend before successful open
EEE286	SpO_2 module host attempted redundant open of sensor trend
EEE287	SpO_2 module sensor trend data unavailable for reading by host
EEE288	SpO_2 module No more sensor trend data available for reading by Host
EEE289	SpO_2 module Sensor Private label/Host sensor Key incompatible
EEE401	CO_2 Module RAM Error
EEE402	CO_2 Module FLASH Error
EEE403	CO_2 Module CRC Error
EEE404	CO_2 Module Pulse Error
EEE405	CO_2 Module Voltage Error
EEE406	CO_2 Module Current Error
EEE407	CO_2 Module Software Error
EEE499	CO_2 Module Error
EEE700	NIBP module RAM error
EEE701	NIBP module ROM error
EEE702	Pressure sensor error
EEE703	Offset error
EEE704	A communication timeout with substitute CPU
EEE705	NIBP internal error
EEE706	NIBP module communication error
EEE801	Analog system ECG & Respiration module error*

Error codes	Conditions
EEE802	Analog system temperature module error*
EEE803	Analog system error*
EEE804	Analog system SpO_2 module communication error*
EEE905	Printer communication error*
EEE906	Battery status checking error*
EEE907	RTC error*
EEE910	Speaker error

Note: An asterisk (*) by an error code explanation in the above table indicates that an audible alarm occurred by the error code cannot be silenced by pressing Alarm Stop Button.

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DISASSEMBLY GUIDE

WARNING: Performance Verification. Do not place the monitor into operation after repair or maintenance has been performed until all Performance Tests and Safety Tests listed in the Performance Verification section of this service manual have been performed. Failure to perform all tests could result in erroneous monitor readings.

WARNING: Before attempting to open or disassemble the monitor, disconnect the power cord from the monitor.

CAUTION: Observe ESD (electrostatic discharge) precautions when working within the unit.

General

This section describes disassembly procedures with detailed disassembly instructions and illustrations. The Disassembly Sequence Flow Chart that is used to access replaceable parts of the monitor is illustrated in Figure 14. The boxes on the flow chart represent the various components or sub-assemblies. A complete listing of the available spare parts and part numbers is in the **Spare Parts** section. Follow the reverse sequence of the disassembly procedures for reassembly.

The monitor can be disassembled down to all major component parts, including:

- PCB assemblies
- acquisition modules, SMPS & LCD
- battery
- cables & wires
- cases
- printer

The following tools are required:

- small Phillips-head (+) screwdriver
- medium Phillips-head (+) screwdriver
- needle-nose pliers

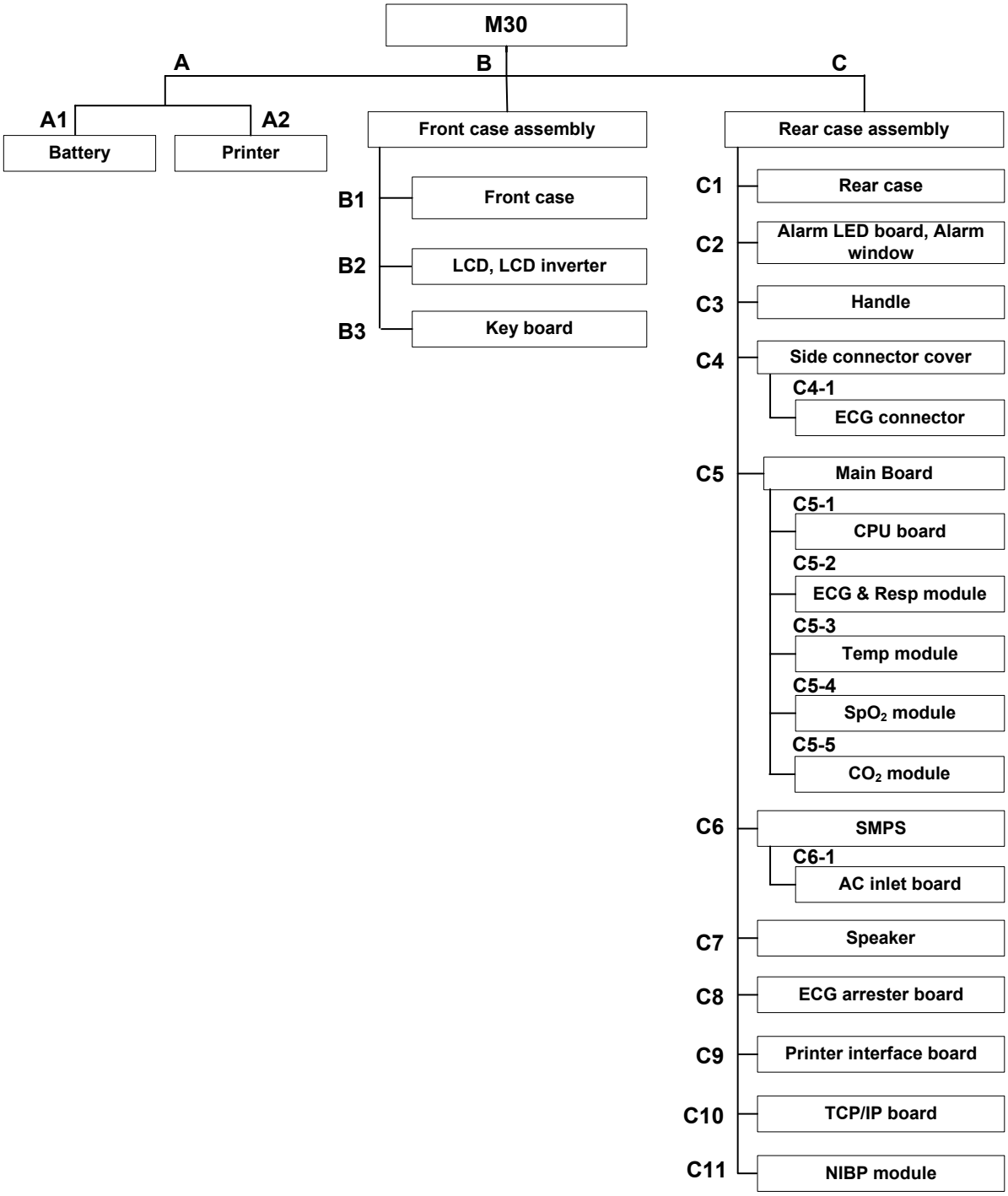

Figure 14. Disassembly Sequence Flow Chart

Replacement Level Supported

The replacement level supported for this product is to the printed circuit board (PCB) and major subassembly level. Once you isolate a suspected PCB, follow the procedures in Disassembly Guide to replace the PCB with a known good PCB. Check to see if the trouble symptom persists, swap back the replacement PCB with the suspected malfunctioning PCB (the original PCB that was installed when you started trouble shooting) and continue troubleshooting as directed in this section.

Prior to Disassembly

1. Turn off the monitor by pressing the ***Power Button***.
2. Disconnect the monitor from the AC power source.

Fuse Replacement

CAUTION: For continued protection against risk of fire, replace only with the same type and rating of fuse.

1. After step C6, SMPS disassembly, remove 2 AC power fuses (F1, F2: 250V/3.15A) if required.
2. Replace with new fuse(s).
3. Reassemble the monitor.

Battery Replacement (A1)

This section describes the steps to remove the battery from the monitor for replacement without disassembling the main case of the monitor.

1. Remove 4 flat-head screws (2x4) on the rear case.
2. Release lock and remove the battery cover (T4155).
3. Carefully remove the battery and then replace with new battery (Ref.M6028).
4. Put on the battery cover.

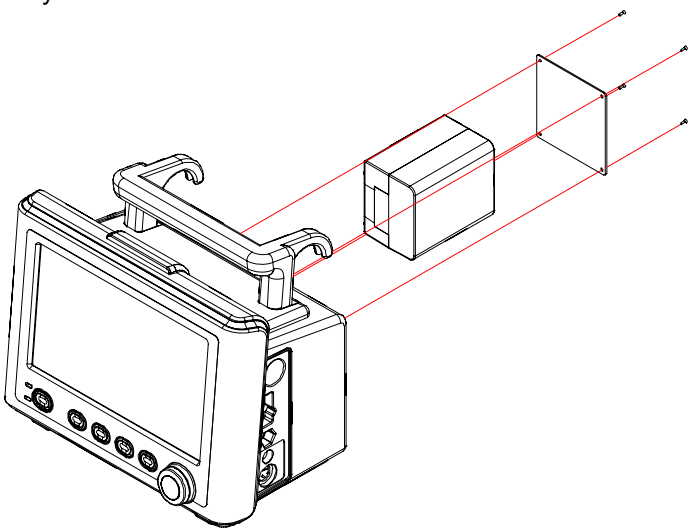

Figure 15. Battery Replacement

Optional Printer Disassembly (A2)

This section describes the steps that may remove an optional printer in the monitor. If you would like to install a printer, follow the reverse sequence of the procedures.

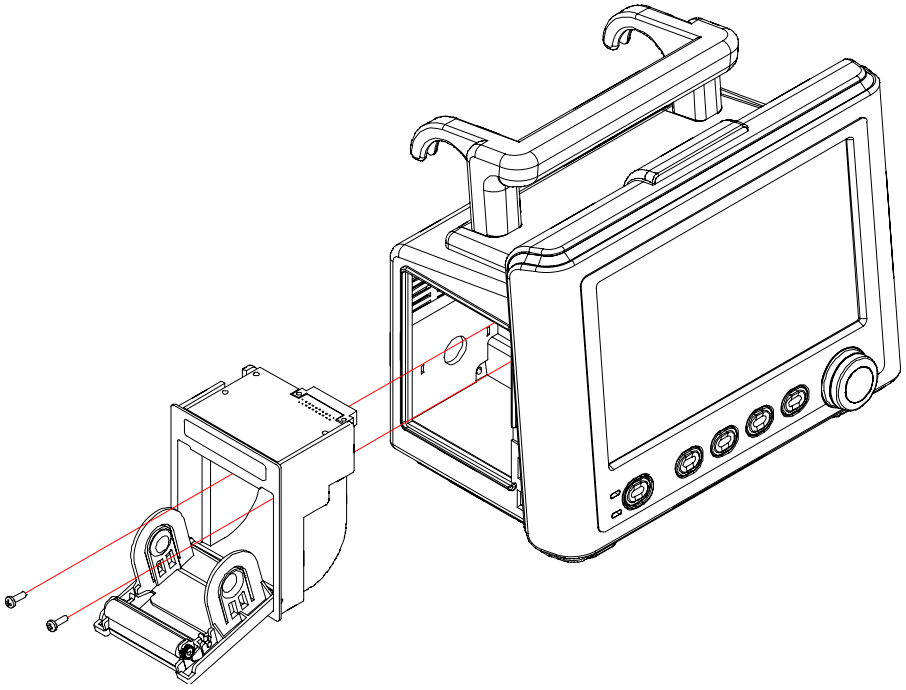

Figure 16. Printer Disassembly

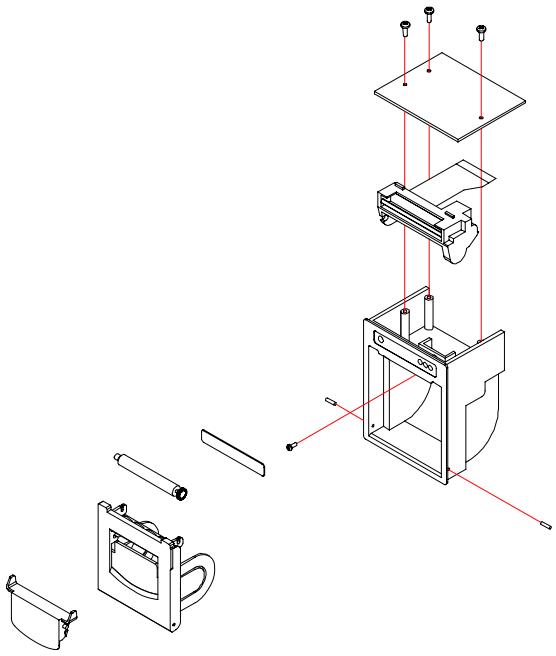

Figure 17. Printer Disassembly - Printer Board, Printer Body Case, Printer Opener Case, Printer Door Case, Printer Mecha, Printer Door Pin, Printer Paper

Table 18. Part Descriptions - Printer Board, Printer Body Case, Printer Opener Case, Printer Door Case, Printer Mecha, Printer Door Pin, Printer Paper

Part Codes	Descriptions	Qty
A0132	Thermal printer paper (50mm)	1
M4031	Thermal printer board	1
T0197	Thermal printer body case	1
T0198	Thermal printer opener case	1
T0199	Thermal printer door case	1
M4020	Thermal printer mecha	1
T4109	Thermal printer door pin (2mm)	2
B0076	Thermal printer label	1

A2. Printer disassembly

1. Open the printer door and remove the printer paper.
2. Remove 2 bind-head screws (3x6) inside the printer door.
3. Remove the printer assembly.
4. Remove the printer label, printer opener case and printer door case from the printer assembly.
5. Remove 1 tapping screw (2x8) inside the printer body case.
6. Remove the 2 printer door pins from the printer body case.
7. Remove the 3 tapping screw (3x8) from the printer board.
8. Remove the printer board and printer mecha from the printer body case.

