SERVICE MANUAL

For YM1000 Vital Signs Monitor

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Notice

Warranty

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Revision History

The documentation part number and revision number indicate its current edition. The revision number changes when a new edition is printed in accordance with the revision history of the documentation. Minor corrections and updates which are incorporated at reprint do not cause the revision number to change. The document part number changes when extensive technical changes are incorporated.

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Warnings

Warnings are identified by the WARNING symbol shown above.

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

WARNING: Explosion hazard. Do not use YM1000 in the presence of flammable anesthetics or gases.

WARNING: Do not spray, pour, or spill any liquid on YM1000, its accessories, connectors, switches, or openings in the chassis.

WARNING: Do not immerse YM1000 or its accessories in liquid or clean with caustic or abrasive cleaners.

WARNING: Ensure that conductive portions of the cables do not come into contact with any other conductive parts.

WARNING: Electrical shock hazard. Disconnect the power cord from YM1000 before attempting to open or disassemble YM1000.

WARNING: The use of accessories, transducers and cables other than those specified may result in increased emission and/or decreased immunity of YM1000 monitor.

WARNING: Do not silence YM1000 audible alarm or decrease its volume if patient safety could be compromised.

WARNING: During safety tests, AC mains voltage will be present on the applied part terminals. Exercise caution to avoid electrical shock hazard.

WARNING: Do not place YM1000 into operation after repair or maintenance until Performance, Safety Tests and NIBP Calibration listed in this service manual have been performed. Failure of these tests could result in erroneous readings.

Cautions

Cautions are identified by the Caution symbol shown above.

Cautions alert the user to exercise care necessary for the safe and effective use of YM1000 monitor.

- **CAUTION:** U.S. Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
- **CAUTION**: Observe ESD (electrostatic discharge) precautions when working within the unit and/or when disassembling and reassembling YM1000 monitor and when handling any of the components of YM1000 monitor.
- **CAUTION**: When reassembling YM1000, over-tightening could strip out the screw holes in the cases, rendering it unusable.
- **CAUTION**: If any problem with YM1000 built in an optional printer, check a printer's door is closed well. Operating error may be caused if the cover is not closed correctly.
- **CAUTION**: If internal battery cable has been disconnected, pay particular attention to polarity of the cable before reattaching. If 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 measure inaccurate data to be displayed or stored.
- **CAUTION**: For continued protection against risk of fire, replace only with same type and rating of fuse.

Manual Overview

This manual contains information for servicing YM1000 monitor.
The monitor subsequently referred to as YM1000 throughout this manual. Only qualified service personnel should service this product. Before servicing YM1000, read the operator's 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 operator's manual.

This manual contains information about YM1000 monitor. YM1000 monitor includes the following configuration:

Config. Features		Config. Features	
N	Standard (NIBP + Pulse Rate)	NP	Standard + Printer
NS	Standard + SpO2	NSP	Standard + SpO2 + Printer
NT	Standard + Temperature	NTP	Standard + Temperature+ Printer
NST	Standard + SpO2 + Temperature	NSTP	Standard + SpO2 + Temperature + Printer

All information in this manual, including the illustrations, is based on the monitor configured with Temperature, SpO2 and Printer options. If your monitor lacks any of these options, some information in this manual does not apply.

Related Documents

To perform test 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 YM1000 operator's manual.
To understand the various blood pressure cuffs, SpO2 sensors and temperature probes that work with the monitor, refer to the individual directions for use that accompany these accessories.

Description of the YM1000 monitor

The purpose and function of Mediana YM1000 monitor is to monitor noninvasive blood pressure (systolic, diastolic, and mean arterial pressures), functional arterial oxygen saturation, pulse rate for adult, pediatric and neonate patients and temperature for adult and pediatric patients in all hospital areas and hospital-type facilities. It may be used during hospital transport and in mobile, land-based environments, such as ambulances, within the specification of the environmental characteristics. Monitor users should be skilled at the level of qualified health care professionals, such as a technician, doctor, nurse or medical specialist.

Note: Hospital use typically covers such areas as general care floors, operating rooms, special procedure areas, intensive and critical care areas, within the hospital plus hospital-type facilities. Hospital-type facilities include physician office based facilities, sleep labs, skilled nursing facilities, surgicenters, and sub-acutecenters.

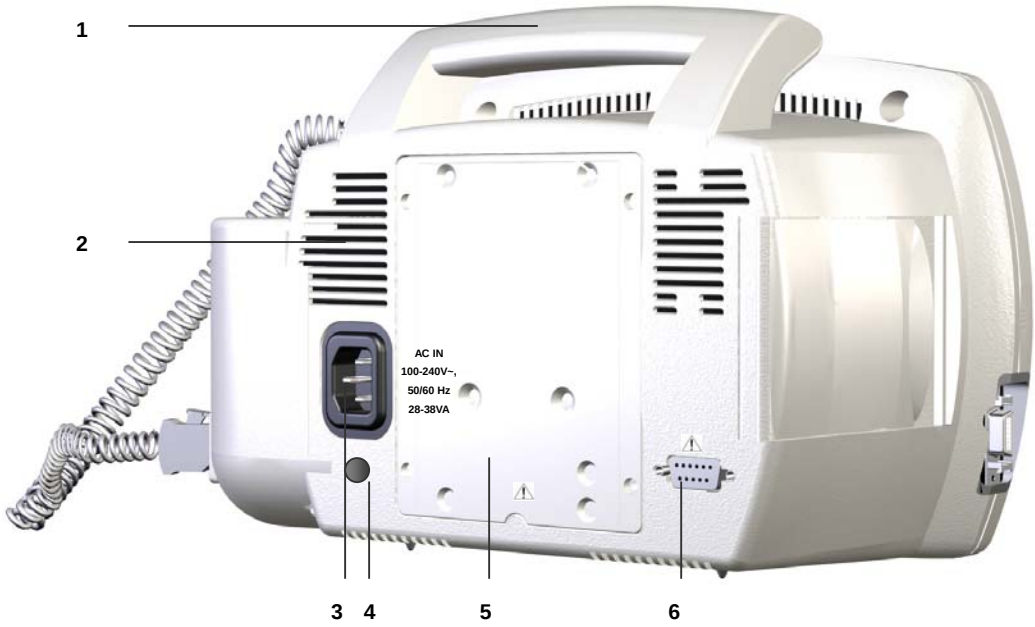
Note: Intra-hospital transport includes transport of a patient within the hospital or hospital-type facility.

The physical and operational characteristics of the monitor are described in the operator's manual and in the Specification section of this manual.

Figure 1 and 2 identify the displays, controls, indicators and symbols of the front and rear panels.

1. Blood Pressure Unit Indicators
2. Systolic Blood Pressure Display
3. Patient Type Indicators
4. Diastolic Blood Pressure Display
5. Pulse Rate Display
6. MAP (Mean Arterial Pressure) Display
7. Print Setting Indicators
8. Print Button
9. Alarm Button
10. Auto Indicator
11. Auto Cycle Display
12. Auto Button
13. Pulse Tone/Alarm Volume Setting Indicators
14. Review Button
15. %SpO2 Display
16. Mode Button
17. Pulse Amplitude Indicator
18. Alarm Silence Indicator
19. Up/Down Selection Button
20. Alarm Silence Button
21. BP start/stop button
22. Temperature Unit/Mode Indicators
23. Temperature Display
24. Power Button
25. Battery Indicator
26. Charging/AC in Indicator
27. Time Display
28. Review Indicator

Figure 1. YM1000 Front Panel

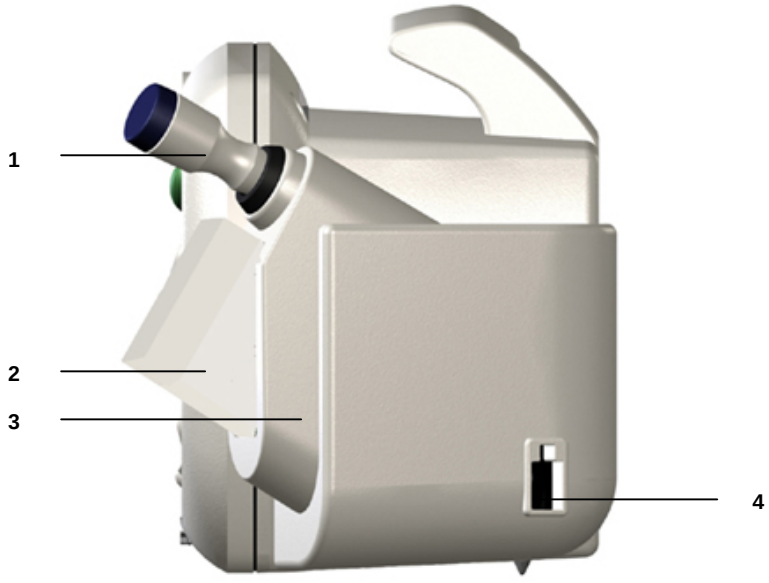


1. Handle
2. Air Ventilator
3. AC Power Connector
4. Equipotential (Ground)
5. Battery Cover (Replacement)
6. RS-232 Data Interface

Figure 2. YM1000 Rear Panel

1. Printer
2. SpO2 sensor/cable connector
3. NIBP hose connector

Figure 3. YM1000 Left Side Panel



1. Temperature probe
2. Probe cover
3. Probe holder
4. Temperature probe connector

Figure 4. YM1000 Right Side Panel

Specification

Physical
Electrical
Environmental
Measurement Parameters
Compliance

Physical

Instrument	
Dimensions	130×180×278 (mm)
Weight	2.7 (kg)

Electrical

AC Power	
Power	100Vac to 240Vac, 50 Hz/60 Hz, 28 to 38 VA
Battery	
Type	Lead acid
Voltage/Capacity	6 V/ 4 Ampere-Hours
Recharge	12 hours with YM1000
Shelf Life	2 years, new fully charged battery
Complies with	91/157/EEC

Environmental

Operation	
Temperature	10 °C (50 °F) to 40 °C (104 °F) Exemption: thermometry module – operating temperature 16 °C (60 °F) to 40 °C (104 °F)
Humidity	15 % RH to 95% RH, non-condensing
Altitude	170 m (557 ft) below sea level 4,877 m (16,000 ft) above sea level
Transport and Storage	
Temperature	–20 °C (-4 °F) to 50 °C (122 °F)
Humidity	15 % RH to 95% RH, non-condensing
Altitude	–610 m (–2,000 ft) below sea level 12,192 m (40,000 ft) above sea level

Note: The system may not meet its performance specifications if stored or used outside the manufacturer's specified temperature and humidity range.

Measurement Parameters

NIBP

Pulse Rate	
Pulse Rate Range	Adult/Pediatric/Neonatal 30 BPM to 220 BPM
Pulse Rate Accuracy	±3 BPM or ±3%, whichever is greater
NIBP (Non-Invasive Blood Pressure)	
Technique	Oscillometric Measurement
Measurement modes	AUTO, MANUAL and STAT
AUTO Mode	Automatic NIBP measurements at intervals of 1, 2, 3, 4, 5, 10, 15, 30, 45, 60, 90, 120, and 240 minutes
MANUAL Mode	Single measurement initiated by NIBP Start/Stop switch
STAT Mode	Series of consecutive measurements for 5 minutes
NIBP pressure measurement range	
Systolic pressure range	Adult: 30 mmHg to 260 mmHg (3.9 kPa to 34.5 kPa) Pediatric: 30 mmHg to 160 mmHg (3.9 kPa to 21.2 kPa) Neonatal: 25 mmHg to 120 mmHg (3.3 kPa to 15.9 kPa)
Diastolic pressure range	Adult: 20 mmHg to 235 mmHg (2.6 kPa to 31.2 kPa) Pediatric: 15 mmHg to 130 mmHg (1.9 kPa to 17.2 kPa) Neonatal: 10 mmHg to 105 mmHg (1.3 kPa to 13.9 kPa)
Mean pressure range	Adult: 20 mmHg to 255 mmHg (2.6 kPa to 33.9 kPa) Pediatric: 15 mmHg to 140 mmHg (1.9 kPa to 18.6 kPa) Neonatal: 10 mmHg to 110 mmHg (1.3 kPa to 14.6 kPa)
Pressure Display Accuracy	Meets ANSI/AAMI SP10:1992+A1:1996
Cuff Pressure Range	0 to 300 mmHg (0 to 40 kPa)
Initial Cuff Inflation	Adult: 100, 120, 140, 160(Default), 180, 200, 220, 240, 270 mmHg (13.3, 15.9, 18.6, 21.2(default), 23.9, 26.6, 29.2, 31.9, 35.9 kPa) Pediatric: 80, 90, 100, 110, 120(default), 130, 140, 150, 160, 170 mmHg (10.6, 11.9, 13.3, 14.6, 15.9(default), 17.2, 18.6, 19.9, 21.2, 22.6 kPa) Neonatal: 50, 60, 70, 80, 90(default), 100, 110, 120, 132 mmHg (6.6, 7.9, 9.3, 10.6, 11.9(default), 13.3, 14.6, 15.9, 17.5 kPa)
Overpressure protector	Adult 280 mmHg (N.C.), 308 mmHg (S.F.C.) Pediatric 220 mmHg Neonatal 154 mmHg
Standards	ANSI/AAMI SP10:1992+A1:1996, IEC60601-2-30:1999 EN1060-1:1995 and EN1060-3:1997.

Note: Systolic and diastolic blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method, within the limits prescribed by the American National Standard, Electronic or automated sphygmomanometers.

SpO2/Pulse Rate

%Saturation		
Range	1% to 100%	
Low Perfusion	0.03% to 20%	
Accuracy	Without Interference-Adults	70% to 100% ±2 digits 1% to 69% unspecified
	Without Interference-Neonate[1]	70% to 100% ±3 digits 1% to 69% unspecified
	Low Perfusion[2]	70% to 100% ±2 digits 1% to 69% unspecified

Pulse Rate		
Range	20 BPM to 300 BPM	
Accuracy	Without Interference[2]	20 BPM to 300 BPM ±3 digits
	Low Perfusion[2]	20 BPM to 300 BPM ±3 digits
Standards	EN865:1997	

[1]Neonate specifications are shown for neonate sensors with YM1000. Saturation accuracy will vary by sensor type recommended by the manufacturer..

