BeneHeart D3/BeneHeart D2

Defibrillator/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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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 defibrillator/ monitors

Passwords

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

- Installation mode: 888888
- Service mode: 332888
- Configuration mode: 315666

Contents

1 Safety

1.1 Safety Information

⚠ DANGER

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

⚠ WARNING

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

⚠ CAUTION

- **Indicates a potential hazard or unsafe maintenance 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 can better service your product.**

1.1.1 Dangers

⚠ DANGER

- **The equipment delivers up to 360 J of electrical energy. Unless properly used as described in these Operating Instructions, this electrical energy may cause serious injury or death. Do not attempt to operate this defibrillator unless thoroughly familiar with these operating instructions and the function of all controls, indicators, connectors, and accessories.**
- **Defibrillation current can cause operator or bystander severe injury or even death. Keep distance with the patient or metal devices connected to the patient during defibrillation.**
- **Do not disassemble the defibrillator. It contains no operator serviceable components and dangerous high voltages may be present. Contact authorized service personnel for repair.**
- **To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents (such as gasoline). Keep the equipment and the operating environment dry and clean.**

1.1.2 Warnings

⚠ WARNING

- **Before putting the system into operation, the operator must verify that the equipment, connecting cables and accessories are in correct working order and operating condition.**
- **Make sure the synchronous input system is applied to this equipment and the input signal is correct if necessary.**
- **To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth. If the installation does not provide for a protective earth conductor, disconnect it from the power line and operate it on smart lithium-ion batteries.**
- **Ensure that the equipment is supplied with continuous electric power during work. Sudden power failure leads to the loss of patient data.**
- **Use and store the equipment in specified environmental condition. The equipment and accessories may not meet the performance specification due to aging, stored or used outside the specified temperature and humidity range.**
- **This equipment is used for single patient at a time.**
- **Medical electrical equipment which does not incorporate defibrillator protection should be disconnected during defibrillation.**
- **Do not defibrillate a patient who lies on the wet ground.**
- **Do not touch the patient and live parts simultaneously.**
- **Do not touch the patient when connecting the peripheral equipment via the I/O signal ports to prevent patient leakage current from exceeding the requirements specified by the standard.**

- **Do not rely exclusively on the audible alarm system for patient monitoring. Adjustment of alarm volume to a low level or off may result in a hazard to the patient. Remember that alarm settings should be customized according to different patient situations and always keeping the patient under close surveillance is the most reliable way for safe patient monitoring.**
- **Do not perform any functional check if the equipment is connected with a patient; otherwise the patient might be shocked.**
- **Remain attentive to the patient during applying therapy. Delay in delivering a shock may result in a rhythm that was analyzed as shockable converting spontaneously to non-shockable and could result in inappropriate delivery of a shock.**
- **For the treatment of patients with implantable pacemakers, place therapy pads or paddles away from internal pacemaker generator if possible to help prevent damage to the pacemaker.**
- **To avoid inadvertent disconnection, route all cables in a way to prevent a stumbling hazard. Wrap and secure excess cabling to reduce risk of entanglement or strangulation by patients or personnel.**
- **Do not touch device connectors, recorder print head, battery connector or other live equipment if in contact with the patient; otherwise patient injury may result.**
- **To ensure patient safety, use only parts and accessories specified in this manual.**
- **Package material may contaminate the environment. Properly dispose of the package material according to applicable waste control regulations and keep it out of children's reach.**

1.1.3 Cautions

⚠ CAUTION

- **Use of Manual Therapy security password requires the clinician to know and remember the password. Failure to enter correct password will prevent the delivery of manual defibrillation, synchronized cardioversion and pacing therapy.**
- **At the end of its service life, the equipment, as well as its accessories, must be disposed of in compliance with the guidelines regulating the disposal of such products to avoid contaminating the environment.**
- **Magnetic and electrical fields are capable of interfering with the proper performance of the equipment. For this reason make sure that all external devices operated in the vicinity of the equipment comply with the relevant EMC requirements. Mobile phones, X-ray equipment or MRI devices are a possible source of interference as they may emit higher levels of electromagnetic radiation.**
- **Before connecting the equipment to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the equipment's label or in this manual.**
- **Always install or carry the equipment properly to avoid damage caused by drop, impact, strong vibration or other mechanical force.**

- **Dry the equipment immediately in case of rain.**
- **Never charge and deliver shock frequently in non-clinical situations. Otherwise equipment damage could occur.**

1.1.4 Notes

NOTE

- **The equipment use a mains plug as isolation means to the mains power supply. Do not locate the equipment in a place difficult to operate the mains plug.**
- **During normal use, the operator shall stand in front of the equipment.**
- **Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.**
- **If the equipment is run on a DC power supply, a DC/AC adapter we supply should be used.**
- **This manual describes all features and options. Your equipment may not have all of them.**

1.2 Equipment Symbols

See the ***BeneHeart D3/ BeneHeart D2 Defibrillator/Monitor Operator's Manual (P/N: 046-010599-00)*** for information about the symbols used on this product and its packaging.

2 Theory of Operation

2.1 The Basics

2.1.1 Overview

The BeneHeart D3/BeneHeart D2 defibrillator/monitor (hereinafter called the equipment) provides four operating modes: Manual Defib, AED, Pacer, and Monitor. The equipment is for use in hospital and pre-hospital settings. It adopts the most advanced biphasic defibrillation technology and can deliver up to 360J of defibrillation energy.

The equipment has an 7.0 inch color TFT LCD display with LED Backlight.

2.1.2 Main Functions

The equipment has the following main functions:

- Manual Defib Mode

In Manual Defib Mode, the operator analyzes the patient's ECG, and, if appropriate, follows this procedure:

1 Select the Manual Defib mode, adjust the energy level if necessary

2 Charge; and

3 Deliver the shock.

Defibrillation may be performed through external paddles or multifunction electrode pads. In Manual Defib Mode, you can also perform synchronized cardioversion.

- AED Mode

In AED mode, the equipment automatically analyzes the patient's ECG rhythm and indicates whether or not a shockable rhythm is detected. Voice prompts provide easy-to-follow instructions and patient information to guide you through the defibrillation process. Messages and flashing buttons are also presented to reinforce the voice prompts.

- Pacer Mode

The Pacer Mode offers non-invasive transcutaneous pacing therapy. Pace pulses are delivered through multifunction electrode pads using a monophasic square waveform.

- Monitor Mode

In Monitor Mode, the equipment is intended for monitoring, displaying, reviewing, storing and printing multiple physiological parameters and waveforms including ECG and pulse oximetry (SpO2),

2.2 Components

The equipment consists of a main unit, accessories and PC software.

The main unit is the core of the equipment. It provides:

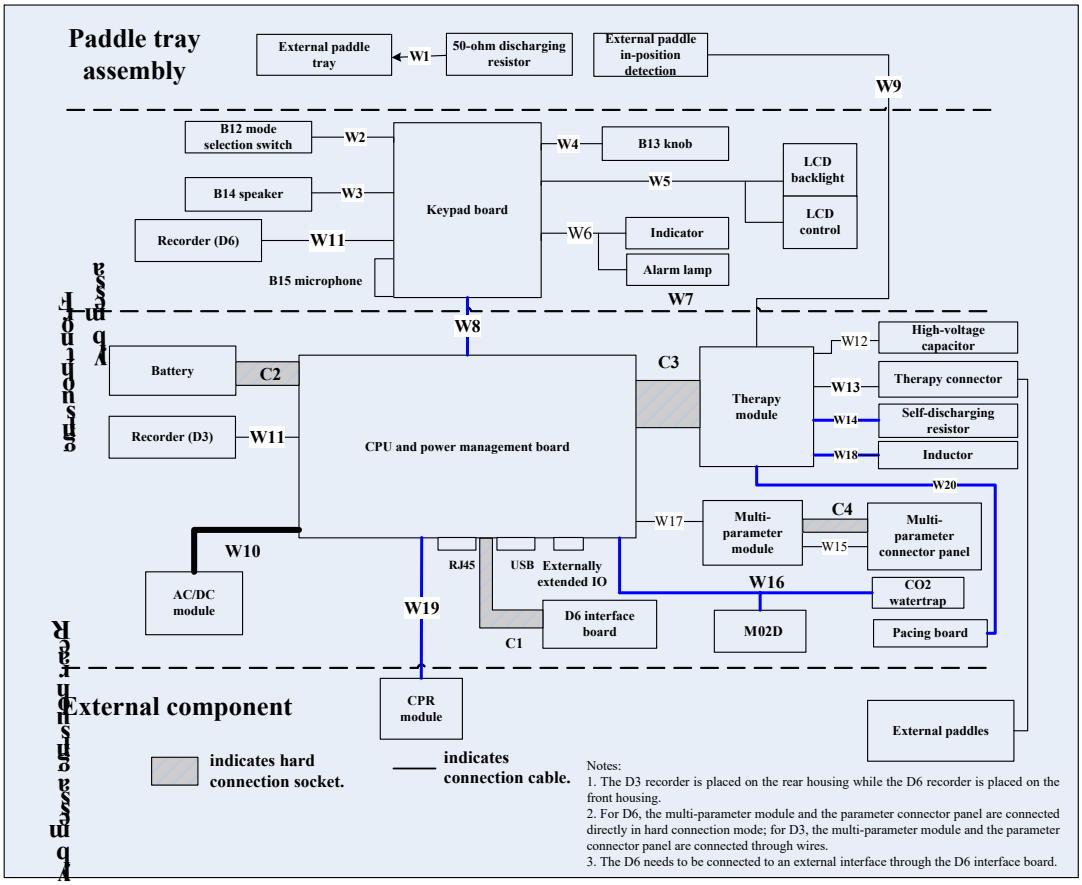
- Overall system control;
- System power supply;
- Display;
- Defibrillation and pacing;
- AED ;
- Man-mahcine interface;
- Audible and visible alarms;
- Multiple parameter measurements;
- External connectors and communication; and
- Recording, printing and data storage.

2.3 Main Unit

The main unit is composed of the front housing assembly, rear housing assembly and the paddle tray assembly. External paddles are rested in the paddle tray.

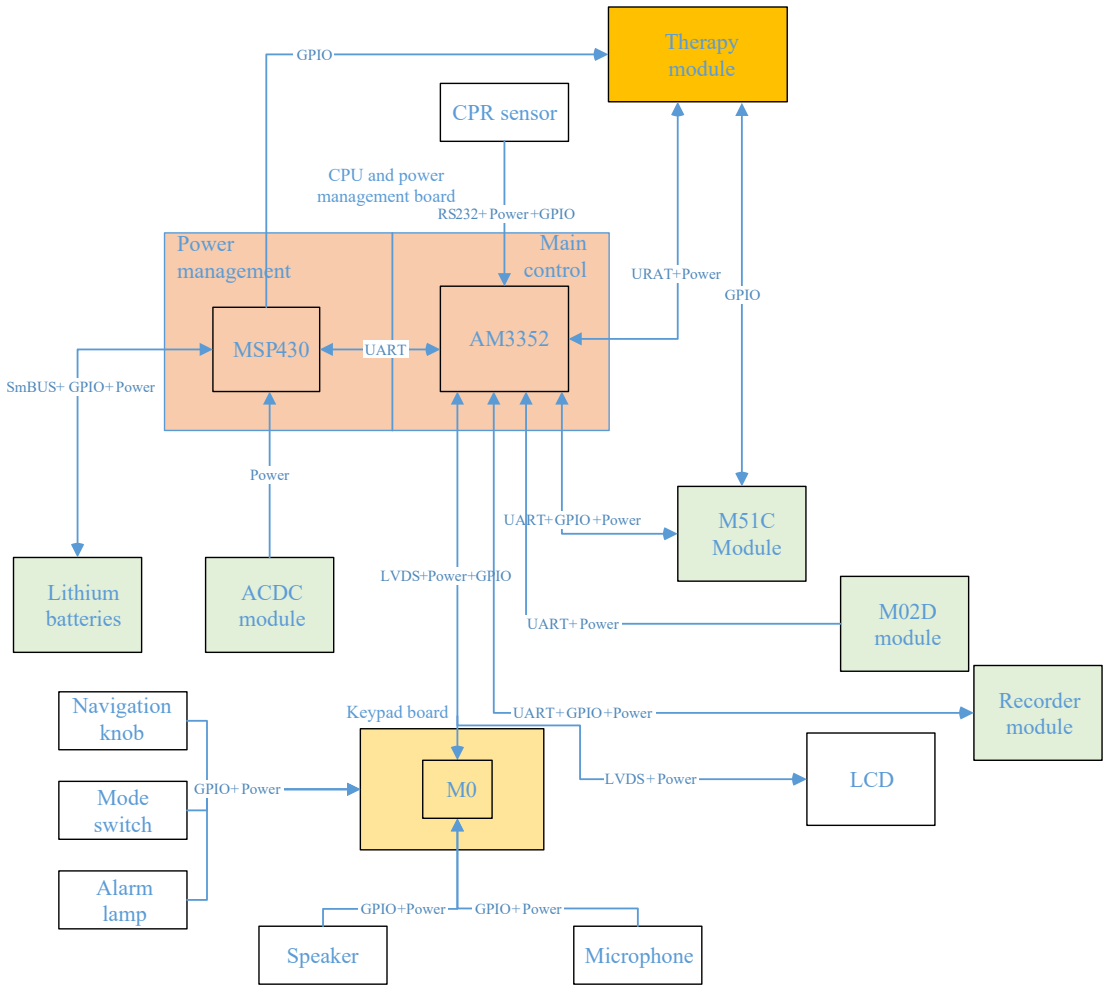
- The front housing assembly mainly consists of LCD, keypad board, speaker, microphone, Mode Select knob, navigation knob, alarm lamp board, front housing and front housing sheet metal, etc.
- The rear housing assembly consists of CPU board, therapy module, high voltage capacitors, MPM module, power management board, fan, measurement module panel, therapy port, recorder and rear housing, etc.
- The paddle tray is for holding the external paddles.

2.3.1 System Structure



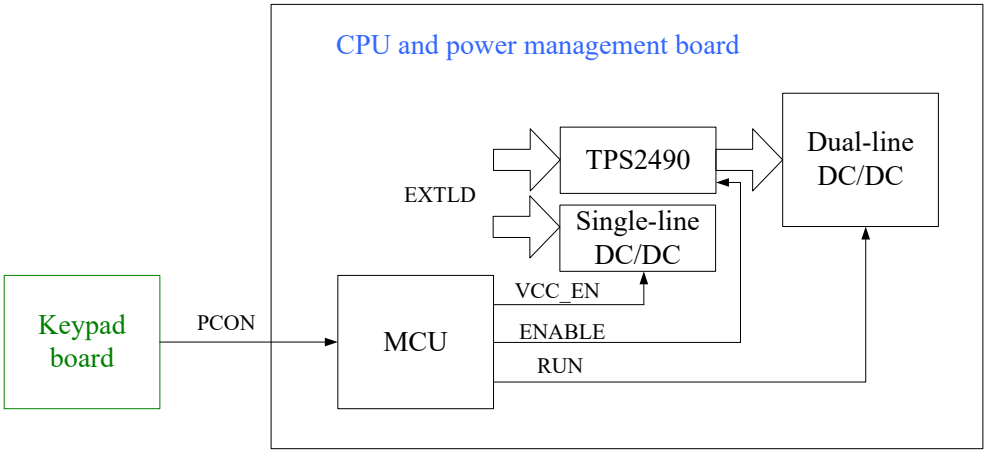
2.3.2 System Signal Flow

The system uses the CPU and power management board as the core. The CPU and power management board is divided into the power management part and the main control part. The processor of the power management part is MSP430, which mainly implements communication with external lithium batteries and power management. The processor of the main control part is AM3352, which communicates with and controls other subsystem modules (including the therapy module, M51C module, M02D module, recorder module, CPR sensor, and keypad board on the front housing). The main control module communicates with other subsystems through asynchronous serial ports. The keypad board on the front housing implements the transit between man-machine interaction interfaces and signal display. The processor is M0, which controls input and output signals of keys, knobs, module switches, and alarm lamps.



2.3.3 Signal Sequence of Power-On/Off

The power-on/off action is triggered by the naviagation knbo on the keypad board of the front housing. The power-on/off process is controlled by the power management processor as follows:



Power-on process: When you rotate the mode switch on the front panel of the defibrillator/monitor to a mode other than "Off", the PCON signal value is changed from 1 to 0 to awake the MCU. The MCU immediately outputs the ENABLE control signal to the TPS2490 enabling the VBUS. Then, the MCU enables the RUN signal control of the dual-line DC-DC module to output 5 V (VBB) and 12 V signals.

Power-off process: When your rotate the mode switch to "Off", the PCON signal value is changed from 0 to 1, and the MCU outputs the ENABLE=0 and RUN=0 signals to shut down the VBUS and the DC-DC module.

2.4 Front Housing Assembly

The front housing assembly consists of display assembly, a keypad board, a speaker, a microphone, a Mode Select knob, a navigation knob, an alarm lamp board, a front housing and front housing sheet metal, etc.

Navigation Knob

You can rotate the knob clockwise or counterclockwise and then press it to confirm a selection. The knob is connected to the keypad board.

Mode Select Knob

A 8-position encoder is used to select the operating mode (Monitor, Manual Defib, AED and Pacer) and power-off. The unused positions are mechanically disabled.

Speaker

The speaker emits alarm tones, key-stroke tone, heart beats and PR sound. It supports the functions of PITCH TONE and the multi-level volume. The speaker is connected to the keypad board.

Microphone

It provides the function of voice recording.

Alarm Lamp Board

The keypad board interfaces with the alarm lamp board. The alarm lamp transmits signals to drive the green and yellow alarm lamp. The drvie current 60mA.

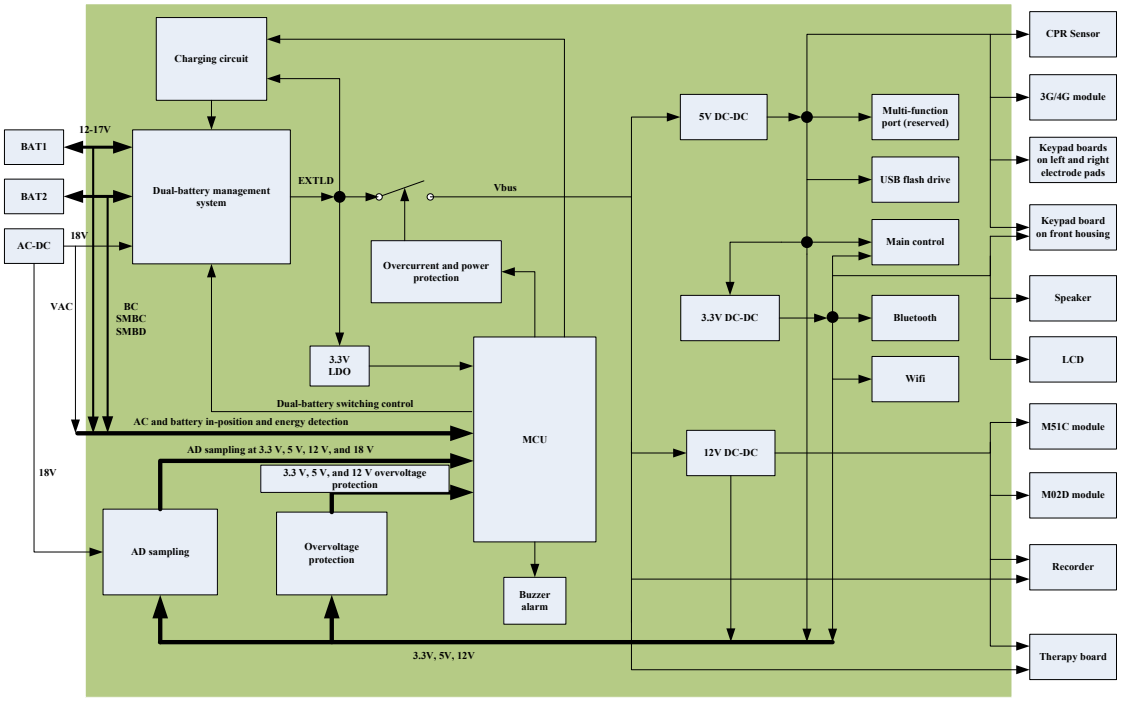
2.5 Paddle Tray

The paddle tray is used to hold paddles. It has a 50 ohm test load and position detective switch inside. When the equipment runs self tests, test current will pass through the test load.

2.6 Rear Housing Assembly

The rear housing assembly consists of the CPU and power management board, therapy module, high voltage capacitors, M51C module, recorder, rear housing, parameter receptacle panel, and therapy port.

2.6.1 Power System



- AC/DC board

It has AC mains as an input and outputs 18VDC.

- Battery

Its rated voltage is 14.8V, 3000mAh. Or, its rated voltage is 15.1V, 5600mAh.

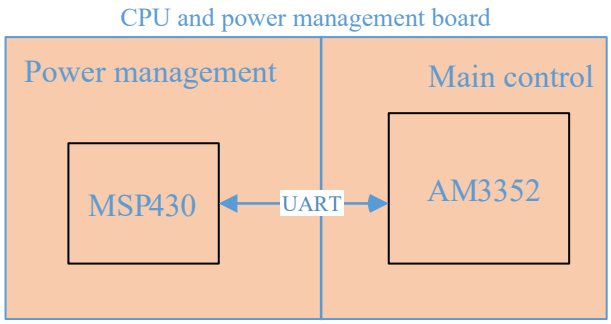
- CPU and power management board

It manages the system power input, supplies different system power, and monitors the power status. The power management part implements battery charging and status information management.

The priority of system power supply is AC mains, Battery. That is to say, when AC is not available, Battery is used.

2.6.2 Main Control System

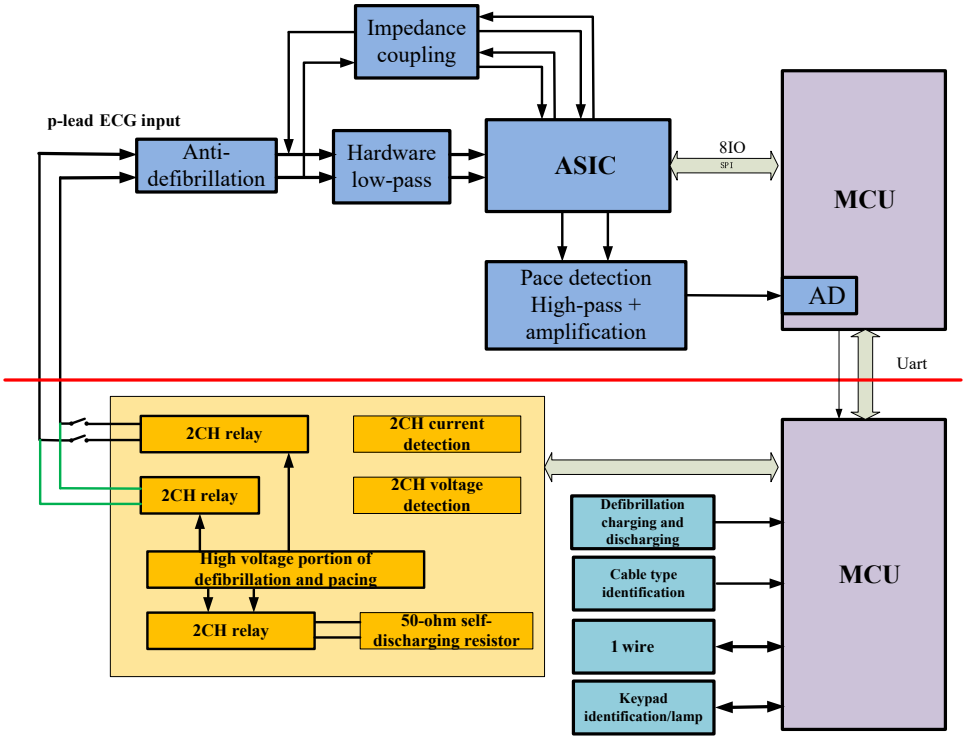
Serving as the core of the system, the main control system implements the display, storage, printing, and review of parameters and waveforms, as well as parameter algorithm processing.