Monitor Disassembly

This section describes the steps to separate the front and rear case assemblies.

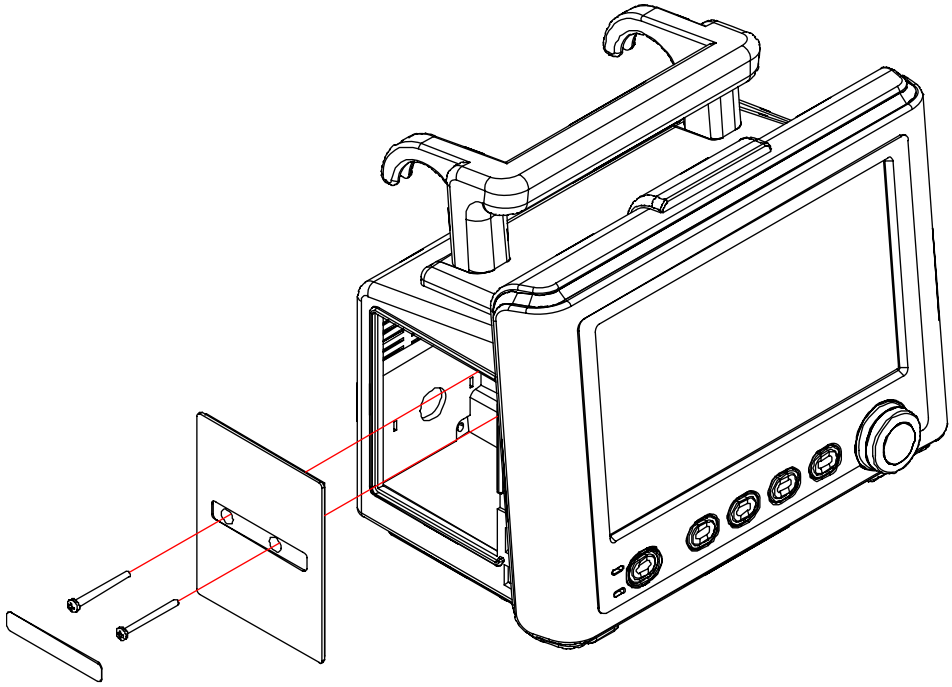

Figure 18. Monitor Disassembly

Table 19. Part Descriptions - Printer Cover

Part Codes	Descriptions	Qty
B0076	Thermal printer label	1
T0200	Thermal printer cover	1

Before steps B and C (1)

1. Remove the printer label on the printer cover.
2. Remove 2 round-head screws (3×50) on the printer cover and then remove the printer cover from the monitor.

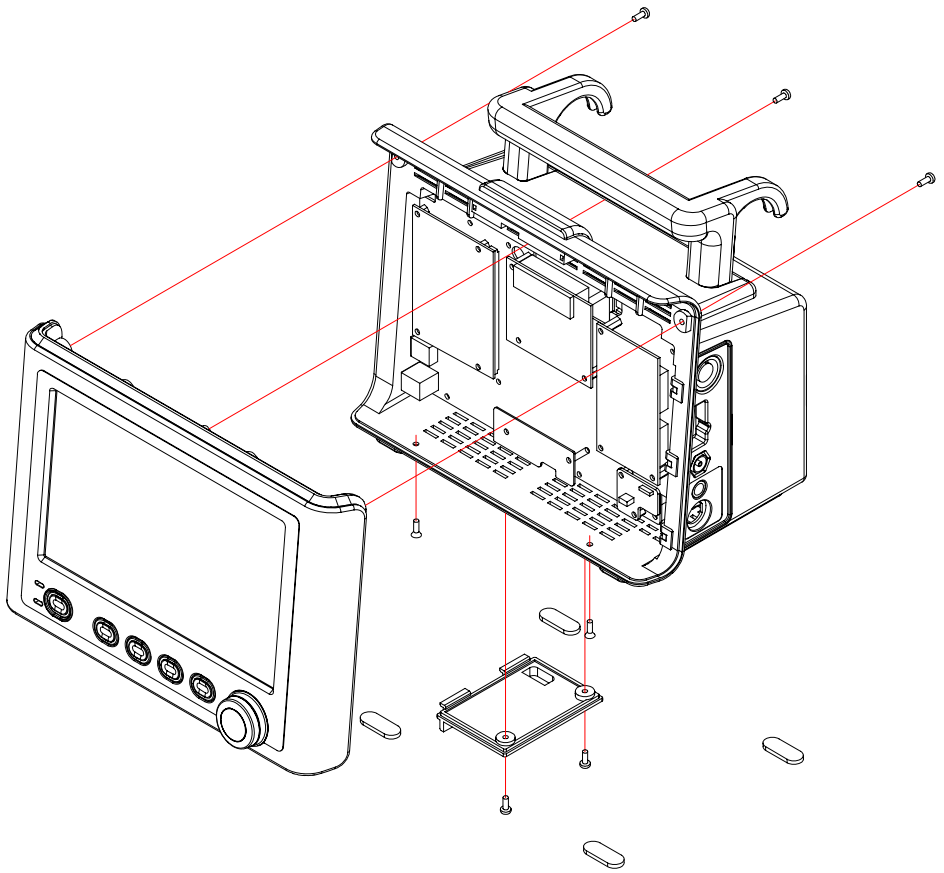

Figure 19. Monitor Disassembly

Table 20. Part Descriptions - Front Case and Rear Case Assembly

Part Codes	Descriptions	Qty
-	Front case assembly (A)	1
-	Rear case assembly (B)	1
T2017	Rear case cover	1
T1006	Rubber foot	4

Before steps B and C (2)

1. Remove the 4 rubber feet from the rear case.
2. Remove 2 bind-head screws (3x6) on the rear case cover.
3. Separate the rear case cover from the rear case.
4. Remove 2 bind-head screws (3x10), 1 bind-head screw (3x6) and 2 flat-head screws (3x6) on the rear case.
5. Separate the inverter cable, LCD data cable and key cable from the main board.
6. Separate the front case from the rear case.

Front Case Disassembly (B)

This section describes the items that may be removed on the front case assembly.

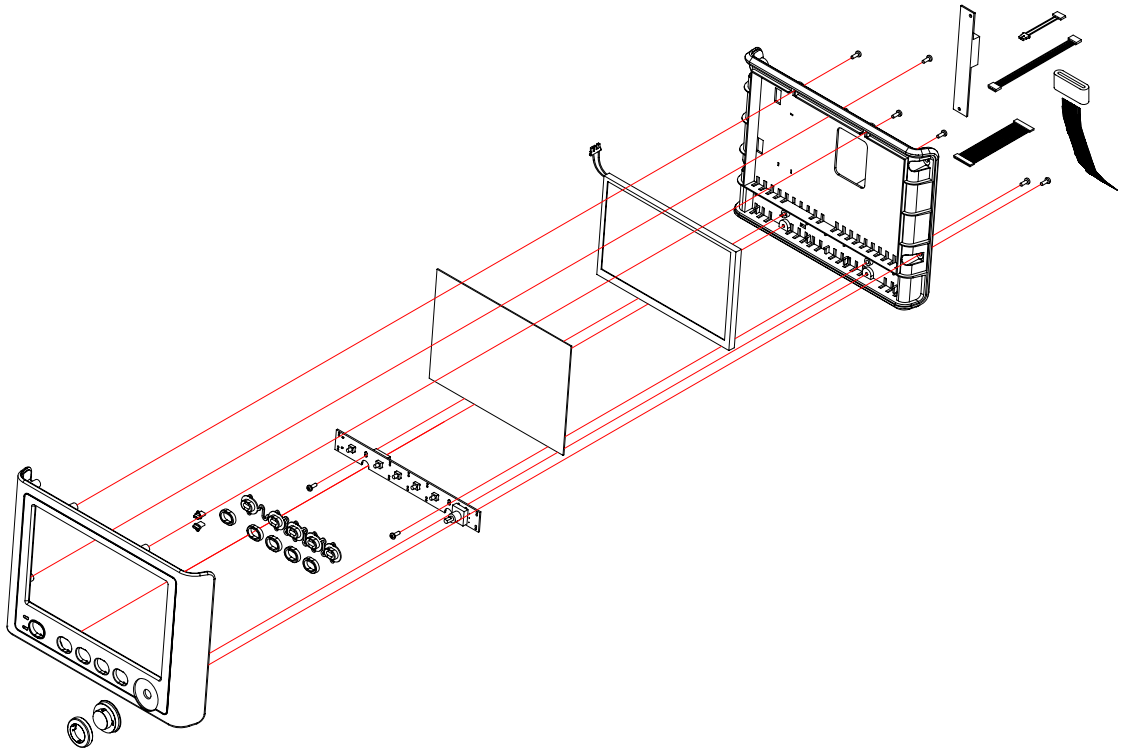

Figure 20. Front Case Disassembly - Front Case, LCD, Key Board

Table 21. Part Descriptions - Front Case, LCD, Key Board

Part Codes	Descriptions	Qty
T0207	Front case	1
T0209	Middle case	1
M8002	LCD inverter	1
W0194	LCD data cable (40pin)	1
W0182	Inverter cable (5pin)	1
T0333	LCD window	1
M4048	TFT-LCD	1
E5012	LCD ferrite core	1
W0187	Key cable (15pin)	1
T0201	Power / Battery window	2
T0213	Button ring (blue)	1
T0223	Button ring (orange)	1
T0224	Button ring (green)	1
T0225	Button ring (white)	2
T0214	Button	1
P1095	Key assembly board	1
T0245	Knob body	1
T0246	Knob grip	1

B1. Front case disassembly

1. Pull the knob straight out to separate from the monitor.
2. Remove the knob body and knob grip from the knob.
3. Remove the 6 round-head screws (3×6) from the front case assembly.
4. Separate the front case from the middle case assembly.

B2. LCD disassembly

1. Remove the LCD data cable and the inverter cable from the middle case.
2. Separate the LCD, LCD window, LCD ferrite core and LCD inverter from the middle case.

B3. Key board disassembly

1. Remove the 2 round-head screws (3×6) from the key board.
2. Remove the key cable from the middle case.
3. Separate the key board from the middle case.
4. Remove the power / battery window, button rings and button from the key board.

Rear Case Disassembly (C)

This section describes the items that may be removed on the rear case assembly.