[2]Specification applies to monitor performance and was validated with Biotek and Nellcor simulators

Temperature

Probe Type	Thermistor probe
Range	26° C to 43° C (80° F to 110°F)
Display Accuracy	±0.1° C (±0.2° F)
Measurement units	° C, ° F
Measurement modes	Predictive, Monitored
Predictive Mode	One-time measurement in a single temperature reading which is displayed at the end of the brief measurement period
Monitored Mode	Continuous measurement over an indefinite period.
Standards	ASTM E1112-00, EN12470-3

Printer

Type	Thermal
Resolution	8 (dots/mm)
Printing speed	45 (mm/s)
Paper width	57 (mm)

Compliance

Item	Compliant with
Classification	Class I (on AC power) Internally powered (on battery power)
Type of protection	Type BF – Applied part
General Safety	93/42/EEC Medical Device Directive
	21CFS820 Code of Federal Regulations
	91/157/EEC Battery Declaration Directive
	93/86/EEC Battery Disposal Directive
	2002/96/EC waste electrical and electronic equipment (WEEE)
	ISO9001:2000 Quality Management Systems-Requirements
	ISO13485:1996 Quality systems-Medical devices-particular requirements for the application of ISO9001
	IEC60601-1:1988+A1:1991+A2:1995 General requirements for safety and essential performance
	IEC60529 Degree of Protection Provided by Enclosures Water Ingress Testing (IPX0)
	EN540:1993 Clinical investigation of medical devices for human subjects
	EN ISO14155-1:2003 Clinical investigation of medical devices for human subjects-Part 1: General requirement
	AAMI HE48:1993 Human factors engineering guidelines and preferred practices for the design of medical devices
	IEC60601-2-49:2001 Particular requirements for the safety of multifunction patient monitoring equipment
	IEC60601-1-1:2000 Safety requirements for medical electrical systems
	IEC60601-1-4:2000 Programmable medical systems
	IEC60601-1-6:2004 Medical electrical equipment Part 1-6:General requirements for safety collateral standard: Usability
	ISO14971:2000 Application of risk management to medical devices
	ISO10993-1:2003 Biological evaluation of medical devices-Part 1: Evaluation and testing
Alarms	EN475:1995 Electrically-Generated alarm signals
	IEC60601-1-8:2003 Alarm systems requirements, tests and guidances in medical electrical equipments
Non-invasive blood pressure	AAMI SP10:2002+A1:2003 Electronic or Automated sphygmomanometers
	EN1060-1:1995 Non-invasive sphygmomanometers
	EN1060-3:1997 Supplementary requirements for electrical-mechanical blood pressure measuring systems
	IEC60601-2-30:1999 Particular requirements for the safety, including essential performance, of automatic cycling indirect blood pressure monitoring equipment
Oxygen saturation	EN865:1997 Pulse oximeters, Particular requirements
Temperature monitoring	E1112-00 Electronic thermometer for intermittent determination of patient temperature

Item	Compliant with
Electromagnetic Compatibility	IEC 60601-1, sub clause 36, IEC/ IEC60601-1-2:2001+A1:2004 Electromagnetic compatibility-requirements & test
	IEC61000-3-2:2004 Harmonic Emission
	IEC61000-3-3:2002 Voltage Fluctuations/Flicker Emission
	IEC61000-4-2:2001 Electrostatic Discharge (ESD)
	IEC61000-4-3:2002 Radiated RF electromagnetic field
	IEC61000-4-4:2004 Electrical fast Transient/Burst (EFT)
	IEC61000-4-5:2001 Surge current
	IEC61000-4-6:2004 Conducted disturbances, induced by RF field
	IEC61000-4-8:2001 Power frequency (50/60H) Magnetic field
	IEC61000-4-11:2004 Voltage dips, short interruptions, and voltage variation on power supply input lines
	CISPR 11:1997 (EN55011:1998) RF Emissions Group 1, Class B Limits and methods of measurement of radio disturbance characteristics of industrial scientific and medical (ISM) radio-frequency equipment
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)
Package	ISTA Pre-Shipment Test Procedures (Procedure 1A, 1994 Rev.)
Reliability	IEC60068-2-27 Environmental testing - Shock
	IEC60068-2-6:1995 Environmental testing –Vibration (sinusoidal)
	IEC60068-2-64:1993, Broadband random (Digital Control) and Guidance

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Routine Maintenance

WARNING: Do not spray or pour any liquid on the monitor or its accessories. Do not immerse YM1000 or its accessories in liquid or clean with caustic or abrasive cleaners.

Cleaning

To clean YM1000, dampen a cloth with a commercial, nonabrasive cleaner and wipe the exterior surfaces lightly.

CAUTION: Do not allow any liquids to come in contact with the power connector or switches or to penetrate connectors or openings in the instrument.

Note: For cuffs, sensors and probes, follow the cleaning instructions in the directions for use that accompany these accessories.

Note: If liquid is spilled on the monitor, clean and dry thoroughly before reuse.

Note: If in doubt about the monitor safety, refer the unit to qualified service personnel.

For surface-cleaning, follow your institution's procedures or:

- YM1000 may be surface-cleaned by using a soft cloth dampened with either a commercial or nonabrasive cleaner, and lightly wiping the top, bottom, and front surfaces of the monitor lightly.

Periodic Safety and Functional Checks

YM1000 requires no routine service or calibration other than cleaning and battery maintenance. The following performance verification tests may be used following repair or during routine maintenance (if required by your local institution).

1. Inspect the exterior of YM1000 for damage.
2. Inspect labels for legibility. If the labels are not legible, contact Mediana Technical Services Department.
3. Verify that the unit performs properly as described in **Performance Verification** section.
4. Perform the electrical safety tests detailed in **Performance Verification** section. If the unit fails these electrical safety tests, do not attempt to repair. Contact Mediana Technical Services Department.

Functional Checks

The following checks should be performed at least every 2 years by a qualified service technician.

1. If the monitor has been visibly damaged or subjected to mechanical shock (for example, if dropped), perform the performance tests as described in **Performance Verification** section.

2. Perform the electrical safety tests as described in **Safety Tests** section. If the unit fails these electrical safety tests, refer to **Troubleshooting** section.

3. Inspect the fuses for proper value and rating
   - qty 2, 2.0 A, 250 volts for AC mains (L/N: F1, F2)
   - qty 1, 6.3 A, 250 volts for internal battery (L/N: F3)

Batteries

If YM1000 has not been used for a long period of time, more than 2 months, the battery will need charging. To charge the battery, connect YM1000 to an AC outlet as described in **Performance Verification** section of this service manual or the **Battery Operation** section of the operator's manual.

Mediana recommends replacing the instrument's battery every 2 years. When YM1000 is going to be stored for 2 months or more, it is recommended to remove the battery prior to storage. To replace or remove the battery, refer to **Disassembly Guide**.

Note: Storing YM1000 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. A full charge of a dead battery takes approximately 12 hours while the monitor is turned off. Mediana recommends that YM1000's sealed, lead acid batteries be replaced at 2-year intervals. Refer to **Disassembly Guide** Section.

CAUTION: If YM1000 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. Recharging the battery is strongly recommended when the battery has not been recharged for 2 or more months.

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

CAUTION: Discarded battery 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 batteries and other device components.

Performance Verification

Introduction

This section discusses the tests used to verify performance following repairs or during routine maintenance. All tests can be performed without removing YM1000 covers. All tests except battery charge and battery performance tests must be performed as the last operation before the monitor is returned to the user.
If YM1000 fails to perform as specified in any test, repairs must be made to correct the problem before the monitor is returned to the user.

Equipment Needed

Table 1 lists the equipment required for performance verification.

Table 1. Required Test Equipments

Equipment	Description
Digital Multi Meter (DMM)	Fluke Model 87 or Equivalent
NIBP Cuff	Durable, Adult 11cm
NIBP Cuff	Durable, Neonatal 5cm
NIBP Hose	Adult, 8 feet
NIBP Hose	Neonatal, 6 feet
NIBP Rigid PVC Vessel	9cm diameter
NIBP Rigid PVC Vessel	5cm diameter
SpO_2 Sensor Extension Cable	DOC-10
Temperature Probe	Oral Probe
NIBP Simulator	Bio-Tek BP Pump 2 or Equivalent
SpO_2 Simulator	NELLCOR SRC-MAX
Temperature Simulator	WelchAllyn 9600 Calibration Tester
Safety Analyzer	METRON QA-90 or Equivalent
Stopwatch	Manual or electronic

Performance Tests

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

Power

1. Connect the monitor to AC power source using proper power cord.
2. Verify Charging/AC in indicator is lit (or flashing).
3. Press Power button over 1 second, and then verify that the monitor is turned on.
4. After the monitor operates in normal mode, disconnect the power cord.
5. Verify Battery indicator is lit instead of Charging/AC in indicator.
6. Press Power button over 1 second, and then verify that the monitor is turned off.

Battery Charge

1. Connect the monitor to AC power source using proper power cord. (the monitor is turned off)
2. Verify Charging/AC in indicator is lit (or flashing).

Note: If Charging/AC in indicator is flashing, the battery needs fully charging.

3. Charge the battery fully until Charging/AC in indicator is no more flashing. It takes for at least 12 hours.
4. To check for a full charge, disconnect the power cord. Press Power button and the NIBP start/stop button simultaneously over 1 second to enter the Service mode. Then select battery voltage level displayed.
5. Verify that current battery voltage display in Service mode indicates '6.0V' or greater.

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 fully charged battery.
2. Turn on the monitor by pressing Power button over 1 second.
3. Connect NIBP simulator to the monitor. Set NIBP simulator:
   SYS of 120mmHg, DIA of 80mmHg, PR of 80 bpm.
4. Set NIBP Auto interval of the monitor to 15 minutes.
5. After more than 2 hours of the monitor operating, verify an audible alarm is sounding and the battery level of the monitor is under 5.4V.
6. Allow the monitor to operate until it automatically powers down due to low battery condition. Verify that high priority alarm occurs 5 seconds before the monitor automatically shuts down.
7. If the monitor passes this test, immediately recharge battery.

Power-On Self-Test

1. Connect the monitor to AC power source and verify Charging/AC in indicator is lit.
2. Observe the monitor front panel. With the monitor off, press Power button. The monitor must perform the following sequence.
    a. All FNDs and indicators are illuminated.
    b. Power-on beeps sounds consecutively.
    c. Upon successful completion of power-on self-test, the display will enter the normal mode.

Note: Power-on self-test takes approximately 7 seconds to complete.

Note: If an error code is displayed, please refer to **Troubleshooting** section.

General Operation Tests

Alarms and Alarm Silence

1. Connect the monitor to an AC power source.
2. Press the monitor Power button to turn the monitor on.
3. Connect NIBP simulator to the monitor.
4. Set NIBP simulator as follows:
   Systolic of 120mmHg, Diastolic of 80mmHg and pulse rate of 150 bpm.
5. Press NIBP start/stop button.
6. Verify following the monitor reaction after measurement completes:
    a. The monitor displays NIBP and pulse rate as specified by the simulator.
    b. Audible alarm sounds and Pulse rate display flashes indicating the parameter has violated default alarm limits.
7. Press Alarm silence button on the front panel of the monitor.
8. Verify the following:
    a. An audible alarm is temporarily silenced.
    b. Pulse rate display continues flashing.
    c. Alarm silence indicator is lit.
    d. Audible alarm returns in approximately 90 seconds.
9. Set NIBP simulator as follows:
   Systolic of 120mmHg, Diastolic of 80mmHg and pulse rate of 80 bpm.
10. Press NIBP start/stop button.
11. Verify following the monitor reaction after measurement completes:
    a. The monitor displays NIBP and pulse rate as specified by the simulator.
    b. The alarm is terminated.
12. Disconnect NIBP simulator from the monitor.
13. Kink NIBP cuff hose connector of monitor and then press NIBP start/stop button.
14. Verify that the monitor displays an error code, E23 and sounds audible alarm.
15. Press Alarm silence button.
16. Verify that the alarm is terminated.

Pulse Tone Volume Control

1. Connect the monitor to an AC power source.
2. Press Power button to turn the monitor on.
3. Connect SpO_2 simulator to the pulse oximetry cable and connect the cable to the monitor.
4. Set SpO_2 simulator as follows: SpO_2 of 90% and pulse rate of 60 bpm.
5. Verify SpO_2/ pulse rate values and pulse amplitude indicator correctly display, and pulse tone sounds.
6. Press the mode button to enter setting mode.
7. Press Up (+) selection button to adjust pulse tone volume from 1 to 8. Return to the monitoring screen.
8. Verify beeping pulse tone increases.
9. Press the mode button to enter setting mode.
10. Press Down (-) selection button to adjust pulse tone volume from 8 to 1. Return to the monitoring screen.
11. Verify beeping pulse tone decreases.
12. Set pulse tone volume to 0, and return to the monitoring screen. Verify pulse tone is no longer audible.
13. Return pulse tone volume to a comfortable level.

Alarm Volume Control

1. Connect the monitor to an AC power source.
2. Press Power button to turn the monitor on.
3. Kink NIBP cuff hose connector of the monitor and then press NIBP start/stop button.
4. Verify that the monitor 'E23' displays and sounds audible alarm.
5. Press the mode button to enter setting mode.
6. Press Up (+) selection button to adjust alarm volume from 1 to 8. Return to the monitoring screen.
7. Verify alarm tone increases.
8. Press the mode button to enter setting mode.
9. Press Down (-) selection button to adjust alarm volume from 8 to 1. Return to the monitoring screen.
10. Verify alarm tone decreases.
11. Return alarm volume to a comfortable level.

Real-Time Clock

1. Connect the monitor to an AC power source.
2. Press Power button to turn the monitor on.
3. Verify that Time display updates every second.

Printer Test

If Printer option installed, the following test procedures will verify printer performance.

1. Connect the monitor to an AC power source.
2. Press Power button to turn the monitor on.
3. Connect all necessary simulators to the monitor.
4. Press Printer button when the monitor displays the measurements.
5. Verify the measurement values are printed out correctly.
6. Press the mode button over 3 seconds (configuration mode) to select Stream print.
7. Kink NIBP cuff hose connector of the monitor and then press NIBP start/stop button.
8. Verify that the monitor 'E23' displays and also prints out.
9. Open the printer door, and then press Print button.
10. Verify that the monitor sounds 'invalid button tone'.

Flash Memory

Perform the following procedure to test the flash memory.

1. Connect the monitor to an AC power source.
2. Press Power button to turn the monitor on.
3. Change alarm limits and other settings.
   - Temperature mode C M
   - Alarm Limit, SYS HI 160
   - Alarm Limit, DIA LO 15
   - Alarm Limit, PR HI 180
   - Alarm Limit, SpO_2 LO 85
4. Kink NIBP cuff hose connector of the monitor to generate an error 'E23'.
5. Turn the monitor off.
6. Press Power button to turn the monitor on again.
7. Verify that previously changed alarm limits and settings are saved/displayed.
8. Press Review button. Verify that 'E23' event is saved/displayed.
9. Turn the monitor off.
10. Press Power button & NIBP start/stop button simultaneously to enter Service mode.
11. Set 'DEFAULT RESET' to 'YES'. The monitor will return to the factory defaults.
12. Turn the monitor off.
13. Press Power button to turn the monitor on again.
14. Verify that alarm limits and settings of the monitor are set to the factory defaults. Refer to Table 8 Factory defaults.
15. Press Review button. Verify invalid button tone sounds and all events of trend data has been removed.

Measurement Parameter Operation Tests

Pneumatic System Operation

These tests verify the functionality of YM1000 pneumatic system.

1. Place the neonatal cuff with a rigid PVC vessel (5cm diameter). Connect the cuff to NIBP cuff hose connector via the neonatal hose.
2. Connect the monitor to an AC power source, and then press Power button to turn the monitor on.
3. Press NIBP start/stop button.
4. Verify that Systolic blood pressure display indicates an error code E23 and an audible alarm sounds.
5. Press the mode button (setting mode) to change Patient type to Neonatal. Return to the monitoring screen.
6. Press NIBP start/stop button. Verify that the monitor inflates.
7. Press NIBP start/stop button. Verify that the monitor deflates.
8. Place the adult cuff with a rigid PVC vessel (9cm diameter). Connect the cuff to NIBP cuff hose connector via the adult hose.
9. Press NIBP start/stop button.
10. Verify that Systolic blood pressure display indicates an error code E22 (or E24) and an audible alarm sounds.
11. Press the mode button (setting mode) to change Patient type to Adult. Return to the monitoring screen.
12. Press NIBP start/stop button. Verify that the monitor inflates.
13. Press NIBP start/stop button. Verify that the monitor deflates.

NIBP air leakage test

1. Connect the monitor to an AC power source.
2. Press Power button and NIBP start/stop button to enter Service mode.
3. Select NIBP Pressure Test by pressing Mode button (see figure 12).
4. Set a desired target pressure between 50and 300mmHg by pressing Up/Down (+/-) selection buttons.
5. Place the adult cuff with a rigid PVC vessel (9cm diameter). Connect the cuff and the adult hose to NIBP simulator. Then connect the adult hose to the monitor.
6. Set NIBP simulator to Pressure test or Leakage test mode.
7. Select the set point of NIBP simulator as the same point of target pressure of the monitor.
8. Press NIBP start/stop button of the monitor as simultaneously pressing start button of NIBP simulator. Current pressure appears on the diastolic pressure display.
9. After current inflating pressure comes up to the desired target pressure, the monitor starts deflating. Ensure that air leakage rate displays.
10. Verify that air leakage rate is within 6mmHg/min.

NIBP overpressure test

1. Connect the monitor to an AC power source, and then press Power button to turn the monitor on.
2. Press Mode button. Set to Adult patient type and NIBP target pressure, 270mmHg.
3. Place the adult cuff with a rigid PVC vessel (9cm diameter). Connect the cuff and the adult hose to NIBP simulator. Then connect the adult hose to the monitor.
4. Set NIBP simulator to Pressure relief or Overpressure test mode.
5. Press NIBP start/stop button of the monitor as simultaneously pressing start button of NIBP simulator. NIBP simulator pressurizes the system until the monitor's over-pressure relief system activates.
6. Verify that peak point displayed on NIBP simulator (point of protection pressure) is within 300mmHg.
   Also this point of protection pressure may be verified at the moment of the monitor's NIBP valve of relieved.