The integrated CPU and power management board consists of the MSP430 for power management and the AM3352 for main control. The MSP430 monitors the power status and controls the power-on/off; the AM3352 implements man-machine interaction, screen display, and AED algorithm. The main control module part and the power management part communicate with each other through asynchronous serial ports.

2.6.3 Therapy System

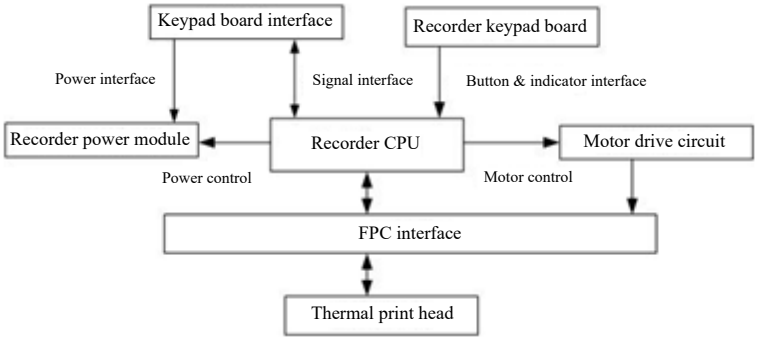
The therapy system implements the measurement of P-lead input ECG and human body impedance, as well as the defibrillation and pacing functions. The pacing function is implemented by the optional pacing module.



2.6.4 Recorder

The recorder implements the parameter and waveform printing function by using the universal TR6F recorder module.

The recorder receives data from the CPU board and then sends the data to a thermal head for printing. The recorder front panel has a key for starting/ stopping the recorder and a green indicator which is lit when working normally. The recorder is connected to the keypad board which board provides connection for the TR6F recorder. The block diagram and functional modules of the recorder are shown as below.

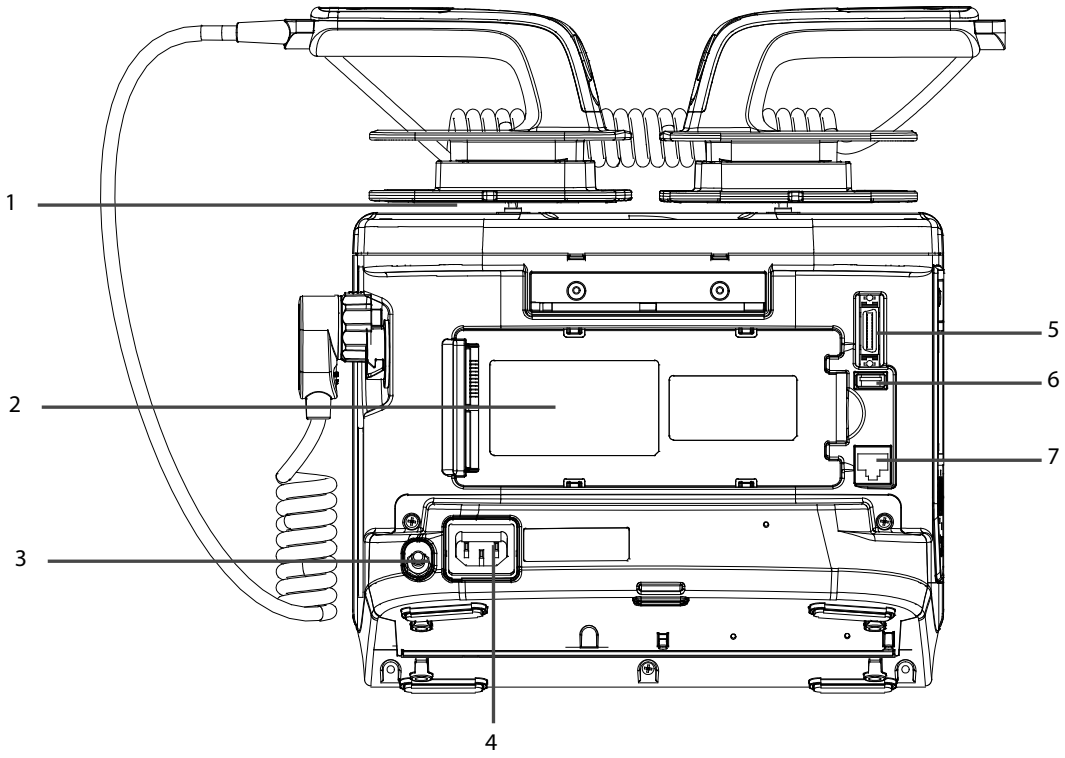


Module	Description
Power Interface	Adjusts input voltage to run each module.
Recorder CPU	Coordinates module communication, controls and processes module status.
Keypad board Interface	Serves as the data communication channel between the keypad board and the recorder CPU.
Motor Drive Circuit	Receives control signals sent by the recorder CPU to drive the step motor.
Keypad and Indicator Interface	Sends keypad commands to CPU and receives CPU commands to control the indicator.
FPC Interface	Sends print head information to CPU and receives CPU commands to control the print head.

2.6.5 Parameter Measurement System

The M51C multi-parameter module implements the parameter measurement function. It mainly implements 3/5-lead ECG, SpO2, NIBP, and RESP measurement functions.

2.7 External Device Connectors



1. Hook
2. Battery
3. Equipotential grounding terminal: When the defibrillator/monitor and other devices are to be used together, their equipotential grounding terminals should be connected together to eliminate the potential difference between them.
4. External power input: It connects an AC power cord or a DC/AC adapter to run the equipment respectively on the external AC mains or DC power supply.
5. Multifunctional connector: It connects a CPR sensor, provides ECG output and defib synchronization input.
6. USB connector
7. Network connector: It is a standard RJ45 connector.

3 Unpacking and Installation

This chapter provides information you need to install a defibrillator/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 new equipment is accepted.

The following pictures show the defibrillator/monitor and accessory packing.

Main unit packing

Accessory packing

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 defibrillator/monitor needs to be connected to network.

⚠ WARNING

- **Only power cables provided with the system may be used. For reasons of safety, power (mains) extension cables or adapters shall not be used.**

Environmental Requirements

⚠ WARNING

- **To avoid explosion hazard, do not use the equipment in the presence of flammable anaesthetics, vapours or liquids.**

CAUTION

- **The environment where the defibrillator/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:

Operating environment	
Operating Temperature	0 to 45℃ (at least 60 minutes of working time when the temperature reduces from room temperature to – 20℃) (5 to 40℃ for CO_2 module)
Operating humidity	10% to 95%, (non-condensing)
Operating altitude	-381mmHg to + 4575mmHg (106.2kPa to 57kPa) 430mmHg to + 790 mmHg for CO_2 module (57.3kPa to 105.3kPa)
Storage environment	
Storage temperature	-30 to 70℃(-20 to 60℃ for CO2 module)
Storage humidity	10% to 95%, (non-condensing)
Storage altitude	-381mmHg to +4575 mmHg (106.2kPa to 57kPa) 430mmHg to + 790 mmHg for CO_2 module (57.3kPa to 105.3kPa)

3.2.2 Electrical Requirements

Check cables and power cords. Make sure that:

1. All system cables, power cords and power plugs 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.

⚠ WARNING

- **Only power sockets with protective grounding can be used.**

The electrical specification is as follows:

Line voltage:	100 to 240VAC (±10%)
Current:	1.8 A
Frequency:	50/60Hz (±3Hz)

3.3 Preparation for Power On

Before connecting the power cord to the defibrillator/monitor's power input, check that

- The mains voltage meets the requirement.
- 3-wire power cord is used. The power socket should be 3-wire also. This ensures that the defibrillator/monitor is properly grounded. Do not use 2-wire power cord or socket.
- The equipotential grounding terminals should be connected together when the defibrillator/monitor and other devices are to be used together.
- The defibrillator/monitor is not placed under the infusion bag or placed where their might be liquid spillage. This protects the defibrillator/monitor from liquid ingress.

3.4 User Test

A user test shall be performed after the defibrillator/monitor is installed. Follow this procedure:

1. Connect AC mains or install the battery.
2. Connect the external paddles. If pads are used, connect the test load.
3. Select the Main Menu button on the equipment's front panel and select **[User Test >>]**. Select all test items and press **[Start]** to perform user test.

NOTE

- **Install the battery and properly place the external paddles in the paddle tray or connect the pads cable and 50 Ω test load. Otherwise the User Test will fail.**

See the ***BeneHeart D3/ BeneHeart D2 Defibrillator/Monitor Operator's Manual (P/N: 046-010599-00)*** for the detailed information on user test.

4 Testing and Maintenance

4.1 Introduction

To ensure the equipment always functions normally, qualified service personnel should perform regular inspection, maintenance and test. This chapter provides a checklist of the testing procedures for the equipment 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 equipment meets the performance specifications. If the equipment 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 [Installation Mode] and [Service Mode] menus to avoid loss of data.**
- **Before testing, service personnel should acquaint themselves with the test tools and make sure that test tools and cables are applicable.**
- **When testing monitoring parameters, move the Mode Select knob to Monitor to access the Monitor Mode.**
- **When performing therapy function tests, move the Mode Select knob to corresponding mode.**

4.1.1 Test Report

After completing the tests, service personnel can record test results by referring the ***Test Report*** at the end of this chapter.

4.1.2 Recommended Frequency

Test item			After repair	Function suspected	6 months	12 months	24 months
Visual inspection			√				
Power-on Test			√				
User test			√				
Function Checks	Recorder check		√			√	
	ECG Cable Test					√	
	Manual defibrillation tests	Charge/ discharge	√	√		√	
		Energy disarming					
		Synchronous defibrillation					
	Pacing test						
Preventive Maintenance (Only Performance Tests)	ECG	Performance test	√	√		√	
		Module calibration	√	√			
	Resp	Performance test	√	√		√	
	SpO2	Performance test	√	√		√	
Performing Tests in the Installation Mode	Maintain NIBP	Performs the NIBP leakage test and NIBP accuracy test		√		√	
	Maintain CO2	Calibrates the CO2 module.		√		√	
	Version	Displays the equipment information		/		/	
	CPR	Displays the battery information of the CPR sensor		/		√	
	Format Data Card	Formats the storage card.		√		√	
	Watchdog Test	Checks if the equipment can be normally restarted.				√	
	Modify Password	Modifies the password for		/		/	

Test item			After repair	Function suspected	6 months	12 months	24 months
Performing Tests in the Installation Mode		entering the installation mode.					
	Electrical safety tests as per IEC60601-1	Earth leakage current	√			√	
		Patient leakage current					
		Patient auxiliary current					

4.2 Visual Test

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 housing, the display screen and the buttons for physical damage.
- Inspect accessories for 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.

4.3 Power On Test

This test is to verify that the defibrillator/ monitor can power on normally. The test is passed if the defibrillator/ monitor starts up by following this procedure:

1. Place the external paddles on paddle tray, insert the battery in the battery compartment, and then connect the equipment with AC mains. In this case, both the AC indicator and battery indicator shall light.
2. Turn the Mode Select knob to Monitor. Check that the equipment passes the self test and is turned on properly.
3. Check the display of technical alarm area, prompt area and battery status indicator on the upper right corner of the main screen to judge whether the equipment runs normally.

If a power-on self test error happens, the service indicator is illuminated, and alarm messages are displayed in the technical alarm area.

4.4 User Test

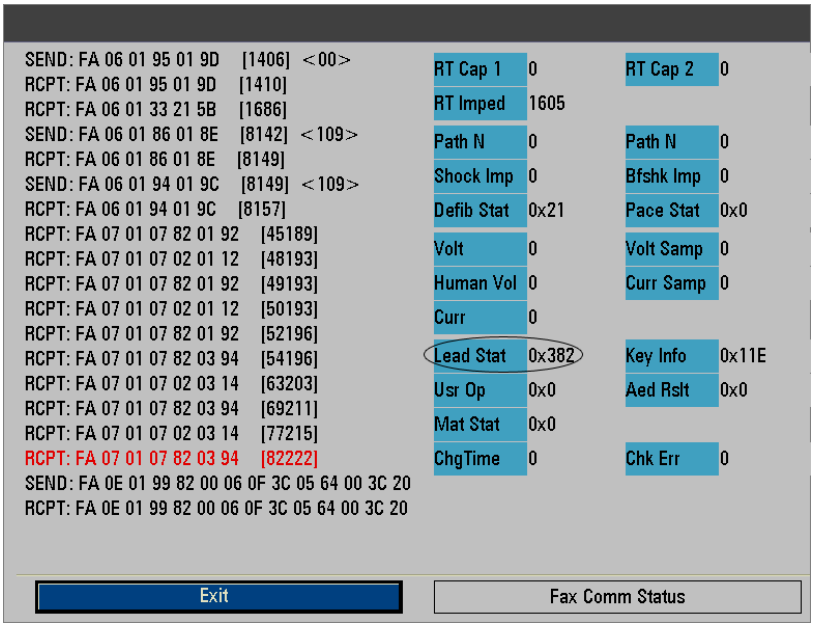
Follow this procedure to perform user test:

1. If you use external paddles, place them on the paddle tray; if you use a pads cable, connect it to the test load.
2. Insert the battery into the equipment. Connect the AC mains if no battery is available.
3. Select the Main Menu button on the equipment's front panel. In the Main Menu, select [User Test>>]. Then a prompt "Enter user test?" pops up. Select "Yes" to enter the User Test screen.
4. Check the test items you want to perform and select [Start] to start user test

The test results indicate the condition of the system. If any item fails, the Red Cross status indicator flashes.

If you cannot pass User Test or the message "Connect paddles cable, and place paddles in paddle tray" is shown when paddle cable is connected and paddles are placed in paddle tray, check paddles status.

Select the Monitor mode. Press and hold the [Event] hardkey, and then press the [Lead Select] hardkey on the front panel, the following screen appears.



Observe the reading of "Lead Stat":

- 0 x 382: Paddles are properly placed in paddle tray.
- 0 x 182: The travel switch indicating paddle status may fail, but impedance is correct.
- 0 x 102 :Paddles are not properly placed in paddle tray and the impedance value is not correct.

4.5 Password for Installation Mode

Accessing installation mode is password protected. The required password is set to 888888 before the equipment leaves the factory.

4.6 Module Performance Tests

4.6.1 Manual Defibrillation Test

Test tools:

- Defibrillator/pacer analyzer

Charge/Discharge

1. Remove the batteries and connect the equipment with AC mains. Turn the Mode Select knob to Manual Defib.
2. Connect the external paddles to the equipment and place the paddles on the defibrillator/pacer analyzer.
3. Enter the Configuration-Main screen. From the Record Setup menu set [**Shock Event**] to [**On**] so that shock events can be recorded automatically if happened.
4. Set the analyzer to Energy Measurement mode. In this case, the energy value should be displayed as 0 or blank.
5. Select the energy level to 1J.
6. Charge/discharge the equipment to verify the energies measured by the analyzer meet the following accuracy:

Selected Energy (J)	Measured Value (J)
1	0 to 3
100	85 to 115
360	306 to 414

7. Set the energy to 100J and 360J respectively. Repeat step 6.
8. Disconnect the equipment from the AC mains. Run the equipment on fully charged battery. Move the Mode Select knob to Manual Defib. Repeat steps 5 to 7.
9. Use multifunctional electrode pads. Repeat steps 5 to 7.
10. Verify that the equipment records the shock events automatically and correctly.

Energy Disarming

1. Run the equipment on fully charged battery. Move the Mode Select knob to Manual Defib.
2. Connect the external paddles to the equipment and place the paddles on the defibrillator/pacer analyzer.
3. Set the analyzer to Energy Measurement mode. In this case, the energy value should be displayed as 0 or blank.
4. Select the energy level to 360J.
5. Charge the equipment.
6. Verify that the charge tone is issued during charging.
7. Press the "Disarm" soft key to discharge the energy internally.
8. Verify that a prompt "Charge Removed" appears and the charge done tone stops.
9. Verify that the value measured by the analyzer is 0J or blank.
10. Enter the Configuration-Main menu, select [**Manual Therapy Setup**] and set [**Time to Auto Disarm**] to [**60s**].
11. Exit "Configuration Management". The equipment restarts automatically.
12. Set the analyzer to Energy Measurement mode. In this case, the energy value should be displayed as 0 or blank.
13. Select the energy level to 360J.
14. Charge the equipment. Count time after charging is completed.. Verify that the prompt "Shock Removed" appears on the equipment and the energy measured by the analyzer is 0J or blank after 60 seconds.
15. Use multifunctional electrode pads. Repeat steps 3 to 14.

Synchronous Defibrillation

1. Connect the external paddles and ECG cable to the equipment. Place the paddles ECG electrodes on the defibrillator/pacer analyzer.
2. Set the analyzer to Measurement Mode and output normal sinus rhythms, e.g. amplitude value 1mV and HR 60bpm.
3. Enter Configuration Management. In the [**Manual Therapy Setup**] menu, set [**Sync After Shock**] to [**On**].
4. Adjust the energy setting of the equipment to be 10J.
5. Press the [**Sync On]** soft key to start synchronous defibrillation. If Remote Sync is switched on, press the [**Sync On]** soft key and select [**Local**] to start synchronous defibrillation
6. Select [Pads] or [Paddles] as the ECG source and begin charging.
7. When charging finishes, press and hold the "Shock" button to deliver a shock.
8. Verify that synchronous discharge succeeds and the delivery energy measured by the analyzer is 10J±2J.
9. Verify that the delay time of synchronous defibrillation measured by the analyzer is less than 60ms.

10. Verify that the synchronous discharge mark appears on the R wave.
11. Verify that the prompt messages are correct during testing.
12. Select lead II as ECG source and perform charging. Repeat steps 7 to 11.
13. Use multifunctional electrode pads. Repeat steps 2 to 12.

4.6.2 Pacing Test

Test tools:

- Defibrillator/pacer analyzer

1. Run the equipment on fully charged battery. Move the Mode Select knob to Pacer. Set [**Pacer Mode**] to [**Fixed**].
2. Connect the pads cable to the equipment and properly place the pads on the defibrillator/pacer analyzer.
3. Set the analyzer to Pacing Measurement mode. Use test load of 50Ω.
4. On the equipment, set [**Pacer rate**] to [**70ppm**] and [**Pacer Output**] to [**30mA**].
5. Press the **[Start Pacing]** soft key. Verify that the pacer rate measured by the analyzer is 70 ppm±1ppm and the pacer output measured is 30 mA±5mA.
6. Press the "Stop Pacing" soft key, and then set [**Pacer rate**] to [**170ppm**] and [**Pacer Output**] to [**200mA**].
7. Press the **[Start Pacing]** soft key. Verify that the pacer rate measured by the analyzer is 170 ppm±2ppm, and the measured current is 200 mA±10mA.

4.6.3 ECG Test

Performance Test

Test tools

- ECG simulator

1. Connect the simulator to the equipment's ECG connector with ECG leadwires.
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 the simulator from the equipment's ECG connector. Verify that ECG Lead Off alarm behaves correctly.
5. On the equipment, set [Paced] to [Yes], the simulator is configured as pace signals. Verify that pace signals are detected and pace pulse marks are displayed.
6. Connect the simulator to the equipment's therapy module with pads.
7. Set the patient simulator as follows: ECG sinus rhythm, HR=80 bpm with the amplitude as 1mV.

8. Check the ECG waves are displayed correctly without noise and the displayed HR value is within 80 ± 1 bpm.
9. Disconnect the simulator from the equipment's therapy module. Verify that ECG Lead Off alarm behaves correctly.
10. On the equipment, set [Paced] to [Yes], the simulator is configured as pace signals. Verify that pace signals are detected and pace pulse marks are displayed.

ECG Calibration

Tool required:

- Vernier caliper

1. Connect the simulator to the equipment's ECG connector with ECG leadwires.
2. Select the ECG parameter area to enter the **[ECG Setup]** menu.
3. Select **[Others>>]** → **[Calibrate]**. A waveform signals appear on the screen and the message **[ECG Calibrating]** is displayed in the prompt information area in the lower left corner of the screen.
4. Compare the amplitude of the waveform with the wave scale. The difference should be within 5%. If needed, you can also print out the waveform and the wave scale.
5. After ECG calibration is completed, select **[Stop Calibrating]**.
6. Connect the simulator to the equipment's therapy module with pads.
7. Repeat steps 3–5.

4.6.4 Resp Test

Test tools

- Resp Patient simulator

1. Connect the patient simulator to the ECG connector on the module.
2. On the defibrillator/monitor, select the Resp widow to enter the Resp Setup menu. Set **[Lead]** to **[II]**.
3. Configure the simulator as follows: set Lead to II, base impedance line to 1500 Ω; delta impedance to 0.5 Ω, and respiration rate to 40 rpm.
4. Check that respiration waveform is not distorted and the displayed Resp value does not exceed 40±2 rpm.

4.6.5 SpO_2 Test

Test tool

- Patient simulator.

1. Connect the patient simulator to the equipment's SpO_2 connector.
2. Select the model and manufacturer of the SpO_2 module under test. Configure the parameter as SpO_2 96% and PR 80 bmp.
3. The displayed SpO_2 and PR values should be within the ranges listed below

		SpO2 (%)	**PR (bmp)**
Mindray		96% ±2%	80±3
Masimo		96% ±2%	80±3
Nellcor	MAX-A, MAX-N, MAX-P, MAX-I	96% ±2%	80±3
	DS-100A, OXI-A/N, OXI-P/I	96% ±3%	

4.6.6 NIBP Tests

Accuracy Test

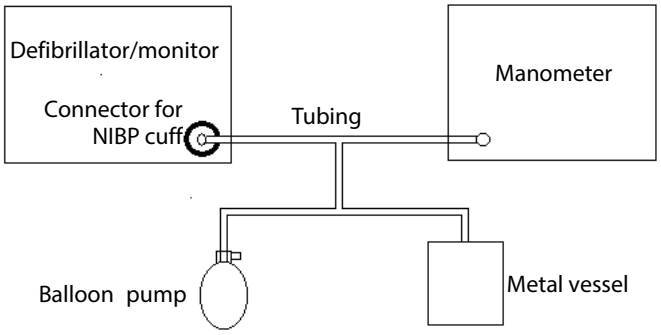
The NIBP accuracy test is required at least once every two years or whenever you doubt the NIBP reading.

Tools required:

- T-shape connector
- Tubing
- Balloon pump
- Metal Vessel, volume 500±25 ml
- Calibrated manometer for reference, accuracy not lower than 1 mmHg

To perform the accuracy test:

1. Connect the equipment as shown below.



2. Before inflation, the reading of the manometer should be 0. If not, disconnect the airway and reconnect it until the readings is 0.

3. Press the Main menu button on the equipment's front panel. Select [**Others>>**] →[**Installation Mode>>**] → enter the required password →[**Maintain NIBP**] →[**Start Accuracy Test**].
4. Compare the value of manometer with the value displayed on the equipment's screen. The difference should be no greater than 3 mmHg.
5. Raise the pressure in the metal vessel to 50 mmHg with the balloon pump. Repeat steps 3 and 4.
6. Raise the pressure in the metal vessel to 200 mmHg with the balloon pump. Repeat steps 3 and 4.

Note

- **You can replace the balloon pump and manometer with a blood pressure simulator to form a test system.**

NIBP Leakage Test

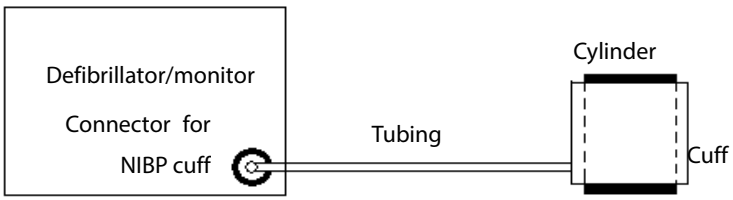
The NIBP leakage test checks the integrity of the system and of the valve. It is required at least once every two years or whenever you doubt the NIBP reading.

