BeneView T1

Patient Monitor

Service Manual

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Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change. Contents of this manual are subject to change without prior notice.

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- Release time: Novermber 2011

Preface

Manual Purpose

This manual provides detailed information about the assembling, dissembling, testing and troubleshooting of the equipment to support effective troubleshooting and repair. It is not intended to be a comprehensive, in-depth explanation of the product architecture or technical implementation. Observance of the manual is a prerequisite for proper equipment maintenance and prevents equipment damage and personnel injury.

Intended Audience

This manual is for biomedical engineers, authorized technicians or service representatives responsible for troubleshooting, repairing and maintaining the monitors

Passwords

A password may be required to access different modes. The passwords are listed below:

- User maintenance: 888888
- Manage Configuration: 315666
- Factory maintenance: 332888
- Demo mode: 2088

Contents

FOR YOUR NOTES

1 Safety

1.1 Safety Information

⚠DANGER

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

⚠WARNING

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.**

⚠CAUTION

- **Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.**

NOTE

- **Provides application tips or other useful information to ensure that you get the most from your product.**

1.1.1 DANGER

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

1.1.2 Warnings

⚠WARNING

- **All installation operations, expansions, changes, modifications and repairs of this product are conducted by authorized personnel.**
- **Disconnect the patient monitor from external power source and remove the battery before disassembling the equipment.**
- **When you disassemble/reassemble a parameter module, a patient leakage current test must be performed before it is used again for monitoring.**
- **The equipment must be connected to a properly installed power outlet with protective earth contacts only. If the installation does not provide for a protective earth conductor, disconnect it from the power line and operate it on battery power, if possible.**
- **Dispose of the package material, observing the applicable waste control regulations and keeping it out of children's reach.**

1.1.3 Cautions

⚠CAUTION

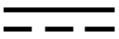
- **Make sure that no electromagnetic radiation interferes with the performance of the equipment when preparing to carry out performance tests. Mobile phone, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or in this manual.**
- **Protect the equipment from damage caused by drop, impact, strong vibration or other mechanical force during servicing.**

1.1.4 Notes

NOTE

- **Refer to Operation Manual for detailed operation and other information.**

1.2 Equipment Symbols

	Attention: Consult accompanying documents (this manual).		Power ON/OFF (for a part of the equipment)
	Battery indicator		External power supply
	Multifunctional connector		External device connector
	ESD warning symbol for Electrostatic sensitive devices.		Network connector
	Manufacture date		Serial number
	Type CF applied part. Defibrillator-proof protection against electric shock.		
	Type BF applied part. Defibrillator-proof protection against electric shock.		
	The product bears CE mark indicating its conformity with the provisions of the Council Directive 93/42/EEC concerning medical devices and fulfils the essential requirements of Annex I of this directive.		
	European community representative		
	Dispose of in accordance to your country’s requirements		

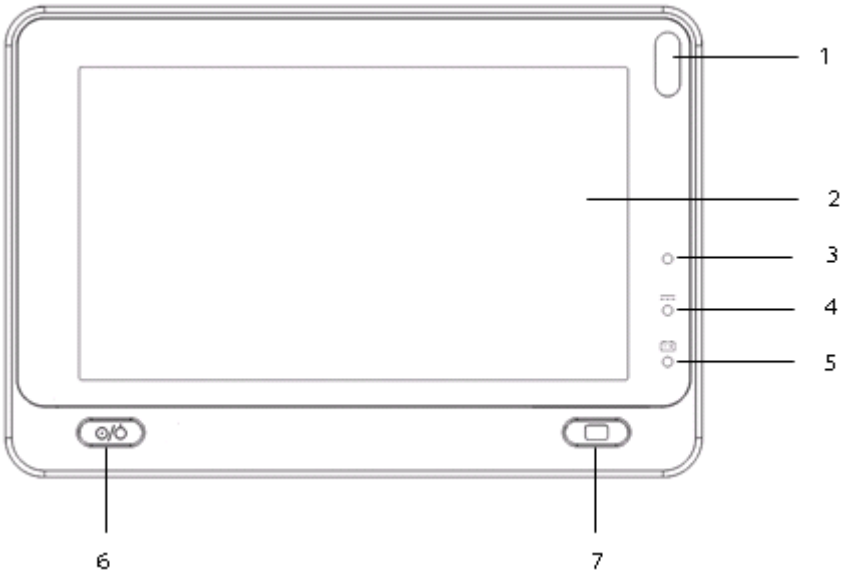
FOR YOUR NOTES

2 Theory of Operation

2.1 Introduction

The BeneView T1 is intended to be used for monitoring, displaying, reviewing, storing and transferring of multiple physiological parameters including ECG, respiration (Resp), temperature (Temp), SpO_2, pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), cardiac output (C.O./PiCCO), and carbon dioxide (CO_2) of single patient.

2.1.1 Front View



1. Alarm lamp

   The Alarm lamp flashes in different color and frequency to match the alarm level.

2. Display Screen

3. Ambient light sensor

   When [**Brightness**] is set to [**Auto**], the system automatically adjusts screen brightens according to the strength of ambient light.

4. External power supply indicator

   - On: when external DC power supply is connected.
   - Off: when external DC power supply is not connected.

5. Battery indicator

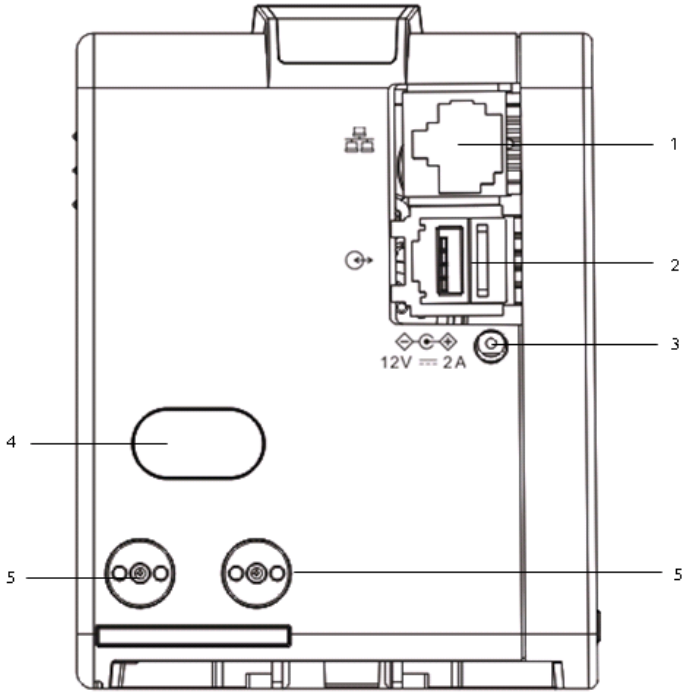
   - On: when the battery is installed and the external DC power supply is connected.

- Off: when no battery is installed, or the installed battery is malfunction, or no external DC power supply is connected when the patient monitor is power off.
- Flash: when the patient monitor operates on battery power.

6. Power On/Off Switch
   - Pressing this switch turns the patient monitor on.
   - When the monitor is on, pressing and holding this switch turns the monitor off.

   An indicator is built in this switch. It turns on when the patient monitor is on and turns off when the patient monitor is off.
7 Lock/unlock switch:
   Sliding this switch rightwards can lock/unlock the touch screen.

2.1.2 Left View



1. Network Connector

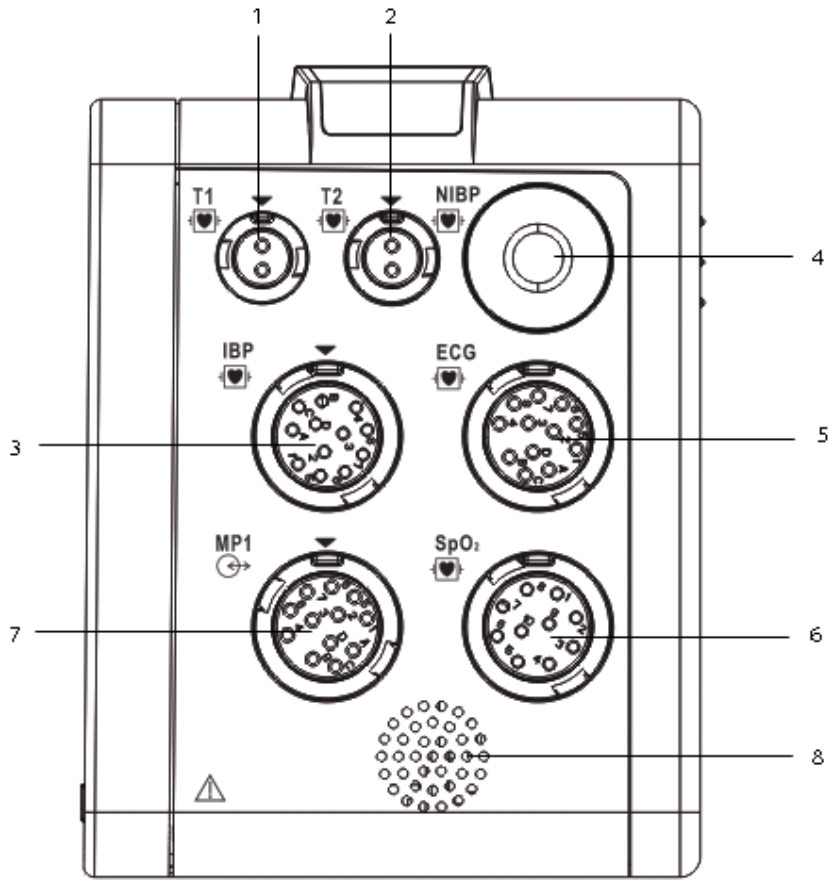
   It is a standard RJ45 connector that connects the patient monitor to the CMS or CIS.
2. External device connector: connects a USB drive.
3. External DC power supply connector
4. Infrared filter

   It is used for communication between T1 and Mindray BeneVeiw monitor.
5. Contact

NOTE

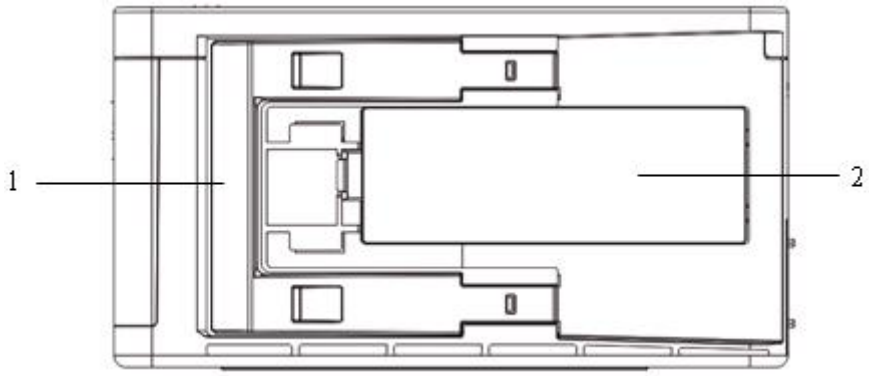
- **To ensure a good contact, clean the contacts regularly, as dust and dirt may collect on them. When cleaning the contacts, wipe them with cotton, dampened with alcohol. (using forceps is recommended)**

2.1.3 Right View



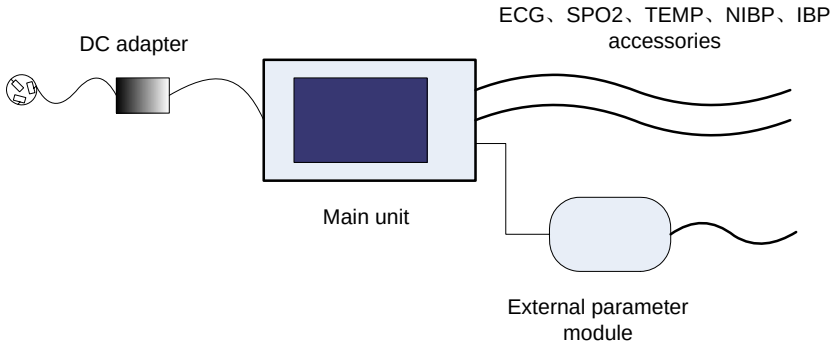
1. Connector for Temp probe 1
2. Connector for Temp probe 2
3. Connector for IBP cable
4. Connector for NIBP cuff
5. Connector for ECG cable
6. Connector for SpO_2 cable
7. Multifunctional connector, connecting external parameter module and outputting analog out and defib synchronization signal.
8. Speaker

2.1.4 Bottom View



1. Latch: locks T1 when T1 is in use with a BeneView patient monitor or the monitor handle. Pressing here releases T1 so that you can take it out from the host monitor or the monitor handle.
2. Battery door

2.2 System Structure

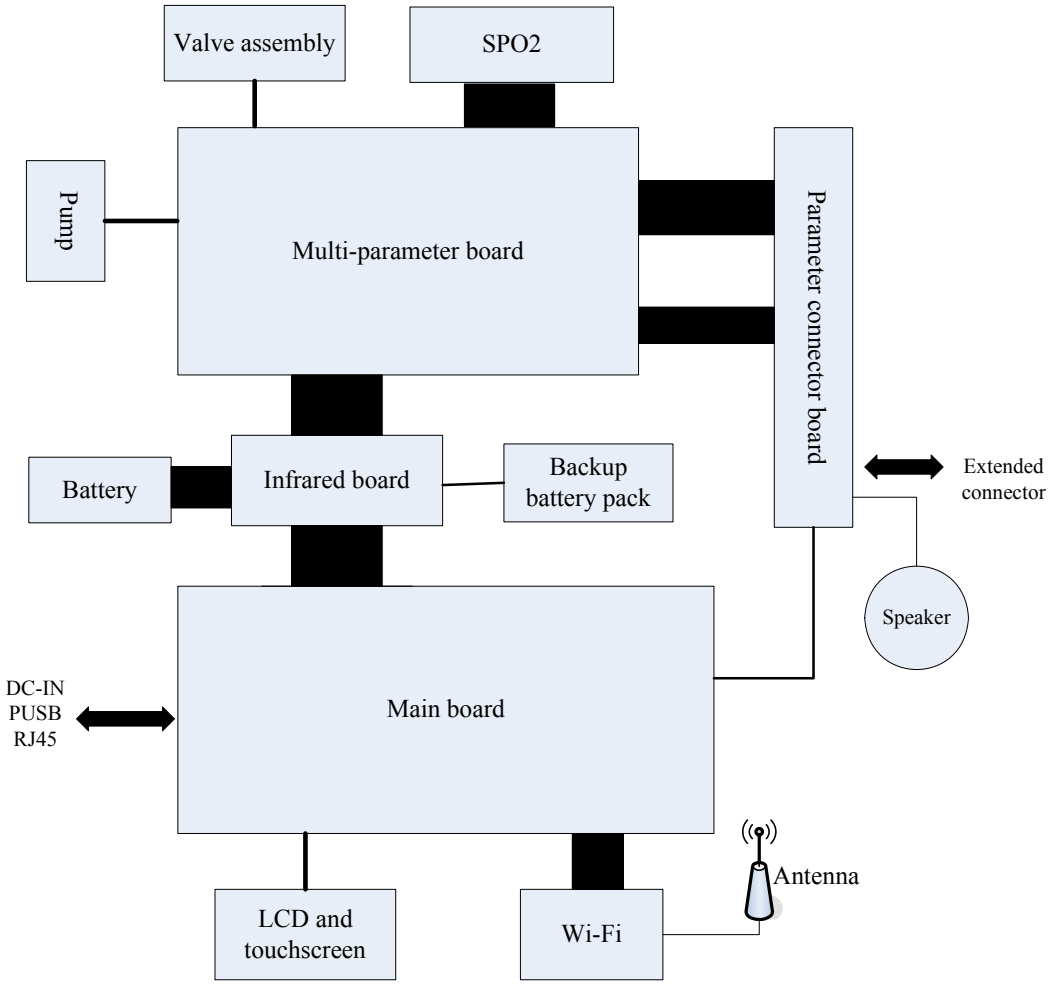


The equipment consists of the DC adapter, main unit, external parameter modules, and accessories.

The DC adapter converts AC power into DC power, and the accessories convert the physiological signals collected from human body into electric signals. This chapter describes the structure of the main unit and external parameter modules.

2.2.1 Main Unit

The following figure shows the main unit architecture of T1.



Note: In this figure, the black blocks are hard wired while the others are flexible wired.

2.2.1.1 Main Board

The main board is the core of control over the entire system. It also implements DC/DC conversion and power management. The main functions of the main board are:

1. Implementing display drive, audio drive, Wi-Fi drive, and touch screen drive;
2. Implementing network communication, data storage, serial port extension, button scanning, and DC/DC conversion;
3. Controlling power on/off, alarm indicating lamp, backlight, and fan;
4. Managing multi-parameter subsystem, smart battery, external parameter modules;
5. Detecting whether the battery is on position;

6. Exchanging data with the infrared communication backboard;,
7. Controlling the power supply to peripheral devices, such as screen backlight, digital drive of the screen, and Wi-Fi; turning off these devices individually or switching them into low power consumption mode.

2.2.1.2 Multi-parameter Board

The multi-parameter board provides the following functions:

1. ECG and Resp measurement;
2. SpO2 measurement (by backboard, supporting Mindray SpO2, Masimo SpO2, and Nellcor SpO2 modules);
3. NIBP measurement;
4. 2-channel TEMP measurement;
5. 2-channel IBP measurement;
6. Isolating the parameter modules, except NIBP, from the earth;
7. Isolating ECG from other parameters;
8. Analog output (one channel for ECG and two channels for IBP);
9. Defib sync output; and,
10. Data exchange with the main board through the serial ports.

2.2.1.3 Parameter Connector Board

The parameter connector board provides the following functions:

1. ECG signal isolation and transmission;
2. SpO2 signal transmission;
3. TEMP signal transmission;
4. IBP signal transmission;
5. Speaker transmission; and,
6. Analog output transmission.

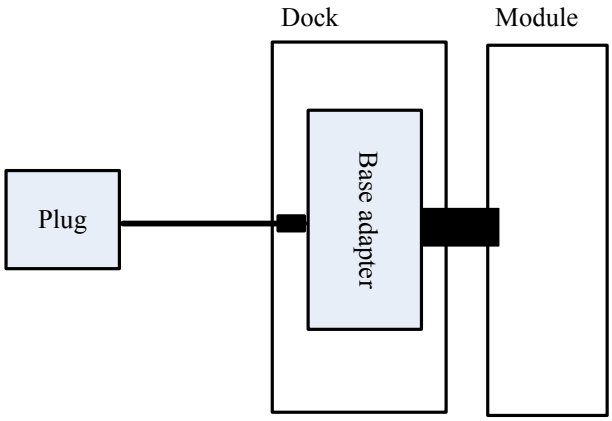
2.2.1.4 Infrared Communication Backboard

The infrared communication backboard implements infrared communication and transmits signals between the multi-parameter board and the main board.

2.2.1.5 Wi-Fi Module

The Wi-Fi module supports wireless network that is compatible with 802.11 b/g standard.

2.2.2 External Parameter Modules



The extended parameter module consists of a module and a dock.
T1 has five kinds of external parameter modules. When connecting with the main unit, the external parameter module should be in use with the dock. The dock for the five different external parameter modules is the same.

2.2.2.1 Dock Adapter

Together with the module adapter, the dock adapter implements electric connection between the dock and the module. The dock adapter provides the following functions:

1. Converting 232 level to TTL level;
2. Realizing module on-position detection. Power is output only when there is a module on the dock.

2.2.2.2 External Parameter Modules

The equipment can be configured with the following external parameter modules:

- Sidestream CO_2 module;
- Microstream CO_2 module;
- Mainstream CO_2 module;
- C.O. module; and,
- PiCCO module.

FOR YOUR NOTES

3 Unpacking and Installation

This chapter provides information you need to install a patient monitor ready for use.

3.1 Unpacking the Equipment

Open the package and take out the packing list. Check that all the articles included in the packing list are available and the quantity and specification are correct.

- All the optional parts purchased by the customer shall also be checked.
- Notify the supplier if provided components are not correct as compared to the packing list.
- In case of damage during transportation, keep the packing material and notify the supplier immediately.
- Keep the packing material till the equipment is accepted.

3.2 Preparation for Installation

3.2.1 Preparation for Installation Site

1. Ensure that the site meets all safety, environmental and power requirements
2. Check that required power sockets are available.
3. Check that a network connector is available if the monitor needs to be connected to the wired network.

⚠ WARNING

- **Use only DC adapter provided with the system.**

Environmental Requirements

To avoid explosion hazard, do not use the equipment in the presence of flammable anaesthetics, vapours or liquids. The environment where the monitor will be used should be reasonably free from vibration, dust and corrosive substances. If these conditions are not met, the accuracy of the system may be affected and damage may occur.

