Guardian/GT Series

Patient Monitor

Service Manual

Release time: October 2022

Revision 1.0

Intellectual Property Statement

⚠ WARNING

- **Federal Law (USA) restricts this device to sale by or on the order of a physician or other practitioner licensed by U.S. state law to use or order the use of this device.**

NOTE

- **This manual describes all features and options. The equipment may not have all of them. Contact MDPro Technical Support department for any questions.**

Manufacturer's Responsibility

Contents of this manual are subject to changes without prior notice.

MDPro is responsible for thesafety, reliability and performance of this product only on the condition that:

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by MDPro authorized personnel;
- The electrical installation of the relevant room complies with the applicable national and local requirements;
- This product is operated under strict observance of the operator's manual.

Return Policy

In the event that it becomes necessary to return a unit to MDPro, follow the instructions below.

1. Obtain a return authorization.
   Contact the MDProService Department and obtain a Customer Service Authorization Number. The Customer Service Authorization Number must appear on the outside of the shipping container. Return shipments will not be accepted if the Customer Service Authorization Number is not clearly visible. Please provide the model number, serial number, and a brief description of the reason for return.
2. Freight policy
   The customer is responsible for freight charges when this product is shipped in for service (including any relevant customs fees or other freight related charges).
3. Return address
   Please send the part(s) or equipment to the address offered by Customer Service Department.

Service

MDPro maintains a network of service representatives. Prior to requesting service, perform a complete operational check of the instrument to verify proper control settings. If operational problems continue to exist, contact MDPro service.
Contact the Service Department at (800) 602-7767 for Technical Support for assistance in determining the nearest field service location.
Please include the instrument model number, the serial number, and a description of the problem with all requests for service.
Any questions regarding the warranty should be directed to your local sales or service representative.

NOTE

- **Upon request, MDPro provides circuit diagrams, component part lists, descriptions, calibration instructions, or other information which assist the user's appropriately qualified technical personnel to repair those parts of the equipment which are designated by MDPro as repairable.**

Contact Information

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Preface

Manual Purpose

This manual provides detailed information about the assembly, disassembly, 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. Use of the manual is necessary for proper equipment maintenance and will help to eliminate equipment damage and personal injury.

This manual is based on the maximum configuration; therefore, some contents may not apply to your monitor. If you have any questions, please contact our Customer Service Department.

Intended Audience

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

Contact your local MDPro Service Organization for information on product courses which address service and support for this product.

Passwords

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

- User maintenance: MIN888 (User adjustable)
- Configuration mode: MIN315 (User adjustable)

It is recommended that the user change the passwords for the user maintenance and configuration mode once they take ownership of the equipment.

Contents

1 Safety

1.1 Safety Information

⚠ WARNING

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

⚠ CAUTION

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

NOTE

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

1.1.1 Warnings

⚠ WARNING

- **This equipment is used for a single patient at a time.**
- **This equipment and its accessories are suitable for use within the patient environment.**
- **To avoid explosion hazard, do not use the equipment in the presence of oxygen-rich atmospheres, flammable anesthetics, or other flammable agents.**
- **Use and store the equipment in the specified environmental conditions. The monitor and accessories may not meet the performance specification due to aging, stored or if used outside the specified temperature and humidity range.**
- **The equipment is not intended to be used within the Magnetic Resonance (MR) environment.**
- **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.**
- **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.**
- **To avoid risk of electric shock, the equipment must only be connected to mains power with protective earth. If a protective earth conductor is not provided, operate it on battery power, if possible.**
- **Do not use the multiple portable socket outlets (MPSO) or AC mains extension cords. Ensure that the sum of the individual ground leakage currents does not exceed the allowable limits.**
- **Do not touch the patient and live parts simultaneously. Otherwise patient injury may result.**
- **Do not come into contact with the patient during defibrillation. Otherwise serious injury or death could result.**
- **Do not open the equipment housings. All servicing and future upgrades must be carried out by trained and authorized personnel.**
- **Do not rely exclusively on the audible alarm system for patient monitoring. Turning the 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 patient situations. Always keep the patient under close surveillance.**
- **The physiological data and alarm messages displayed on the equipment are for reference only and cannot be directly used for diagnostic interpretation.**
- **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 by patients or personnel.**
- **The software equipment copyright is solely owned by Mindray. No organization or individual shall resort to modifying, copying, or exchanging it or to any other infringement on it in any**

form or by any means without due permission.

1.1.2 Cautions

⚠ CAUTION

- **Use only parts and accessories specified in this manual.**
- **Ensure that the equipment is supplied with continuous electric power during work. Sudden power failure may cause data loss.**
- **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 phone, 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 or water spray.**
- **Some settings are password protected and can only be changed by authorized personnel. Contact your department manager or biomedical engineering department for the passwords used at your facility.**
- **Dispose of the package material as per the applicable waste control regulations. Keep it out of children's reach.**
- **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. If you have any questions concerning disposal of the equipment, please contact the MDPro Service Department.**

1.1.3 Notes

NOTE

- **Put the equipment in a location where you can easily view and operate the equipment.**
- **The equipment uses a mains plug as isolation means to the mains power. Do not locate the equipment in a place difficult to operate the mains plug.**
- **The typical operator's position is in front of the monitor.**
- **The software was developed in compliance with IEC62304. The possibility of hazards arising from software errors is minimized.**
- **This manual describes all features and options. Your equipment may not have all of them.**
- **Keep this manual in the vicinity of the equipment so that it can be obtained conveniently when needed.**

1.2 Equipment Symbols

See the ***Guardian/GT Series Patient Monitor Operator's Manual*** for information about the symbols used on this product and its packaging.

2 Operation Theory

2.1 Overview

The Guardian/GT series multi-parameter monitor supports comprehensive patient management and provide various physiological parameters and physiological alarms to facilitate patient monitoring. They boast powerful data review features as well as flexible wired network configurations and applications. A suite of CAA applications can aid physicians in the diagnosis, and a best possible monitor management application is also available to improve the management efficiency and quality of monitors in hospitals.

In addition to the touch screen, users can also use shortcut keys to operate the monitor.
With an advanced human-computer interaction design, clinical applicability and versatile CDS applications, the Guardian/GT series can serve as a complete hospital IT solution.

2.2 Product System Architecture

- Guardian/GT Series main unit uses the 10.1" TFT WXGA display
- Guardian/GT Series uses the touch screen and shortcut buttons as input devices, with an optional remote control.
- The built-in recorder is optional.

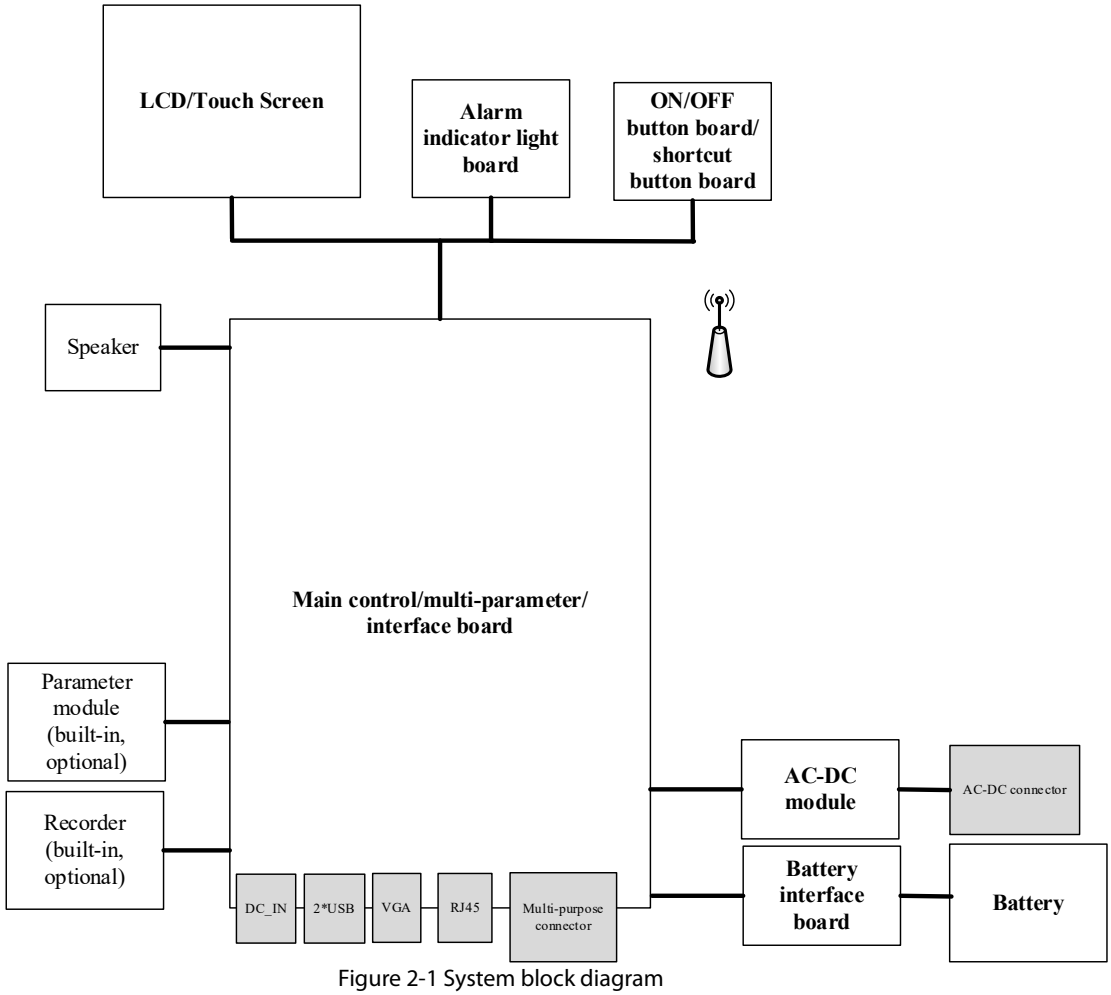


Figure 2-1 System block diagram

2.2.1 Main Control/Parameter/Interface Board

The main control board includes the main control CPU, program memory, data memory, system configuration memory, power management MCU, battery charging circuit and DC-DC circuit. A multi-parameter module circuit (ECG/Resp/SpO_2/NIBP) is also integrated on this board. The internal

interface and external interfaces are also provided on the board. The internal interfaces include an interface for the recorder, an internal parameter module interface, and an interface between the AC-DC and the battery. The external interfaces include a VGA display interface, a USB interface, an Ethernet interface and a multi-function interface.

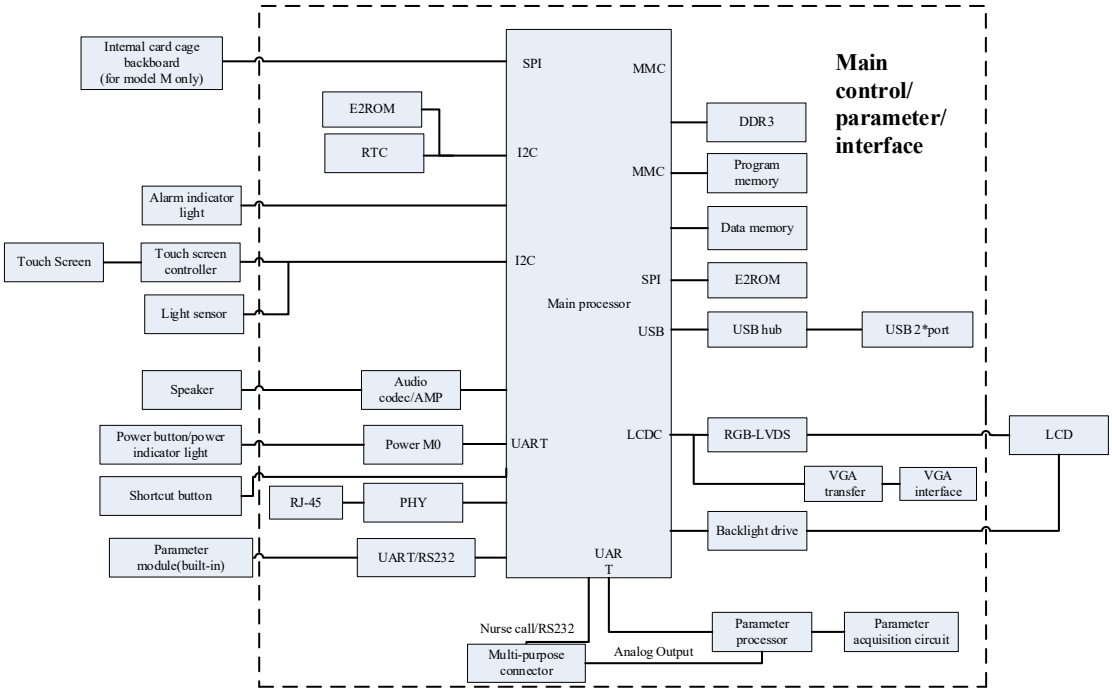


Figure 2-2 Block diagram of the main board

2.2.2 Power Supply Architecture

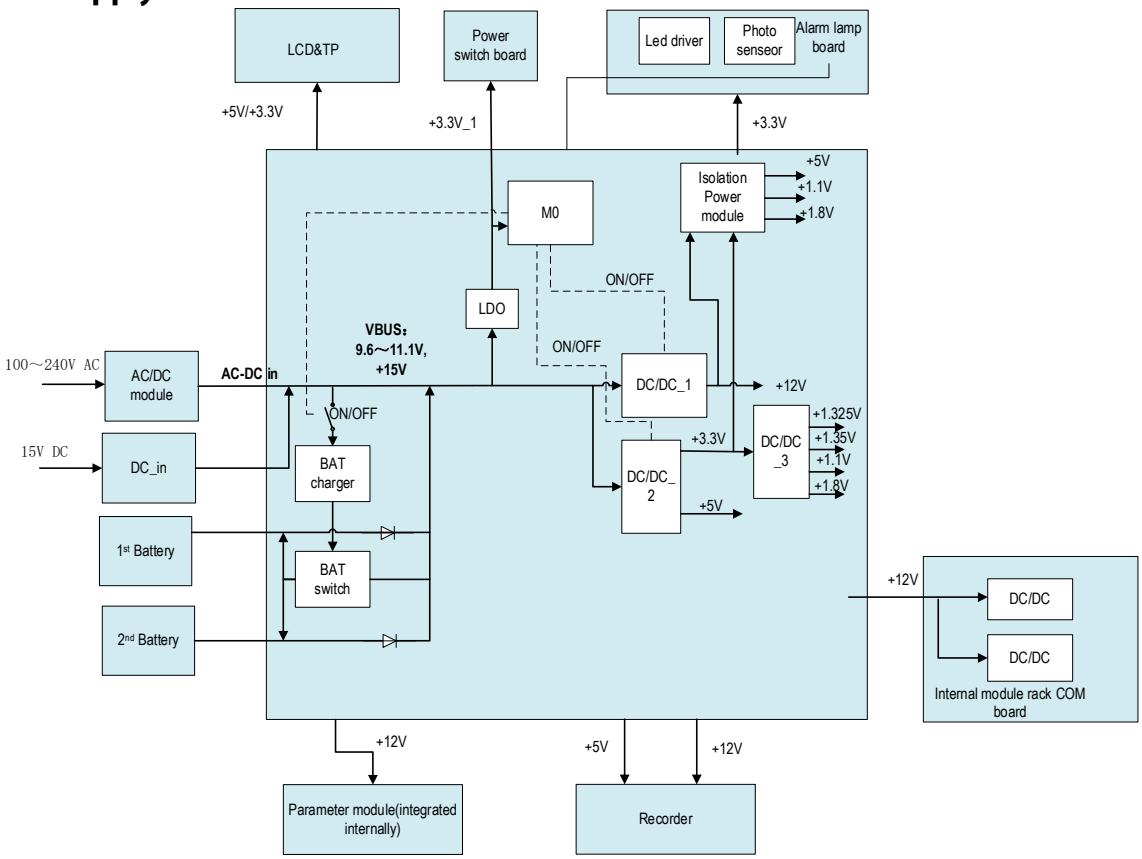


Figure 2-3 Power supply architecture

The AC/DC power module outputs 15V to the main control board, and 3.3V, 5V and 12V can be generated through the internal DC-DC_2 and DC_DC_1 with conversion circuit in the main control board to provide a power supply to other modules or boards in the main unit. The battery charging circuit is powered by 15V, and the AC power supply and power supply can be switched according to AC on-line detection. The Guardian/GT Series can be configured with only one battery.
+12V is the power supply for the internal module rack, recorder and parameter collection circuit. The power module for parameter collection adopts the DC-DC isolation design. DC_DC_3 is used to power the main processor.

2.2.3 Alarm Lamp Board

The LED alarm lamp and light sensor (optional) are provided on the board. The light sensor implements the ambient light detection and is used to adjust brightness of the LCD background light.

2.2.4 Power-On/Off Board/Shortcut Button Board

The power switch indicator and shortcut button are integrated on the same board.

2.3 Data Logic Flow

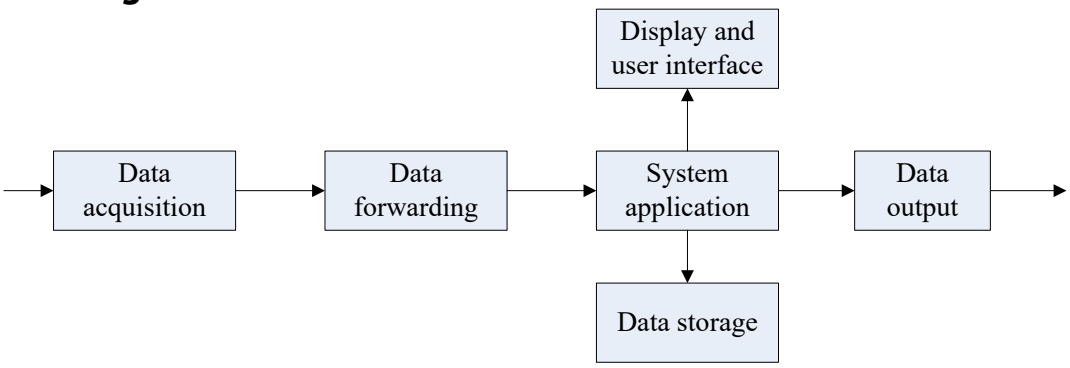


Figure2-4 Data flow diagram

The monitoring parameters are collected and analyzed through the module, and then forwarded to the system software through the internal or external module rack. The system software displays the waveform, numerical value and alarm information. The data, alarm information and numerical value are also stored in the internal data memory at the same time. Meanwhile, they can also be sent to the central station or other monitors through the wired network.

