BeneHeart D1

Automated External Defibrillator

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 equipment.

Password

The default password to access the configuration edit mode is 3156.

Contents

FOR YOUR NOTES

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.**
- **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.**
- **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.**

1.1.2 Warnings

⚠WARNING

- **Check for mechanical damages before each use. If case of any damage, do not apply it to patients.**
- **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.**
- **Run the equipment only on the supplied disposable or rechargeable battery.**
- **Charge the rechargeable battery only with the supplied BatteryFeed 20 charger station.**
- **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 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 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.**
- **Keep a distance of at least 20cm away from the monitor when Wi-Fi function is in use.**

1.1.3 Cautions

⚠CAUTION

- **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.**
- **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.**

1.1.4 Notes

NOTE

- **Refer to Operator's Manual for detailed operation and other information of the defibrillator/monitor.**

1.2 Equipment Symbols

See the ***BeneHeart D1 Automated External Defibrillator Operator's Manual (P/N: 046-004673-00)*** for information about the symbols used on this product and its packaging.

2 Theory of Operation

2.1 The Basics

2.1.1 Overview

There are two configurations for BeneHeart D1 (hereinafter called the equipment): Pro and Public. Pro provides manual defibrillation, AED, and 3-lead ECG monitoring functions while Public provides only AED working mode. It is intended for use in hospital and pre-hospital settings. The equipment adopts the most advanced biphasic defibrillation technology and can deliver up to 360J of defibrillation energy. The whole equipment is of horizontal structure and is configured with 7-inch color LCD display with LED backlight.

2.1.2 Main Functions

Below is a brief introduction of the main functions:

- Manual defibrillation

  The manual defibrillation mode supports manual defibrillation and synchronized cardioversion functions. External multi-functional electrode pads are used when performing defibrillation.

  In manual defibrillation mode, the operator analyzes the patient's ECG waveforms and does the following if necessary:

  1. Select energy,
  2. Charge,
  3. Deliver shock.

- AED

  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.

- 3-lead ECG monitoring

  In monitor mode, the equipment performs 3-lead ECG monitoring. The monitored information can be displayed, reviewed and stored.

2.2 Components

The equipment consists of a main unit, accessories and PC software. The main unit is the core of the system and implements the following functions:

- Overall system control;
- System power supply and power management;
- Display;
- Manual defibrillation;
- AED;
- Man-machine interface;
- Audio and visual alarm indications;
- 3-lead ECG monitoring;
- External connectors and communication; and,
- Data storage.

2.3 Main Unit

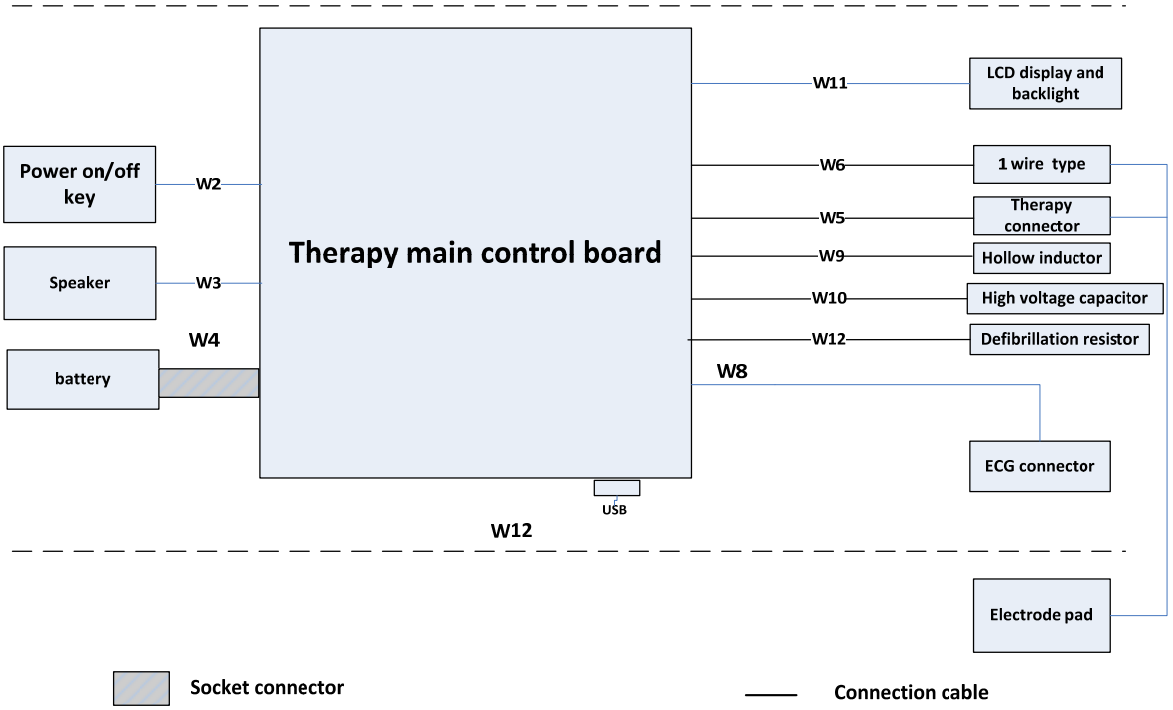
The main unit of the equipment is composed of the front housing assembly, module bracket assembly and rear housing assembly.

- The front housing assembly is mainly composed of LCD display, power on/off key, discharge key, screen softkeys, microphone, buzzer, front housing etc.
- The module bracket assembly is mainly composed of module bracket, speaker, ECG parameter socket, defibrillation capacitor, discharge inductor, discharge resistor, therapy main control board, defibrillation output port, Wi-Fi module etc.
- The rear housing assembly is cmposed of rear housing and battery door etc.

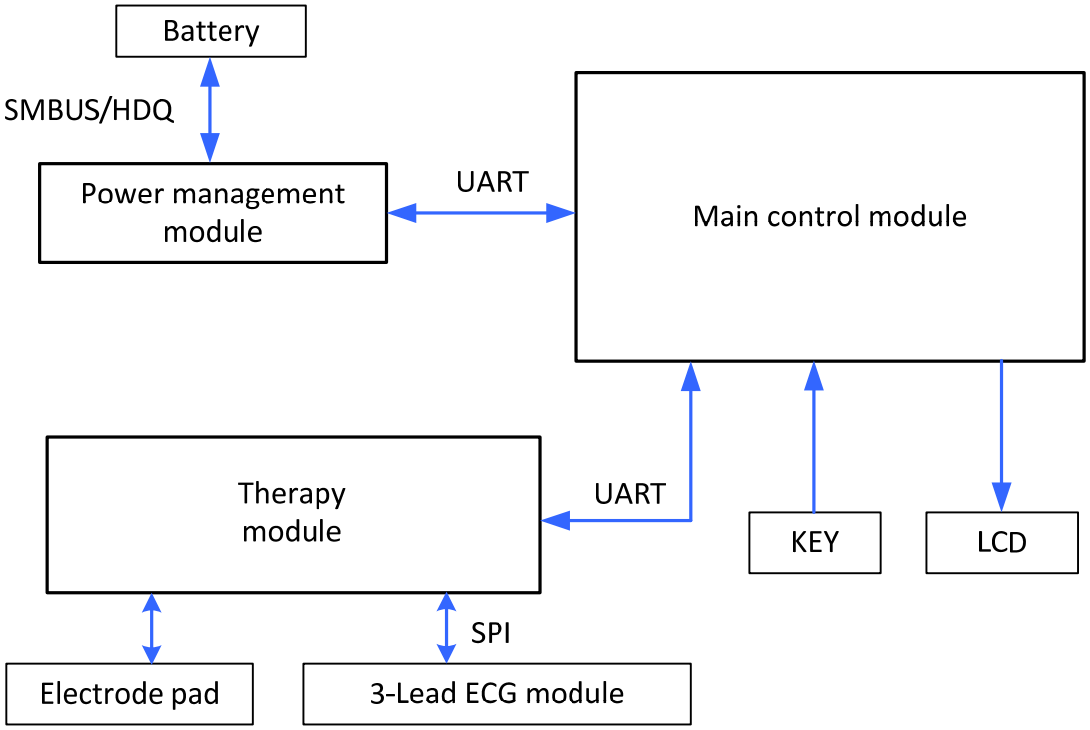
The whole system is composed of the following subsystems:

- Input subsystem, including the power on/off key, discharge key, screen softkeys and microphone.
- Output subsystem, including the display, buzzer and speaker.
- Processing and communication subsyste, including main control module, therapy module, parameter module and power management module.
- Power management subsystem, including the batteries and power management module.
- External device connection subsystem, including the USB connector and wireless network connection.

System Structure



System Signal Flow



2.3.1 Front Housing Assembly

The front housing assembly is mainly composed of LCD display, power on/off key, discharge key, screen softkeys, microphone, buzzer, front housing etc. The LCD display and screen softkeys are separately connected to the therapy main control board via cables. The power on/off keypad board is connected to the therapy main control board via internal connection line inside the equipment. Other components are directly placed on the therapy main control board.

Power on/off key

The power on/off key provides power on/off function and is connected to the therapy main control board.

Discharge key

The discharge key is a discharge trigger button and is placed on the therapy main control board.

Screen softkeys

The screen softkeys provide the selection of functions displayed on the screen and is connected to the therapy main control board.

Buzzer

The buzzer provides alarm tone.

Microphone

The microphone provides sound recording function.

2.3.2 Module Bracket Assembly

The module bracket assembly is mainly composed of module bracket, speaker, 3-lead ECG parameter measurement module, defibrillation capacitor, discharge inductor, discharge resistor, therapy main control board, defibrillation output port, Wi-Fi module etc.

Speaker

The speaker provides main unit alarm tone, heart beat tone, and voice output.

3-lead ECG parameter measurement module

The 3-lead ECG parameter measurement module provides 3-lead ECG monitoring and supports arrhythmia analysis and synchronized defibrillation R wave output. The 3-lead ECG parameter measurement module communicates with the therapy module via SPI port.

Therapy main control board

The therapy main control board performs the functions of therapy, 3-lead ECG monitoring and input and output ports control etc. In terms of functions, the therapy main control board includes power management part, therapy module part and main control part.

The main control part performs the functions of system man-machine interface control, data storage and network communication etc.

The therapy part performs the functions of ECG and impedance signals sampling and processing, defibrillation charging/discharging, and AED algorithm analysis etc.

The power management part performs the functions of system battery management, power monitoring etc.

The whole equipment works with main control as the core. The main control part, therapy part and power management part communicate via asynchronous serial port.