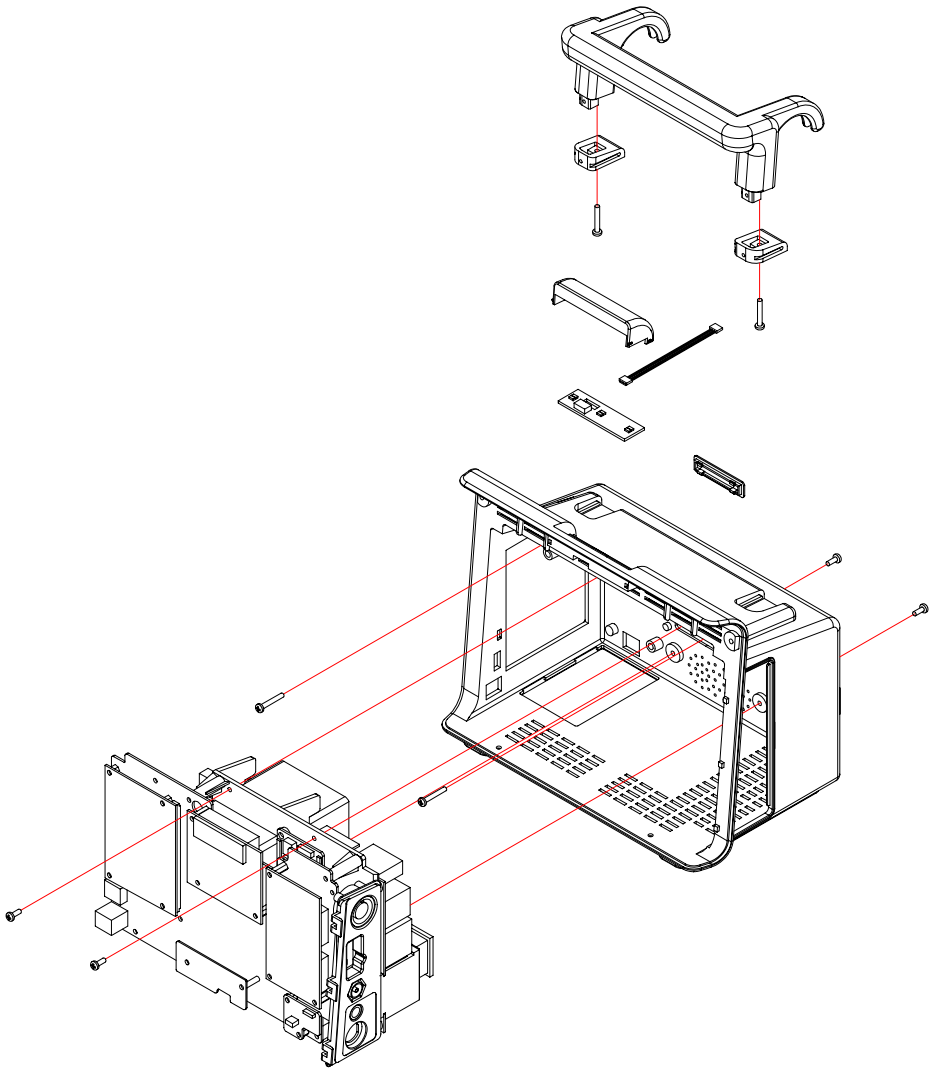

Figure 21. Rear Case Disassembly - Handle, Alarm LED Board, Alarm Window, Inner Case

Table 22. Part Descriptions - Handle, Alarm LED Board, Alarm Window, Inner Case

Part Codes	Descriptions	Qty
T0205	Handle	1
T0206	Handle holder (left)	1
T0222	Handle holder (right)	1
T0203	Alarm window	1
W0181	Alarm LED cable (4pin)	1
P1100	Alarm LED assembly board	1
T0221	Vent cover	1
T0211	Rear case	1

C1. Rear case disassembly

1. Remove 2 bind-head screws (3×6) on the rear case assembly.
2. Remove 2 round-head screws (3×6) on the inner case assembly.
3. Separate the inner case assembly from the rear case.
4. Remove the vent cover and alarm window from the rear case.

C2. Alarm LED board and Alarm window disassembly

1. Remove the alarm LED cable from the rear case assembly.
2. Remove the alarm LED board from the rear case assembly.

C3. Handle disassembly

1. Remove 2 tapping screws (3x10) on the rear case.
2. Remove 2 tapping screws (3x10) on the handle assembly.
3. Remove the handle from the rear case assembly.
4. Remove the 2 handle holders from the handle assembly.

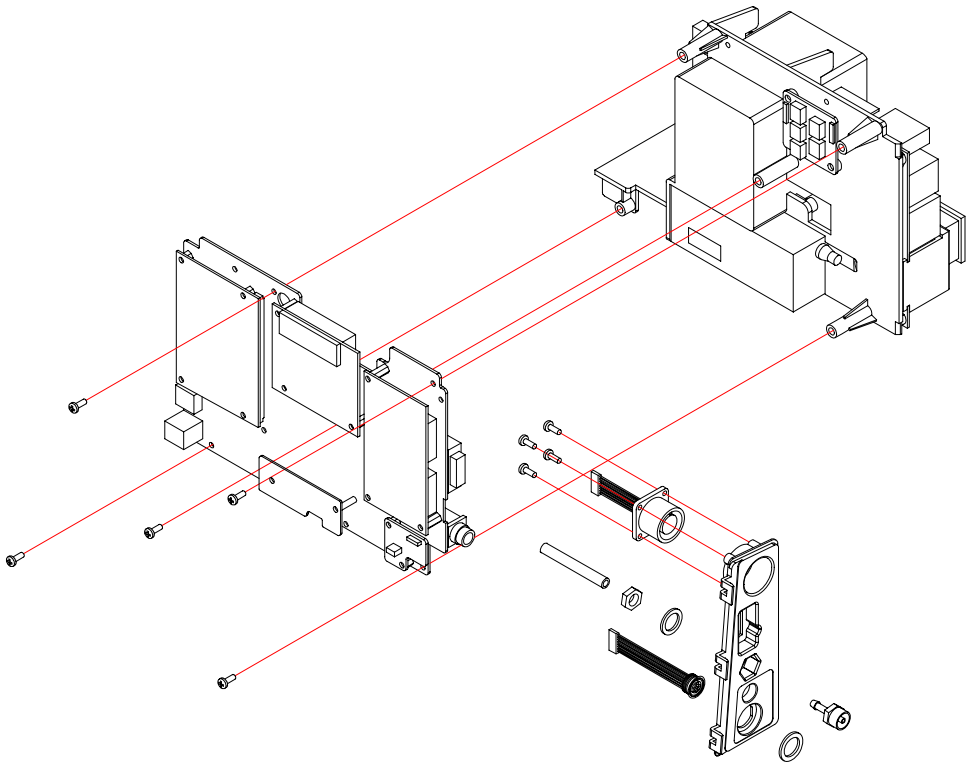

Figure 22. Rear Case Disassembly - Main Board, Side Connector Cover, ECG Connector, CO_2 Connector

Table 23. Part Descriptions - Main Board, Side Connector Cover, ECG Connector, CO_2 Connector

Part Codes	Descriptions	Qty
P1105 / P1093	Main Board for Nellcor SpO_2 module / for Mediana SpO_2 module	1/1
T0212	Side connector cover	1
E4114	Luer fitting/NIBP connector	1
E4231	ECG connector (6pin)	1
W0158	$EtCO_2$ connector (8pin)	1

C4. Side connector cover disassembly

1. Remove the side connector from the inner case.
2. Remove the luer fitting/NIBP connector from the side connector cover.

C4-1. ECG connector disassembly

1. Remove 4 tapping screws (3x8) from the ECG connector.
2. Remove the ECG connector from the side connector cover.

C5. Main Board disassembly

1. Remove 5 round-head screws (3x6) from the Main Board.
2. Separate the ECG arrester cable, DC power cable, TCP/IP cable, SMPS control cable, external DC cable and battery cable from the main board.
3. Remove the Main Board from the inner case assembly.

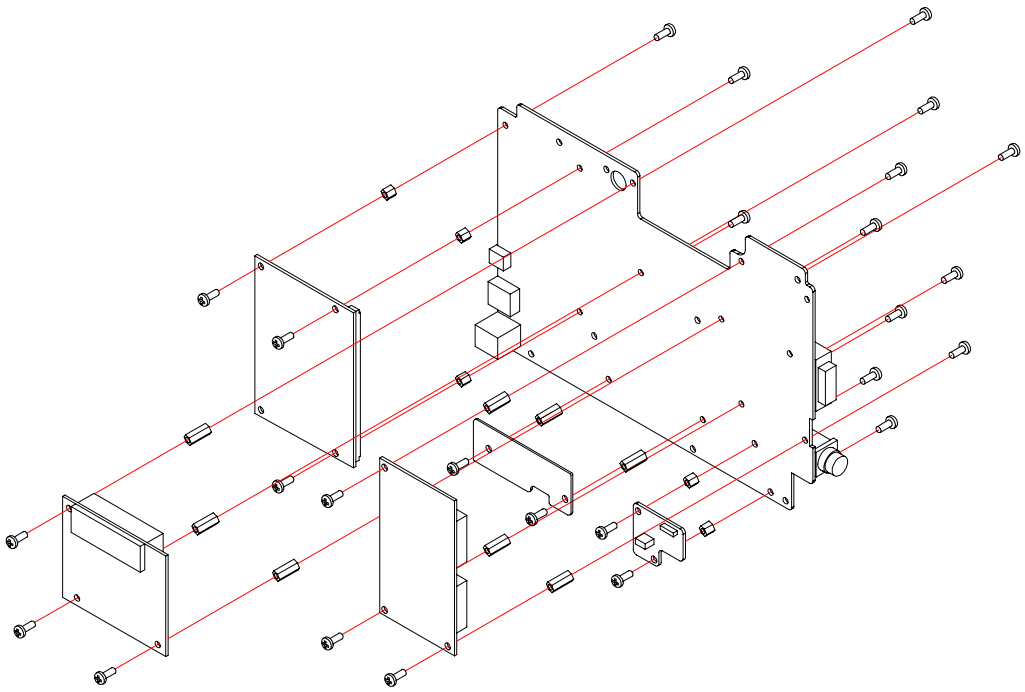

Figure 23. Rear Case Disassembly - ECG & Respiration Module, SpO_2 Module, CO_2 Module, CPU Module (For Nellcor SpO_2 Module)

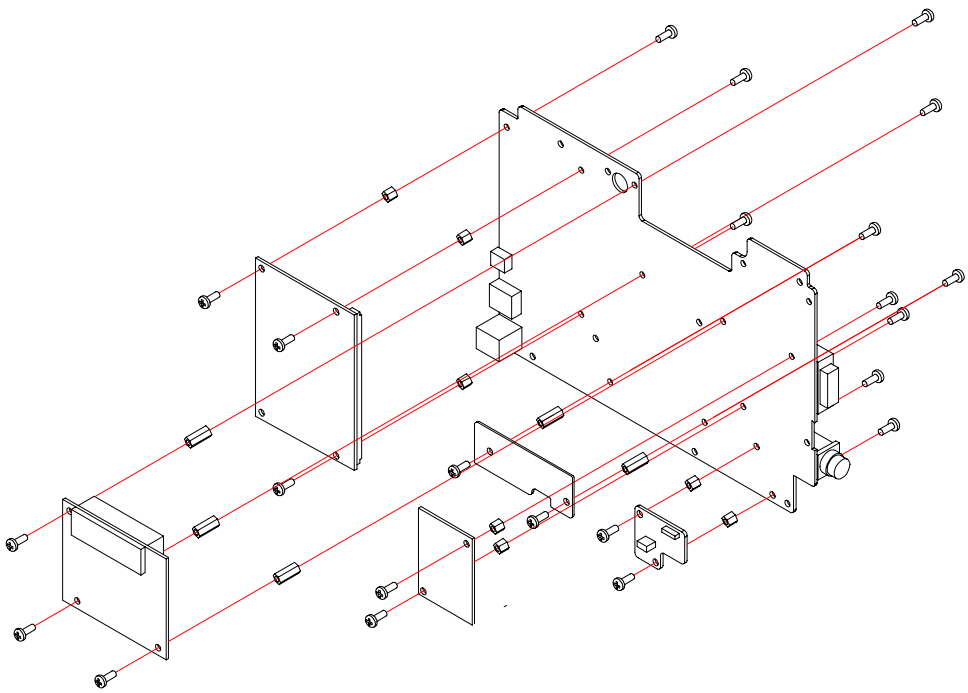

Figure 24. Rear Case Disassembly - ECG & Respiration Module, SpO_2 Module, CO_2 Module, CPU Module (For Mediana SpO_2 Module)

Table 24. Part Descriptions - ECG & Respiration Module, SpO_2 Module, CO_2 Module, CPU Module

Part Codes	Descriptions	Qty
P1094	ECG & Respiration module	1
P1098	CPU board	1
P1099	Temperature module	1
M0009 / P1102	Nellcor SpO_2 module / Mediana SpO_2 module	1/1
P1117	CO_2 module (Option)	1

C5-1. CPU board disassembly

1. Remove 6 round-head screws (3x4) from the CPU board and the Main Board to remove 3 supporters fastening the CPU board.
2. Remove the CPU board from the Main Board.