2.4 Power-On/Off Signal Flow

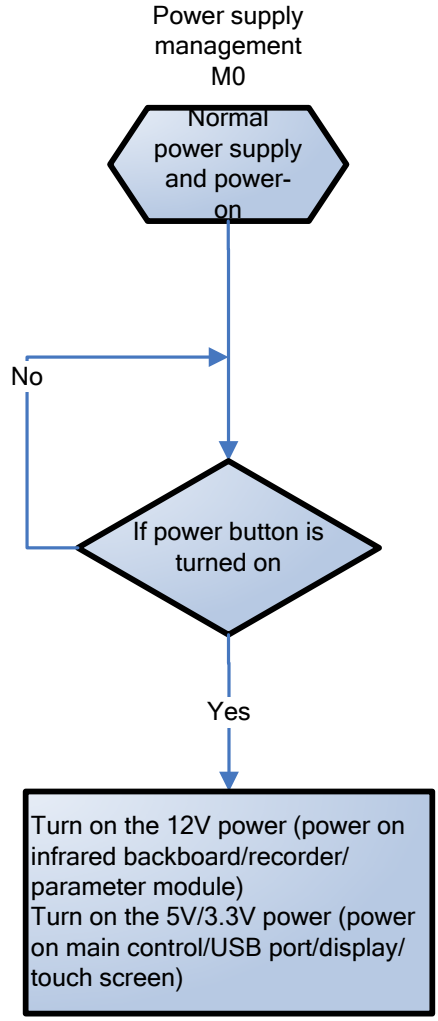


Figure2-5 Power-on flowchart

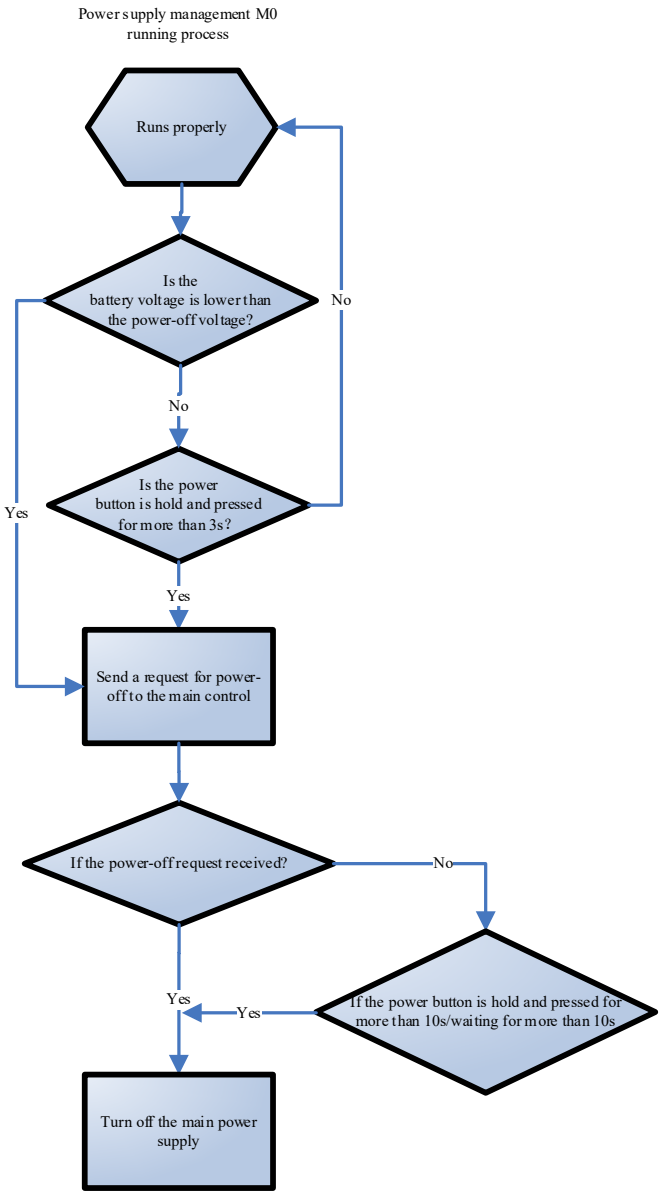


Figure2-6 Power-off flowchart

3 Testing and Maintenance

3.1 Introduction

To ensure the monitor always functions properly, qualified service personnel should perform regular inspection, maintenance and testing. This chapter describes the procedures for testing the monitor with recommended test tools and frequency. The service personnel should perform testing and maintenance as required and use the appropriate test tools.

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

⚠CAUTION

- **All tests should be performed only by qualified service personnel.**
- **Care should be taken when changing the settings in Maintenance and Configuration menus to avoid loss of data.**
- **Service personnel should possess a working knowledge of the test tools and make sure that test equipment and cables are applicable.**

3.1.1 Test Equipment

See the following sections.

3.1.2 Test Report

After completing the tests, record the test results in the table described in section 5.10.14 Maintenance Test Report, and deliver the report to our Service Department.

3.1.3 Preventative Maintenance

The following sections provide a list of recommended preventative maintenance procedures. It is recommended to maintain the patient monitor at least once every two years (and once a year for CO_2 module). (See the following sections for detailed test procedures and contents)

- Visual inspection
- NIBP Test
- CO_2 module tests and calibration

3.1.4 Recommended Frequency

Check/Maintenance Item		Frequency
Preventative Maintenance		
Visual inspection		When first installed or reinstalled.
NIBP test	NIBP accuracy test	1. When the user suspects that the measurement is incorrect. 2. Following any repair or replacement of the relevant module. 3. For NIBP module, at least once every two years; for CO_2 module, once a year.
	Leakage test	
	Overpressure protection circuit test	
Sidestream and microstream CO_2 test	Leakage test	
	Performance test	
	Module calibration	
Performance Test		
ECG test	Performance test	1. When the user suspects that the measurement is incorrect. 2. Following any repair or replacement of the relevant module. 3. At least once every two years. For CO_2 module, at least once a year.
	Module calibration	
Resp performance test		
SpO_2 test		
NIBP test	NIBP accuracy test	
	Leakage test	
Temp test		
Sidestream and microstream CO_2 tests	Leakage test	
	Performance test	
	Module calibration	
Nurse call relay performance test		If the user suspects that the nurse call or analog output is not working properly.
Analog output test		
Electrical Safety Test		
Electrical Safety Tests	Enclosure leakage current test	1. Following any repair or replacement of the power module. 2. When the monitor is dropped. 3. At least twice a year or as required.
	Earth leakage test	
	Patient leakage current	
	Patient auxiliary current	
Other Tests		
Power-on test		1. When the monitor is installed for the first time or is reinstalled. 2. Following any repair or parts replacement.
Recorder check		Following any repair or replacement of the recorder.
Network print check		1. When first installed. 2. Whenever the printer is serviced or replaced.
Battery check	Functionality test	1. When first installed. 2. Whenever a battery is replaced.
	Performance test	Once every two months or when the battery run time is reduced significantly.

3.2 Preventative Maintenance

3.2.1 Visual Inspection

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

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

3.2.2 NIBP Test

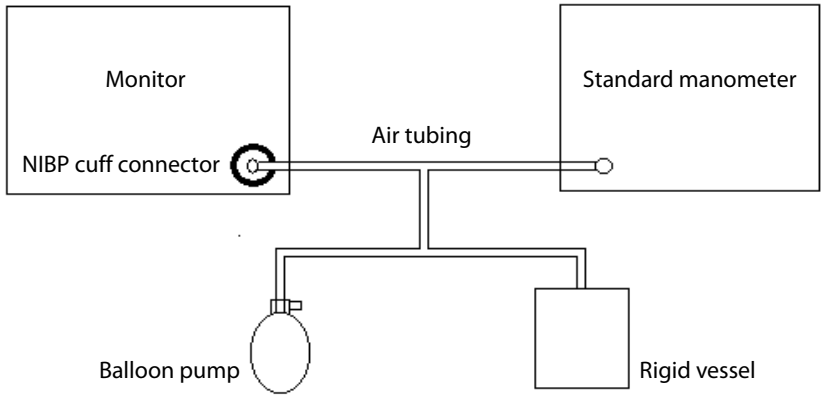
NIBP Accuracy Test

Tools required:

- T-shape connector
- Air tubing
- Balloon pump
- Rigid vessel with volume 500±25 ml
- Reference manometer (PN: 211H197F0011, calibrated with accuracy equal to or greater than 1 mmHg)

Follow this procedure to perform the test:

1. Connect the monitor and the test tools as shown below.



2. Before inflation, check whether the reading on the manometer is 0. If not, open the valve of the squeeze bulb to let the whole airway open to atmosphere. Close the valve after the reading turns to zero.
3. Select **Main Menu** → **Maintenance** → enter password → **Module** → **NIBP** → **NIBP Accuracy Test**.
4. Check that the reading of the manometer and that of the monitor are both 0 mmHg.
5. Raise the pressure in the rigid vessel to 50 mmHg using the balloon pump. Then wait for 10 seconds so that the measured values become stable.
6. Check the readings of the standard pressure meter and the monitor. The difference between the two should be within 3mmHg. If it is greater than 3 mmHg, contact your service personnel.
7. Raise the pressure in the rigid vessel to 200 mmHg using the balloon pump. Then wait for 10 seconds so that the measured values become stable. Repeat step 6.

NOTE

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

Leakage Test

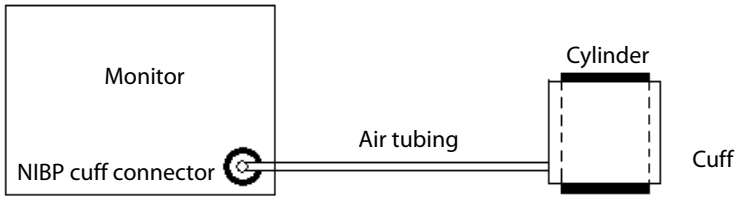
Tools required:

- NIBP cuff for adult patient
- Air tubing
- Cylinder

Follow this procedure to perform the test:

1. Set **Patient Category** to **Adult**.
2. Connect the NIBP cuff to the NIBP connector on the monitor.

3. Wrap the cuff around the cylinder as shown below.



4. Select **Main Menu** → **Maintenance** → enter password → **Module** → **NIBP** → **NIBP Leakage Test**. The message **NIBP Leakage Test** is displayed in the NIBP parameter area.
5. The cuff automatically deflates after 20s, which means NIBP leakage test is completed.
6. If no message is displayed in the NIBP parameter area, it indicates that the system has no leak. If the message **NIBP Pneumatic Leak** is displayed, it indicates that the system may have a leak. In this case, check that all connections are in good condition and the cuff and air tubing have no leakage. Then perform the test again.

You can also perform a manual leakage test:

1. Perform steps 1-4 in the NIBP Accuracy Test section.
2. Raise the pressure in the rigid vessel to 250 mmHg using the balloon pump. Then wait for 5 seconds so that the measured values become stable.
3. Record the current pressure value, and use a timer to count time. Then record the pressure value after 60 seconds.
4. Compare the two values and make sure the difference is not greater than 6 mmHg.

Overpressure Protection Circuit Test

Tools required:

- T-shape connector
- Air tubing
- Balloon pump
- Rigid vessel with volume 500±25 ml
- Reference manometer (calibrated with accuracy equal to or greater than 1 mmHg)

1. Perform steps 1-4 in the NIBP Accuracy Test section.
2. Select Main Menu → Maintenance → enter password → Factory Maintenance → NIBP → Test.
3. In **Overpressure Protection Circuit Test**, select **Adult/Pediatric** for **Patient Category**, and adjust the pump output pressure to 320-330 mmHg. After the pressure stabilizes, select the **Test** button to start the test. When the test succeeds, the NIBP menu will display the message of **Test Successful**. If the pressure exceeds 320-330 mmHg, the message **Test Failed** will be displayed.
4. In **Overpressure Protection Circuit Test**, select **Neo** for **Patient Category**, and adjust the pump output pressure to 160-165 mmHg. After the pressure stabilizes, select the **Test** button on the right side of the menu to start test. When the **test** succeeds, the NIBP menu will display the message of **Test Successful**. If the pressure exceeds 160-165 mmHg, the message **Test Failed** will be displayed.

3.2.3 Sidestream and Microstream CO_2 Modules Tests and Calibration

Leakage Test

1. Wait until the CO_2 warmup is finished and then completely block the gas inlet of the module or water trap (by using your finger or other objects). The sidestream and microstream CO_2 modules will behave as follows:
   - Sidestream: Plug the sidestream CO_2 module into the module rack of the main unit. Wait one minute until the module warmup is finished and then completely block the gas inlet of the module (you may use a pneumatic plug or your finger to manually occlude the port). An alarm message **CO_2 Airway Occluded** will appear on the screen. Block the gas inlet for another 60

seconds. Select **Maintenance** → enter password → **Module** → **CO_2** → **CO_2 Module Calibration**. If the flow rate is less than 10 ml/min and the alarm message continues, it indicates that the module does not leak. If the alarm message **CO_2 Airway Occluded** disappears, or the flow rate is greater than or equal to 10 ml/min, it indicates that the module leaks.

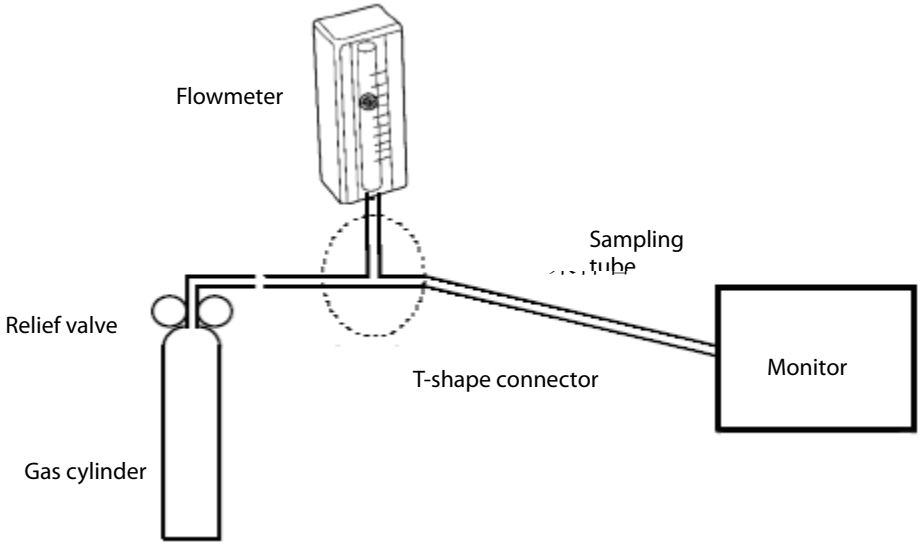
- ◆ Microstream: Block the gas inlet for 3 seconds. The alarm message **CO_2 Purging** is displayed on the screen. Block the gas inlet for another 30 seconds. If the alarm message **CO_2 Airway Occluded** is displayed, it indicates that the module does not leak.

Accuracy Test

Tools required:

- A steel gas cylinder with 5%or 6% CO_2 and balance gas N_2
- A steel gas cylinder with >40% and balance gas 100% N_2 (applicable to sidestream CO_2 module with O_2 module equipped)
- T-shape connector
- Air tubing
- Flowmeter

1. Plug the module into the module rack.
2. Wait until the CO_2 module warmup finishes. Check the airway for leakage and perform a leakage test as well to make sure that the airway has no leakage.
3. Select **Maintenance** → **Module** → **CO_2** → **CO_2 Module Calibration**.
4. Connect the test system as follows:



5. Verify that the real-time CO2 value is within 5%or 6% in the Calibrate CO2 menu (for microstream CO2, the value is 45±2 mmHg).

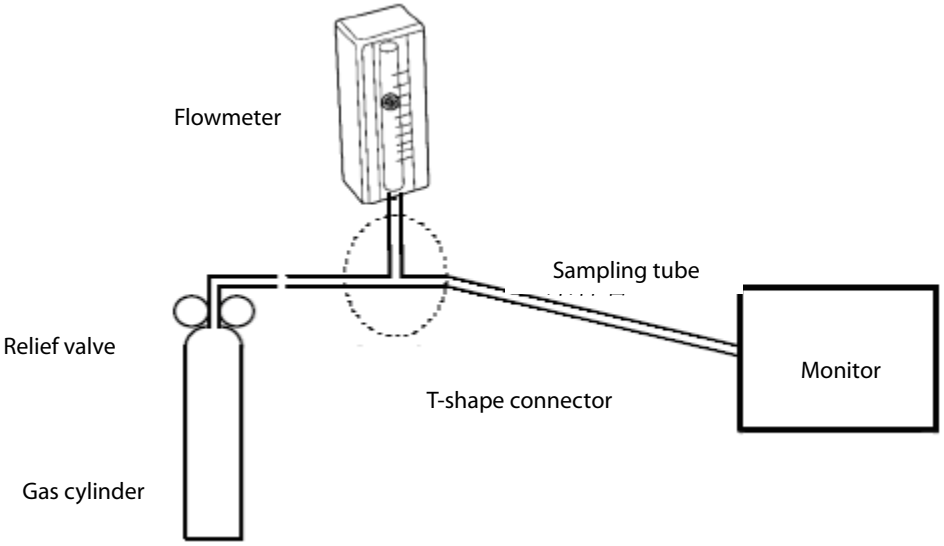
Module Calibration

Tools required:

- A steel gas cylinder with 5%or 6% CO_2 and balance gas N_2
- T-shape connector
- Air tubing
- Flowmeter

1. Make sure that the sidestream or microstream CO_2 module has been warmed up or started up.
2. Check the airway for leakage and perform a leakage test as well to make sure that the airway has no leakage.

3. Select **CO_2 Calibration** → **Main Menu** → **Maintenance** → enter the user maintenance password → **Module** → **CO_2**.
4. In the **CO_2** menu, select **Zero**.
5. After the zero calibration succeeds, connect the monitor and the test tools as follows:



6. Open the relief valve and adjust it until the flowmeter has a stable reading between 10 ml/min and 50 ml/min.
7. In the **Calibrate CO_2** menu, enter 5%or 6% (the CO_2 concentration) in the **CO_2** % field.
8. The measured CO_2 concentration is displayed in the **Calibrate CO_2** menu. After the measured CO_2 concentration becomes stable, select **Calibrate** to calibrate the CO_2 module.

If the calibration is finished successfully, the message **Calibration Completed** is displayed in the **Calibrate CO_2** menu. If the calibration failed, the message **Calibration Failed** is displayed. In this case, check whether the operations are correct and perform another calibration. If the calibration fails several times, return the module for repair.

3.3 Power-On Test

This test aims to verify that the monitor can power up properly. Follow this procedure to perform the test:

1. Connect the patient monitor to the AC mains. The AC mains LED and battery LED illuminate.
2. Press the power on/off switch to turn on the patient monitor. The system sounds a beep indicating the self test on alarm sounds is passed. The alarm lamps light red, yellow and cyan respectively, and then go off, indicating the self test on alarm sounds is passed.
3. The patient monitor enters the main screen and start-up is finished.

3.4 Module Performance Tests

3.4.1 ECG Tests

ECG Performance Test

Tools required:

- Patient simulator Medsim300B or equivalent

1. Connect the patient simulator with the ECG module using an ECG cable.
2. Set the patient simulator as follows: ECG sinus rhythm, HR = 60 bpm, and amplitude = 1 mV.
3. Verify that the ECG waves are displayed correctly without noise and the displayed HR value is within 60±1 bpm.
4. Disconnect each of the leads one by one and observe the corresponding lead off message displayed on the screen.
5. Set the output of the simulator to deliver a paced signal, and set **Paced** to **Yes** on the monitor. Check the pace pulse marks on the monitor screen.

ECG Verification

Tools required:

- Vernier caliper

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

If necessary, you can print out the square wave and wave scale through the recorder and then measure the difference.

3.4.2 Resp Test

Tools required:

- Patient simulator Medsim300B or equivalent

1. Connect the patient simulator and the monitor using a non ESU-proof cable and set lead II as the respiration lead of the monitor.
2. Configure the simulator as follows: lead II as the respiration lead, the base impedance line as 500 Ω, the delta impedance as 1 Ω, and the respiration rate as 20 rpm.
3. Verify that the Resp wave is displayed without any distortion and the displayed Resp value is within 20±1 rpm.

3.4.3 SpO_2 Test

Tools required:

- None.