Wi-Fi module

The Wi-Fi module provides the wireless communication inlet for the main unit.

2.3.3 Rear Housing Assembly

The rear housing assembly is composed of rear housing and battery door.

2.4 Batteries

Battery provides power for the system. The equipment supports intelligent rechargeable lithium batteries and disposable lithium manganese batteries.

- Intelligent rechargeable lithium batteries: rated voltage of 14.8V, 3000 mAh.
- Disposable lithium manganese batteries: rated voltage of 12V, 4200 mAh.

2.5 External Device Connectors

1. Electrode pad connector
2. USB connector
3. Battery compartment
4. Handle
5. CPR sensor
6. ECG socket (for Pro only)

3 Unpacking and Installation

This chapter provides information you need to install the equipment 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.

Operator's Manual

Accessories

Main unit and battery

3.2 Preparation for Installation

3.2.1 Preparation for Installation Site

1. Ensure that the site meets all safety and environmental requirements.
2. Ensure that the battery capacity is sufficient.
3. Check that a network connector is available if the defibrillator/monitor needs to be connected to network.

⚠WARNING

- **Only specified battery can be used.**

3.2.2 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.**

Environmental Specification

Main unit			
Item	**Temperature**	**Relative humidity**	**Barometric pressure**
Operating	0°C to 50°C (Room temperature—work for at least 60 min after the temperature reaches 20°C)	0% to 95%, non-condensing	57.0kPa to 106.2kPa
Storage	-30°C to 70°C	0% to 95%, non-condensing	57.0kPa to 106.2kPa

Charger station			
Item	**Temperature**	**Relative humidity**	**Barometric pressure**
Operating	0 °C to 45°C	10% to 95%, non-condensing	57.0kPa to 106.2kPa
Storage	-30°C to 70°C	10% to 95%, non-condensing	57.0kPa to 106.2kPa

3.3 Power On the Equipment

⚠CAUTION

- **Make sure that the battery capacity is sufficient and that the battery is correctly installed before powering on the defibrillator/monitor.**

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

1. Press the **Power On/Off** button. Select  softkey from the pop-up menu to enter maintenance screen.
2. Select [**User Test**] on the maintenance screen.
3. Push the corresponding softkey or select the corresponding button following the on-screen instructions.
4. After the system displays prompt message and broadcasts audio message, select whether to hear the audio message based on the actual situation.

After completing these operations, the system automatically completes the other test items. If all test items are normal, the test result is "PASS". If there is any failed item, the test result of battery insertion is "FAIL". The system gives relevant prompt and failure code based on the failed item.

FOR YOUR NTOES

4 Software Upgrade

4.1 Upgrade Procedures

You can use USB device with upgrade package to upgrade the system software and module software of the defibrillator/monitor as follows:

1. Use the USB device in the format of FAT32 and create a folder named “UPGRADE_AMP” in the USB device.
2. Create a folder named “Aed” under the directory of “UPGRADE_AMP” of the USB device.
3. Copy the upgrade file named “usb_upgrade.elf” into the “UPGRADE_AMP” folder.
4. Copy the upgrade package into the “Aed” folder.
5. Insert the USB device into the USB connector of the defibrillator/monitor.
6. Hold the keys marked “1” and “2” in the following pictures while pushing the power on/off key to start the monitor. After entering the upgrade screen, select through keys “1” and “2” and confirm your selection through key “3” to upgrade the following programs of the defibrillator/monitor.
   - System software
   - Language library
   - BMP resource files (including screen icons, start-up screen, standby screen)
   - General configurations (including passwords, company name)
   - System functional configuration
   - Power management module
   - Therapy module

Public

Pro

4.2 Precautions

- Multiple upgrade files can be placed under the directory "X:\UPGRADE_AMP\AED\". You need to select manually for upgrading.
- The upgrade files placed under the directory "X:\UPGRADE_AMP\AED\" must be named in English. Otherwise the file name displayed will be unreadable.
- ".pkg", ".snpkg", ".snmpkg" and ".mpkg" files can be upgraded.

5 Testing and Maintenance

5.1 Introduction

The service personnel should perform regular check, maintenance and test of the equipment to ensure its long-term stable operation. This chapter provides the basic test methods for the equipment with recommended test frequency and test tools. The service personnel should perform the testing and maintenance procedures as required and use the appropriate test tools.

The testing procedures provided in this chapter are intended to verify if the equipment meets the performance specification. If the test result fails to satisfy the requirement during the test, it indicates that the equipment or some functional module of the equipment is faulty. In this case, repair or replacement must be done immediately. For other information, contact our Customer Service Department.

⚠CAUTION

- **All tests shall be performed by qualified service personnel only.**
- **Take care when setting and changing the selection in [Maintenance] menu to prevent loss of data.**
- **Before testing, the service personnel should acquaint themselves with the test tools and make sure that test tools and cables are applicable.**

5.1.1 Test Report

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

5.1.2 Recommended Frequency

Test item		Frequency
Visual inspection		1. During assembling for the first time or after each re-assembling.
Power-on Test		1. During assembling for the first time or after each re-assembling. 2. After each repair or replacement of the main unit components.
User test		1. During assembling for the first time or after each re-assembling. 2. After each repair or replacement of the main unit components.
AED test		1. After each repair or replacement of the main unit components. 2. At least once every year.
Manual defibrillation test	Charge/discharge	1. After disassembling. 2. When the user has doubt in the therapy function. 3. At least once every 6 months.
	Energy disarming	
	Synchronous defibrillation	
ECG test	Performance test	1. When the user has doubt in the accuracy of measured values. 2. After repair or replacement of modules. 3. Performance test should be done at least once every two years.
	Module calibration	

Test item		Frequency
Electrical safety test	Enclosure leakage current	1. After repair or replacement of the power module and therapy module. 2. At least once every two years.
	Patient leakage current	
	Patient auxiliary current	

5.2 Visual Inspection

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

- Carefully inspect the housing, the display screen and the buttons for physical damage.
- Inspect accessories for signs of damage.
- Inspect multifunctional electrode pad connections for loose connectors, bent pins or frayed cables.
- Inspect all connectors on the equipment for loose connectors or bent pins.
- Make sure that safety labels and data plates on the equipment are clearly legible.

5.3 Power On Test

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

1. Insert the battery in the battery compartment. The green power indicator light is lit and the screen is lit.
2. If the system enters the battery insert test screen, push the **Power On/Off** key to turn off the equipment. Push the **Power On/Off** key again to turn on the equipment.
3. Check the display of alarm information area and the battery capacity icon in the upper right corner of the main screen to judge whether the equipment runs normally.

If a fault is detected during power-on test, the alarm message will be displayed in the alarm information area on the screen.

5.4 User Test

This test is to verify if the defibrillation function, ECG monitoring function and batteries of the equipment work normally. Follow this procedure to perform user test:

1. Connect the multi-functional electrode pad to the electrode pad connector of the equipment.
2. Insert the battery into the battery compartment of the equipment and re-place the battery door.
3. Push the **Power On/Off** key. Select [**Maintenance**]→[**User Test**] to enter the User Test screen.
4. Follow the on-screen instructions to perform controls test, audio test and auto test.
5. Check the test result to judge whether the equipment runs normally. If any test item fails, the corresponding failure code will be displayed on the screen.

5.5 Module Performance Tests

5.5.1 Manual Defibrillation Test

Test tools:

- Defibrillator/pacer analyzer

Charge/Discharge

1. Connect the multi-functional electrode pad connector to the pads connector of the equipment and connect the electrode pad to the defibrillator/pacer analyzer properly.
2. Set the analyzer to output normal sinus rhythms, e.g. amplitude value 1mV and HR 60bpm.
3. Push the **Power On/Off** key to start the equipment. Enter AED mode. Verify that the equipment can perform the rhythm analysis, charging and discharging properly.
4. Enter the **Config. Edit** menu， set **Shock Series** in the **AED Setup** menu separately to 200 J, 300 J or 360 J.
5. Restart the equipment, and re-enter AED mode. Perform the charging and discharging, 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

6. Verify that the shock events are recorded automatically and correctly.

5.5.2 Manual Defibrillation Test

Test tools:

- Defibrillator/pacer analyzer

Charge/Discharge

1. Power on and enter manual defibrillation mode.
2. Connect the multi-functional electrode pad connector to the pads connector of the equipment and connect the electrode pad to the defibrillator/pacer analyzer properly.
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 1J.
5. 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

6. Set the energy to 100J and 360J respectively. Repeat step 5.
7. Verify that the shock events are recorded automatically and correctly.

Energy Disarming

1. Connect the multi-functional electrode pad connector to the pads connector of the equipment and connect it to the defibrillator/pacer analyzer properly.
2. Install a fully charged or new battery onto the equipment. Power on the equipment and enter Manual Defib mode.
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. Repeat steps 3 through 6.
11. Count time after charging is completed. Verify that the prompt "Shock Removed" appears on the equipment after 60 seconds and the energy measured by the analyzer is 0J or blank.

Synchronous Defibrillation

1. Insert the multi-functional electrode pad connector and the ECG cable connector to the electrode pad connector and ECG connector of the equipment respectively. Connect the electrode pad and ECG leads to 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. Push the **Power On/Off** key to start the equipment. Enter Manual Defib mode. Push the [**Enter Sync**] and [**Yes**] keys to enter synchronous defibrillation mode.
4. Adjust the energy setting of the equipment to be 10J.
5. Push the [**Lead**] key and select ECG lead. The ECG signals which the ECG lead collects are displayed on the screen.
6. Charge the equipment.
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. Push the [**Lead**] key and select electrode pad lead. The ECG signals which the electrode pad lead collects are displayed on the screen.
13. Repeat steps 6 through 11.

5.5.3 ECG Test

Performance Test

Test tools:

- ECG simulator

1. Insert the ECG cable connector to the ECG connector of the equipment. Connect the ECG lead to the ECG simulator.
2. Push the [**Lead**] key and select ECG lead. Set the 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. Push the **Power On/Off** key and select  →[**Config.**]→[**Config. Edit**]→enter the required password→[**General Setup**]→[**ECG Setup**]. Then set [**Pacemaker Detection**] to [**On**].
6. On the equipment, set the simulator to be configured as pace signals. Verify that pace signals are detected and pace pulse marks are displayed.
7. Insert the electrode pad connector to the electrode pad connector of the equipment. Connect the electrode pad to the ECG simulator.
8. Push the [**Lead**] key and select electrode pad lead. Set the simulator as follows: ECG sinus rhythm, HR=80 bpm with the amplitude as 1mV.
9. Check the ECG waves are displayed correctly without noise and the displayed HR value is within 80 ±1 bpm.
10. Disconnect the simulator from the equipment's therapy module. Verify that ECG Lead Off alarm behaves correctly.
11. On the equipment, set the simulator to be configured as pace signals. Verify that pace signals are detected and pace pulse marks are displayed.