The environmental specification is as follows:

Main unit		
Item	**Operating conditions**	**Storage conditions**
Temperature (℃)	0 to 40	-30 to 70
Relative humidity (noncondensing)	15% to 95%	10% to 95%
Barometric (kPa)	57.0 to 107.4	16.0 to 107.4

Microstream CO_2 module		
Item	**Operating conditions**	**Storage conditions**
Temperature (℃)	0 to 40	-20 to 60
Relative humidity (noncondensing)	15% to 95%	10% to 95%
Barometric (mmHg)	57.3 to 105.3	57.3 to 105.3

Sidestream CO_2 module		
Item	**Operating conditions**	**Storage conditions**
Temperature (℃)	5 to 40	-20 to 60
Relative humidity (noncondensing)	15% to 95%	10% to 95%
Barometric (mmHg)	57.3 to 105.3	57.3 to 105.3

Mainstream CO_2 module		
Item	**Operating conditions**	**Storage conditions**
Temperature (℃)	0 to 40	-20 to 60
Relative humidity (noncondensing)	15% to 90%	10% to 90%
Barometric (mmHg)	57.0 to 107.4	53.3 to 107.4

C.O. module		
Item	**Operating conditions**	**Storage conditions**
Temperature (℃)	0 to 40	-20 to 60
Relative humidity (noncondensing)	15% to 95%	10% to 95%
Barometric (mmHg)	57.0 to 107.4	16.0 to 107.4

PiCCO module		
Item	**Operating conditions**	**Storage conditions**
Temperature (℃)	10 to 40	-20 to 60
Relative humidity (noncondensing)	15% to 75%	10% to 90%
Barometric (mmHg)	57.0 to 107.4	16.0 to 107.4

Battery charger		
Item	**Operating conditions**	**Storage conditions**
Temperature (℃)	0 to 40	-20 to 60
Relative humidity (noncondensing)	15% to 95%	10% to 95%
Barometric (mmHg)	57.0 to 107.4	16.0 to 107.4

NOTE

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

3.2.2 Electrical Requirements

This patient monitor is connected to external power supply through a DC adapter. Only power sockets with protective grounding can be used. Make sure that:

1. All cables and connectors are not damaged, and pins are not loose. Otherwise, remove it from use.
2. The insulation of patient cables and leadwires is not damaged, and connectors are not loose.

The electrical specification of the DC adapter is as follows:

Line voltage	100 to 240 VAC (±10%)
Current	0.6 to 0.4 A
Frequency	50/60 Hz

3.3 Monitor Installation

Refer to ***3.14 Installing the Monitor, BeneView T1 Operating Manual.***.

3.4 Preparation for Power On

1. Before you start the patient monitor, check the patient monitor and make sure that all external cables, plug-ins and accessories are properly connected.
2. Connect the monitor with the DC adapter. If you run the patient monitor on battery power, ensure that the battery is sufficiently charged.
3. Press the power on/off switch on the monitor's front.

4 Hardware and Software Upgrade

4.1 Hardware Upgrade

Only monitors configured with Mindray ECG algorithm can be upgraded with the following hardware upgrade packages. The monitor's ECG algorithm configuration remains unchanged after hardware upgrade.

4.1.1 Upgrade Package

Upgrade package	Monitor config. before upgrade	Description of upgrade package	PN of upgrade package
IBP	Mindray SpO2+5-lead Mindray ECG algorithm	IBP upgrade package (Mindray SpO2+5-lead Mindray ECG algorithm)	801-9281-00013-00
	Nellcor SpO2+5-lead Mindray ECG algorithm	IBP upgrade package (Nellcor SpO2+5-lead Mindray ECG algorithm)	801-9281-00014-00
	Masimo SpO2+5-lead Mindray ECG algorithm	IBP upgrade package (Masimo SpO2+5-lead Mindray ECG algorithm)	801-9281-00015-00
	Mindray SpO2+12-lead Mindray ECG algorithm)	IBP upgrade package (Mindray SpO2+12-lead Mindray ECG algorithm)	801-9281-00016-00
	Nellcor SpO2 12-lead Mindray ECG algorithm	IBP upgrade package (Nellcor SpO2 12-lead Mindray ECG algorithm)	801-9281-00017-00
	Masimo SpO2+12-lead Mindray ECG algorithm	IBP upgrade package (Masimo SpO2+12-lead Mindray ECG algorithm)	801-9281-00018-00
12-lead ECG	/	12-lead Mindray ECG algorithm upgrade package	801-9281-00022-00
IBP+12-lead ECG	Mindray SpO2	IBP+12-lead Mindray ECG algorithm upgrade package (Mindray SpO2)	801-9281-00019-00

Upgrade package	Monitor config. before upgrade	Description of upgrade package	PN of upgrade package
	Nellcor SpO2	IBP+12-lead Mindray ECG algorithm upgrade package (Nellcor SpO2)	801-9281-00020-00
	Masimo SpO2	IBP+12-lead Mindray ECG algorithm upgrade package (Masimo SpO2)	801-9281-00021-00
Wi-Fi	/	Wi-Fi upgrade package	801-9281-00023-00

4.1.2 Hardware Upgrade Method

4.1.2.1 Upgrading the Monitor to Have IBP Function

When upgrading the monitor to have IBP monitoring function, please use the parameter board and parameter connector panel assembly in the upgrade package to replace the original parameter board and parameter connector panel assembly. To upgrade the monitor:

1. Refer to ***7.3.2.2Disassembling the parameter board (Mindray SPO2/Nellcor SPO2/Masimo SPO2)*** and ***7.3.3.2 Removing the Parameter Connector Panel Assembly*** to remove the parameter board and parameter connector panel assembly.
2. Use the parts in the upgrade package to replace the original parameter board and parameter connector panel assembly.
3. Reassemble the monitor.
4. Turn on the monitor, and then select [**Main Menu**]→[**Maintenance>>**]→[**Factory Maintenance>>**]→enter the required password→[**Device Configuration**], and then select[**IBP1/IBP2**].

5 Refer to ***5.4Module Performance Tests*** to test the monitor.

4.1.2.2 Upgrade the Monitor to Have 12-lead ECG Function

Refer to ***4.1.2.1Upgrading the Monitor to Have IBP Function***, use the parameter board in the upgrade package to replace the original parameter board.

4.1.2.3 Upgrade the Monitor to Have 12-lead ECG Function and IBP monitoring Function

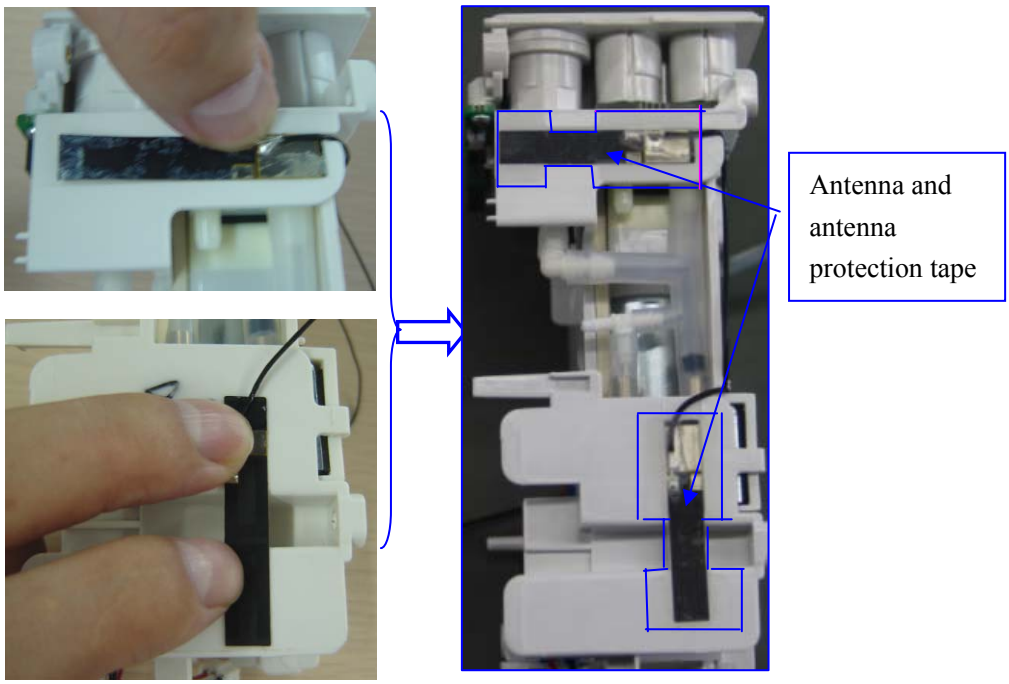
Refer to ***4.1.2.1Upgrading the Monitor to Have IBP Function***, u use the parameter board and parameter connector panel assembly in the upgrade package to replace the original parameter board and parameter connector panel assembly.

4.1.2.4 Upgrade the Monitor to Have Wi-Fi Function

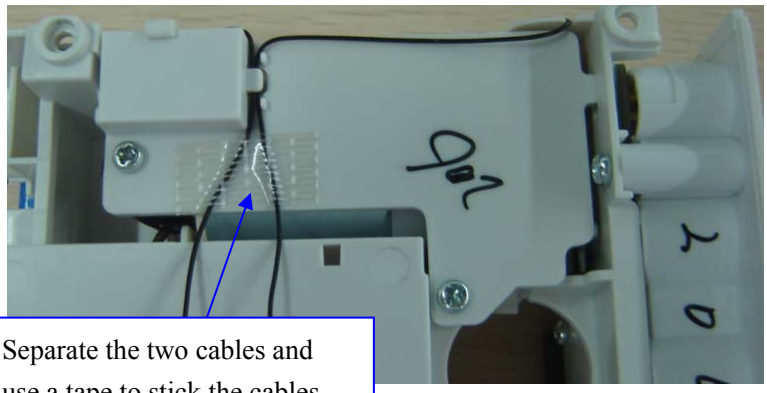
When upgrading the monitor to have Wi-Fi function, you need to assembly the Wi-Fi module (Cyberlink module PCBA) and the antenna in the upgrade package to the monitor. To upgrade the monitor:

1. Refer to 7.3.3 Disassembling the Front Housing Assembly to separate the front housing assembly and the main frame assembly.
2. Stick the antenna in the antenna slot in the main frame, and then apply the antenna protection tape on the antenna.

   The antenna should be stick to the antenna slot as indicated in the following picture. Protect the antenna from being damaged during assembling the antenna. The antenna should not bent or twist in the slot. When the antenna is in place, press the protection tape to make sure the antenna is tightly secured on the main frame.



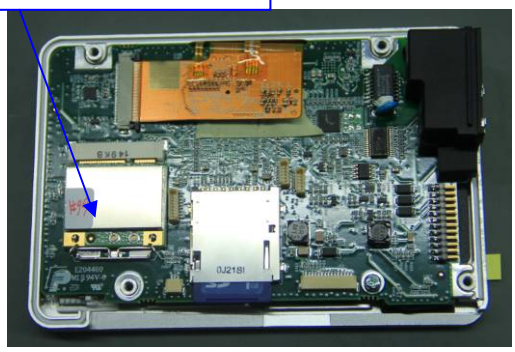
3. Route the antenna cables and fix the cables in the cable holder, and then separate the two cables and use a tape to stick the cables on the main frame. Press the tape to make sure the cables are tightly secured on the main frame.



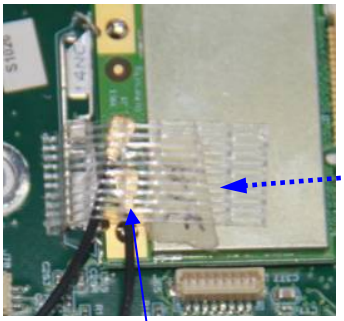
Separate the two cables and use a tape to stick the cables on the main frame

4. Install the Cyberlink module PCBA in the socket on the main board.

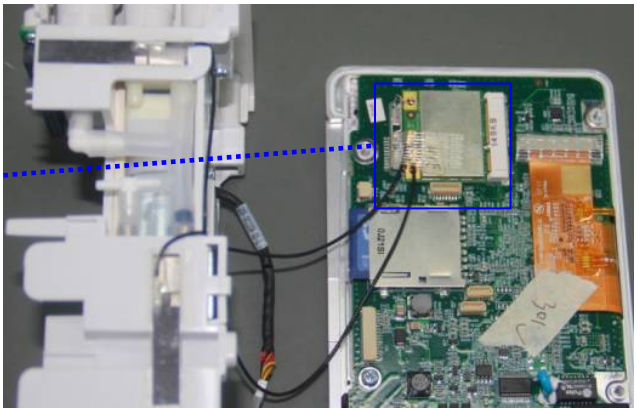
Cyberlink module PCBA



5. Insert the antenna plugs in the Wi-Fi sockets (socket on the left for the cable on the left and socket on the right for the cable on the right). Stick the antenna plug with a tape and press the tapes to tightly secure the plugs.



Use a tape to secure the antenna plugs



6. Route the cables and then reassemble the monitor.
7. Turn on the monitor, and then select [**Main Menu**]→[**Maintenance>>**]→[**User Maintenance>>**]→enter the required password→[**Network Setup>>**], and set set[**Network Type**] to [**WLAN**]. Test if the Wi-Fi function operates properly.

4.2 Software Upgrade

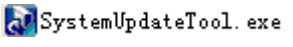
You can upgrade system software and module software by running the ***Mindray Patient Monitor Software Upgrade Tool (PN: 110-000493-00)*** on a PC. Through this tool, you can also view software upgrade log. By connecting the monitor to be upgraded and a PC running the upgrade tool to the same network or directly connect the monitor and the PC via a crossover network cable, you can upgrade the following software:

- System software package (PN: 110-002038-00)
- Power management software (PN: 110-001798-00)
- Parameter module software, including
  - Multi-parameter module software: Mindray ECG board software (PN: 110-001839-00), Mortara ECG board software (PN: 110-001978-00),
  - Mindray SpO2 board software (PN: 110-001842-00),
  - External module adapting board software (PN: 110-001994-00),
  - Sidestream CO2 module software (PN: 110-001838-00),
  - C.O. module software (PN: M03B-30-86661), and
  - PiCCO module software (PN: 110-001206-00, 110-001207-00).

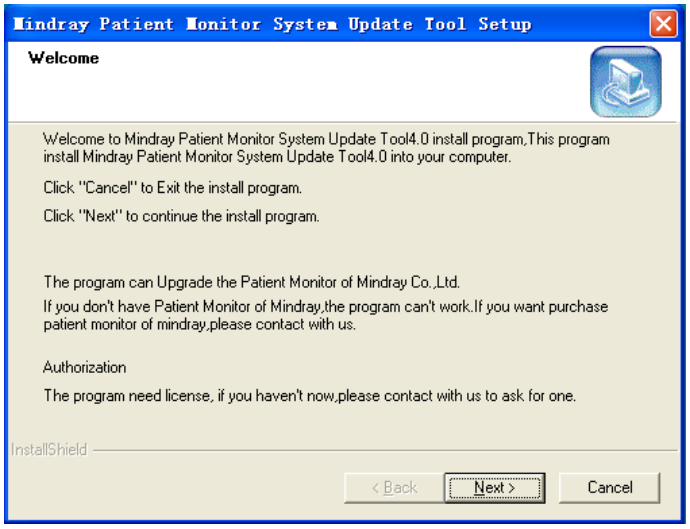
NOTE

- **No specific sequence is required for upgrading above software.**
- **When upgrading the Multi-parameter module software and Mindray SpO2 board software, choose upgrade software that meets the monitor configuration. That is to see, if your monitor is configured with Mindray ECG, you should use the Mindray ECG board software (PN: 110-001839-00) to upgrade the monitor; if your monitor is configured with Mortara ECG, you should use the Mortara ECG board software (PN: 110-001978-00); if your monitor is configured with Mindray SpO2 module, you should use the Mindray SpO2 board software (PN: 110-001842-00); if your monitor is configured with Masimo or Nellcor SpO2 module, upgrade is unnecessary. The monitor will not work if you select wrong upgrade software.**

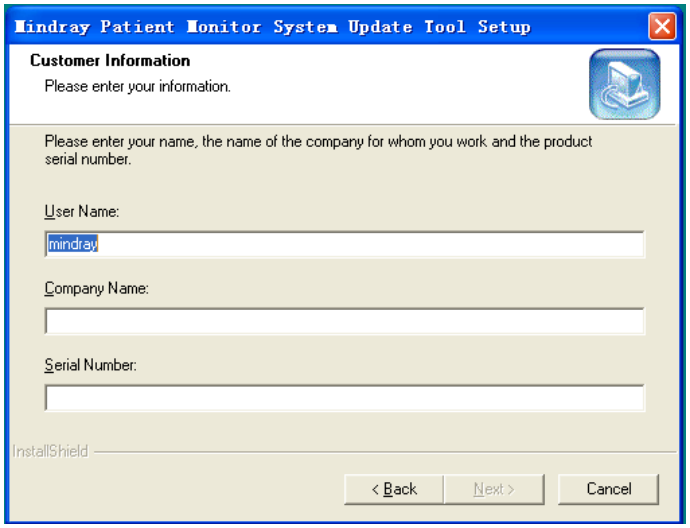
4.2.1 Installing Mindray Patient Monitor Software Upgrade Tool

1. Find the installation program 

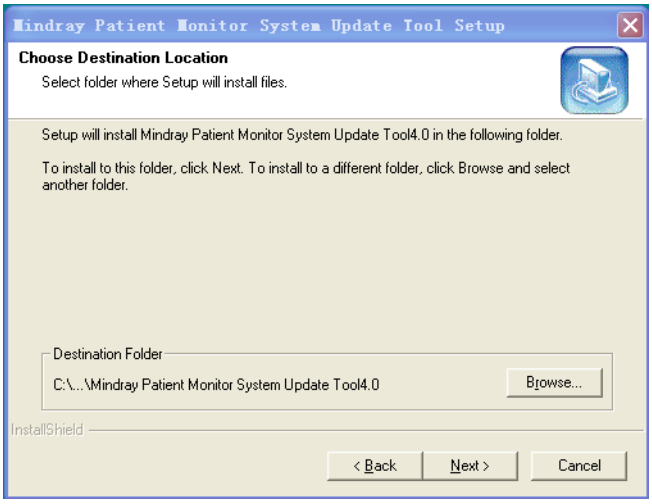
and double click it to start installation.
2. Select installation language.
3. Click [**Ok**] and the following screen appears. Click [**Next>**] to go to the next step.



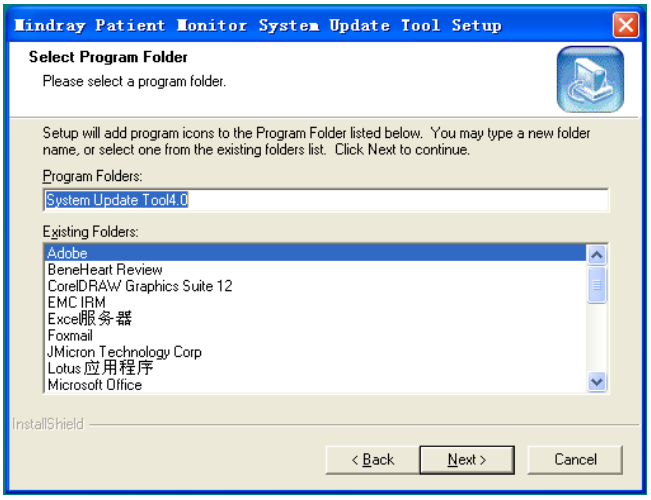
4. Enter User Name, Company Name and Serial Number.



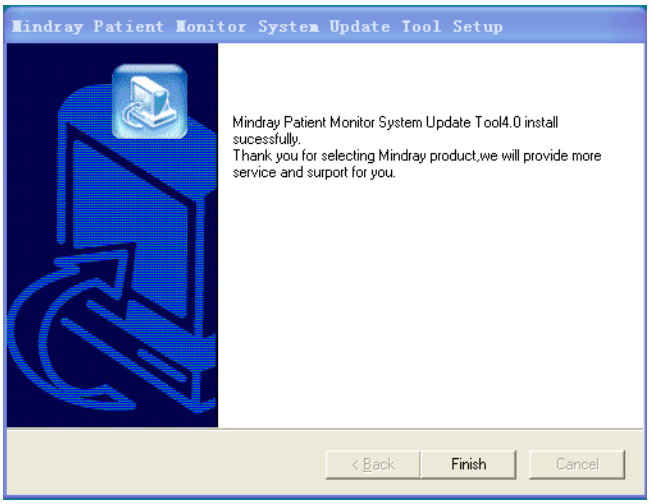
5. Specify the destination folder for installing this program. Then select [**Next**>] .



6. Select Program Folder. Then select [**Next>**] .



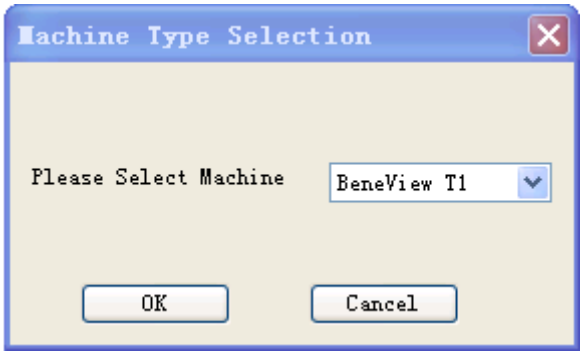
7. Click [**Finish**] to complete installation.



4.2.2 Software Upgrade Procedure

Before software upgrade, select [**Main Menu**]→[**Maintenance>>**]→[**Factory Maintenance>>**]→enter the required password→[**Software Version**] to check the current software version, refer to ***5.10.3 Software Version***.