1. Connect the SpO_2 sensor to the SpO_2 connector on the monitor. Set **Patient Category** to **Adult** and **PR Source** to **SpO_2** on the monitor.
2. Apply the SpO_2 sensor to your ring finger (it is assumed that you are healthy).
3. Check the Pleth wave and PR reading on the screen and make sure that the displayed SpO_2 is within 95% and 100%.
4. Remove the SpO_2 sensor from your finger and check that the SpO_2 sensor off alarm is triggered.

Measurement accuracy verification:
The SpO_2 accuracy of the MPM module has been verified in clinical studies by comparison with arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed and about two-thirds of the measurements are expected to fall within the specified accuracy range compared to CO-oximeter measurements.

NOTE

- **A simulator can only verify whether the monitor is functional. The accuracy of a pulse oximeter monitor or a SpO_2 sensor needs to be verified by clinical data.**

3.4.4 NIBP Test

Refer to section ***4.2.2NIBP Test.***

3.4.5 Temp Test

Tools required:

- Resistance box (with accuracy greater than or equal to 0.1 Ω)

1. Connect the two pins of any Temp connector of a module to the two ends of the resistance box using two wires.
2. Set the resistance box to 1354.9 Ω (the corresponding temperature is 37°C).
3. Verify each Temp channel of the monitor and make sure that the displayed value is within 37±0.1°C.

3.4.6 Sidestream and Microstream CO_2 Modules Tests and Calibration

Refer to section ***4.2.3Sidestream and Microstream CO2 Modules Tests and Calibration***.

3.5 Nurse Call Relay Performance Test

Tools required:

- Multimeter

1. Connect the nurse call cable to the Nurse Call Connector of the patient monitor.
2. Enter **Demo** mode. Then, select **Main Menu** → **Maintenance** → enter the user maintenance password → **Alarm** → Nurse Call.
3. In the **Nurse Call** menu, select all options of **Alm Lev** and **Alm Cat.** and set **Contact Type** to **Open**.
4. In the **Nurse Call** menu, set **Signal Type** to **Pulse**. Cause the monitor to generate an alarm and verify the output are pulses of 1s width and the relay contacts are closed (can be measured with a multimeter) when there is an alarm.
5. In the **Nurse Call** menu, set **Signal Type** to **Continuous**. Cause the monitor to generate an alarm and verify the output is continuous high level and the relay contacts are closed (can be measured with a multimeter) when there is an alarm.

3.6 Analog Output Test

Tools required:

- Patient simulator
- Oscilloscope

1. Connect the patient simulator to the monitor using an ECG cable and connect the oscilloscope to the Auxiliary Output Connector of the patient monitor.
2. Verify that the waves displayed on the oscilloscope are identical with those displayed on the monitor.

3.7 Electrical Safety Tests

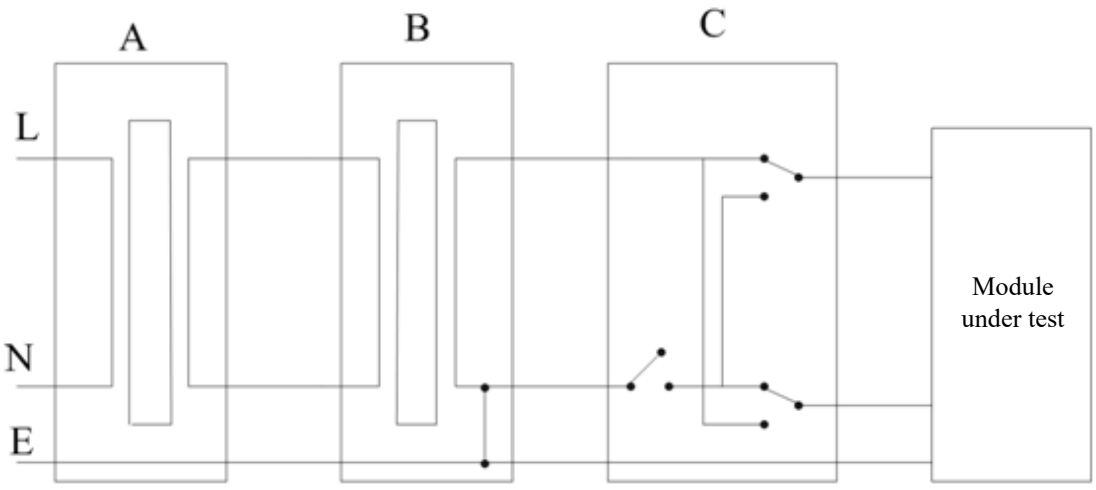
⚠WARNING

- **Electrical safety tests are a proven means of detecting abnormalities that, if undetected, could prove dangerous to either the patient or the operator.**
- **All tests can be performed using commercially available safety analyzer test equipment. Maintenance personnel shall ensure the adaptability, functional completeness and safety of the test equipment, and be familiar with their usage.**
- **Electrical safety tests shall comply with the following standards: IEC 60601-1.**
- **In case of other stipulations in local laws and regulations, implement electrical safety tests by following relevant stipulations.**
- **All devices driven by AC power and connected to medical instruments in patient zones must comply with the IEC 60601-1 standard. Electrical safety tests on these devices must be implemented in accordance with the test interval of the monitor.**

Electrical safety tests are used to timely detect potential electrical safety risks that might cause injuries to patients, operators or maintenance personnel. Electrical safety tests must be carried out under normal environmental conditions (that is, normal temperature, humidity and barometric pressure).

The electrical safety tests described in this chapter uses the 601 safety analyzer as an example. The safety analyzer used in different regions may vary. Make sure that the electrical safety test scheme you used is applicable.

Device connection is shown in the following figure.



A: AC power (programmable power supply, regulate frequency)

B: Isolation figure for leakage current test on tooling

C: Safety tester

Tools required:

- Safety analyzer
- Isolation transformer

3.7.1 Enclosure Leakage Current Test

1. Connect the safety analyzer to a 264 V AC 60 Hz power supply.
2. Use the power cord to connect the EUT to the auxiliary power output connector of the safety analyzer.
3. Connect one end of the red lead to the "Red input terminal" of the safety analyzer, and clip the other end on the metal foil attached on the surface of the outer enclosure of the EUT.
4. Power on the safety analyzer. Press **5-Enclosure leakage** on the panel to access the interface for enclosure leakage current test.
5. Check that the enclosure leakage current is not greater than 100 μA in normal condition and is not greater than 300 μA in the single fault condition.

3.7.2 Earth Leakage Current Test

1. Connect the safety analyzer to a 264 V AC 60 Hz power supply.
2. Connect the application part of the EUT to the RA terminal of the safety analyzer.
3. Use the power cord to connect the EUT to the auxiliary power output connector of the safety analyzer.
4. Power on the safety analyzer. Press **4-Earth leakage** on the panel to access the interface for earth leakage current test.
5. Check that the earth leakage current is not greater than 300 μA in normal condition and is not greater than 1000 μA in single fault condition.

3.7.3 Patient Leakage Current Test

1. Connect the safety analyzer to a 264 V AC 60 Hz power supply.
2. Connect the application part of the EUT to the RA terminal of the safety analyzer.
3. Use the power cord to connect the EUT to the auxiliary power output connector of the safety analyzer.
4. Power on the safety analyzer. Press **6-Patient leakage** on the panel.
5. Press the **APPLIED PART** button repeatedly to select AC and DC measurement. When DC is selected, the "DC" text is displayed next to the limit.
6. Check that the patient leakage current is not greater than 10 μA in normal condition and is not greater than 50 μA in single fault condition.

3.7.4 Patient Auxiliary Current Test

1. Connect the safety analyzer to a 264 V AC 60 Hz power supply.
2. Use the power cord to connect the EUT to the auxiliary power output connector of the safety analyzer.
3. Connect the ECG cable of the EUT to the RA terminal of the safety analyzer.
4. Power on the safety analyzer. Press **8-Patient Auxiliary Current Test** on the panel to access the interface for patient auxiliary current test.
5. Press the **APPLIED PART** button repeatedly to select AC and DC measurement. When DC is selected, the "DC" text is displayed next to the limit.
6. Check that the patient auxiliary current is not greater than 10 μA in normal condition and is not greater than 50 μA in single fault condition.

3.8 Recorder Check

Tools required:

- None.

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

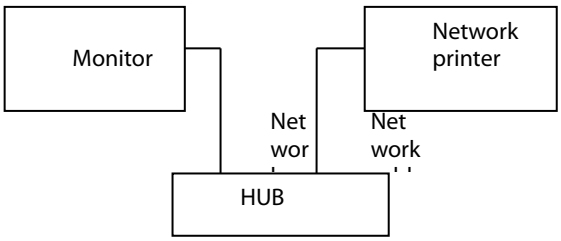
3.9 Network Print Check

Tools required:

- Hub and network cable

3.9.1 Equipment Connection and Setup

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



2 IP setup: Select **Main Menu** → **Maintenance** → enter the user maintenance password → **Network Setup**. Set the IP address of the monitor to one in the same network segment as that of the network printer (refer to the instructions for use of the printer).

3.9.2 Print Function Test

1 Enter the Demo mode of the monitor.

2 Select Main Menu → **Screen Setup** → **Screen Layout** → select ECG Full-Screen 7 Lead Interface.

3 Select Main Menu → **Normal Report** → **ECG Report**. Select the normal report and click Print. The network printer prints the ECG report.

3.10 Battery Check

Tools required:

- None.

Functionality Test

1. Verify that the patient monitor works properly when running on AC power.
2. Remove the AC power cord and verify that the patient monitor still works properly.

Performance Test

Perform the test procedure in the **Battery** section in the Operator's Manual and verify the operating time of the battery meets the product specification.

3.11 Factory Maintenance

3.11.1 Accessing Factory Maintenance Menu

Select the **Main Menu** quick key → go to the third page → select **Maintenance** from the **System** column → enter the factory maintenance password → select **OK** → select **Factory Maintenance**.

3.11.2 Monitor Information (Log Export)

Before inserting the USB drive, make sure the file format is FAT32. Then, insert the USB drive into the USB port of the monitor's main unit (Note: Not the USB port of the iView's main unit!)
Access the **Monitor Information** menu. Then you can view the information about the monitor's main unit, such as CPU temperature, Wi-Fi signal strength, and hard disk capacity.
Click Export Log in the lower left corner to export all monitor log information.

3.11.3 Settings

Access the **Setup** menu to perform the ECG alarm setting or other settings.

3.11.4 Debugging

Access the **Debug** menu to perform debugging related settings.

3.11.5 Clinical Data

Access the **Clinical Data Collection** menu to perform settings related to clinical data collection.
When Clinical Data Location is set to Local, the clinical data is stored on the monitor. You can export the

data to the USB drive in the way of log export.
When **Clinical Data Location** is set to **Udisk**, the clinical data is directly stored on the USB drive.

3.11.6 Clinical Data Transfer

Access the Clinical Data Transfer menu to select clinical data to be sent.

3.11.7 Software Version

In the Maintenance menu, select Software Version to show software version information.

Maintenance Test Report
(See the above sections for detailed test procedures and contents.)

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

Test items	Test records	Test results (Pass/Fail)
Visual inspection		
The case, display screen, buttons, power cord, bracket and accessories have no obvious signs of damage.		
The external connecting cables are not frayed and the connector pins are not loose and/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 monitor start up properly.		
Performance test		
ECG Performance Test		
ECG waves are displayed correctly without noise and the displayed HR value is within 60±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 20±1 rpm.		
SpO_2 Test		
Measure SpO_2 on a healthy person's finger and a Pleth wave and PR value are displayed. The displayed SpO_2 value is within 95%-100%.		
SpO_2 sensor off alarm function is normal.		
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 6 mmHg/min.		
Temp test		
The value displayed for each Temp channel of the monitor is within 37±0.1°C.		
The TB value displayed on the monitor is within 37±0.1°C.		
The CO_2 Apnea alarm behaves correctly.		
The displayed CO_2 value is withing 45±2 mmHg.		

Sidestream CO_2 test		
Block the gas inlet of the module or water trap. The sidestream CO_2 flow rate is less than 10 ml/min, and the alarm message "CO_2 Airway Occluded" is displayed. This indicates that there is no leakage.		
The displayed CO_2 value is within 6±0.2%.		
Microstream CO_2 test		
Block the gas inlet of the module or water trap for about 30 seconds. The alarm message "CO_2 Airway Occluded" is displayed. It indicates that there is no leakage.		
The displayed CO_2 value is withing 45±2 mmHg.		
Nurse call relay performance test		
The relay contacts are close when an alarm occurs.		
Analog output test		
The waves displayed on the oscilloscope are identical with those displayed on the monitor.		
Electrical safety tests		
The enclosure leakage current is not greater than 100 μA in normal condition and is not greater than 300 μA in single fault condition.		
The earth leakage current is not greater than 300 μA in normal condition and is not greater than 1000 μA in single fault condition.		
The patient leakage current is not greater than 10 μA in normal condition and is not greater than 50 μA in single fault condition.		
The patient auxiliary current is not greater than 10 μA in normal condition and is not greater than 50 μA in single fault condition.		
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, etc. the patient monitor should give corresponding prompt messages. After the problem is removed, the recorder should be able to work correctly.		
Automatic alarm recording for each parameter functions correctly when parameter alarms occur.		
Network print check		
The network printer can print ECG reports correctly.		
Battery check		
The monitor can operates correctly from battery power when an AC power failure accidentally occurs.		
The operating time of the battery meets the product specification.		

Test conclusion:
Qualified or not: (Yes No)
Signature of tester: Date:

4 Troubleshooting

4.1 Introduction

This chapter lists the problems that might arise from the use of the monitor, and recommended measures. You may check the monitor as per the table given in this chapter to identify and resolve problems. For more information about the troubleshooting, please contact the MDPro Service Department.

4.2 Part Replacement

For the monitor, the PCB, main parts and components can be replaced. Once a faulty PCB is confirmed, replace the PCB according to the operation guide in the maintenance and disassembly parts. After the replacement, confirm that the monitor can operate normally and has passed all the performance tests. For the information about replaceable parts, see ***7*** Parts.

4.3 Check before Powering on the Monitor

In addition, check the appearance for damages before powering on. Particularly, when the touch screen of the display assembly is damaged, stop using the monitor immediately.

4.4 Software Version Check

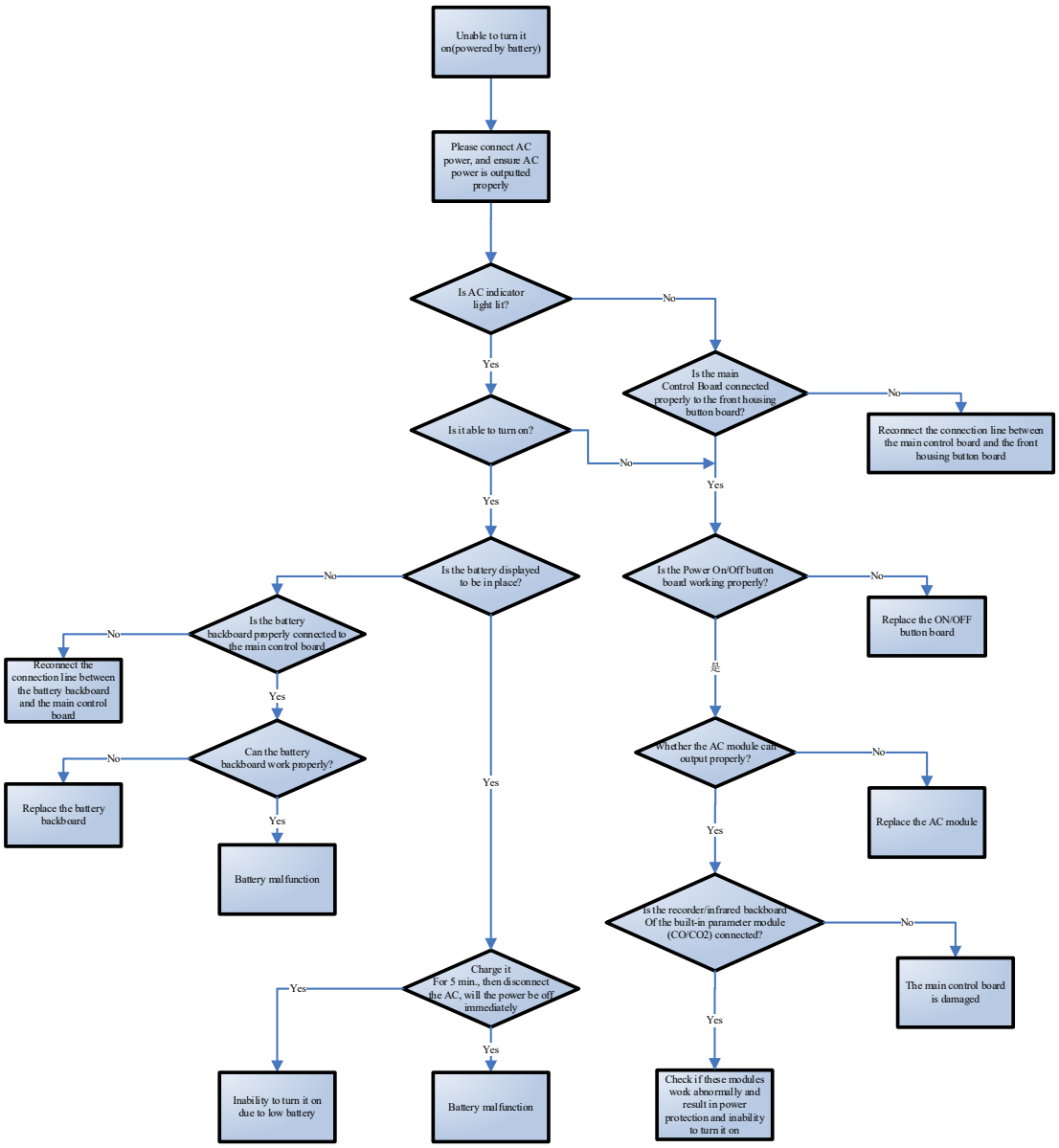
Some troubleshooting tasks may involve software version compatibility. For information about the configuration and software version of your patient monitor, contact the MDPro Service Department. To check the software version, do as follows:

Select **Main Menu** → go to the third page → select **Maintenance** → from the **System** column → enter the factory maintenance password → **Version >>**. In the displayed menu, you can check the version information of the system software.