C5-2. ECG & Respiration module disassembly

1. Remove 6 round-head screws (3x6) from the ECG & respiration module and the Main Board to remove 3 supporters fastening the ECG & respiration module.
2. Separate the ECG & respiration module from the Main Board.

C5-3. Temperature module disassembly

1. Remove 4 round-head screws (3x4) from the temperature module and the Main Board to remove 2 supporters fastening the temperature module.
2. Remove the temperature module from the Main Board.

C5-4. SpO_2 module disassembly

For Nellcor SpO_2 module

1. Remove 6 round-head screws (3x6) from the SpO_2 module and the Main Board to remove 3 supporters fastening the SpO_2 module.
2. Remove the SpO_2 module from the Main Board.

For Mediana SpO_2 module

1. Remove 4 round-head screws (3x4) from the SpO_2 module and the Main Board to remove 2 supporters fastening the SpO_2 module.
2. Remove the SpO_2 module from the Main Board.

C5-5. CO_2 module (Option) disassembly

1. Remove 4 round-head screws (3x6) from the CO_2 module and the Main Board to remove 2 supporters fastening the CO_2 module.
2. Remove the CO_2 module from the Main Board.

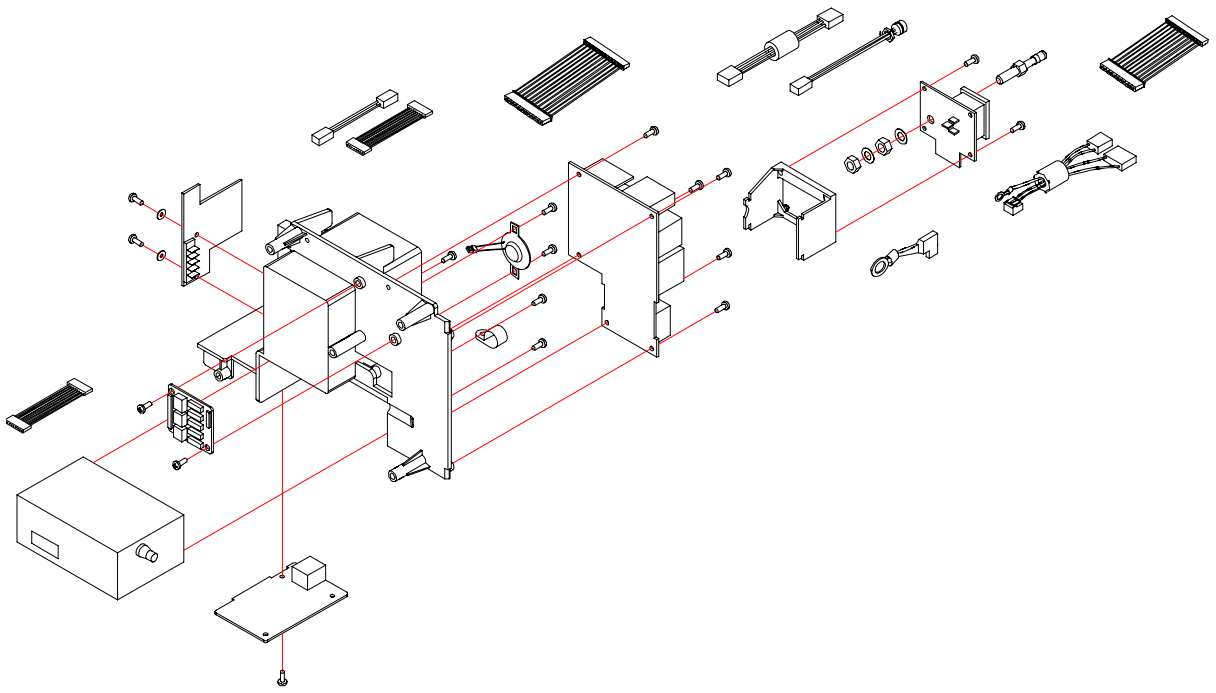

Figure 25. Rear Case Disassembly - SMPS, AC Inlet, Speaker, ECG Arrester Board, Printer Interface Board, TCP/IP Board, NIBP Module

Table 25. Part Descriptions - SMPS, AC Inlet, Speaker, ECG Arrester Board, Printer Interface Board, TCP/IP Board, NIBP Module

Part Codes	Descriptions	Qty
M2024	SMPS	1
T0210	Inner case	1
W0192	AC GND (ring to flug)	1
T0265	AC inlet holder	1
W0190	AC inlet cable (power & GND)	1
P1103	AC inlet assembly board	1
W0183	SMPS control cable (8pin)	1
W0185	TCP/IP cable (11pin)	1
W0186	Printer interface cable (12pin)	1
T4128	GND pin	1
E9021	Speaker	1
W0193	Battery cable (3pin)	1
P1097	Printer interface assembly board	1
W0189	DC power cable (2pin)	1
W0191	External DC cable (2pin)	1
W0188	ECG arrester cable (6pin)	1
P1096	ECG arrester assembly board	1
P1104	TCP/IP connector board	1
P1101	TCP/IP assembly board (option)	1
M0015	NIBP Module	1

C6. SMPS disassembly

1. Remove the SMPS control cable, DC power cable, external DC cable and battery cable from the SMPS.
2. Remove 5 round-head screws (3x6) from the SMPS.
3. Separate the SMPS from the inner case.

C6-1. AC inlet board disassembly

1. Remove the AC holder from the SMPS.
2. Remove 2 round-head screws (3x6) from the AC inlet board.
3. Separate the AC inlet cable from the AC inlet board.
4. Remove the AC inlet board from the AC holder.
5. Remove the GND pin form the AC inlet board.

C7. Speaker disassembly

1. Separate the speaker wire from the printer interface board.
2. Remove the 2 round-head screws (3x6) from the speaker.
3. Remove the speaker from the inner case.

C8. ECG arrester board disassembly

1. Remove the ECG arrester cable from the ECG arrester board.
2. Remove 2 round-head screws (3x6) from the ECG arrester board.
3. Remove the ECG arrester from the inner case.

C9. Printer interface board disassembly

1. Separate the printer interface cable from the printer interface board.
2. Remove 2 flat-head screws (2x4) from the printer interface board.
3. Remove the printer interface board from the inner case.

C10. TCP/IP connector board or TCP/IP assembly board (option) disassembly

1. Separate the TCP/IP cable from the TCP/IP connector board or TCP/IP assembly board (option).
2. Remove 1 round-head screw (3x6) from the TCP/IP connector board or TCP/IP assembly board (option).
3. Remove the TCP/IP connector board or TCP/IP assembly board (option) from the inner case.

C11. NIBP Module disassembly

1. Remove 2 round-head screws (3x6) from the inner case.
2. Separate the NIBP module from the inner case.

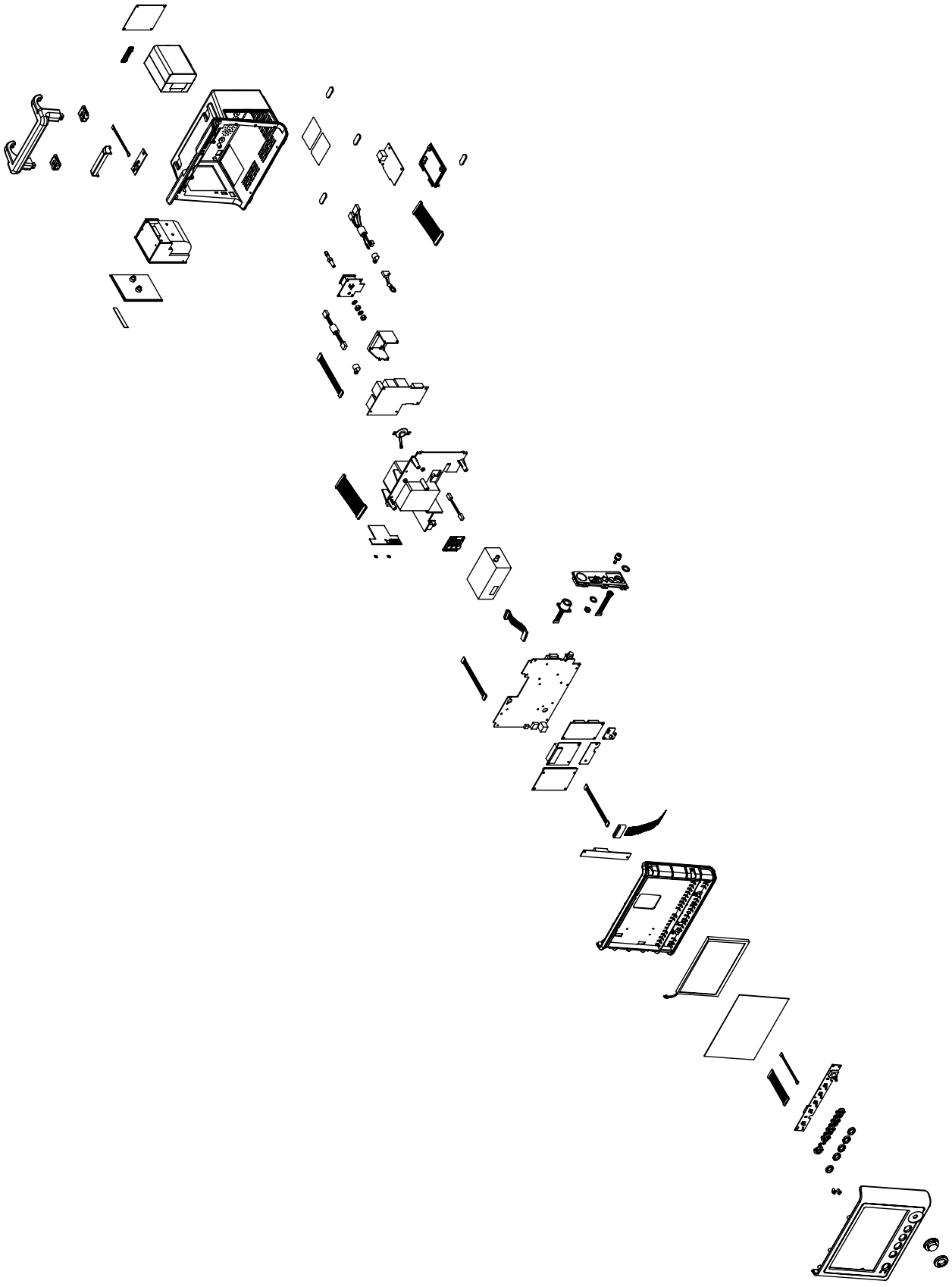

Figure 26. M30 Exploded View

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SPARE PARTS

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

General

Spare parts, along with part numbers, are shown in Table 26. “Item No.” corresponds to the circled callout numbers in Figure 27.