1. Connect the monitor to be upgraded and a PC running the upgrade tool to the same network or directly connect the monitor and the PC via a network cable (a crossover network cable is recommended).
2. Set IP address to 77.77.1.XX and subnet mask to 255.255.255.0 on the PC.
3. Run Mindray Patient Monitor Software Upgrade Tool on the PC and set Machine to [**BeneView T1**].



4. On the Mindray Patient Monitor Software Upgrade Tool screen, select [**Select Package**] and select packages you want to upgrade. Then select [**Start**].
5. Turn on the patient monitor. Select [**Main Menu**]→[**Maintenance>>**]→[**Factory Maintenance>>**]→enter the required password→[**Diagnose**], **【Enter Upgrade Mode】** to start software upgrade.

After software upgrade is finished, restart the patient monitor and check if the software is correctly upgraded.

For the details of software upgrade, refer to help and instructions for use of ***Mindray Patient Monitor Software Upgrade Tool***.

⚠ CAUTION

- **Disconnect the equipment from the patient and make sure the important data are saved before upgrade.**
- **Do not shut down or power off the equipment when upgrading the system software. Otherwise, it may cause the equipment to break down.**
- **Software upgrade should be performed by qualified service personnel only.**
- **Crossover network cable is recommended when a PC is connected for software upgrade.**

NOTE

- **After upgrading the boot program, re-upgrade the system software and other programs to ensure compatibility.**
- **Make sure the version of the upgrade package is what you desired. To obtain the latest upgrade package, please contact Mindray Customer Service Department.**
- **If you have upgrade the Linux kernel (including the drive), the system software and bootstrap installed in the patient monitor will be cleaned. Therefore, you should also upgrade the system software and bootstrap after the Linux kernel (including the drive) is upgraded.**

5 Testing and Maintenance

5.1 Introduction

To ensure the patient monitor always functions normally, qualified service personnel should perform regular inspection, maintenance and test. This chapter provides a checklist of the testing procedures for the patient monitor with recommended test equipment and frequency. The service personnel should perform the testing and maintenance procedures as required and use appropriate test equipment.

The testing procedures provided in this chapter are intended to verify that the patient monitor meets the performance specifications. If the patient monitor or a module fails to perform as specified in any test, repairs or replacement must be done to correct the problem. If the problem persists, contact our Customer Service Department.

⚠CAUTION

- **All tests should be performed by qualified service personnel only.**
- **Care should be taken to change the settings in [User Maintenance] and [Factory Maintenance] menus to avoid loss of data.**
- **Service personnel should acquaint themselves with the test tools and make sure that test tools and cables are applicable.**

5.1.1 Test Equipment

See the following sections.

5.1.2 Test Report

Upon completion of the tests, the table of preventative maintenance test reports and the table of maintenance test reports in this chapter should be kept properly.

5.1.3 Preventative Maintenance

Below are preventative maintenance tests which need to be performed on the monitor. See the following sections for detailed maintenance procedures.

- Visual inspection
- NIBP test and calibration
- Microsteam and Sidestram CO2 test and calibration

5.1.4 Recommended Frequency

Check/Maintenance Item		Frequency
Preventative Maintenance Tests		
Visual inspection		1. When first installed or reinstalled.
NIBP test	Pressure check	1. If the user suspects that the measurement is incorrect. 2. Following any repairs or replacement of relevant module. 3. At least once a year.
	Leakage test	
	Calibration	
Sidestream and Microstream CO2 tests	Leakage test	
	Performance test	
	Calibration	
Performance Tests		
ECG test and calibration	Performance test	1. If the user suspects that the measurement is incorrect. 2. Following any repairs or replacement of relevant module. 3. At least once every two years. Note: At least once a year is recommended for NIBP and CO2.
	Calibration	
Resp performance test	/	
SpO2 test	/	
NIBP test and calibration	Pressure check	
	Leakage test	
	Calibration	
Temp test	/	
IBP test and calibration	Performance test	
	Pressure calibration	
C.O. test	/	

Check/Maintenance Item		Frequency
Mainstream CO2 test and calibration	/	
Sidestream and Microstream CO2 tests and calibration	Leakage test	
	Performance test	
	Calibration	
PiCCO test		
Analog output performance test	/	If the user suspects that the analog output does not work well.
Electrical Safety Tests		
Electrical safety tests	Refer to ***A Electrical Safety Inspection.***	1. Following any repair or replacement 2. After the monitor drops. 3. At least once every two years.
Other Tests		
Power on test		1. When first installed or reinstalled. 2. Following any maintenance or the replacement of any main unit parts.
Touchscreen calibration	/	1. When the touchscreen appears abnormal. 2. After the touchscreen is replaced.
Battery check	Functionality test	1. When first installed. 2. Whenever a battery is replaced.
	Performance test	Once a year or if the battery run time reduced significantly.

5.2 Preventative Maintenance Procedures

5.2.1 Visual Inspection

Inspect the equipment for obvious signs of damage. The test is passed if the equipment has no obvious signs of damage. Follow these guidelines when inspecting the equipment:

- Carefully inspect the case, display screen, buttons and knob for obvious signs of damage.
- Inspect the power cord, and module accessories for obvious signs of damage
- Inspect all external connections for loose connectors, bent pins or frayed cables.
- Inspect all connectors on the equipment for loose connectors or bent pins.
- Make sure that safety labels and data plates on the equipment are clearly legible.

5.2.2 NIBP Tests and Calibration

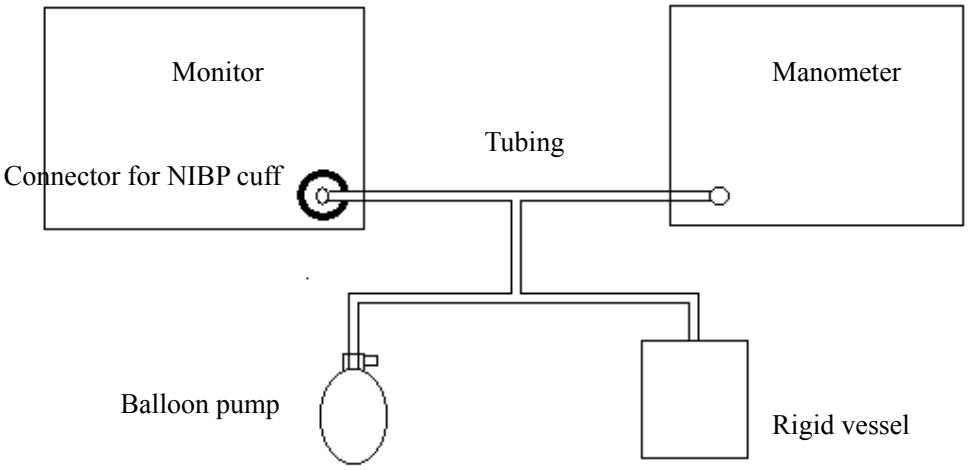
NIBP Accuracy Test

Tools required:

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

Follow this procedure to perform the test:

1. Connect the equipment as shown below.



2. Before inflation, check that the reading of the manometer should be 0. If not, turn off the balloon pump to let the whole airway open to the atmosphere. Turn on the balloon pump after the reading is 0.
3. Select [**Main Menu**]→ [**Maintenance >>**]→ [**NIBP Accuracy Test**].
4. Check the manometer values and the monitor values. Both should be 0mmHg.
5. Raise the pressure in the rigid vessel to 50 mmHg with the balloon pump. Then, wait for 10 seconds until the measured values become stable.
6. Compare the manometer values with the monitor values. The difference should be ±3 mmHg. If it is greater than ±3 mmHg, calibrate the monitor by referring to ***NIBP Calibration***.
7. Raise the pressure in the rigid vessel to 200 mmHg with the balloon pump. Then, wait for 10 seconds until the measured values become stable and repeat step 6.

NOTE

- **You can use an NIBP simulator to replace the balloon pump and the reference manometer to perform the test.**
- **You can use an appropriate cylinder and a cuff instead of the rigid vessel.**

NIBP Leakage Test

NOTE

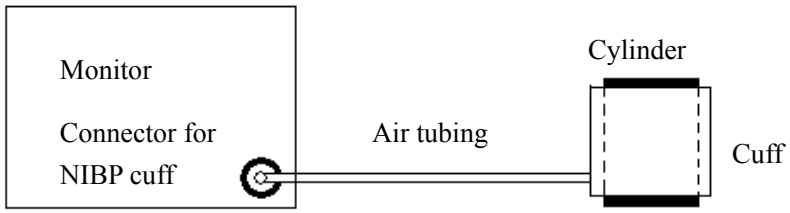
- **You should perform NIBP leakage test before any other NIBP concerned test and calibration..**

Tools required:

- NIBP cuff for adult patient
- Appropriate tubing
- Cylinder

Follow this procedure to perform the test:

1. Set [**Patient Cat.**] to [**Adu**].
2. Connect the NIBP cuff with the NIBP connector on the monitor.
3. Apply the cuff to the cylinder as shown below.



4. Select [**Main Menu**]→ [**Maintenance>>**]→ [**NIBP Leakage Test**]. The message [**Leakage Testing**…] is displayed in the NIBP parameter area.
5. The cuff automatically deflates after 20s, which means NIBP leakage test is completed.

   If no message is displayed in the NIBP parameter area, it indicates that the system has no leakage. If the message [**NIBP Pneumatic Leak**] is displayed, it indicates that the system may have a leakage. In this case, check if all connections are good and the cuff and tubing have no leakage. Perform the test again after making sure all connections are good and the cuff and tubing have no leakage.

You can either perform a manual leakage test:

1. Perform procedures steps 1 to 4 in the ***NIBP Accuracy Test*** section.
2. Raise the pressure in the rigid vessel to 250 mmHg with the balloon pump. Then, wait for 5 seconds to let the measured values becoming stable.
3. Record the current pressure value, and meanwhile use a time counter to count the time. Then, record the pressure value after 60s.
4. Compare the two pressure values and make sure the difference should not be greater than 6 mmHg.

NIBP Calibration

Tools required:

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

Follow this procedure to perform a NIBP calibration:

1. Perform procedures 1 to 4 in the ***NIBP Accuracy Test*** section.
2. Select [**Main Menu**]→ [**Maintenance >>**]→ [**Factory Maintenance >>**]→ enter the required password→ [**Calibrate NIBP >>**].
3. Set [**NIBP Pressure**] to 150 mmHg in the [**NIBP Measurement Circuit**]. Raise the pump pressure to 150 mmHg. After the pressure value is stabilized, select the [**Calibrate**] button to start a calibration.
5. Set patient category to [**Adu/Ped**] in the [**Overpressure Protection Circuit**], and raise the pressure to 330 mmHg. After the pressure value is stabilized, select [**Calibrate**] to start a calibration.
6. Set the patient category to [**Neo**] in the [**Overpressure Protection Circuit**], and raise the pressure to 165 mmHg. After the pressure value is stabilized, select [**Calibrate**] to start a calibration.

All calibration results are displayed in the [**Calibrate NIBP**] menu. If the calibration fails, check the test system for leakage and perform another calibration.

5.2.3 Sidestream and Microstream CO_2 Module Tests

Leakage test

Follow this procedure to perform the test:

1. Connect the CO_2 module with the patient module.
2. Wait until CO_2 warmup is finished and then use your hand or other objects to completely block the gas inlet of the module or watertrap. The sidestream and microstream CO2 modules will behave as follows:
   - Sidestream: The alarm message [**CO2 FilterLine Err**] is displayed on the screen after certain time. Block the gas inlet for another 30 s. If the alarm message does not disappear, it indicates that the module does not leak.
   - Microstream: The alarm message [**CO2 Purging**] is displayed on the screen after certain time. Block the gas inlet for another 30s. If alarm message [**CO2 FilterLine Err**] is shown, it indicates that the module does not leak.

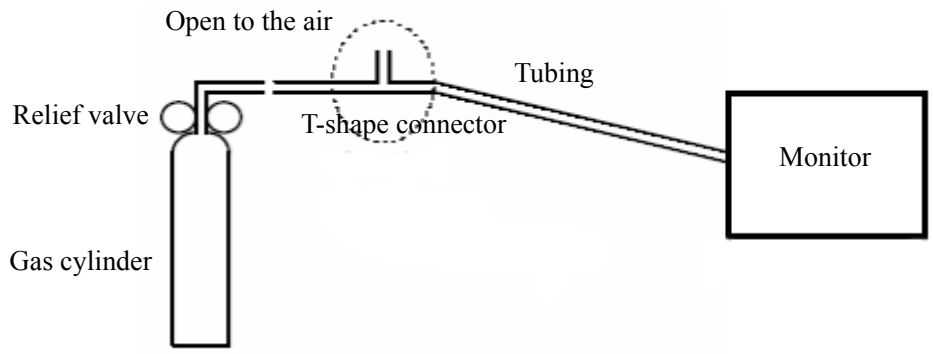
Accuracy Test

Tools required:

- A steel gas cylinder with 6±0.05% CO2 and balance gas N2
- T-shape connector
- Tubing

Follow this procedure to perform the test:

1. Connect the CO_2 module with the patient module.
2. Wait until the CO2 module warmup is finished, and check the airway for leakage and perform a leakage test as well to make sure the airway has no leakage.
3. Enter [**User Maintenance**]→ [**Maintain CO2 Purging**]→ [**Calibrate CO2>>**].
4. Connect the test system as follows:



5. Open the relief valve to vent standard CO2 and make sure that there is an excess gas flow through the T-shape connector to air..
6. Check the realtime CO2 value is within 6.0±0.3％ in the [**Calibrate CO2**] menu.

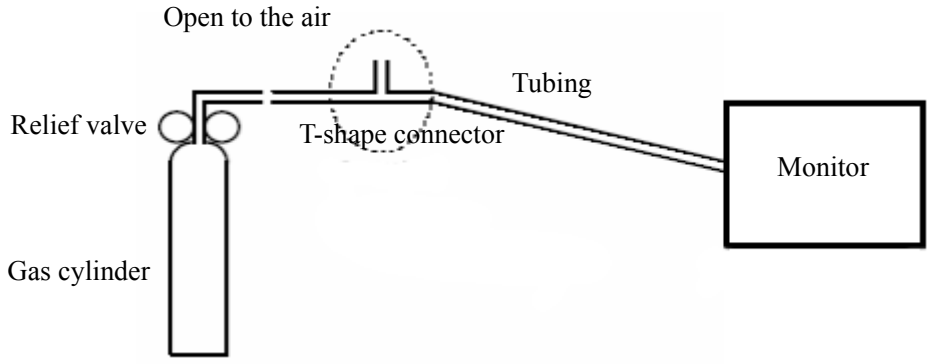
Calibration

Tools required:

- A steel gas cylinder with 6±0.05% CO2 and balance gas N2
- T-shape connector
- Tubing

Follow this procedure to perform a calibration:

1. Make sure that the sidestream or microstream CO_2 module has been warmed up or started up.
2. Check the airway for leakage and perform a leakage test as well to make sure the airway has no leakage.
3. Select [**Main Menu**]→ [**Maintenance >>**]→ [**User Maintenance** >>]→ enter the required password→ [**Maintain CO2 >>**]→ [**Calibrate CO2 >>**].
4. In the [**Calibrate CO2**] menu, select [**Zero**].
5. After the zero calibration is finished successfully, connect the equipment as follows:



6. Open the relief valve to vent standard CO2 and make sure that there is an excess gas flow through the T-shape connector to air.
7. In the [**Calibrate CO2**] menu, enter the vented CO_2 concentration in the [**CO2**] field.
8. In the [**Calibrate CO2**] menu, the measured CO_2 concentration is displayed. After the measured CO_2 concentration becomes stable, select [**Calibrate CO2**] to calibrate the CO_2 module.

If the calibration is finished successfully, the message [**Calibration Completed!**] is displayed in the [**Calibrate CO2**] menu. If the calibration failed, the message [**Calibration Failed!**] is displayed. In this case, perform another calibration.

5.2.4 Preventative maintenance test report

Customer name		
Customer address		
Servicing person		
Servicing company		
Equipment under test (EUT)		
Model of EUT		
SN of EUT		
Hardware version		
Software version		
Test equipment	**Model/No.**	**Effective date of calibration**

Test items	**Test records**	**Test results(Yes/No)**
Visual inspection		
The case, display screen, buttons, knob, SMR, modules, power cord, wall-mount bracket and accessories have no obvious signs of damage.		Yes No
The external connecting cables are not frayed and the connector pins are not loose and bent.		Yes No
The external connectors are not loose or their pins are not bent.		Yes No
The safety labels and data plate are clearly legible.		Yes No
NIBP test		
The difference is within ±3 mm when 0, 50 or 200 mmHg is set for NIBP accuracy test.		Yes No
There is no leakage with NIBP, or the manual leakage test result does not exceed 6mmHg/min.		Yes No

Sidestream CO2 test		
Block the gas inlet of the module or watertrap. The sidestream CO2 flowrate is slower than 10ml/min and an alarm of CO2 Filterline Err is given. It indicates that there is no leakage.		Yes No
The displayed CO2 value is within 6±0.05%.		Yes No
Microstream CO2 test		
Block the gas inlet of the module or watertrap. An alarm of CO2 Filterline Err is given. It indicates that there is no leakage.		Yes No
The displayed CO2 value is within 6±0.05%.		Yes No

5.3 Power On Test

This test is to verify that the patient monitor can power up correctly. The test is passed if the patient monitor starts up by following this procedure:

1. Insert the battery in the battery compartment and connect the patient monitor to external power supply through a DC adapter. Then the external power supply LED and battery LED light.
2. Press the power on/off switch to switch on the patient monitor.

The monitor performs self-test as soon as the monitor is powered on. During the self-test, the alarm lamp turns yellow and red, and then turns off; the monitor gives a beep. This indicates that the visual and audible alarm indicators operate properly.

5.4 Module Performance Tests

5.4.1 ECG Tests and Calibration

ECG Performance Test

Tool required:

- Fluke Medsim 300B patient simulator recommended

Follow this procedure to perform the test:

1. Connect the patient simulator with the ECG connector using an ECG cable.
2. Set the patient simulator as follows: ECG sinus rhythm, HR=80 bpm with the amplitude as 1mV.
3. Check the ECG waves are displayed correctly without noise and the displayed HR value is within 80 ± 1 bpm.
4. Disconnect each of the leads in turn and observe the corresponding lead off message displayed on the screen.

5. Set that the simulator outputs paced signals and set [**Paced**] to [**Yes**] on the monitor. Check the pace pulse marks on the monitor screen.

ECG Calibration

Tool required:

- Vernier caliper

Follow this procedure to perform a calibration:

1. Select the ECG parameter window or waveform area→ [**Filter**]→ [**Diagnostic**].
2. Select [**Main Menu**]→ [**Maintenance>>**].
3. Select [**Calibrate ECG**]. A square wave appears on the screen and the message [**ECG Calibrating**] is displayed.
4. Compare the amplitude of the square wave with the wave scale. The difference should be within 5%.
5. After completing the calibration, select [**Stop Calibrating ECG**].

5.4.2 Resp Performance Test

Tool required:

- Fluke Medsim 300B patient simulator recommended

Follow this procedure to perform the test:

1. Connect the patient simulator to the module using a non ESU-proof cable and set lead II as the respiration lead.
2. Configure the simulator as follows: lead II as the respiration lead, base impedance line as 1500 Ω; delta impedance as 0.5 Ω, respiration rate as 40 rpm.
3. Check the Resp wave is displayed without any distortion and the displayed Resp value is within 40 ± 2 rpm.

5.4.3 SpO_2 Test

Tool Required:

- None.

Follow this procedure to perform the test:

1. Connect SpO2 sensor to the SpO_2 connector of the monitor. Set [**Patient Cat.**] to [**Adu**] and [**PR Source**] to SpO2 on the monitor.
2. Apply the SpO2 sensor to your ring finger (Assume that you stay healthy).
3. Check the Pleth wave and PR reading on the screen and make sure that the displayed SpO2 is within 95% and 100%.
3. Remove the SpO2 sensor from your finger and make sure that an alarm of SpO2 Sensor Off is triggered.

NOTE

- **A functional tester cannot be used to assess the accuracy of a pulse oximeter monitor. However, it can be used to demonstrate that a particular pulse oximeter monitor reproduces a calibration curve that has been independently demonstrated to fulfill a particular accuracy specification.**

5.4.4 NIBP Tests

Refer to ***5.2.2 NIBP Tests***.

5.4.5 Temp Test

Tool required:

- Resistance box (with accuracy above 0.1Ω)

Follow this procedure to perform the test:

1. Connect the two pins of any Temp connector of a module to the two ends of the resistance box using 2 wires.
2. Set the resistance box to 1354.9Ω (corresponding temperature is 37ºC).
3. Verify that the displayed value is within 37 ± 0.1ºC.
4. Repeat steps 1 to 3 and verify another temperature channel.

5.4.6 IBP Tests

IBP Performance Test

Tool required:

- Medsim300B patient simulator, or MPS450, or equivalent equipment
- IBP adapter cable for test (P/N 009-002199-00 for Medsim 300B, P/N 009-002198-00, for MPS450)

Follow this procedure to perform the test:

1. Connect the patient simulator through the monitor's IBP connector.
2. Make the patient simulator outputs 0 to an IBP channel.
3. Select IBP Zero in the IBP setup menu to make a zero calibration.
4. Configure the patient simulator as P (static) = 200 mmHg.
5. The displayed value should be within 200 ± 4 mmHg.
6. If the error is beyond ±4 mmHg, calibrate the pressure module. If the IBP module was calibrated with a dedicated reusable IBP sensor, check the calibration together with this IBP sensor.
7. Let the patient simulator output 120/80 mmHg ART signal and 120/0 mmHg LV signal to the IBP channel and check that the IBP wave is displayed correctly.