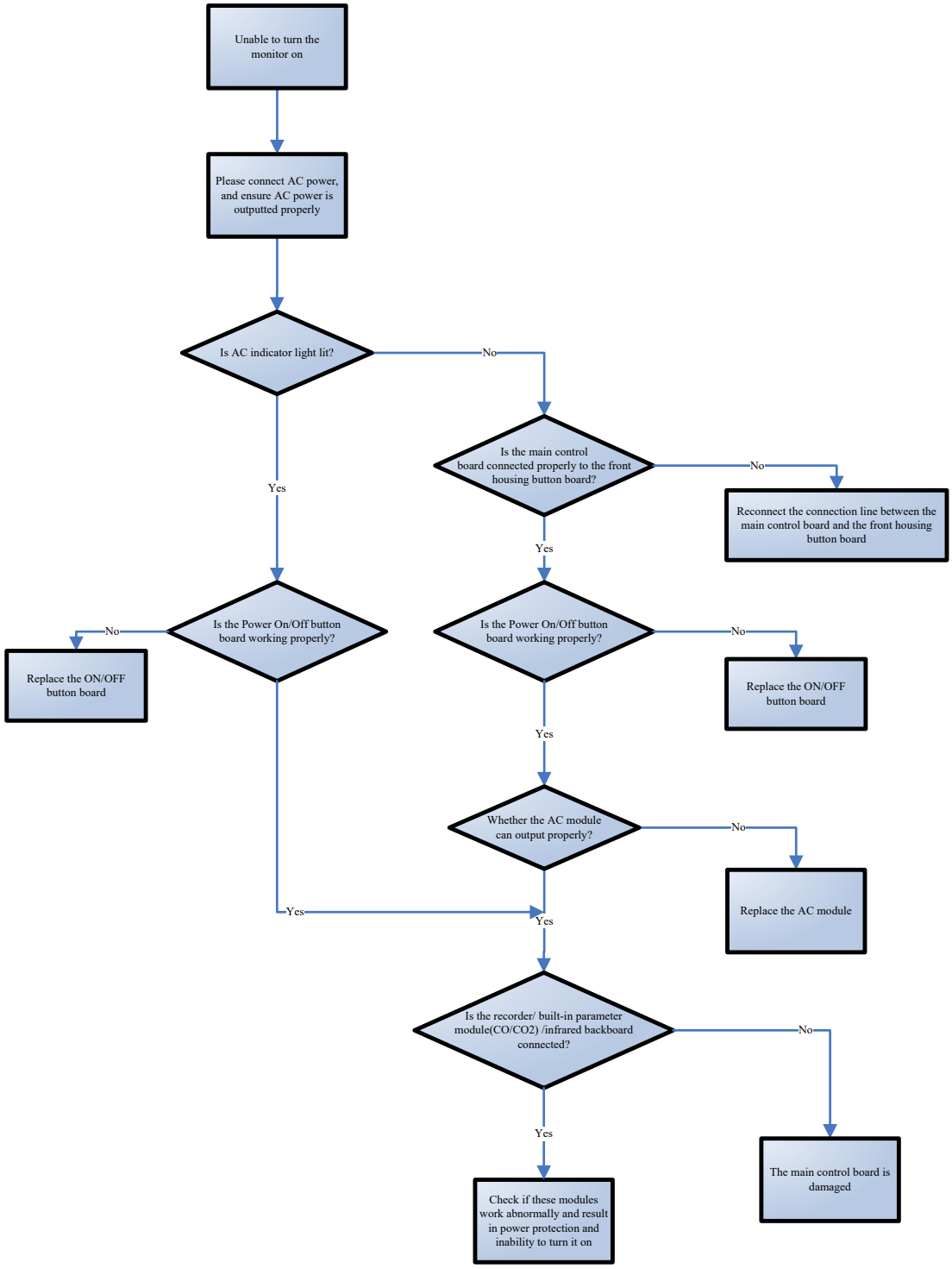
4.5 Troubleshooting Guide

4.5.1 Power-On/Off Failures

Failure Description	Possible Cause	Troubleshooting
Power on failure	AC mains not connected or insufficient battery power or battery damaged	■ Verify the AC mains is properly connected. ■ Verify the battery capacity is sufficient and the battery is not damaged.
	Cable defective or improperly connected	■ Verify the cable connecting the power-on/off button board to the main control board is not damaged. ■ Verify the connecting cable connectors and corresponding sockets are not damaged.
	Power-on/off button board damaged	Replace the power-on/off button board.
	Power module defective	Replace the power module.
	The main board is faulty.	Replace the main control board.
	Power supply protection	■ If the main unit connects to other devices such as the external parameter module, USB drive, and scanner, first disconnect these devices from the main unit. If the monitor can be started after the disconnection, an external device may fail, leading to power supply protection. ■ If the main unit is not connected to other devices, check whether there is any short circuit fault in the internal module rack backpane or main control board and it leads to protection of the power output.



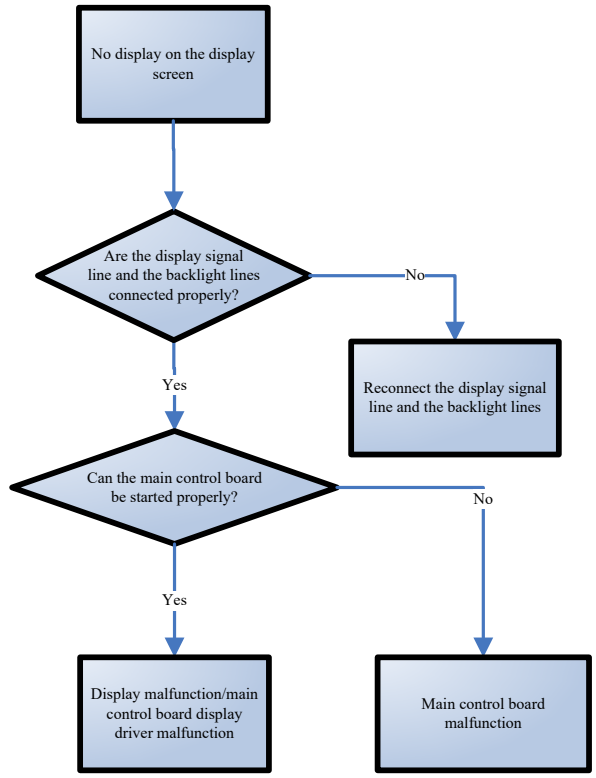
Troubleshooting flowchart for the inability to turn the device on due to battery failure



Troubleshooting flowchart for the inability to turn the device on due to AC power failure

4.5.2 Display Failures

Failure Description	Possible Cause	Troubleshooting
The display screen does not function or the display is abnormal, but the main unit can operate	Cable defective or improperly connected	■ Verify the cables (screen cable and backlight cable) connecting the display screen to the main control board are correctly connected. ■ Verify the connecting cable connectors and corresponding sockets are not damaged.
	LCD screen defective	Replace the front housing assembly.
	Main control board software abnormal	Upgrade the software of the main control board.
	Backlight driver defective	Replace the main board.
	Display driver defective	Replace the main board.
The touchscreen does not respond.	Cable defective or improperly connected	■ Verify the cable connecting the touch screen to the main control board is properly connected. ■ Verify the connecting cable connectors and corresponding sockets are not damaged.
	Touch screen defective	Replace the front housing and touch screen.
	Main control board software abnormal	Upgrade the software of the main control board.
	The main board is faulty.	Replace the main board.



Display troubleshooting flowchart

4.5.3 Alarm Failures

Failure Description	Possible Cause	Troubleshooting
Alarm LED off or cannot be turned off while the	Cable defective or improperly connected	■ Verify the cable connecting the alarm LED board to the main control board is properly connected. ■ Verify the connecting cables and connectors are not

audible alarm is provided		damaged.
	Alarm lamp board failure	Replace the alarm lamp board.
	The main board is faulty.	Replace the main board.
No audible alarm sounds emitted when alarm lamp is activated	Audible alarm disabled	Check whether the alarm sound is muted; select Main Menu → System >> → Maintenance >> → enter the user maintenance password → Alarm >>, and adjust the Minimum Alarm Volume to an appropriate value in the pop-up menu. In the Others window of the Alarm Setup menu, set Alm Volume to appropriate setting.
	Speaker failure	Replace the speaker.
	Cable defective or improperly connected	Verify the cable connecting the speaker to the main control board is properly connected.
	The main board is faulty.	Replace the main board.

4.5.4 Recorder Failures

Failure Description	Possible Cause	Troubleshooting
No printout	Recorder module disabled	Verify the recorder status LED is lit. If it is lit, recover its function in "Factory Maintenance".
	Printing paper jam	Reinstall the paper roll properly.
	Cable defective or improperly connected	■ Verify the cable connecting the recorder and the main control board is properly connected. ■ Verify the connecting cables and connectors are not damaged.
	Recorder failure	Replace the recorder.
	The main board is faulty.	Replace the main board.
Poor printing quality	Printing paper thermal coating failure	Replace the printing paper.
	Thermal head dirty	Clean the thermal head.
	Recorder failure	Replace the recorder.

4.5.5 Output Interface Failures

Failure Description	Possible Cause	Troubleshooting
No output for the nurse call signal	Main control board defective	Replace the main board.
USB Device Unusable.	The main board is faulty.	Replace the main board.
Network interface failure	The main board is faulty.	Replace the main board.
VGA interface failure	Display not matched with the VGA interface time sequence	Check whether the display supports the resolution of 1280*800 (10-inch/12-inch model) or 1376*768 (15-inch).
	Main control board defective	Replace the main board.

4.5.6 Battery Failures

Failure Description	Possible Cause	Troubleshooting
Battery cannot supply power	Battery damaged	Replace the battery.
	Cable defective or improperly connected	■ Verify the cable connecting the main control board to the battery interface board is correctly connected. ■ Verify the connecting cables and connectors are not damaged.
Battery cannot be recharged or cannot be fully recharged	Battery damaged	Replace the battery.
	Cable defective or improperly connected	■ Verify the cable connecting the main control board to the battery interface board is correctly connected. ■ Verify the connecting cables and connectors are not damaged.
	The main board is faulty.	Replace the main board.

4.5.7 Parameter Module Failure

Failure Description	Possible Cause	Troubleshooting
ECG/Resp/SPO_2/ NIBP/Temp failure	Incorrect software version	Check the MPM and system software versions and update the software.
	Parameter circuit is damaged	Replace the main board.
	Cable defective or improperly connected	■ Check whether the parameter interface board and the main board are properly connected. ■ Check whether these connection cables and connectors are intact.
	Accessories may be damaged	Replace the accessories.
	Check whether the parameter configuration is correct	According to the user manual, check whether the corresponding parameter configuration is enabled
SPO_2 module (Masimo/Nellcor) failure	Accessories may be damaged	Replace the accessories.
	SPO_2 module failure	Replace the module.
CO_2 (built-in) module failure	Internal hose connection failure	■ Check if the internal hose is properly connected. ■ Check if the internal hose is damaged.
	System software configuration error	Check if the modules in the system software are configured correctly.
	Module damaged	Replace the module.
	Cable defective or improperly connected	■ Check if the CO_2 module is properly connected to the main control board. ■ Check if the wire is damaged.
	The main board is faulty.	Replace the main board.

4.5.8 Network Related Problems

Failure Description	Possible Cause	Troubleshooting
Frequent dropouts	Improper network cable connection	Make sure that the network cable is properly connected and is not close to the power cord of high power equipment, and the length of the network cable is less than or equal to 50 m.
	The network setting is incorrect.	Check whether an IP address conflict exists in the network. If yes, reset the network.
The patient monitor is connected to a network but cannot view	The network cable is not connected properly.	Make sure that the network cable is properly connected and is not close to the power cord of high power equipment, and the length of the network cable is less than or equal to 50 m.
	There are too many monitors to be	Confirm the maximum number of simultaneously connected monitors according to the Operator's Manual.

other patients in the Viewbed window	viewed.	
	The network setting is incorrect.	Check whether an IP address conflict exists in the network. If yes, reset the network.

4.5.9 Software Upgrade Failure

Failure Description	Possible Cause	Troubleshooting
The program cannot be upgraded.	The connection is faulty.	■ Check if the network cable is connected to the monitor's network interface instead of iView's network interface. ■ Ensure the normal operation of the network hub or switch, and verify the hub cable is properly connected.
	Incorect upgrade package	Please select the corresponding correct wrong upgrade package.
	Incorrect IP address configuration for the PC	Configure a fixed IP address from range 77.77.1.2 to 77.77.1.253 as specified for the monitor. You are not advised to upgrade a program t to when the monitor is connected to a network with multiple PCs.

5 Upgrade

5.1 Introduction

This monitor supports upgrade of the monitoring parameter function modules, upgrade of the functional assemblies, and network upgrade of software.

NOTE

- **For function upgrades involving disassembly of the monitor, eliminate static electricity before the disassembly. When removing some parts with the electrostatic sensitive mark, wear protective devices such as electrostatic ring or anti-electrostatic gloves, otherwise the parts might be damaged.**
- **Properly connect and route the cables and wires when reassembling the equipment to avoid pinched hoses and electrical short circuits.**
- **Use specified screws to reassemble the equipment. If improper screws are tightened by force, the monitor may become damaged and the screws or parts may fall off during use, causing unpredictable equipment damage or injury to patient or users may occur.**
- **Follow the correct sequence to disassemble the monitor.**
- **Before removing assemblies, make sure that all the cables have been unplugged. During removal, take caution to avoid damaging calbes by pulling or damaging the connector.**
- **Place the removed screws and other parts separately by category so that they can be used in the re-installation. Do not drop, contaminate or lose them.**

5.2 Upgrade of Parameter Function Modules

This monitor supports upgrade of the following parameter function modules:

Built-in Parameter Module	P/N	Name and Specification	Remarks
Sidestream CO_2 module	115-059974-00	Integrated 10/12-inch sidestream CO_2 material package FRU	
Microstream CO_2 module	115-059956-00	Integrated microstream CO_2 material package FRU	
Nellcor SpO2 module	115-059808-00	Built-in NC SpO2 maintenance package	
Masimo SpO2 module	115-068492-00	Built-in MS SpO2 maintenance package	

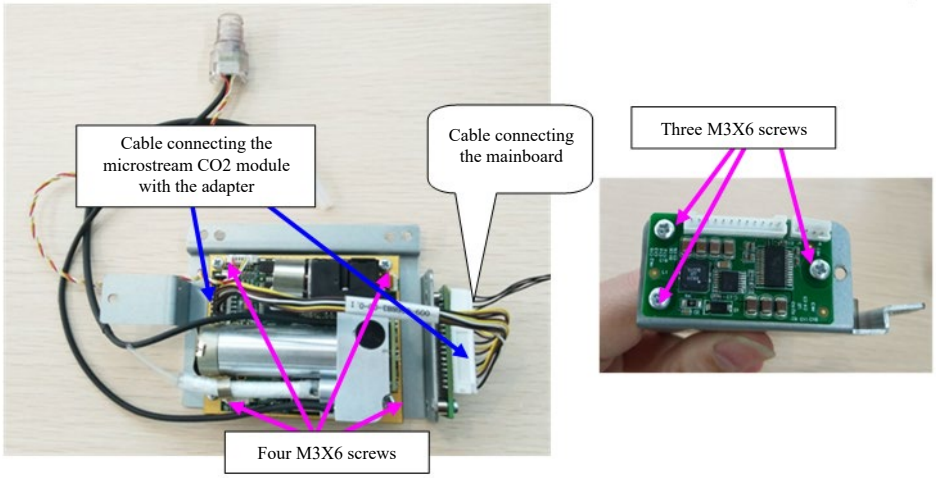
Refer to the Guardian/GT Series Patient Monitor Operator's Manual for the use of parameter modules. The following content describes the upgrade methods of the parameter modules:

5.3 Upgrading the Gas Module

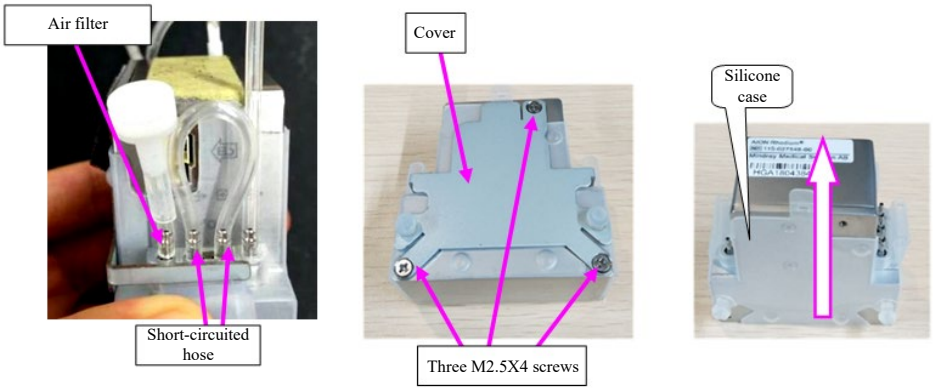
When upgrading the gas function, replace the gas module, cables connecting the gas module and main control board, and cables connecting the gas module and parameter interface board with the materials in the upgrade package.

Follow this procedure:

1. Separate the front and rear housings of the monitor by referring to ***6 Repair and Disassembly***.
2. Assemble the microstream CO_2 module, and sidestream CO_2 module in the material package using sheet metals and cables by referring to ***6 Repair and Disassembly***. The monitor supports only single gas module upgrade.

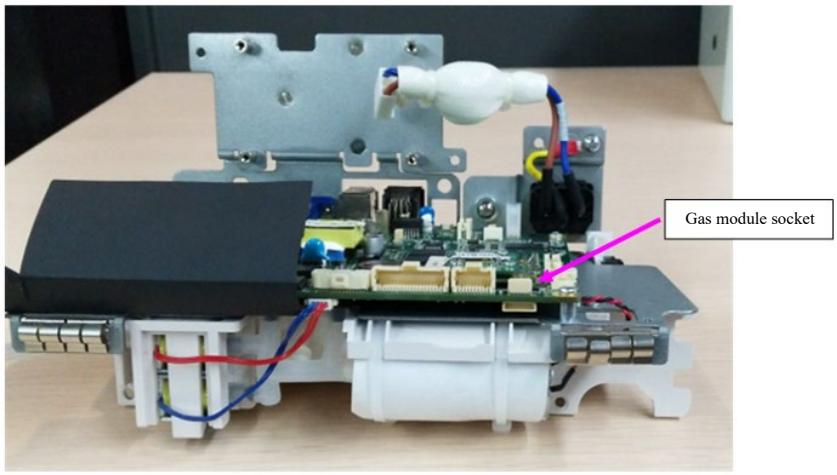


Microstream CO_2 module composition diagram



Sidestream CO_2 module composition diagram

3. Fix the gas module to the bracket of the monitor rear housing, and connect it with the main control board.



4. Reassemble the monitor.
5. Start the monitor. Select **Main Menu** → **Maintenance** → **Factory Maintenance** → **Factory Default**. Set **Support CO_2 Class** to correspond with the upgraded gas module. Then, restart the monitor to allow the configuration to take effect.
6. Test the upgraded monitor by referring to ***3.2.3 Sidestream and Microstream CO2 Modules Tests and Calibration***.

5.4 Upgrade of Functional Assemblies

NOTE

- **When upgrading analog output and CIS function for a patient monitor with standard configuration, you need to replace old PCBAs in the patient monitor with corresponding PCBAs included in the upgrade kit in addition to installing the corresponding functional assemblies in the monitor.**

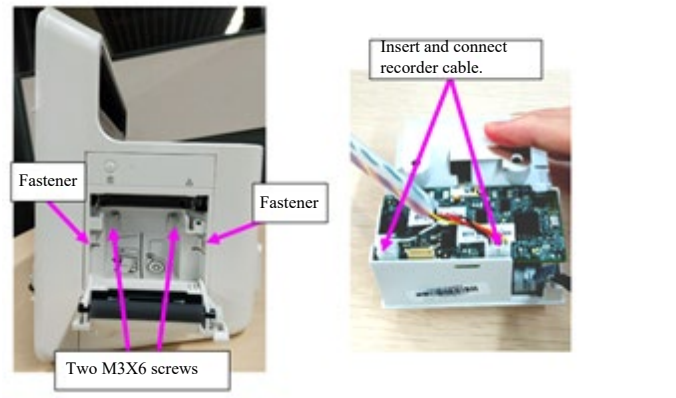
You can upgrade the recorder functional assembly for this monitor..