5.6 Electrical Safety Tests

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

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, 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.		
Electrical Safety Inspections		
Refer to Appendix ***A Electrical Safety Inspection***.		
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		

6 Troubleshooting

6.1 Overview

In this chapter, the equipment problems are listed along with possible causes and recommended corrective actions. Refer to the tables to check the equipment, 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 Parts Replacement

Printed circuit boards (PCBs), major parts and components in the equipment are replaceable. Once you isolate a defective PCB, follow the instructions in ***Chapter 7 Disassembly and Repair*** to replace the PCB with a known good one and check that the trouble disappears or the equipment 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 ***Chapter 8 Parts***.

6.3 Checking Equipment Status

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

1. Push the **Power On/Off** key and select the  softkey.
2. Select the [**Device Info.**] softkey to check the system software and hardware version, device type, status etc.

6.4 Checking Technical Alarm

Before troubleshooting the equipment, check for technical alarm message. If an alarm message is presented, eliminate the technical alarm first. For detailed information on technical alarm message and possible cause and corrective action, refer to the ***BeneHeart D1 Automated External Defibrillator Operator's Manual (P/N: 046-004673-00)*** for information about the symbols used on this product and its packaging.

6.5 Troubleshooting Guide

6.5.1 Defibrillation Problems

Symptom	Possible Cause	Corrective Action
The equipment is charged too slowly.	The battery is out of charge or damaged.	Install a fully charged battery or new battery.
	The charging part of the therapy module is damaged.	Replace the therapy main control board.
A shock cannot be delivered by pressing the Shock button on the equipment's front panel in Manual Defib Mode or AED Mode.	The key is damaged.	Perform user selftest to locate the failure. If the discharge key is damaged, user selftest will be failed. Replace the therapy main control board.
	The Charge Button fails to be pressed down effectively due to the failure or dislocated silica gel keypad.	Replace or reshuffle the silica gel key.
The message. "Disarming Failed" is displayed.	The self-disarming circuit of the therapy module is damaged.	Replace the therapy main control board.
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 is detected. 1. The electrode pads are detached from the patient. 2. The electrode pads are damaged.	1. Ensure good connection between the patient and electrode pad. 2. If the problem persists, replace the electrode pads.
	The therapy main control board is damaged.	Replace the therapy main control board.
Defibrillation malfunction.	The Defibrillation hardware circuit is defective.	Replace the therapy main control board.

6.5.2 Power On/Off Problems

Symptom	Possible Cause	Corrective Action
The equipment fails to start. The status indicator light turns red and starts to flash or could not be lit.	The battery capacity is insufficient.	Check if the battery capacity is sufficient.
	The connection line is failed.	1. Check if the connection line between the power on/off key and the therapy main control board is properly connected. 2. Check if the connection line and connector are damaged.
	The power on/off key is damaged.	Replace the power on/off board.

6.5.3 Display Problems

Symptom	Possible Cause	Corrective Action
The LCD screen is blank and the display image display is abnormal but the equipment works properly.	The connection line is failed.	1. Check if the connection line between the display and the therapy main control board is properly connected. 2. Check if the connection line and connector are damaged.
	The LCD display is damaged.	Replace the LCD display.
	The main control board is damaged.	Replace the therapy main control board.

6.5.4 Alarm Problems

Symptom	Possible Cause	Corrective Action
No alarm sound is produced and the alarm area is displayed normally.	Audio alarm is disabled.	Select  →[**Config.**]→[**Config. Edit**]→enter the required password→[**General Setup**]→[**Alarm Setup**]. Then set [**Alm Volume**] to [**Low**] or [**High**].
	The connection line is failed.	1. Check if the connection line between the speaker and the therapy main control board is properly connected. 2. Check if the connection line and connector are damaged.
	The speaker is damaged.	Replace the speaker.
	The therapy main control board is damaged.	Replace the therapy main control board.

6.5.5 Button Problems

Symptom	Possible Cause	Corrective Action
Buttons do not respond.	The connection line is failed.	1. Check that the connection line between the keypad and the keypad board is properly connected. 2. Check if the connection line between the keypad board and the therapy main control board is properly connected. 3. Check if the connection line and connector are damaged.
	The keypad board is damaged.	Replace the keypad board.
	The therapy main control board is damaged.	Replace the therapy main control board.

6.5.6 Output Interface Problems

Symptom	Possible Cause	Corrective Action
USB Device does not function (provided that the peripheral devices are good)	The initialization of USB connector has an error.	Re-plug the USB device for initialization.
	The therapy main control board is damaged.	Replace the therapy main control board.

6.5.7 Power Supply Problems

Symptom	Possible Cause	Corrective Action
Battery failure	The battery is damaged.	Replace the battery.
	The battery interface is failed.	1. Check if the battery is installed in place. 2. Check if the battery interface is damaged. 3. If the battery interface is damaged, replace the therapy main control board.

NOTE

- **When the power module has a failure, it may cause problems to other components, e.g. the equipment 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 Chapter 2 Theory of Operation for the operating voltage and measurement points of each component.**

6.5.8 Software Upgrade Problems

Symptom	Possible Cause	Corrective Action
System program upgrade fails.	Power failure or unintended power off during system program upgrade.	Retry upgrade.
Program upgrade fails.	Incorrect connection.	Initialization error of the USB device. It is nor unidentifiable.
	Wrong upgrade package.	Upgrade package shall be ".pkg" files. Select package according to system requirement.

6.6 Technical Alarm Messages

Measurement	Alarm Message	Cause and solution
ECG	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 Lead Off	The ECG electrode has become detached from the patient or the connector from the equipment. Check the connection of the electrodes and leadwires.
	ECG YY Lead Off (YY represents the leadwires LL, LA, and RA, as per AHA standard, or C, F, and L as per IEC standard)	
System	Unit Error!	Equipment malfunction. Perform a user test or restart the equipment.
	Power Board Comm Err	Communication with the power management module failed. Restart the equipment.
	Power Board Selftest Err	System power failure. Restart the equipment.
	Power Board Volt Err	
	Battery Err	There is a problem with the battery. Check the battery for damage; verify that correct battery is used. Replace the battery if necessary.
	Battery Aged	Rechargeable battery is aged. Replace the battery.
	Low Battery	Replace the battery.
	Battery Depleted!	
	Main Control Selftest Err	An error occurred in main control poweron test. Restart the equipment.
	RT Clock Need Reset	Reset system time.
	RT Clock Err	An error occurred to the RTC chip. Contact our Customer Service Department.
	Memory Error	Memory read write failure or initialization error. Restart the equipment.
	Machine Type Error	An error occurred to the system power supply. Restart the equipment.
	Disarming Failed	Failed to disarm the energy. Perform a user test. If the failure occurs, record the service code and contact our Customer Service Department.
	Charge Failed	Failed to charge. Perform a user test. If the failure occurs, record the service code and contact our Customer Service Department.
	Shock Failed	Failed to shock. Perform a user test. If the failure occurs, record the service code and contact our Customer Service Department.
	Unknown Pads	The electrode pads are not properly connected or the pads are defective. Replug the pads. If the problem persists, replace the pads. If the problem still remains unsolved, contact our Customer Service Department.
	Pads Abnormal	The type of pads is recognized, but the one-wire communication failed. Re-plug the pads. If the problem persists, contact our Customer Service Department.

Measurement	Alarm Message	Cause and solution
System	Pads Expires	The pads have expired. Replace the pads.
	Pads expiring soon	The pads are expiring soon. Replace the pads timely.
	Load Config Err	An error occurred when loading configuration file. Reconfigure the equipment. If the changes cannot be saved, contact our Customer Service Department.
	Operation Mode Error	When starting the main control, the obtained default startup mode is inconsistent with that from the IO. Contact our Customer Service Department..
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 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.

6.7 Error Codes

6.7.1 Therapy Module Error Codes

Error code	Error description
0 to 9	Reserved
10	Power-on selftest failure: CPU
11	Power-on selftest failure: register
12	Power-on selftest failure: RAM
13	Power-on selftest failure: External watchdog
15	Abnormal chip reset
14 to 19	Reserved
20	High voltage sampling internal AD realtime selftest error
21	Chip calculation function error
22	External sampling AD realtime selftest error 3-lead
23	External sampling AD realtime selftest error P lead
24 to25	Reserved
26	Biphasic voltage difference exceeds 500V at the start of charging.
27 to 29	Reserved
30	1s after starting charging: V1/2<=65V
31	When charging: V1/2 drops more than 10% of V1/2tgt.
32	When charging: |V1-V2|>100V
33	When charging: V1/2>=2400V
34	Charging is not completed within 40s after starting charging.
35	After the end of charging: V1>(V1Tgt*1.2)
36	When maintaining charging: V1/2<=50V
37	During maintaining charging: V1/2>(V1Tgt*1.2)
38	Overcurrent occurs in the case of selfdischarging.
39	After self-discharging:V1/2>=40V

Error code	Error description
40	Overvoltage protection occurs.
41 to 49	Reserved
50	Zeroing sampling value has an error.
51	Calibration sampling value has an error.
52	Calibration of calculated slope has an error.
53	Unsuccessful zeroing before calibration.
54	Calibration message FLASH erase error.
55	Calibration message FLASH write error.
56	Calibration message FLASH read error.
57 to 200	Reserved
60	Input impedence is not 50 Ω
65	Calibration message FLASH erase error.
66	Calibration message FLASH write error.
67	Calibration message FLASH read error
70	Normal pad type detecting ”one-wire” message read error.
201	Functional selftest failure: Internal AD
202	Functional selftest failure: Clock selftest timeout (not completed)
203	Functional selftest failure: Clock frequency error
204 to 209	Reserved
210	Functional selftest failure: Before charging: Uniphasal realtime voltage>160V
211	Functional selftest failure: Charging timeout: 3s not completed.
212	Functional selftest failure: During maintaining charging: V1/2 > (Vtgt*1.2)
213 to 215	Reserved
216	Functional selftest failure: Discharging circuit: Only close I_LO, current available
217	Functional selftest failure: Discharging circuit: Close I_LO, close II_LO, current available
218	Functional selftest failure: Discharging circuit: Close biphasal disarming circuit, current unavailable
219	Functional selftest failure: Discharging circuit: Close biphasal disarming circuit. Current sampling value fails to satisfy the relation of 10 times.
220	Functional selftest failure: Discharging circuit: Disconnect biphasal disarming circuit, current available
221	Functional selftest failure: Discharging circuit: Close uniphasal disarming circuit, current unavailable
222	Functional selftest failure: Discharging circuit: Close uniphasal disarming circuit. Current sampling value fails to satisfy the relation of 10 times.
223	Functional selftest failure: Discharging circuit: Disconnect uniphasal disarming circuit, current available
224	Functional selftest failure: Discharging circuit: Close bridge arm. Discharging internal resistance abnormality.
225	Reserved
226	Functional selftest failure: After self-discharging:V1/2>=40V
227 to 229	Reserved
230	Functional selftest failure: P-lead impedance: Disconnect all switches
231	Functional selftest failure: P-lead impedance: Close Test_Relay and Def_Relay
232	Functional selftest failure: P-lead impedance: Disconnect Def_Relay
233 to 239	Reserved
240	Functional selftest failure: Pad selftest: 1-Wire read error
241	Functional selftest failure: Pad selftest: Unknown pad type