8 Repeat the steps above for all the IBP channels.

IBP Pressure Calibration

Method 1

Tools required:

- Medsim300B patient simulator, or MPS450, orequivalent equipment
- IBP adapter cable for test (P/N 009-002199-00 for Medsim 300B, P/N 009-002198-00, for MPS450)

Follow this procedure to perform the test:

1. Connect the patient simulator with the monitor's IBP connector.
2. Set the patient simulator to 0 for the desired IBP channel.
3. Select IBP Zero in the IBP setup menu to make a zero calibration.
4. Configure the patient simulator as P (static) = 200 mmHg.
5. Select [**Main Menu**]→ [**User Maintenance >>**]→ [**Cal**. **IBP Press. >>**]. In the [**Cal. IBP Press.**] menu, set the calibration value to 200 mmHg.

6. Select the [**Calibrate**] button next to the desired IBP channel to start a calibration.

If the calibration is completed successfully, the message [**Calibration Completed!**] will be displayed. Otherwise, a corresponding message will be displayed.

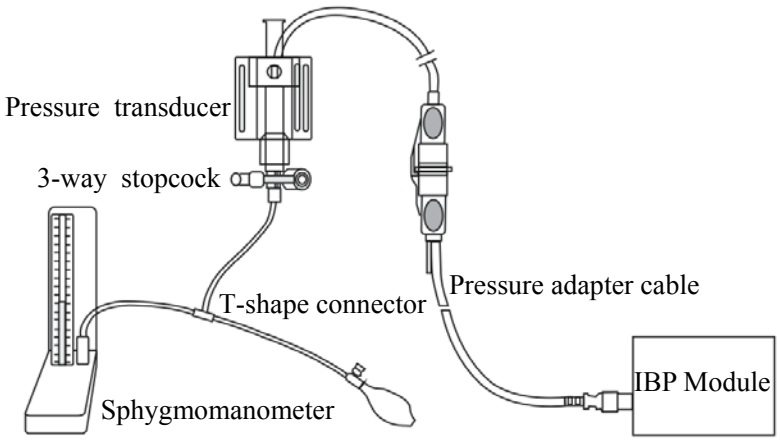
Method 2

Tools required:

- Standard sphygmomanometer
- Balloon pump
- Tubing
- T-shape connector

To perform a calibration:

1. Connect the 3-way stopcock, the sphygmomanometer and the balloon pump through a T-shape connector, as shown below.
2. Vent the transducer to the atmospheric pressure by turning on the 3-way stopcock to the air. Zero the transducer, and then open the stopcock to the sphygmomanometer.
3. Select [**Main Menu**]→[**Maintenance >>**]→ [**User Maintenance >>**]→enter the required password→ [**Cal**. **IBP Press. >>**]. In the [**Cal. IBP Press.**] menu, set the calibration value to 200 mmHg..
4. Inflate using the balloon pump until the reading of sphygmomanometer approximates the preset calibration value.



5. Adjust the calibration value in the [**Maintain IBP**] menu until it is equal to the reading of sphygmomanometer
6. Select the [**Calibrate**] button to start a calibration

The message [**Calibration Completed!**] is displayed after a successful calibration. If the calibration failed, the prompt [**Calibration Failed!**] will be displayed.

5.4.7 C.O. Test

Tools required:

- Medsim300B Patient simulator, or MPS450, or equivalent equipment
- C.O. adapter box (CI-3 module/cable, P/N: 3010-0289 for 300B; P/N: 5180500 for MPS450)
- C.O. trunk cable (PN: 0010-21-42716)

Follow this procedure to perform the test:

1. Connect the patient simulator and the C.O. module using a C.O. trunk cable and a C.O. adapter box.
2. Set the blood temperature (BT) to 37ºC on the patient simulator and check the temperature value displayed on the monitor is 37 ± 0.2ºC.
3. On the patient monitor set [**Auto IT**] to [**Off**], [**IT**] to 2ºC, and [**Comp. Const.**] to 0.595 in the [**C.O. Setup**] menu. Select [**C.O. Measure**] to enter the C.O. measurement window.
4. Select [**Start**] in the C.O. measurement window to start C.O. measurements,
5. On the patient simulator, set C.O. to 5L/min and wait for 3 to 10 seconds.
6. Verify that the C.O. value displayed on the monitor is 5±0.25L/min.

5.4.8 Mainstream CO_2 Tests

NOTE

- **Select [Main Menu]→[Maintenance >>]→ [User Maintenance >>]→enter the required password→[Maintain CO2], make sure that the setting of [Barometric Pressure] is correct before performing mainstream CO2 tests.**

Tools required:

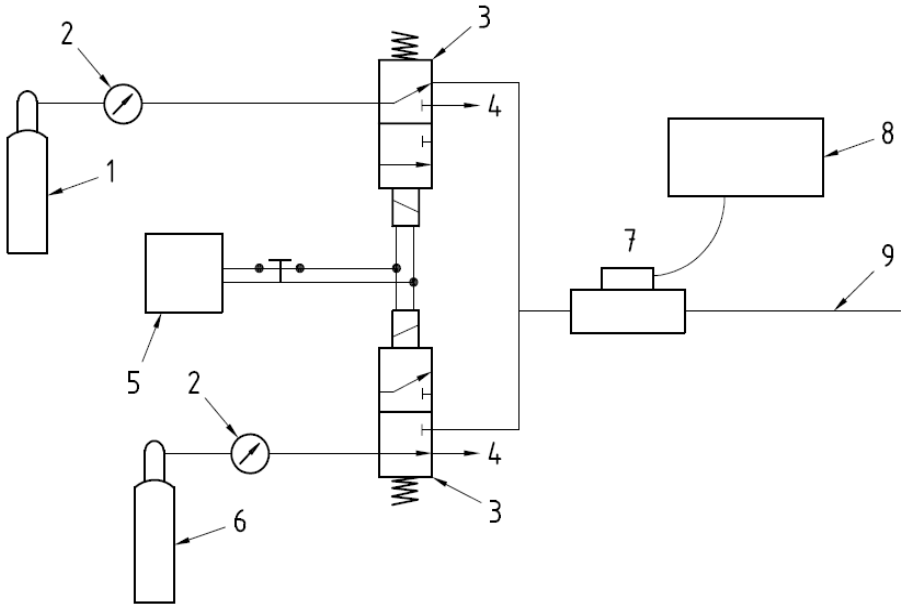
- A steel gas cylinder with 6±0.05% CO2
- A steel gas cylinder with compressed air or N2 (with standard concentration)
- Two 3-way valves (power supply controlled)
- Flowmeter
- Power supply
- Tube

1. Wait until CO_2 warmup is finished and then select [**Start Zero Cal.**] from [**CO2 Setup**] menu to start a zero calibration. If the zero calibration fails, the prompt message [**CO2 Zero Failed**] is displayed. Otherwise, the baseline of waveform recovers to zero.

2 Set [**Apnea Delay]** to 10 s in the [**Adjust CO2 Limits**] menu.

3 Blow to the CO_2 sensor to generate a CO_2 waveform and then place the sensor in the air. Check if the alarm message [**CO2 Apnea]** is displayed on the screen.

4 Connect the test system as follows



In the figure above,

1. A steel gas cylinder with 6±0.05% CO2
2. Flowmeter
3. 3-way valve (power supply controlled)
4. Open to air
5. Power supply (controlling two 3-way valves)
6. Compressed air or N2 with standard concentration
7. Mainstream CO2 sensor
8. Patient monitor
9. Tube (preventing back flow)

5 Adjust the power supply and turn on/off 3-way valves to ensure that that only one cylinder is connected to the Mainstream CO2 sensor via the 3-way valves at one time and the flowmeter reading is stable and within 2 and 5L/min.

6 Switch between the two cylinders to connect Mainstream CO2 sensor at an intervals of 6 to 10s and check if the displayed CO2 value is within 6.0±0.3%.

5.4.9 Sidestream and Microstream CO_2 Module Tests

See section ***5.2.3 Sidestream and Microstream CO2 Module Tests***3

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5.4.10 PiCCO Tests

Performance Test

Tool required:

- Medsim300B patient simulator
- PiCCO IBP test cable (6800-J87)

Follow this procedure to perform the test:

1. Connect the patient simulator, the PiCCO IBP test cable and the PiCCO module.
2. Let the patient simulator outputs 0 mmHg respectively to the pArt channel and the pCVP channel.
3. In the [**pArt Setup**] menu, select [**pArt Zero >>**]→[**Zero**].
4. In the [**pCVP Setup**] menu, select [**pCVP Zero >>**]→[**Zero**].
5. Let the patient simulator output static pressure 200 mmHg to pArt channel and 20 mmHg to pCVP channel.
6. The pArt value displayed on the monitor should be within 200 ± 4 mmHg, and pCVP value within 20 ± 1 mmHg.
7. If the pArt error is beyond ±4 mmHg or pCVP error beyond ±1 mmHg, calibrate the PiCCO module. If the module was calibrated with a dedicated reusable IBP sensor, check the calibration together with this IBP sensor.
8. Let the patient simulator output ART signal to the pArt channel and pCVP signal to the pCVP channel, verify that the pArt and pCVP waves are displayed correctly.

Pressure Calibration

Method 1

Tools required:

- Medsim300B patient simulator
- PiCCO IBP test cable (6800-J87)

Follow this procedure to perform the test:

1. Connect the patient simulator, the PiCCO IBP test cable and the PiCCO module.

2. Let the patient simulator outputs 0 mmHg respectively to the pArt channel and the pCVP channel.
3. In the [**pArt Setup**] menu, select [**pArt Zero >>**]→[**Zero**].
4. In the [**pCVP Setup**] menu, select [**pCVP Zero >>**]→[**Zero**].
5. Set static pressure to 200 mmHg on the patient simulator.
6. Select [**Main Menu**]→[**Maintenance >>**]→[**User Maintenance >>**]→ [**Cal**. **IBP Press. >>**]. In the [**Cal. IBP Press.**] menu, set the calibration pressure to 200 mmHg.
7. Select the [**Calibrate**] button next to the desired IBP channel to start a calibration.

If the calibration is completed successfully, the message [**Calibration Completed!**] will be displayed. Otherwise, a corresponding message will be displayed.

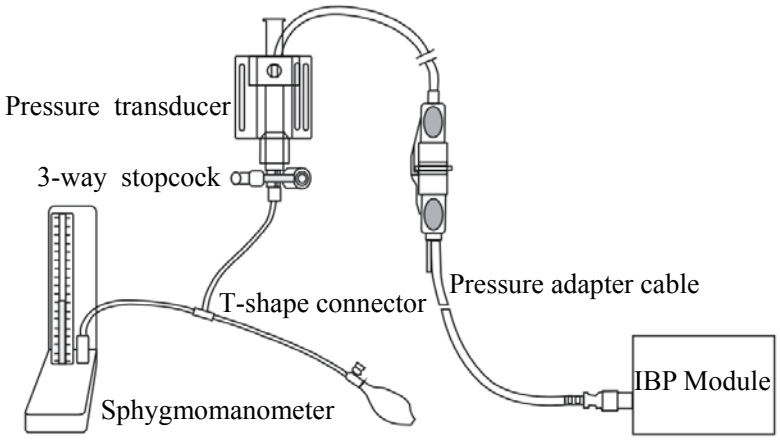
Method 2

Tools required:

- Standard sphygmomanometer
- Balloon pump
- Tubing
- T-shape connector

To perform a calibration:

1. Connect the 3-way stopcock, the sphygmomanometer and the balloon pump through a T-shape connector, as shown below.
2. Vent the transducer to the atmospheric pressure by turning on the 3-way stopcock to the air. Zero the transducer, and then open the stopcock to the sphygmomanometer.
3. Select [**Main Menu**]→[**Maintenance >>**]→ [**User Maintenance >>**]→enter the required password→ [**Cal**. **IBP Press. >>**]. In the [**Cal. IBP Press.**] menu, set the calibration pressure to 200 mmHg..
4. Inflate using the balloon pump until the reading of sphygmomanometer approximates the preset calibration value.



5. Adjust the calibration value in the [**Maintain IBP**] menu until it is equal to the reading of sphygmomanometer
6. In the [**Cal. IBP Press.**] menu, select the [**Calibrate**] button next to the desired IBP channel to start a calibration

The message [**Calibration Completed!**] is displayed after a successful calibration. If the calibration failed, the prompt [**Calibration Failed!**] will be displayed.

C.O. Test

Tools required:

- Medsim300B Patient simulator, or MPS450, or equivalent equipment
- C.O. adapter box (CI-3 module/cable, P/N: 3010-0289 for 300B, P/N: 5180500 for MPS450)
- PiCCO test cable (6800-J88)

Follow this procedure to perform the test:

1. Connect the patient simulator and the C.O. module using a C.O. trunk cable and a C.O. adapter box.
2. Set the blood temperature (BT) to 37ºC on the patient simulator and check the temperature value displayed on the monitor is 37 ± 0.2ºC.
3. In the [**CCO Setup**] menu, select [**PiCCO Guide>>**], and set the ACC value to 342 for the [**Cat.Type**] option.
4. Turn the injectate temperature (TI) knob on the C.O. adapter box to set the TI to 25 ± 1ºC for the patient simulator.
5. In the PiCCO screen, select [**Start**] to start C.O. measurement. As soon as the prompt [**Inject XXml**] is displayed, adjust TI to 2 ± 1ºC, and then to 25 ± 1ºC.
6. On the patient simulator, set C.O. to 5L/min and wait for 3 to 10 seconds.
7. Verify that the C.O. value displayed on the monitor is correct.

5.5 Analog Output Performance Test

Tool required:

- Medsim300B Patient simulator, or MPS450, or equivalent equipment
- Oscillograph

1. Connect the patient simulator to the monitor using an ECG or IBP cable.
2. Connect the oscillograph to the monitor's multifunctional connector.
3. Verify that the waves displayed on the oscillograph are identical with those displayed on the monitor.

5.6 Electrical Safety Test

See ***A Electrical Safety Inspection*** for electrical safety tests.

5.7 Touchscreen Calibration

Tools required:

- None.

1. Select [**Main Menu**]→ [**Maintenance >>**]→ [**Cal. Touchscreen**]. The ⊕ symbol will appear at different positions of the screen.
2. Select, in turn, the central point of the ⊕ symbol.
3. After the calibration is completed, the message [**Screen Calibration Completed!**] is displayed. Select [**Ok**] to confirm the completion of the calibration.

5.8 Network Print Test

Note

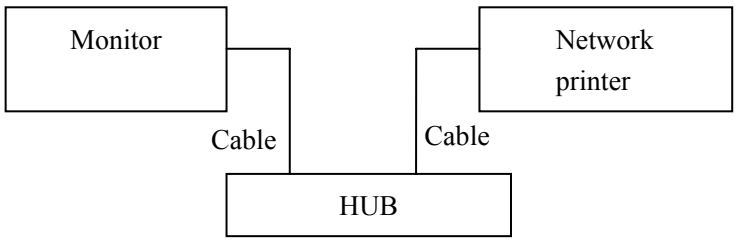
- **HP LaserJet 1505n or 2035n laser printer is recommended for this patient monitors.**

Tools required:

- Hub and network cable

5.8.1 Equipment Connection and Setup

1 Connect the patient monitor and network printer to a HUB using common network cables as follows:



2 Set IP address as follows: Select [**Main Menu**]→ [**Maintenance >>**]→ [**User Maintenance >>**]→ enter the required password→ [**IP Address Setup >>**] and set the IP address of the patient monitor in the same network segment with that of the network printer. (See the instructions for use accompanying the printer)

3 Search for printer by selecting [**Main Menu**]→ [**Print Setup >>**]→ [**Printer Setup >>**]→ [**Search Printer**]. After a while, the printer's model and IP address will appear in the box beside [**Printer**].

5.8.2 Print Function Test

1 Enter the Demo mode of the patient monitor.

2 Select [**Main Menu**]→ [**Print Setup >>**]→ [**Realtime Reports >>**]→ [**Normal Report**] and then select [**Print**]. The network printer shall print out the report correctly.

5.9 Battery Check

Tools required:

- None.

Function Test

1. Remove the battery from the monitor's battery compartment.
2. Verify that the patient monitor works correctly when running on the external DC power supply.
3. Insert the battery as per the procedure provided in the Operator's Manual.
4. Disconnect the external DC power and verify that the patient monitor still works correctly.

Performance Test

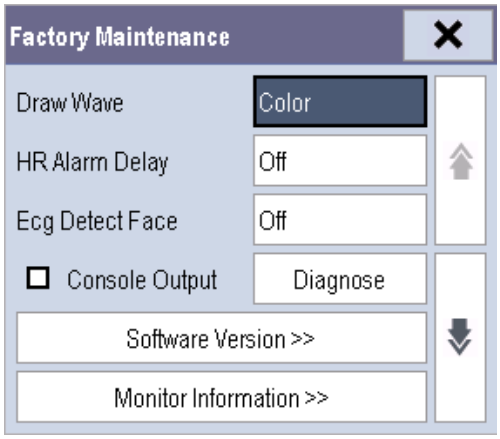
Perform the test by referring to the ***Battery*** chapter in the Operator's Manual and verify the operating time of the battery meets the product specification.

5.10 Factory Maintenance

5.10.1 Accessing Factory Maintenance Menu

To access the factory maintenance menu, select [**Main Menu**]→ [**Maintenance** >>] → [**Factory Maintenance**]and then enter the required password.

The [**Factory Maintenance**] menu is shown below.



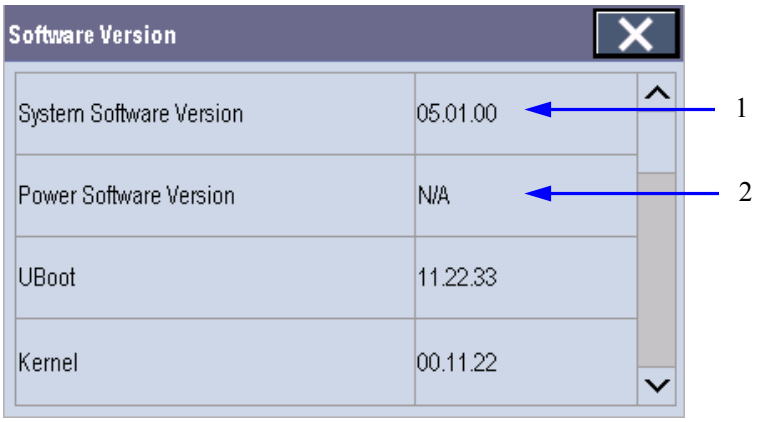
5.10.2 Drawing Waves

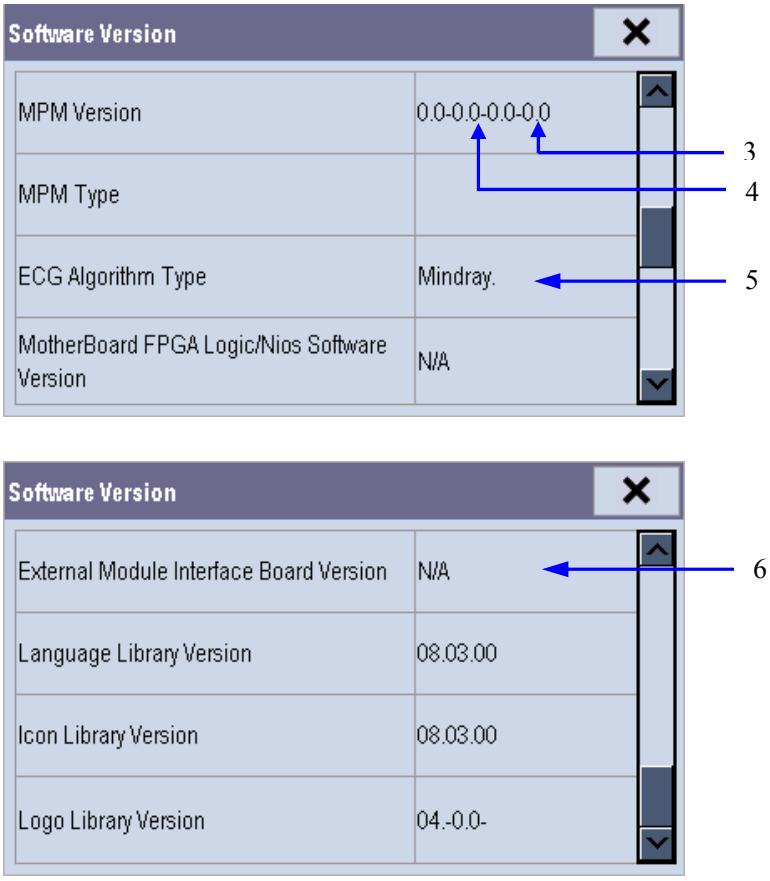
There are two methods to draw waves.

- Color: selecting Color will have smoother waveforms.
- Mono: selecting Mono will have a wider viewing angle.