Functional Assembly	P/N	Name and Specification	Remarks
Recorder	115-059807-00	Recorder material package FRU	

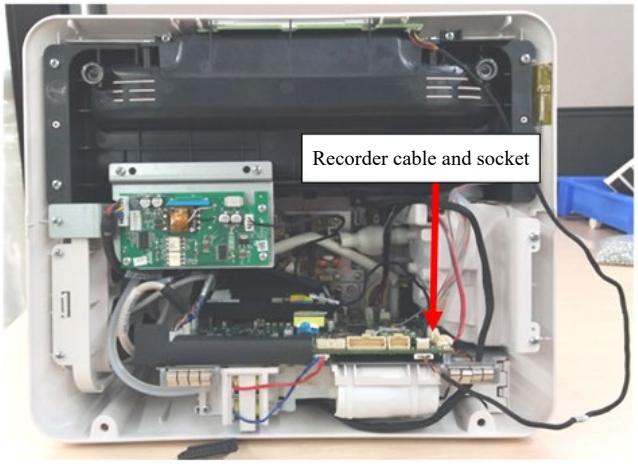
5.4.1 Upgrading Recorder Function

When upgrading the recorder function, replace the recorder and cables connecting the recorder and main control board with the materials in the upgrade package.
Follow this procedure:

1. Separate the front and rear housings of the monitor by referring to 6 Repair and Disassembly.
2. Install the recorder to the bracket of the rear housing recorder by referring to 6 Repair and Disassembly.



3. Fix the recorder module to the bracket of the monitor rear housing, and connect it with the main control board.



4. Reassemble the monitor.
5. Start the monitor. Select **Main Menu** → **Maintenance** → **Factory Maintenance** → **Factory Default**. Turn on the **Recorder** switch. Then, restart the monitor to allow the configuration to take effect.
6. Start the monitor to test whether the recorder function is operating properly.

6 Repair and Disassembly

6.1 Tools

During disassembly and part replacement, the following tools may be required:

- Small Phillips screwdriver
- Phillips screwdriver
- Tweezers
- Needle nose pliers
- Diagonal pliers

6.2 Preparations for Disassembly

Before disassembling the monitor, make the following preparations:

- Stop monitoring the patient, turn off the monitor, and disconnect all the accessories and peripheral devices.

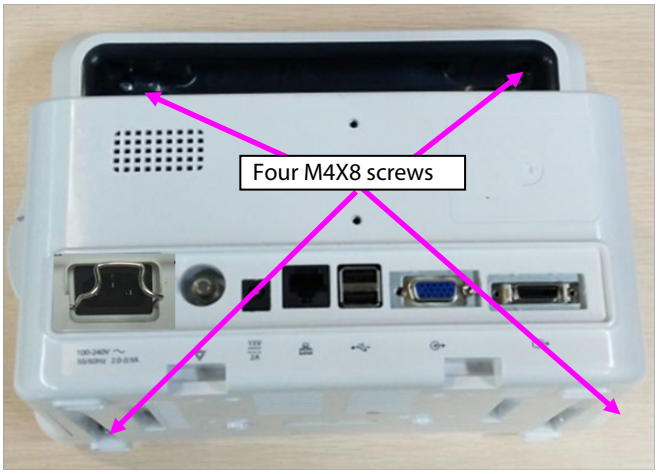
⚠WARNING

- **Before disassembly, be sure to eliminate static electricity. When removing some parts with the electrostatic sensitive marks, wear protective devices such as antistatic wristband or gloves to avoid parts damage or human injury.**
- **Properly connect and route the cables and wires when reassembling the monitor to avoid short circuits.**
- **Use specified screws to reassemble the monitor. If improper screws are tightened by force, the monitor may be damaged and the screws or part may fall off during use, causing unpredictable equipment damage or human injury.**
- **Follow the correct sequence to disassemble the monitor.**
- **Place the removed parts by category to facilitate reassembly. Do not drop, contaminate or lose them.**
- **To reassemble the monitor, first install the assemblies, and then the main unit. Carefully route the cables.**
- **Make sure that the waterproof materials are properly applied during reassembly.**

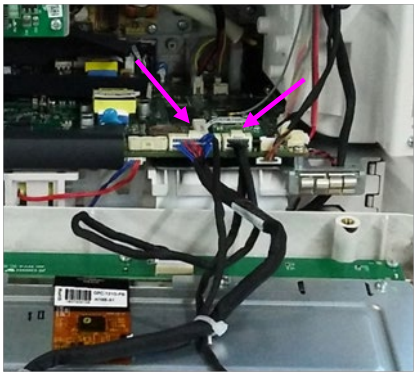
6.3 Guardian/GT Series Main Unit Disassembly

6.3.1 Disassembling Front/Rear Housing Assembly of Main Unit

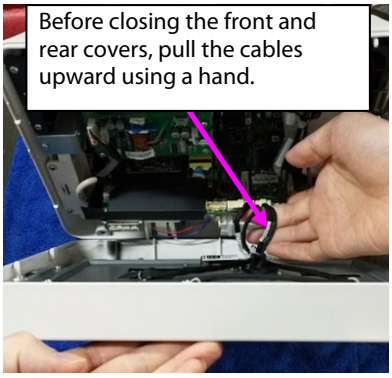
1. Use a Phillips screwdriver to loosen four M4X8 screws.



2. Open the front and rear housings, and remove the display screen connection cable and keypad connection cable.

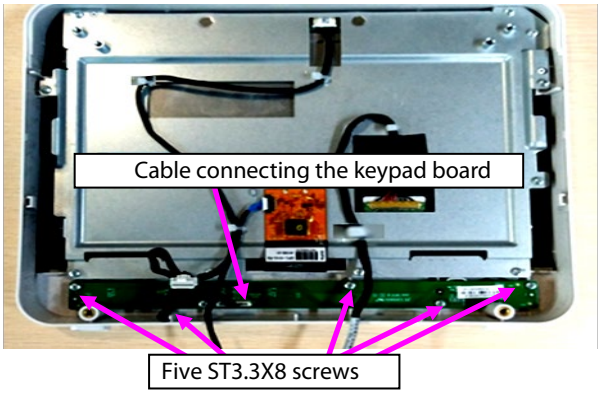


Note: During reassembly, close the front and rear covers and pull the cables upward using a hand.



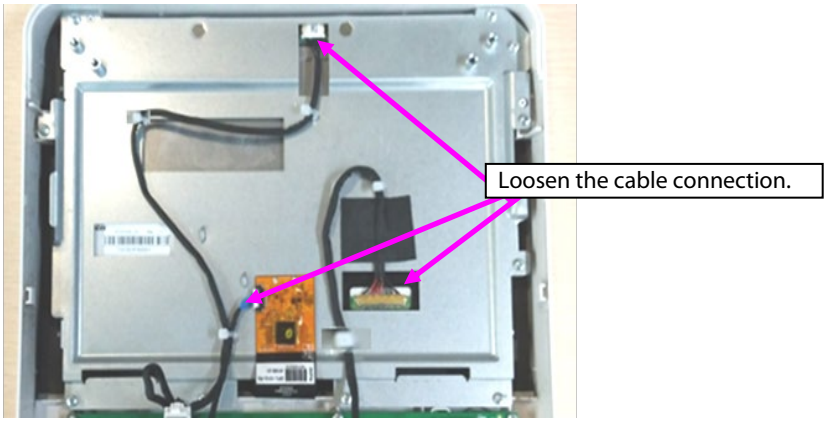
6.3.2 Disassembling Keypad Board

1. Remove the cable connecting the keypad board.
2. Loosen the five ST3.3X8 screws as shown in the figure, and take the keypad board out.



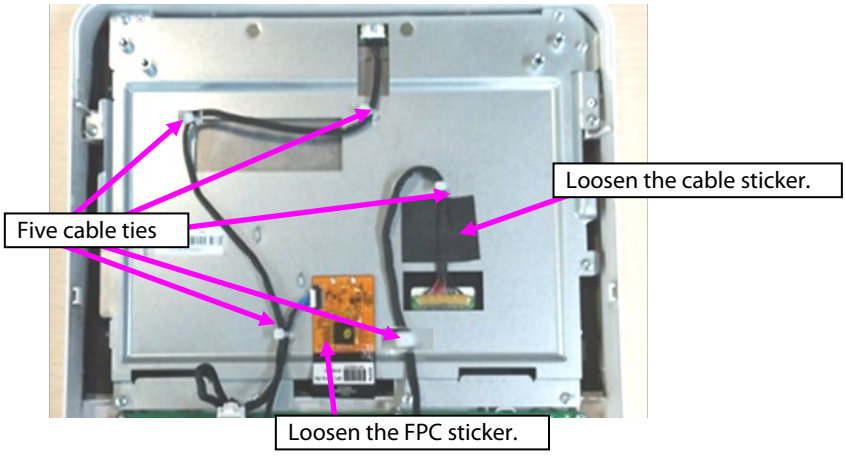
6.3.3 Disassembling Display Screen and Alarm Lamp

1. Remove the cables connecting with the touch screen, display screen, and alarm lamp.

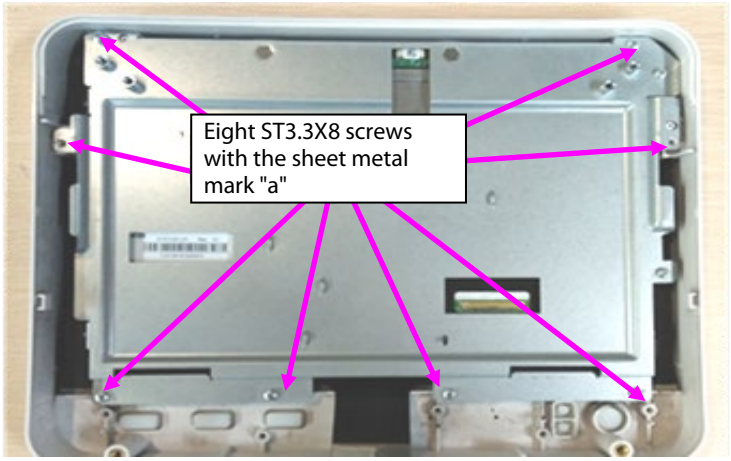


2. Remove the five cable ties from cables, and loosen the cables stuck to the sheet metal.

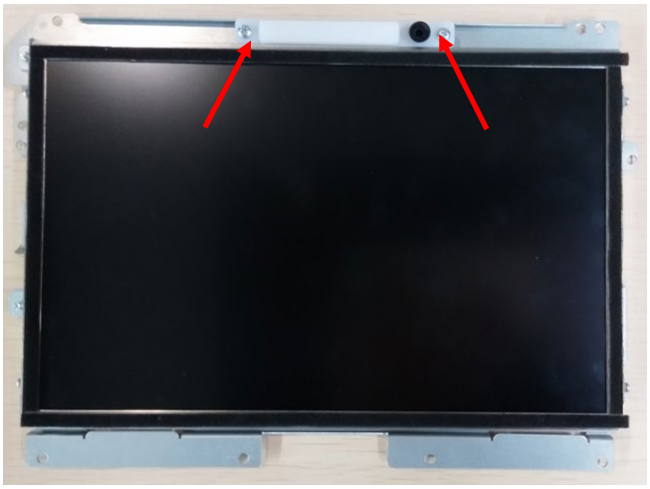
3. Loosen the sticker connecting the touch screen PFC with the sheet metal.



4. Loosen the eight ST3.3X8 screws as shown in the figure, and remove the display assembly.

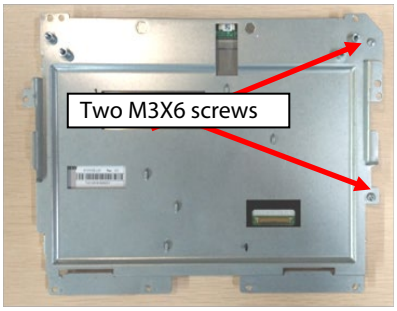


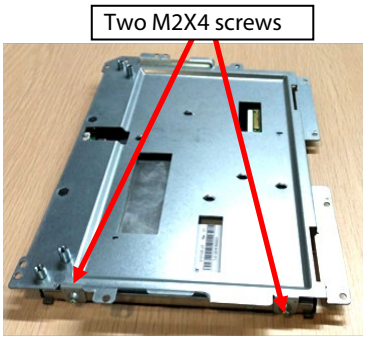
5. Remove the two M3X6 screws, and remove the alarm lamp board.

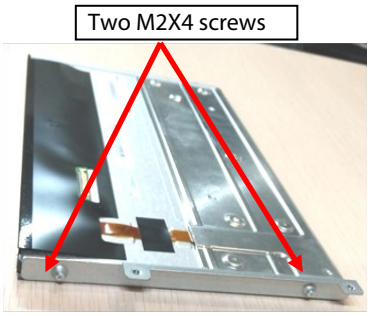


6. Loosen the two M3X6 screws with the mark "b" on the right top of the sheet metal.
7. Loosen the two M2X4 screws at the left side of the sheet metal.

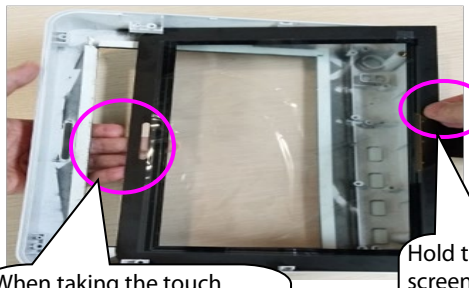
8. Loosen the two M2X4 screws at the left side of the sheet metal, and remove the display screen.

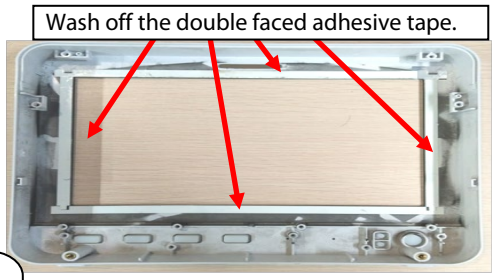




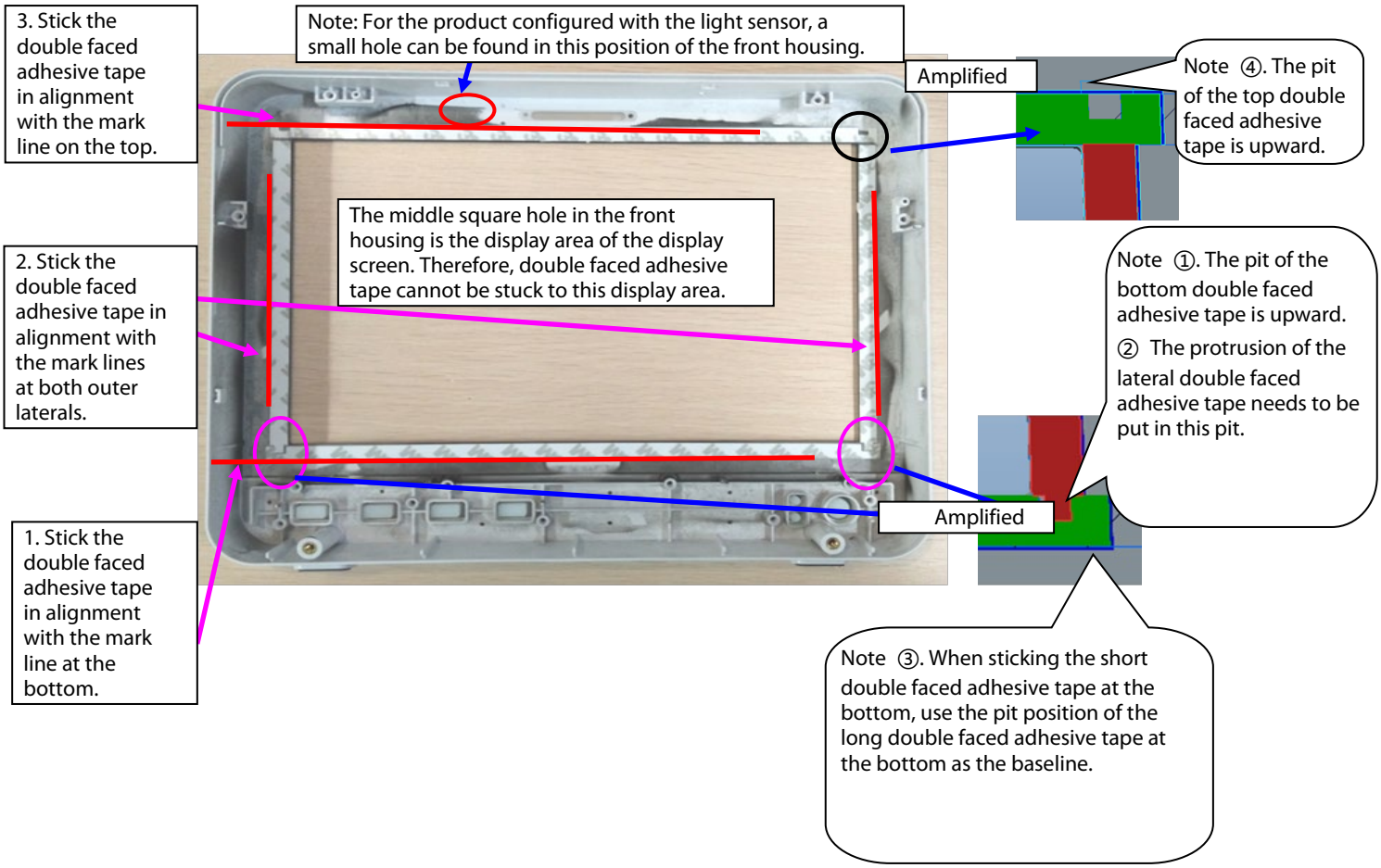


9. Loosen the sticker connecting the touch screen with the front housing, and then tilt and take the touch screen out.

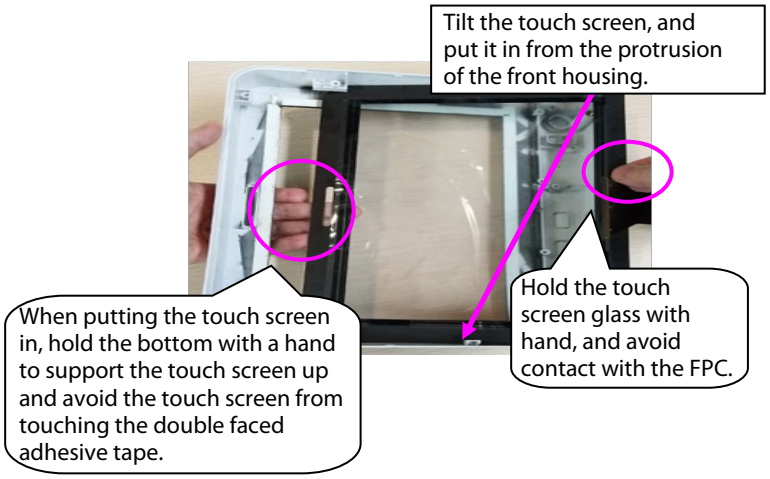




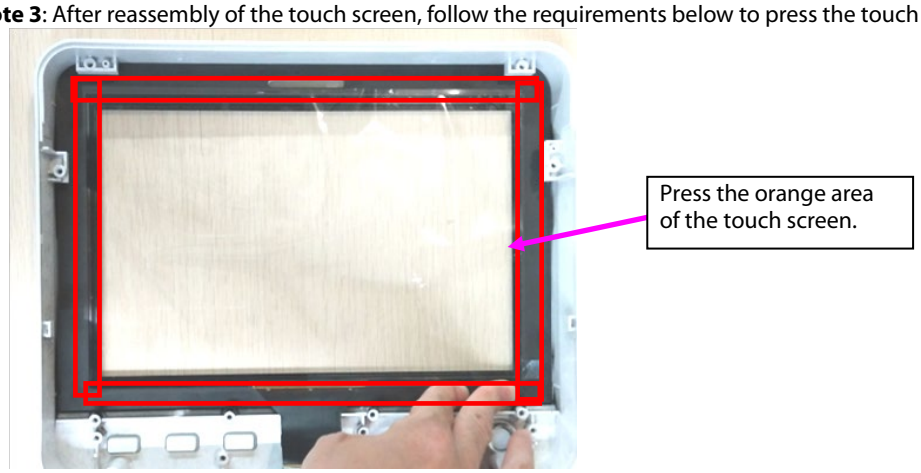
Note 1: During reassembly of the touch screen rubber stripe, follow the requirements below.