Tools required:

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

To perform the leakage test:

1. Connect the cuff to the equipment's NIBP connector.
2. Wrap the cuff around the cylinder as shown below.



3. Press the Main menu button on the equipment's front panel. Select [**Others>>**] →[**Installation Mode>>**] → enter the required password →[**Maintain NIBP**] →[**Start Accuracy Test**].

After about 20 seconds, the equipment automatically deflates. This means the leakage test finishes.

When the accuracy test is completed, the result will be displayed. If the message [**NIBP Pneumatic Leak**] is displayed, it indicates that the NIBP airway may have leakages. Check the tubing and connections for leakages, and then perform a leakage test again.

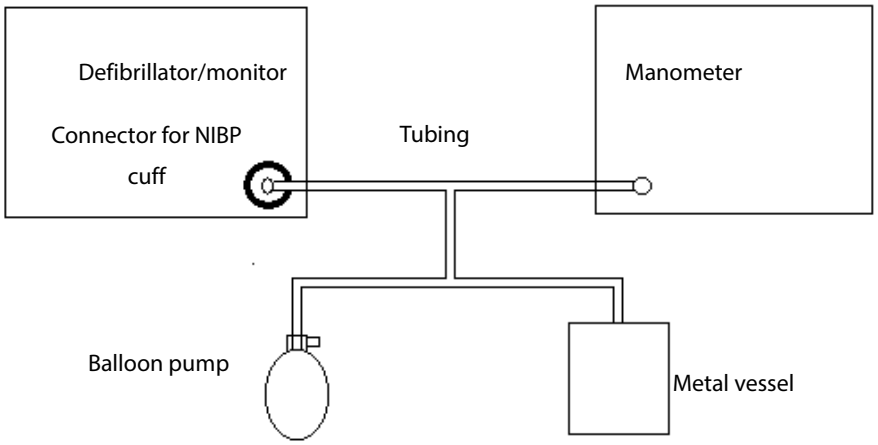
When you select the [Start Leakage Test] button, it turns to be **[Stop Leakage Test].** Select **[Stop Leakage Test]**, leakage test stops and the button turns to be **[Start Leakage Test]** again.

Calibrating NIBP

Tools required:

- T-shape connector
- Tubing
- Balloon pump
- Metal Vessel, volume 500±25 ml
- Calibrated manometer, accuracy higher than 1 mmHg

1. Connect the equipment as shown below



2. Before inflation, the reading of the manometer should be 0. If not, disconnect the airway and reconnect it until the readings is 0.
3. Press the Main menu button on the equipment's front panel. Select [**Others>>**] →[**Service Mode>>**] → enter the required password →[**Calibrate NIBP**].
4. Calibrate pressure. To do so, set the calibration value to 150 mmHg and adjust the pump output pressure to 150 mmHg. After the system is stable, click the [**Calibrate**] button to start calibration.
5. Calibrate overpressure. To do so,
   - Set **[Patient Cat.]** to **[Adu/Ped]** and adjust pump output pressure to 330 mmHg. Click the **[Calibrate]** button and start calibration. Or
   - Set **[Patient Cat.]** to **[Neo]** and adjust pump output pressure to 165 mmHg. Click the **[Calibrate]** button and start calibration.

All the calibration results will be displayed in the [**Calibrating NIBP**] screen. If the calibration fails, please check the connections and then perform a calibration again.

4.6.7 CO_2 Module Tests

Leakage Check

1. Access the **[CO2 Setup]** menu and set **[Operating Mode]** to **[Measure].** Wait for CO_2 warm-up.
2. Block the CO_2 module gas inlet completely. This will cause different reactions from the Sidestream and Microstream CO_2 modules.
   - Sidestream: Check that alarm message **[CO2 Filter Line Err]** is displayed on the screen in 3s. Block the gas inlet for another 30s, if the alarm message does not disappear, the module does not leak.
   - Microstream CO_2 module: **[CO2 Purging…]** is displayed in 3s. Block the gas inlet for another 30s, if the alarm message **[CO2 Tubing Err]** appears, the module does not leak.

Module Calibration

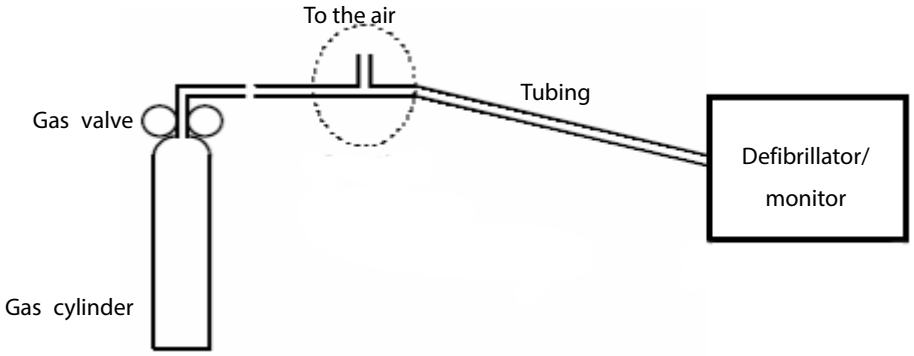
Test tools

- Gas cylinder, with 6% of CO_2 and balance gas N_2.
- T-shape connector
- Tubing

For sidestream CO_2 module, zeroing is required before calibration. Enter [**CO2 Setup**] menu and select [**Zero**] to perform zeroing.

To calibrate the CO_2 module, follow this procedure:

1. Make sure that the CO_2 module has been warmed up or started up.
2. Connect the gas cylinder with the tubing using a T-shape connector as shown below. Check the airway and make sure there are no leaks.



3. Vent the tubing to the CO_2 by opening the gas valve.
4. Access the **[Maintain CO2]** menu. To do so, Press the Main Menu button on the equipment's front panel. Select **[Others>>]** →**[Installation Mode>>]** →enter the required password → **[Maintain CO2]**.

5. In the **[Maintain CO2]** menu, select a CO_2 value equal to the vented CO_2 concentration.
6. In the **[Calibrate CO2]** menu, the measured CO_2 concentration is displayed. Wait till the measured CO_2 concentration becomes stable; select [Calibrate] to start CO_2 calibrate.

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

4.7 Electrical Safety Tests

See ***A Electrical Safety Inspection***..

4.8 Recorder Check

Tools required:

- None.

1. Print ECG waveforms. The recorder should print correctly and the printout should be clear.
2. Simulate some recorder problems, such as out of paper, paper jam, etc. the defibrillator/ monitor should give corresponding prompt messages. After the problem is removed, the recorder should be able to work correctly.
3. Switch automatic alarm recording for each parameter ON and then set each parameter's limit outside set alarm limits. Corresponding alarm recordings should be triggered when parameter alarms occur.

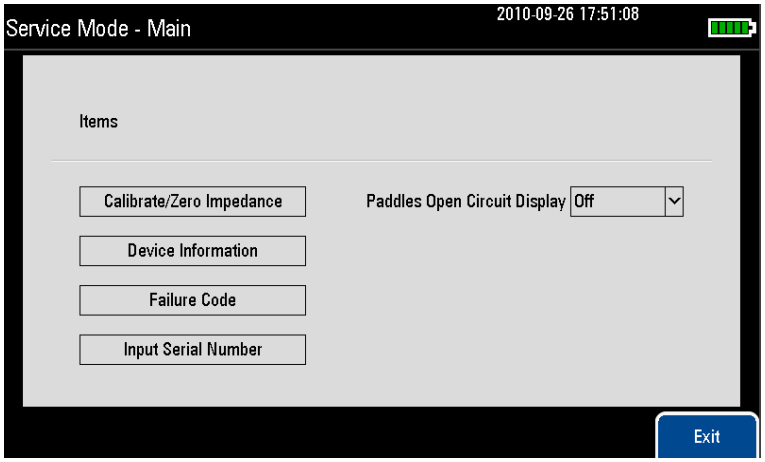
4.9 Factory Service

4.9.1 Password for Service Mode

Accessing service mode is password protected. The required password is set to 332888 before the equipment leaves the factory.

4.9.2 Accessing Service Mode Menu

To access the factory service menu, Press the Main menu button on the equipment's front panel. Select [Others>>]→ [Maintenance>>]→ [Service Mode>>]→ enter the required passwords. The Service Mode-Main menu is shown below.



4.9.3 Impedance Measurement

Normally impedance measurement is unnecessary. However, you can perform impedance checking after replacing the therapy module.

1. If not pre-connected, connect the pads cable to the equipment.
2. Connect a test load of 300 ohms to the pads cable.
3. Start the equipment and select the Monitor mode. Press and hold the **[Event]** hardkey, and then press the **[Lead Select]** hardkey on the front panel, the following screen appears.

4. Verify that the reading of "RT Imped" is between 3000±450.

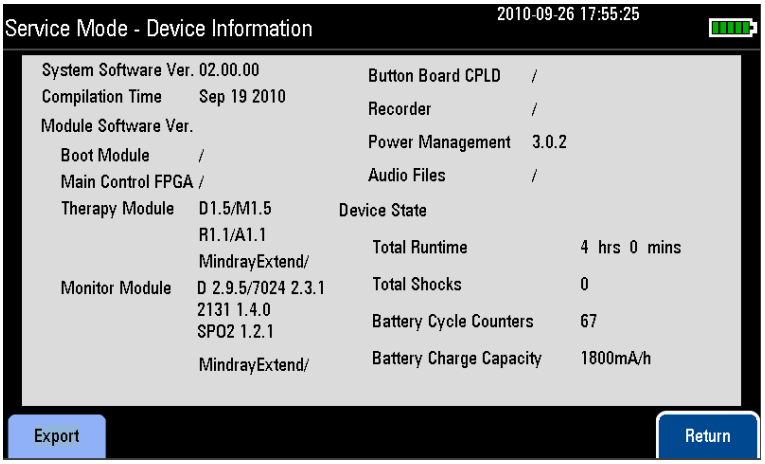
NOTE

- **If 300 ohms test load is not available, you can use a 50 ohms test load to perform impedance checking. In this case, Verify that the reading of "RT Imped" is between 500±75.**

If the reading of "RT Imped" is not correct, replace the therapy module.

4.9.4 Device Information

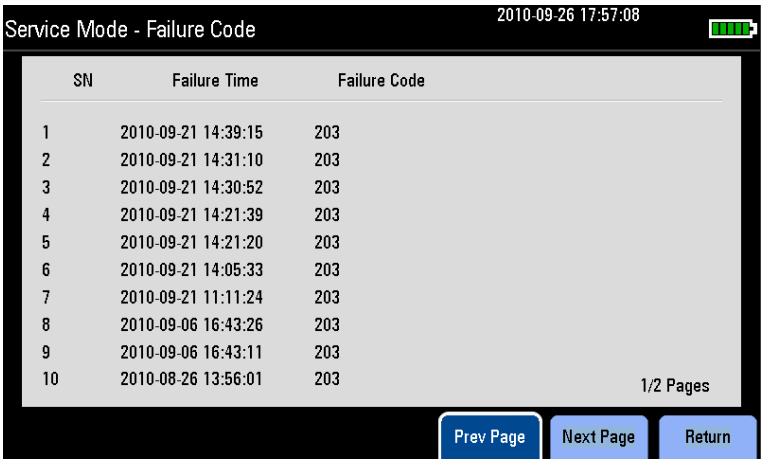
Press the Main menu button on the equipment's front panel. Select **[Others>>]**→ **[Maintenance>>]**→ **[Service Mode>>]**→ enter the required passwords→ **[Device Information]**. In the Device Information list, you can view the device information such as software version, system status, and etc, as shown below.



In the Device Information screen, you can select **[Export]** to export error codes and shock delivery data to a USB flash memory.

4.9.5 Checking Failure Code

Press the Main Menu button on the equipment's front panel. Select **[Others>>]**→ **[Maintenance>>]**→ **[Service Mode>>]**→ enter the required passwords→ **[Failure Code]** to check error codes. This helps the service personnel to identify failures.



Refer to ***6.8 Error Codes*** for the description of each error code.

4.9.6 Inputting Serial Number

Press the Main Menu button on the equipment's front panel. Select **[Others>>]**→ **[Maintenance>>]**→ **[Service Mode>>]**→ enter the required passwords→ **[Input Serial Number]** to input the equipment's serial number.

After inputting the serial number, you can view it by accessing Installation Mode and select [Version].

4.9.7 Paddle Open Circuit Display

This **[Paddle Open Circuit Display]** switch is for testing only. In normal operation, it should be set to **[Off]**.

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 (Pass/Fail)
Visual inspection		
The case, display screen, buttons, knob, modules, power cord, and accessories have no obvious signs of damage.		
The external connecting cables are not frayed and the connector pins are not loose or bent.		
The external connectors are not loose or their pins are not bent.		
The safety labels and data plate are clearly legible.		
Power-on test		
The power-on test is passed. The power indicator and alarm system work correctly and the equipment start up properly.		
Performance test		
Manual Defibrillation Test		
When the equipment runs on AC mains and external paddles are used, the equipment can be properly charged and discharged; the energy delivered meets the requirement for accuracy, and the shock information is correctly recorded.		
When the equipment runs on fully charged battery and external paddles are used, the equipment can be properly charged and discharged; the energy delivered meets the requirement for accuracy, and the shock information is correctly recorded.		
When the equipment runs on AC mains and multifunctional electrode pads are used, the equipment can be properly charged and discharged; the energy delivered meets the requirement for accuracy, and the shock information is correctly recorded.		
When the equipment runs on fully charged battery and multifunctional electrode pads are used, the equipment can be properly charged and discharged; the energy delivered meets the requirement for accuracy, and the shock information is correctly recorded.		
When external paddles are used, the charge tone is correctly issued when the equipment is being charged. The prompt "Charged Removed" is shown on the screen and the charge done tone stops when the Disarm hotkey is pressed. The equipment does not discharge externally. When **[Time to Auto Disarm]** is set to **[60s]**, the prompt "Charged Removed" is shown on the screen and the charge done tone stops after 60 seconds at the completion of charging. The equipment does not discharge externally.		
When pads are used, the charge tone is correctly issued when the equipment is being charged. The prompt "Charged Removed" is shown on the screen and the charge done tone stops when the Disarm hotkey is pressed. The equipment does not discharge externally. When **[Time to**		

Test items	Test records	Test results (Pass/Fail)
Auto Disarm] is set to **[60s]**, the prompt "Charged Removed" is shown on the screen and the charge done tone stops after 60 seconds at the completion of charging. The equipment does not discharge externally.		
When external paddles are used for synchronous defibrillation and ECG source is paddles and lead II respectively, the prompt is correct and a Sync mark appears above each R wave. The delivered energy measured is 10J±2J and the synchronous shock is delivered within 60 ms of the peak of the R-wave.		
When pads are used for synchronous defibrillation and ECG source is paddles and lead II respectively, the prompt is correct and a Sync mark appears above each R wave. The delivered energy measured is 10J±2J and the synchronous shock is delivered within 60 ms of the peak of the R-wave.		
Pacing Test		
When set **[Pacer rate]** to **[70ppm]** and **[Pacer Output]** to **[30mA]**, the pacer rate measured by the analyzer is 70 ppm±1ppm and the pacer output measured is 30 mA±5mA.		
When set **[Pacer rate]** to **[170ppm]** and **[Pacer Output]** to **[200mA]**, the pacer rate measured by the analyzer is 170 ppm±2ppm, and the measured current is 200 mA±10mA.		
ECG performance test		
ECG waves are displayed correctly without noise and the HR value is within 80±1 bpm.		
ECG Lead Off alarm behaves correctly.		
Paced signals are detected and pace pulse marks are displayed when **[Paced]** is set to **[Yes]**		
The difference between the amplitude of the ECG calibration square wave and that of the wave scale is not greater than 5%.		
Resp test		
The Resp wave is not distorted and the Resp value is within 40±2 rpm.		
SpO2 test		
The displayed SpO_2 and PR values should be within the specified ranges.		
NIBP test		
The difference is within ±3 mm when 0, 50 or 200 mmHg is set for NIBP accuracy test.		
There is no leakage with NIBP, or the manual leakage test result does not exceed 6mmHg/min.		
CO_2 test		
Block the gas inlet of the module or watertrap. The CO_2 flowrate is slower than 10ml/min and an alarm of CO2 Filterline Err is given. It indicates that there is no leakage.		

Test items	Test records	Test results (Pass/Fail)
The displayed CO_2 value is within 6±0.05%.		
Electrical safety tests		
Refer to Appendix ***A Electrical Safety Inspection***.		
Recorder check		
The recorder can print ECG waves correctly and the printout is clear.		
Set the recorder to some problems such as out of paper, paper jam, etc. the equipment gives corresponding prompt messages. After the problem is removed, the recorder is able to work correctly.		
Automatic alarm recording for each parameter functions correctly when parameter alarms occur.		

Tested by: _____ Date: _____

FOR YOUR NOTES

5 Hardware and Software Upgrade

5.1 Hardware Upgrade

5.1.1 Upgrade MPM module

You can upgrade MPM module to any of the following configuration:

- ECG+Mindray SpO2 modules: 115-049471-00 MPM upgrade package
- ECG+Nellcor SpO2 modules: 115-049472-00 MPM upgrade package
- ECG+NIBP modules: 115-049474-00 MPM upgrade package
- ECG+Mindray SpO2+NIBP modules: 115-049475-00 MPM upgrade package
- ECG+Masimo SpO2+NIBP modules: 115-049476-00 MPM upgrade package
- ECG+Nellcor SpO2+NIBP modules: 115-049477-00 MPM upgrade package

The upgrade procedure is as follows:

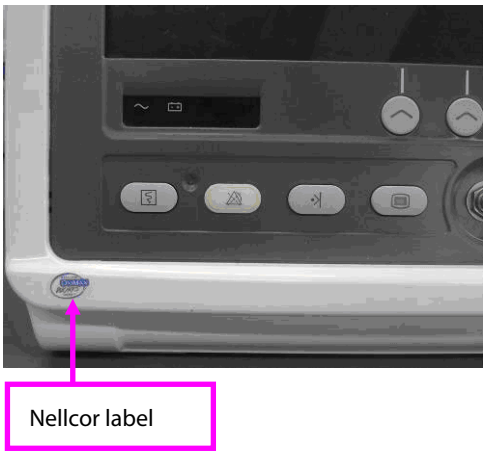
1. Remove the MPM module assembly and parameter panel assembly as described in. ***7.3.5 Disassembling the MPM Module Assembly*** and ***7.3.6 Removing the Parameter Panel Assembly***.
2. Replace the old measurement module panel and MPM module with those in the MPM upgrade kit.
3. Reassemble the equipment.

If the upgrade MPM module is equipped with Masimo SpO_2, you need to stick a Masimo label at the lower left corner of the front housing and a No Implied License label below the measurement module panel, as indicated in the following pictures.

Masimo label

No Implied License label

If the upgraded MPM module is equipped with Nellcor SpO_2, you need to stick a Nellcor label at the lower left corner of the front housing, as indicated in the following pictures.



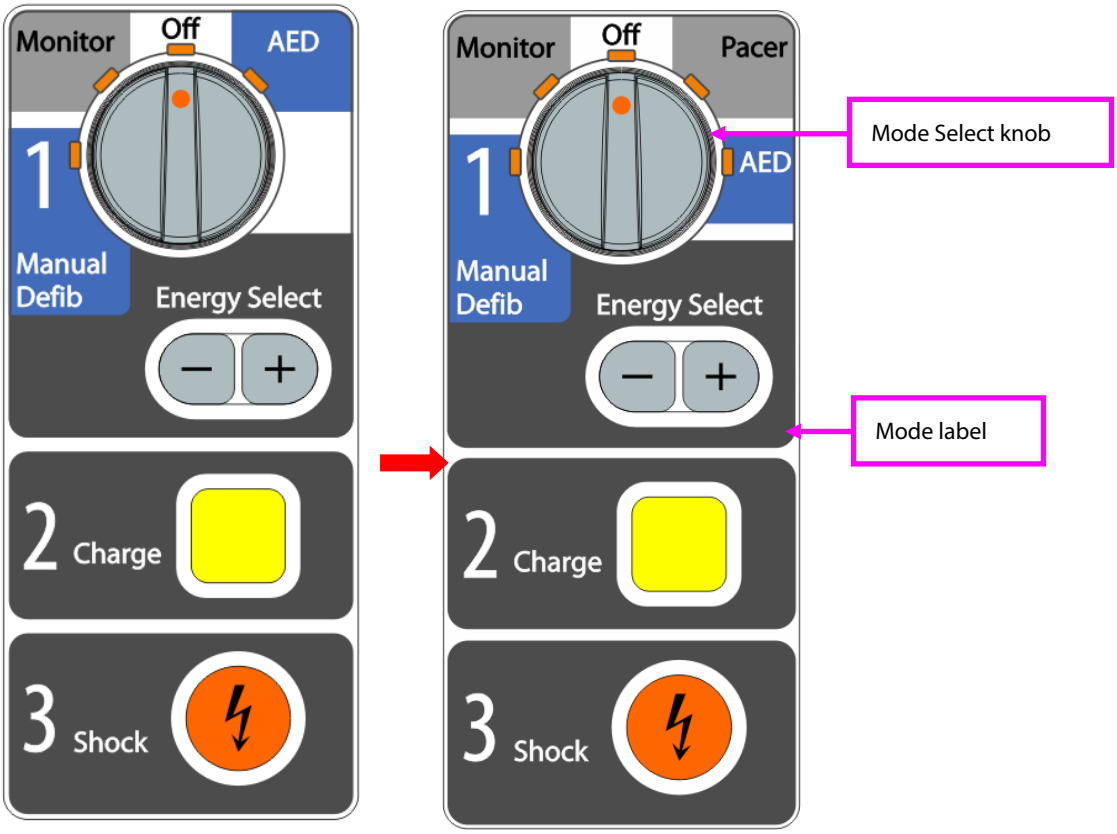
After upgrade the MPM module, perform the tests described in ***4.6.3 ECG Test***, ***4.6.4 Resp Test***, ***4.6.5 SpO2 Test***, ***4.7Electrical Safety Tests***, and ***4.8 Recorder Check***.

5.1.2 Upgrade the Therapy Module

You can use 115-049460-00 pacer function upgrade kit to upgrade the therapy module so that equipment has pacing function. After upgrading the therapy module, choose Mode label (with pacing function) with the language you need.

Follow this procedure to upgrade the therapy module:

1. Remove therapy module as described in ***7.3.7 Removing the Therapy Module***. Be noted that you need not to remove the parameter panel assembly and MPM module assembly.
2. Take off the Mode Select knob. Peel off the Mode label, see the picture below.
3. Replace the old therapy module using the one with pacing function in the upgrade kit.
4. Replace the old Mode Select knob and Mode label using new ones in the upgrade kit.
5. Reassemble the equipment.



After upgrade the therapy module, perform the tests described in ***4.6.1 Manual Defibrillation Test***, ***4.6.2 Pacing Test***, and ***4.7 Electrical Safety Tests***.