Error code	Error description
242 to 249	Reserved
250	Functional selftest failure: P lead ECG: Channel: AGND peak-to-peak value error
255	Functional selftest failure: P lead ECG: Channel: AVCC-AGND peak-to-peak value error
257	Functional selftest failure: P lead ECG: Channel: DAC sinusoidal wave peak-to-peak value error
258 to 259	Reserved
260	Functional selftest failure: 3-lead ECG: Channel: GND peak-to-peak value error
265	Functional selftest failure: 3-lead ECG: Channel: GND-1mV peak-to-peak value error
266 to 269	Reserved
270	Macro-energy selftest failure: The pads are connected to the human body when charging.
271	Q6 short-circuit, discharging failure
273	The tolerance of the large capacitance has a great deviation.
274	Defibrillation dual-energy backup calibrication error.
277	Defibrillation discharging resistance has a great deviation.

6.7.2 Power Module Error Codes

Error code	Error description
101	Battery discharge short-circuit failure
102	Battery charge short-circuit failure
103	Battery AFE discharge overcurrent failure
104	Battery AFE watchdog failure
105	Battery main control watchdog failure
106	Battery permanent error flag
107	Battery over-voltage failure
108	Battery under-voltage failure
109	Battery pack over-voltage failure
110	Battery pack under-voltage failure
111	Battery second-level charge over-current failure
112	Battery second-level discharge over-current failure
113	Battery charging over-current failure
114	Battery discharge over-current failure
115	Battery charging over-temperature failure
116	Battery discharge over-temperature failure
117	Battery overcharge failure
118	Battery overcharge current failure
119	Battery overcharge voltage failure
120	Battery fast charge timeout failure
121	Battery pre-charge timeout failure
122 to 142	Reserved
143	Rechargeable battery communication error
144	Power voltage failure
145	Battery charging failure
146	Automated test failure

Error code	Error description
147	Main control communication timeout
148	Disposable battery communication error
149 to 150	Reserved
151	Power supply voltage error
152	Power-on selftest error
153	Reserved
154	Battery aged
155	RTC selftest failure
156	Power on/off key adhesion
161	VBUS failure
162	5VD failure
163	10V failure
164	DVDD failure
165	18V failure
166	AVSS failure
167	3VB failure
601	Cell undervoltage
602	Cell overvoltage
603	Overcurrent during charge 1
604	Overcurrent during charge 2
605	Overcurrent during discharge 1
606	Overcurrent during discharge 2
607	Overload during discharge
608	Overload during discharge latch
609	short-circuit during charge
610	short-circuit during charge latch
611	Short-circuit during discharge
612	Short-circuit during discharge latch
613	overtemperature during charge
614	overtemperature during discharge
615	Cell undervoltage compensated
616	Overtemperature FET
617	precharge timeout
618	charge timeout
619	overcharge
620	overcharging current
621	overcharging voltage
622	over-precharge current
623	Undertemperature during charge
624	Undertemperature during discharge

6.7.3 Main Control System Error Codes

Error code	Error description
400	No fan
401	Speaker does not exist.
402	No storage card
403	Power board communication error
404	Therapy module communication error
405	Main control module power-on selftest error
406	Realtime clock error
407	Storage card read&write error
408	Keypad communication error
409	Machine type error
410	Recorder failure
411	Key user selftest error
412	Speak user selftest error
413	Realtime clock not accurate
414	Key adhesion
415	Program CRC check error

7 Disassembly and Repair

7.1 Tools Required

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

- Discharge fixture
- Phillips screwdriver
- Tweezers
- Multimeter
- Sharp nose plier

7.2 Preparations for Disassembly

Before disassembling the equipment, finish the following preparations:

1. Stop patient monitoring and therapy, turn off the equipment and disconnect all the accessories and peripheral devices.
2. Remove the battery.

⚠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.**

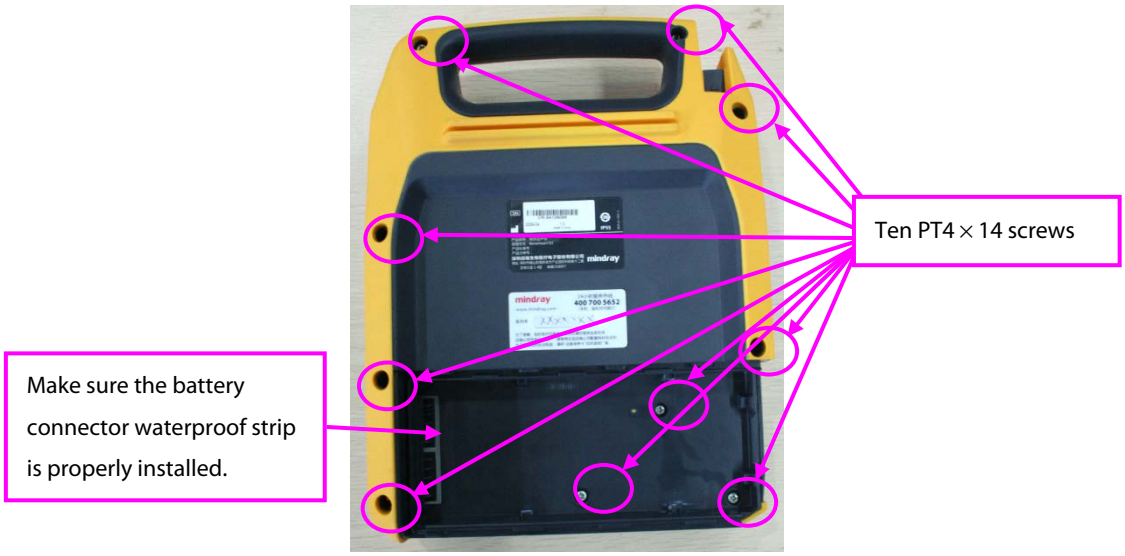
7.3 Disassembling the Main Unit

WARNING

- **To disassemble the equipment, place the equipment on a work surface free from foreign material, avoiding damaging the antiglare screen and the knob.**
- **All the operations shall 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, remove the batteries and wait for at least two hours before removing the capacitor.**

7.3.1 Remove the Rear Housing

1. Lay down the defibrillator/monitor on the flat surface with the display facing downward. Remove the battery door. Remove the ten PT4×14 screws with the screwdriver.
2. Separate the rear housing from the front housing from the bottom.

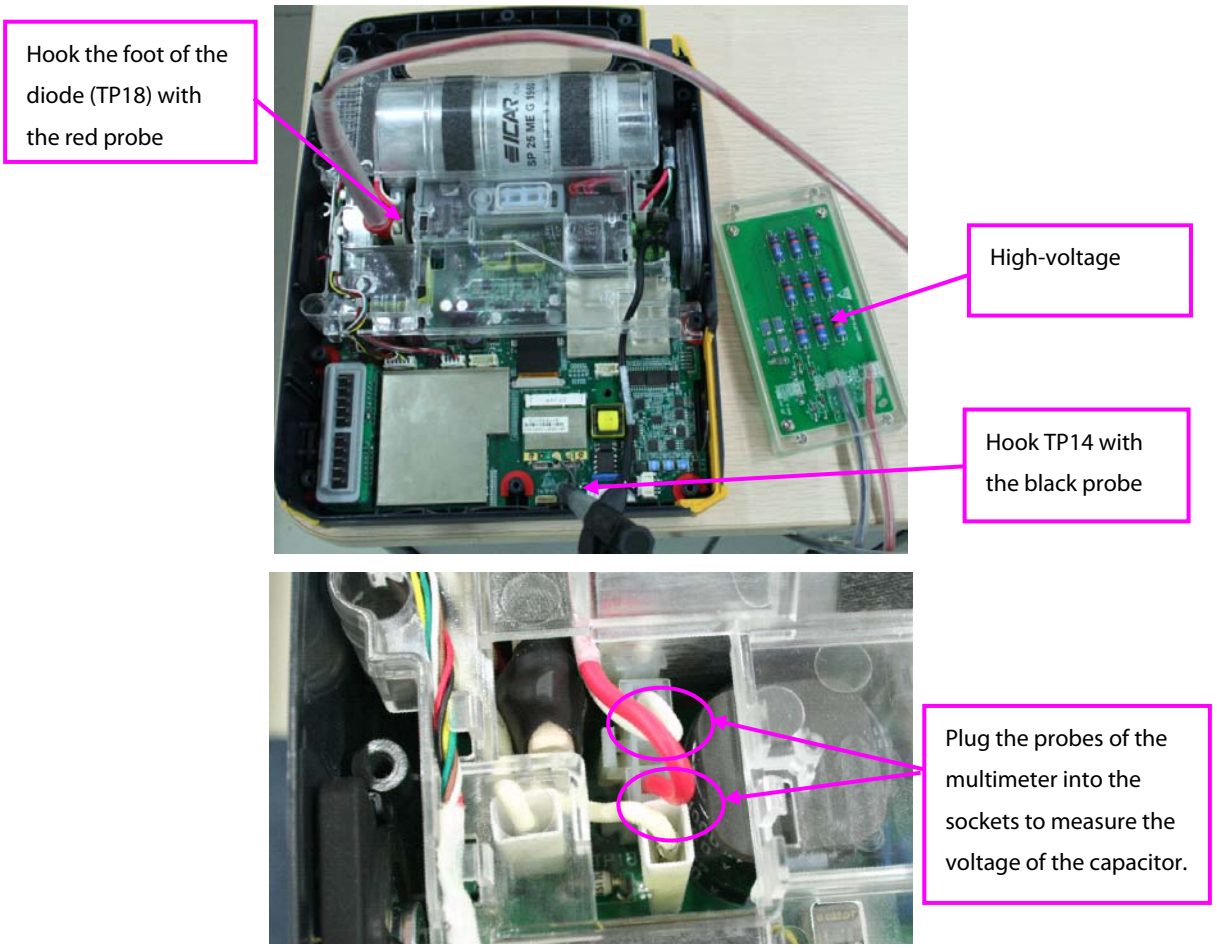


NOTE

- **When re-assembling, check if the battery connector waterproof strip is properly installed onto the therapy main control board.**