Note 2: During reassembly of the touch screen, follow the requirements below.

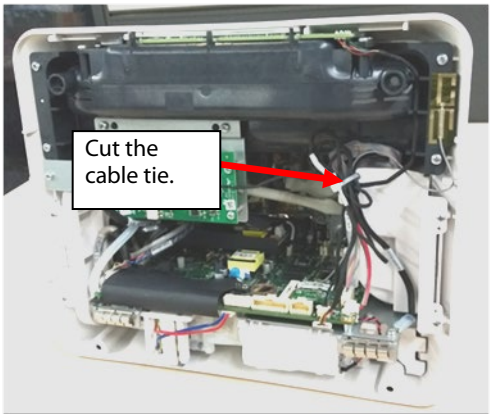


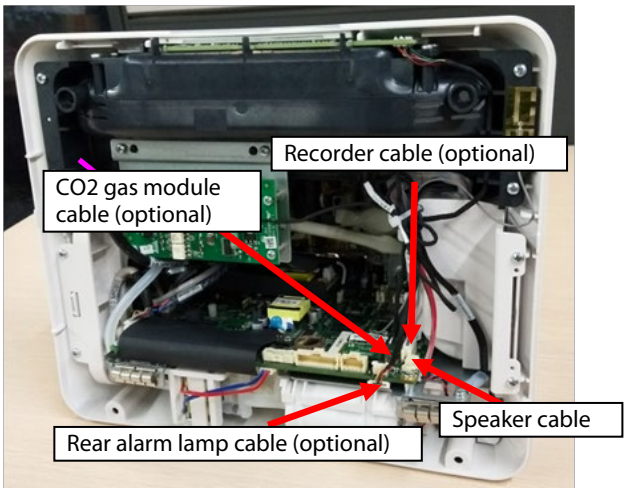
Note 3: After reassembly of the touch screen, follow the requirements below to press the touch screen.



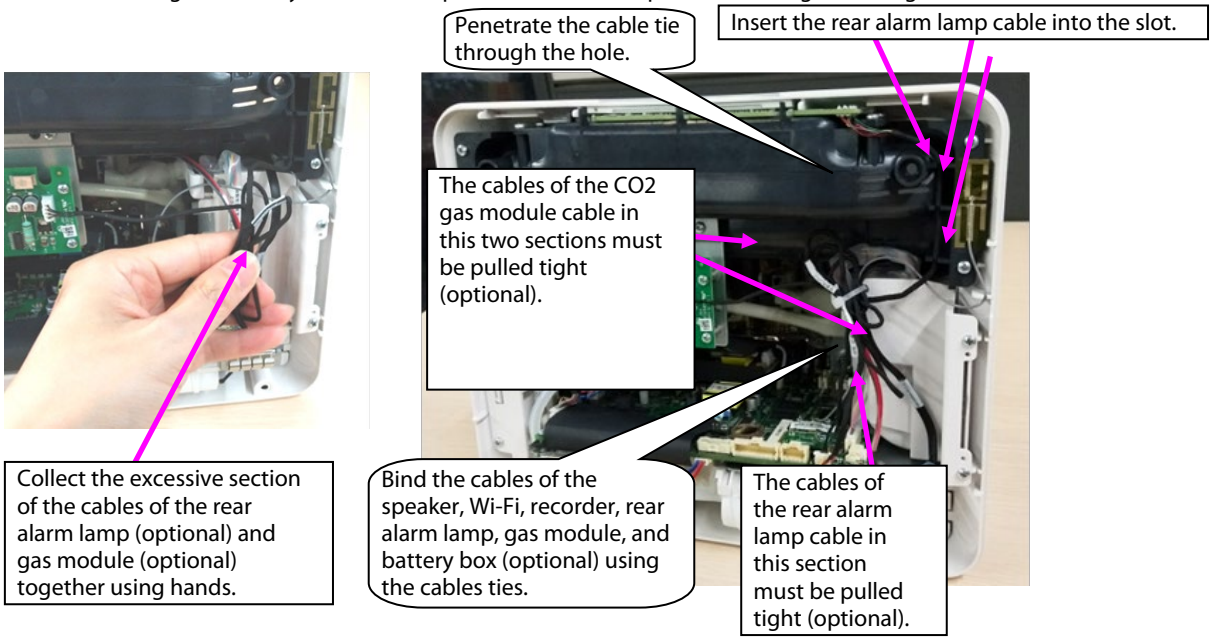
6.3.4 Disassembling Wi-Fi and Parameter Interface Board

1. Remove cables.

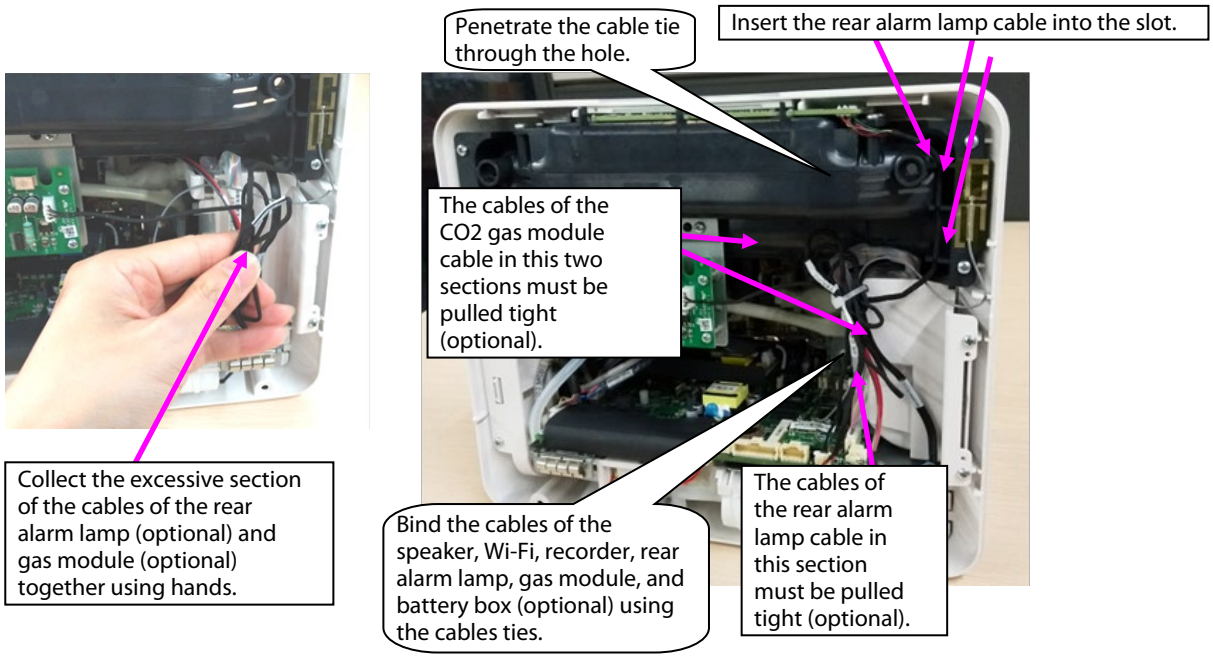




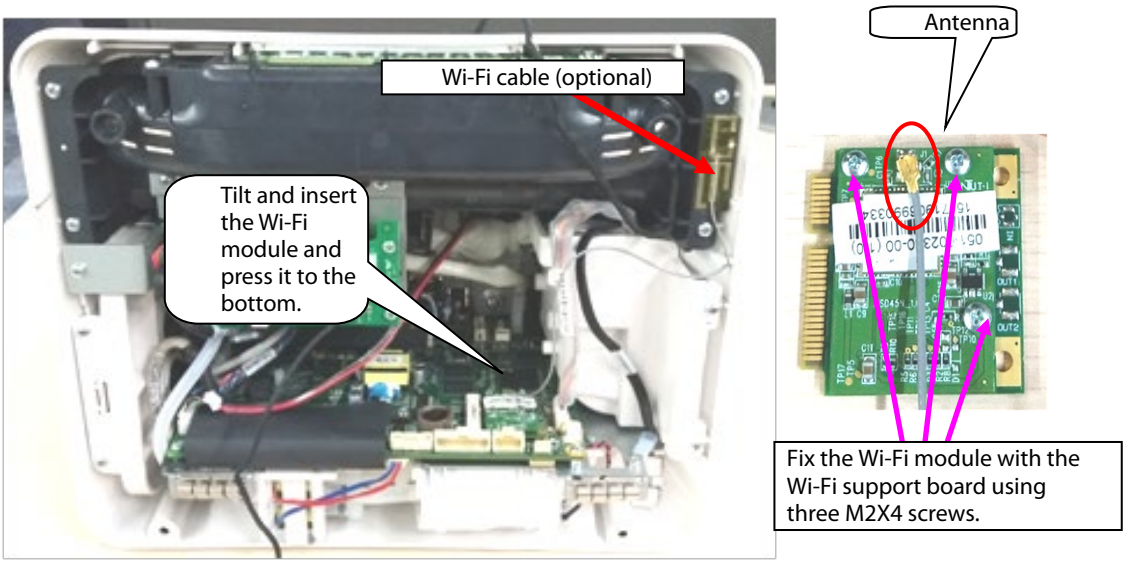
Note: During reassembly, follow the requirements below to perform binding and fixing.



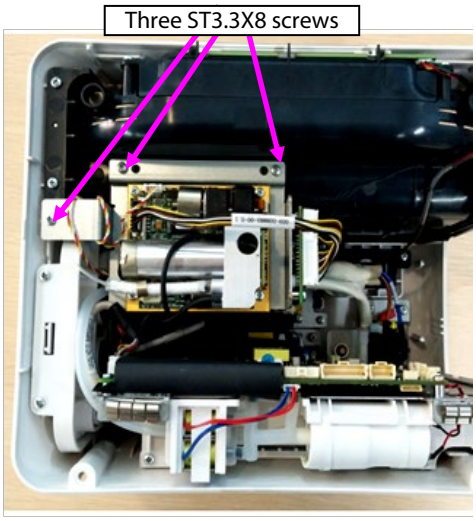
2. Disassemble the Wi-Fi module (if any).
   a. Take the Wi-Fi module out.
   b. Remove the Wi-Fi cable.
   c. Loosen the three M2X4 screws fixing the Wi-Fi module and Wi-Fi support board, and take the Wi-Fi module and Wi-Fi support board out.

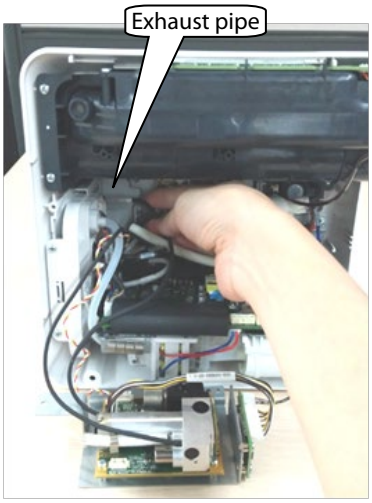


Note: During reassembly of the Wi-Fi module, follow the requirements below.

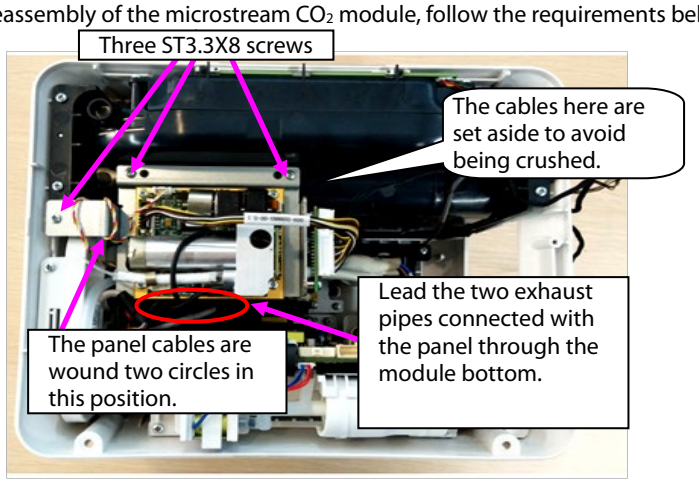


3. Disassemble the microstream CO_2 module (if any).
   a. Loosen three ST3.3X8 cross recessed pan head tapping screws using the screwdriver, and take the module out.
   b. Remove the connection between the microstream module exhaust pipe and panel exhaust pipe.

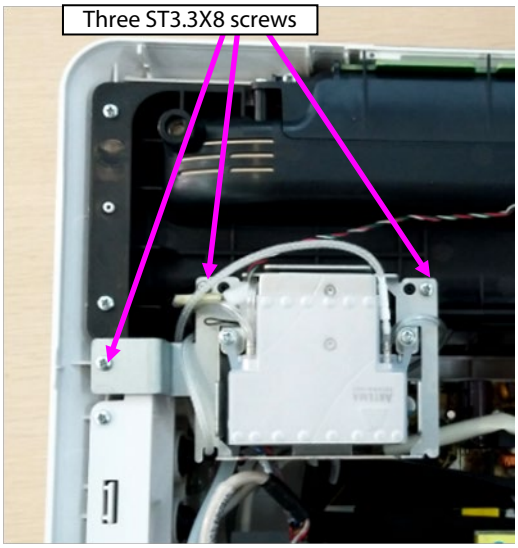


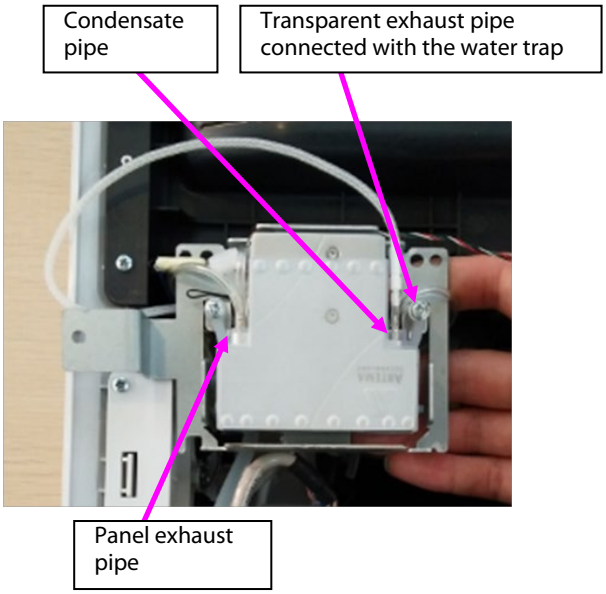


Note: During reassembly of the microstream CO_2 module, follow the requirements below.

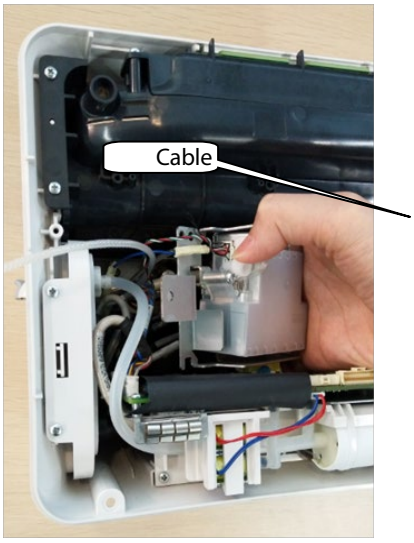


4. Disassemble the sidestream CO_2 module (if any).
   a. Loosen three ST3.3X8 cross recessed pan head tapping screws using the screwdriver, and loosen the pipe of the sidestream CO2.

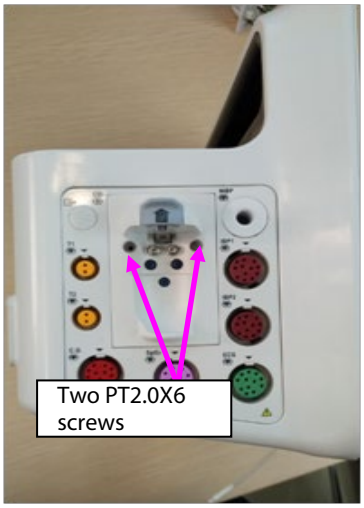


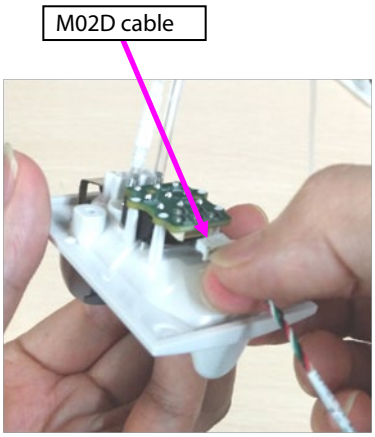


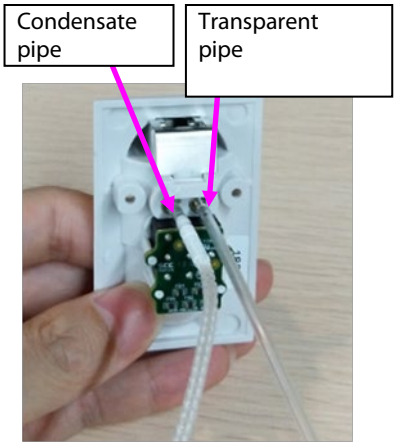
b. Loosen the cable connection, and take the module out.