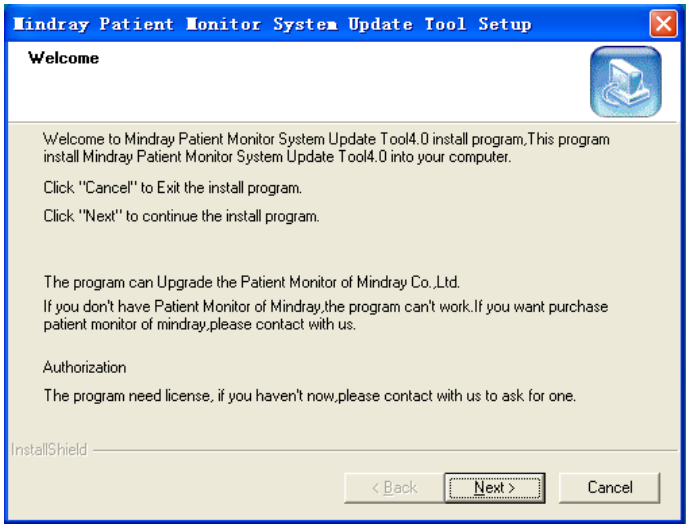
5.2 Software Upgrade through a PC

You can upgrade system software and module software using Mindray Patient Monitor Software Upgrade Tool. You can also view software upgrade log. Mindray Patient Monitor Software Upgrade Tool can directly run on a PC. By connecting the defibrillator/monitor to a PC via a crossover network cable, you can upgrade the following software:

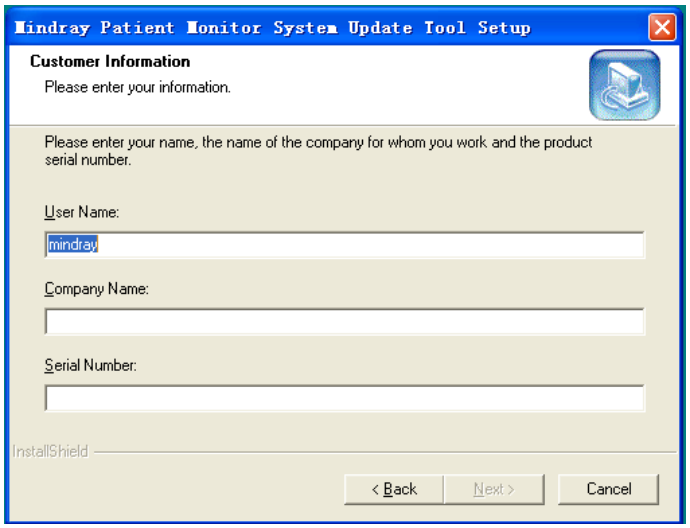
- Bootstrap
- System software
- Language library
- BMP files (including screen icons, start-up screens, standby screens)
- General configurations (including passwords, company logo)
- System functional configuration
- FPGA program
- Power module software
- MPM module software and therapy module software
- CO_2 module

5.2.1 Installing Mindray Patient Monitor Software Upgrade Tool

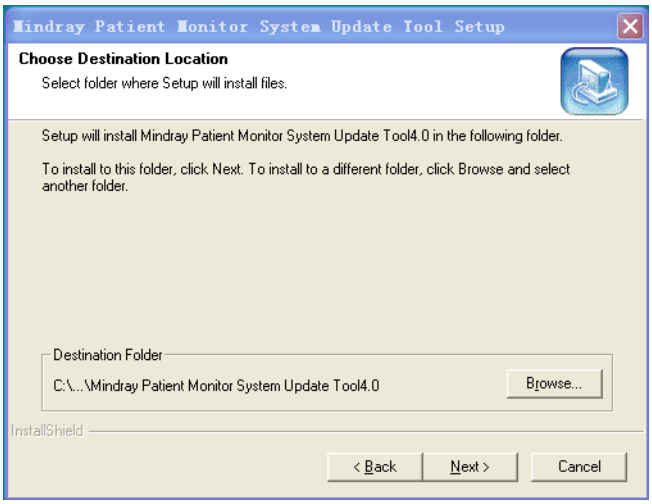
1. Find the installation program SystemUpdateTool.exe and double click it to start installation.
2. Select installation language.
3. Click **[Ok]** and the following screen appears. Click **[Next]** to go to the next step.



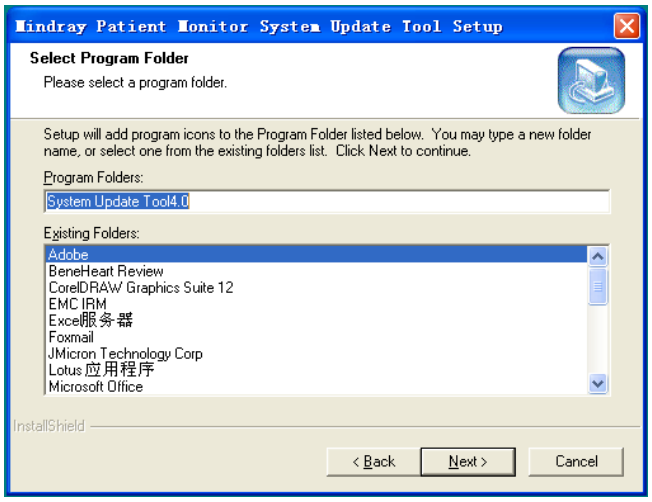
4. Enter User Name, Company Name and Serial Number.



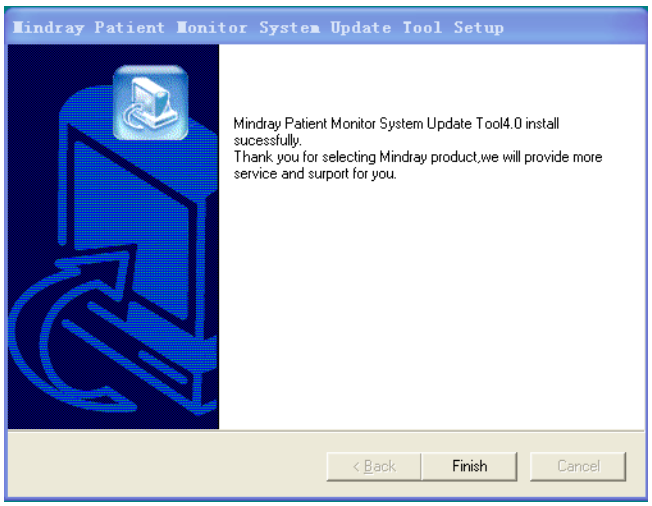
5. Specify the destination folder for installing this program. Then select **[Next].**



7. Select Program Folder. Then select **[Next]**.



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



5.2.2 Software Upgrade Procedure

1. Connect the defibrillator/monitor to be upgraded with a PC.
2. Set IP address to 77.77.1.XX and subnet mask to 255.255.255.0.
3. Run Mindray Patient Monitor Software Upgrade Tool on the PC and set Machine to BeneHeart.
4. On the Mindray Patient Monitor Software Upgrade Tool screen, select [Select Package] and select packages you want to upgrade. Then select [Start].
5. Simultaneously hold the [Record] key and [Menu] key on the defibrillator/monitor's front panel, and then turn on the equipment.

After software upgrade is finished, turn off the equipment, and then disconnect AC mains and remove the battery. If you do not disconnect the power supply after software upgrade, the status indicator will flash and the beeper will sound.

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 boot program. Otherwise, it may cause the equipment to break down.**
- **Program upgrade should be performed by qualified service personnel only.**
- **Crossover network cable shall be used if a PC is connected for equipment upgrade.**

NOTE

- **After upgrading the boot program, re-upgrade the system program and other programs to ensure compatibility.**
- **Make sure the version of the upgrade package is the one that you desired. If you want to obtain the latest upgrade package, contact Mindray Customer Service Department.**

5.3 Software Upgrade through a USB Disk

5.3.1 Applicable

Model	SN	Remark
BeneHeart D5/D6	DZ-XXXXXXXX DI-XXXXXXXX	This procedure is only applicable to the device which software version is 04.03.00.16 and above
BeneHeart D2/D3	EZ-XXXXXXXX EI-XXXXXXXX	

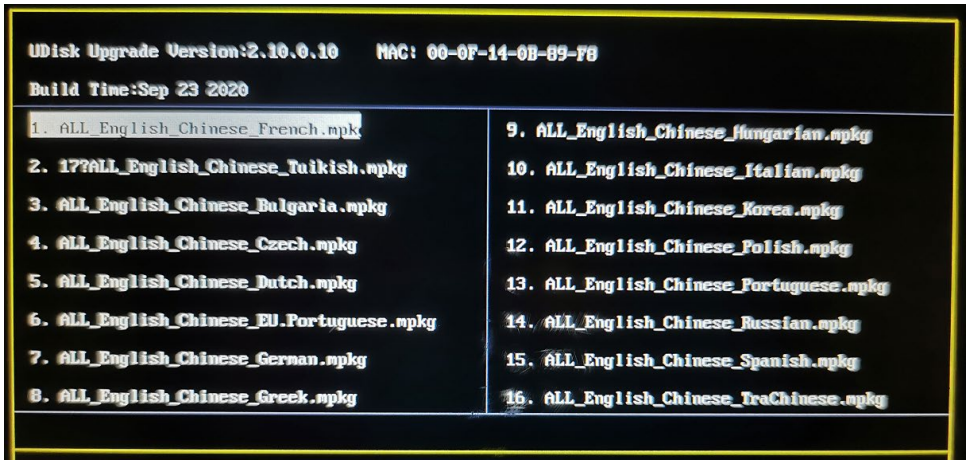
5.3.2 Tool

Index	Tools	Qty.
1	USB disk	1

5.3.3 Upgrade Procedure

1. Prepare a USB Disk
    a. Prepare a common USB disk which the system capacity is larger than 2GB and choose FAT 32
    b. Create following folders in the boot directory of the USB Disk UPGRADE_AMP/Beneheart/
    c. Copy the BIOS program NewBeneHeart_Installer.pkg (Do not change this file name) to the UPGRADE_AMP/ Beneheart
    d. Copy the upgrade file (PKG or MPKG) to the UPGRADE_AMP/Beneheart.
2. Connection
    a. Insert the prepared USB disk into the USB port of the machine.
3. Upgrade
    a. Turn off the defibrillator, Press and hold Summary (or 12 Lead) button and Main Menu button of D5/D6 at same time, then turn on the defibrillator, to enter upgrade mode.
    b. Note: For D2/D3 machine simultaneously press and hold Menu and Record button (or NIBP button), and turn on the defibrillator to enter the upgrade mode.

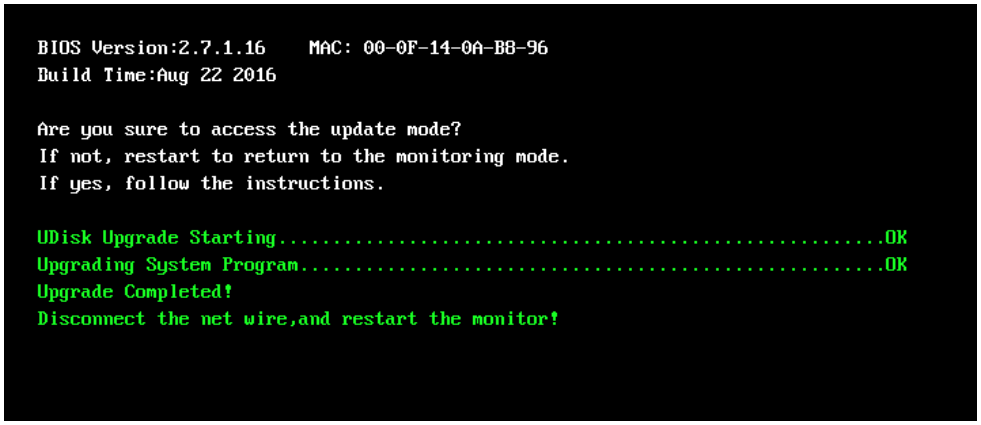
4. Select the File



A maximum of 16 upgrade packages can be displayed in the left and right columns. Rotate the navigation knob to select the desired upgrade package and press down the knob to confirm.

5. Completed

The *upgrade completed* will be showed in the screen when the upgrade is completed. Restart the device to activate the new system software.



6. NOTE

   a. Disconnect the defibrillator from the patient and make sure that important data are saved before upgrade.

   b. Do not shut down or power off the equipment when upgrading the BIOS program and FPGA program. Otherwise, the equipment may break down.

   c. Upgrade should be performed by qualified service engineer only. Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

   d. Make sure the version of the upgrade package is your desired one. If you want to obtain the latest upgrade package, please contact Mindray Customer Service Department.

6 Troubleshooting

6.1 Overview

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

The problems 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 defibrillator/monitor are replaceable. Once you isolate a defective PCB, follow the instructions in 0
Disassembly and Repair to replace the PCB with a known good one and check that the trouble disappears or the defibrillator/monitor passes all performance tests. If the trouble remains, replace the 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 Defibrillator/Monitor Status

Some troubleshooting tasks may require you to identify the hardware version and status of your defibrillator/ monitor. To check equipment status,

1. Select [Main Menu] →[Review >>]→[Event Review >>]. Then you can view the information on system start time, self check, etc.
2. You can also view the information on the defibrillator/monitor's current status by pressing the Menu key on the equipment's front panel, and then selecting [Others>>]→[Maintenance >>]→[Service Mode>>]→ enter the required password →[Device Information>>].

6.4 Checking Device Information

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

To identify your software version, press the Menu key on the equipment's front panel, and then select **[Others>>]** →**[Maintenance>>]**→**[Installation Mode>>]**→ enter the required password→ **[Version]**. In the Version screen, you can view system software version and module software version.

You can also press the Menu key on the equipment's front panel, and then select **[Others>>]** →**[Maintenance>>]**→**[Service Mode>>]**→ enter the required password →**[Device Information>>]** to check system software version, module software version, and device status .

6.5 Checking Technical Alarm

Before troubleshooting the defibrillator/monitor, check for technical alarm message. If an alarm message is presented, eliminate the technical alarm first. For detailed information on technical alarm message, possible cause and corrective action, see the ***BeneHeart D3/ BeneHeart D2 Defibrillator/Monitor Operator's Manual (P/N: 046-010599-00)***l.

6.6 Troubleshooting Guide

6.6.1 Defibrillation Problems

Symptom	Possible Cause	Corrective Action
The equipment does not charge by pressing the Charge button on the front panel.	Keypad board failure.	1. Connect external paddles. Press the "Charge" button on the Apex paddle to start charging. If the "Charge" button on the paddles works, it indicates the keypad board fails. 2. Replace the keypad board.
	The Charge button fails to be pressed down effectively due to the damaged or dislocated silica gel keypad.	Disassemble the keypad board to replace or reshuffle the keypad.
The equipment cannot be charged by pressing the Charge button on the external paddles.	Paddles not connected properly.	Reconnect the paddles.
	Paddles failure.	1. Isolate the problem by connecting pads to perform charging/discharging. 2. If the paddles are failed, replace them.
	Failure of therapy module.	Replace the therapy module.
	Failure of connection wire to the therapy module.	Replace the connection wire.

Symptom	Possible Cause	Corrective Action
The equipment is charged too slowly	Battery failure.	Replace the battery or connect the equipment with external power supply.
	CPU and power management board failure.	Replace the CPU and power management board.
	Therapy module failed.	Replace the therapy module.
A shock cannot be delivered by pressing the Shock button on the equipment's front panel in Manual Defib Mode or AED Mode.	Keypad board failure.	1. Locate the problem by connecting paddles to perform charging / discharging. 2. If the keypad board is defective, replace it.
	The Charge Button fails to be pressed down effectively due to the failure or dislocated silica gel keypad.	Disassemble the keypad board to replace or reshuffle the keypad.
A shock cannot be delivered by pressing the Shock button on the paddles.	Paddles not connected properly.	Reconnect the paddles.
	Paddles failure.	1. Locate the problem by connecting pads to perform charging/discharging. If normal discharge can be performed, it indicates the paddles are defective. 2. Replace the paddles.
	Failure of therapy module.	Replace the therapy module.
	Connection wire to the therapy module broken.	Replace the connection wire.
The message. "Disarming Failed" is displayed.	Failure of therapy module.	Replace the therapy module.
The equipment can be properly charged, but the energy is disarmed automatically at the completion of charging or when the equipment is being discharged.	Too high or too low patient impedance detected. 1. Pads/paddles are detached from the patient. 2. Pads/paddles failure. 3. Pads cable failure.	Ensure good connection between the patient and pads/paddles. If the problem persists, replace Pads, paddles or Pads cable.
	Failure of therapy module.	Replace the therapy module.
Defibrillation malfunction.	Defibrillation hardware circuit defective.	Replace the therapy module.
Energy Select buttons on the equipment front panel do not work.	Keypad board failure.	1. Locate the problem by connecting paddles to perform energy setting. 2. If the keypad board is defective, replace it.
	The Energy Select Buttons fail to be pressed down due to the damaged or dislocated silica gel keypad.	Disassemble the keypad board to replace or reshuffle the keypad.

Symptom	Possible Cause	Corrective Action
Energy Select buttons on the paddles do not work	Paddles not connected properly.	Reconnect the paddles.
	Paddles failure.	Replace the paddles.
	Failure of therapy module.	Replace the therapy module.
	Connection wires to the therapy module broken.	Replace the connection wires.
The message "Defibrillation malfunction" presented at power-on	Configuration files not properly upgraded.	Upgrade the configuration files.
	Therapy module failure	Replace the therapy module.

6.6.2 Pacing Problems

Symptom	Possible Cause	Corrective Action
Does not deliver correct pacing current.	Failure of the therapy module	Replace the therapy module.
Does not deliver correct pacing rate.	Failure of the therapy module.	Replace the therapy module.
Pacer Equip Malfunction	Pacer hardware failure.	Replace the therapy module.

6.6.3 Power On/Off Problems

Symptom	Possible Cause	Corrective Action
The defibrillator/monitor fails to start. AC LED or battery LED does not light	AC mains not connected or battery too low.	Check that AC mains is properly connected or battery capacity is sufficient.
	Power supply protection.	Refer to ***6.6.10 Power Supply Problems***.
	Cables defective or poorly connected.	1. Check that the cables between the power switch and the keypad board, the keypad board and the power management board and between the power module and the power management board are correctly connected. 2. Check that wires and connectors are not defective.
	Power switch or keypad board failure	Replace the power switch or keypad board.
	AC/DC board defective	Replace the AC/DC board.
	CPU and power management board failure	Replace the CPU and power management board.

6.6.4 Display Problems

Symptom	Possible Cause	Corrective Action
The LCD screen is blank, but the defibrillator/monitor works properly.	Connection cable defective or poorly connected.	1. Check that wires between the display and the keypad board, and between the keypad board and the CPU and power management board are correctly connected. 2. Check that the cables and connectors are not defective.
	LCD Display failure	Replace the display.
	Keypad board failure	Replace the keypad board.
	CPU and power management board failure.	Replace the CPU and power management board.
Secondary display does not function.	Cable failure	1. Check that the wires between the display and the defibrillator/monitor are correctly connected. 2. Check that the cables and connectors are not defective.
	CPU and power management board failure.	Replace the CPU and power management board.
Secondary display displays snows or flashing specks	Connection cable defective or poorly connected.	1. Check that the wires between the display and the defibrillator/ monitor are correctly connected. 2. Check that the cables and connectors are not defective.
	CPU and power management board failure.	Replace the CPU and power management board.
Images overlapped or distorted	FPGA failure	Update or upgrade FPGA.
	Connection cable defective or poorly connected.	1. Check that the wire between the display and keypad board is correctly connected. 2. Check that the cables and connectors are not defective.
The colour of images deviates from the standard configuration.	Connection cable defective or poorly connected.	1. Check that wires between the display and the keypad board and between the keypad board and the power management board are correctly connected. 2. Check that the cables and connectors are not defective.
	Display failure	Replace the display.
	Keypad board failure	Replace the keypad board.
	CPU and power management board failure.	Replace the CPU and power management board.
Images overlapped or distorted	FPGA failure	Update or upgrade FPGA
	Connection cable defective or poorly connected.	1. Check that the wire between the display and keypad board is correctly connected. 2. Check that the cables and connectors are not defective.

6.6.5 Alarm Problems

Symptom	Possible Cause	Corrective Action
The alarm lamp is not light or extinguished but alarm sound is issued	Connection cable defective or poorly connected.	1. Check that wire between alarm LED board and keypad board are properly connected. 2. Check that connection wires and connectors are not defective.
	Alarm LED board failure	Replace the alarm LED board.
	Keypad board failure	Replace the keypad board.
	CPU and power management board failure.	Replace the CPU and power management board.
No alarm sound is issued but alarm lamp is lit	Audio alarm disabled	Check that alarm tone volume is set to a value other than zero by pressing the Menu key on the equipment's front panel, and then selecting [Alarm Setup >>].
	Connection cable defective or poorly connected.	1. Check that the wire between the speaker and keypad board is properly connected. 2. Check that connection wires and connectors are not defective.
	FPGA audio logic ERROR	Upgrade the audio logic part of the FPGA program.
	Speaker failure	Replace the speaker.
	CPU and power management board failure.	Replace the CPU and power management board.

6.6.6 Button and Knob Problems

Symptom	Possible Cause	Corrective Action
Buttons do not respond.	Connection cable defective or poorly connected.	1. .Check that the wire between the keypad and the keypad board is properly connected. 2. Check that that the wire between the keypad board and the CPU and power management board is properly connected. 3. Check if the connection wires and connectors are defective.
	Keypad board failure	Replace the keypad board.
	CPU and power management board failure.	Replace the CPU and power management board.
Mode Select knob does not respond.	Connection cable defective or poorly connected.	1. Check that wires between the knob to keypad board, and between the keypad board and the power management board are properly connected. 2. Check that connecting wires and connectors are not defective.

Symptom	Possible Cause	Corrective Action
Mode Select knob does not respond.	Knob failure	Replace Mode Select knob.
	Keypad board failure	Replace the keypad board.
	CPU and power management board failure.	Replace the CPU and power management board.
Navigation knob does not respond.	Connection cable defective or poorly connected.	1. Check that wires between the knob to keypad board, and between the keypad board and the power management board are properly connected. 2. Check that connection wires and connectors are not defective.
	Knob failure.	Replace the navigation knob.
	Keypad board failure	Replace the keypad board.
	CPU and power management board failure.	Replace the CPU and power management board.

6.6.7 Recorder Problems

Symptom	Possible Cause	Corrective Action
No printout	Connection cable defective or poorly connected.	1. Check the wire between the recorder and the keypad board is connected properly. 2. Check that connection wires and connectors are not defective.
	Recorder power supply failure	Check if the power module outputs 5 V DC and 12V DC correctly.
	Recorder failure	Replace the recorder.
Poor print quality or paper not feeding properly	Paper roll not properly installed	Stop the recorder and re-install the paper roll.
	Print head dirty	1. Check the thermal print head and the paper roller for foreign matter. 2. lean the thermal print head with an appropriate clean solution.
	Recorder failure	Replace recorder.
Blank printout	Paper-roll installed reversely.	Reload paper-roll.
	Recorder failure	Replace the recorder.

6.6.8 Output Interface Problems

Symptom	Possible Cause	Corrective Action
Sync input failure	CPU and power management board failure.	Replace the CPU and power management board.
	Interface board failure	Replace the interface board.
USB Device does not function (provided that the peripheral devices are good)	CPU and power management board failure.	Replace the CPU and power management board.

6.6.9 Memory Card Problems

Symptom	Possible Cause	Corrective Action
Memory card malfunctions	Memory card failure	Format the memory card. If the problem persists, replace the CPU and power management board.

6.6.10 Power Supply Problems

Symptom	Possible Cause	Corrective Action
Battery failure	Battery damaged.	Replace battery.
	Battery interface failure.	1. Check batteries are installed properly. 2. Check if the battery interface is defective. 3. If the battery interface is defective, replace the power management board.
	CPU and power management board failure.	Replace the CPU and power management board.
Batteries can not be fully charged.	Battery damaged.	Replace batteries.
	Battery interface failure.	1. Check batteries are installed properly. 2. Check if the battery interface is defective. 3. If the battery interface is defective, replace the power management board.
	CPU and power management board failure.	Replace the CPU and power management board.
Battery cannot be charged	Battery failure.	Replace battery and recharge the replacement battery. If the replacement battery can be recharged, the original one fails.
	Cable defective or poorly connected	1. Check batteries are installed properly. 2. Check if the battery interface is defective. 3. If the battery interface is defective, replace the power management board.
	CPU and power management board failure.	Replace the CPU and power management board.
No +3.3 V A output	1. Power supply failure	1. Turn off the defibrillator/monitor then restart

Symptom	Possible Cause	Corrective Action
No +3.3 V B output Not +5.0 V output No +12 V output	2. CPU and power management board failure.	it. 2. If the problem remains, disconnect the AC mains for 5 s and reconnect it, then restart the defibrillator/ monitor. 3. If the problem still remains, replace the power management board.