5.10.3 Software Version

Selecting [**Software Version**] will show software version information. The [**Software Version**] menu is as follows:



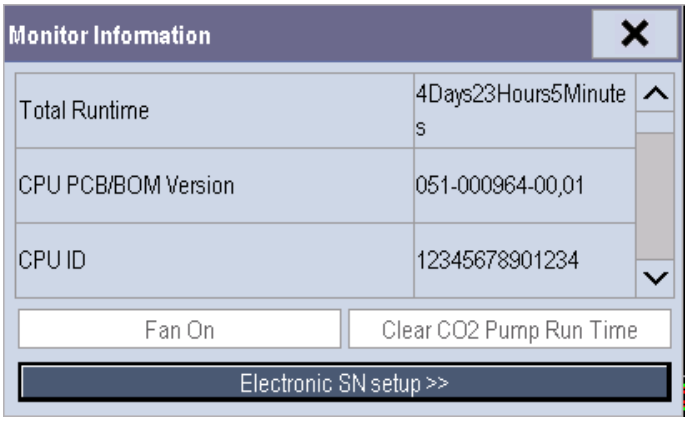


In the pictures above,

1. Version of system software package
2. Version of power management software
3. Version of SpO2 board software, for monitors configured with Nellcor or Masimo SpO2 board, it is 0.0.
4. Version of multi-parameter module software
5. ECG algorithm type
6. Version of external module interface board software

5.10.4 Monitor Information

Selecting [**Monitor Information**] will show the status of the patient monitor. Monitor information is displayed as follows:



5.10.5 Calibrate NIBP

For details, refer to section ***5.2.2 NIBP Tests***.

Maintenance and Test Report

(See the above sections for detailed test procedures and contents)

Customer name		
Customer address		
Servicing person		
Servicing company		
Equipment under test (EUT)		
Model of EUT		
SN of EUT		
Hardware version		
Software version		
Test equipment	**Model/No.**	**Effective date of calibration**

Test items	**Test records**	**Test results (Yes/No)**
Visual inspection		
The case, display screen, buttons, power cord, and accessories have no obvious signs of damage.		Yes No
The external connecting cables are not frayed and the connector pins are not loose and bent.		Yes No
The external connectors are not loose or their pins are not bent.		Yes No
The safety labels and data plate are clearly legible.		Yes No
Power-on test		
The power-on test is passed. The power indicator and alarm system work correctly and the monitor start up properly.		Yes No
Performance test		

ECG performance test and calibration		
ECG waves are displayed correctly without noise and the HR value is within 80±1 bpm.		Yes No
ECG Lead Off alarm behaves correctly.		Yes No
Paced signals are detected and pace pulse marks are displayed when [**Paced**] is set to [**Yes**]		Yes No
The difference between the amplitude of the ECG calibration square wave and that of the wave scale is not greater than 5%.		Yes No
Resp test		
The Resp wave is not distorted and the Resp value is within 40±2 rpm.		Yes No
SpO2 test		
Measure SpO2 on a healthy person's finger and a Pleth wave and PR value are displayed. The displayed SpO2 value is within 95% and 100%		Yes No
NIBP test and calibration		
The difference is within ±3 mm when 0, 50 or 200 mmHg is set for NIBP accuracy test.		Yes No
There is no leakage with NIBP, or the manual leakage test result does not exceed 6mmHg/min.		Yes No
Temp test		
The value displayed for each Temp channel of the monitor is within 37±0.1ºC.		Yes No
IBP test and calibration		
The static pressure value displayed for each IBP channel is within 200±4 mmHg.		Yes No
The ART and LV waves for each IBP channel are displayed correctly.		Yes No
C.O. test		
The TB value displayed on the monitor is within 37±0.2ºC.		Yes No
The displayed C.O. value is within 5±0.25L/min.		Yes No
Mainstream CO2 test		
The mainstream CO2 is zeroed successfully and the waveform baseline recovers to zero.		Yes No
CO2 Apnea alarm behaves correctly.		Yes No
The displayed CO2 value is within 6.0±0.3%.		Yes No

Sidestream CO2 test and calibration		
Block the gas inlet of the module or watertrap. The sidestream CO2 flowrate is slower than 10ml/min and an alarm of CO2 Filterline Err is given. It indicates that there is no leakage.		Yes No
The displayed CO2 value is within 6.0±0.3%.		Yes No
Microstream CO2 test and calibration		
Block the gas inlet of the module or watertrap. An alarm of CO2 Filterline Err is given. It indicates that there is no leakage.		Yes No
The displayed CO2 value is within 6.0±0.3%		Yes No
PiCCO test		
TB reading displayed on the monitor is between 37±0.2℃		Yes No
The C.O. value is correctly displayed		
The displayed static pressure values of pArt is between 200±4 mmHg		
The displayed static pressure values of pCVP is between 10±1 mmHg		
The waveforms of pArt and pCVP are displayed correctly.		Yes No
Analog output performance test		
The waves displayed on the oscillograph are identical with those displayed on the monitor.		Yes No
Electrical safety tests		
Refer to ***A Electrical Safety Inspection***. All the electrical safety tests should be passed		Yes No
Touchscreen calibration		
The touchscreen is calibrated successfully		Yes No
Network print test		
The network printer can print out ECG reports correctly.		Yes No
Battery check		
The monitor can operates correctly from battery power when external DC power fails accidentally		Yes No
The operating time of the battery meets the product specification.		Yes No

Test conclusion:

Tested by:_____ Test Date:_____

6 Troubleshooting

6.1 Introduction

In this chapter, patient monitor problems are listed along with possible causes and recommended corrective actions. Refer to the tables to check the patient monitor, identify and eliminate the troubles.

The troubles we list here are frequently arisen difficulties and the actions we recommend can correct most problems, but not all of them. For more information on troubleshooting, contact our Customer Service Department.

6.2 Part Replacement

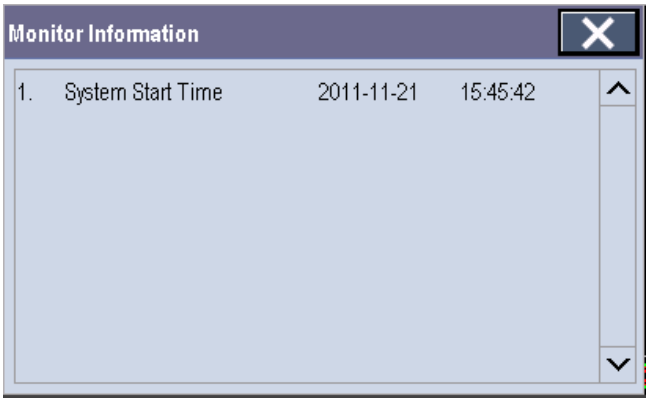
Printed circuit boards (PCBs), major parts and components in the patient monitor are replaceable. Once you isolate a PCB you suspect defective, follow the instructions in ***7 Disassemblyy and repair*** to replace the PCB with a known good one and check that the trouble disappears or the patient monitor passes all performance tests. Defective PCB can be sent to us for repair. If the trouble remains, exchange the replacement PCB with the original suspicious PCB and continue troubleshooting as directed in this chapter.

To obtain information on replacement parts or order them, refer to ***8 Parts***.

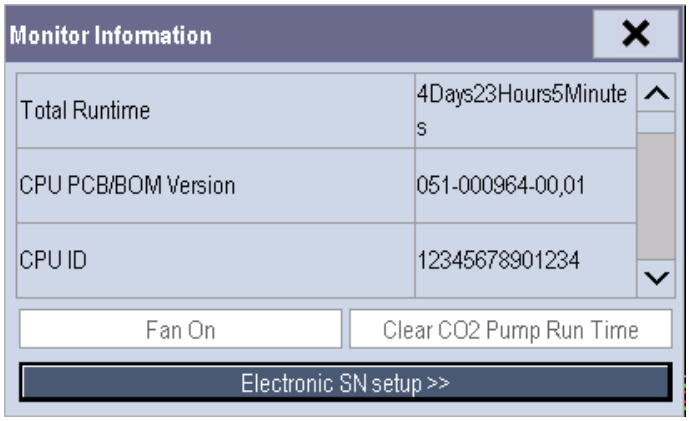
6.3 Checking Patient Monitor Status

Some troubleshooting tasks may require you to identify the hardware version and status of your monitor.

To view the information on system start time, self check, etc, select [**Main Menu**]→[**Maintenance >>**]→[**Monitor Information >>**].



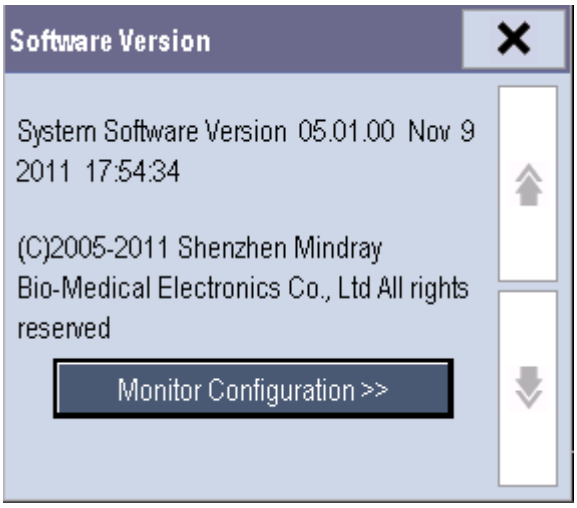
You can also view the information on the monitor's current status by selecting [**Main Menu**]→[**Maintenance >>**]→[**Factory Maintenance >>**]→enter the required password→[**Monitor Information >>**].



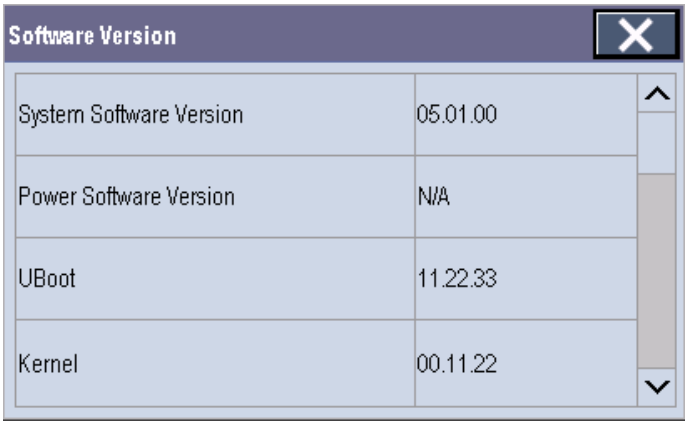
6.4 Checking Software Version

Some troubleshooting may involve software compatibility. Thus it requires you to know your monitor configuration and software version. For detailed information on version compatibility, please contact our Customer Service Department.

To view information on the monitor configuration and system software version, select [**Main Menu**]→[**Maintenance >>**]→[**Software Version >>**].



You can also view the information on system software version and module software version by selecting [**Main Menu**]→[**Maintenance >>**]→[**Factory Maintenance >>**]→enter the required password→[**Software Version>>**].



6.5 Checking Technical Alarms

Before troubleshooting the patient monitor, check for technical alarm messages. If an alarm message is presented, eliminate the technical alarm first.

For detailed information on technical alarm message, possible cause and corrective action, refer to the patient monitor's Operation Manual.

6.6 Troubleshooting Guide

6.6.1 Power On/Off Failure

Symptoms	Possible Cause	Correction Action
The patient monitor fails to start. The external power supply LED or battery LED does not light.	The DC adapter not connected or battery too low	Check that the DC adapter is properly connected or battery capacity is sufficient.
	DC adapter defective	Replace the DC adapter.
	Main board defective	Replace the main board.

6.6.2 Display Failures

Symptoms	Possible Cause	Correction Action
The display is blank or black.	Display defective	Replace the front housing assembly.
	Main board defective	Replace the main board.
Images overlapped or distorted	Display defective	Replace the front housing assembly.
	Main board defective	Replace the main board.
Touchscreen does not respond.	Touchscreen disabled	Check if the message "Screen locked. Please move the lock/unlock key to unlock the screen" is displayed. If yes, slide the lock/unlock key to the right to unlock the screen.
	Display defective	Replace the front housing assembly.
	Main board defective	Replace the main board.
Touch position not correctly respond	Touchscreen not calibrated	Calibrate the touchscreen.

6.6.3 Alarm Problems

Symptoms	Possible Cause	Correction Action
The alarm lamp is not light or extinguished.	Main board defective	Replace the main board.
No alarm sound is issued.	Audio alarm disabled	1. Check if the "  " icon is displayed. If yes, the audio alarm is silenced. 2. Check if the "  " icon is displayed. If yes, the alarm is paused or switched off.
	Cable defective	1. Check that the cable between the speaker and parameter connector board is properly connected. 2. Check that the cable between the main board and parameter connector board is properly connected.
	Speaker defective	Replace the speaker.
	Main board defective	Replace the main board.

6.6.4 Button Failures

Symptoms	Possible Cause	Correction Action
The lock/unlock key does not respond.	Main board defective	Replace the main board.

6.6.5 External Parameter Module Failure

Symptoms	Possible Cause	Correction Action
Failed to connect the external parameter modules to T1	Dock failure	Replace the dock.
	External parameter module failure	Replace the external parameter module.
	Main board defective	Replace the main board.
	Parameter connector board failure	Replace the parameter connector board.
	Connecting cable failure	Check that the connecting cable between the main board and the parameter connector board is not damaged.

6.6.6 Input/Output Interface Failure

Symptoms	Possible Cause	Correction Action
No analog out signal	The parameter board of standard configuration is used	Choose the optional parameter board that supports the analog out function.
	Parameter board failure	Replace the parameter board.
	Main board defective	Replace the main board.
	Parameter connector board failure	Replace the parameter connector board.
	Connecting cable failure	Check that the connecting cable between the main board and the parameter connector board is not damaged.
Unable to use the USB devices	Main board defective	Replace the main board.
	USB devices problem	Make sure that the USB device operates properly before connecting it to the external device connector.

6.6.7 Storage Failure

Symptoms	Possible Cause	Correction Action
The storage function fails.	SD card defective	Replace the SD card.
	Main board defective	Replace the main board.

6.6.8 Power Supply Failures

Symptoms	Possible Cause	Correction Action
Battery cannot be fully charged.	Battery defective	Replace the battery.
	Main board defective	Replace the main board.
Battery cannot be recharged.	Battery defective	Replace the battery.
	Main board defective	Replace the main board.
No +5.0 V output	1. Power supply protection 2. Main board defective	1. Turn off the patient monitor and then restart it. 2. If the patient monitor cannot be restarted, replace the main board.
No +12 V output		

NOTE

- **When the power module has a failure, it may cause problems to other components, e.g. the monitor suddenly breaks down during start-up, as the power module may have a power supply protection. In this case, troubleshoot the power module per the procedure described in the table above.**
- **Components of the main unit are powered by the power module. In the event that a component malfunctions, check if the operating voltage is correct.**

6.6.9 Wired Network Related Problems

Symptoms	Possible Cause	Correction Action
Unable to connect the wired network	Incorrect network cable connection	Check network cable connection. network cable shall not be longer than 50 m.
	Incorrect IP address setting	Check for IP address conflict. If yes, reconfigure the IP address.
	Network cable defective	Replace the network cable.
	Main board failed.	Replace the main board.
The monitor is frequently off line or disconnects from the network.	Incorrect network cable connection	Check network cable connection. network cable shall not be longer than 50 m.
	Incorrect IP address setting	Check for IP address conflict. Reconfigure IP address.

6.6.10 Wi-Fi Related Problems

Symptoms	Possible Cause	Correction Action
The monitor is frequently off line or disconnects from the Wi-Fi network.	The Wi-Fi signal is unstable in the operating area	Check the signal quality of the hospital Wi-Fi network.
	Wi-Fi antenna detached or not properly connected to the Wi-Fi module	Disassemble the monitor and fix the Wi-Fi antenna.
Unable to connect the Wi-Fi network.	Incorrect IP address configuration	Check for IP address conflict. If yes, reconfigure the IP address.
	The Wi-Fi signal is unstable in the operating area	Check the signal quality of the hospital Wi-Fi network.
	The monitor's Wi-Fi antenna is detached or not connect the Wi-Fi module	Fix the Wi-Fi antenna.
	Main board defective	Replace the main board.

6.6.11 Software Upgrade Problems

Symptoms	Possible Cause	Correction Action
Program upgrade fails	Incorrect network connection	1. Check the network connector on the patient monitor. 2. Make sure that the hub or switch runs normally. Check that correct network cable is in use and has been connected correctly.
	Wrong upgrade package has been downloaded	Upgrade package shall be .pkg files. Select package according to system requirement.
	Incorrect IP address setting	Configure a fixed IP address in range C as specified for the patient monitor. We recommend not to perform software upgrade when the patient monitor is connected to a network having multiple PCs.
	Main board defective	Replace the main board.

7 Disassembly and Repair

7.1 Tools Required

To disassemble and replace the parts and components, the following tools may be required:

- P2 screwdriver
- M3 socket screw driver
- Tweezers
- Sharp nose pliers

7.2 Preparations for Disassembly

Before disassembling the equipment, finish the following preparations:

- Stop patient monitoring, turn off the equipment, and disconnect all the accessories and peripheral devices.
- Disconnect the DC power source and remove the battery.

⚠CAUTION

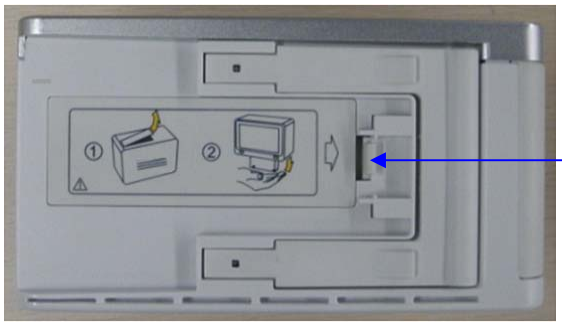
- **Before disassembling the equipment, be sure to eliminate the static charges first. When disassembling the PCBAs and parts labeled with static-sensitive symbols, make sure you are wearing electrostatic discharge protection such as antistatic wristband or gloves to avoid damaging the equipment.**
- **Properly connect and route the cables and wires when reassembling the equipment to avoid short circuit.**
- **Select appropriate screws to assemble the equipment. If unfit screws are tightened by force, the equipment may be damaged and the screws or part may fall off during use, causing unpredictable equipment damage or human injury.**
- **Follow correct sequence to disassembly the equipment. Otherwise, the equipment may be damaged permanently.**
- **Disconnect all the cables before disassembling any parts. Be careful not to damage any cables or connectors.**
- **Place removed screws and disassembled parts properly, preventing them from being lost or contaminated.**
- **Place the screws and parts from the same module together to facilitate reassembling.**

- **To reassemble the equipment, first assemble the assemblies, and then the main unit. Carefully route the cables.**
- **Make sure that the waterproof material is properly applied during reassembling.**

7.3 Disassembly

7.3.1 Removing the Battery Door and Battery

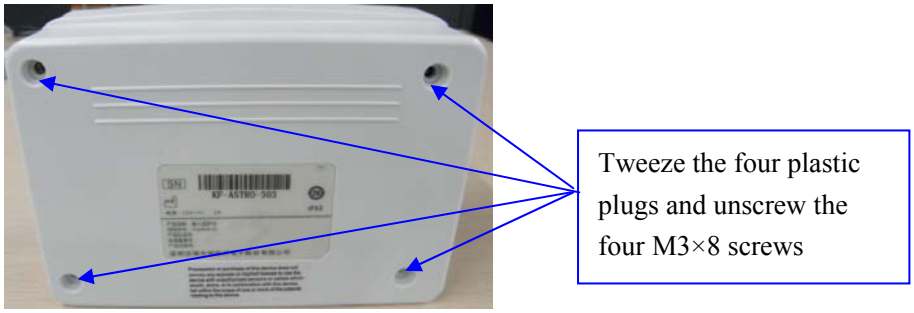
1. Open the battery door. If a battery is installed, take out the battery.