NIBP transducer accuracy test

1. Follow the procedure of NIBP air leakage test specified above.
2. During the deflation of the cuff pressure, verify that the difference is within ±3mmHg between monitor's current pressure and simulator's current pressure.

Pulse Oximetry Operation

If SpO_2 option installed, the following test procedures will verify SpO_2 performance.

1. Connect the monitor to an AC power source.
2. Turn on the monitor by pressing Power button.
3. Connect SpO_2 simulator to the pulse oximetry cable and connect the cable to the monitor.
4. Set SpO_2 simulator as follows: SpO_2 of 75% and pulse rate of 60 bpm.
5. The monitor will:
   - sound an audible alarm
   - display an SpO_2 of 75 ±2 digits (flashing)
   - display a pulse rate of 60 ±3 bpm
   - display Pulse amplitude indicator
6. Disconnect the pulse oximetry cable from the monitor.
7. Verify that the monitor displays an error code, E42 and sounds audible alarm.

Temperature Operation

If Temperature option installed, the following test procedures will verify temperature performance.

1. Connect the monitor to an AC power source.
2. Press Power button to turn the monitor on.
3. Connect temperature probe to the temperature connector of the monitor.
4. Set Temperature tester to 96.4° F.
5. Press the mode button (setting mode) to select 'F M' (monitored mode).
6. Insert the temperature probe into '…' of Temperature tester when 'Ready' indicator of the test is on.
7. After 3 minutes, verify that the monitor displays 96.1° F ~ 96.7° F.
   - Measurement accuracy: ±0.2° F
   - Temperature tester accuracy: ±0.1° F
8. Return the probe into the probe holder.
9. Verify that Temperature display indicates '- -'.

Safety Tests

YM1000 safety tests meet the standards of, and are performed in accordance with, IEC60601-1, Clause 19 (Second Edition, 1988; Amendment 1, 1991-11, Amendment 2, 1995-03), for instruments classified as Class I, Type BF.

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 mains 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 the voltage 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 test as recommended by analyzer operating instructions.

Table 2. 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

Note: Earth leakage current is measured under various conditions of the AC mains and protective earth conductor. For each condition, the measured leakage current must not exceed that indicated in Table 2.

Note: NC-normal condition / SFC-single fault condition / RM-reverse mains/line voltage

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 the applied voltage 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 200 cm^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 note exceed the values listed in Table 3.

Table 3. 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
SRC 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 BF 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 mains power cord to the analyzer as recommended by the analyzer operating instructions.
3. Apply NIBP cuff wrapped tightly around an appropriate metal cylinder.
4. Connect a test cable between the cylinder and an input connector on analyzer.
5. Turn on YM1000.
6. Perform the patient leakage current test as recommended by the analyzer operating instructions.
7. Repeat the patient leakage current test for SpO_2 and temperature patient connections, if those options configured, using the appropriate test cables.

Note: Patient leakage current is measured under various conditions of the AC mains and protective earth conductor. For each condition, the measured leakage current must not exceed that indicated in Table 4.

Note: This test requires a test cable for each patient connector. Test cables for NIBP, 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 4. Patient Leakage Current Values

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
SRC Open Earth RM (SFC OERM)	500

Patient Leakage Current - (Mains Voltage on the Applied Part)

WARNING: AC mains 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 BF 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 above Patient Leakage Current.

1. Configure electrical safety analyzer as recommended by analyzer operating instructions.
2. Connect the monitor's AC mains power cord to analyzer as recommended by analyzer operating instructions.
3. Apply NIBP cuff wrapped tightly around an appropriate metal cylinder.
4. Connect a test cable between the cylinder and an input connector on analyzer.
5. Turn on YM1000.
6. Perform test as recommended by analyzer operating instructions.
7. Repeat test for SpO_2 and temperature patient connections, if those options configured, using 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 5.

Table 5. Patient Leakage Current Values—Mains Voltage on Applied Part

Test Condition	Allowable Leakage Current (microamps)
Normal polarity (SFC)	5000
Reverse polarity (SFCRM)	5000

Patient Auxiliary Current

This test measures patient auxiliary current in accordance with IEC60601-1, clause 19, for Class I, type BF equipment. The applied voltage for IEC60601-1 the voltage is 264 volts, 50 to 60 Hz. Patient auxiliary current is measured between each test cable 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 Patient Leakage Current.

1. Configure the electrical safety analyzer as recommended by the electrical analyzer's operating instructions.
2. Connect monitor's AC mains power cord to the electrical analyzer as recommended by the electrical analyzer's operating instructions.
3. Connect the patient test lead combination in table 6 to the appropriate input connector on the electrical analyzer.
4. Turn on YM1000.
5. Perform patient auxiliary current test per table 7 as recommended by 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 6. Test Lead Combinations

First Test Lead	Second Test Lead
Temperature probe	NIBP cuff
Temperature probe	SpO_2 sensor
NIBP cuff	SpO_2 sensor

Table 7. Allowable 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
SRC Open Earth RM (SFC OERM)	500

Service Mode and Demo Mode

Introduction

This section describes Service mode that allows authorized personnel to review/check system version, battery voltage level, NIBP inflation cycle, total system runtime, factory default reset, night panel, NIBP calibration, NIBP pressure test and sound calibration in order to obtain service-related information about the monitor. Also this section explains how to demonstrate the monitor (Demo mode).

Service Mode

Follow the procedure below to enter Service mode.

1. With the monitor powered off, press Power button and NIBP start/stop button simultaneously.
2. System version displays on the monitor.
3. Press Mode button to select a mode item.

System Version

The revision level of the system software displays: system software version, NIBP module version, SpO2 module version and Temperature module version.

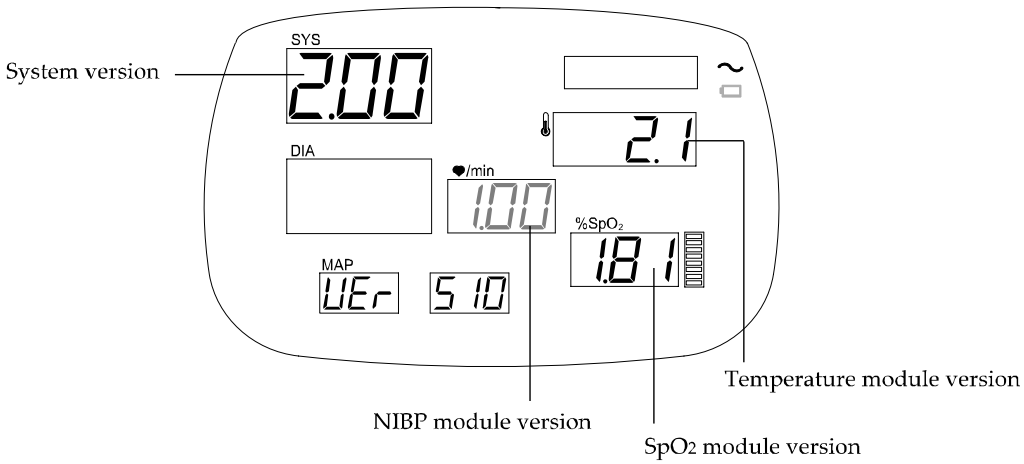

Figure 5. System Version

Note: The system version shown above is only a sample.

Battery Voltage Level

Current battery voltage level is displayed (unit of voltage: V).

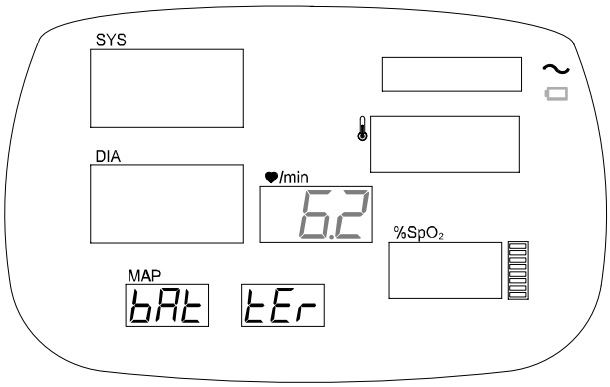

Figure 6. Battery Voltage Level

NIBP Inflation Cycle

The number of NIBP inflation cycles operated is displayed.

Note: The values of NIBP inflation cycle may not be reset, but it will be reset to zero when a new Main PCB assembly is installed.

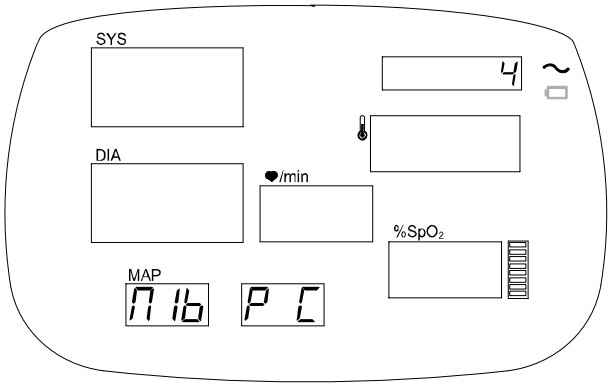

Figure 7. NIBP Inflation Cycle

Total System Runtime

Total Runtime displays the number of hours, rounded to the nearest hour, that the monitor has been operational.

Note: The values of Total Runtime may not be reset, but it will be reset to zero when a new Main PCB assembly is installed.

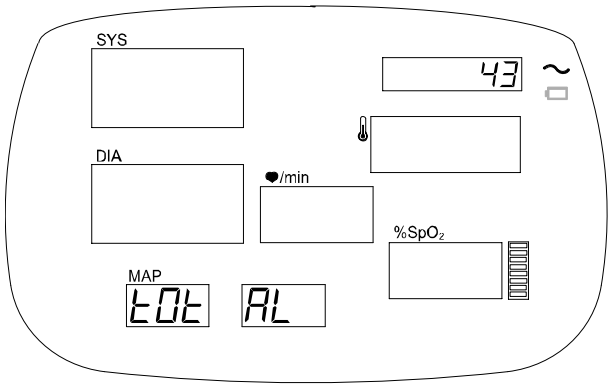

Figure 8. Total Runtime

Factory Default Reset

To reset the monitor operating parameters to the factory default settings, press the Mode button until " DEFAULT RESET=NO" is displayed.

To reset to the factory default values, select 'YES' using only Up (+) selection button. The monitor immediately resets to the defaults and the confirmation tone sounds.

To leave the settings unchanged, select 'NO' using only Down (-) selection button.

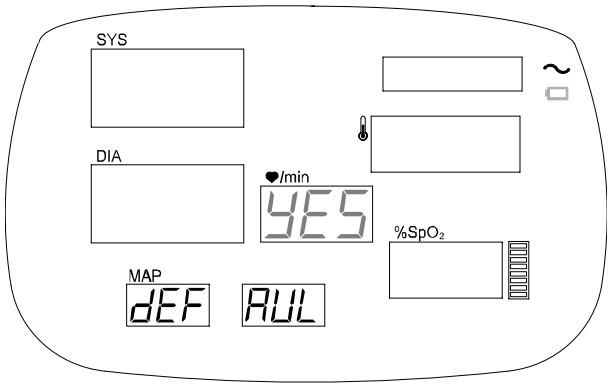

Figure 9. Factory Defaults Reset

Factory default settings are described in Table 8.

Table 8. Factory Default Settings for YM1000

Parameter		Ranges		Defaults
Systolic (mmHg) Alarm Limits	Neonatal	Low: 25 to 115	High: 30 to 120	50, 100
	Pediatric	Low: 30 to 155	High: 35 to 160	75, 145
	Adult	Low: 30 to 255	High: 35 to 260	75, 220
Diastolic (mmHg) Alarm Limits	Neonatal	Low: 10 to 100	High: 15 to 105	30, 70
	Pediatric	Low: 15 to 125	High: 20 to 130	35, 100
	Adult	Low: 20 to 250	High: 25 to 255	35, 110
MAP (mmHg) Alarm Limits	Neonatal	Low: 10 to 105	High: 15 to 110	35, 80
	Pediatric	Low: 15 to 135	High: 20 to 140	50, 110
	Adult	Low: 20 to 250	High: 25 to 255	50, 120
PR (bpm) Alarm Limits	Neonatal	Low: 25 to 295	High: 30 to 300	100, 200
	Pediatric	Low: 25 to 295	High: 30 to 300	50, 150
	Adult	Low: 25 to 295	High: 30 to 300	50, 120
SpO2 % Alarm Limits	Neonatal	Low: 50 to 98	High: 52 to 100	85, 98
	Pediatric	Low: 50 to 98	High: 52 to 100	90, 100
	Adult	Low: 50 to 98	High: 52 to 100	90, 100
Patient Type		Adult, Pediatric, Neonatal		Adult
NIBP Units		mmHg, kPa		mmHg
NIBP initial cuff inflation	Neonatal	50, 60, 70, 80, 90, 100, 110, 120, 132 mmHg (6.6, 7.9, 9.3, 10.6, 11.9, 13.3, 14.6, 15.9, 17.5 kPa)		90 mmHg (11.9 kPa)
	Pediatric	80, 90, 100, 110, 120, 130, 140, 150, 160, 170 mmHg (10.6, 11.9, 13.3, 14.6, 15.9, 17.2, 18.6, 19.9, 21.2, 22.6 kPa)		120 mmHg (15.9 kPa)
	Adult	100, 120, 140, 160, 180, 200, 220, 240, 270 mmHg (13.3, 15.9, 18.6, 21.2, 23.9, 26.6, 29.2, 31.9, 35.9 kPa)		160 mmHg (21.2 kPa)
NIBP Auto Interval		Off, STAT, 1, 2, 3, 4, 5, 10, 15, 30, 45, 60, 90, 120, 240		15
Temperature Units/Modes		°C, °F, °C M, °F M		°F
Pulse Tone Volume		0 to 8		4
Alarm Volume		1 to 8		4
Night Panel		On, Off		Off
Nurse call state		Normal Open, Normal Close		Normal Open
Date format		Y-M-D, D-M-Y		Y-M-D
Sound mode		Full, Mid, Mute		Full
Print Control		Manual, Stream		Manual

Night Panel

Night panel is used to adjust the light intensity of the display.
With 'Night Panel' selected,
- select 'YES' using only Up (+) selection button to degrade the light intensity between 21:00 to 06:00.
- select 'No' using only Down (-) selection button not to use this option.

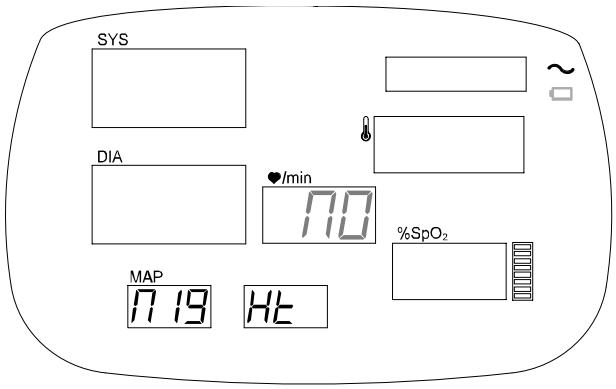

Figure 10. Night Panel

Nurse Call State

Nurse call state is used to select the operating type for Nurse call.
With 'Nurse Call State' selected,
- select 'NO' (Normal Open) using only Up (+) selection button.
- select 'NC' (Normal Close) using only Down (-) selection button.

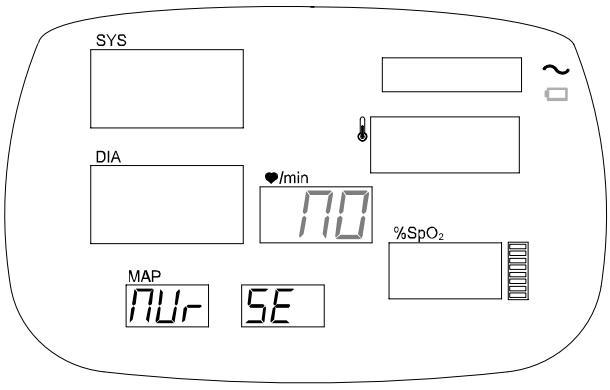

Figure 11. Nurse Call State

Date Format

The monitor support two date formats.
With 'Date Format' selected,
- select 'Y-D' (Year-Month-Day) using only Up (+) selection button.
- select 'D-Y' (Day-Month-Year) using only Down (-) selection button.