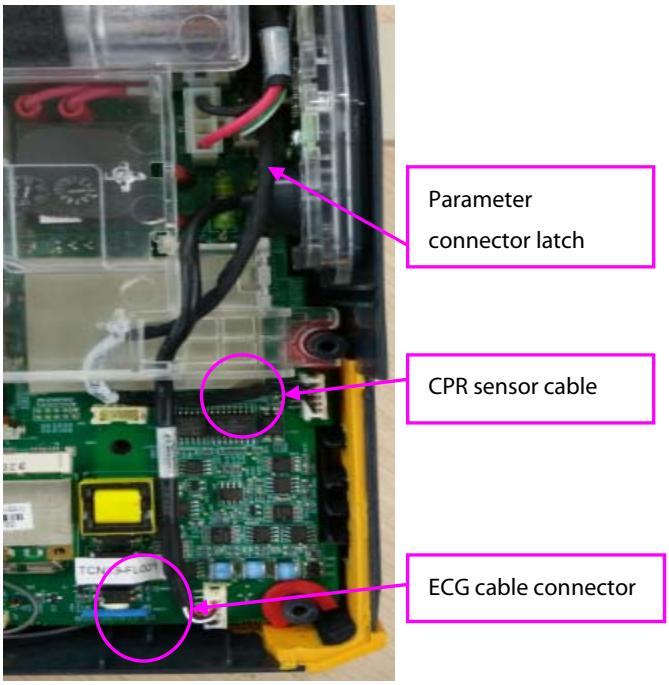
7.3.2 Discharge Using the Discharge Fixture

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 foot of the diode (TP18) beside the capacitor socket with the fixture's red probe. Wait till the indicator light on the fixture is extinguished. The capacitor is not completely discharged if the indicator light remains lit.
2. Set the multimeter to DC 1000V. Measure the discharge capacitor and check if the reading of the multimeter is lower than 30V. If yes, you can safely disassemble the equipment now.

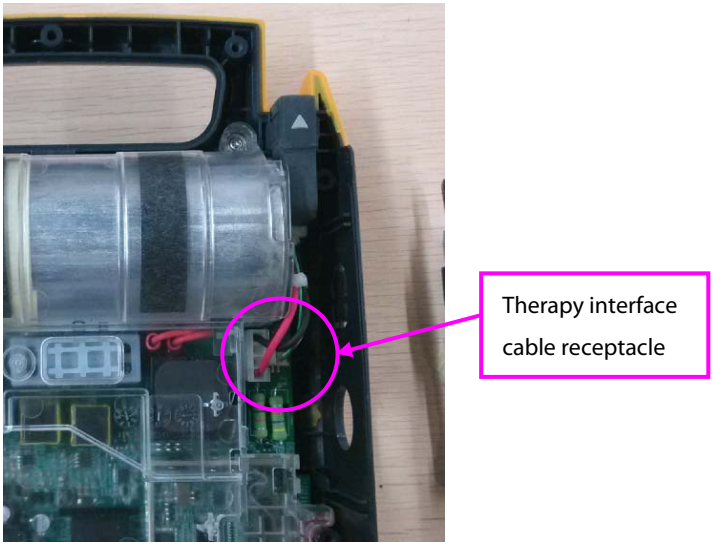


7.3.3 Remove the Parameter Connector, Therapy Connector Cable and Speaker

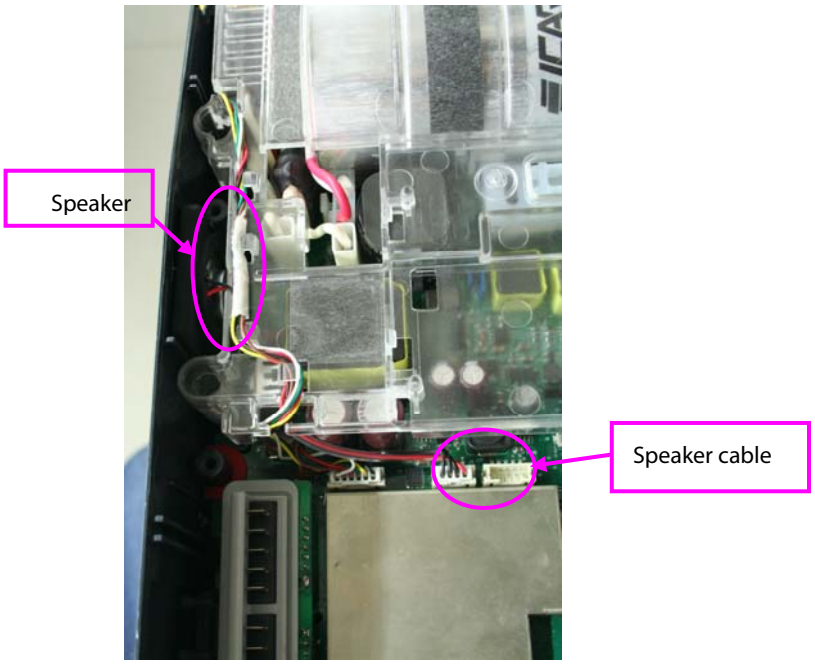
1. If there is a ECG connector cable or CPR sensor cable, unplug the parameter connector latch and then the connection cable from the therapy control board. Then remove the parameter connector.



2. Disconnect the therapy connector cable from the socket of therapy main control board and remove it from the front housing.



3. Disconnect the speaker cable from the socket of therapy main control board and remove it from the front housing.

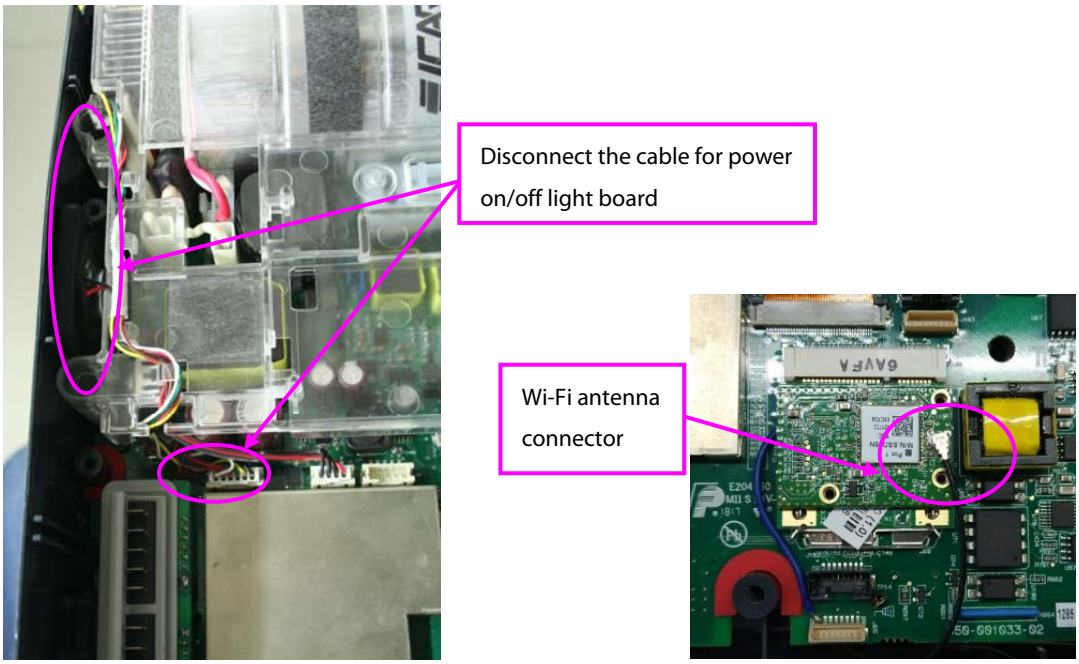


NOTE

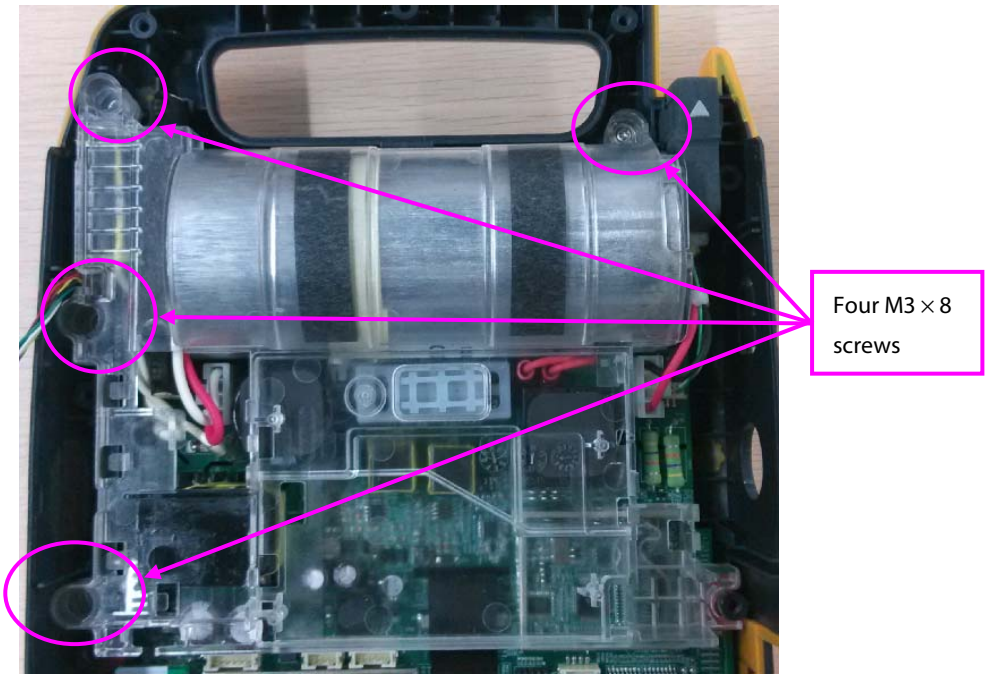
- **When re-assembling, make sure the ECG cable is not above the transformer. Or it might be pressed by the rear housing.**

7.3.4 Remove the Module Bracket

1. Remove the cable for power on/off light board from the therapy main control board and take it out from the cable trough on the module bracket. If Wi-Fi is configured, you also need to remove the Wi-Fi antenna from the therapy main control board.