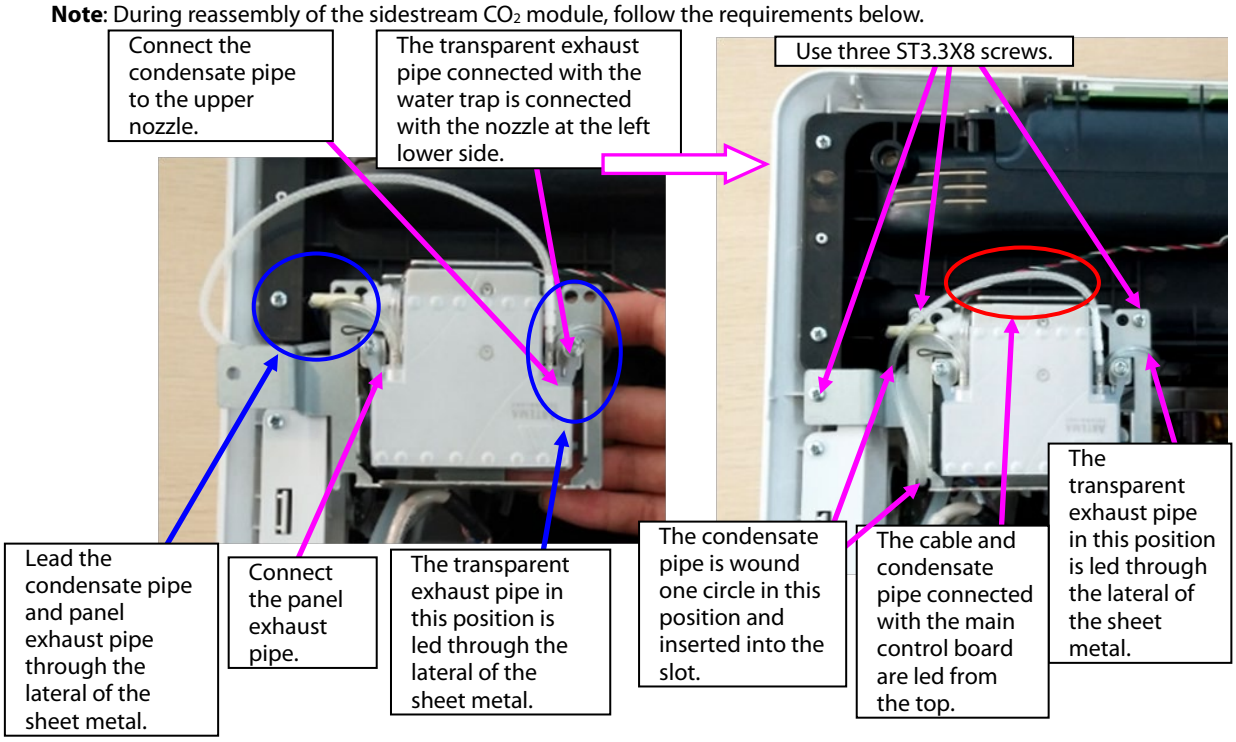
c. Remove the two PT2.0X6 screws on the panel water trap, and take the water trap out.



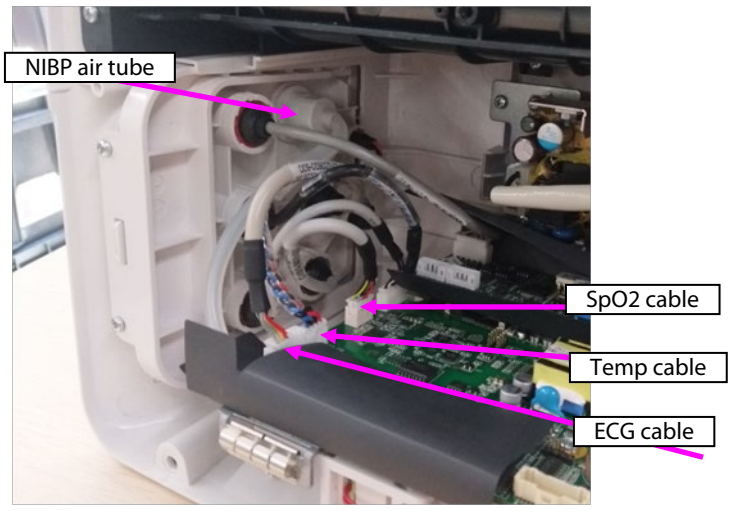


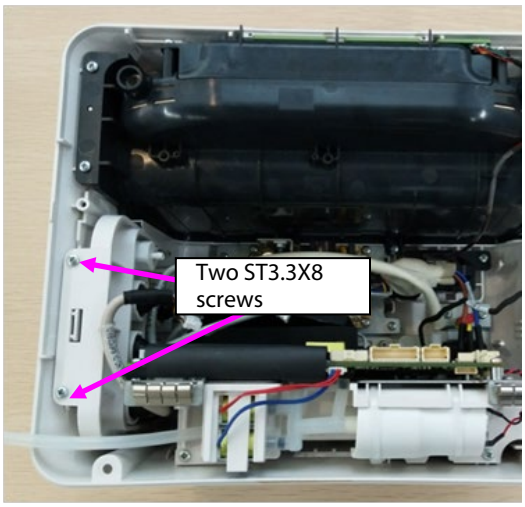


Note: During reassembly of the sidestream CO_2 module, follow the requirements below.

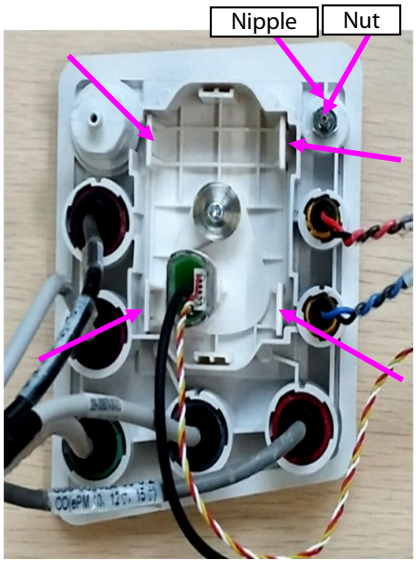


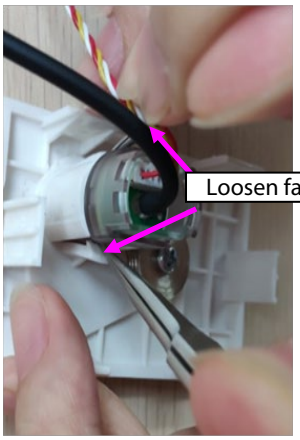
5. Remove the panel cable from the main control board, and remove the NIBP air tube.
6. Remove two ST3.3X8 cross recessed pan head tapping screws using the screwdriver, and take the panel fixing pin and panel assembly out.



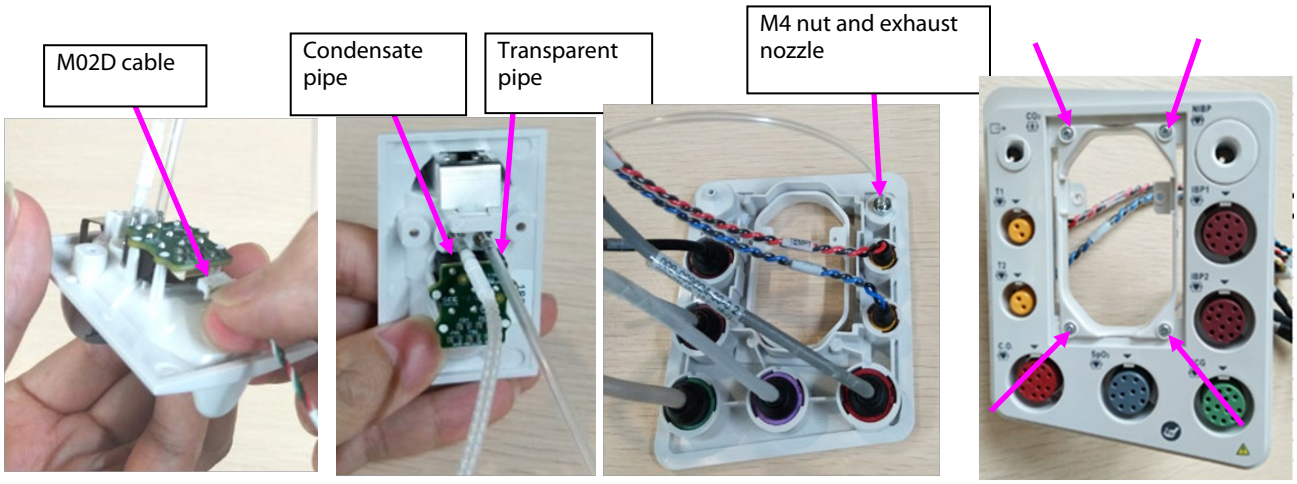


7. Disassemble the microstream water trap of microstream module (if any).
   a. Use pliers or tweezers to jack the fastener on the panel, and take the microstream water trap seat out.
   b. Loosen the M5 screw from the upper right corner of the panel, and take the exhaust nozzle out.
   c. Use tweezers to loosen the fastener on the water trap seat, and take the microstream connector out.





8. Disassemble the sidestream water trap of sidestream module (if any).
   a. Remove the cable or pipe from the water trap.
   b. Remove the exhaust pipe from the panel, loosen the M4 screw on the exhaust nozzle, and take the nozzle out.
   c. Loosen the M5 screw/M4 nut on the panel, and take the exhaust nozzle out.
   d. Loosen the four PT2.0X6 screws on the panel, and take the bracket of the sidestream water trap out.



9. Disassemble the panel cable.
   a. According to the figure, rotate different parameter cables counter-clockwise, and remove them.
   b. Take the spring out.

Diagram (with no CO2 gas module)

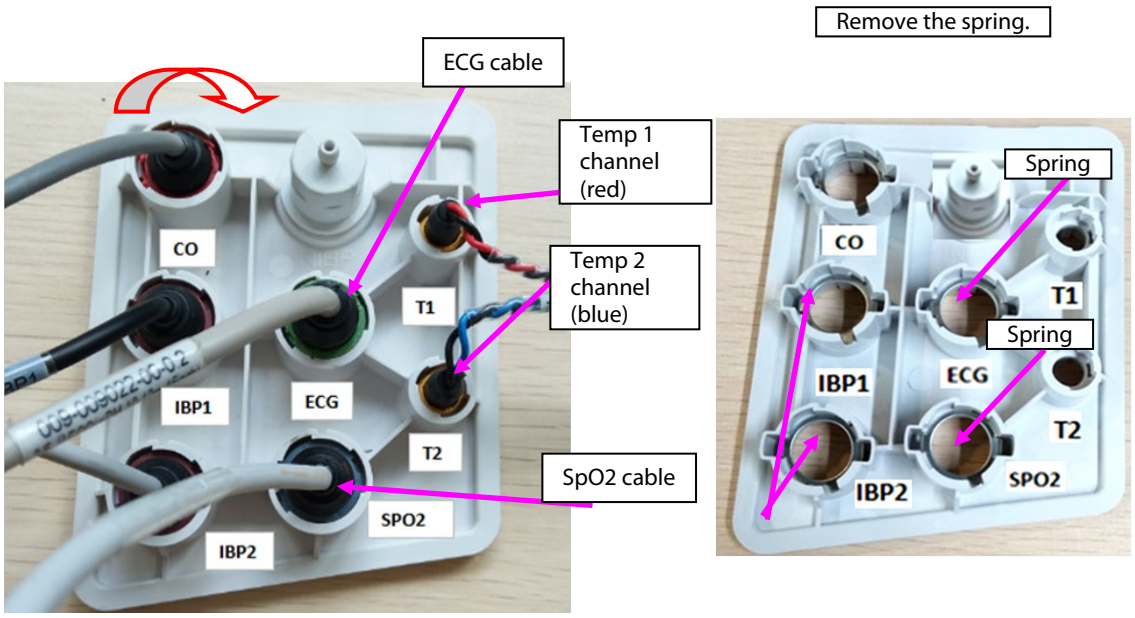
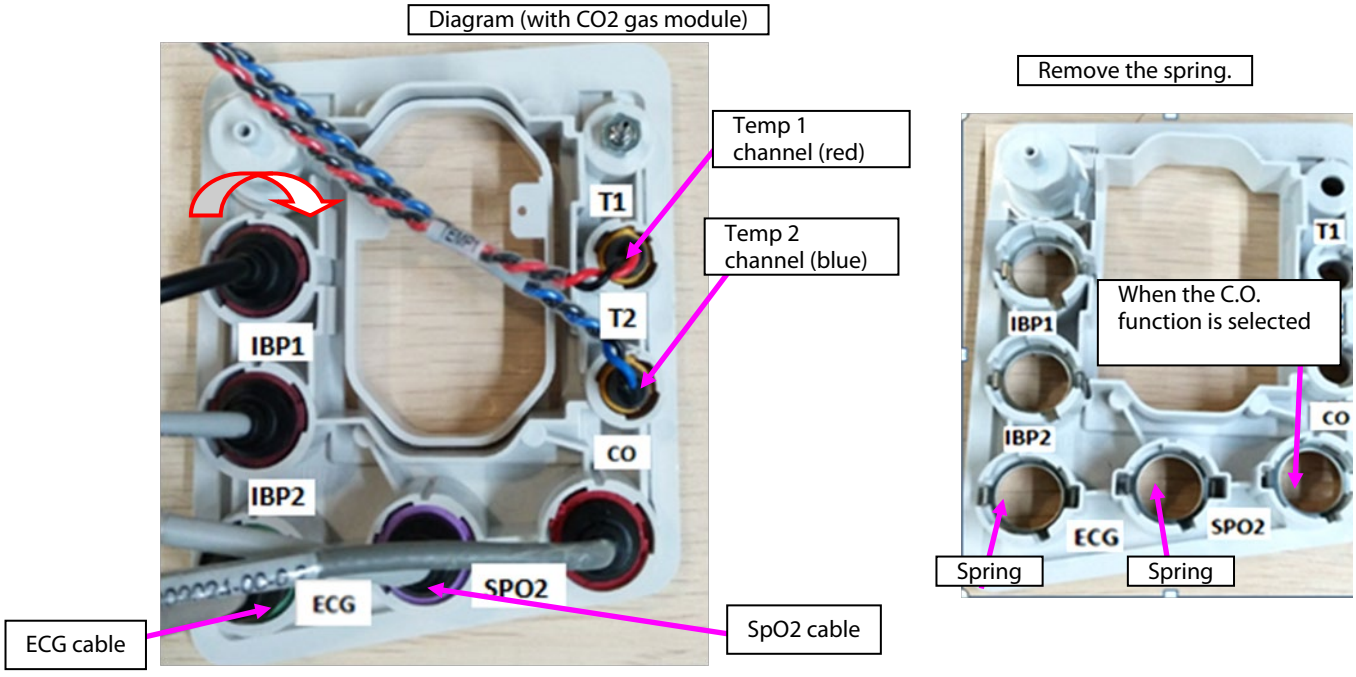
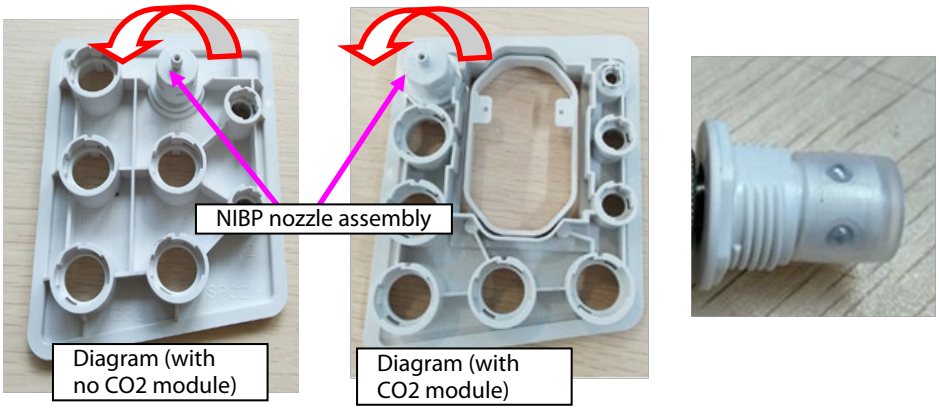


Diagram (with CO2 gas module)



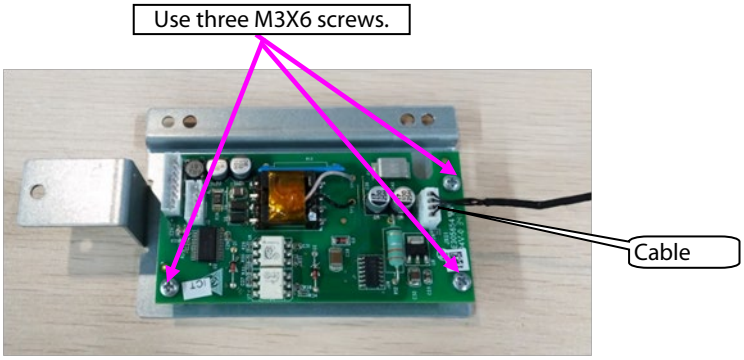
Note: During reassembly, follow the requirements below to perform cable assembling.

10. Disassemble the NIBP nozzle: Rotate the NIBP nozzle counter-clockwise, and disassemble the NIBP nozzle.

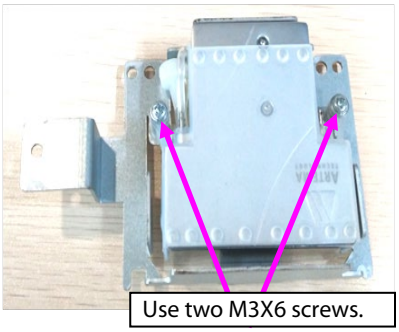


6.3.5 Disassembling Gas Module

1. When microstream CO_2 is configured:
   a. Remove the cable connecting the microstream CO2 module with the transition board.
   b. Remove the cable connecting the main control board.
   c. Loosen the four M3X6 screws as shown in the figure, and take the microstream CO2 module out.
   d. Loosen the three M3X6 screws, and take the transition board out.

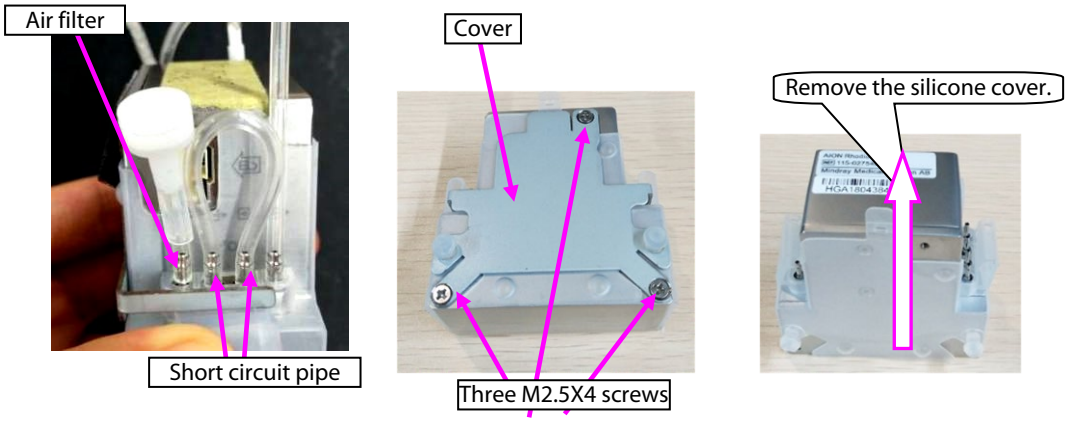


2. When sidestream CO_2 is configured:
   a. Loosen the two M3X6 screws as shown in the figure, and take the sidestream gas module out.



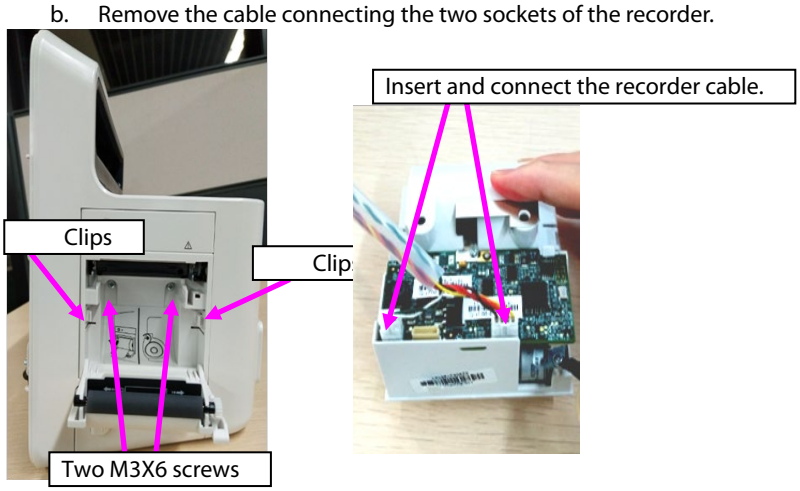
   b. Take the air filter and short circuit pipe out.
   c. Loosen the three M2.5X4 countersunk screws, and take the cover out.

d. Remove the silicone cover.