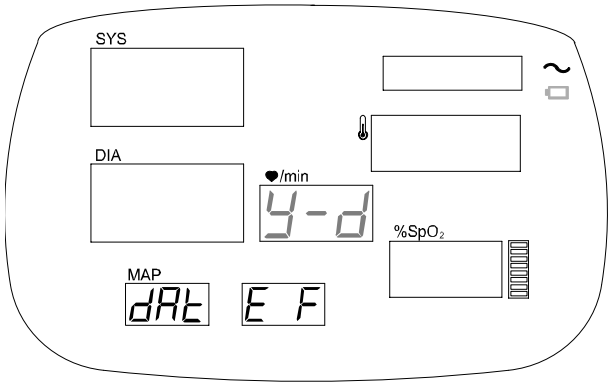

Figure 12. Date Format

Sound Mode

You can activate the specific sound as indicated in the following table via Sound Mode. With 'Sound Mode' selected, select a number between from 1 to 3 using Up (+) or Down (-) selection button. The number, 1, 2 or 3, is corresponded to full, mid or mute.

Table 9. Sound Mode

	Variety power-on beep	Measur-ement done	Temp probe in/out	AC in/out	Confir--mation tone	Valid/ Invalid button tone
1 (full)	O	O	O	O	O	O
2 (mid)	X	X	X	O	X	O
3 (mute)	X	X	X	X	X	X

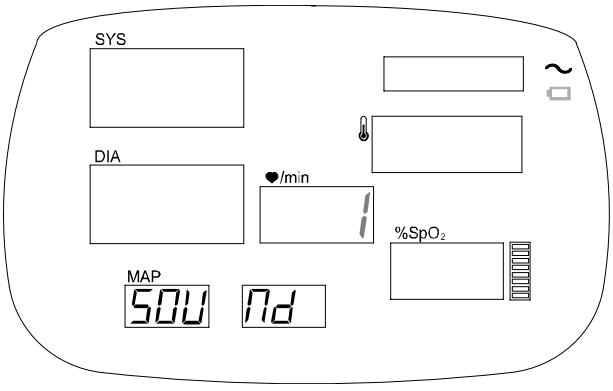

Figure 13. Sound Mode

Print Speed

This menu is intended for factory use only.

NIBP Calibration

'NIBP Calibration' is used to calibrate NIBP pneumatic pump.
With 'NIBP Calibration' selected,

1. Connect the NIBP adult hose to the monitor.
2. Kink the distal end (farthest from the monitor).
3. Press Up (+) selection button to start calibration.
4. The monitor displays 'ING' during the calibration.
5. Wait for about 20 seconds to complete.
6. Verify that Time display indicates one of digits from 040000 to 070000 after 'End' message appears. (If fails, refer to **Troubleshooting** section.)
7. Turn off the monitor.
8. After a few seconds, power on the monitor.

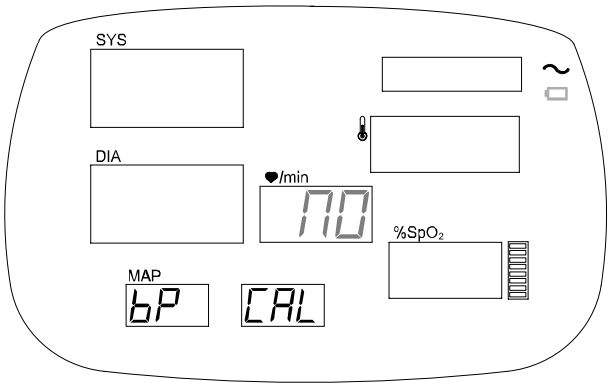

Figure 14. NIBP Calibration

NIBP Zero Setting
The NIBP pressure is calibrated at the factory. No periodic recalibrations are required by service personnel.
The Module automatically performs a baseline (zero pressure) calibration every 10-15 minutes during operation or sleep mode. (The exact time between baseline calibrations can vary depending on whether a measurement cycle is in progress at the time the next baseline calibration should take place.)

NIBP Pressure Test

The real-time value of the system pneumatic pressure is displayed in mmHg.
For more information, refer to **Performance Verification** section.
With 'NIBP Pressure Test' selected,

1. Place the adult cuff with a rigid PVC vessel (9cm diameter). Connect the cuff and the adult hose to NIBP simulator. Then connect the adult hose to the monitor.
2. Set NIBP simulator to a test mode required.
3. Adjust a desired target pressure using Up/Down (+/-) selection buttons.
4. Press NIBP start/stop button.

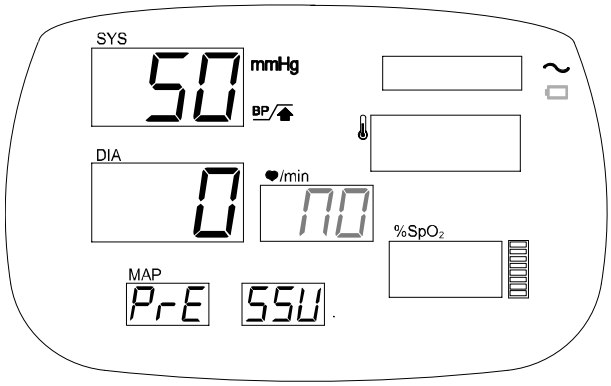

Figure 15. NIBP Pressure Test

NIBP Upgrade

This menu is used for the software upgrade of NIBP module. Call Mediana Technical Service Department for the software if required. Refer to the instructions for use for the software upgrade for the detailed information.

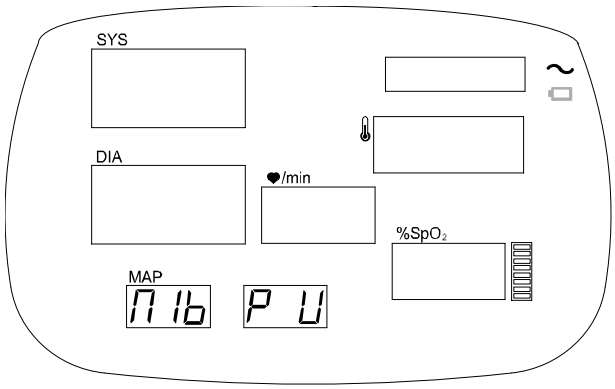

Figure 16. NIBP Upgrade

Sound Calibration

'Sound Calibration' is used to set a level of sound volume at factory.
With 'Sound Calibration' selected,

1. Press Up (+) selection button.
2. Verify that the level 1 of the volume sounds continuously.

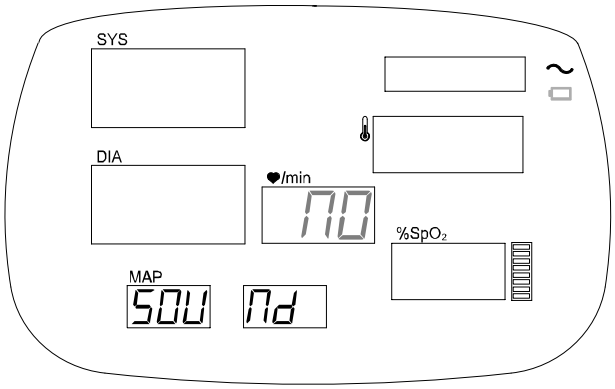

Figure 17. Sound Calibration

Demo Mode

The purpose of Demo mode is to show a visual presentation demonstrating how YM1000 monitor works. The following procedure is set to Demo mode.

1. With the monitor powered off, press Power button and Alarm silence button simultaneously.
2. The monitor is now set to Demo mode, and demonstrates a typical the monitoring display.

Note: No setting changes allowed.

Note: Only beep tones may be off or on by pressing Up/Down (+/-) selection buttons. Alarm silence button can be accessed in order to demonstrate Alarm silence indicator illuminated.

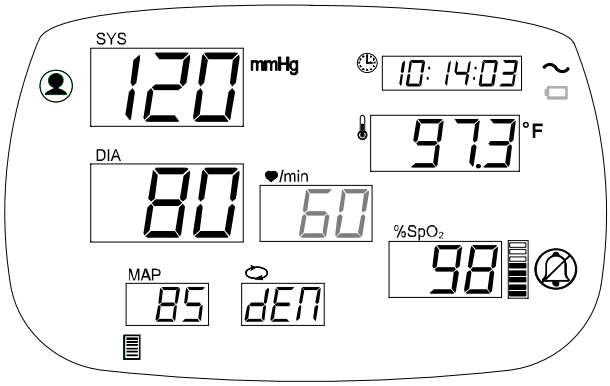

Figure 18. Demo Mode Display

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Firmware download

Introduction

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 and utility required.

Equipment Needed

Table 10 lists the equipment required for Firmware download.

Table 10. Required Equipments for Firmware download

Equipment	Description
Firmware Downloading Cable	9-pin Serial Cable (use only Mediana provided)
Firmware Downloading Software	Rabbit Field Utility
Personal Computer	With Serial Port

How to Download

1. Turn off the monitor.
2. Connect Firmware downloading cable to the data interface port of the monitor.
3. Connect the other side of Firmware downloading cable to a PC.
4. Run **RFU.EXE (Rabbit Field Utility)** on the PC.
5. Choose **Setup**.
6. Click on **Communication**.
7. Check **Use Serial Connection** and **Enable Processor Detection**.
8. Set Baud Rate to 115200.
9. Select an appropriate COM Port that current Firmware downloading cable connected.
10. Click OK.
11. Press Power button to turn on the monitor.
12. Verify that Network indicator is flashing.
13. Choose **File** > **Load Flash Image**.
14. Use the browser to select **a binary file** e.g. 20040630_VER1.00_MEDIANA.BIN.
15. Click OK to start downloading.

16. After completion of downloading, turn off the monitor.
17. Disconnect Firmware downloading cable from the monitor and PC.
18. Press Power button and NIBP start/stop button simultaneously to enter **Service mode** of the monitor.
19. Press Mode button to go to **DEFAULT RESET**.
20. Select DEFAULT RESET=YES to reset the monitor to factory defaults.
21. Turn off the monitor.
22. After a few seconds, turn the monitor on.
23. Perform the tests specified in **Performance Verification** section.

Note: Only Mediana provided Firmware download cable must be used. Otherwise, Main BD may be damaged.

Note: Software versions of OEM boards are not field-upgradeable. (NIBP, SpO_2 or Temperature module.) Replace the subsystem board with a higher (current) version if necessary.

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

Troubleshooting

Introduction

This section explains how to troubleshoot YM1000 if problems arise.
Tables are supplied that list possible difficulties and recommended actions to correct the difficulty.

How to Use This Section

Use this section in conjunction with **Performance Verification** section and **Spare Parts** section. To remove and replace a part you suspect is defective, follow the instructions in **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 Services.

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

Troubleshooting Guide

Problems with YM1000 are separated into the 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 Services.

Power

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

CAUTION: Electrical shock hazard. Disconnect a power cord from YM1000 before attempting to open or disassemble YM1000.

1. Before further troubleshooting of the power problems:

1-1. Review customer complaint and determine if it is safe to plug in and turn on YM1000.
1-2. Verify that Charging/AC in indicator is lit (or flashing) as a power cord is connected.
1-3. Check fuses (F1, F2 and F3) located on SMPS. If blown, replace fuses.
1-4. Check the connection of 8-pin wire between Main BD and SMPS.
1-5. Check the connection of 5-pin wire between Battery and SMPS.

2. When AC power cord is connected to YM1000, Charging/AC in indicator on the front panel is not lit.

2-1. Check fuses (F1, F2 and F3) located on SMPS. If blown, replace fuses.
2-2. Replace 8-pin wire connected between Main BD and SMPS.
2-3. Replace Main BD if problem persists.
2-4. Replace SMPS if problem persists after Main BD replaced.
2-5. Replace FND module if problem still persists.

3. YM1000 fails to power-up when Power button is pressed.

3-1. Check on action 1-2 to 1-5.
3-2. Download Firmware (see **Firmware download** section).
3-3. Replace 8-pin wire of Main BD connected to SMPS if problem persists.
3-4. Replace Main BD if problem persists.
3-5. Replace Rubber button.
3-6. Replace SMPS if problem persists.

4. YM1000 is operating on AC main, but not operating on Battery.

4-1. Check on action 1-2 to 1-5.
4-2. The battery may be discharged. To recharge the battery, connect a power cord to AC mains over 12 hours (refer to Battery charge in **Performance Verification** section).
Note: The monitor may be used with a less than fully charged battery but with a corresponding decrease in operating time from that charge. The battery may be defective.
4-3. Replace Battery if problem persists after fully charged.
4-4. Replace SMPS if problem persists after Battery replaced.

Display

The followings are symptoms of problems relating to non-functioning displays, and recommended actions. If the action requires replacement of a PCB assembly or module, refer to **Disassembly Guide**.

1. Display is totally black (no data is visible) after system powers up.
- 1-1. Replace Main BD.
- 1-2. Replace FND module.

2. Not all display segments light during POST.
- 2-1. Verify that Main BD connector is properly connected to FND module.
- 2-2. Replace FND module if problem persists.
- 2-3. If problem persists, replace Main BD after FND module replaced.

3. Values are erratically displayed after system powers up.
- 3-1. Verify that Main BD connector is properly connected to FND module.
- 3-2. Replace FND module if problem persists.
- 3-3. If problem persists, replace Main BD after FND module replaced.

4. No visual alarm displayed during alarm condition.
- 4-1. Ensure that alarm limits are properly set.
- 4-2. Ensure that patient type is correctly set.
- 4-3. Ensure that patient measurement cables are properly connected and placed.
- 4-4. Replace Main BD if problem persists.
- 4-5. Replace acquisition modules (NIBP, SpO_2 or Temperature) if problem persists.

Sound

The followings are symptoms of problems and recommended actions relating to sound. If the action requires replacement of a PCB assembly or module, refer to **Disassembly Guide**.

1. Audible tones do not sound after system powers up.
- 1-1. Verify that Sound mode is set to 3 (min) in the service menu.
- 1-2. Verify that Speaker is working properly. If necessary, replace Speaker.
- 1-3. Check the connection of 2-pin wire between Speaker and Main BD.
- 1-4. If problem persists, replace Main BD.

2. Sound volume is too low to be heard.
- 2-1. Check if a level of volume is set to minimum value.
  Refer to page 30, 31 in the operator's manual.
- 2-2. Adjust the trim-pot (R117) on Main BD.
- 2-3. If problem persists, replace Main BD.

3. Audible tones sound, but a level of sound volume does not change even a level is set to 8.
- 3-1. Adjust the trim-pot (R117) on Main BD.
- 3-2. If problem persists, replace Main BD.

Buttons

The following is a symptom of problems and recommended actions relating to buttons. If the action requires replacement of a PCB assembly, refer to **Disassembly Guide**.

1. Buttons do not respond and/or buttons are operating with pressed.
1-1. Replace Rubber button on Main BD.
1-2. If problem persists, replace Main BD.

2. Buttons do respond, but no button tones when pressed.
2-1. Verify that Sound mode is set to 3 (min) in service menu.
2-2. Ensure that Speaker is damaged to fail.
2-3. Check the connection of 2-pin wire between Speaker and Main BD.
2-4. Adjust the trim-pot (R117) on Main BD.
2-5. If problem persists, replace Main BD.

NIBP Performance

The followings are symptoms of problems and recommended actions relating to NIBP operational performance. If the action requires replacement of a PCB or module, refer to **Disassembly Guide**.

1. Dashes '- - -' are flashing on NIBP display.
1-1. Go to Service mode. Perform NIBP Calibration (see **Service Mode** section).
1-2. If NIBP Calibration is not able to perform, check the connection of 24-pin ribbon cable between NIBP module and Main BD.
1-3. If problem persists, replace NIBP module.
1-4. Replace Main BD, if problem persists after NIBP module replaced.