Obtaining Replacement Parts

Mediana provides technical assistance information and replacement parts. To obtain replacement parts, contact Mediana Technical Service Department. Refer to parts by the part names and part numbers.

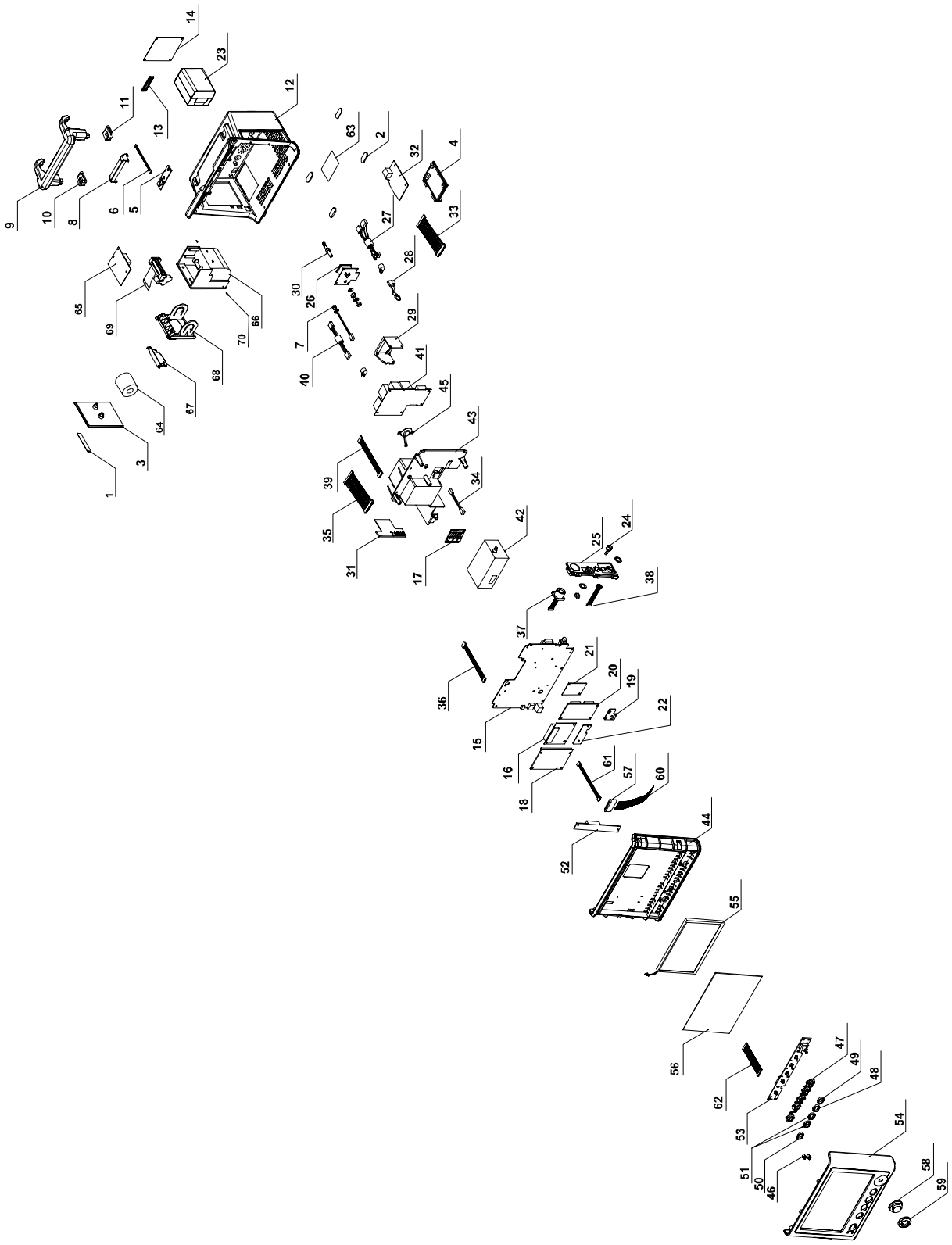

Figure 27. M30 Exploded View - Spare Parts

Table 26. Spare Part List

Item	Part Code	Description
1	B0076	Printer label
2	T1006	Rubber foot
3	T0200	Thermal printer cover
4	T0217	Rear case cover
5	P1100	Alarm LED assembly board
6	W0181	Alarm LED cable 4pin
7	W0191	External DC cable 2pin
8	T0203	Alarm window
9	T0205	Handle
10	T0206	Handle holder (left)
11	T0222	Handle holder (right)
12	T0211	Rear case
13	T0221	Vent cover
14	T4155	Battery cover
15	P1105	Main Board (for Nellcor SpO_2 module)
	P1093	Main Board (for Mediana SpO_2 module)
16	P1094	ECG & Respiration module
17	P1096	ECG arrestor assembly board
18	P1098	CPU board
19	P1099	Temperature module
20	M0009	SpO_2 Module (Nellcor)
21	P1102	SpO_2 Module (Mediana)
22	P1117	CO_2 Module (Option)
23	M6028	Li-ion battery pack (2200mAh)
24	E4114	Luer Fitting/NBIP connector
25	T0212	Side connector cover
26	P1103	AC inlet assembly board
27	W0190	AC Inlet cable (power & GND)
28	W0192	AC GND cable (ring to flug)
29	T0265	AC inlet holder
30	T4128	GND pin
31	P1097	Printer interface assembly board
32	W0186	Printer Interface cable 12pin
33	P1104	TCP/IP connector board
	P1101	TCP/IP assembly board (option)
34	W0189	DC power cable 2pin
35	W0185	TCP/IP cable 11pin
36	W0183	SMPS control cable 8pin
37	E4231	ECG connector 6pin
38	W0158	EtCO2 connector 8pin
39	W0188	ECG arrester cable 6pin
40	W0193	Battery cable 3pin
41	M2024	SMPS

Item	Part Code	Description
42	M0015	NIBP module
43	T0210	Inner case
44	E9021	Speaker
45	T0209	Middle case
46	T0201	Power / battery window
47	T0214	Button
48	T0224	Button ring (green)
49	T0223	Button ring (orange)
50	T0213	Button ring (blue)
51	T0225	Button ring (white)
52	M8002	LCD inverter
53	P1095	Key assembly board
54	T0207	Front case
55	M4048	TFT-LCD
56	T0333	LCD window
57	E5012	LCD ferrite core
58	T0245	Knob body
59	T0246	Knob grip
60	W0194	LCD data cable 40pin
61	W0182	Inverter cable 5pin
62	W0187	Key cable 15pin
63	B0084	Product label
64	A0132	Thermal printer paper (50mm)
65	M4031	Thermal printer board
66	T0197	Thermal printer body case
67	T0198	Thermal printer opener case
68	T0199	Thermal printer door case
69	M4020	Thermal printer mecha
70	T4109	Thermal printer door pin (2mm)
-	A0063	DC input cable
-	A7124	Operator’s manual
-	A7135	Service manual

Note: Please refer to the operation manual for accessories.

PACKING FOR SHIPMENT

General Instructions

To ship the monitor for any reason, follow the instructions in this section.

Pack the monitor carefully. Failure to follow the instructions in this section may result in loss or damage not covered by the Mediana Limited Warranty. See Limited Warranty information in the M30 Instruction Manual. If the original shipping carton is not available, use another suitable carton.

Returning the M30 Monitor

Pack the monitor 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.

Repacking in Original Carton

If available, use the original carton and packing materials. Pack the monitor as follows:

1. Place the monitor and, if necessary, accessory items in original packaging.
2. Place in shipping carton and seal carton with packaging tape.

Repacking in a Different Carton

If the original carton is not available, use the following procedure to pack the monitor:

1. Place the monitor in an anti-static bag.
2. Locate a corrugated cardboard shipping carton with at least 20 kg/m^2 (4.1lbs /ft^2) bursting strength.
3. Fill the bottom of the carton with at least 7cm (2.75in) of packing material.
4. Place the bagged unit on the layer of packing material and fill the box completely with packing material.
5. Seal the carton with packing tape.

Note: Please contact Mediana Technical Service Department for repair services.

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SPECIFICATION

Display

Screen Size	8.5” 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)

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	ECG:	Type CF with defibrillator protection
	NIBP:	Type CF with defibrillator protection
	SpO_2:	Type CF with defibrillator protection
	Temperature	Type CF with defibrillator protection
	$EtCO_2$	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 (.33 lb)
Resolution	8 dot/mm
Number of channels	1 to 3 channels
Paper Type	Thermal
Paper Width	50 mm
Pint Speeds	25 mm/s, 50 mm/s

Electrical

Instrument	
Power Requirements	AC Power 100 to 240VAC, 50/60 Hz, 110VA
Fuses	qty 2, T3.15 A, 250 volts / T5.0 A, 250 volts
Battery	
Type	Li-ion battery
Operating time	1 hour (2200mAh), 3 hours (4400mAh), 5 hours (6600mAh) *At the following condition:* *no printing* *no external communication* *no audible alarm sound* *one NIBP measurement per 15 minutes at 25°C*
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
Life Cycle	6 months, new battery fully-charged After 2 months storage the M30 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 1060hPa
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)	150 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)	150 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)	150 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 (off, level 1~7)
Pitch (± 20Hz)	650 Hz (ECG) (162 + 5*SpO_2) Hz (SpO_2 80% to 100%) (562 * ($0.992^{(80 - SpO_2)}$) Hz (SpO_2 below 80%)
Pulse width (± 20msec)	100 msec
Number of pulses	N/A
Repetitions	No repeat
Key Beep	
Volume level	Adjustable (off, level 1~7)
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)	813 Hz
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 ±1% whichever is greater
Average Response Time	5 seconds (from 80 to120 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 ±2mV to ±700mV with pulse widths of 0.1 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 (×1)
Pacing Pulse Detection	On, Off
ST Level Analysis	On, Off
Arrhythmia 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
ECG (Arrhythmia Supplemental Information as required by AAMI EC13)	
Heart rate calculation	Heart rate is computed by averaging the 20 most recent RR intervals if there is more than 21 QRS for 10 sec. If there is less than 21 QRS, heart rate is computed by averaging RR intervals occurring for 10 sec.