NOTE

- **When the power module has a failure, it may cause problems to other components, e.g. the defibrillator/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, SMR and parameter modules are powered by the power module. In the event that a component malfunctions, check if the operating voltage is correct. Refer to 2 Theory of Operation for the operating voltage and measurement points of each component.**

6.6.11 Software Upgrade Problems

Symptom	Possible Cause	Corrective Action
Boot file upgrade fails	Power failure or unintended power off during boot file upgrade	Return the CPU board to factory for repair.
Program upgrade fails	Incorrect network connection	1. Check that the network cable is properly connected and is not too long (shorter than 50m). 2. Make sure that the network cable is of the right type. Network cable with crossed wires inside is used for LAN upgrade and those with parallel wires inside for WAN.
	Wrong upgrade package	Upgrade package shall be .pkg files. Select package according to system requirement.
	Incorrect IP address configuration	Configure a fixed IP address in range C as specified for the defibrillator/monitor. We recommend not to upgrade a program when the defibrillator/monitor is connected to a network with multiple PCs.

6.7 Technical Alarm Messages

Measurement	Alarm Message	Cause and solution
XX	XX SelfTest Err	An error occurred to the XX module, or there is a problem with the communications between the module and the host. Restart the equipment.
	XX Init Err	
	XX Comm Err	
	XX Comm Stop	
	XX Overrange	The measured XX value is not within the specified range for XX measurement. Contact our Customer Service Department.
ECG	ECG Lead Off	The ECG electrode has become detached from the patient or the lead wire has become disconnected from the trunk cable. Check the connection of the electrodes and leadwires.
	ECG YY Lead Off (YY represents the leadwires V, LL, LA, and RA, as per AHA standard, or C, F, L and R as per IEC standard.)	
	Pads/Paddles off	The pads/paddles have been detached from the patient or the therapy cable is loose. Check that the pads/paddles and therapy cable are properly connected.
	ECG Noise	The ECG signal is noisy. Check for any possible sources of signal noise form the area around the cable and electrode, and check the patient for excessive motion.
	ECG Signal Invalid	ECG amplitude is so low that ECG signal is undetectable. Check for any possible source of interference from the area around the cable and electrode; check the patient's condition.
SpO2	SpO2 Sensor Off	The SpO_2 sensor has become detached from the patient or the module, or there is a fault with the Sp O_2 sensor, or an unspecified Sp O_2 sensor has been used. Check the sensor application site and the sensor type, and make sure the sensor is not damaged. Reconnect the sensor or use a new sensor.
	SpO2 Sensor Fault	
	SpO2 No Sensor	
	SpO2 Unknow Sensor	
	SpO2 Sensor Incompatible	
	SpO2 Too Much Light	There is too much light on the Sp O_2 sensor. Move the sensor to a place with lower level of ambient light or cover the sensor to minimize the ambient light.
	SpO2 Low Signal	The Sp O_2 signal is too low or too weak. Check

Measurement	Alarm Message	Cause and solution
SpO2	SpO2 Weak Signal	the patient's condition and change the sensor application site. If the error persists, replace the sensor.
	SpO2 Weak Pulse	
	SpO2 Low Perf	
	SpO2 Interference	The Sp O_2 signal has been interfered. Check for any possible sources of signal noise form the area around the sensor, and check the patient for excessive motion.
	SpO2 Non-Pulsatile	
	SpO2 Board Fault	There is a problem with the Sp O_2 measurement board. Do not use the module and contact our Customer Service Department.
NIBP	NIBP Loose Cuff	The NIBP cuff is not properly connected, or there is a leak in the airway.
	NIBP Air Leak	
	NIBP Pneumatic Leak	Check the NIBP cuff and pump for leakages.
	NIBP Cuff Type Wrong	The cuff type applied mismatches the patient category. Verify the patient category and replace the cuff.
	NIBP Air Press. Err	An error occurred to the air pressure. Verify that the equipment application site meets the environmental requirements and check if there is any source that affects the air pressure.
	NIBP Weak Signal	The patient's pulse is weak or the cuff is loose. Check the patient's condition and change the cuff application site. If the problem persists, change the cuff.
	NIBP Sig. Saturated	The NIBP signal is saturated due to excess motion or other sources.
	NIBP Overrange	The patient's NIBP value may be beyond the specified measurement range.
	NIBP Excessive Motion	Check the patient's condition and reduce the patient motion.
	NIBP Equip Err	An error occurred during NIBP measurement and therefore the equipment cannot perform analysis correctly. Check the patient's condition and NIBP connections, or replace the cuff.
	NIBP Time Out	
	NIBP Measure Failed	
	NIBP Reset For Err	An illegal reset occurred during NIBP measurement. Check if the airway is occluded.
CO2	CO2 Sensor High Temp	Check, stop using or replace the sensor.
	CO2 Occlusion	The airway or watertrap was occluded. Check the airway and remove the occlusion.
	CO2: Change Watertrap	Change the watertrap.

Measurement	Alarm Message	Cause and solution
CO2	CO2 Watertrap Mismatch	Check the patient category, replace a matched watertrap.
	CO2 No Watertrap	Check the watertrap connections.
	CO2 Zero Failed	Check the CO_2 connections. After the sensor's temperature becomes stabilized, perform a zero calibration again.
	CO2 Module Error	There is a problem with the CO_2 module, or a problem with the communications between the host and the CO_2 module. Restart the equipment.
CPR sensor	CPR Sensor Err	There is a self-test error or communication problem with the CPR sensor. Contact our Customer Service Department.
	CPR Sensor Low Battery	The battery power of the CPR sensor is low. Charge the battery by connect the CPR sensor to the equipment.
	CPR Sensor Need Service	The compressions using the CPR sensor exceed the expected numbers. Contact our Customer Service Department.
	CPR Sensor Cable Fault	An error occurred to the CPR sensor cable. Replace the CPR sensor cable.
	Change CPR Sensor Battery	The CPR sensor battery is aging. Contact our Customer Service Department.
	CPR Sensor Bat. Charge Err	The CPR sensor cannot be charged. Contact our Customer Service Department.
Main control system	No Speaker	Make sure that the speaker is connected.
	Power Board Comm Err	An error occurred to the power board, or there is a problem with the communications between the power board and the host. Restart the equipment.
	Keyboard Comm Err	An error occurred to the keypad board, or there is a problem with the communications between the keypad board and the host. Restart the equipment.
	Therapy Module Comm Err	An error occurred to the therapy module, or there is a problem with the communications between the therapy module and the host. Restart the equipment. If the problem persists, contact our Customer Service Department.
	Main Control Selftest Err	The main control voltage is abnormal. Replace the main control board.

Measurement	Alarm Message	Cause and solution
Main control system	Wifi Module Fault	Contact our Customer Service Department.
	Machine Type Error	
	RT Clock Need Reset	Reset system time.
	RT Clock Err	An error occurred to the RTC chip, or the button cell is depleted. Replace corresponding part.
	Memory Err	There is a problem with the data card. Format the CF card. If the problem persists, contact our Customer Service Department.
	Last User Test Failed	Run a successful user test.
	Last Auto Test Failed	Run a successful user test again.
	No CMS	The equipment is disconnected from the CMS. Check the network connection.
	IP Address Conflict	Network IP conflicts. Check the network settings.
Power board	Power System Selftest Err	An error occurred to the system power supply. Restart the equipment.
	Power Board Volt Err	
	Low Battery	Change battery or connect the equipment to the AC power source to charge the batteries.
	No Battery	Battery is not installed. Install the battery.
	Battery Depleted! System will shut shown imminently. Connect to AC Mains or Replace Battery.	Connect the equipment to AC mains.
	Battery Err	There is a problem with the batteries. Check the batteries for damage; verify that correct batteries are used. Replace the batteries if necessary.
	Battery Aged	Replace the battery.
	Battery failed charging	Battery failure or power board hardware failure. Replace the battery. If the problem persists, replace the power board.
Therapy module	Therapy Equip selftest Err	An error occurred during therapy module self test. Restart the equipment or replace the therapy module low voltage board.

Measurement	Alarm Message	Cause and solution
Therapy module	Defib Malfunction	The defibrillation function fails or both the defibrillation and pacing functions fail. Restart the equipment and test defibrillation function. If the problem persists, contact our Customer Service Department.
	Pacer Malfunction!	The pacing function fails. Restart the equipment and test pacer function. If the problem persists, contact our Customer Service Department.
	Disarming Failed	There is a problem with the therapy module disarming circuit. Replace the therapy module low voltage board and high voltage board.
Monitoring module	Mornitor Module Selftest Err	An error occurred during MPM module power-on self test. Replace the MPM module.
	Monitor Module Reset Err	MPM module reset abnormally. In this case, the MPM module restores to default configuration. You can ignore this problem.
	Monitor Module Voltage Err	The voltage of MPM module is abnormal. Replace the MPM module.
Recorder	Recorder Init Err	Restart the equipment.
	Recordhead Overheated	The recorder has been working for a prolonged time. Clear the recording tasks and resume the recording till the recorder's print head cools down.
	Recorder Overcurrent	Re-load the recorder paper.
Pacer	Pads cable Off	Check that pads cable is properly connected.
	Pads Off	Check that pads are properly connected.
	ECG Lead Off	Check that ECG leadwires are properly connected.
	Pacer Stopped Abnormally	Check paddles. Check that pads well contact with patient's skin. Make sure pads are properly applied, and then start pacing again.
Others	Load Config Err	Check if the configuration is correct, or restore the factory configuration.

6.8 Error Codes

6.8.1 Therapy Module Error Codes

Type	Error Code	Description
Power-on self-test	1	CPU (M0+) power-on self-test failed
	2	RAM (M0+) power-on self-test failed
	3	ROM (M0+) power-on self-test failed
	4	Watchdog (M0+) power-on self-test failed
	5	ADC (M0+) power-on self-test failed
	6	Register (M3) power-on self-test failed
	7	RAM (M3) power-on self-test failed
	8	ROM (M3) power-on self-test failed
	9	Watchdog (M3) power-on self-test failed
	10	ASIC (M0+) power-on self-test failed
	11	CPU (M3) power-on self-test failed
Reset information	45	M0+ abnormal reset
	46	ASIC exception
	47	M3 abnormal reset
	48	M3 and M0+ communication error
Real-time self-test	49	M3 real-time ADC self-test error
	50	M3 chip calculation function error
Defibrillation	51	|V1-V2| > 500 V at the onset of charging
	52	V1 <= 65 V or V2 <= 65 V 1s after charging starts
	53	The V1/V2 decline exceeds more than 10% of V1/V2tgt during charging
	54	|V1-V2| > 128 V during use and |V1-V2| > 108 V during self-test in the case of charging
	55	V1 >= 2400 V or V2 >= 2400 V during charging
	56	Charging not completed within 25s after charging starts
	57	V1 > (V1Tgt*1.2) after charging ends
	58	V1 <= 50 V or V2 <= 50 V during charging retention
	59	V1 > (V1Tgt*1.2) or V2 > (V1Tgt*1.2) during charging retention
	60	Overcurrent during self-discharging
	61	V1 >= 40 V or V2 >= 40 V after self-discharging
	62	Overvoltage protection occurred
Impedance calibration	63	Zeroing sampling value error
	64	Gain calibration sampling value error
	65	Slope calculation error in gain calibration
	66	Zeroing failed before gain calibration
	67	An error occurred when calibration information is written into the flash memory

Type	Error Code	Description
Impedance calibration	68	An error occurred when calibration information in the flash memory is read
Pacing	71	Pacing power error
	72	Pacing relay error
	73	Pacing frequency error
	74	Pacing current error
	75	Pacing DA error
	76	Pacing voltage error
	77	Pacing overcurrent protection point too high
	78	Pacing overcurrent protection failure
Function self-test	201	AD self-test failed in function self-test
	202	Clock self-test timeout and uncompleted in function self-test
	203	Clock frequency self-test failed in function self-test
	210	Defibrillation charging failed in function self-test
	211	Function self-test charging timeout
	212	Function self-test charging retention failed
	216	Discharge circuit self-test failed in function self-test
	217	Discharge circuit self-test failed in function self-test
	218	Discharge circuit self-test failed in function self-test
	219	Discharge circuit self-test failed in function self-test
	220	Discharge circuit self-test failed in function self-test
	221	Discharge circuit self-test failed in function self-test
	222	Discharge circuit self-test failed in function self-test
	223	Discharge circuit self-test failed in function self-test
	224	Discharge circuit self-test failed in function self-test
	226	Self-discharging completion self-test failed in function self-test
	230	Self-test failed in minor signal impedance detection in function self-test
	231	Defibrillation relay short-circuited in minor signal impedance detection in function self-test
	232	Test load relay short-circuited in minor signal impedance detection in function self-test
	258	P-lead ECG self-test failed in function self-test
	259	PFlag & RFlag self-test failed in function self-test
	260	M3 5V7 power failure
	261	M3 +-5 V power failure
	262	M3 +18 V power failure
	263	M3 3V3 power failure
	264	M0 AVCC power failure
	265	M0 AVSS power failure
	266	M0 +2V5 power failure

Type	Error Code	Description
Function self-test	267	M0 -2V5 power failure
	268	M0 ASIC_VREF power failure
	269	M0 DVDD power failure
	270	Charging prohibited after the in-vivo cable is connected to the human body in self-test
	271	Discharging failed due to discharging circuit short-circuited
	273	The capacitance of the energy-storage capacitor exceeds the threshold in self-test
	274	Defibrillation energy dual-backup check error
	275	Pacing frequency dual-backup check error
	276	Pacing current dual-backup check error
	277	Big error in defibrillation discharge resistance

6.8.2 Power Module Error Codes

Type	Error Code	Description
Register failure	101	Battery discharging short circuit failure
	102	Battery charging short circuit failure
	103	Battery AFE discharging overcurrent failure
	104	Battery AFE watchdog failure
	105	Battery controller watchdog failure
	106	Setting of the battery permanent failure flag bit
	107	Battery overvoltage failure
	108	Battery undervoltage failure
	109	Battery pack overvoltage failure
	110	Battery pack undervoltage failure
	111	Battery Level-2 charging overcurrent failure
	112	Battery Level-2 discharging overcurrent failure
	113	Battery charging overcurrent failure
	114	Battery discharging overcurrent failure
	115	Battery charging over-temperature failure
	116	Battery discharging over-temperature failure
	117	Battery over-charge failure
	118	Battery over-charge current failure
	119	Battery over-charge voltage failure
	120	Battery fast charge timeout failure
	121	Battery pre-charge timeout failure
Other error codes of power board	143	Battery communication error
	144	Power voltage error
	145	Battery charging failure
	146	Power-on self-test error
	147	Main control failure

Type	Error Code	Description
Other error codes of power board	148	Disposable battery communication error
	151	Low battery
	152	Ultra-low battery
	153	Battery failure
	154	Battery aged
	155	RTC self-test failed
	156	Power-on/off button adhesion
	161	VBUS failure
	162	5VD failure
	163	10V failure
	164	DVDD failure
	165	18V failure
	166	AVSS failure
	167	3VB failure

6.8.3 Main Control Error Codes

Error Code	Description
401	No speaker
402	No storage card
403	Power board communication error
404	Therapy board communication error
405	Main control module power-on self-test error
406	Real-time clock error
407	Storage card read/write error
408	Keypad self-check error
409	Machine type recognition error
410	Recorder communication error
411	Front housing keypad self-test error
412	Speaker self-test error
413	Inaccurate real-time clock
414	Button adhesion
415	Program CRC check error
416	Poles expired
417	AT battery discharge error
419	UT battery discharge error
421	An error occurred when an SPI obtains the version
422	Wi-Fi module failure
423	Failed to load user configuration
424	Maintenance indicator user self-test error
425	M3 self-test error
426	Power board self-test error

6.8.4 M51C Error Codes

Error Code	Description
506	After the NIBP self-test fails or the equipment is powered on, an error occurs in the air pump, A/D sampling, or pressure sensor, or a pointer error occurs during software operation.

FOR YOUR NOTES

7 Disassembly and Repair

7.1 Tools Required

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

- Phillips screwdrivers
- Tweezers
- Sharp nose pliers
- 7# socket wrench
- Adjustable spanner
- Defibrillator/monitor high-voltage discharge fixture (0651-TF11)

7.2 Preparations for Disassembly

Before disassembling the equipment, finish the following preparations:

- Stop patient monitoring and therapy, turn off the equipment and disconnect all the accessories and peripheral devices.
- Disconnect the AC power source and remove the battery.
- To avoid high voltage hazard, strictly follow the procedure as defined in section ***7.3.4 Discharging the Capacitor*** for disassembling.

⚠ WARNING

- **Before disassembling the equipment, be sure to eliminate the static charges first. When disassembling the 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.**

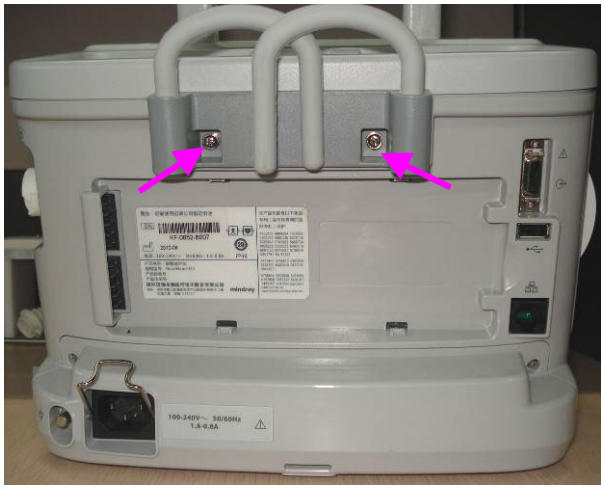
7.3 Disassembling the Main Unit

⚠ WARNING

- **To disassemble the equipment, first remove the external assemblies, such as the hook mount (if configured), paddle tray assembly, and front housing assembly in turn, and then the internal assemblies and parts.**
- **The power supply assembly and recorder can be removed without removing any other assemblies.**
- **To disassemble the equipment, place the equipment on a work surface free from foreign material, avoiding damaging the antiglare screen, LCD and the knob. Be careful not to break the two cotters on the front ends of rear housing.**
- **All the operations should be performed by qualified service personnel only. Make sure to put on the insulating gloves during service operations.**
- **Before remove the therapy board, you must use the dicharge fixture to discharge the capacitor first. If you do not have a discharge fixture, disconnect AC mains and remove batteries, wait for at least 2 hours before removing the capacitor.**

7.3.1 Removing Hook Mount (if configured)

1. Stand the equipment on the work surface with the back of the equipment facing to you. Loose and remove the two M3×16 Philips screws; take off the φ3 flat washers and spring washers.

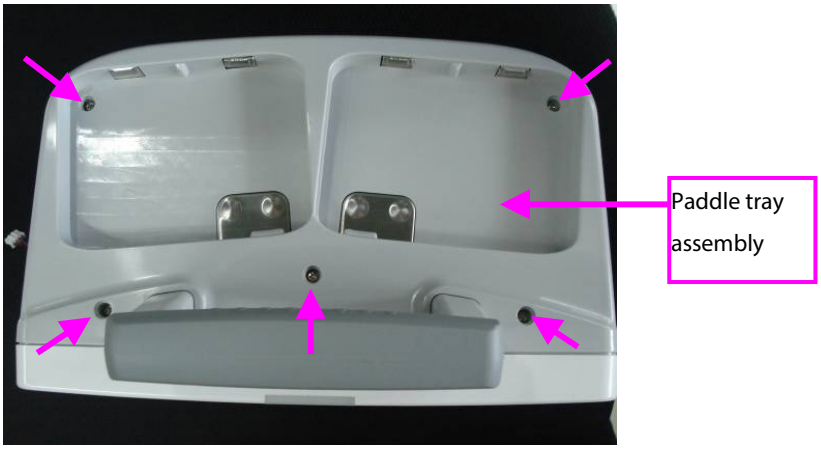


2. Pull out the hooks.

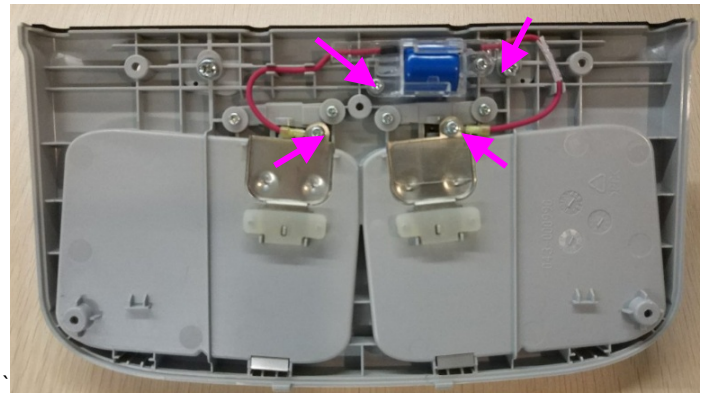
7.3.2 Removing Paddle Tray

1. Stand the equipment on the work surface with the back of the equipment facing to you. Tweeze the five plastic plugs filling the screw holes.

2. Loose and unscrew the five M3×8 Philips screws. Remove the paddle tray.



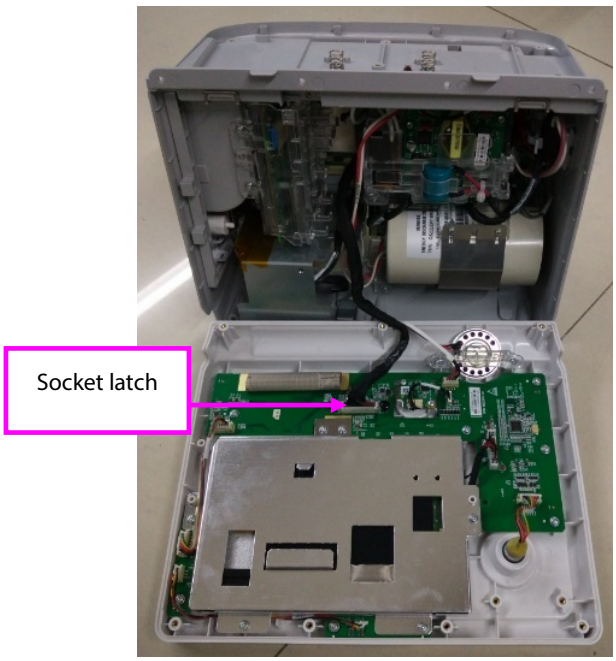
3. Unscrew the two PT3×8 Philips tapping screws and two M3×6 Philips combined screws. Disconnect and remove the test load cable.



7.3.3 Separating the Housing

1. Lay the equipment on a padded work surface with the display facing down and the bottom of the equipment nearest to you. Be careful not to damage the LCD and controls. Loose and remove the seven M3×10 Philips screws.

2. Stand the equipment on the work surface. Carefully separate the front housing assembly and the rear housing assembly. Remove the rocket latch , and then disconnect the cable between the main board and keypad board to remove the front housing.