2. After NIBP calibration, the digit shown in Time display is outside of 040000~070000.
2-1. Turn off the monitor.
2-2. Go to Service mode. Perform NIBP Calibration again (see **Service Mode** section).
2-3. If problem persists, verify that internal silicon tubing is kinked or disconnected.
2-4. Replace NIBP module and pump if problem still persists.

3. Often error codes, E22, E23 and/or E24 display(s).
3-1. Ensure that an appropriate cuff and hose are used to correspond with Patient type selected.
3-2. Go to Service mode. Perform NIBP Calibration (see **Service Mode** section).
3-3. If problem persists, replace NIBP pump.

4. Error code, E29 displays.
4-1. Replace both NIBP module and pump.
4-2. If problem persists, replace Main BD.

SpO_2 Performance

The followings are symptoms of problems and recommended actions relating to SpO_2 operational performance. If the action requires replacement of a PCB or module, refer to **Disassembly Guide**.

1. No displays (blank) on SpO_2 display.
1-1. Replace SpO_2 module.
1-2. If problem persists, replace Main BD.

2. Dashes '- -' are displaying on SpO_2 display, but no data measured.
2-1. Verify that red LED of SpO_2 sensor is on. If not, replace the SpO_2 sensor.
2-2. Ensure that the LED intensity increases when opening the SpO_2 sensor.
2-3. If problem persists, replace SpO_2 module.

3. Error code, E49 displays.
3-1. Replace SpO_2 module.

Temperature Performance

The followings are symptoms and recommended actions to address problems with temperature operational performance. If the action requires replacement of a PCB or module, refer to **Disassembly Guide**.

1. No displays (blank) on Temperature display.
1-1. Check the connection of 5-pin wire between Temperature PCB and Main BD.
1-2. Replace Temperature PCB if problem persists.
1-3. Replace Temperature module if problem still persists.
1-4. If problem persists after Temperature module replaced, replace Main BD.

2. Dashes '- -' are displaying on Temperature display, but no data measured.
2-1. Use another temperature probe.
2-2. Check the connection of 5-pin wire between Temperature PCB and Main BD.
2-3. Replace Temperature PCB if problem persists.
2-4. Replace Temperature module if problem still persists.

3. Error codes, E63 and/or E64 often display(s).
3-1. Use another temperature probe.
3-2. Replace Temperature module if problem persists.

4. Error code, E65 often displays.
4-1. Replace Temperature PCB.
4-2. Replace Temperature module if problem persists.

5. Error code, E69 displays.
5-1. Replace Temperature module.

Printer

The followings are symptoms of problems and recommended actions related to printing. If the action requires replacement of a PCB or module, refer to **Disassembly Guide**.

1. Print setting indicator does not light after system powers up.
- 1-1. Check the connection of 6-pin wire between Printer and Main BD.
- 1-2. Replace Printer.
- 1-3. Replace Main BD if problem persists after Printer replaced.

2. Print setting indicator is lit, but no printing after Print button pressed.
- 2-1. Ensure that Printer door is properly closed.
- 2-2. Check if Printer paper runs out.
- 2-3. Ensure that Printer paper is placed appropriately.
- 2-4. Check the connection of 6-pin wire between Printer and Main BD.
- 2-5. Replace Printer if problem still persists.

Firmware download

The followings are symptoms and recommended actions to address problems with firmware download. If the action requires replacement of a PCB, refer to **Disassembly Guide**.

1. Network indicator is not flashing with the pressure of Power button after Firmware downloading cable connected.
- 1-1. Check on action 1-2 to 1-5 of Power troubleshooting (page…).
- 1-2. Ensure that Mediana Firmware downloading cable is connected.
- 1-3. Ensure that Firmware downloading cable is properly connected to the data interface port of the monitor. Also ensure that the other side of Firmware downloading cable is well connected to a PC.
- 1-4. Check the connection of 9-pin serial wire of the monitor inside.
- 1-5. Replace Main BD if problem persists.

2. Network indicator is flashing, but Firmware download/update fails.
- 2-1. Ensure that COM port of Field utility is properly set.
- 2-2. Verify that COM port of a PC operates correctly.
- 2-3. Reboot a PC.
- 2-4. Ensure that Mediana Firmware downloading cable is connected.
- 2-5. Ensure that Firmware downloading cable is properly connected to the data interface port of the monitor. Also ensure that the other side of Firmware downloading cable is well connected to a PC.
- 2-6. Check the connection of 9-pin serial wire of the monitor inside.
- 2-7. Replace Main BD if problem persists.

Others

The followings are symptoms of problems and recommended actions that may happen related to operating the monitor. If the action requires replacement of a PCB or module, refer to **Disassembly Guide**.

1. No operation but Network indicator flashing after system powers up.

1-1. If a cable connected to the data interface port of the monitor, disconnect the cable. Then, turn on the monitor.
1-2. Replace Main BD if problem persists.
1-3. Replace 9-pin serial wire if problem persists after Main BD replaced.

2. During POST, all display segments and indicators are illuminated but stopped to process.

2-1. Press Power button to turn the monitor off.
2-2. Verify that the monitor powers off. If the system still powered on, open Battery cover. Then separate Battery terminals to power off the system.
2-3. Download the latest version of Firmware if problem persists.
2-4. Replace Main BD if problem still persists.

3. Error code, E02 often displays after completion of POST.

3-1. Check the connection of 8-pin wire between SMPS and Main BD.
3-2. Check the connection of 5-pin wire between SMPS and Battery.
3-3. Ensure that Battery is fully charged.
3-4. Replace Battery if problem persists.
3-5. Replace Main BD if problem persists after Battery replaced.

4. Settings and/or measured data are not saved in the memory of the monitor.

4-1. Replace Main BD.

5. Time display is not updated and/or does not indicate current time.

5-1. Replace Lithium battery (BT1) on Main BD.
5-2. Replace Main BD if problem persists.

6. Error code, E09 often displays.

6-1. Replace both SMPS and Main BD.

Error Codes

When YM1000 detects an error condition, the monitor will attempt to show an error code on the display screen.

If such an error occurs during the monitoring operation, the monitor will sound a low-priority alarm. Audible alarm can be terminated if the alarm silence button pressed, but it depends on error codes and conditions.

Table 11 provides a complete list of error codes and problem identification.

Table 11. Technical Error Codes

Error Codes	Description
E01	Battery failure
E02	Abnormally shutdown last time
E09	System error (malfunction)
E21	Air leakage
E22	Cuff not detected
E23	Kinked or neonate hose
E24	Cuff too large for neonate
E25	Overpressure condition
E26	Motion artifact
E27	Weak pulse or no pulse detected
E28	Valid BP not found
E29	NIBP module error (malfunction)
E41	Sensor off
E42	Sensor disconnected
E43	Bad sensor
E44	Loss of pulse
E49	SpO2 module error (malfunction)
"P"	Loss of tissue contact
E62	Probe disconnected
E63	Probe error
E64	Probe heated too high
E65	Ambient temperature out of range
E69	Temperature module error (malfunction)

Disassembly Guide

WARNING: Do not place YM1000 into operation after repair or maintenance until Performance, Safety Tests and NIBP Calibration listed in this service manual have been performed. Failure of these tests could result in erroneous readings.

WARNING: Electrical shock hazard. Disconnect the power cord from YM1000 before attempting to open or disassemble YM1000.

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

Note: Some spare parts have a business reply card attached. When you receive these spare parts, please fill out and return the card.

General

This section describes disassembly procedures detailed disassembly instructions and accompanied by illustrations. Disassembly Sequence Flow Chart that is used to access replaceable parts of YM1000 is illustrated in Figure 19. 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 **Spare Parts** section. **Follow the reverse sequence of the disassembly procedures for reassembly**.

YM1000 can be disassembled down to all major component parts, including:

- PCB assemblies
- acquisition modules
- FND module
- Printer
- SMPS
- Battery
- Speaker
- cables & wires
- brackets & cases

The following tools are required:

- small, Phillips-head (+) screwdriver
- medium, Phillips-head (+) screwdriver
- 5mm, Box wrench
- 10mm, Box wrench
- 0.35inch Spanner
- needle-nose pliers

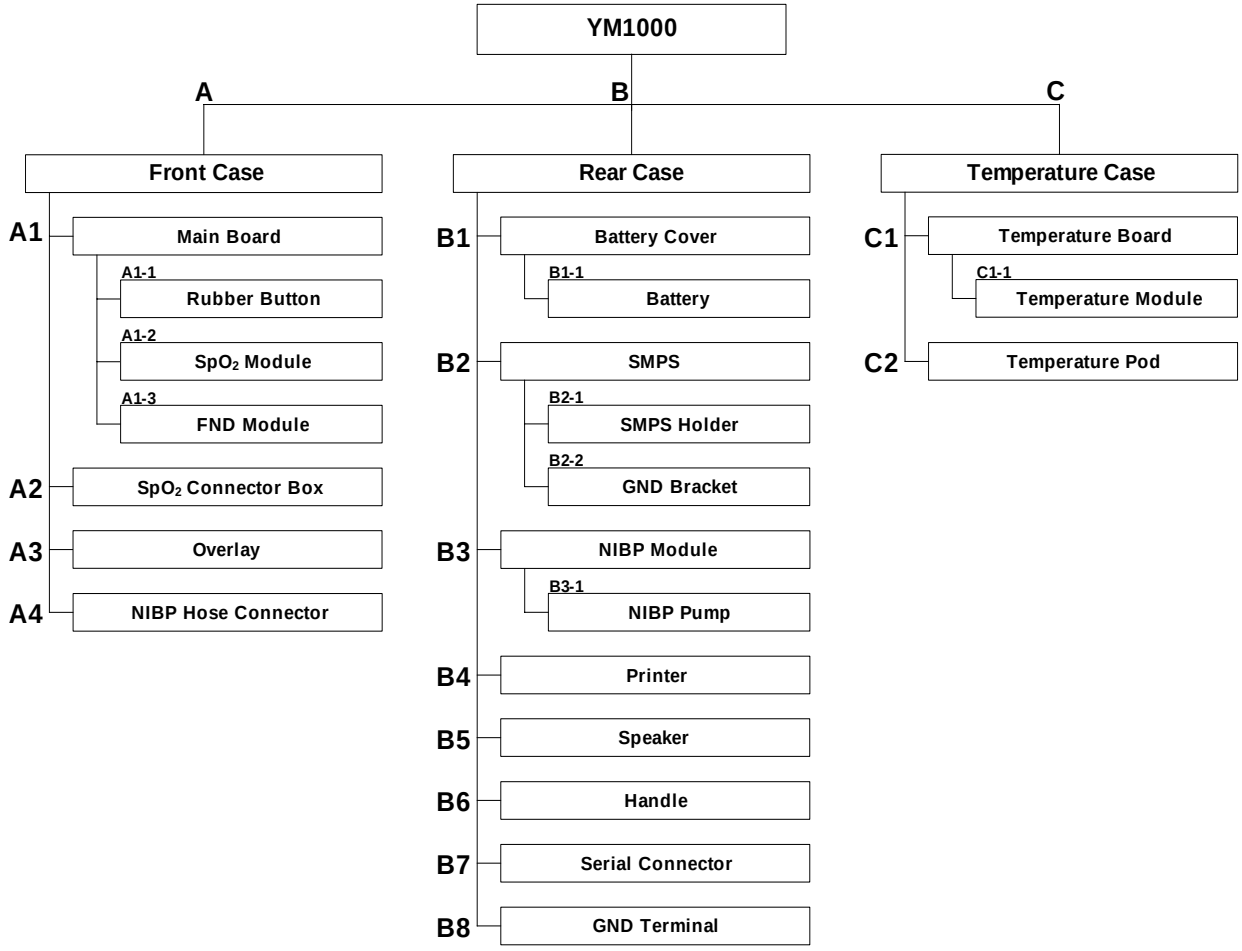


Figure 19. Disassembly Sequence Flow Chart

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 detected in this section.

Prior to Disassembly

1. Turn YM1000 off by pressing the Power On/Off switch.
2. Disconnect the monitor from the AC power source

Fuse Replacement

1. After **Step B2**, remove 2 AC main fuses (F1, F2: 250V/2A) out of the socket if required.
2. Remove 1 battery fuse (F3: 250V/6.3A) out of the socket if required.
3. Replace (a) new fuse(s).
4. Reassembly the monitor.

Battery Replacement

This section describes the steps to remove the battery from YM1000 for replacement without disassembling the main case of the monitor

B1. Battery disassembly

5. Remove 4 small flat-head screws (S8094-0) fastening Battery cover.
6. Remove Battery cover.
7. Remove Battery carefully from the monitor.
8. Disconnect the wire between 2 Battery terminals.

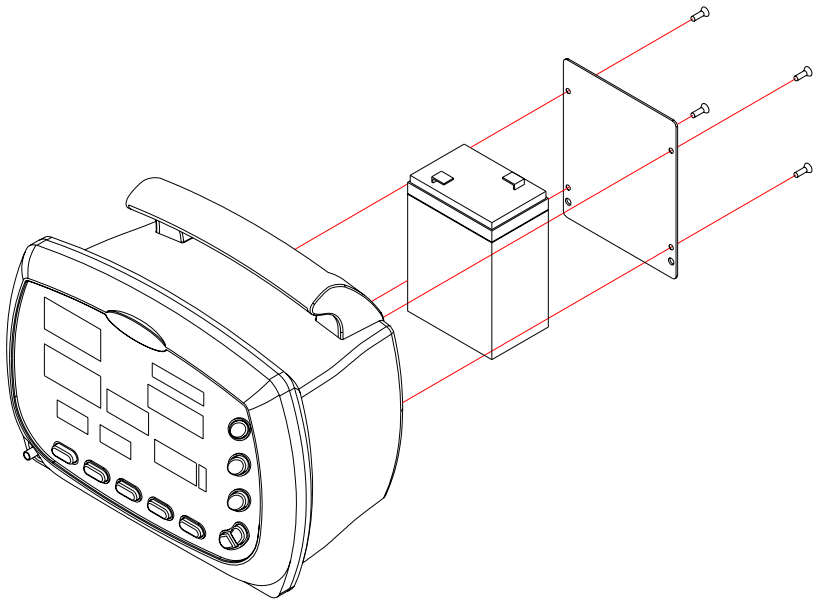


Figure 20. Battery Disassembly

Monitor Disassembly

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

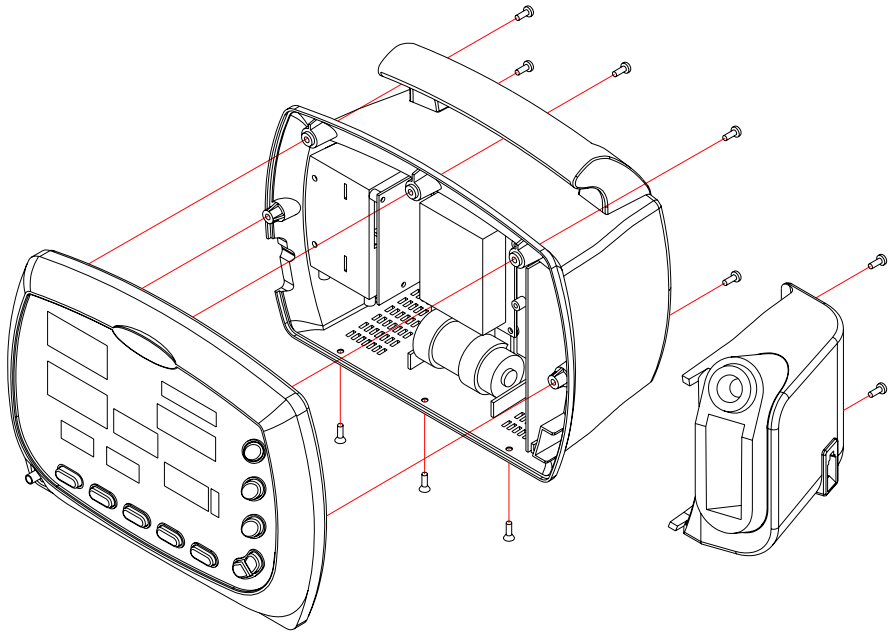


Figure 21. Monitor Disassembly

Table 12. Part Descriptions – Monitor Assembly

Part Codes	Descriptions	Qty
-	Front case assembly (A)	1
-	Rear case assembly (B)	1
-	Temperature case assembly (C)	1
S8071-0	Screw 3 × 8 (tapping)	2
S8070-0	Screw 3 × 8 (flat-head)	3
S8091-0	Screw 3 × 12	3
S8092-0	Screw 3 × 16	2

Before the steps A, B and C

1. If Temperature option installed, remove 2 tapping screws (S8071-0) on the rear of the temperature case.
2. Disconnect Temperature wire to separate the temperature case from the rear case.
3. Remove 3 flat-head screws (S8070-0) on the bottom of the monitor.
4. Remove 5 screws (S8091-0, S8092-0) on the rear case.
5. Separate the front case from the rear case.
6. Carefully disconnect all cables running between cases: disconnect SMPS wire, NIBP cable, Printer wire, Speaker wire, Serial wire and NIBP hose.