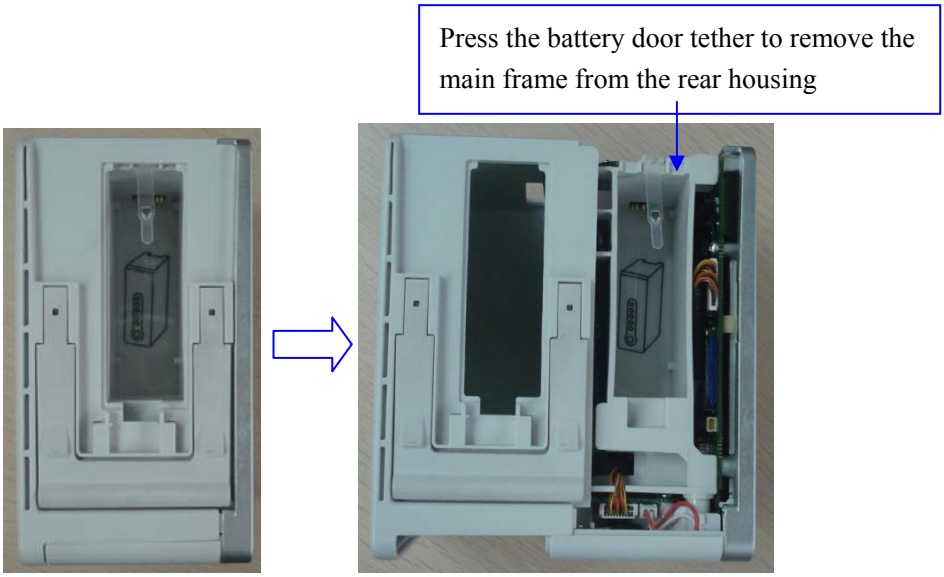
2. Use you finger to press the battery door tether and then detach the battery door, as shown below:

7.3.2 Disassembling the Rear Housing Assembly

1. Tweeze the four plastic caps covering the screw holes. Then loose and unscrew the four M3×8 screws as shown below:

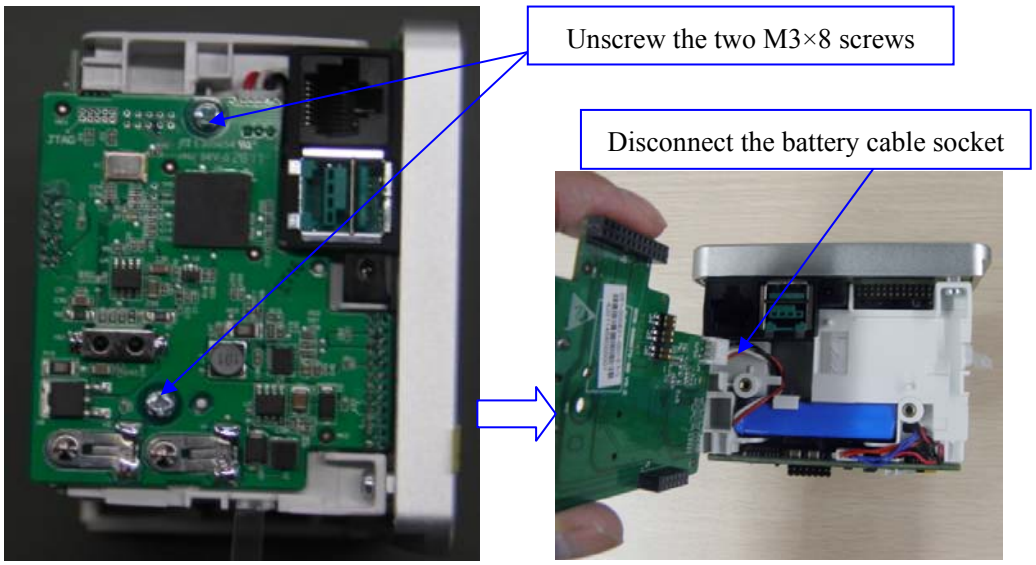


2. Carefully separate the front housing from the rear housing. Press the battery door tether to remove the main frame from the rear housing.



7.3.2.1 Disassembling the Infrared Communication Board

Unscrew the two M3×8 screws that fix the infrared communication board and remove the board from the main frame. Disconnect the socket for backup battery cable before removing the infrared communication board.

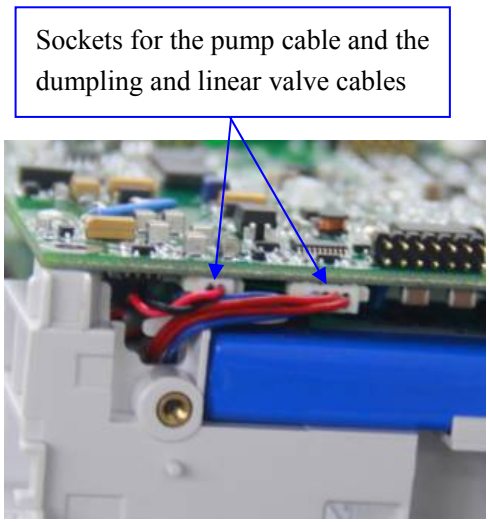


NOTE

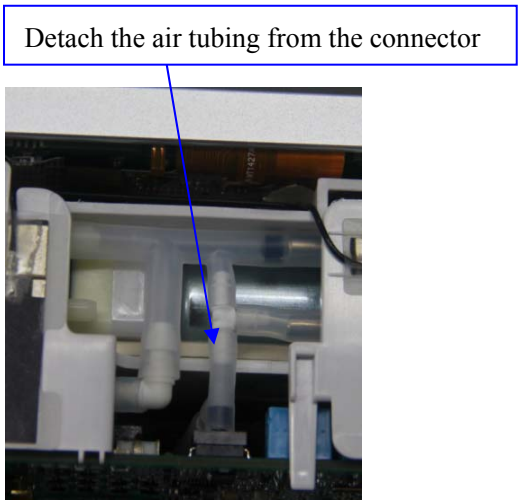
- **When disassembling the infrared communication board, use tweezers to raise the board, and then remove the board to prevent from bending the pins. Before reassembling the board, check if the pins are ok.**

7.3.2.2 Disassembling the parameter board (Mindray SPO_2/Nellcor SPO_2/Masimo SPO_2)

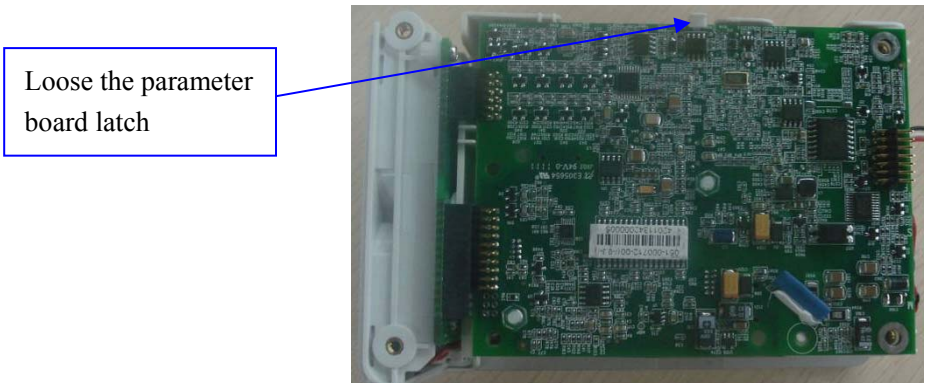
1. Disconnect the sockets for dumpling valve cable, linear valve cable and pump cable from the main board.



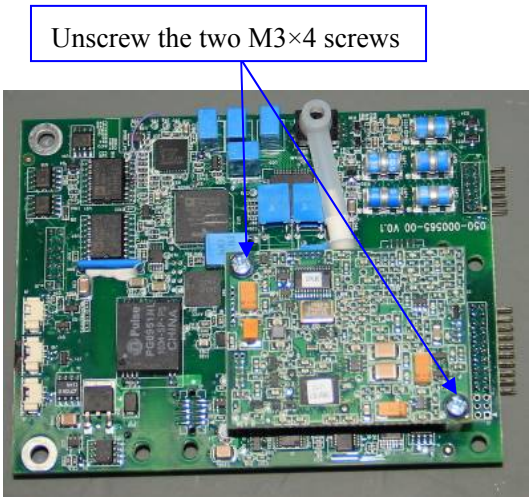
2. Detach the air tubings connecting the parameter module and the pump and valve assembly from their connectors.



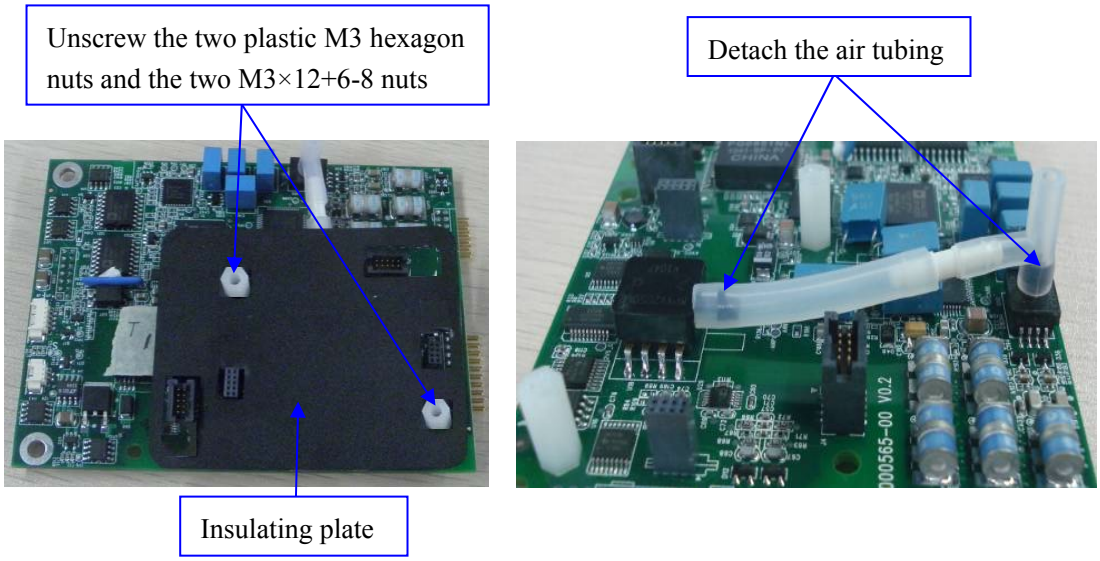
3. Loose the parameter board latch and remove the parameter board from the main frame.



4. Unscrew the two M3×4 screws that fix the SpO2 board, and then remove the SpO2 board.

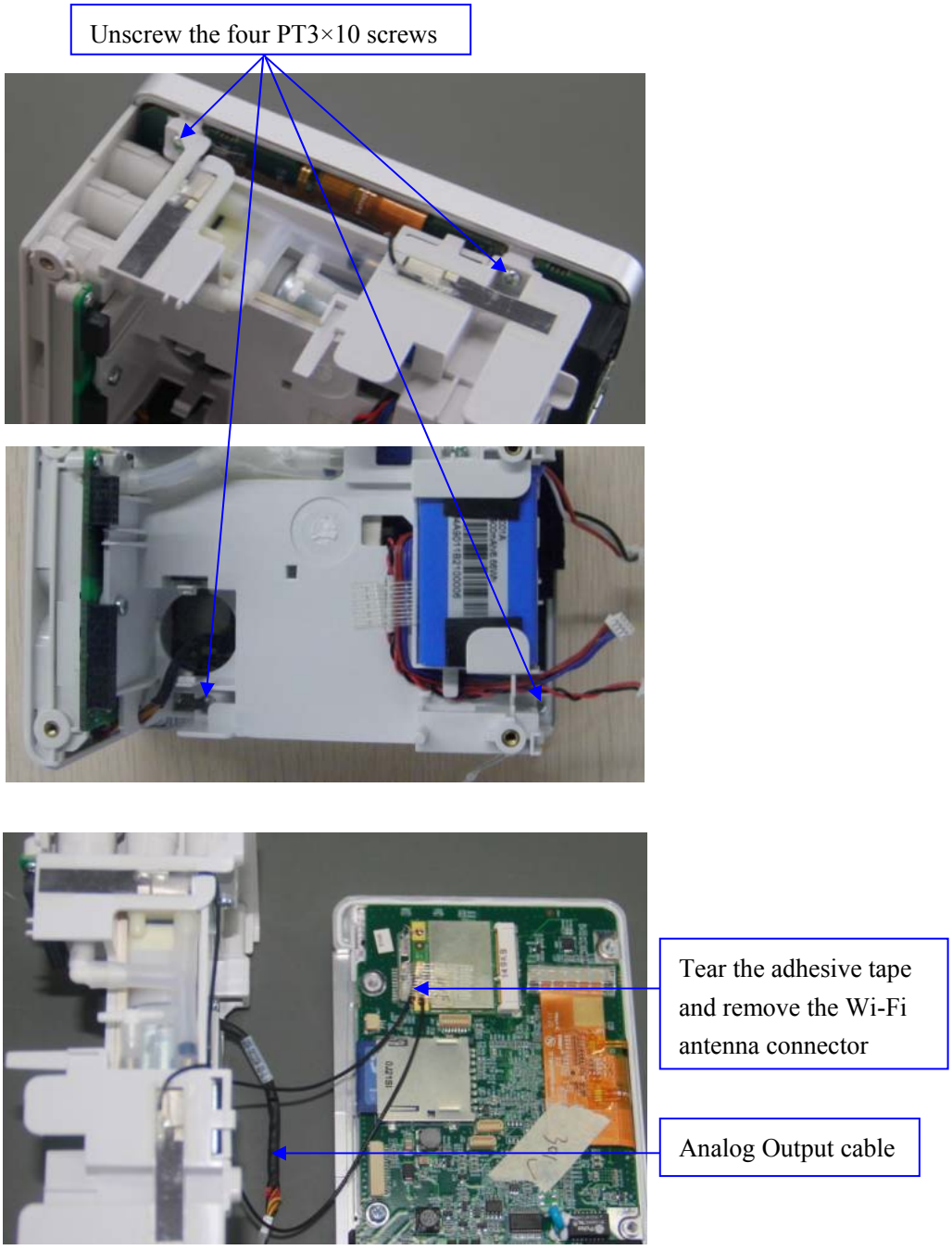


5. Remove the insulating plate. Then unscrew the two plastic M3 hexagon nuts and the two M3×12+6-8 nuts. Detach the air tubing.



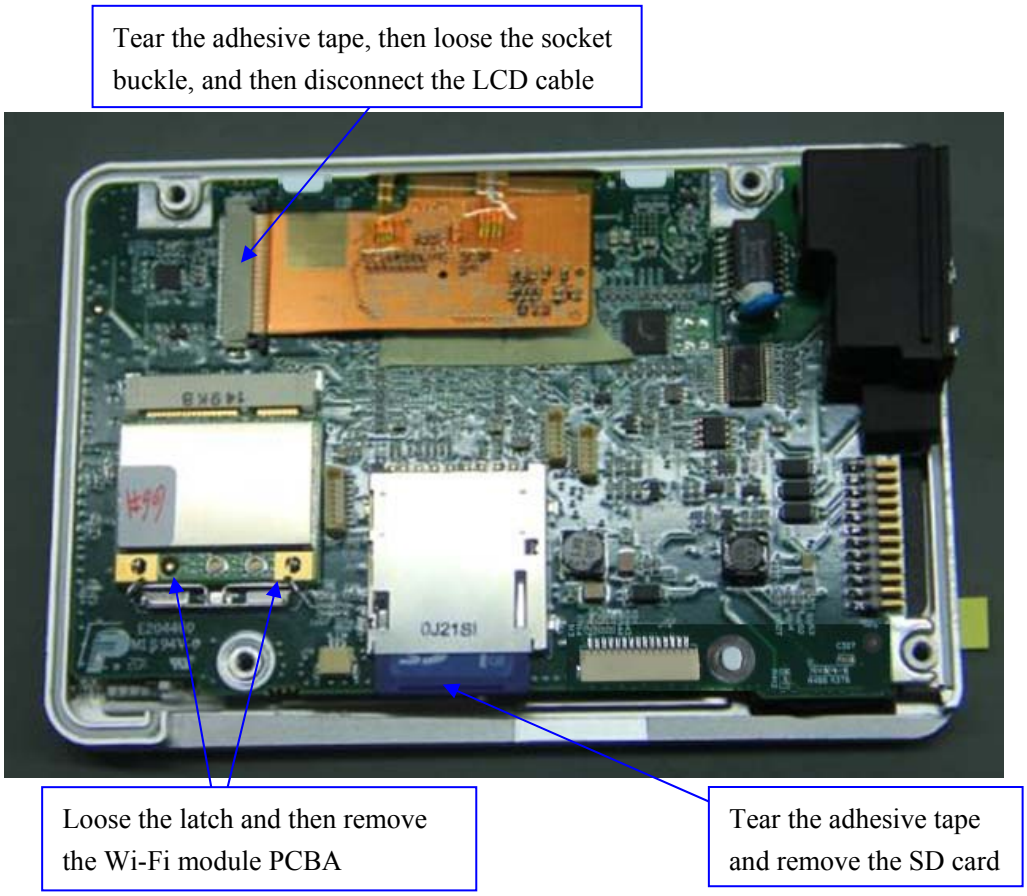
7.3.3 Disassembling the Front Housing Assembly

1. Unscrew the four PT3×10 screws that fixes the front housing assembly and remove the front housing assembly from the main frame. Make sure to disconnect the connectors for Wi-Fi antenna and analog output cable, see the figure below.



7.3.3.1 Removing the Wi-Fi Module, the SD Card and the Main Board

1. Loose the latch fixing the Wi-Fi module PCBA to remove the Wi-Fi module PCBA from the main board.
2. Tear the adhesive tape, and then press the SD card to remove it from the main board.
3. Loose the socket buckle, and then detach the LCD cable from the main board connector. Remove the main board from the front housing assembly main frame, as shown in the figure below.

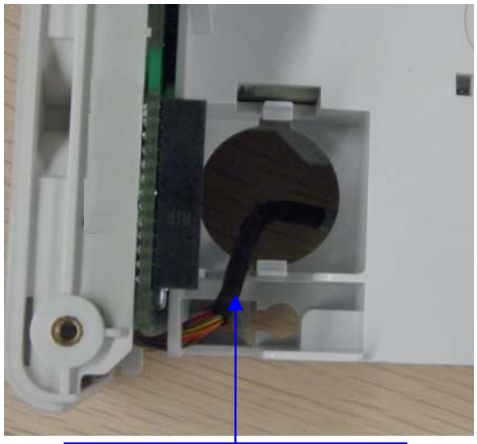


NOTE

- **Make sure to set the language to what the customer require after repairing the main board. Refer to the operator's manual for how to set the language.**
- **Please use a tape to stick the Wi-Fi antenna to the original place after replacing the antenna.**

7.3.3.2 Removing the Parameter Connector Panel Assembly

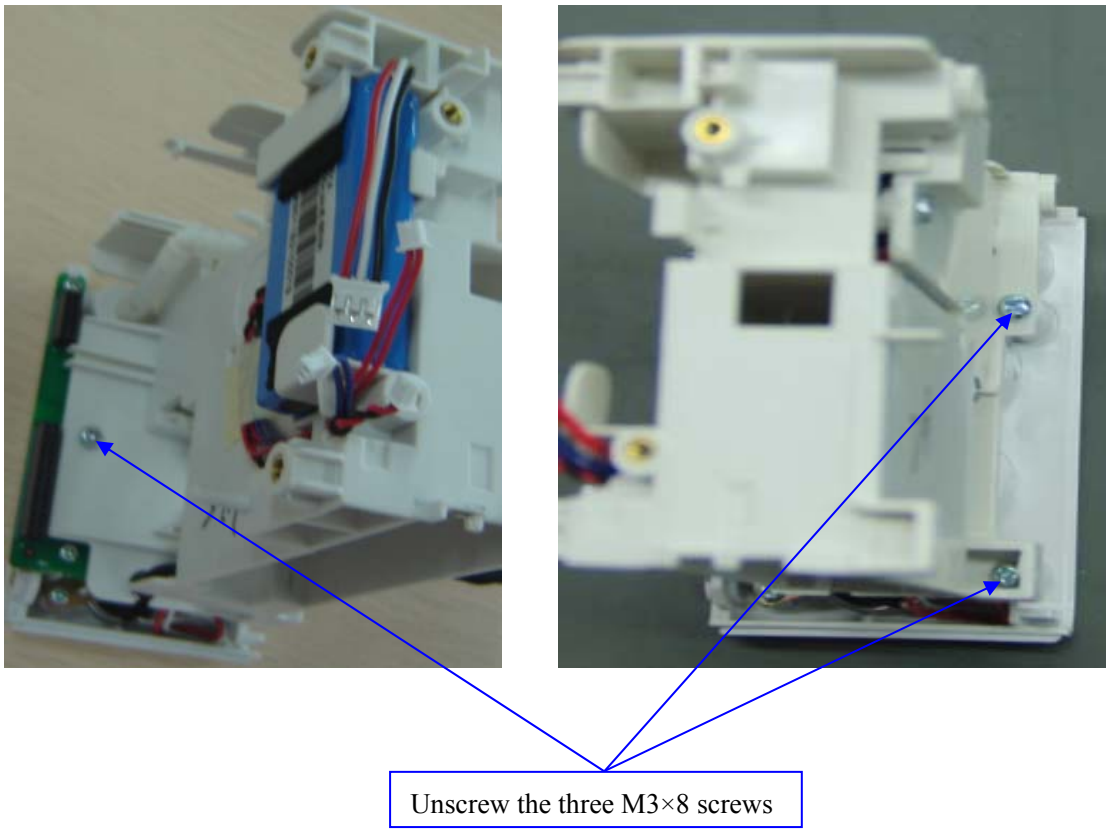
1. Draw the analog out cable from the fan hole on the main frame, and then disconnect the NIBP air tubing.