NOTE

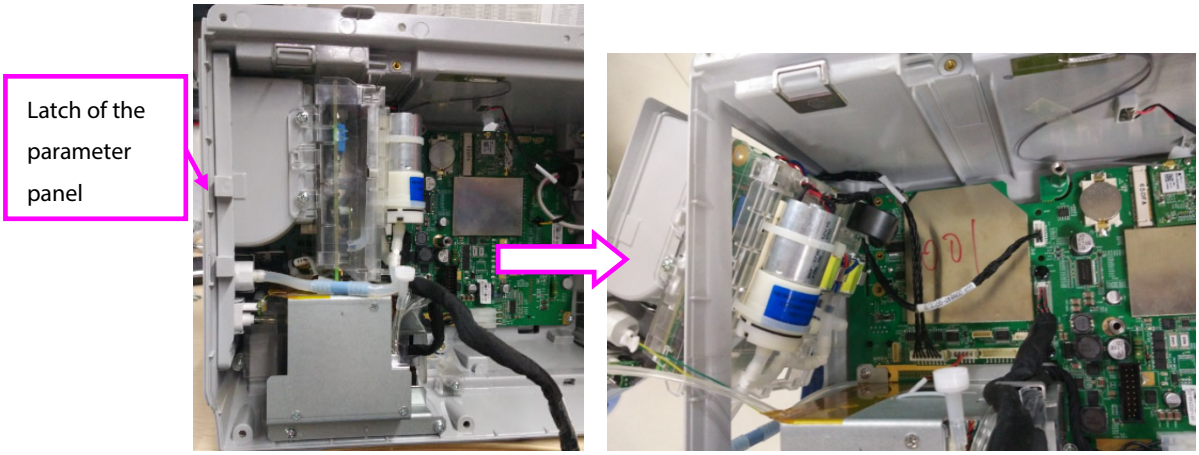
- **When reassemble the equipment, be sure to check if front housing water proof strip is correctly placed.**

7.3.4 Discharging the Capacitor

1. Use the high-voltage discharge fixture (0651-TF11) to discharge the capacitor by hooking the high-voltage ground end (TP1) with the black probe of the fixture, and hooking the high-voltage socket (TP3) with the fixture's red probe. Wait till all the indicating lamps on the fixture turns off. The capacitor is not completely discharged if the indicator remains on.
2. Set the multimeter to DC 1000V. Measure the discharge resistance and check if the reading of the multimeter is lower than 30V. If yes, you can safely disassemble the equipment now.

7.3.5 Disassembling the MPM Module Assembly

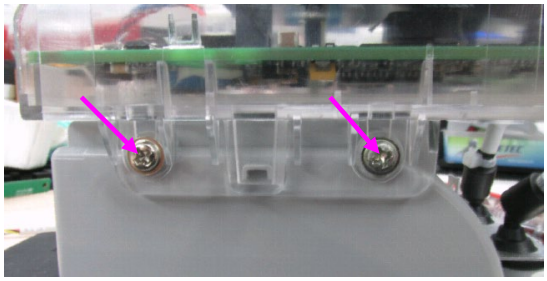
1. Lay down the equipment flat, remove the latch of the parameter connector panel upwards, and then remove the MPM module laterally.



2. Remove the recorder wire connected between the MPM module and CPU and power board and the wire between the MPM module and the main control board from the main control board.

7.3.6 Removing the Parameter Panel Assembly

1. Remove the two M3×8 cross recessed pan head screws with washers from the parameter panel to separate the MPM module from the parameter panel.

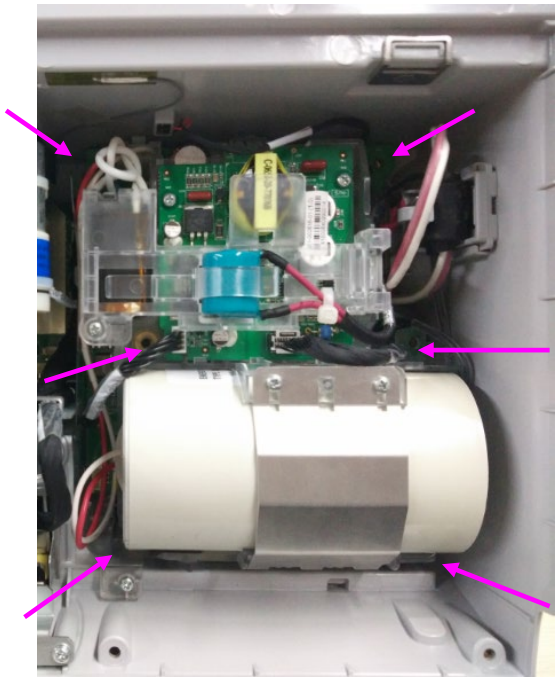


7.3.7 Removing the Therapy Module

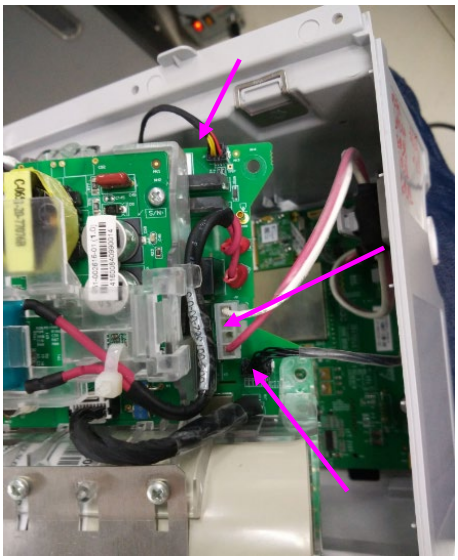
WARNING

- **Before removing the therapy board, you should discharge the capacitor first, refer to *7.3.4 Discharging the Capacitor* for the instructions.**

1. Remove the six M4×12 cross recessed combination screws from the therapy module, and then pull out the therapy module upwards.



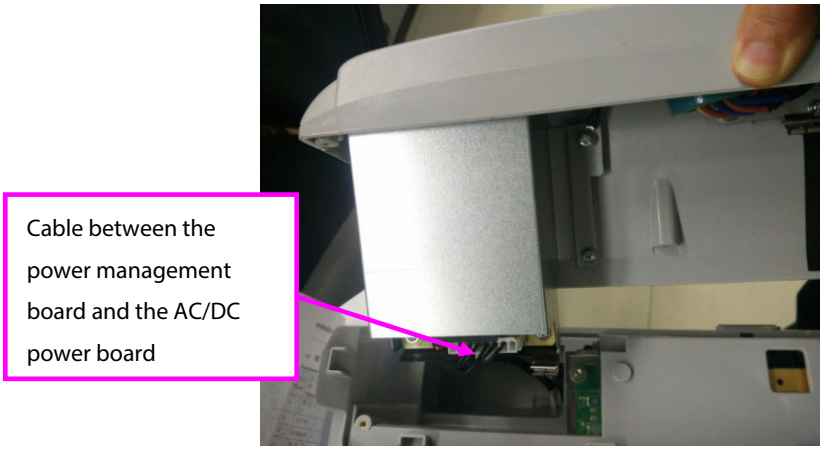
2. Remove the in-position detection switch cable and two defibrillation port cables from the therapy module.



7.3.8 Disassembling the Power Base Assembly

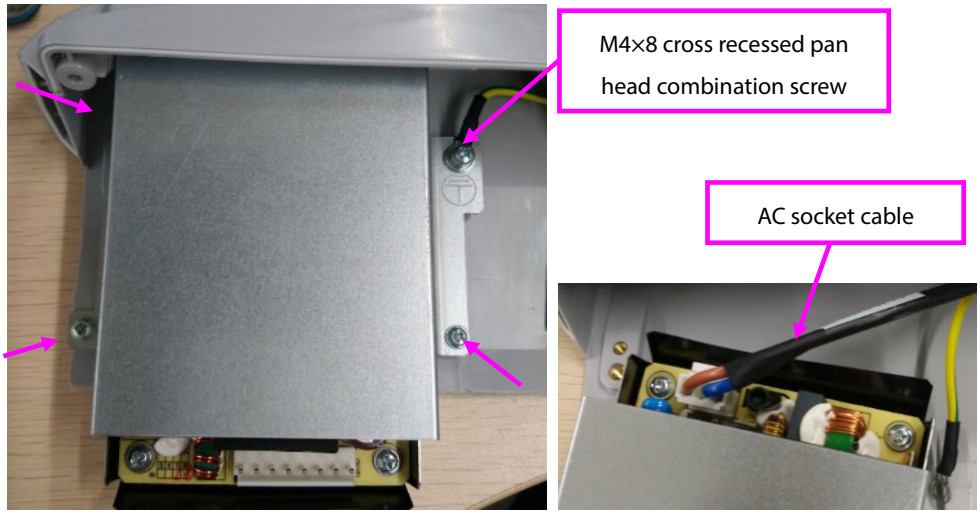
1. Lay the equipment on a padded work surface with the display side facing down and the bottom of the equipment nearest to you. Loose and remove the three M3×8 Philips screws and pull out the power base assembly.

3. Disconnect the cable between the power management board and AC/DC power supply module. Remove the power base assembly.



7.3.9 Disassembling the AC/DC Power Supply Board

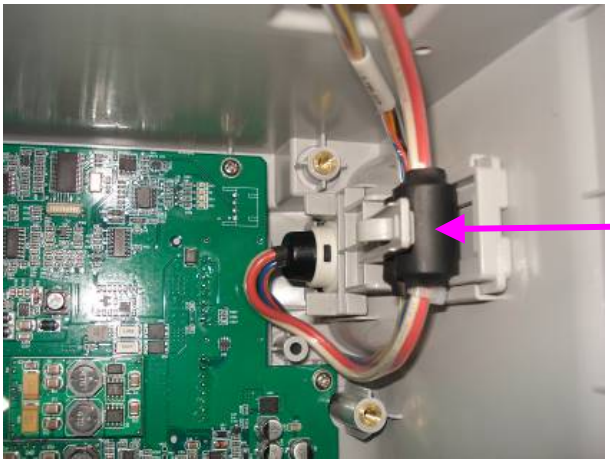
1. Use the screwdriver to loosen and remove the three M3×8 cross recessed pan head screws with washers and one M4×8 cross recessed pan head combination screws, remove the AC socket cable, and remove the defibrillation AC switching power board and shielding cover.



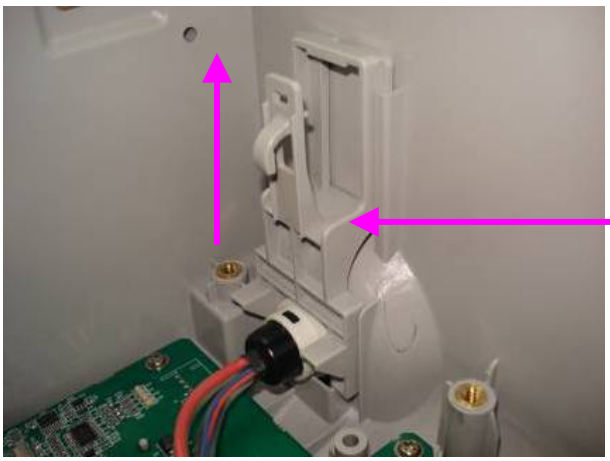
2. Use the screwdriver to loosen and remove the four M3×8 cross recessed pan head screws with washers, and separate and take out the power board from the shielding metal sheet.

7.3.10 Disconnecting the Therapy Port Cable

1. Remove the magnetic ring on the therapy port cable.

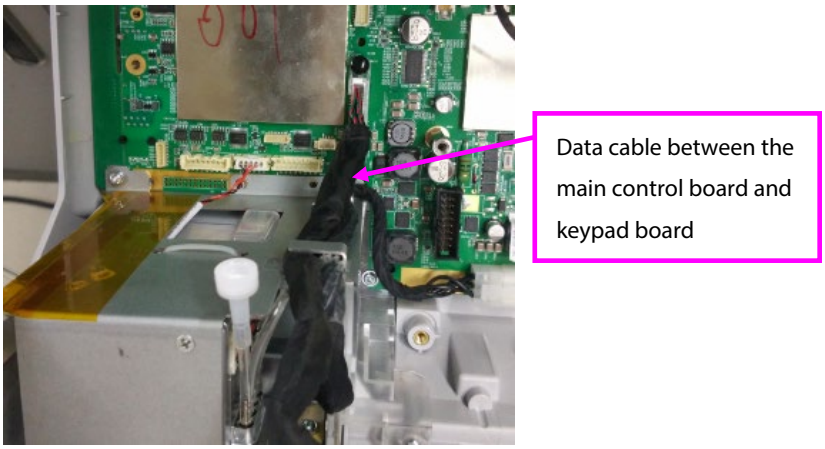


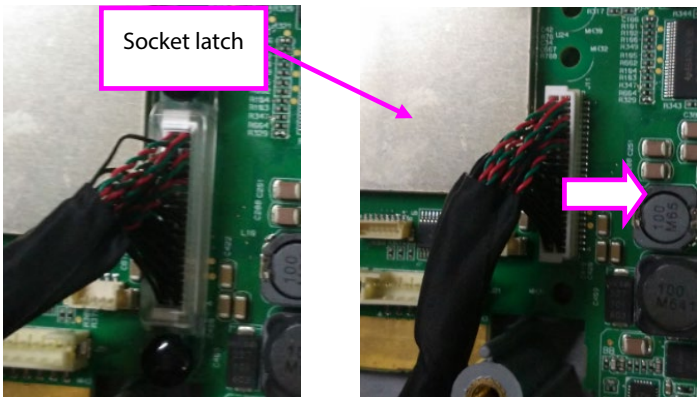
2. Pull the therapy port latch upward, and then disconnect the therapy port cable.



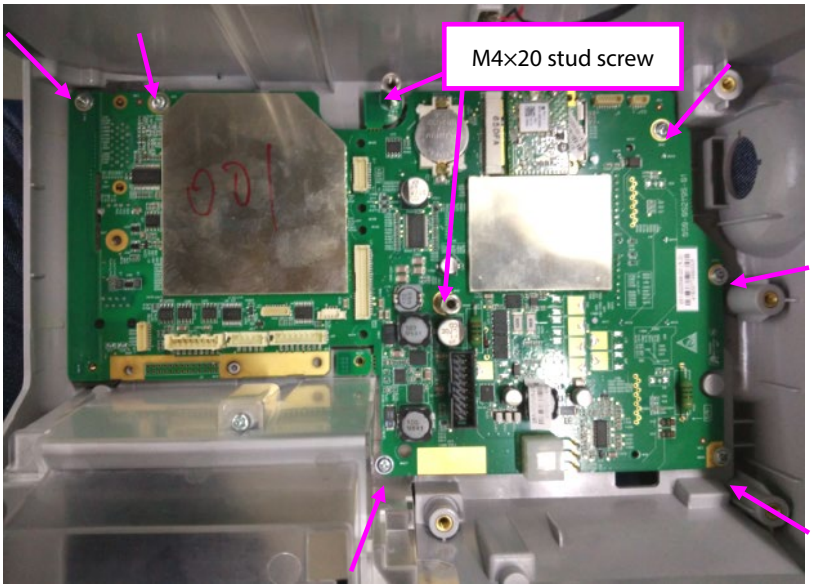
7.3.11 Removing the Main Board Assembly

1. Remove the socket latch, and then remove the data cable between the main control board and the keypad board from the power management board.

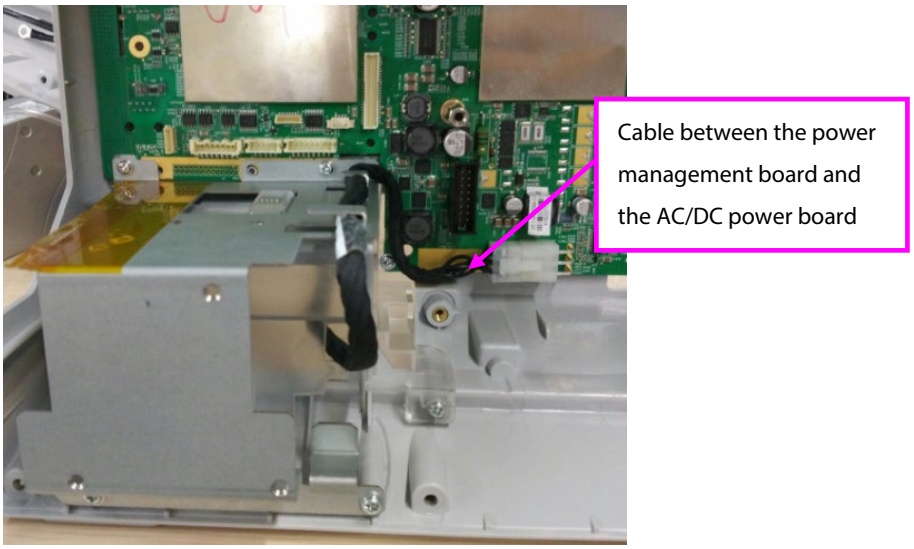




2. Use the screwdriver to remove the six M3×8 cross recessed pan head screws with washers and use the 7# socket wrench to remove the two M4×20 stud screws.



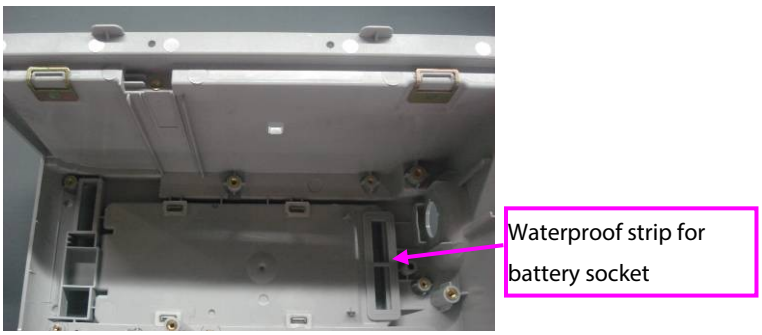
3. Pull the cable between the power management board and the AC/DC power board out of the rear housing gap and take out the main control board assembly.



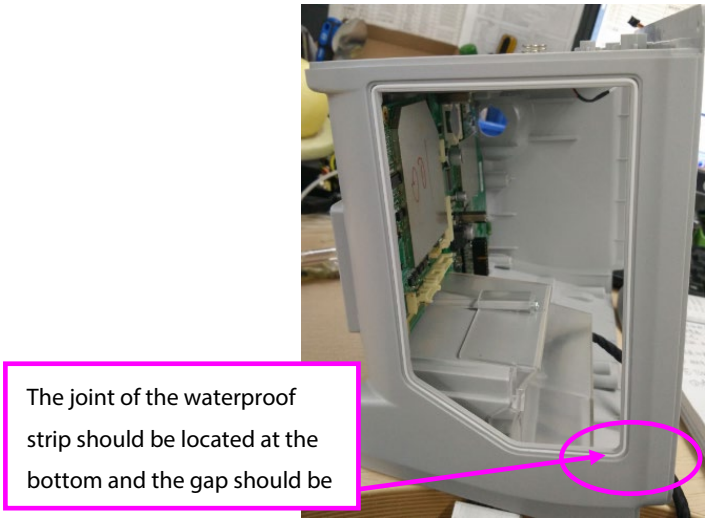
7.3.12 Checking Waterproof Strips before Reassembling

Before reassembling the equipment, make sure that the waterproof material on the rear housing assembly and power base assembly is stuck to the proper places.

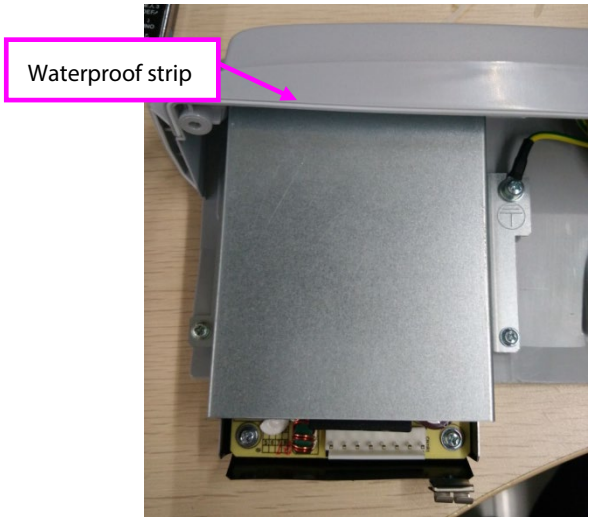
1. Check that the waterproof strip is properly stuck on battery socket.



2. Check that the white waterproof strip is adhered to the proper place.



3. Check that the waterproof strip on the power base is adhered to the proper place.



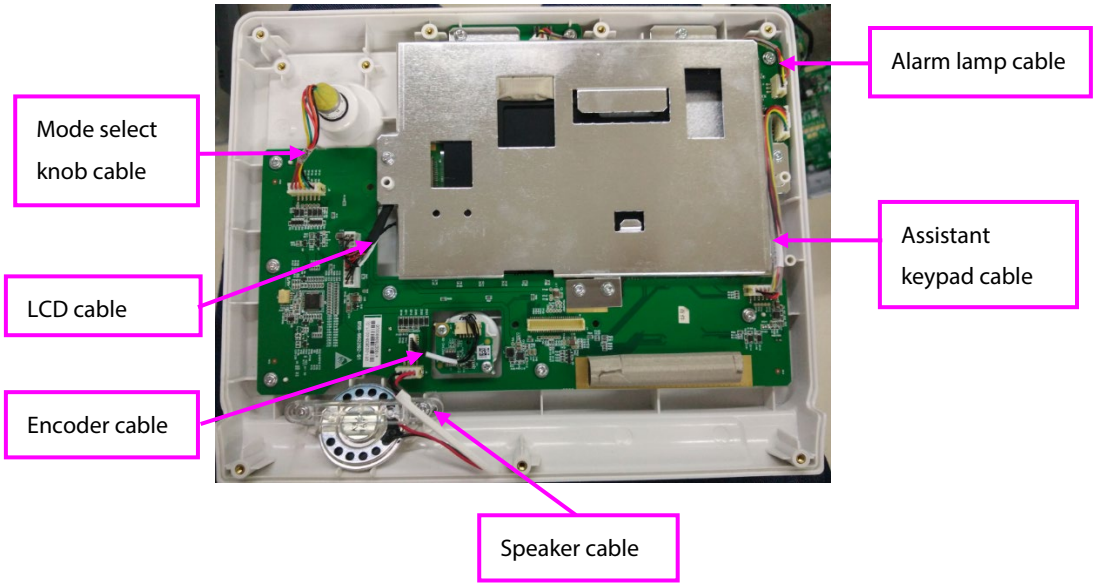
7.4 Disassembling the Front Housing Assembly

NOTE

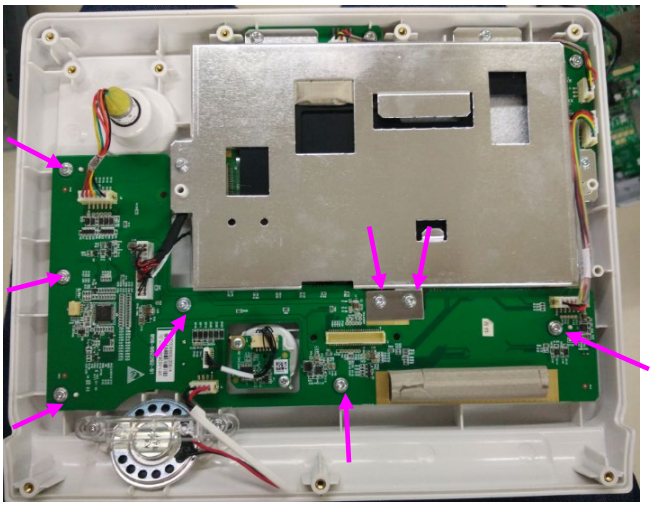
- **To disassemble the equipment, place the equipment on a work surface free from foreign material, avoiding damaging the antiglare screen, LCD and the knobs.**
- **Make sure the speaker is not damaged after repairing any other front housing assembly. Verify that the speaker works properly by powering on the equipment and testing the speaker.**
- **Clear the LCD before reassembling it.**

7.4.1 Removing the Keypad Board

1. Disconnect all the cables from the mode select knob cable, encoder cable, speaker cable, LCD cable, assistant keypad board cable and the alarm lamp cable.