Front Case Disassembly (A)

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

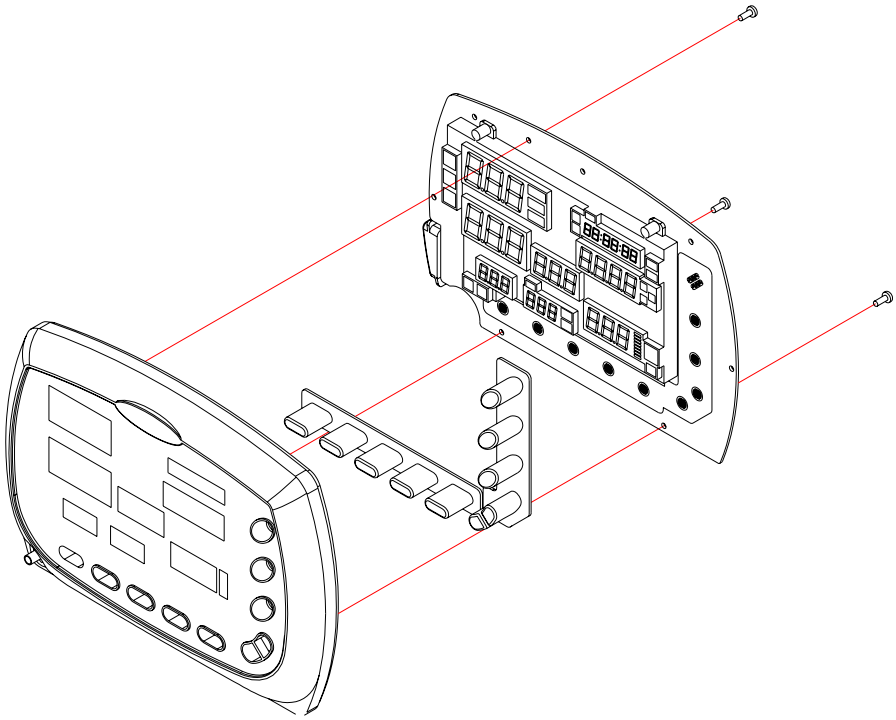


Figure 22. Front Case Disassembly

Table 13. Part Descriptions – Front Case Assembly

Part Codes	Descriptions	Qty
T0024-0	Front case	1
T1000-0	Rubber button vertical	1
T1001-0	Rubber button horizontal	1
-	Main BD ass'y	1
S8007-0	Screw 3 × 6	3

A1. Main BD disassembly

1. Remove the marked 3-point screw (S8007-0) on the Main BD.
2. Separate Main BD from the front case assembly.

A1-1. Rubber Button disassembly

1. After step A1, remove 2 rubber buttons (T1000-0, T1001-0) from Main BD.

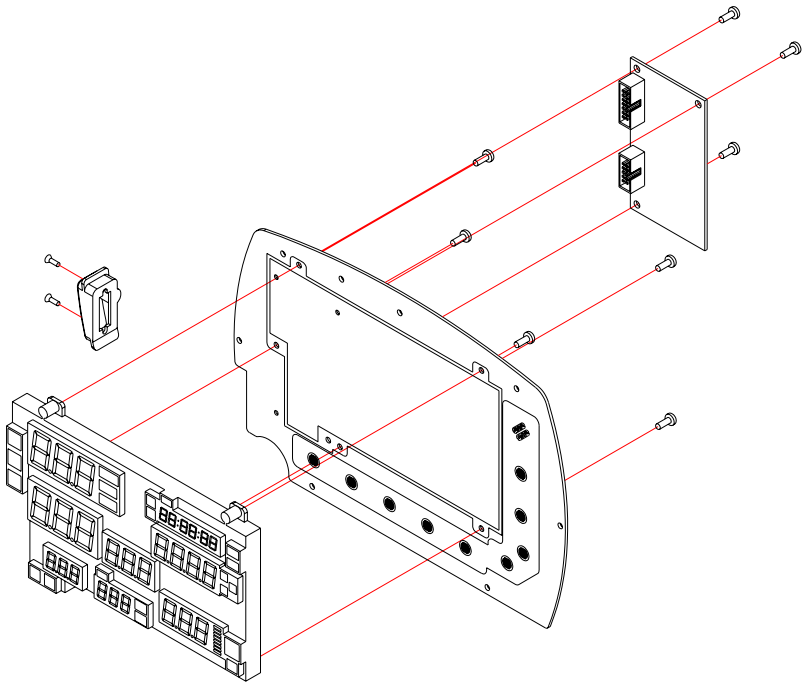


Figure 23. Main BD, SpO2, FND modules Disassembly

Table 14. Part Descriptions – Main BD, SpO2, FND Modules Assembly

Part Codes	Descriptions	Qty
M4019-0	FND module	1
T0025-0	SpO2 connector box	1
P1028-0	Main BD	1
M0001-0	SpO2 module	1
S8007-0	Screw 3 × 6	8
S8010-0	Screw 2.5 × 6 (flat-head)	2

A1-2. SpO2 module disassembly

1. After step A1, remove 3 screws (S8007-0) holding SpO2 module.
2. Remove SpO2 module.

A1-3. FND module disassembly

1. After step A1, remove 5 screws (S8007-0) holding FND module.
2. Remove FND module.

A2. SpO2 connector box disassembly

1. After step A1, remove 2 flat-head screws (S8010-0).
2. Remove SpO2 connector box.

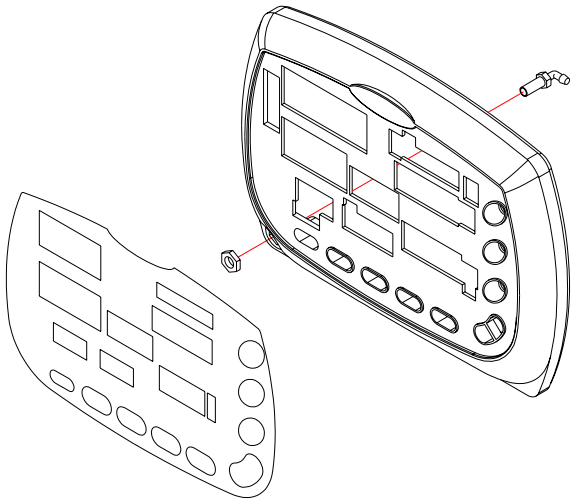


Figure 24. Front Case Disassembly – Overlay, NIBP cuff hose connector

Table 15. Part Descriptions – Overlay, NIBP Cuff Hose Connector

Part Codes	Descriptions	Qty
T0024-0	Front case	1
T8005-0 ~ T8012-0	Front overlay	1
T4104-0	NIBP cuff hose connector	1

A3. Overlay disassembly

1. After step A1, push out Overlay from the inside of the front case to remove.
2. Remove Overlay.

A4. NIBP cuff hose connector disassembly

1. After step A1, use a spanner to unfasten NIBP cuff hose connector.
2. Remove NIBP cuff hose connector.

Rear Case Disassembly

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

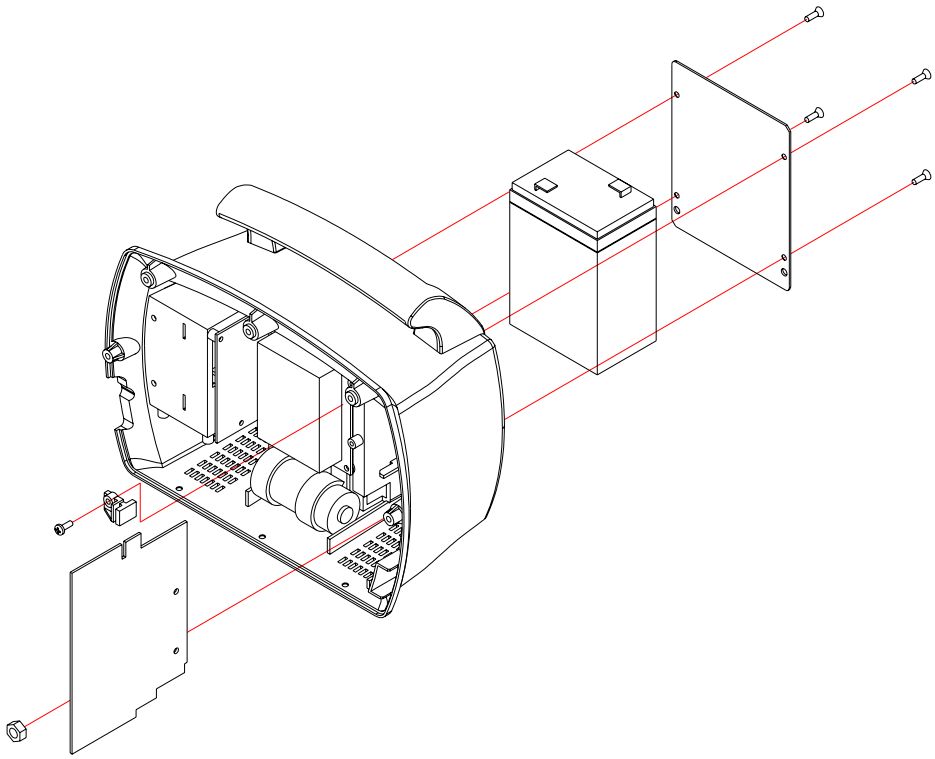


Figure 25. Rear Case Disassembly- Battery, SMPS

Table 16. Part Descriptions – Battery, SMPS Assembly

Part Codes	Descriptions	Qty
M2010-0	SMPS	1
T4108-0	GND bracket	1
T0029-0	SMPS holder	1
M6007-0	Lead acid battery	1
T4107-0	Battery cover	1
S8094-0	Screw 3 × 8 (small flat-head)	4
S8002-0	Screw 3 × 8 (with washer)	1

B2. SMPS disassembly

1. Remove 1 screw (S8002-0) located on the right top of SMPS.
2. Remove a nut holding GND bracket with 10mm box wrench
3. Pull out SMPS, and then separate SMPS holder from SMPS.

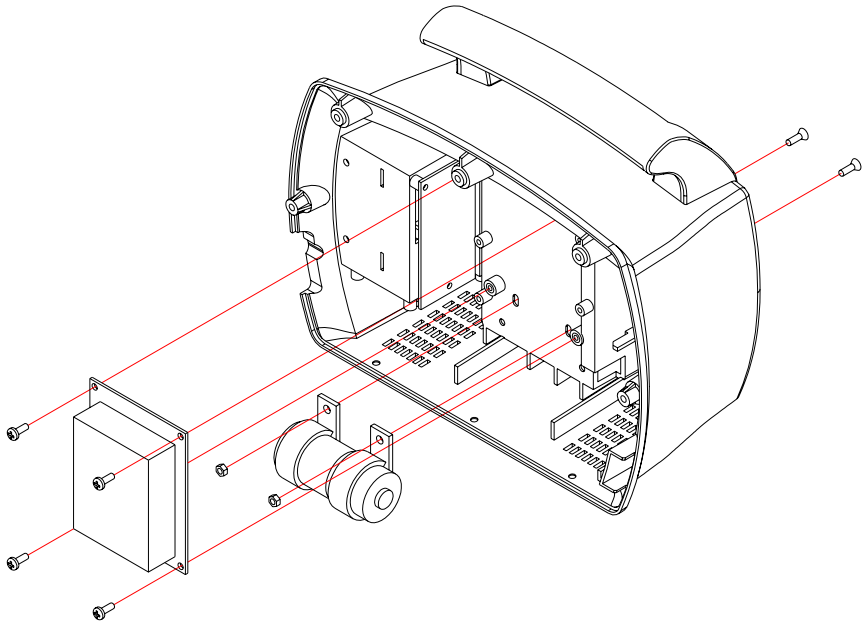


Figure 26. Rear Case Disassembly- NIBP module

Table 17. Part Descriptions – NIBP Module Assembly

Part Codes	Descriptions	Qty
M0005-0	NIBP module	1
S8007-0	Screw 3 × 6	4
S8070-0	Screw 3 × 8 (flat-head)	2
S8097-0	Nut M3	2

B3. NIBP module disassembly

1. Remove NIBP pump harness from the connector.
2. Remove 4 screws (S8007-0) holding NIBP module.
3. Remove NIBP module.
4. Remove 2 screws (S8070-0) and 2 nuts (S8097-0) fastening NIBP pump.
5. Remove NIBP pump.

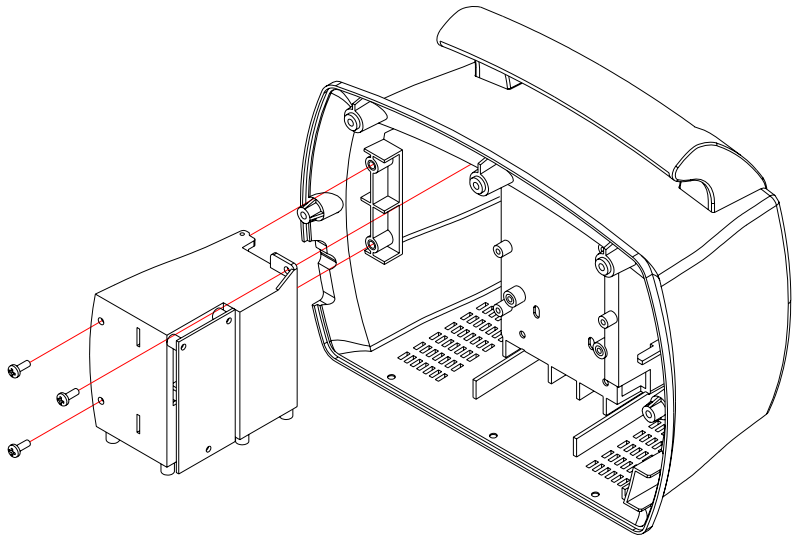


Figure 27. Rear Case Disassembly- Printer

Table 18. Part Descriptions – Printer Assembly

Part Codes	Descriptions	Qty
M4020-0	Printer	1
S8090-0	Screw 3 × 8	3 (1)
S8093-0	Screw 3 × 25	0 (2)

* ( ) refers to the number of required screws if a print option is not installed in.

B4. Printer disassembly

1. Remove 1 screw (S8090-0) holding on the right top of Printer.
2. Remove 2 screws (S8090-0) on the front side of Printer.
   * If no print option in, remove 2 screws (S8093-0) on the front side of Printer.
3. Open Printer door.
4. Pull out Printer to remove from the rear case assembly.