Draw the analog out cable from the fan hole

Disconnect the NIBP air tubing

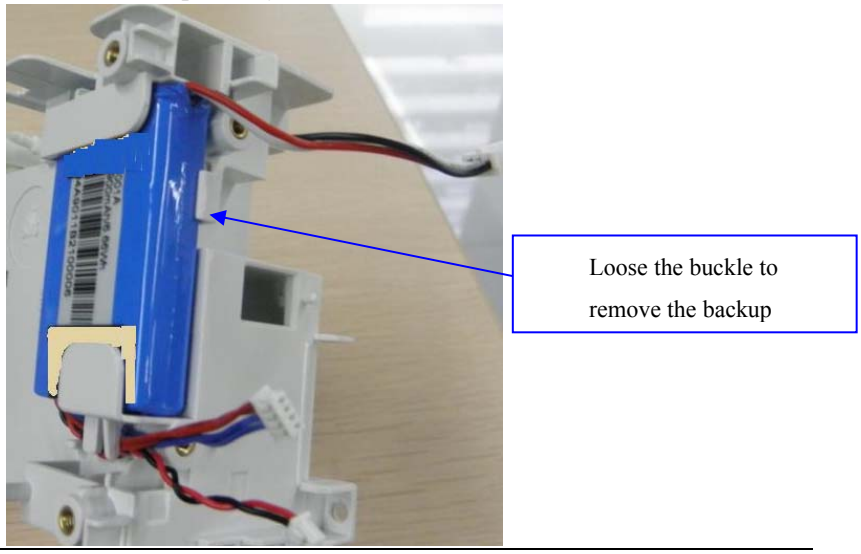
2. Unscrew the three M3×8 screws that fixes the parameter connector assembly and remove the assembly from the main frame.



Unscrew the three M3×8 screws

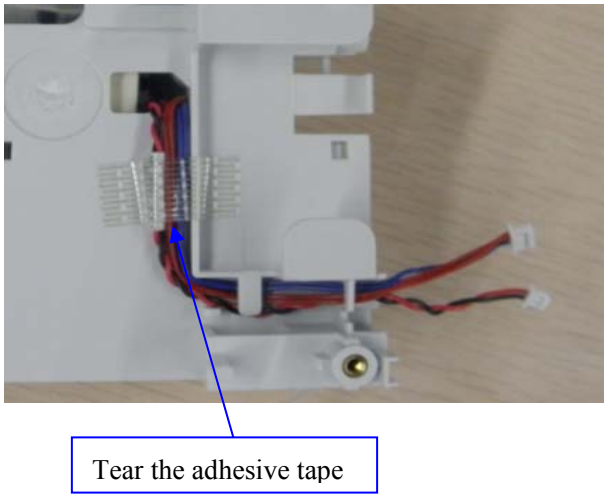
7.3.3.3 Removing the Backup Battery

Loose the buckle to remove the backup battery from the main frame.

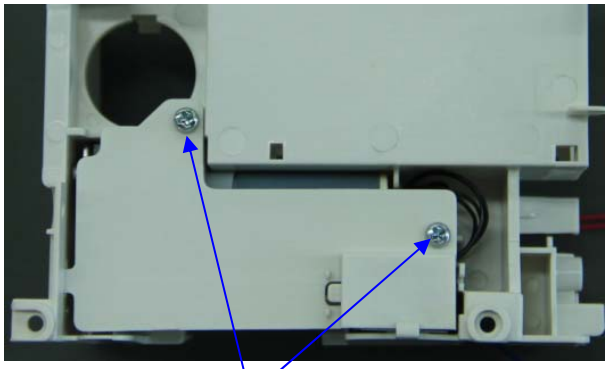


7.3.3.4 Disassembling the Pump, the Dumpling Valve and the Slow Valve

1. Tear the adhesive tape that fix the valve and pump cable. Remove the cable from the cable holder.

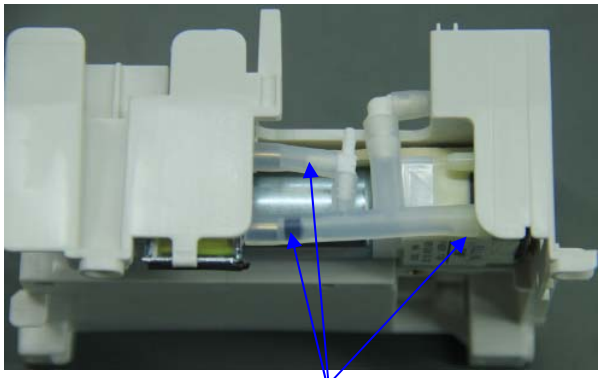


2. Unscrew the two M3×8 screws that securing the NIBP module fixing plate. Remove the NIBP module fixing plate.



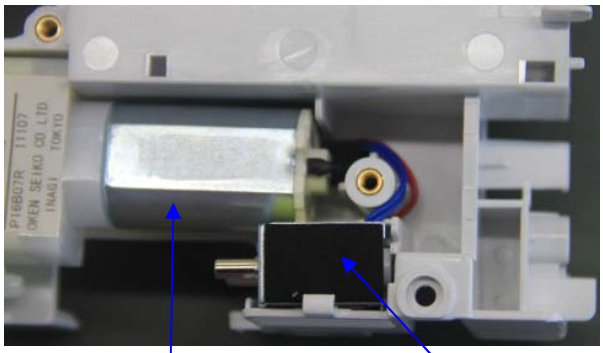
Unscrew the two M3×8 screws

3. Disconnect the air tubings connecting the pump, the dumpling valve and the linear valve.



Disconnect the air nozzle from the pump and the valves

4. Remove the pump and the valves. Before removing the pump and the valves, take the valve and pump cables from the main frame to avoid damaging the cables.



Pump

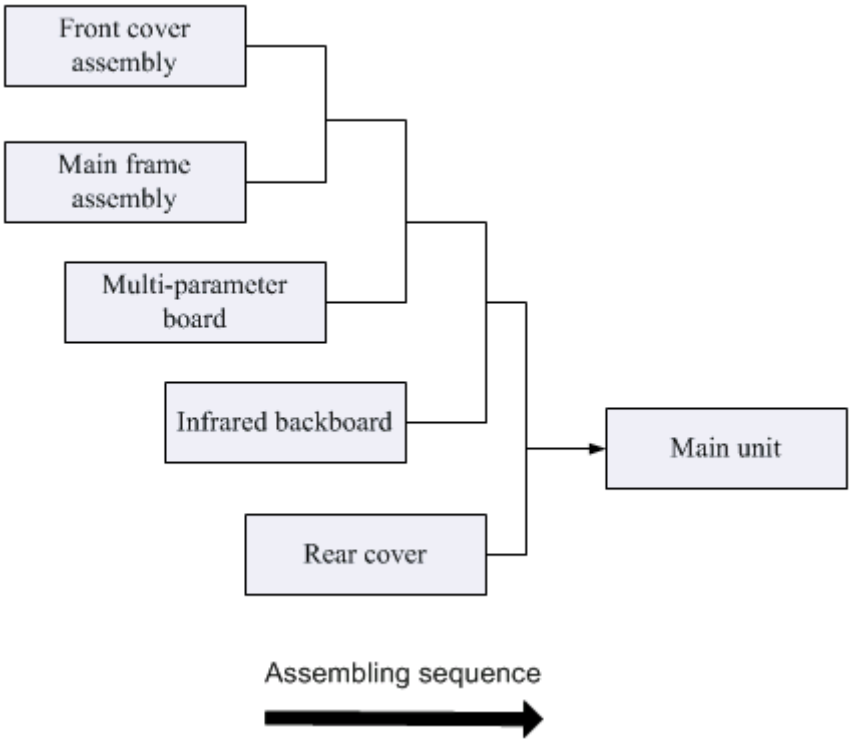
Dumpling and linear valves

8 Parts

8.1 Introduction

This chapter contains the exploded views and replaceable parts lists of the main unit and other assemblies. It helps the service engineers to identify the parts during disassembling the patient monitor and replacing the parts. The part number listed in the Parts List is only for checking the FRU part number which is also included in the Parts List. Please provide the FRU parts number if you want to purchase the spare parts.

The figure below shows the hardware architecture of the equipment's main unit.

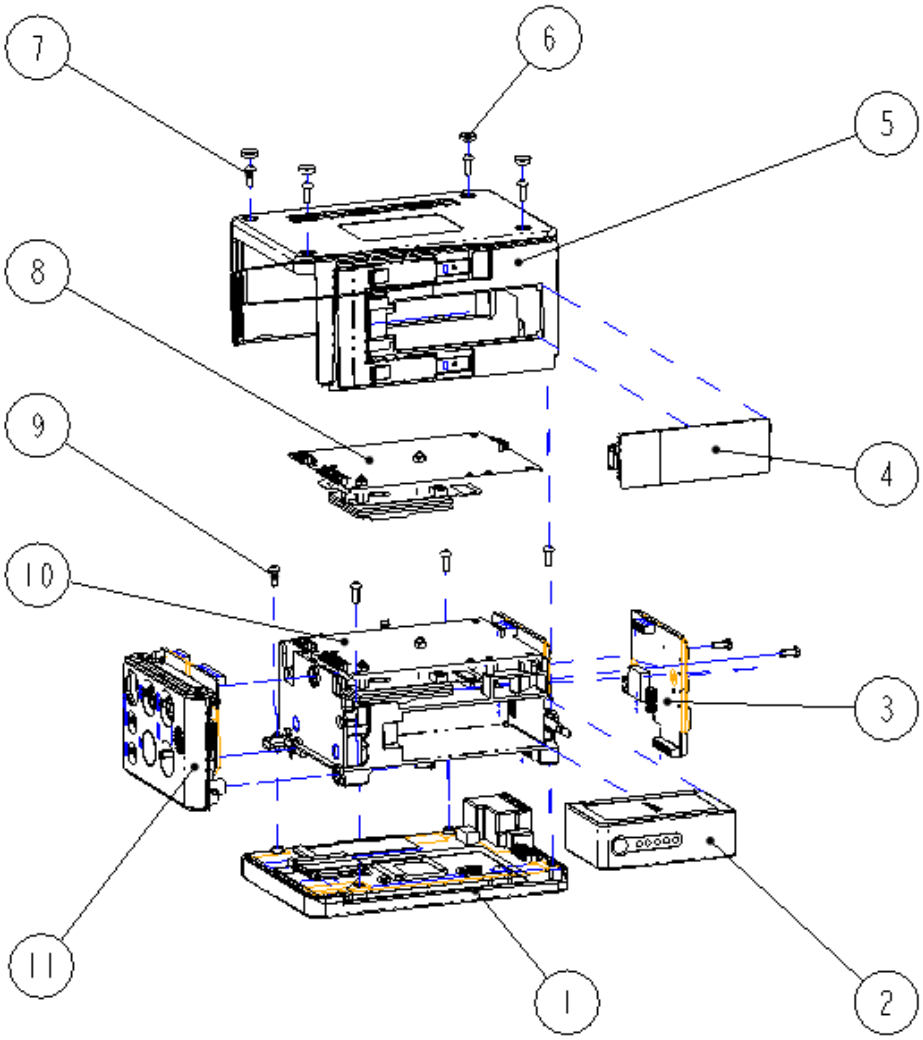


NOTE

- **The part number listed in the Parts List is only for checking the FRU part number which is also included in the Parts List. Please provide the FRU parts number if you want to purchase the spare parts.**

8.2 Main Unit

8.2.1 Exploded View



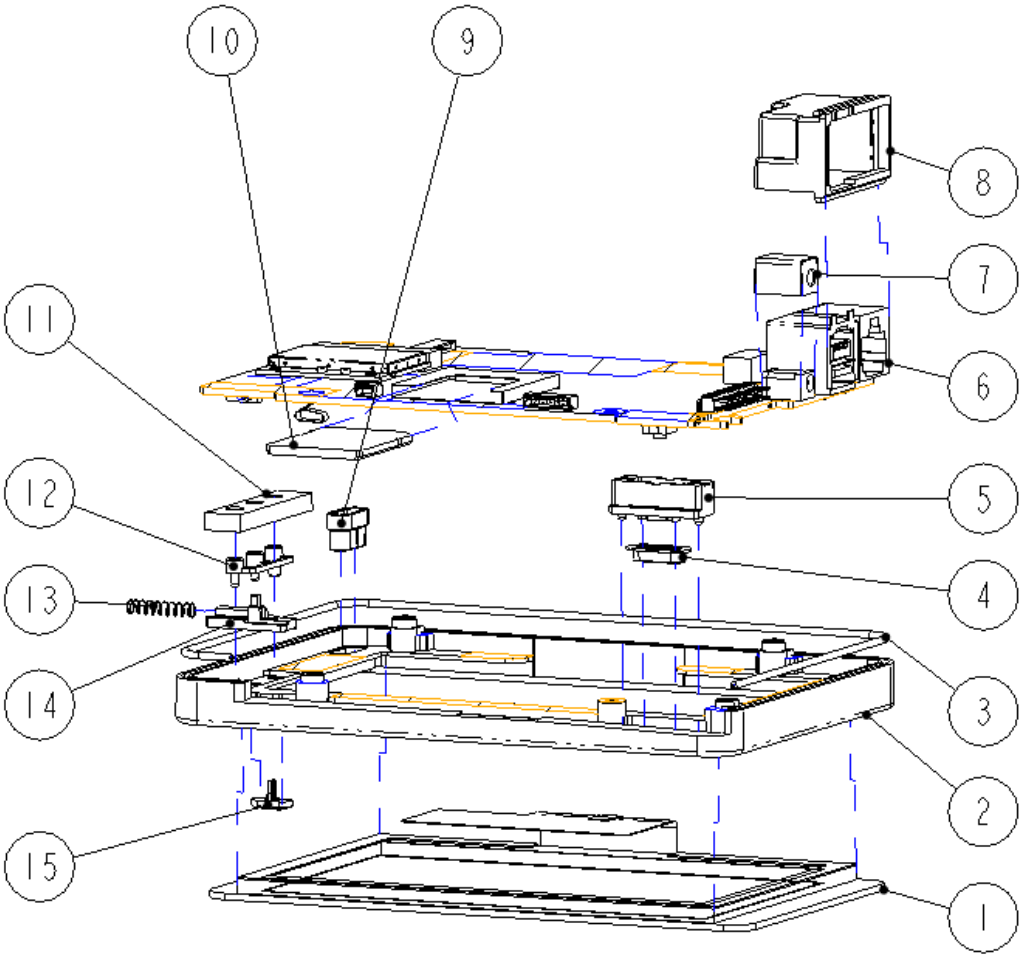
8.2.2 Parts List

SN	Part number	Description	FRU part number	Remark
1	/	Front Cover assembly	/	/
2	/	Lithium battery	/	/
3	/	Infrared Communication Backboard	051-000821-00	/
4	/	Battery door	115-010241-00	/
5	/	Rear cover assembly	115-010241-00	/

SN	Part number	Description	FRU part number	Remark
6	/	Screw hole cover	/	/
7	/	Phillips screw, pan head, M3×8	/	/
8	/	Parameter assembly	/	/
9	/	Crosshead tapping screw, pan head, PT3×10	/	/
10	/	Main frame assembly	/	/
11	/	Parameter connector assembly	115-010235-00	Mindray SpO2+IBP
	/		115-010236-00	Nellcor SpO2+IBP
	/		115-010237-00	Masimo SpO2+IBP
	/		115-010238-00	Mindray SpO2, no IBP
	/		115-010239-00	Nellcor SpO2, no IBP
	/		115-010240-00	Masimo SpO2, no IBP

8.3 Front Cover Assembly

8.3.1 Exploded View



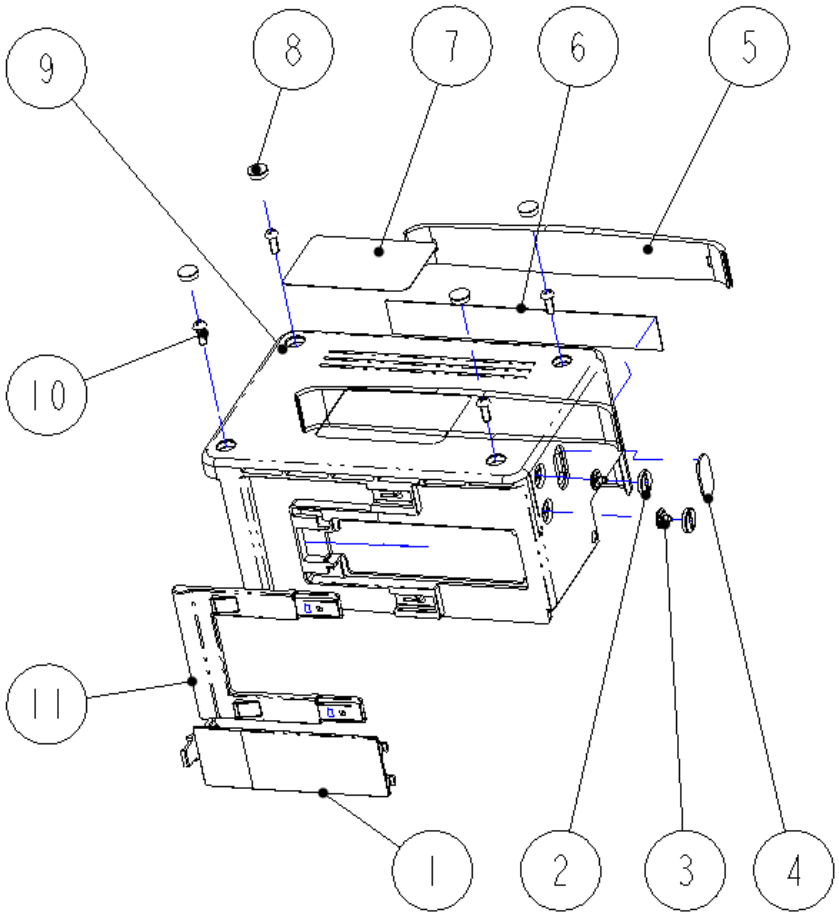
8.3.2 Parts List

SN	Part number	Description	FRU part number	Remark
1	/	LCD, TFT 5-inch	801-9281-00002-00	/
2	/	Front Cover		/
3	/	Silicone tube		/
4	/	Power button		/
5	/	Silicone base for power button		/
9	/	Light guider for alarm LED		/
11	/	Lamp shade		/
12	/	Light guider for indicating LED		/
13	/	Spring		/

SN	Part number	Description	FRU part number	Remark
14	/	Screen lock/unlock slider		/
15	/	Screen lock/unlock button		/
6	051-000731-00	9281 Main board	801-9281-00001-00	/
7	/	Waterproof cover for power supply		/
8	/	Waterproof cover		/
10	/	SD storage card (SLC)	023-000278-00	/

8.4 Rear Cover Assembly

8.4.1 Exploded View

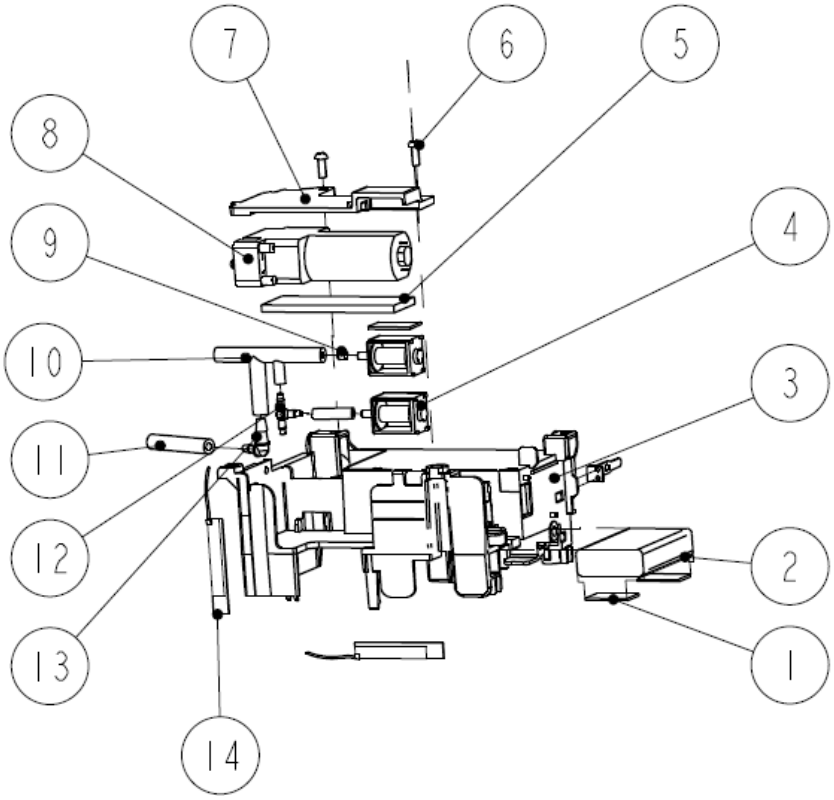


8.4.2 Parts List

SN	Part number	Description	FRU part number	Remark
1	/	Battery door	115-010241-00	/
2	/	Contact nut		/
3	/	Contact screw		/
4	/	Infrared lens		/
5	/	Guide strip		/
6	/	Slot cover		/
7	/	Label		/
8	/	Screw hole cover		/
9	/	Rear cover		/
10	/	Phillips screw, pan head, M3×8		/
11	/	Latch		/