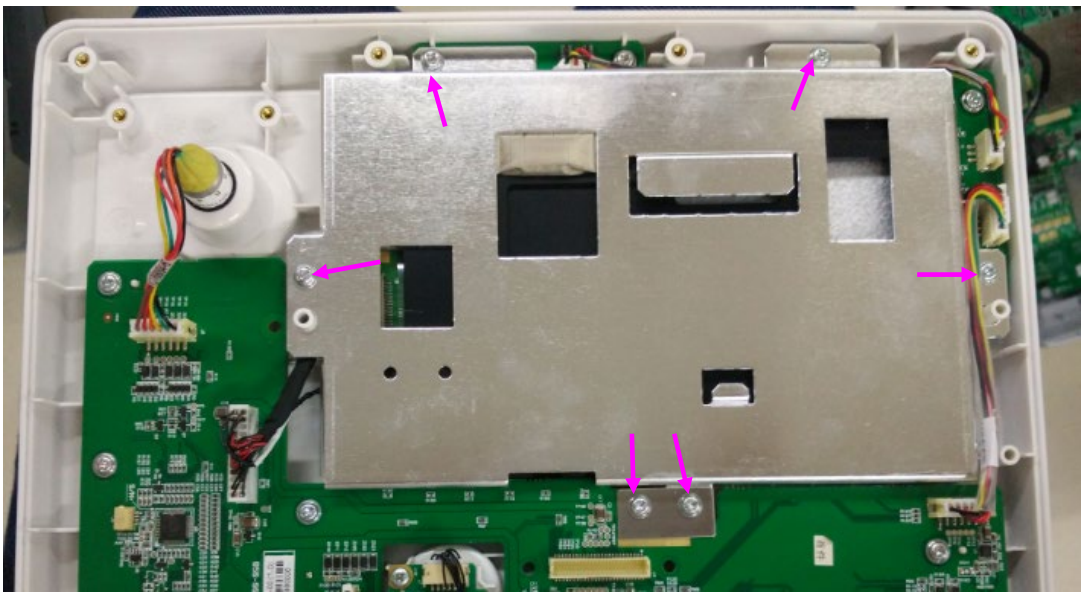


2. Remove the two M3×8 Philips screws securing the grounding plate, and the six M3×8 Philips screws from the keypad board. Take out the kayped board.

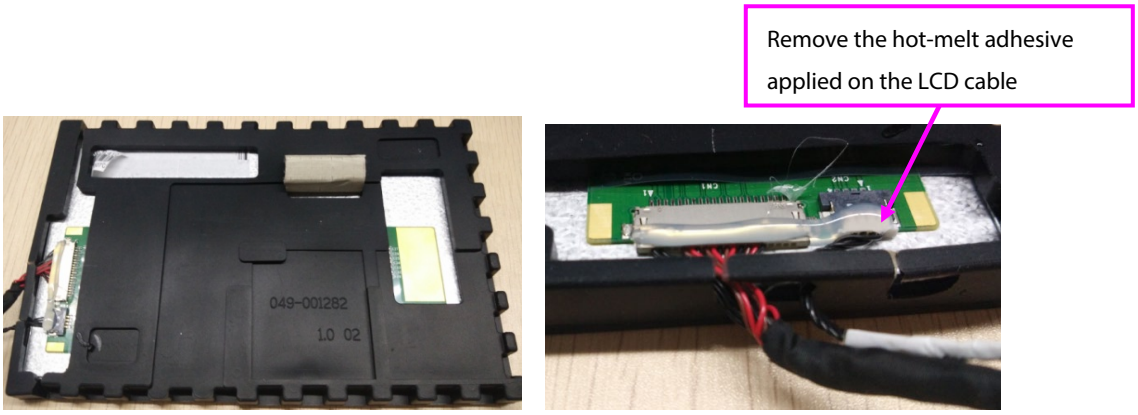


7.4.2 Removing Display Assembly

1. Remove the four M3×8 Philips screws securing the keypad board. If the grounding plate is not removed, you need to unscrew the two M3×8 Philips screws securing the grounding plate. Remove the LCD bracket before removing the display assembly.



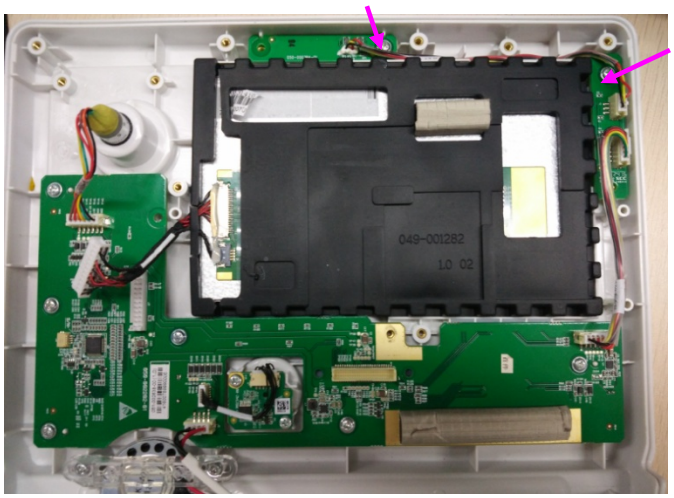
2. Remove the hot-melt adhesive applied on the LCD cable, and then disconnect the LCD cable. Take out the LCD from the silicone jacket.



7.4.3 Removing the Alarm Lamp Board and Assistant Keypad Board

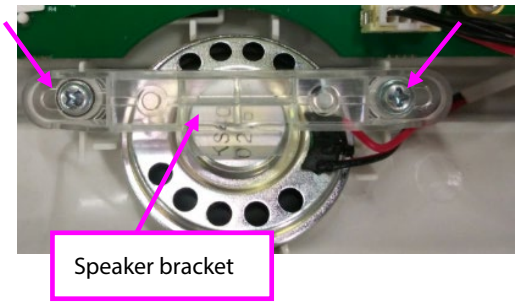
To remove the alarm lamp board and assistant keypad board, remove the LCD bracket first, see ***7.4.2 Removing Display Assembly***.

1. Disconnect the alarm lamp cable.
2. Remove the two M3×8 Philips screws, and then take out the alarm lamp board and assitant keypad board.



7.4.4 Removing the Speaker

1. Remove the two M3×8 Philips screws. Take off the speaker bracket, and then remove the speaker.



After repairing any part of the front housing assembly, verify that the speaker is not damaged by powering on the equipment and testing the speaker.

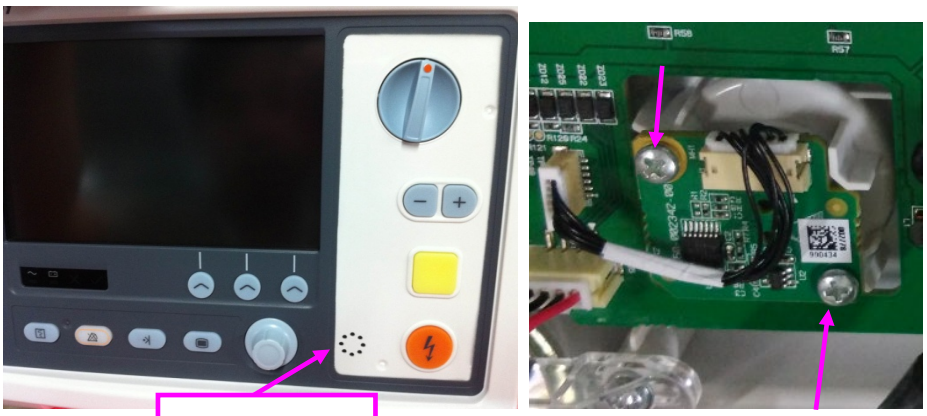
7.4.5 Removing the Mode Select Knob

Pull the switch off its shaft. Loosen and remove the nut and washer using a socket wrench or sharp nose pliers. Disconnect the cable from the knob.

When assemble the Mode Select knob, check that it is aligned with the labelling. Adjust the knob using sharp nose pliers if necessary.

7.4.6 Removing the Encoder

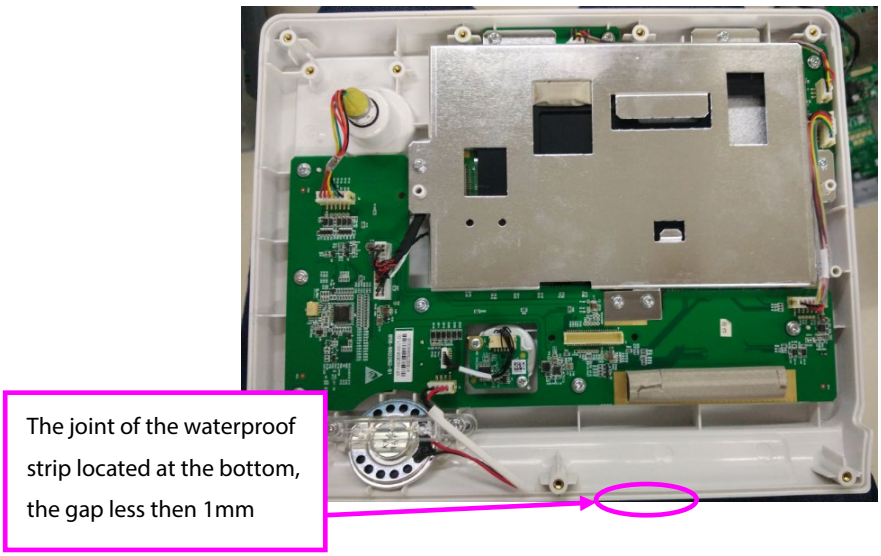
1. Remove the navigation knob.
2. Disconnect the encoder cable.
3. Pull the encoder off its shaft. Loosen and remove the nut and washer using a socket wrench. Disconnect the encoder cable.



7.4.7 Checking Waterproof Material on the Front Housing

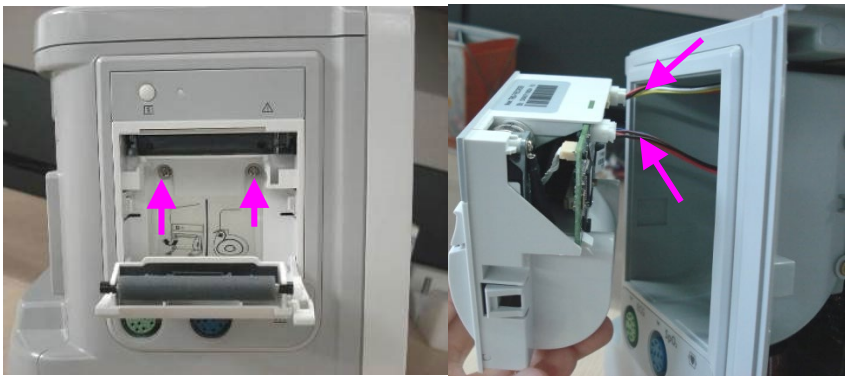
Before reassembling the equipment, make sure that the waterproof material on the front housing are placed to the proper places.

Check that the white waterproof strip is properly adhered to the slot around the edge of the front housing.



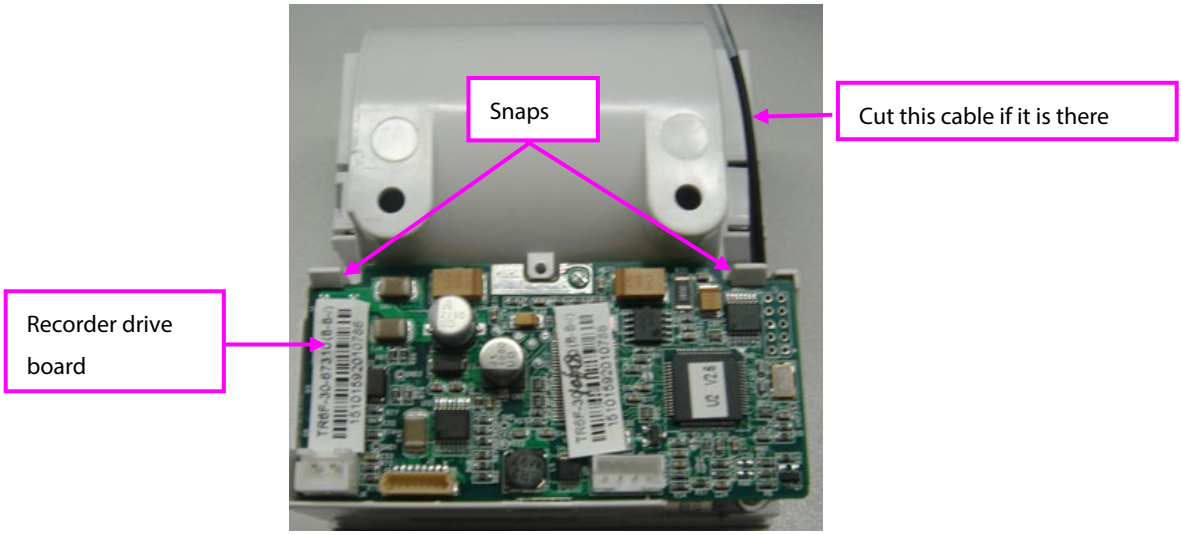
7.5 Removing the Recorder

1. Remove the two M3×6 Philips screws. Pull the recorder out of the recorder well.
2. Disconnect the cable from the recorder, and then remove the recorder.

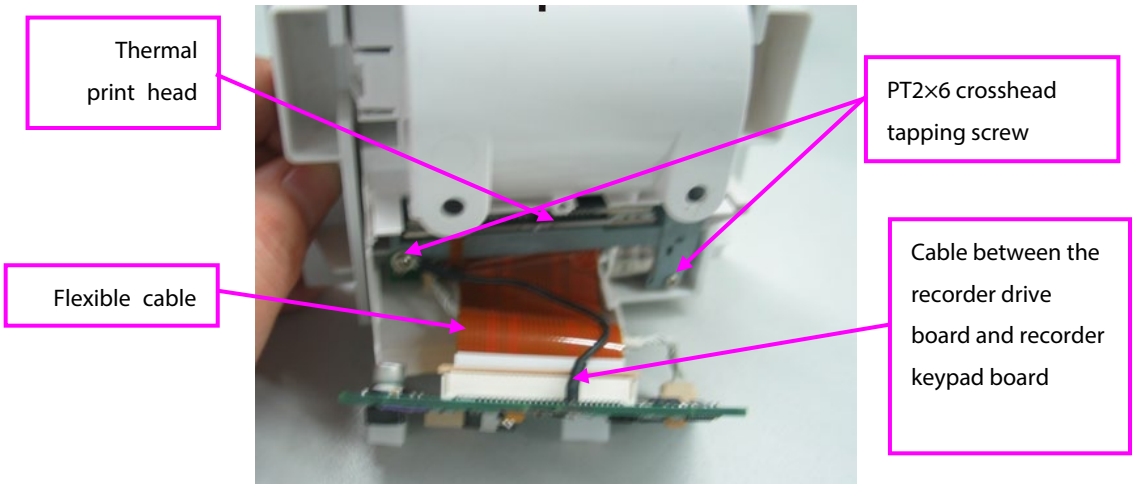


7.6 Disassembling the Recorder

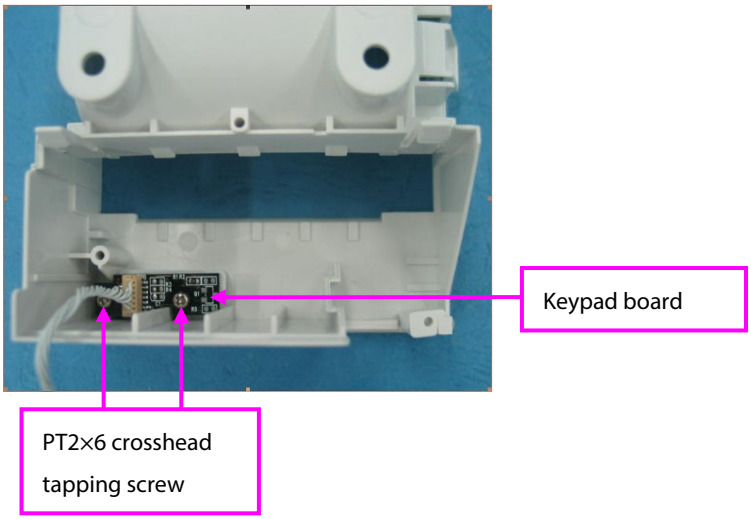
1. Loosen the two snaps and remove the recorder drive board.



2. Loosen and remove the two PT2×6 crosshead tapping screws. Disconnect the flexible cable and the connection cable between the recorder drive board and recorder keypad board. Remove the thermal print head and recorder drive board.



3. Remove the two PT2×6 crosshead tapping screws, and then remove the keypad board.

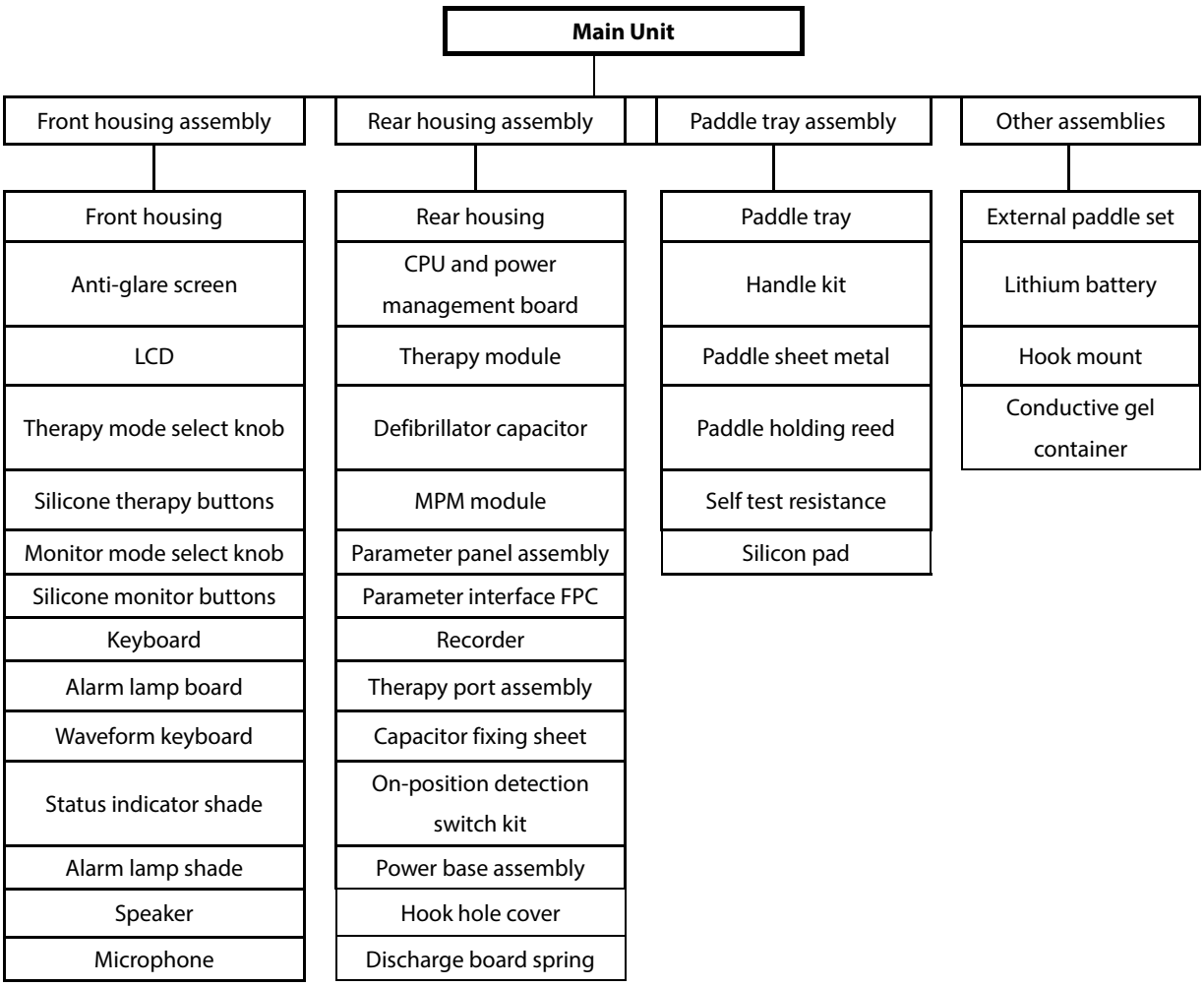


8 Parts

8.1 Introduction

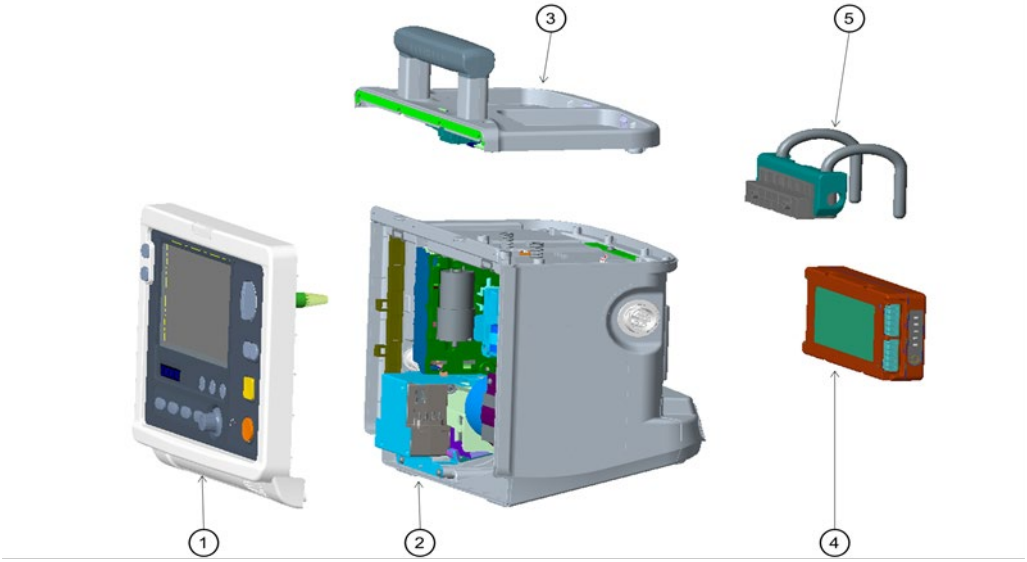
This chapter contains the equipment's exploded views and parts lists. It helps the engineer to identify the parts during disassembling the equipment and replacing the parts. This manual is based on the maximum configuration. Your equipment may not have some parts and the quantity of the screws, stacking sleeves, and etc may be different with those included in the parts lists.