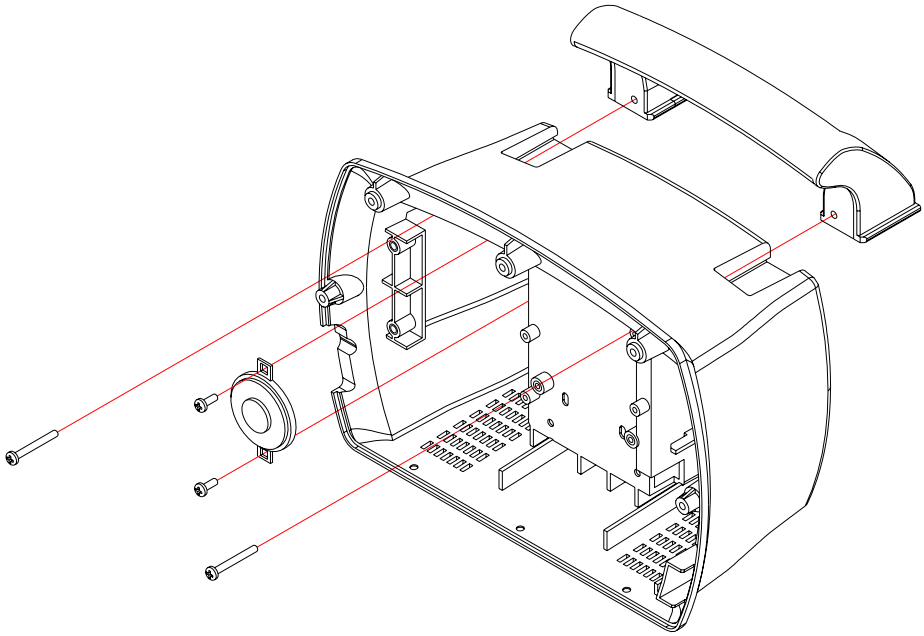


Figure 28. Rear Case Disassembly – Speaker, Handle, etc

Table 19. Part Descriptions – Speaker, Handle, etc Assembly

Part Codes	Descriptions	Qty
E9007-0	Speaker	1
T0027-0	Handle	1
S8066-0	Screw 3 × 5 (tapping)	2
S8096-0	Screw 3 × 25 (tapping)	2

B5. Speaker disassembly

1. After step B4, remove 2 screws (S8066-0) holding Speaker.
2. Remove Speaker.

B6. Handle disassembly

1. Remove 2 screws (S8096-0) fastening Handle.
2. Push Handle backward to separate from the rear case.

B7. Serial connector disassembly

1. Remove 2 nuts fastening Serial connector on the rear case with 5mm box wrench.
2. Remove Serial connector.

B8. GND terminal disassembly

1. After step B2, remove a nut holding GND terminal with 10mm box wrench.
2. Remove GND terminal.

Temperature Case Disassembly

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

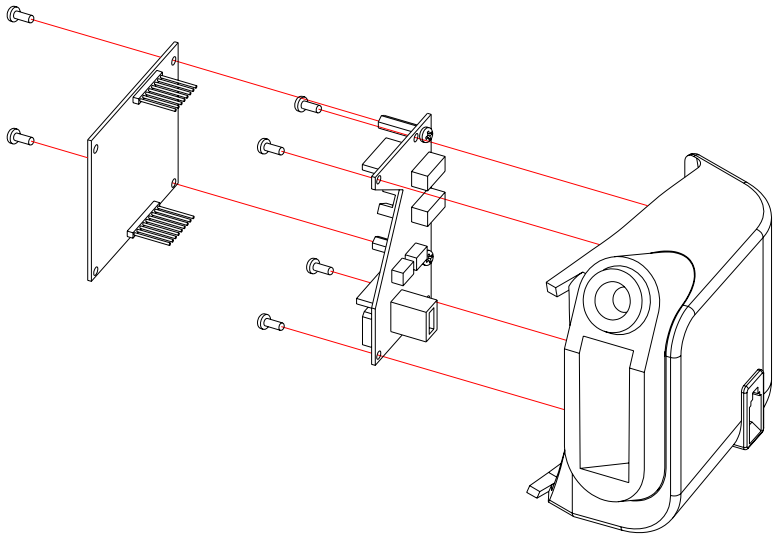


Figure 29. Temperature Case Disassembly – Temperature Module

Table 20. Part Descriptions – Temperature Module Assembly

Part Codes	Descriptions	Qty
P1029-0	Temperature BD	1
M0006-0	Temperature module	1
S8007-0	Screw 3 × 6	2
S8071-0	Screw 3 ×8 (tapping)	4

C1.Temperature module disassembly

1. Remove 2 screws (S8007-0) holding Temperature module.
2. Remove Temperature module.
3. Disconnect Temperature wire.
4. Remove 4 screws (S8071-0) fastening Temperature BD.
5. Remove Temperature BD.

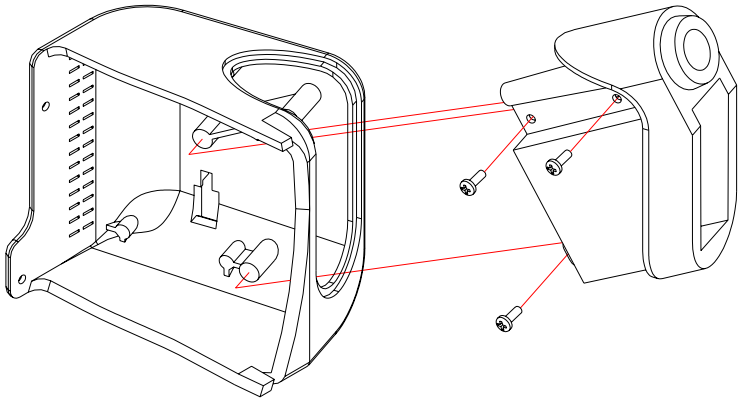


Figure 30. Temperature Case Disassembly

Table 21. Part Descriptions – Temperature Case Assembly

Part Codes	Descriptions	Qty
T0030-0	Temperature case	1
T0031-0	Temperature probe holder	1
S8090-0	Screw 3 × 8	2
S8002-0	Screw 3 × 8 (with washer)	1

C2. Temperature case disassembly

1. After step C1, remove 3 screws holding Temperature probe holder.
2. Remove Temperature probe holder from Temperature case.

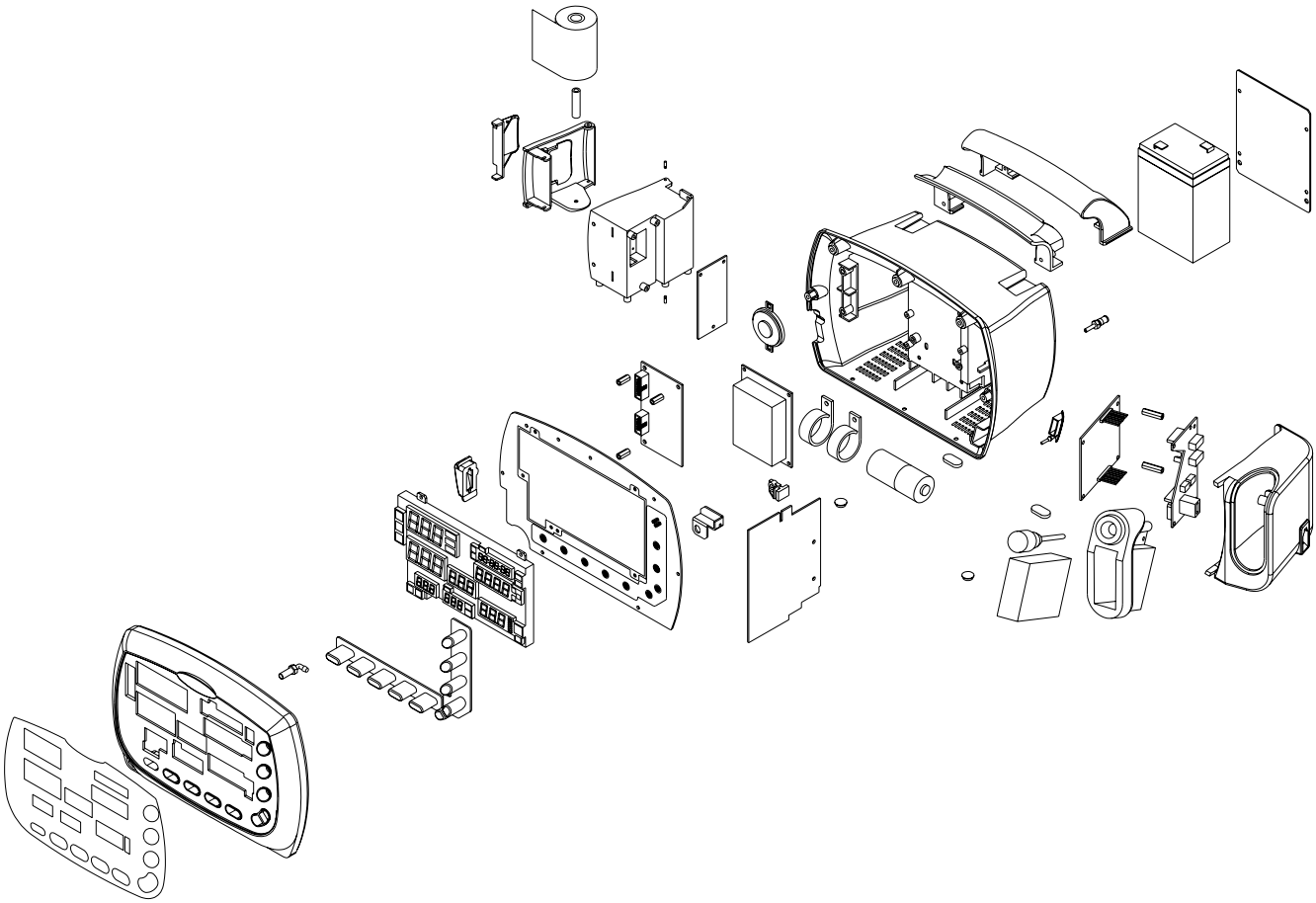


Figure 31. YM1000 Exploded View

Spare Parts

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

Introduction

Spare parts, along with part numbers, are shown in Table 21. “Item No.” corresponds to the circled callout numbers in Figure 8.

Obtaining Replacement Parts

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

Parts List

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

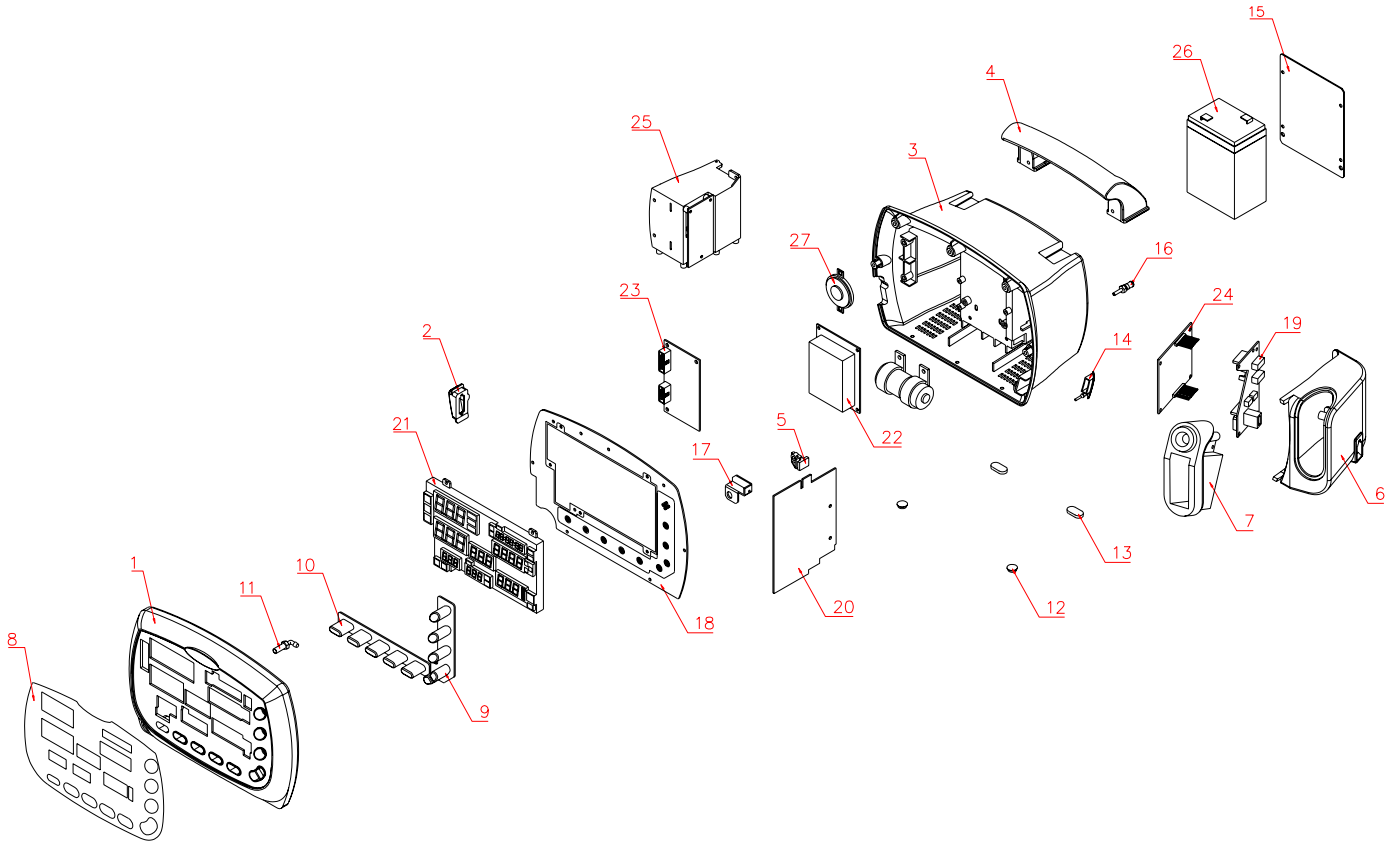


Figure 32. YM1000 Exploded View – Spare Parts

Table 22. YM1000 Parts List

No.	Part Code	Item
Cases		
1	T0024-2	Front case
2	T0025-0	SpO2 connector box
3	T0026-0	Rear case
4	T0027-0	Handle
5	T0029-0	SMPS holder
6	T0030-0	Temperature case
7	T0031-0	Temperature probe holder
Structure Components		
8	T8005-0	Front overlay / NST
8	T8006-0	Front overlay / NSTP
8	T8007-0	Front overlay / NS
8	T8008-0	Front overlay / NSP
8	T8009-0	Front overlay / NT
8	T8010-0	Front overlay / NTP
8	T8011-0	Front overlay / N
8	T8012-0	Front overlay / NP
9	T1000-0	Rubber button vertical
10	T1001-0	Rubber button horizontal
11	T4104-0	NIBP cuff hose connector
12	T1005-0	Rubber foot circular
13	T1006-0	Rubber foot oval
14	T1007-0	Temperature connector cover
15	T4107-0	Battery cover
16	T4003-0	GND terminal
17	T4108-0	GND bracket
Electrical Components		
18	P1028-2	Main BD
19	P1029-0	Temperature BD
20	M2010-1	SMPS
21	M4019-0	FND module
22	M0005-0	NIBP module
23	M0001-0	SpO2 module
24	M0006-0	Temperature module
25	M4020-0	Printer
26	M6007-0	Lead acid battery
27	E9007-0	Speaker
Harness		
-	W0107-0	SMPS wire / 8-pin
-	W0108-0	Battery wire / 5-pin
-	W0109-0	NIBP cable / 24-pin

No.	Part Code	Item
-	W0110-0	Serial wire / 9-pin
-	W0111-0	Temperature wire / 5-pin
-	W0112-0	Printer wire / 6-pin
Screws / Spacers		
-	S8007-0	Screw 3 × 6
-	S8090-0	Screw 3 × 8
-	S8002-0	Screw 3 × 8 (with washer)
-	S8091-0	Screw 3 × 12
-	S8092-0	Screw 3 × 16
-	S8093-0	Screw 3 × 25
-	S8010-0	Screw 2.5 × 6 (flat-head)
-	S8070-0	Screw 3 × 8 (flat-head)
-	S8094-0	Screw 3 × 8 (small flat-head)
-	S8066-0	Screw W 3 × 5 (tapping)
-	S8071-0	Screw 3 × 8 (tapping)
-	S8096-0	Screw 3 × 25 (tapping)
-	S8097-0	Nut M3

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 warranty. If the original shipping carton is not available, use another suitable carton; North American customers may call Mediana Technical Services to obtain a shipping carton.
Prior to shipping the monitor, contact your supplier or the Mediana office (Technical Services Department) for a returned goods authorization (RGA) number. Mark the shipping carton and any shipping documents with the returned goods authorization number.