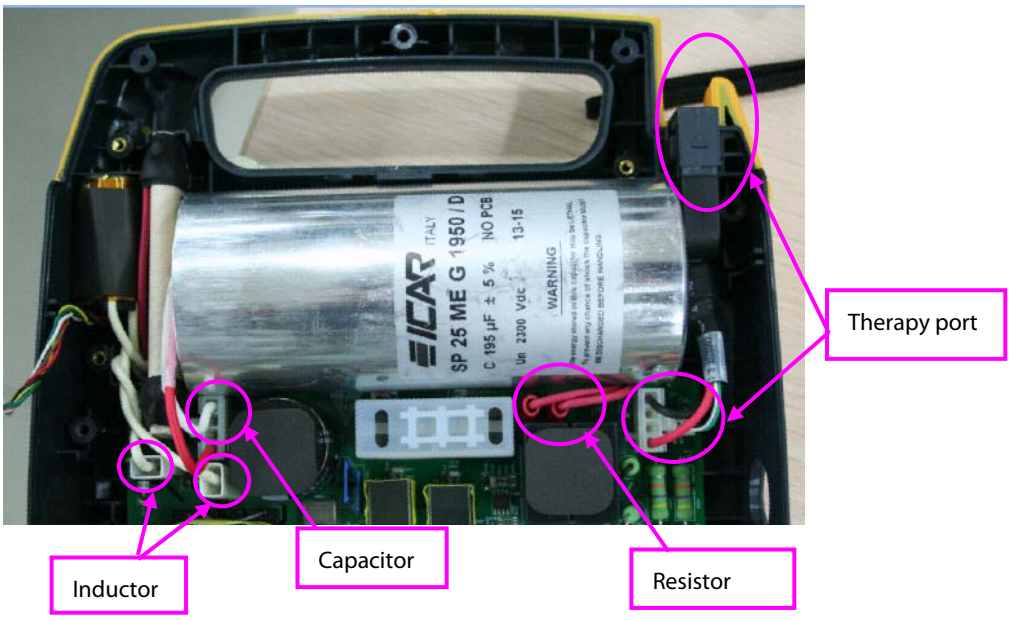


2. Remove the four M3 × 8 screws with washer using the screwdriver to remove the module bracket.

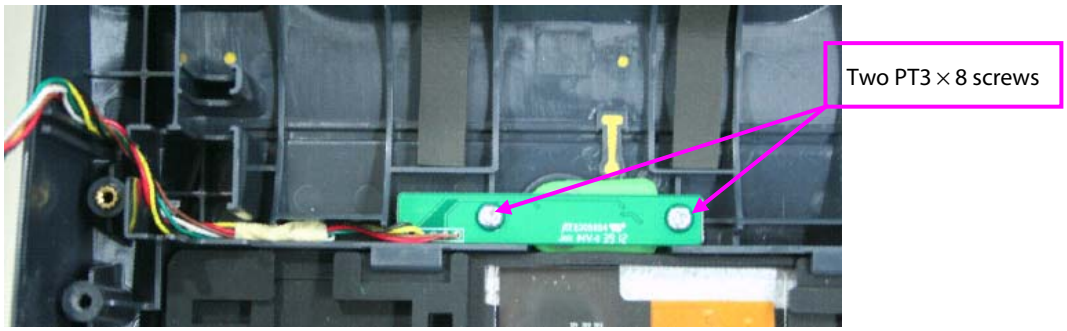


7.3.5 Remove the Therapy Port, Capacitor, Resistor, Inductor and Power On/Off Light Board

1. Disconnect the therapy port cable from the socket of therapy main control board and remove it from the front housing.
2. Disconnect the capacitor cable from the socket of therapy main control board and remove it from the front housing.
3. Disconnect the resistor cable from the socket of therapy main control board with a sharp nose plier and remove it from the front housing.
4. Disconnect the inductor cable from the socket of therapy main control board and remove it from the front housing.

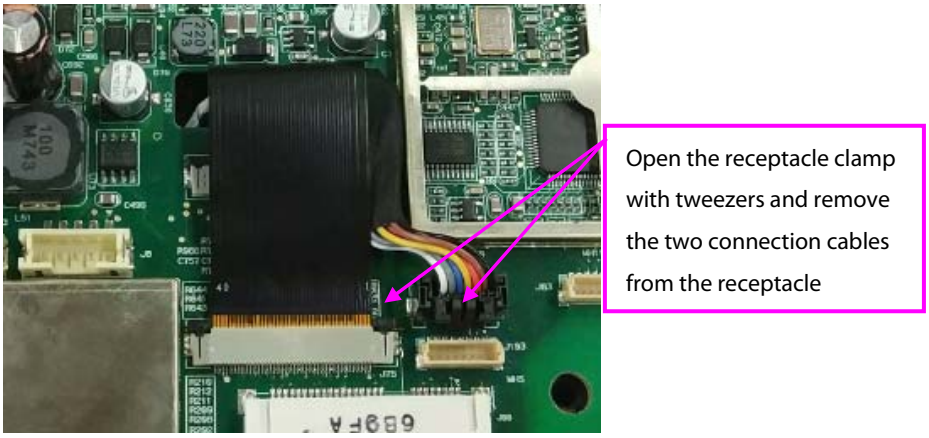


4. Unscrew the two PT3 × 8 screws and take out the power on/off light board.

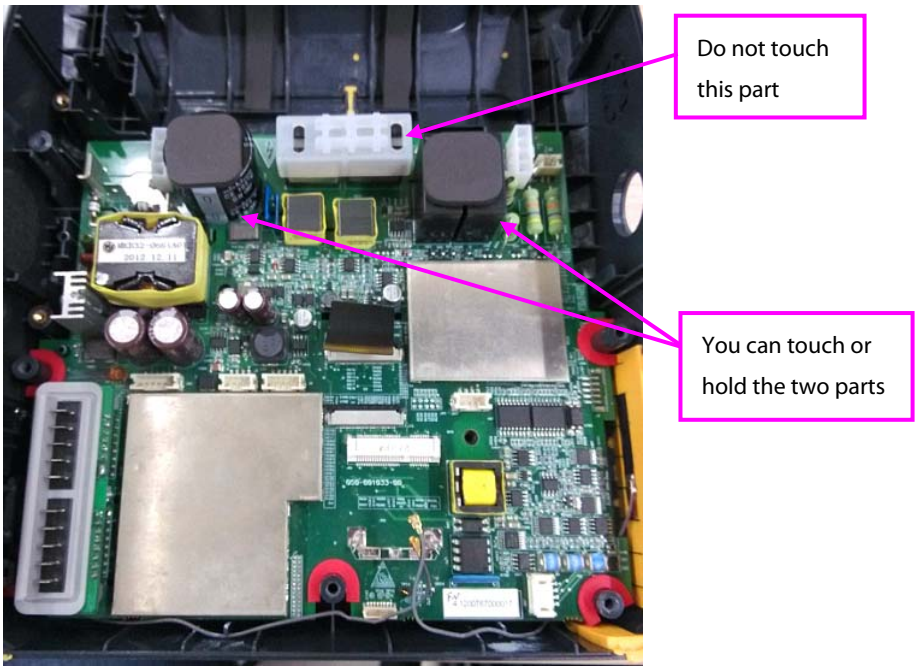


7.3.6 Remove the Therapy Main Control Board

1. Remove the screen FPC on the therapy main control board and keypad board connection cable from the socket with tweezers. If Wi-Fi is configured, you also need to remove the Wi-Fi module.



2. Hold the relay or biphasal capacitor to remove the therapy main control board.



NOTE

- **Do not hold the IGBT part when disassemblign and assembling the therapy main control board.**
- **The main board buffer cushion must be assembled and kept plat when assembling the therapy main control board.**
- **Pay attention to cabling when installing the Wi-Fi antenna to avoid pressing the Wi-Fi antenna.**

7.3.7 Remove the LCD Display and Keypad Board

1. Take out the LCD display from the silica gel wrap. Remove the LCD display from the front housing.

2. Open the LCD lens from inward. Then remove the keypad board.

7.3.8 Check before Re-assembling

Before re-assembling, make sure that the waterproof materials on the rear housing assembly and power socket assembly are properly pasted and are in good condition.

1. Check that the waterproof strip on the therapy main control board is properly assembled.
2. Check that the ECG port cable and Wi-Fi antenna cabling are correct.
3. Check that the waterproof strip on the rear housing is properly assembled.

8 Parts

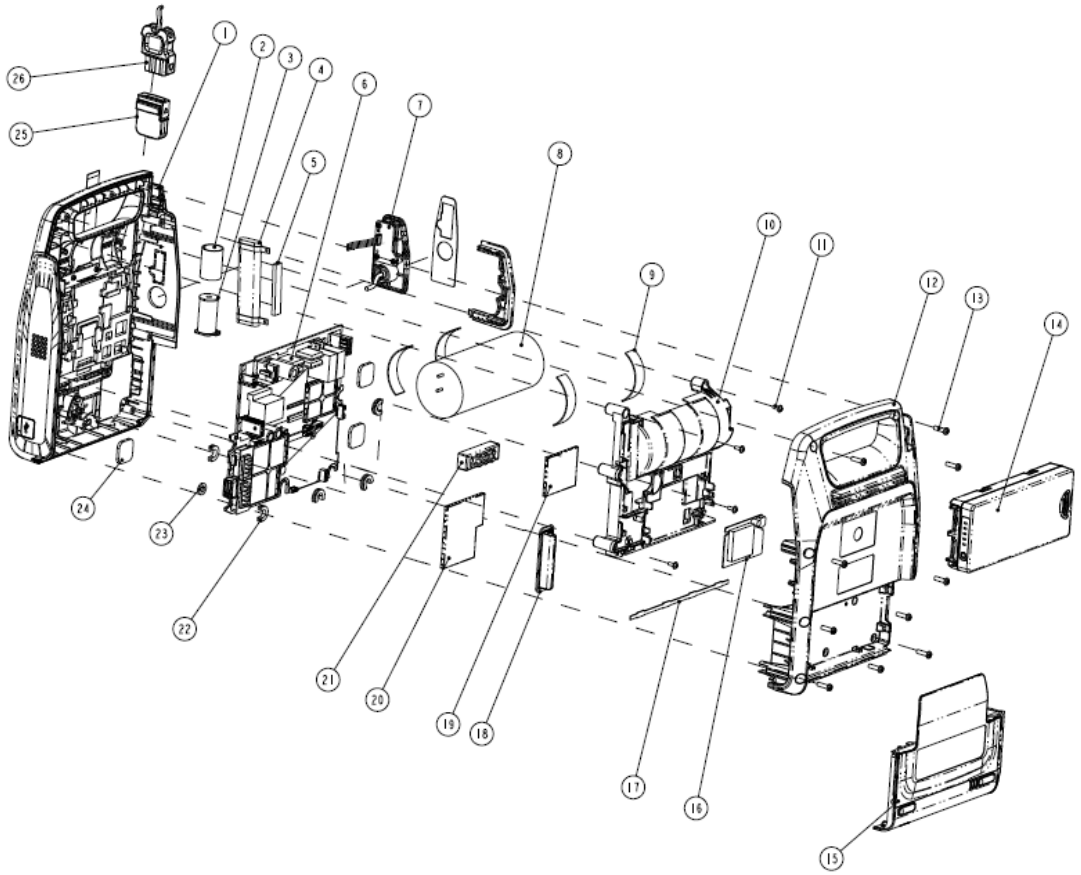
8.1 Introduction

This chapter contains the exploded views and parts lists of the defibrillator/monitor. 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 system architectural diagram of the main unit is not shown here since the equipment is exploded in full (battery door assembly is separately exploded). Parts relationship is reflected only in the exploded views.