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



8.2 Main Unit

8.2.1 Exploded View

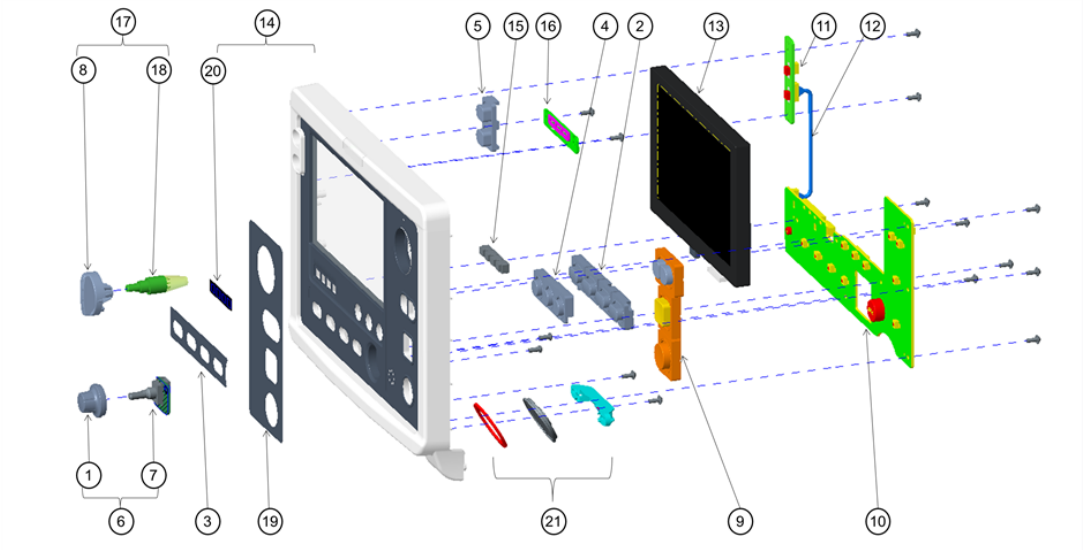


8.2.2 Parts List

No.	Order Number	Part Description	Qty	Remark
1	/	Front Housing Assembly	1	/
2	/	Rear Housing Assembly	1	/
3	/	Paddle Tray Assembly	1	/
4	115-007858-00	Li-ion Bat Pack (14.8V3000mAh LI24I001A)	1	SN: EL-/ET-
	115-062369-00	Li-ion Battery (5600mAh LI24I005A)		SN: EZ-/EI-
5	115-007587-00	Pothook kit	1	/

8.3 Front Housing Assembly

8.3.1 Exploded View



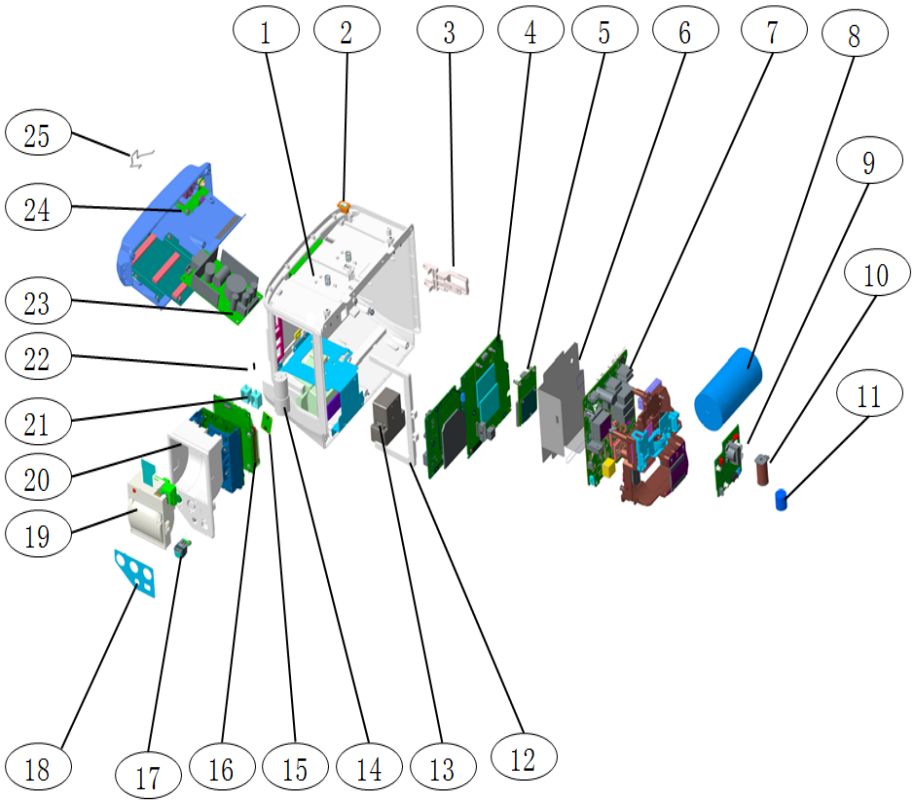
8.3.2 Parts List

No.	Order Number	Part Description	Qty	Remark
1	043-001114-00	knob-monitor	1	/
2	049-000216-00	Monitor Key(D3)	1	Without NIBP
	047-011909-00	silica gel key (D3/NIBP/silk screen)		With NIBP
3	047-003791-00	monitor key overlay(D3/English)	1	Without NIBP
	047-011897-00	key label(D3/NIBP/english/silk screen)		With NIBP
4	049-000217-00	Screen Key 1(D3)	1	/
5	049-000218-00	Screen Key 2(D3)	1	/
6	115-049435-00	Encoder assembly	1	Include 1,7
7	051-002778-00	Defibrillation Coder Board PCBA	1	/
8	0651-20-76734-51	mode knob	1	/
9	049-000215-00	Defib. Key(D3)	1	/
10	051-002638-00	0652 Front Keyboard PCBA	1	/
11	051-002851-00	0652 auxiliary keyboard PCBA	1	/
12	009-001102-00	assistant keyboard connecting line	1	/
13	115-049468-00	Truly Screen assembly	1	Include LCD & Cable
	115-049469-00	Tianma Screen assembly		Include LCD & Cable
14	115-049465-00	D3 front cover assembly	1	Include 20
	115-049466-00	D2 front cover assembly		Include 20
15	049-000170-00	lens-status	1	/

No.	Order Number	Part Description	Qty	Remark
16	043-000986-00	lens-alarm	1	/
	051-000491-00	0652 alarm light PCBA	1	/
17	801-0651-00126-00	encoder assembly	1	Include 8，18
	801-0651-00043-00	encoder assembly		Include 8，18
18	0651-21-76884	mode switch cable	1	/
19	047-003789-00	mode overlay(D3/English)	1	/
	047-005443-00	Mode label (D3/No pacer/English)		/
20	047-003792-00	overlay of product maintenance led	1	/
21	115-041367-00	Speaker FRU(D3/D6)	1	/

8.4 Rear Housing Assembly

8.4.1 Exploded View



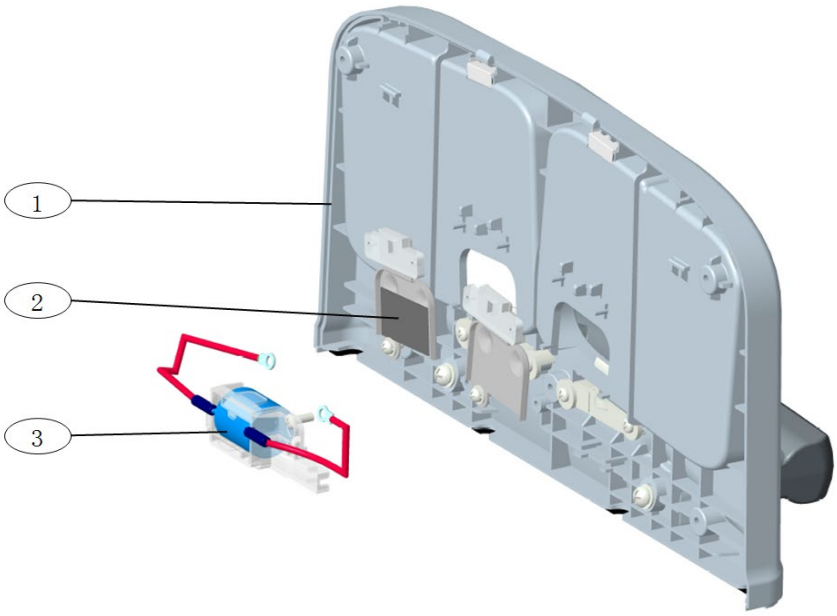
8.4.2 Parts List

No.	Order Number	Part Description	Qty	Remark
Rear Housing Part				
1	115-049467-00	D3 rear cover assembly	1	/
2	115-049429-00	Examine the switch assembly	1	/
3	043-001116-00	blot-defibrillation	1	/
Main Control Part				
4	115-056282-00	0652 Main Control and Power Manage Board FRU	1	/
5	115-050525-00	Wifi upgrade kit(5G/ NO Mainboard)	1	/
Therapy Module Part				
6	047-018369-00	therapy module insulating trip	1	/
7	051-002615-00-00	Therapy Board FRU(with SW)	1	/
8	009-008106-00	Dry type Cable to treatment module	1	/
9	051-002616-00	Pace Board	1	/
10	006-000239-00	IND 1.5mH 5.6Ω	1	/
11	009-007382-00	Treatment of Plate load test cable (HVR)	1	/
MPM Assembly Part				
12	043-007617-00	lock-recorder-D3	1	/
13	115-027548-00	AION Rhodium CO2 Analyzer	1	/
14	082-000862-00	pump. 12VDC with 120 wire and connector	1	/
21	082-000864-00	valve.CJV13-A12B2	1	/
15	051-002353-00	M51C-9008V3.0 SPO2 PCBA	1	/
	100-000340-00	MSX2040 masimo SPO2 board （forNon-Mahwah）		/
	101-000469-00	Nellcor SPO2 PCBA		/
16	051-002766-00	M51C 5L,MR/NC-SPO2,AO(D3)	1	/
	051-002767-00	M51C 5L,3-SPO2,NIBP,AO(D3)		/
17	115-036134-00	DRYLINE PRIME Receptacle with no panel	1	/
22	082-000098-00	630F Reducer	1	/
18	047-019272-00	Parameter label of 0652 (ECG+SPO2)	1	/
	047-019273-00	parameter label of 0652 (ECG+SPO2+CO2)		/
	047-019274-00	parameter label of 0652 (ECG+NIBP)		/
	047-019275-00	parameter label of 0652 (ECG+SPO2+NIBP)		/
	047-018634-00	0652 Parameter Label(ECG+SPO2+NIBP+CO2)		/
20	115-012155-00	Parameter Panel assembly	1	ECG
	115-012152-00	Parameter Panel assembly		ECG+Mindray
	115-012153-00	Parameter Panel assembly		ECG+Nellcor
	115-012154-00	Parameter Panel assembly		ECG+Masimo
	115-021528-00	Parameter Panel assembly		ECG+NIBP
	115-021529-00	Parameter Panel assembly		ECG+Mindray+NIBP

No.	Order Number	Part Description	Qty	Remark
	115-021530-00	Parameter Panel assembly		ECG+Masimo+NIBP
	115-021531-00	Parameter Panel assembly		ECG+Nellcor+NIBP
19	801-6800-00080-00	TR6F Recorder	1	/
	0000-10-11079	thermal printer head		50mm
Power Base Assembly Part				
23	115-065041-00	DELTA Power Supply Board(18V 100W) FRU	1	/
24	115-049470-00	D3 Power base assembly	1	/
25	0651-20-76990	AC plug locked hook	1	/

8.5 Paddle Tray Assembly

8.5.1 Exploded View

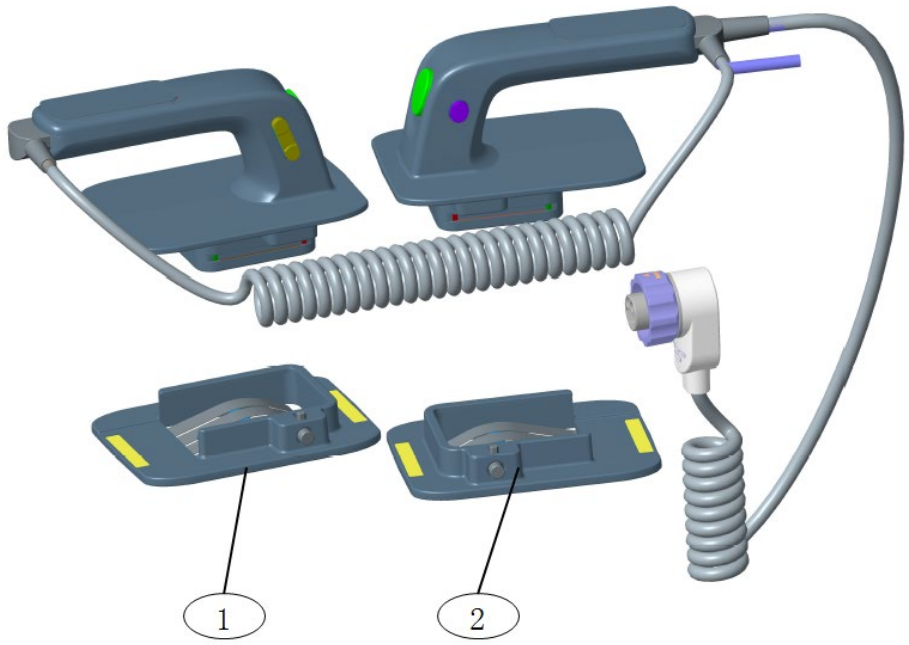


8.5.2 Parts List

No.	Order Number	Part Description	Qty	Remark
1	801-0652-00014-00	Electrode base assembly	1	/
2	115-067390-00	bracket-electrode FRU	1	Include 2 pcs
3	801-0651-00124-00	test load cable	1	/

8.6 External Paddles Assembly

8.6.1 Exploded View



8.6.2 Parts List

No.	Order Number	Part Description	Qty	Remark
1	115-032394-00	Adult sternum paddle kit	1	/
2	115-032395-00	Adult apex paddle kit	1	/
/	0651-30-77114	External Paddles	1	Include 1,2

8.7 Others

No.	Order Number	Part Description	Qty	Remark
1	009-008397-00	New Defi Docking cable	1	/
2	009-006848-00	Defi AC-DC to main control Power cable	1	/
3	115-067299-00	Internal Wire to Defibrillator Socket	1	/
4	009-006840-00	Defi multi_para to main control cable	1	/
5	009-007343-00	Defibrillation Coder Cable	1	/
6	009-006838-00	New Defibrillation LCD cable tianma D3	1	/
7	009-007721-00	Defibrillation LCD cable Truly (D3)	1	/
8	009-006837-00	Defi before and after the shell cable	1	/
9	1000-21-00122	CABLE GROUND, EQUIPOTENT,T5/T8	1	/
10	M07-00131F---	FUSE Time-lag 250V 3.15AD5X20	1	/
11	115-049460-00	Pace upgrade package	1	/
12	115-049471-00	ECG/Mindray upgrade package	1	/
13	115-049472-00	ECG/Nellcor upgrade package	1	/
14	115-049474-00	ECG/NIBP upgrade package	1	/
15	115-049475-00	ECG/Mindray/NIBP upgrade package	1	/
16	115-049476-00	ECG/Masimo/NIBP upgrade package	1	/
17	115-049477-00	ECG/Nellcor/NIBP upgrade package	1	/
18	115-050533-00	M02D CO2 module upgrade package	1	/
19	115-050532-00	M02D CO2 module upgrade package	1	/
20	115-050531-00	M02D CO2 module upgrade package	1	/
21	115-056520-00	WIFI to 3G Module Package FRU	1	/
22	TR6F-20-67301	Recorder gate (mold MR67301)	1	/
23	A30-000001---	PAPER,THERMAL(50MM X 20M/ROLL)	1	/

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

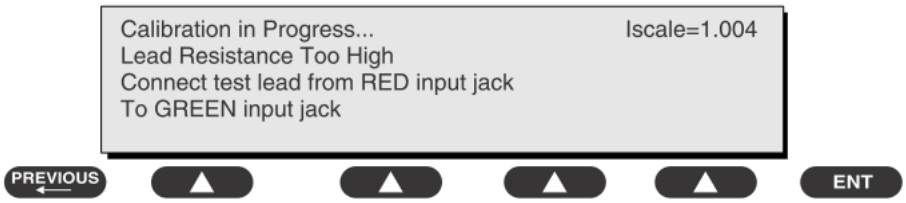
A.4 Protective Earth Resistance

Protective Earth Resistance is measured using the RED test lead attached to the DUT Protective Earth terminal or enclosure. Select the test current by pressing SOFT KEY 3 to toggle between 1AMP, 10AMP, and 25AMP. The front panel outlet power is turned off for this test.

The following conditions apply: L1 and L2 Open.

Preparation

1. First select the test current that will be used for performing the Protective Earth Resistance test by pressing AMPERES (SOFT KEY 3).
2. Connect the test lead(s) between the RED input jack and the GREEN input jack.
3. Press CAL LEADS. The 601PRO will measure the lead resistance, and if less than 0.150 Ohms, it will store the reading and subtract it from all earth resistance readings taken at the calibrated current.



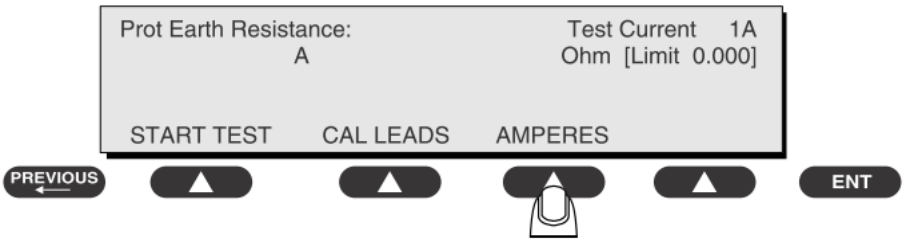
If the calibration fails, the previously stored readings will be used until a passing calibration has occurred.:

⚠WARNING

- **During Earth Resistance testing, the DUT must be plugged into the 601PRO front outlet. If the DUT fails Earth Resistance, discontinue tests and label the device defective.**

To Perform the Test

1. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet.
2. Attach the 601PRO RED input lead to the device's Protective Earth terminal or an exposed metal area.
3. Press shortcut key 3. The Protective Earth Resistance test is displayed.
4. Press SOFT KEY 3 to select a test current (1AMP, 10AMP, or 25AMP). The selected test current is displayed in the upper right corner of the display.



5. Press START TEST to start the test. The test current is applied while resistance and current readings are taken. This takes approximately 5 seconds.
6. Press the print data key at any time to generate a printout of the latest measurement(s).

NOTE

- **When "Over" is displayed for Ohms, this signifies that a valid measurement was not obtained because either an open connection was detected or that the measurement was not within range. Readings greater than 9.999 Ohms will be displayed as Over.**

In Case of Failure

Once it reaches the limitation, stop using and inform the Customer Service Engineer for analysis and disposal.

Limits

- R = 0.1Ω Maximum

A.5 Earth Leakage Test

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

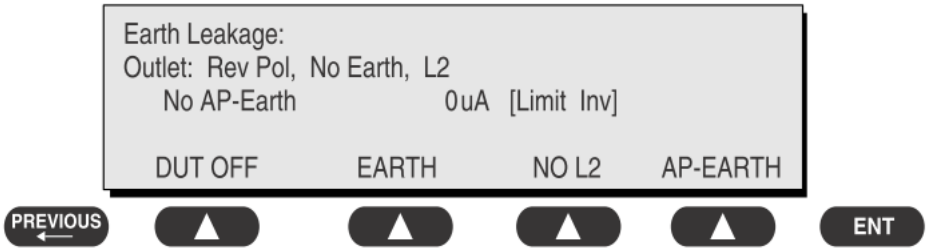
Leakage current is measured the following ways:

- 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.
- Inspect wiring for bad crimps, poor connections, or damage.
- 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

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

A.6 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:

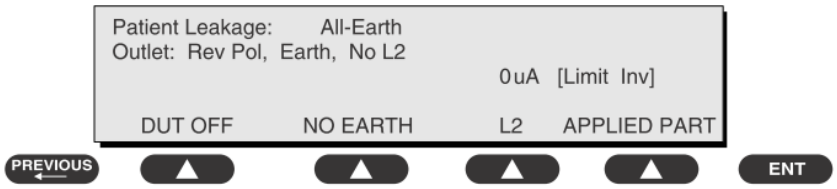
- Normal Polarity, Earth Open, Outlet ON Normal Polarity, Outlet ON
- Normal Polarity, L2 Open, Outlet ON Reversed Polarity, Outlet ON
- Reversed Polarity, Earth Open, Outlet ON Reversed Polarity, L2 Open, Outlet ON

⚠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.**
- **For external or internal paddle, the patient leakage current test should be tested when the EUT was charging.**

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.
- Inspect wiring for bad crimps, poor connections, or damage.
- 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 ECG (Defibrillator proof) and other CF applied parts
  - 10 μA in Normal Condition
  - 50 μA in Single Fault Condition
- For BF applied parts
  - 10 μA DC,100μA AC in Normal Condition
  - 50 μA DC,500μA AC in Single Fault Condition

A.7 Mains on Applied Part Leakage

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

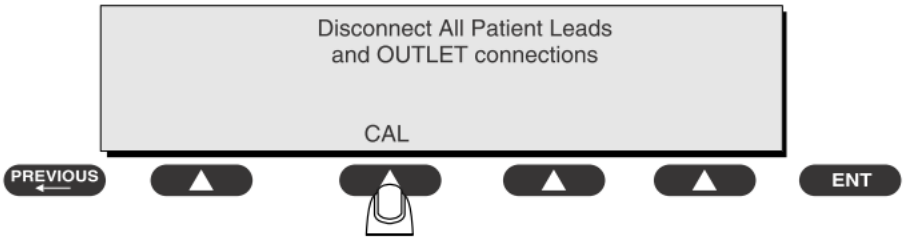
The following outlet conditions apply when performing the Mains on Applied Part test.

- 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.

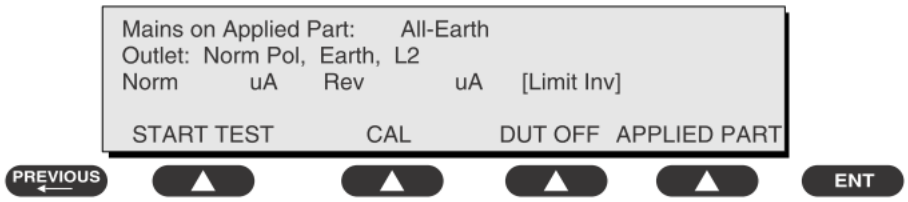
3. When the calibration is finished, the Mains on Applied Part test will reappear.

⚠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.
- Inspect wiring for bad crimps, poor connections, or damage.
- 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

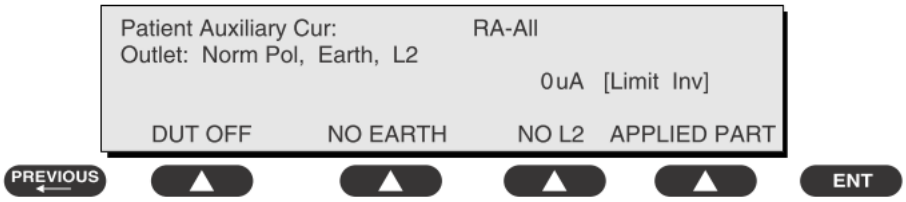
- For ECG (Defibrillator proof) and other CF applied parts
  - 50 µA
- For BF applied parts
  - 5000 µA

A.8 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.**
- **For external or internal paddle, the patient auxiliary current test should be tested when the EUT was charging.**

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.
- Inspect wiring for bad crimps, poor connections, or damage.
- 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 ECG (defibrillator proof) and other 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.9 Functional test

For functional test items, please refer to relevant functional tests in ***4 Testing and Maintenance***.

ELECTRICAL SAFETY INSPECTION FORM

Overall assessment:

- Scheduled inspection: Test item 1, 2, 3, 9
- Unopened repair type: Test item 1, 2, 3, 9
- Opened repair type, not modify the power board and patient circuit board: Test item 1, 2, 3, 4, 5, 9
- Opened repair type, modify the power board or patient circuit board: Test item 1, 2, 3, 4, 5, 6, 7, 8, 9

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 Labelling				
4	Protective Earth Resistance		_____Ω		Max 0.1 Ω
5	EARTH Leakage	Normal condition(NC)	_____μA		Max NC:500μA, SFC:1000μA
		Single Fault condition(SFC)	_____μA		
6*	Patient Leakage Current	Normal condition(NC)	_____μA		Max CF AP NC:10μA, SFC: 50μA BF AP NC:100μA, SFC: 500μA
		Single Fault condition(SFC)	_____μA		
7*	Mains on Applied Part Leakage				Max CF AP: 50μA BF AP: 5000μA
8*	Patient Auxiliary Current	Normal condition(NC)	_____μA		Max CF AP NC:10μA, SFC: 50μA BF AP NC:100μA, SFC: 500μA
		Single Fault condition(SFC)	_____μA		
9	Functional test (parameters tested):				

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

Deficiency / Note:

Name: _____ Date/Signature_____

FOR YOUR NOTES

P/N: 046-011557-00(2.0)