Pack to shipping the monitor, contact your supplier or the Mediana office (Technical Services Department) for a returned goods authorization number. Mark the shipping carton and any shipping documents with the returned goods authorization (RGA) number. Return YM1000 by any method that provides proof of delivery.

Returning the YM1000

Contact Mediana Technical Services Department for shipping instructions, including a Returned Goods Authorization (RGA) number. Unless otherwise instructed by Mediana Technical Services Department, it is not necessary to return other accessory items with the monitor. Pack YM1000 in its original shipping carton. If the original carton is not available, use a suitable carton with appropriate packing material to protect it 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.
3. Label carton with shipping address, return address and RGA number, if applicable.

Repacking In a Different Carton

If the original carton is not available, use the following procedure to pack YM1000:

1. Place the monitor in a plastic bag.
2. Locate a corrugated cardboard shipping carton with at least 200 pounds per square inch (psi) bursting strength.
3. Fill the bottom of the carton with at least 2 inches 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.
6. Label the carton with the shipping address, return address, and RGA number, if applicable.

System Processing Description

System Overview
NIBP Processing
SpO2 Processing
Temperature Processing

System Overview

System Block Diagram

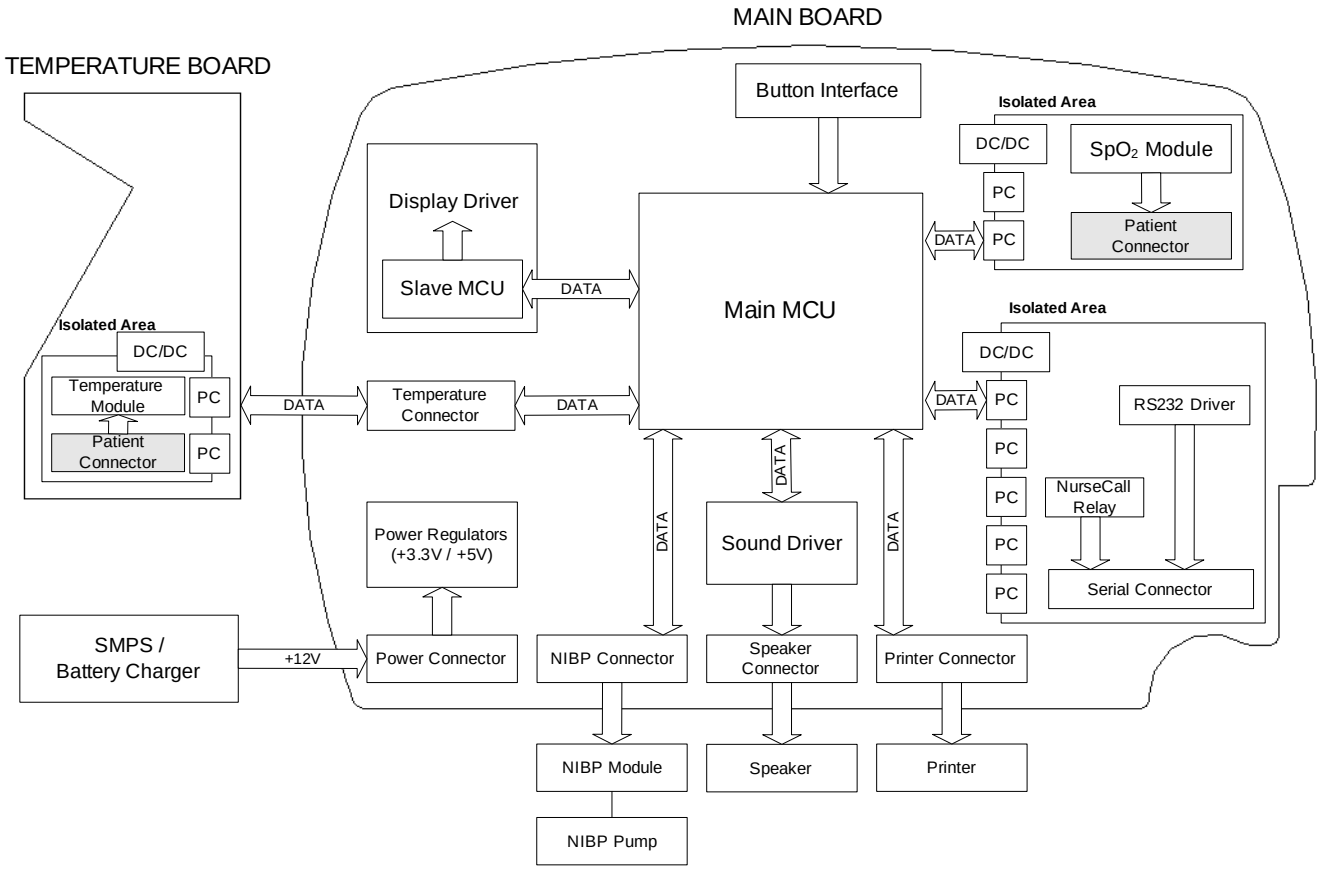


Figure 33. YM1000 System Block Diagram

YM1000 monitor is a multi-function the monitor for use on adult, pediatric and neonatal patients; non-invasive blood pressures, arterial oxygen saturation, pulse rate, and temperature.

In addition to the 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 error codes when conditions are detected that would degrade or prevent valid measurements;
- Creating and reviewing saved data/event;
- Providing input to an optional recorder for printout of data.

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

Unit Description

SMPS

The YM1000 allows the user to connect the monitor to AC power ranging from 100 volts AC to 240 volts AC. AC power enters directly the YM1000's Power Supply. A 2-amp fuse protects both the "Line" and "Neutral" lines. These user-non-accessible fuses are located on a fuse socket, which is part of the Power Supply located in the YM1000. The YM1000 uses a switch mode power supply (SMPS). This Power Supply provides the DC power needed to charge the battery and to power the Main Board. The output of the transformer varies, depending on load and input. High frequency noise from the AC line and from the Main Board is filtered before passing through the bridge rectifier. The bridge rectifier provides the DC power used in the YM1000. The positive output is 12 volts DC.

Battery Charger

The power supply will charge the battery any time YM1000 is connected to AC power even if the monitor is not turned on. The voltage applied to the battery is 7.5 ± 0.3 volts DC.

Battery

A lead-acid battery is used in the YM1000. It is rated at 6 volts DC, 4 amp hours. When new and fully charged, the battery will operate the monitor for 2 hours. A new battery will last 10 minutes from the time the low battery alarm is declared until the unit is shut down due to battery depletion. Recharging the battery to full capacity takes 12 hours. Changing from AC to battery power does not interrupt the normal monitoring operation of the YM1000.

Power Regulator

The Power Regulator receives the inputs from the SMPS, the Battery, and generates an appropriate power rate.

Main MCU

The Main MCU is the heart of the YM1000. The MCU is a Rabbit 3000. Rabbit 3000 manages each modules to generate signal outputs from data received on the base of the internal algorithm. The MCU controls sound generation, button check and SMPS operation. The Rabbit 3000 also communicates with NIBP Module, SpO_2 Module, Temperature Module, Printer, Display driver and Personal Computer.

Slave MCU
Slave MCU is Toshiba TMP86PM47U. Slave MCU is mainly used for display driver. Slave MCU checks on Battery voltage level to transfer the level to Main MCU, and also it controls SMPS function during Firmware downloading mode.

Button Interface
10 buttons including Power button interfaces Main board directly. Button access controls the monitor functions including power on/off, operating mode transition, alarm limit adjustment, alarm silence function, and etc.

Display Driver
Front panel display provides visual patient data and monitor status. At power up, all indicators are illuminated to allow verification of their proper operation. Display consists of FND Module. FND module is integrated with Display Drive IC, GM6486. FND module is able to display red, amber and/or green.
7-segments display patient measurement data, time and/or values. Pulse amplitude indicator displays in the format of 8-segments. The pulse amplitude indicator illuminates with each pulse beat. The number of segments illuminated indicates the relative signal strength of the pulse beat. Indicators are also located on the front panel display. Indicators are illuminated indicating a function that is active. Functions indicated by the Indicators are AC/battery status, alarm silence, patient type, NIBP & temperature unit and print mode.

Sound Driver
Sound frequency generated from Main MCU is transferred to output to the Speaker via LM386 audio amplifier. The gain of this amplifier changes sound level of volume as a resistor is adjusted.

NIBP Patient block
NIBP patient block measures NIBP data interfaced with WelchAllyn NIBP module POEM. More information about NIBP measurement theory is specified in NIBP Processing.

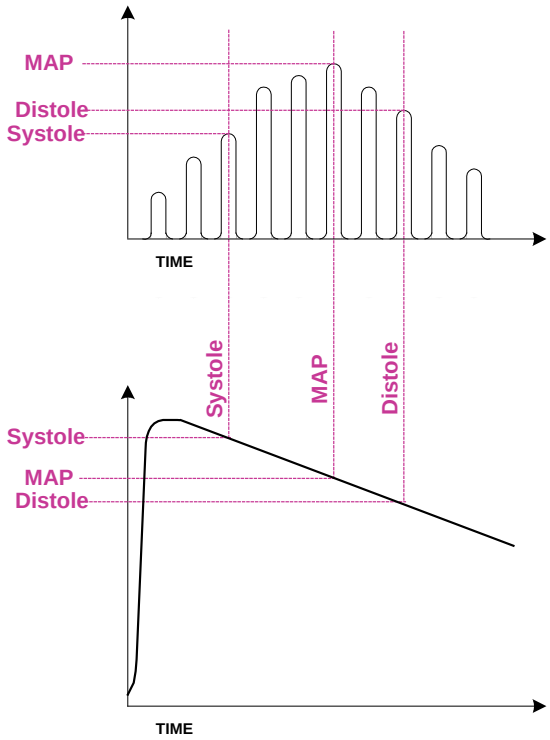
SpO_2 Patient block
SpO_2 patient block measures oxygen saturation data and pulse rate interfaced with Nellcor Oximetry module MP-506 / Nell-3. More information about Oximetry theory is specified in SpO_2 Processing.

Temperature Patient block
Temperature patient block measures Temperature data. interfaced with WelchAllyn Temperature module SureTemp. More information about Temperature measurement theory is specified in Temperature Processing.

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 and other artifact created by pressure valve, technical errors of electrical components, and the origin error of oscillometric method. The origin error of oscillometric comes from the basic theory of that the MAP is determined by the pulse. Therefore, there might be an error of the time between two pulses. In another words, the greatest amplitude point of pulses could not represent the MAP point exactly.

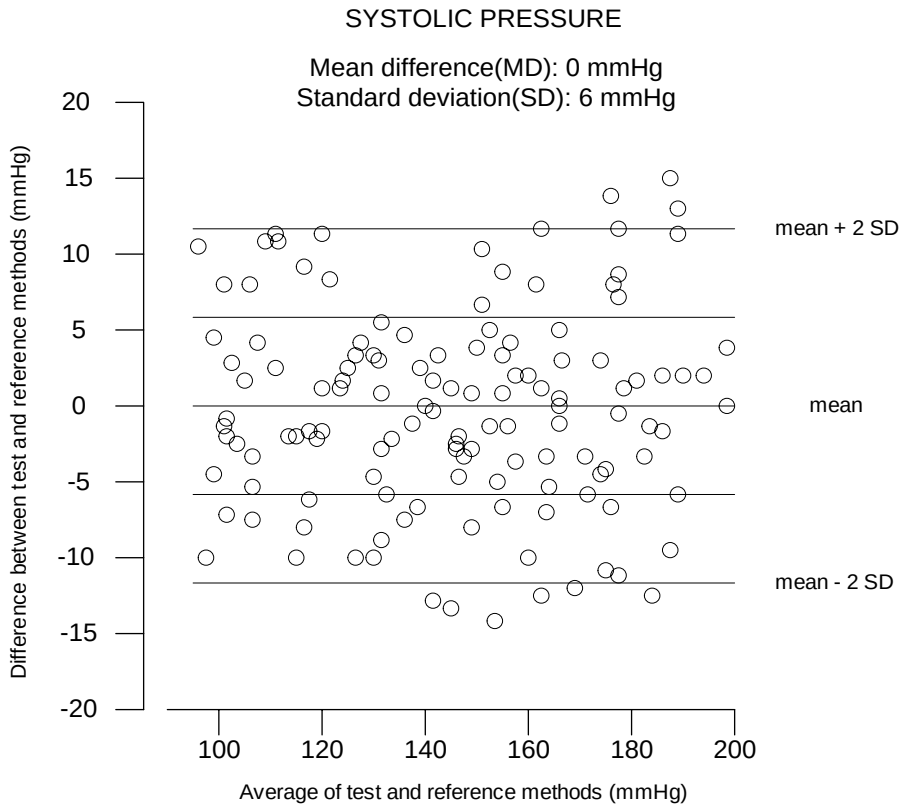
On clinical trial perspective, overall system accuracy is not easy to be determined. The clinical trial test protocols have been tried and have been described in many treatises, and international standards. So, there are many methods to determine the overall system accuracy of Automated Sphygmomanometer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

The popular standard for the overall system accuracy is AAMI, SP-10 1992; 1996 (Electronic or automated sphygmomanometers).

The main test conditions are as follow:

A. Data comparing the Intra-arterial or the auscultatory by the clinical experts with the automated sphygmomanometer.
B. For data collection and the 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

Overview

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.

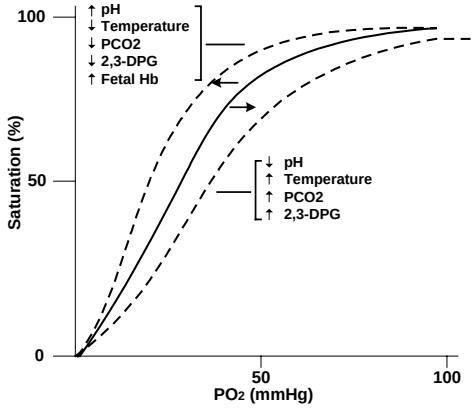
Pulse oximetry is based on two principles: that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), and that the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography). The monitor 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 *OXIMAX* 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

Because light absorption by hemoglobin is wavelength dependent and because the mean wavelength of LEDs varies, an oximeter must know the mean wavelength of the OXIMAX sensor's red LED to accurately measure SpO_2. During the 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.

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.



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:

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

Temperature Processing

Overview

Patient temperature can be measured via an oral/axillary, rectal, or skin surface probe. A predictive algorithm in conjunction with the thermistor based thermometer is used for fast temperature or monitoring temperature.

Predictive temperature

Thermometers that render a temperature reading before steady state is achieved are classified as predictive thermometers. Predictive thermometers reduce the time required for measurement by using algorithms to "predict" what the temperature would be if the probe were left in place until steady state is achieved.

Monitor temperature

A function or mode of an electronic thermometer used to continuously monitor temperature until it reached the thermal steady state (unchanging). The thermal steady state is achieved orally in approximately 3 minutes, and axillary in approximately five minutes.

Measuring Principle

The YM1000 temperature probe utilizes a negative temperature coefficient (NTC) thermistor and control circuitry in combination with the temperature module's predictive algorithm to calculate patient temperatures.
NTC thermistors have a large temperature coefficient of resistance and change in resistance as temperature changes. This predictable change in resistance is the basis for predictive thermometry.
The Oral/axillary probe is pre-warmed to approximately 34℃ (94°F). The probe warming process is a closed loop feedback control system incorporating pulse width modulation (PWM) control. The probe warmer circuitry is used to heat the probe tip prior to taking a temperature reading in order to speed the convergence of the prediction algorithm. A fail safe hardware shut off circuit is included to ensure the heater will shut down in the event of a software failure.

- When the probe is first extracted and colder than 33.9℃, the heater pulse widths are at a maximum percentage On vs Off to warm the probe quickly.
- When the probe reached 33.9℃, the pulse widths narrow to a duty cycle just enough to maintain temperature.
- When the probe is placed in the mouth, the heat supplied by the mouth makes the pulse widths reduce to zero. This reduction to zero (and probe being at least up to 33.1℃ (91.6°F) triggers the start of the prediction algorithm.

The shape of the rising temperature curve is monitored and the best fit to a curve is found. When the curve fit is stable, the final predicted temperature is provided.