8.2 Main Unit

8.2.1 Exploded View

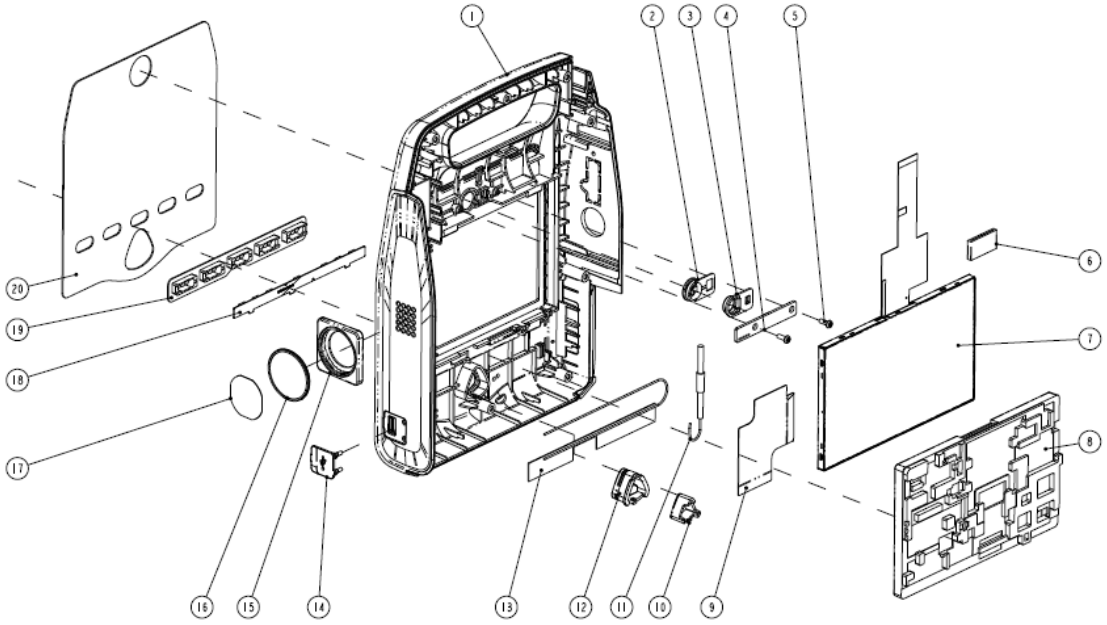


8.2.2 Parts List

SN	FRU part number	Description	Remark
1	/	Front housing assembly	/
2	/	Cushion poron (inductance)	/
3	006-000239-00	IND 1.5mH 5.6Ω high-voltage hollow coil	/
4	009-003226-00	Self-discharging resistance connection cable	/
5	/	Buffer cushion 0653	/
6	115-049166-00	Therapy main-control board (PUB)	115-049167-00 Therapy main-control board (PRO) 115-049168-00 Therapy main-control board (PRO ECG)
19			
20			
21			
22			
7	/	Parameter panel assembly	/
8	009-003227-00	I phase capacitance connection cable	/
9	115-049164-00	Module bracket	/
10			
11	/	Cross pan head screw with washer M3X8	/
12	043-003106-00	Back housing (0653)	/
13	/	Self-tapping screw PT4X14	/
14	022-000124-00	Battery Li-MnO2 12V 4200mAh LM34S001A	/
15	/	Battery cover assembly	/
16	051-003010-00	4G LTE module PCBA	/
17	/	Waterproof film	/
18	049-000174-00	Waterproof strip for battery connector	/

8.3 Front Housing Assembly

8.3.1 Exploded View

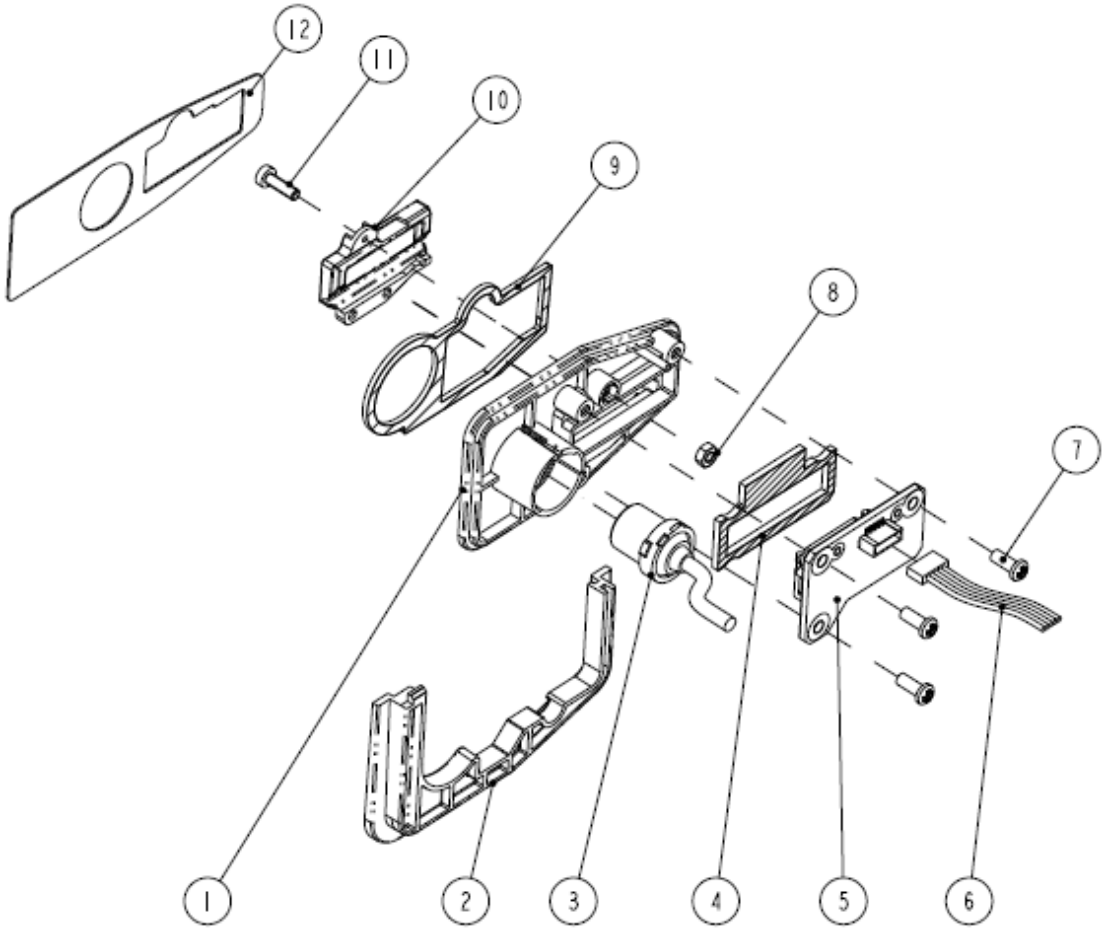


8.3.2 Parts List

SN	FRU part number	Description	Remark
1	115-049169-00	Front housing assembly (3 keys)	115-049170-00Front housing assembly (5 keys)
17			
18			
19			
20			
2	049-000533-01	Power button (0653)	/
3	043-002943-01	Power key bracket	/
4	051-001306-01	AED power key board	/
5	/	Self-tapping screw PT3X8	/
6	115-049165-00	LCD display assembly	/
7			
8			
9	/	ECG insulator	/
10	043-002944-01	Discharge key bracket	/
11	/	WIFI antenna	/
12	049-000534-01	Discharge key (0653)	/
13	/	4G LTE antenna	/
14	049-000514-00	USB wrap	/
15	049-000511-00	Speaker wrap	/
16	020-000039-00	SPEAKER 8ohm 1W wire	/