8.5 Main Frame Assembly

8.5.1 Exploded View

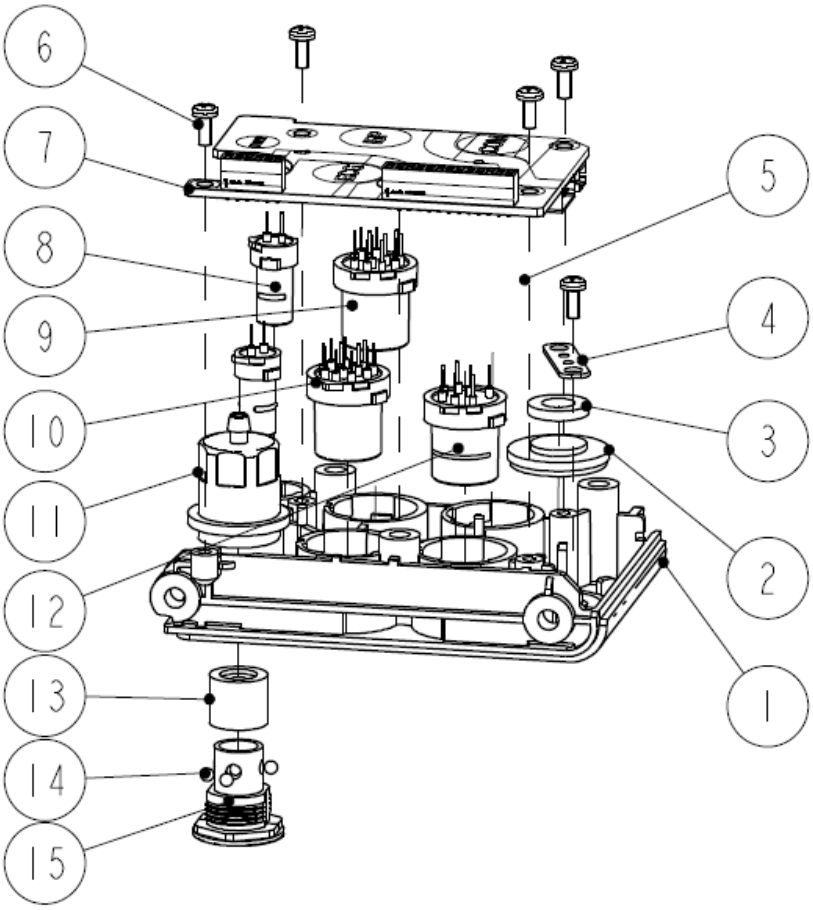


8.5.2 Parts List

SN	Part number	Description	FRU part number	Remark
1	/	Shock absorption block	801-9281-00004-00	/
4	/	Air valve		
2	/	Backup lithium battery	022-000058-00	/
3	/	Main frame (with tether)	801-9281-00024-00	/
5	/	Shock absorption cushion for pump	801-9281-00003-00	/
8	/	Pump, PI6B07		/
6	/	Screw, pan head, Phillips M3×8	/	/
7	/	NIBP fixing board	043-001737-00	/
9	/	630F reducer	801-9281-00005-00	/
10	/	4-channel silicone tube		/
11	/	Silicone tube		/
12	/	Plastic connector		/
13	/	Connector		/
14	/	Antenna	115-010234-00	/

8.6 Parameter Connector Assembly

8.6.1 Exploded View



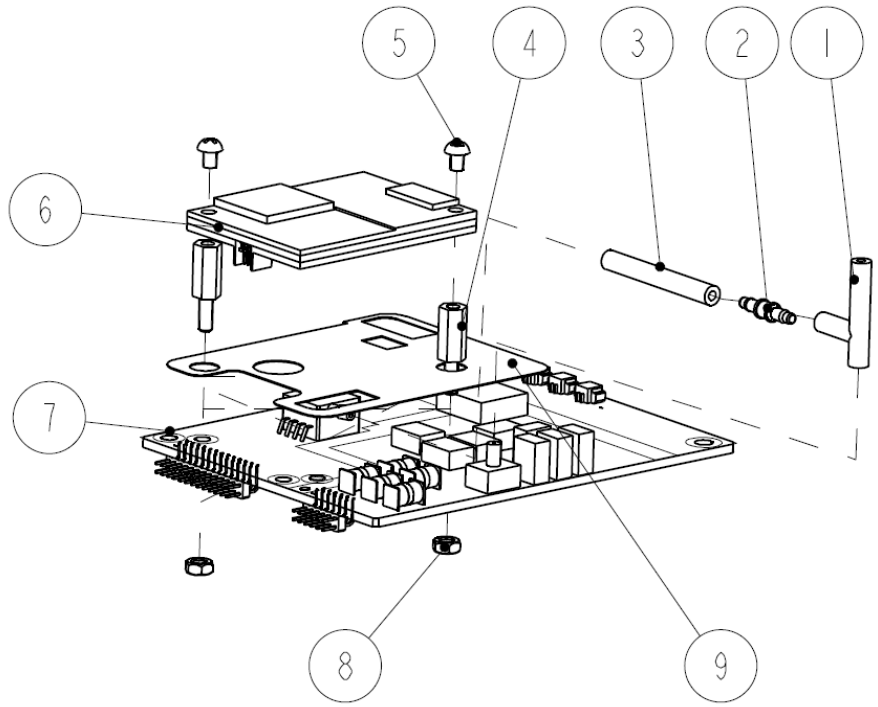
8.6.2 Parts List

SN	Part number	Description	FRU part number	Remark
1	/	Parameter panel	115-010235-00 or 115-010236-00, or 115-010237-00, or 115-010238-00, or 115-010239-00, or 115-010240-00	Refer to the equipment's parameter module configuration to choose correct FRU part number, see ***8.2.2 Parts List.***
2	/	Speaker		
3	/	Speaker cushion		
4	/	Connector fastening plate		
5	/	Multifunctional connector socket, 9281		
6	/	Screw, self-tapping, PT2.6×6		
7	/	Connector board PCBA		
8	/	TEMP connector housing		

SN	Part number	Description	FRU part number	Remark
9	/	IBP connector housing		
10	/	ECG connector housing		
11	/	NIBP external pedestal		
12	/	SpO2 connector housing		
13	/	Silicon jacket		
14	/	Steal ball, φ2.5		
15	/	NIBP internal pedestal (hexagon)		

8.7 Parameter Assembly

8.7.1 Exploded View



8.7.2 Parts List

SN	Part number	Description	FRU part number	Remark
1	/	3-channel silicone tube	801-9281-00005-00	/
2	/	Plastic connector		/
3	/	Silicone tube		/
4	/	Plastic hexagon bolt	/	/

SN	Part number	Description	FRU part number	Remark
5	/	Screw, pan head cross recessed, M3×4	/	/
6	051-000943-00	SpO_2 board	115-010245-00	Mindray SpO2
	040-001149-00		115-010244-00	Masimo SpO2
	0671-00-0102-01		115-010243-00	Nellcor SpO2
8	/	Plastic hexagon nut, M3×0.5	/	/
9	/	SpO2 board insulator	/	/
7	051-000973-00	Multi-parameter module	051-000973-00	5-lead Mindray ECG algorithm /Mindray SpO2/no IBP, 5-lead Mindray ECG algorithm /Nellcor SpO2/no IBP
			801-9281-00009-00	Mortara ARR+3/5-lead /no IBP
			801-9281-00011-00	Mortara ARR +3/5-lead ST, no IBP
	051-000974-00		051-000974-00	5-lead Mindray ECG algorithm with IBP, 5-lead Mindray ECG algorithm /Masimo SpO2 without IBP
			801-9281-00010-00	Mortara ARR+3/5-lead +IBP
			801-9281-00012-00	Mortara ARR+3/5-lead ST+IBP
	051-000975-00		051-000975-00	12-lead Mindray ECG algorithm
			801-9281-00006-00	Mortara ARR+12-lead
			801-9281-00007-00	Mortara ARR+12-lead ST
			801-9281-00008-00	Mortara ARR+12-lead ST+ resting 12-lead ECG

8.8 Other Replaceable Parts

SN	Part number	Description	FRU part number	Remark
1	009-002208-00	Analog out cable	009-002208-00	/

A Electrical Safety Inspection

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

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

The consistent use of a safety analyzer as a routine step in closing a repair or upgrade is emphasized as a mandatory step if an approved agency status is to be maintained. The safety analyzer also proves to be an excellent troubleshooting tool to detect abnormalities of line voltage and grounding, as well as total current loads.

A.1 Power Cord Plug

A.1.1 The Power Plug

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

A.2 Device Enclosure and Accessories

A.2.1 Visual Inspection

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

A.2.2 Contextual Inspection

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

A.3 Device Labeling

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

- Main unit label
- Integrated warning labels

A.4 Earth Leakage Test

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

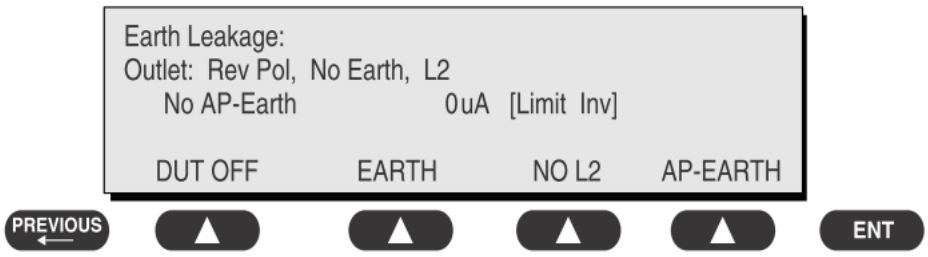
Leakage current is measured the following ways:

- Earth Leakage Current, leakage current measured through DUT outlet Earth
- Earth Leakage Current AP-EARTH (ALL Applied Parts connected to Earth), leakage current measured through DUT outlet Earth

There is no need to attach a test lead; the 601PRO automatically connects the measuring device internally.

To Perform the Test

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet, and turn on the device.
2. Attach the device's applied parts to the 601PRO applied part terminals if applicable.
3. Press shortcut key 4.The Earth Leakage test appears on the display, and the test begins immediately:



- SOFT KEY 1 toggles the DUT outlet Polarity from Normal to Off to Reverse.
- SOFT KEY 2 toggles the DUT outlet from Earth to No Earth.
- SOFT KEY 3 toggles the DUT outlet from L2 to No L2.
- SOFT KEY 4 toggles the AP to Earth to No AP to Earth.

4. Press the print data key at any time to generate a printout of the latest measurement.

In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.
- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

For USA,

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

For other countries:

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

A.5 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements may have either a true RMS or a DC-only response.

Preparation

Perform a calibration from the Mains on Applied Part menu.

The following outlet conditions apply when performing this test:

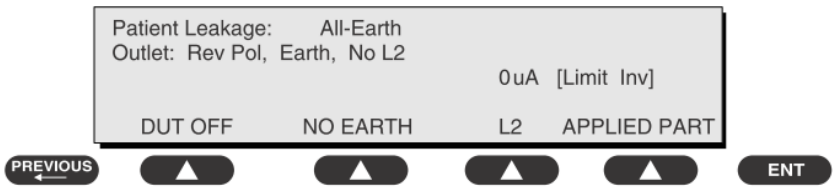
- Normal Polarity, Earth Open, Outlet ON Normal Polarity, Outlet ON
- Normal Polarity, L2 Open, Outlet ON Reversed Polarity, Outlet ON
- Reversed Polarity, Earth Open, Outlet ON Reversed Polarity, L2 Open, Outlet ON

⚠WARNING

- **If all of the applied parts correspond to the instrument type, the applied parts will be tied together and one reading will be taken. If any of the applied parts differ from the instrument type, all applied parts will be tested individually, based on the type of applied part. This applies to Auto and Step modes only.**

To Perform the Test

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet, and turn on the device.
2. Attach the applied parts to the 601PRO's applied part terminals.
3. Press shortcut key 6. The Patient Leakage test is displayed, and the test begins immediately.



4. Press APPLIED PART (SOFT KEY 4) at any time to select the desired applied part leakage current.
5. Modify the configuration of the front panel outlet by pressing the appropriate SOFT KEY on the 601PRO.
6. Press the print data key at any time to generate a printout of the latest measurement.

NOTE

- **If the current test standard being used does not include Patient Leakage DC readings, or the DC option is not enabled, then DC readings will not be available through the APPLIED PART SOFT KEY selections. Refer to Chapter 8, Standards and Principles.**

In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.
- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

For CF applied parts

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

For BF applied parts

- 10μA DC,100μA AC in Normal Condition
- 50μA DC, 500μA AC in Single Fault Condition

A.6 Mains on Applied Part Leakage

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

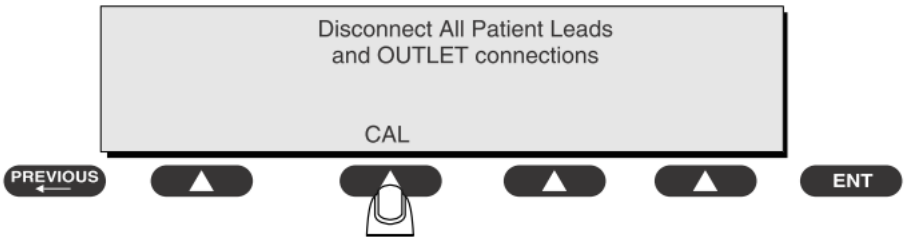
The following outlet conditions apply when performing the Mains on Applied Part test.

- Normal Polarity;
- Reversed Polarity

Preparation

To perform a calibration from the Mains on Applied Part test, press CAL (SOFT KEY 2).

1. Disconnect ALL patient leads, test leads, and DUT outlet connections.
2. Press CAL to begin calibration, as shown:



   If the calibration fails, the previously stored readings will be used until a passing calibration has occurred. Also, the esc/stop key has no effect during calibration.

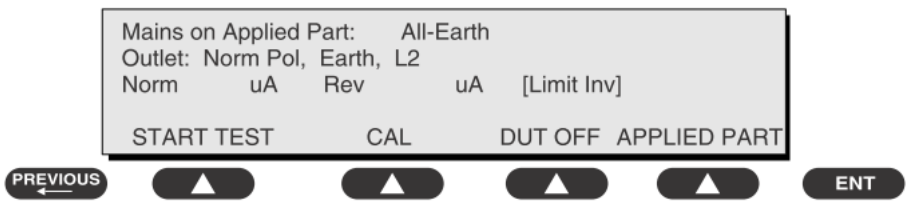
3. When the calibration is finished, the Mains on Applied Part test will reappear.

⚠WARNING

- **A 2-beep-per-second signal indicates high voltage present at the applied part terminals while a calibration is being performed.**
- **High voltage is present at applied part terminals while measurements are being taken.**

To Perform the Test

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601
2. Attach the applied parts to the 601PRO applied part terminals.
3. Attach the red terminal lead to a conductive part on the DUT enclosure.
4. Press shortcut key 7. The Mains on Applied Part test is displayed.



5. Select the desired outlet configuration and applied part to test using the appropriate SOFT KEYS:
6. Press START TEST (SOFT KEY 1) to begin the test.
7. Press the print data key to generate a printout of the latest measurement.

NOTE

- **If all of the applied parts correspond to the instrument type, the applied parts will be tied together and one reading will be taken. If any of the applied parts differ from the instrument type, all applied parts will be tested individually, based on the type of applied part. This applies to Auto and Step modes only.**

In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.
- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

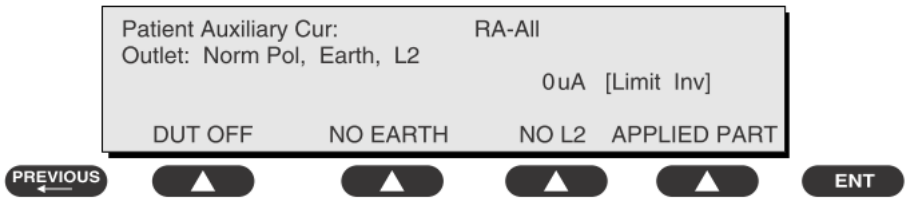
- For CF applied parts: 50μA
- For BF applied parts: 5000μA

A.7 Patient Auxiliary Current

Patient Auxiliary currents are measured between any selected ECG jack and the remaining selected ECG jacks. All measurements may have either a true RMS or a DC-only response.

Preparation

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet, and turn on the device.
2. Attach the patient leads to the 601PRO ECG jacks.
3. Define the Lead Types from the View Settings Option (refer to: Lead Type Definitions in Section 5 of this chapter).
4. Press shortcut key 8. The Patient Auxiliary Current test is displayed, and the test begins immediately. Display values are continuously updated until another test is selected.



5. Press SOFT KEYS 1-4 to select leakage tests
6. Press APPLIED PART (SOFT KEY 4) at any time to select the desired applied part leakage current:
7. Modify the configuration of the front panel outlet by pressing the appropriate SOFT KEY on the 601PRO:
8. Press the print data key at any time to generate a printout of the latest measurement.

NOTE

- **If the current test standard being used does not include Patient Auxiliary Current DC readings, or the DC option is not enabled, then DC readings will not be available through the APPLIED PART SOFT KEY selections.**

In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.
- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

For CF applied parts,

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

For BF applied parts,

- 10μA DC, 100μA AC in Normal Condition
- 50μA DC, 500μA AC in Single Fault Condition

A.8 Functional test

For functional test items, please refer to relevant functional tests in ***5 Testing and Maintenance***..

ELECTRICAL SAFETY INSPECTION FORM (American Version)

Overall assessment:

Scheduled inspection	Test item: 1, 2, 3, 8
Unopened repair type	Test item: 1, 2, 3, 8
Opened repair type, not modify the power part including transformer or patient circuit board	Test item: 1, 2, 3, 4,8
Opened repair type, modify the power part including transformer or patient circuit board	Test item: 1, 2, 3, 4, 5, 6, 7, 8

<table>
<tr><td colspan="5">Location:</td><td colspan="2">Technician:</td></tr>
<tr><td colspan="5">Equipment:</td><td colspan="2">Control Number:</td></tr>
<tr><td colspan="3">Manufacturer:</td><td colspan="2">Model:</td><td colspan="2">SN:</td></tr>
<tr><td colspan="5">Measurement equipment /SN:</td><td colspan="2">Date of Calibration:</td></tr>
<tr><td colspan="5">INSPECTION AND TESTING</td><td>Pass/Fail</td><td>Comments</td></tr>
<tr><td>1</td><td colspan="4">Power Cord Plug</td><td></td><td></td></tr>
<tr><td>2</td><td colspan="4">Device Enclosure and Accessories</td><td></td><td></td></tr>
<tr><td>3</td><td colspan="4">Device Labeling</td><td></td><td></td></tr>
<tr><td rowspan="2">4</td><td rowspan="2">Earth Leakage</td><td>Normal condition(NC)</td><td>____μA</td><td></td><td rowspan="2">Max:
NC: 300μA
SFC: 1000μA</td></tr>
<tr><td>Single Fault condition(SFC)</td><td>____μA</td><td></td></tr>
<tr><td rowspan="2">5*</td><td rowspan="2">Patient Leakage Current</td><td>Normal condition(NC)</td><td>____μA</td><td></td><td rowspan="2">Max:
CF applied part:
NC:10μA, SFC: 50μA
BF applied part:
NC:100μA, SFC: 500μA</td></tr>
<tr><td>Single Fault condition(SFC)</td><td>____μA</td><td></td></tr>
<tr><td>6*</td><td colspan="3">Mains on Applied Part Leakage</td><td>____μA</td><td></td><td>Max:
CF applied part: 50μA
BF applied part: 5000μA</td></tr>
<tr><td rowspan="2">7*</td><td rowspan="2">Patient Auxiliary Current</td><td>Normal condition(NC)</td><td>____μA</td><td></td><td rowspan="2">Max:
CF applied part:
NC:10μA, SFC: 50μA
BF applied part:
NC:100μA, SFC: 500μA</td></tr>
<tr><td>Single Fault condition(SFC)</td><td>____μA</td><td></td></tr>
<tr><td>8</td><td colspan="3">Functional test (parameters tested):</td><td></td><td></td></tr>
</table>

Note: The test items marked "*" are needed only for incoming inspections and after repairs or modifications that may have affected lead leakage [NFPA 99 (2005)8.5.2.1.3].

Deficiency /Note:

Name/ Signature: _____ Date:_____

ELECTRICAL SAFETY INSPECTION FORM (International version)

Overall assessment:

Scheduled inspection	Test item: 1, 2, 3, 8
Unopened repair type	Test item: 1, 2, 3, 8
Opened repair type, not modify the power part including transformer or patient circuit board	Test item: 1, 2, 3, 4,8
Opened repair type, modify the power part including transformer or patient circuit board	Test item: 1, 2, 3, 4, 5, 6, 7, 8

Location:				**Technician:**	
Equipment:				**Control Number:**	
Manufacturer:		**Model:**		**SN:**	
Measurement equipment /SN:				**Date of Calibration:**	
INSPECTION AND TESTING				**Pass/Fail**	**Comments**
1	Power Cord Plug				
2	Device Enclosure and Accessories				
3	Device Labeling				
4	Earth Leakage	Normal condition(NC)	____μA		Max NC:500μA SFC:1000μA
		Single Fault condition(SFC)	____μA		
5*	Patient Leakage Current	Normal condition(NC)	____μA		Max CF applied part NC:10μA, SFC: 50μA BF applied part NC:100μA, SFC: 500μA
		Single Fault condition(SFC)	____μA		
6*	Mains on Applied Part Leakage		____μA		Max: CF applied part: 50μA BF applied part: 5000μA
7*	Patient Auxiliary Current	Normal condition(NC)	____μA		Max: CF applied part: NC:10μA, SFC: 50μA BF applied part: NC:100μA, SFC: 500μA
		Single Fault condition(SFC)	____μA		
8	Functional test (parameters tested):				

Note: The test items marked "*" are needed only for incoming inspections and after repairs or modifications that may have affected lead leakage [NFPA 99 (2005)8.5.2.1.3].

Deficiency /Note:

Name /Signature: _____ Date:_____