Heart rate meter accuracy and response to irregular rhythm	Provides correct heart rates, as follows: Ventricular bigeminy: 76 to 80 bpm Slow alternating ventricular bigeminy: 55 to 60 bpm Rapid alternating ventricular bigeminy: 116 to 117 bpm Bidirectional systoles: 86 to 91 bpm
Respiration, leads-off sensing, and active noise suppression	Respiration frequency: 61 to 62 kHz Lead-off sensing current: amp: less than 0.02uA common: less than 0.078uA
Time to alarm for cardiac standstill	Average: 4.0 sec
Time to alarm for low heart rate	Average: 5.5 sec
Time to alarm for high heart rate	Average: 5.6 sec
Time to alarm for tachycardia	Ventricular tachycardia waveform Amplitude 1mV, Heart rate 206bpm: 16.48 sec One-half waveform (0.5mV): 11.64 sec Twice waveform (2mV): 5.81 sec Amplitude 2mV, Heart rate 195bpm: 8.74 sec One-half waveform (1mV): 12.03 sec Twice waveform (2mV): 1.75 sec

Respiration

IM Respiration	
Technique	Impedance Pneumography
Range	0, 3 to 120 breaths/min
Accuracy	±3 breaths/min
Leads	RA to LA
Lead Off Condition	Detected and displayed
Defibrillator Protection	Protected
AW Respiration	
Technique	Nondispresive Infrared Spectroscopy
Range	0 to 50 breaths/min
Accuracy	±1 breaths/min
Display Sweep Speeds	6.25 mm/s, 12.5 mm/s, 25.0 mm/s
Wave Size	Auto, Level 1~8

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	Adult/Pediatric: 300 mmHg (N.C), 330 mmHg (S.F.C) Neonatal: 150 mmHg (N.C), 165 mmHg (S.F.C)
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)*

SpO_2

Pulse Rate		
Range	*Nellcor module:*	20 to 300 BPM
	Mediana module:	30 to 300 BPM
Accuracy	*Nellcor module:*	±3 BPM
	Mediana module:	±2 % or 2 BPM, whichever is greater
SpO_2		
Range	*Nellcor module:*	1 to 100 %
	Mediana module:	0 to 99 %
Low Perfusion (Nellcor module only)	0.03 to 20 %	
Accuracy	*Nellcor module:* Without Interference-Adult/Pediatric Without Interference-Neonatal Low Perfusion *Mediana module:* Without Interference-Adult/Pediatric/Neonatal	70 to 100 % ±2 digits 1 to 69 % unspecified 70 to 100 % ±3 digits 1 to 69 % unspecified 70 to 100 % ±2 digits 1 to 69 % unspecified 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	

Note: 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 660nm and 890nm with the energy not exceeding 15mW (for Nellcor module) and 660nm with the energy not exceeding 2mW and 905nm with the energy not exceeding 2~2.4mW (for Mediana module).

Capnography

Parameter Displayed	$EtCO_2$, $InCO_2$
Range	0 mmHg ~ 150 mmHg (0kPa ~ 20kPa, 0% ~ 20%)
Accuracy	0-40mmHg ±2mmHg of reading 41-70mmHg ±5% of reading 71-100mmHg ±8% of reading 101-150mmHg ±10% of reading
Display Accuracy	±2mmHg
Response Time	Mainstream: Less than 60ms Sidestream: Less than 3sec.
Baromatric Pressure Correction	-152.4 to 4572 meters (-500 to 15,000 feet), 775 to 429 mmHg, Automatic
Gas Compensation	User selective at O_2 >60% and N_2O >50%
Stability and drift	Short term drift: Less than 0.8 mmHg over 4 hours. Long term drift: Accuracy specification will be maintained over a 120 hour period.
Accuracy Change for interfering Gases and Vapors Anesthetic and interfering agents	0-40 mmHg ±1 mmHg additional error 41-70 mmHg ±2.5% additional error 71-100 mmHg ±4% additional error 101-150 mmHg ±5% additional error Additional worst case error when compensation for O_2 and N_2O is correctly selected for actual fractional gas constituents present.
Warm Up Time	2 minutes maximum
Sweep Speeds	6.25mm/sec, 12.5 mm/sec and 25.0 mm/sec
Sound Noise Level	Less than 41dB when ambient sound pressure level is 22dB

Temperature

	Thermistor Temp
Probe Type	Thermistor probe YSI 400 series and 700 series
Measurement Method	Thermistor
Range	0 to 50°C (32 to 122°F)
Display Accuracy	±0.1°C
Probe Accuracy	±0.1°C (YSI 400 series) ±0.2°C (YSI 700 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 ● a graph for HR/PR, Resp, SpO_2 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
Capnography	ISO21647:2004 Particular requirements for the basic safety and essential performance of respiratory gas monitors
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)

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SYSTEM PROCESSING

System Overview

The M30 monitor is a multi-function monitor for use on adult, pediatric and neonatal patients; ECG, heart rate, non invasive blood pressures, arterial oxygen saturation, pulse rate, respiration rate, capnography, and temperature.
In addition to monitoring and displaying the status of these physiological parameters, the instrument performs various microprocessor-programmed analytical functions;

- Creating both visual and audible alarm signals when settable limits are violated;
- Creating and displaying warning/error messages when conditions are detected that would degrade or prevent valid measurements;
- Creating and displaying graphical or tabular trend data;
- Providing input to an optional printer for printout of current data or stored trend data.

The monitor is essentially a battery-powered instrument. An internal charging unit is designed to accept only an AC line voltage.

System Block Diagram

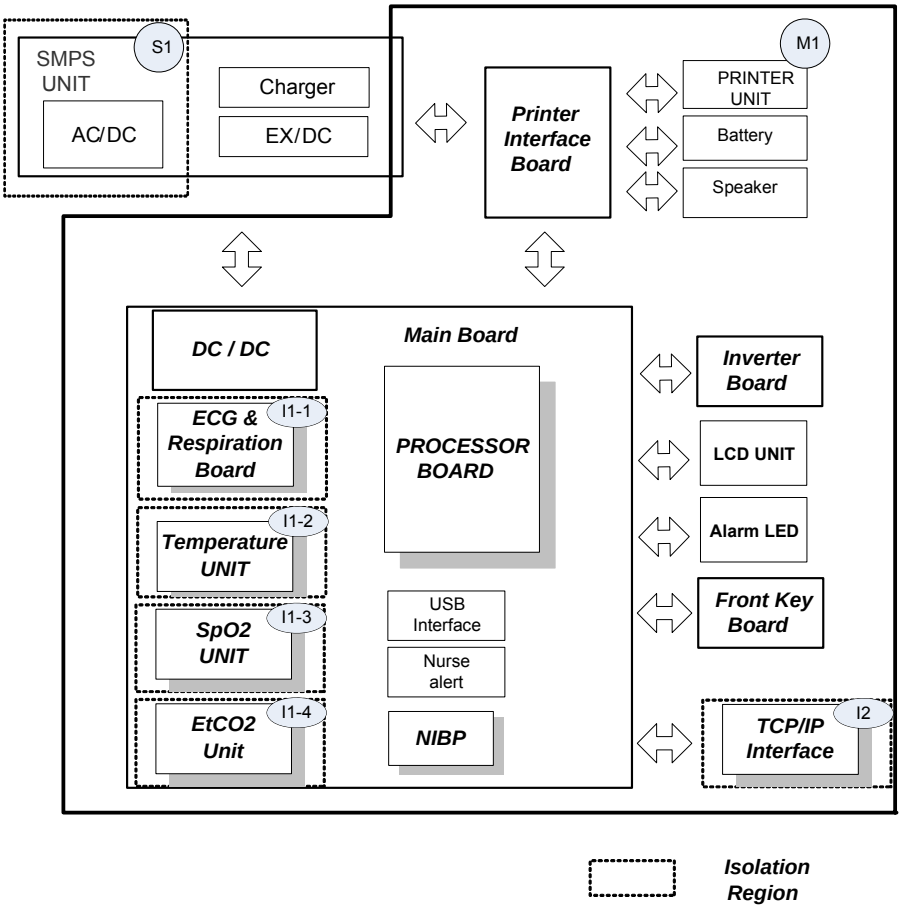


Figure 28. System Block Diagram

- **Power unit:** consists of SMPS and battery charger

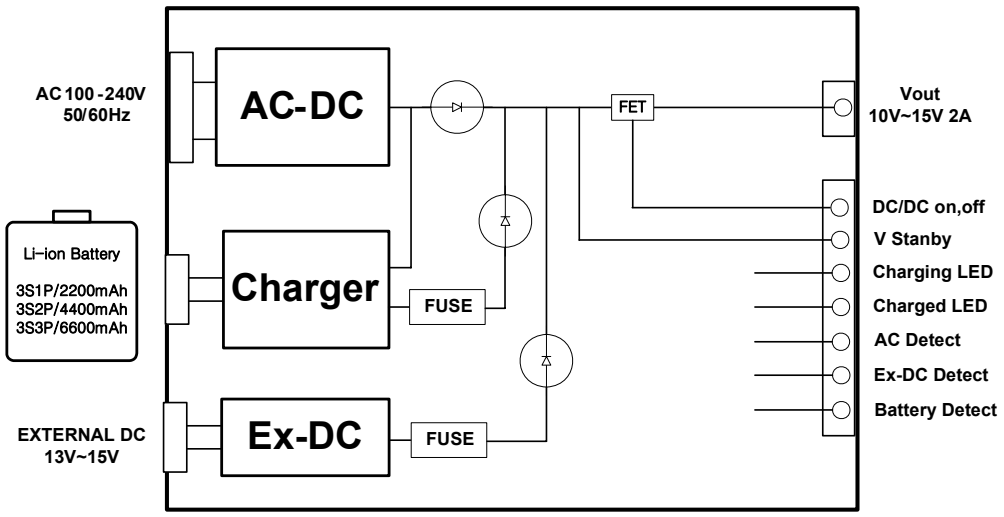


Figure 29. Power Unit Block Diagram

- **Processor unit:** consists of Samsung® S3C2440A CPU, SDRAM, Boot ROM and Flash.

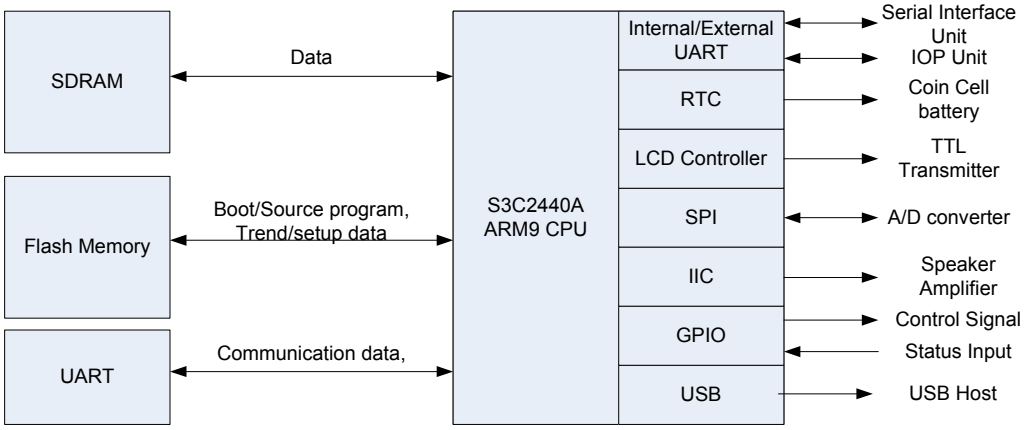


Figure 30. Process Unit Block Diagram

- **User-control unit:** consists of jog dial, 5 functional buttons, optical encoder, power on indicator LED, Battery charging indicator LED and battery charging status indicator LED.

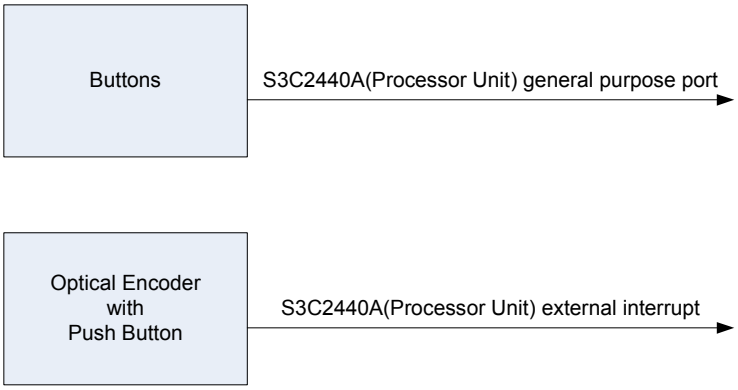


Figure 31. User-Control Unit Block Diagram

- **Sound unit:** consists of S3C2440A, ARM CPU, 2-channel amplifiers and speaker.