8.4 Battery Door Assembly

8.4.1 Exploded View

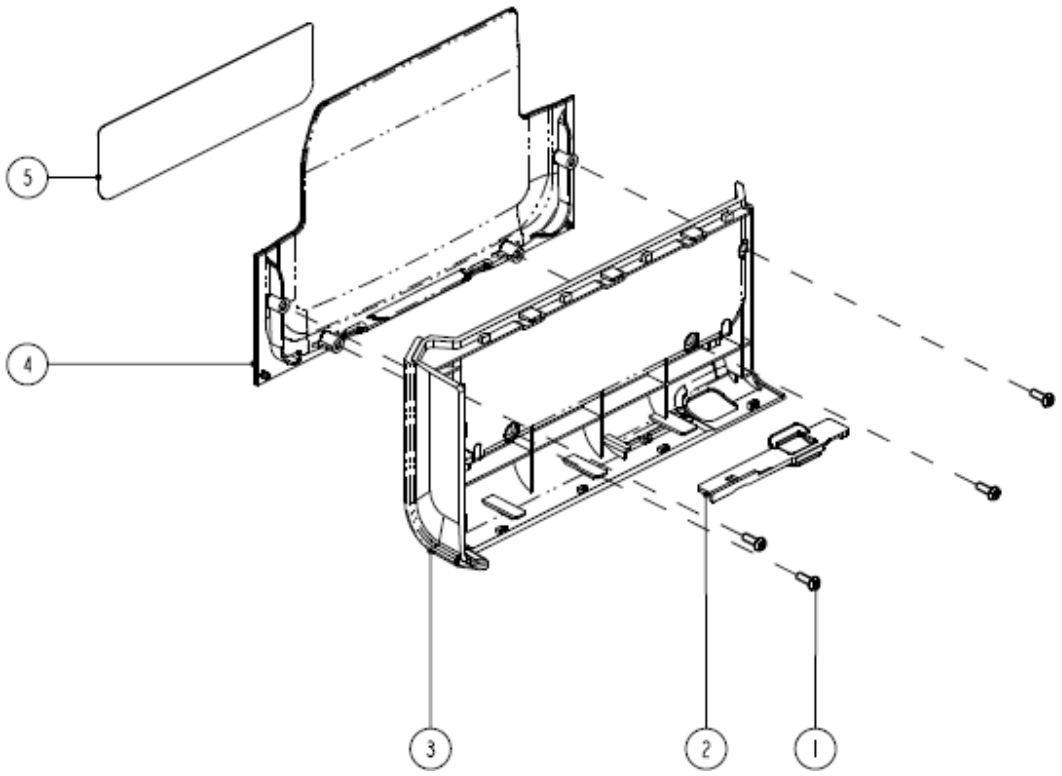


8.4.2 Parts List

SN	FRU part number	Description	Remark
1	/	Parameter face (0653)	/
2	043-002938-00	Parameter face fixture	/
3	/	Connection cable between MPM and parmeter panel	/
4	/	Waterproof cushion for multi-function connector	/
5	/	AED CPR connecting carrier PCBA	/
6	/	AED CPR built-in cables	/
7	/	Self-tapping screw ST3.3X8	/
8	/	Stainless steel hexagon nut M3	/
9	/	Waterproof cushion for parameter face	/
10	/	CPR wrap	/
11	/	Socket cap plastic screw M3X10	/
12	/	0653 Parameter face	/

8.5 Battery Door Assembly

8.5.1 Exploded View



8.5.2 Parts List

SN	FRU part number	Description	Remark
1	/	Screw, Self-Tapping PT3×8	/
2	/	Battery door lock	/
3	/	0653 battery door	/
4	/	Electrode Pads Fix Cover	/
5	/	Operation instruction label (0653)	/

FOR YOUR NOTES

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. Please 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 Device Enclosure and Accessories

A.1.1 Visual Inspection

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

A.1.2 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.2 Device Labelling

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

- Main unit label
- Integrated warning labels

A.3 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and enclosure (normal condition). All measurements have a true RMS only.

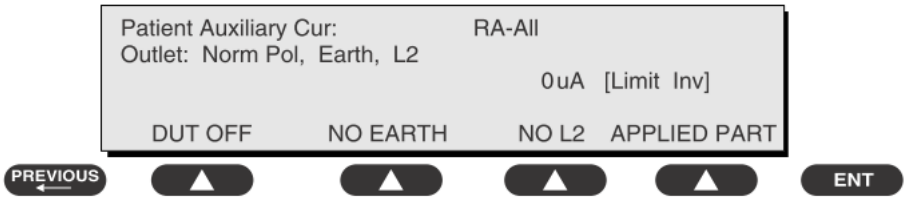
For INTERNALLY POWERED EQUIPMENT**,** it has no earth , so it only has the normal condition. Use **"**Patient Auxiliary Current" menu to test the patient leakage current.

⚠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.**

Preparation

1. From the MAIN MENU, put the battery on the DUT and turn on the device.
2. Attach the patient leads to the 601PRO RA，apply metal foil of maximum 20 cm x 10 cm in intimate contact with the enclosure or relevant part of the enclosure, then attach the metal foil to the 601PRO RL.
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 the print data key at any time to generate a printout of the latest measurement.

In Case of Failure

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

LIMITS

For CF applied parts

- 10μA in Normal Condition

For BF applied parts

- 100μA in Normal Condition

A.4 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 enclosure made of insulating material, which is placed in any position of normal use upon a flat metal surface connected to earth with imensions at least equal to the plan-projection of the enclosure. Measurements are taken with the test voltage (110% of mains) to applied parts in the normal conditions

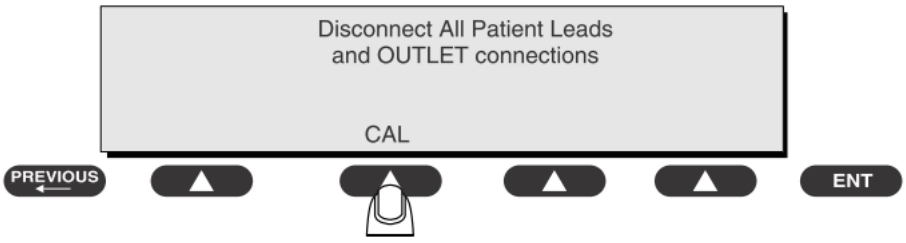
The following outlet conditions apply when performing the Mains on Applied Part test.

- 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.

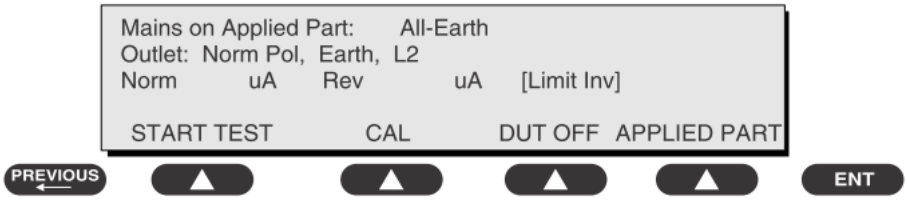
3. When the calibration is finished, the Mains on Applied Part test will reappear.

⚠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, put the battery on the DUT and turn on the device.
2. Attach the applied parts to the 601PRO applied part terminals.
3. Attach the red terminal lead to a conductive part on the DUT enclosure.
4. Press shortcut key 7. The Mains on Applied Part test is displayed.



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

NOTE

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

In Case of Failure

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

LIMITS

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

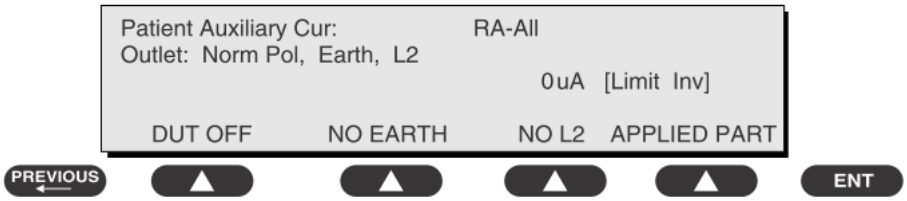
A.5 Patient Auxiliary Current

Patient Auxiliary currents are measured between any selected Applied Part connector and the remaining Applied Part connector s. All measurements may have a true RMS only response.

For INTERNALLY POWERED EQUIPMENT, it only has the normal condition.

Preparation

1. From the MAIN MENU, put the battery on the DUT 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 the print data key at any time to generate a printout of the latest measurement.

In Case of Failure

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

LIMITS

For CF applied parts,

- 10μA in Normal Condition

For BF applied parts,

- 100μA in Normal Condition

A.6 Scheduled Electrical Safety Inspection

For scheduled electrical safety inspection, test items 1, 2, 3, 4 and 5 included in the ***ELECTRICAL SAFETY INSPECTION FORM*** shall be performed.

ELECTRICAL SAFETY INSPECTION FORM

<table>
<tr><td colspan="4">Location:</td><td colspan="2">Technician:</td></tr>
<tr><td colspan="4">Equipment:</td><td colspan="2">Control Number:</td></tr>
<tr><td colspan="3">Manufacturer:</td><td>Model:</td><td colspan="2">SN:</td></tr>
<tr><td colspan="4">Measurement equipment /SN:</td><td colspan="2">Date of Calibration:</td></tr>
<tr><td colspan="4">INSPECTION AND TESTING</td><td>Pass/Fail</td><td>Limit</td></tr>
<tr><td>1</td><td colspan="3">Device Enclosure and Accessories</td><td></td><td></td></tr>
<tr><td>2</td><td colspan="3">Device Labeling</td><td></td><td></td></tr>
<tr><td rowspan="2">3</td><td rowspan="2">Patient Leakage Current</td><td rowspan="2">Normal condition (NC)</td><td>☐BF____μA</td><td rowspan="2"></td><td rowspan="2">Max:
CF applied part:
NC:10μA
BF applied part:
NC:100μA</td></tr>
<tr><td>☐CF____μA</td></tr>
<tr><td rowspan="2">4</td><td colspan="2" rowspan="2">Mains on Applied Part Leakage</td><td>☐BF____μA</td><td rowspan="2"></td><td rowspan="2">Max:
CF applied part: 50μA
BF applied part: 5000μA</td></tr>
<tr><td>☐CF____μA</td></tr>
<tr><td rowspan="2">5</td><td rowspan="2">Patient Auxiliary Current</td><td rowspan="2">Normal condition (NC)</td><td>☐BF____μA</td><td rowspan="2"></td><td rowspan="2">Max:
CF applied part:
NC:10μA
BF applied part:
NC:100μA</td></tr>
<tr><td>☐CF____μA</td></tr>
</table>

Note: The equipment sold to the United States shall comply with the requirement of UL60601-1; others shall comply with the requirement of IEC60601-1.

Name/ Signature: _____ Date:_____

A.7 Electrical Safety Inspection after Repair

The following table specifies test items to be performed after the equipment is repaired.

Repair with main unit not disassembled		Test items: 1, 2
Repair with main unit disassembled	When therapy control with patient electrically-connected is repaired or replaced	Test items: 1, 2, 3, 4, 5

ELECTRICAL SAFETY INSPECTION FORM

Location:				**Technician:**	
Equipment:				**Control Number:**	
Manufacturer:		**Model:**		**SN:**	
Measurement equipment /SN:				**Date of Calibration:**	
INSPECTION AND TESTING				**Pass/Fail**	**Limit**
1	Device Enclosure and Accessories				
2	Device Labeling				
3	Patient Leakage Current	Normal condition (NC)	☐BF____μA ☐CF____μA		Max: CF applied part: NC:10μA BF applied part: NC:100μA
4	Mains on Applied Part Leakage		☐BF____μA ☐CF____μA		Max: CF applied part: 50μA BF applied part: 5000μA
5	Patient Auxiliary Current	Normal condition (NC)	☐BF____μA ☐CF____μA		Max: CF applied part: NC:10μA BF applied part: NC:100μA

Note: The equipment sold to the United States shall comply with the requirement of UL60601-1; others shall comply with the requirement of IEC60601-1.

Name/ Signature: _____ Date:_____

FOR YOUR NOTES