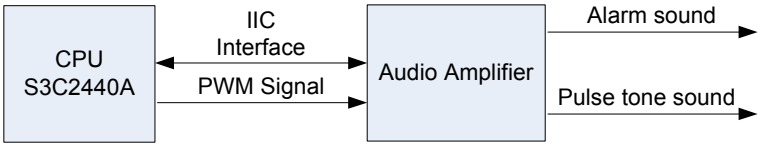


Figure 32. Sound Unit Block Diagram

- **Communication unit :** UART

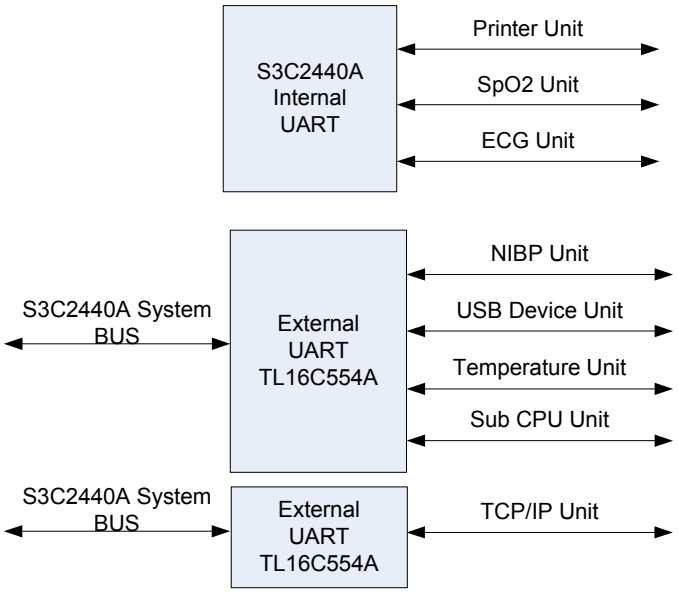


Figure 33. Communication Unit Block Diagram

- **GUI (graphic user interface) unit:** consists of TFT LCD, inverter for backlight and internal LCD controller.

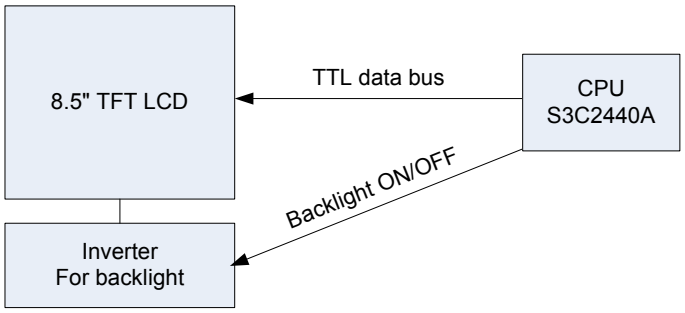


Figure 34. GUI Unit Block Diagram

- **Thermal Printer unit:** prints data records.

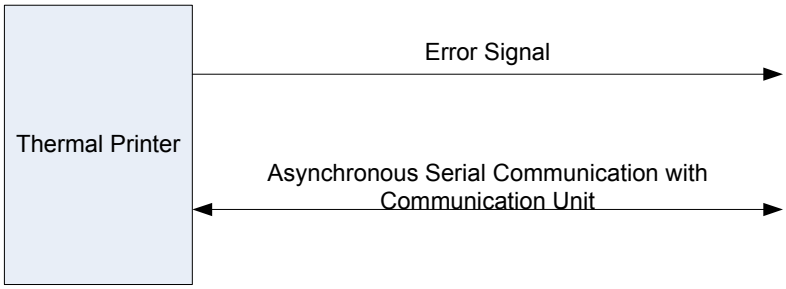


Figure 35. Thermal Printer Unit Block Diagram

- **NIBP unit:** measures non-invasive blood pressure data.

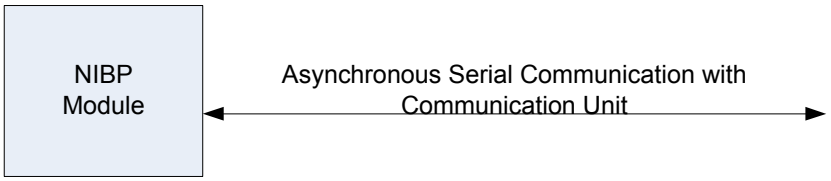


Figure 36. NIBP Unit Block Diagram

- **ECG unit:** measures electrocardiographic waveform data.

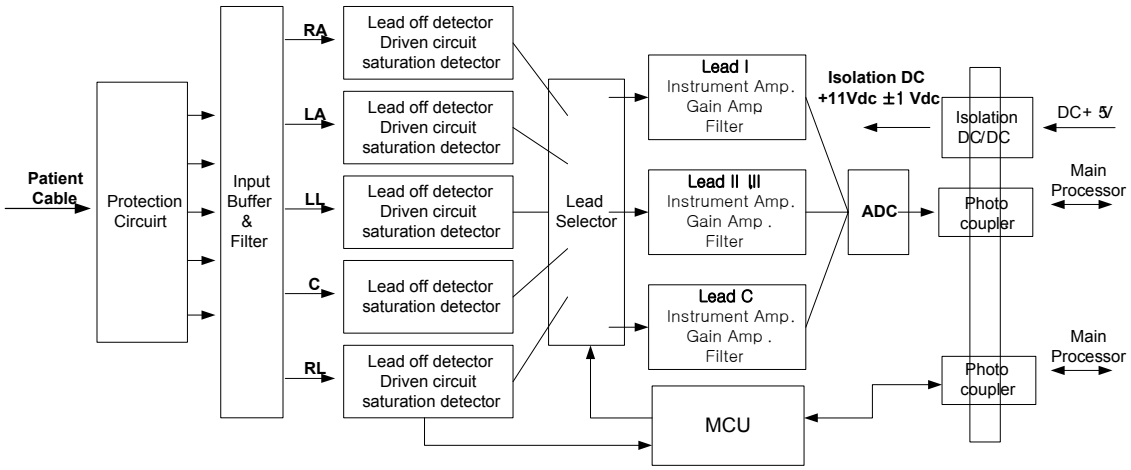


Figure 37. ECG Unit Block Diagram

- **Respiration unit:** measures respiration rate data.

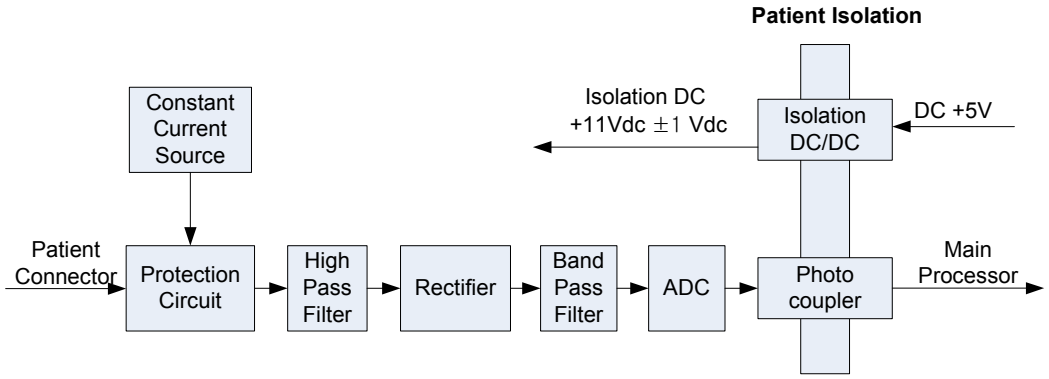


Figure 38. Respiration Unit Block Diagram

- **SpO_2 unit:** measures oxygen saturation data.

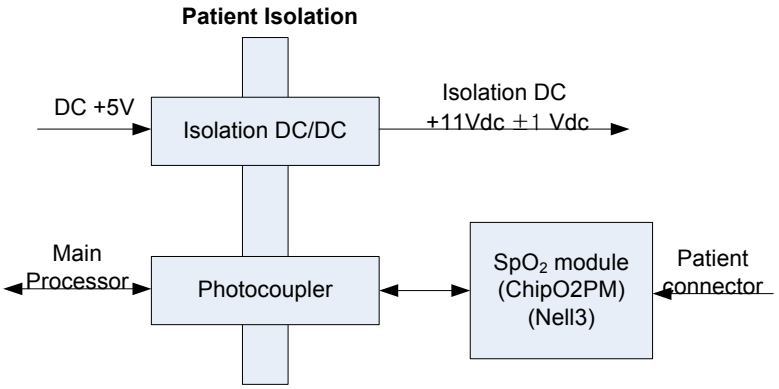


Figure 39. SpO_2 Unit Block Diagram

- **Temperature unit:** measures temperature data.

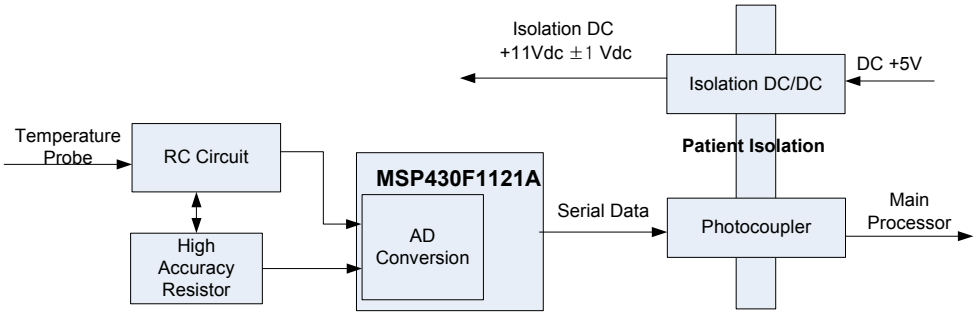


Figure 40. Temperature Unit Block Diagram

- **CO_2 unit:** measures CO_2 data.

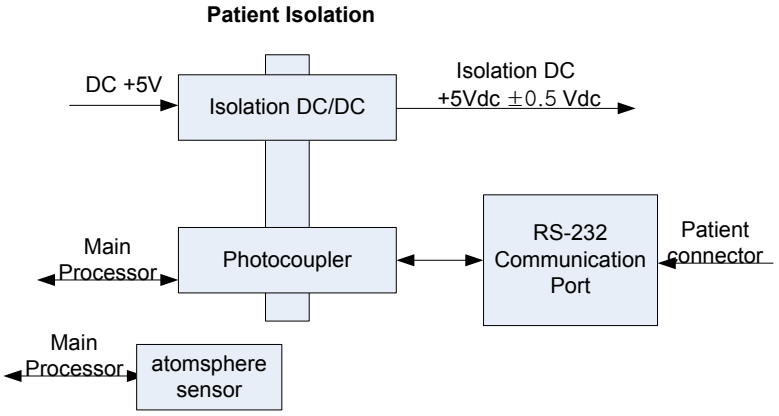


Figure 41. CO_2 Unit Block Diagram

ECG Processing

The measurement of the skin surfaces electrocardiogram is based on the electrical signals on the skin surface, produced as the heart muscle contracts and relaxes. The signals are detected by electrodes placed on the patient's body. The information on heart activity carried by these signals varies with the placing of the electrodes.

The technique used in ECG senses the varying potential difference between two points at the skin surface which respond to the chemical actions of the muscular activity of the heart.

Three electrodes are attached to the patient's right arm (RA), left arm (LA) and left leg (LL). The varying potentials at these locations are cable-connected to the ECG circuit inputs where they are conditioned, and the difference of potential between two selected leads is digitized before transmitting through opto-isolators to the processor. The processor-installed algorithms operate on the signals to develop drivers for the graphic display and to compute the heart rate in beats per minute (bpm).

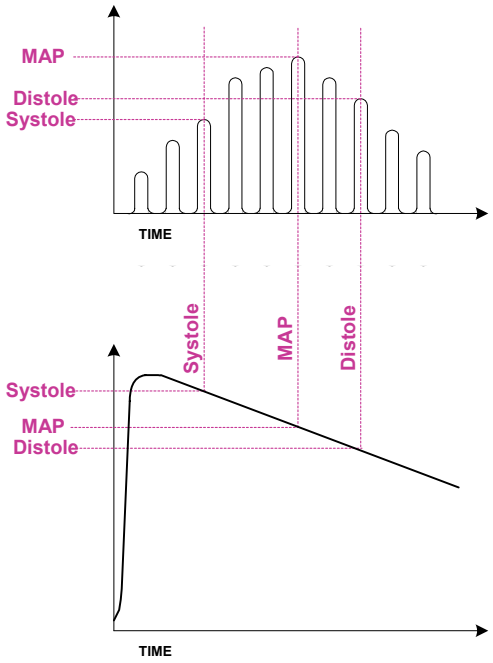
In addition to the acquisition of the QRS waveform complex, the ECG input and subsequent signal processing computing circuitry perform a number of other functions:

- They detect a lead-off condition if one of the electrode connections is disrupted.
- They detect the presence of pacemaker signals within the QRS waveform complex of the ECG.

NIBP Processing

Overview

The oscillometric technique does not use Korotkoff sounds to determine blood pressure. The oscillometric technique monitors the changes in cuff pressure caused by the flow of blood through the artery. The monitor inflates the cuff to a pressure that occludes the artery. Even when the artery is occluded, the pumping of the heart against the artery can cause small pressure pulses in the cuff baseline pressure. The monitor lowers cuff pressure at a controlled rate. As the cuff pressure goes down, blood starts to flow through the artery. The increasing blood flow causes the amplitude of the pressure pulses in the cuff to increase. These pressure pulses continue to increase in amplitude with decreasing cuff pressure until they reach a maximum amplitude at which point they begin to decrease with decreasing cuff pressure. The cuff pressure at which the pulse amplitude is the greatest is known as Mean Arterial Pressure (MAP). The manner in which the pulse amplitudes vary is often referred to as the pulse envelope. The envelope is an imaginary line that connects the peak of each pressure pulse and forms an outline. The shape of the envelope is observed by the monitor using a variety of techniques to determine the diastolic and systolic blood pressure.



- **Oscillometric Response (Pressure Pulses)**
- **Cuff Pressure**

Overall Accuracy Discussion

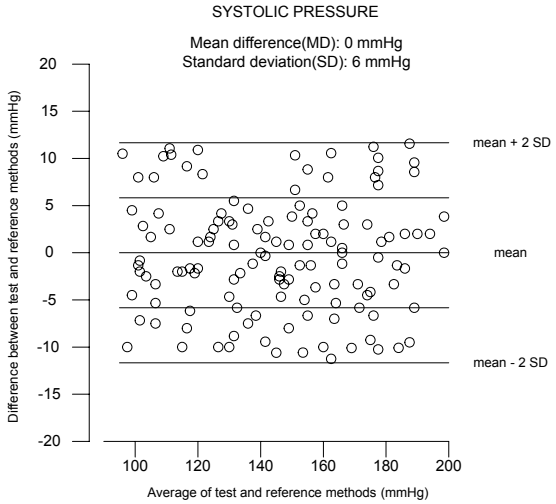
Overall system accuracy shall be determined by considering various influences of the pressure sensor accuracy, motion artifacts, other artifacts created by the pressure valve, technical errors of electrical components, and the origin error of oscillometric method. The origin error of oscillometric comes from the basic theory that the MAP is determined by the pulse. Therefore, there might be an error in determining the time between two pulses. In other words, the greatest amplitude point of detected pulses can not represent the MAP point exactly.

On the clinical trial perspective, overall system accuracy is not easy to determine. The clinical trial test protocols have been tried and have been described in many treatises and international standards. So, there are many methods to determine the overall system accuracy of Automated Sphygmomanometers using the oscillometric method. But, there are no absolute test protocols to determine the overall system accuracy of Automated Sphygmomanometers using the oscillometric method. Normally, the Gold standards of Blood pressure for reference are the intra-arterial pressure and the auscultatory method.

The popular standard for overall system accuracy is AAMI SP-10:2002+A1:2003 (Electronic or automated sphygmomanometers).

The main test conditions are as follows:

A. Comparing Intra-arterial or auscultatory data by clinical experts with the automated sphygmomanometer.
B. For data collection and data analysis, Bland-Altman Plot is used.
C. On the systolic, diastolic, and MAP, the Deltas of all measurements shall be met under +/- 5mmHg of mean difference (MD), and +/- 8mmHg of standard deviation (SD).
   (Delta = Intra-arterial or Auscultatory – Automated sphygmomanometer)



(EXAMPLE) Agreement between test and reference methods for systolic pressure. Hypothetical data

SpO_2 Processing

Pulse oximetry works by applying a sensor to a pulsating arteriolar vascular bed. The sensor contains a dual light source and photodetector. Bone, tissue, pigmentation, and venous vessels normally absorb a constant amount of light over time. The arteriolar bed normally pulsates and absorbs variable amounts of light during systole and diastole, as blood volume increases and decreases. The ratio of light absorbed at systole and diastole is translated into an oxygen saturation measurement (SpO_2). Because a measurement of SpO_2 is dependent upon light from the sensor, excessive ambient light can interfere with this measurement.

Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). The monitor determines SpO_2 by passing red and infrared light into an arteriolar bed and measuring changes in light absorption during the pulsatile cycle. Red and infrared low-voltage light-emitting diodes (LED) in the oximetry SpO_2 sensor serve as light sources; a photo diode serves as the photo detector. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by blood is related to hemoglobin oxygen saturation. To identify the oxygen saturation of arterial hemoglobin, the monitor uses the pulsatile nature of arterial flow. During systole, a new pulse of arterial blood enters the vascular bed, and blood volume and light absorption increase. During diastole, blood volume and light absorption reach their lowest point. The monitor bases its SpO_2 measurements on the difference between maximum and minimum absorption (measurements at systole and diastole). By doing so, it focuses on light absorption by pulsatile arterial blood, eliminating the effects of nonpulsatile absorbers such as tissue, bone, and venous blood.

Automatic Calibration (Nellcor module)

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 SpO_2 sensor's red LED to accurately measure SpO_2. 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 SpO_2.

Additionally, to compensate for differences in tissue thickness, the light intensity of the sensor's LEDs is adjusted automatically.

No Calibration Required (Mediana module)
Pulse oximeter requires neither production, nor user calibration. The relationship between light absorption by hemoglobin and reported SpO_2 is stored in the device memory during manufacturing of the device. This relationship is established for given LED wavelengths and given sensor construction, by comparison with blood gas measurements, using statistically significant number of samples.

Measured versus Calculated Saturation
The measured SpO_2 value from an oximeter may differ from the saturation value that is calculated from a blood gas partial pressure of oxygen (PO_2). This usually occurs because the calculated saturation was not appropriately corrected for the effects of variables that shift the relationship between PO_2 and saturation: pH, temperature, partial pressure of carbon dioxide (PCO_2), 2, 3-DPG, and fetal hemoglobin.

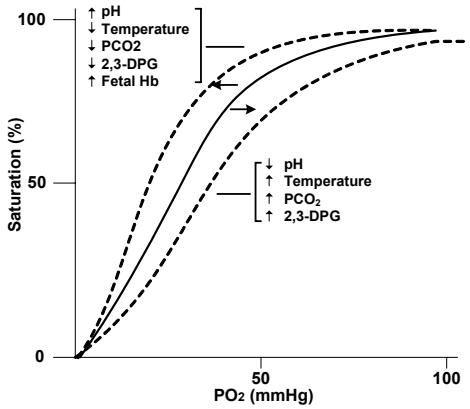


Figure 42. Oxyhemoglobin Dissociation Curve

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:

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

SpO_2 Accuracy (Nellcor module)
The saturation (SpO_2) accuracy specification and/or pulse rate (PR) performance were analyzed by comparative oximetry performance (COPS) tests between M30 SpO_2 module and MP506 module with the same version of the oximetry algorithm from Nellcor®. This was to demonstrate that the performance of M30 SpO_2 module was equivalent to that of MP506, which had been validated during both standard motion, combined motion and cold-induced peripheral vasoconstriction (low perfusion) conditions by direct comparison to measurements of arterial oxygen saturation (SaO_2) obtained from arterial blood samples analyzed with Instrumentation Laboratory (IL) CO-Oximeters under Nellcor's clinical protocol, Invasive Controlled Hypoxia Studies.

SpO_2 Accuracy (Mediana module)
The saturation (SpO_2) accuracy specification was proven by comparisons with the arterial blood gas measurements. Statistically significant number of samples at SpO_2 levels ranging from 70% to 99% was collected on male and female volunteers, with different skin colors.
Pulse rate accuracy specification was proven by laboratory simulator tests, where oximeter was connected to the Oximetry simulator, set to the precise number of pulses per minute.

Respiration Processing

The respiration monitoring is designed to use the variation of thoracic impedance. The chest contains various materials, ranging from bone to air. Each of these materials has different electrical properties and is located in a different portion of the chest. The materials of the chest vary in electrical resistivity (the amount of electrical resistance between opposite faces of a cube of that material), which is an important determinant of electrical impedance in the body.

Two of the major components of the chest, blood and air, are at opposite ends of the scale. Furthermore, the volume of each of these materials varies with time over the cardiac and breathing cycles. The variation of the thoracic impedance is caused by the difference between air and blood in the thoracic impedance. Blood has relatively low resistivity, which varies over the cardiac cycle owing to changing blood volumes in the heart and in the vascular compartment. Air, on the other hand, has high electrical resistivity and hence impedance, and it undergoes wide volume changes in the lungs during normal breathing. i.e. the impedance of blood is 150 ohm/cm and the impedance of air is 5000 ohm/cm.

The patient's respiration is detected by using two of the three leads of the ECG electrodes (RA and LA, or RA and LL) and cable. The electrical impedance between a pair of electrodes is determined by dividing the voltage difference between the two electrodes by the current that passes between them. When the electrodes are placed on the actual structure, respective structures change.

A low-level excitation signal is applied to these leads, and the variation of the thoracic impedance caused by breathing is sensed and processed for display and measurement. This variation is processed to the voltage value for the measurement.

In order to transfer the thoracic impedance by a transformer, it uses a minimum constant current of the sine wave carrier signal. The transferred thoracic impedance is changed to the voltage signal by using bridge circuit and differential amplifier. Then, ECG signal is removed by filter, and carrier frequency is removed by full wave rectifier and filter in order to extract only thoracic impedance in amplifying at the definite level of signal. This extracted thoracic impedance signal is used to measure the respiration by digital signal processing.

Temperature Processing

Measurement of patient temperature is accomplished by processing the signal from a probe containing a resistor whose resistance is temperature dependent. The class of such components is called thermistor.

Temperature measurement used by the M30 monitor is based on a thermistor whose resistance is inversely proportional to its temperature. By measuring the thermistor's resistance, its temperature can be calculated. The resistance of the thermistor is measured by passing a current through it and measuring the voltage developed across it. The M30 monitor is designed to accept the signals from a range of temperature probes from the YSI-400 and YSI-700 series. The probes may be used for skin or rectal temperature measurement. Probes are furnished with a standard 10-foot lead; extension leads are available. The signal from the probe is conditioned by the monitor input circuitry, processed, and used to drive the numeric display.

CO_2 Processing

The M30 CO_2 sensor measures CO_2 by using the infrared technique. The principle is based on the fact that CO_2 molecules absorb infrared (IR) light energy of specific wavelengths, with the amount of energy absorbed being directly related to the CO_2 concentration. When an IR beam is passed through a gas sample containing CO2, the electronic signal from the photodetector (which measures the remaining light energy) is measured. This signal is then compared to the energy of the IR source and adjusted to accurately reflect CO_2 concentration in the sample. The M30 CO_2 sensor's response to a known concentration of CO_2 is stored at the factory in the sensor's memory. A reference channel accounts for optical changes in the sensor, allowing the system to remain in calibration without user intervention.