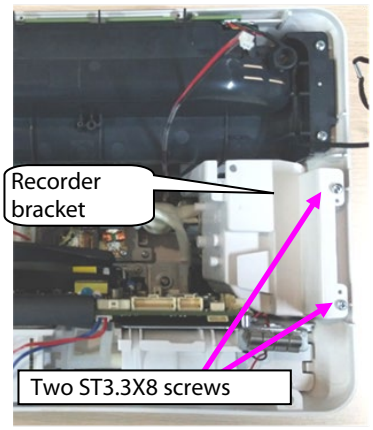


6.3.6 Disassembling Recorder/Recorder Bracket

1. Disassemble the recorder (if any):
   a. Loosen the two M3X6 screws fixing the recorder, loosen the two fasteners of the recorder, and take the recorder out.
   b. Remove the cable connecting the two sockets of the recorder.

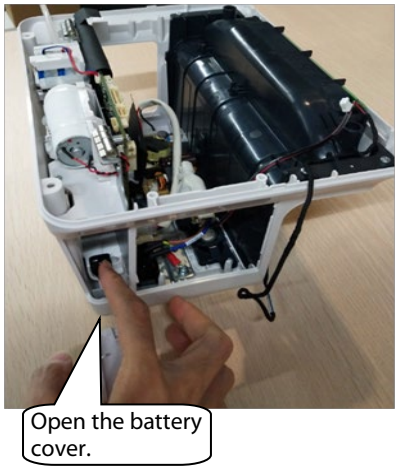


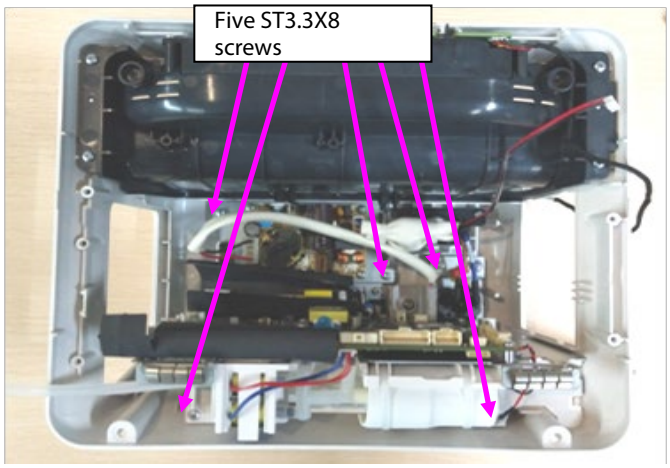
2. Take the recorder bracket out: Loosen the two ST3.3X8 screws on the recorder bracket, and take the recorder bracket out.



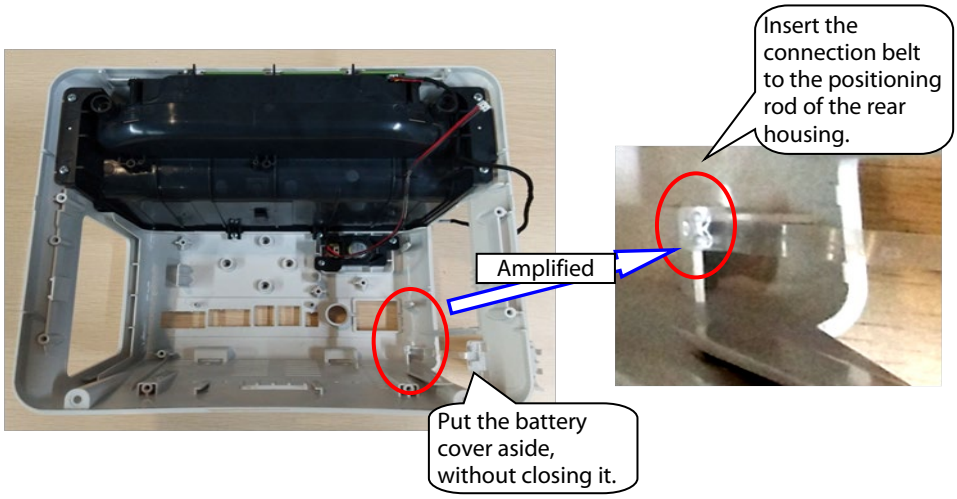
6.3.7 Disassembling Main Frame Assembly

1. Loosen the battery cover.
2. Loosen the five ST3.3X8 screws as shown in the figure, and remove the main support assembly.

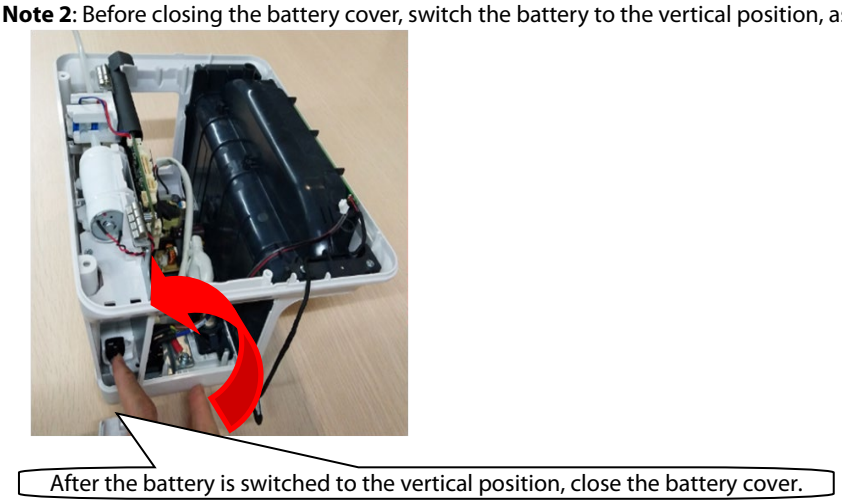




Note 1: Before reassembling the main support assembly, insert the connection belt of the battery cover to the positioning rod of the rear housing, as shown in the following figure.

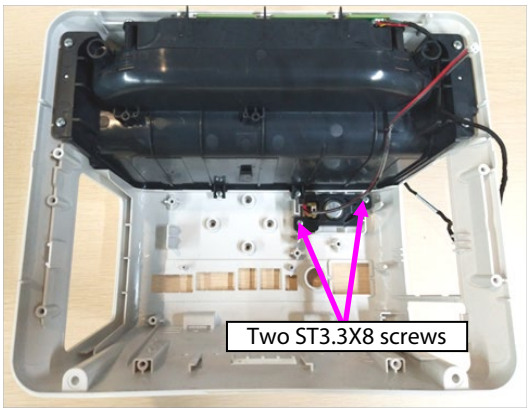


Note 2: Before closing the battery cover, switch the battery to the vertical position, as shown in the figure.



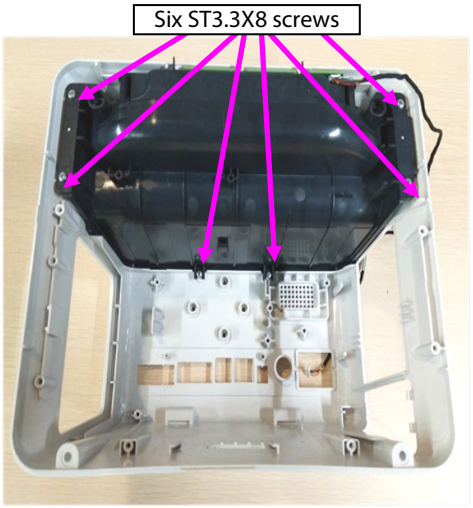
6.3.8 Disassembling Speaker

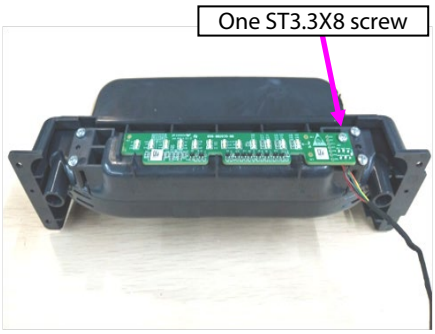
1. Loosen the two ST3.3X8 screws of the speaker assembly as shown in the figure, and take the speaker component out.



6.3.9 Disassembling Rear Alarm Lamp (if any)

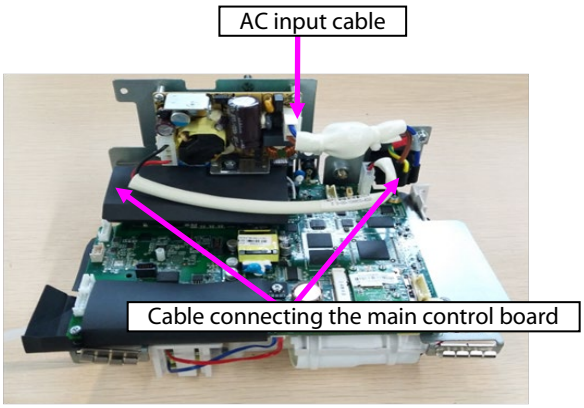
1. Loosen the six ST3.3X8 screws on the cover assembly as shown in the figure, and take the top cover assembly out.
2. Loosen the one ST3.3X8 screw on the rear alarm lamp as shown in the figure, and take the rear alarm lamp out.

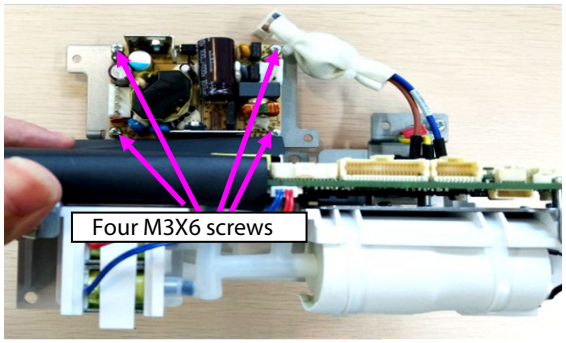




6.3.10 Disassembling Power Module

1. Remove the AC input cable, and remove the cable connecting the power module with the main control board out.
2. Loosen the four M3X6 screws of the power module, and take the power module out.

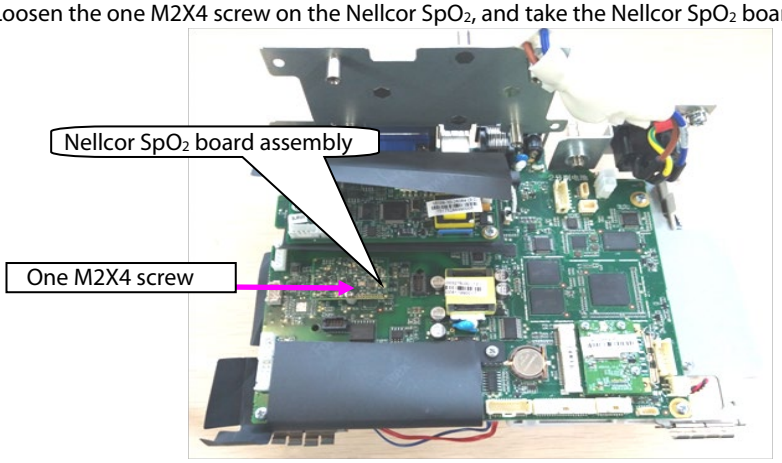




6.3.11 Disassembling Nellcor/Masimo SpO_2 Module (if any)

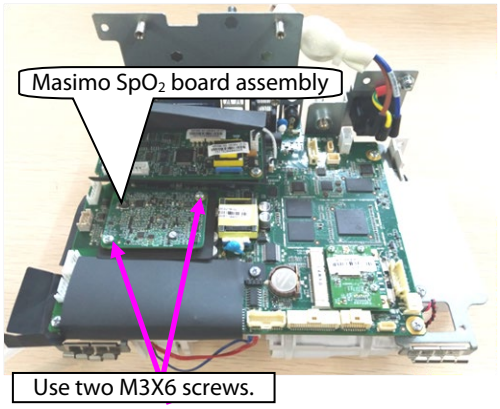
1. When Nellcor SpO_2 is configured:

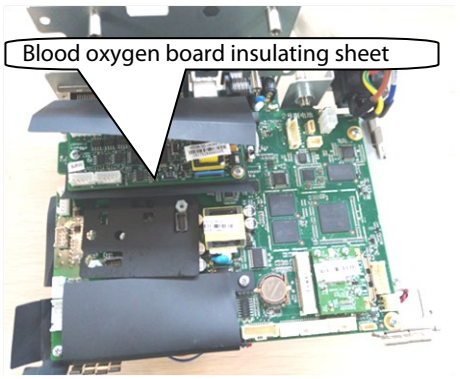
Loosen the one M2X4 screw on the Nellcor SpO_2, and take the Nellcor SpO_2 board out.



2. When Masimo SpO_2 is configured:

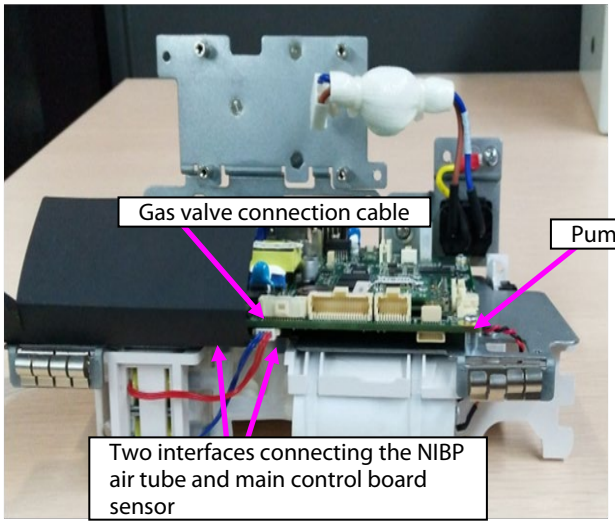
Loosen the two M3X6 screws on the Masimo SpO_2, and take the Masimo SpO_2 board and insulation sheet out.



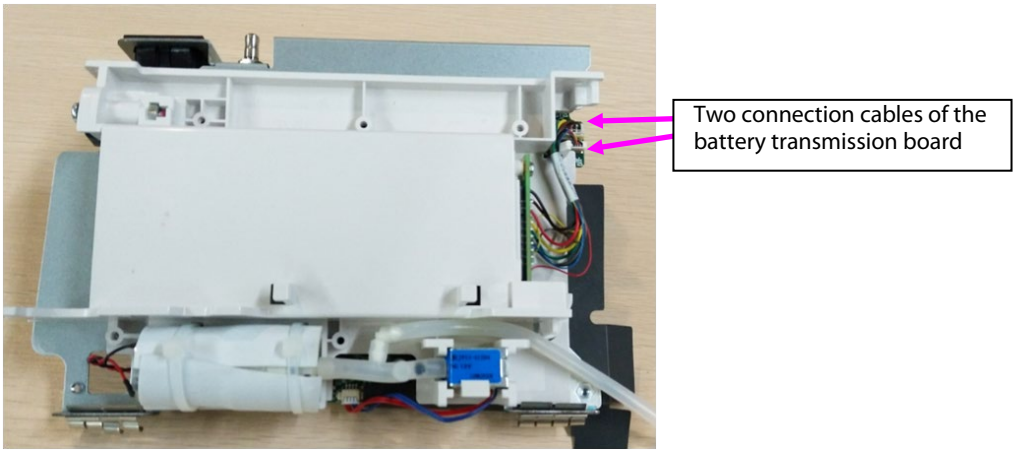


6.3.12 Disassembling Main Control Board

1. Remove the pump/valve connection cables from the main control board.
2. Take the two interfaces of the NIBP air tube from the main control board sensor.

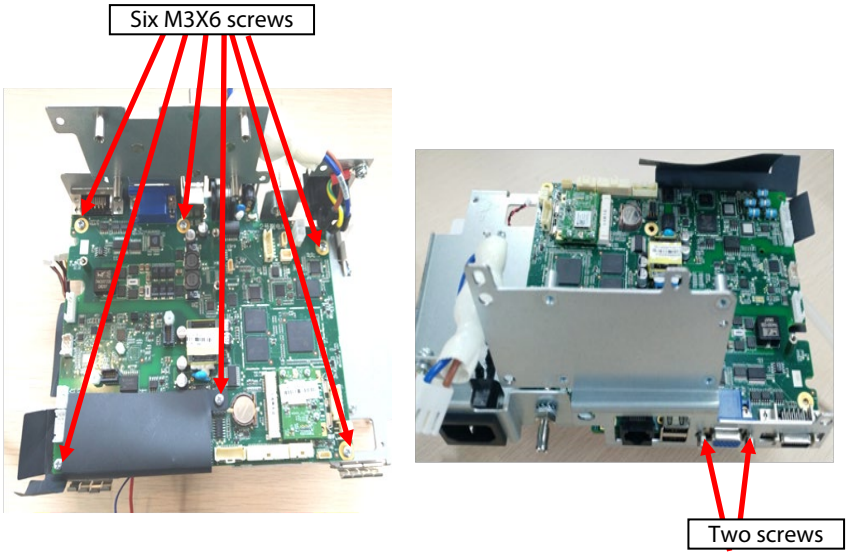


3. Remove the connection cable of the battery transition board from the main control board.

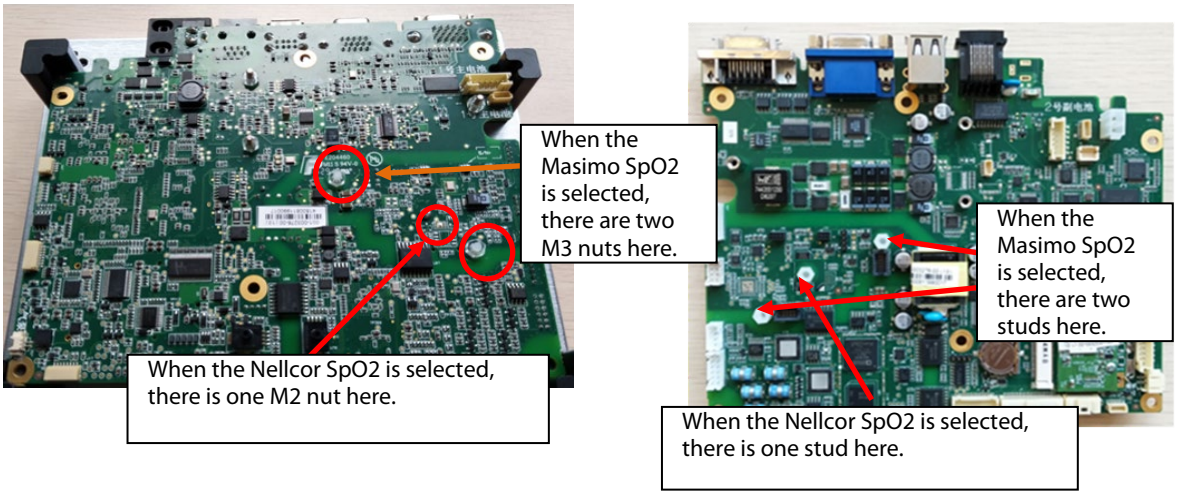


4. Loosen the six M3X6 screws from the main support.

5. Loosen the two screws on the rear of the main support sheet metal, and take the main control board out.

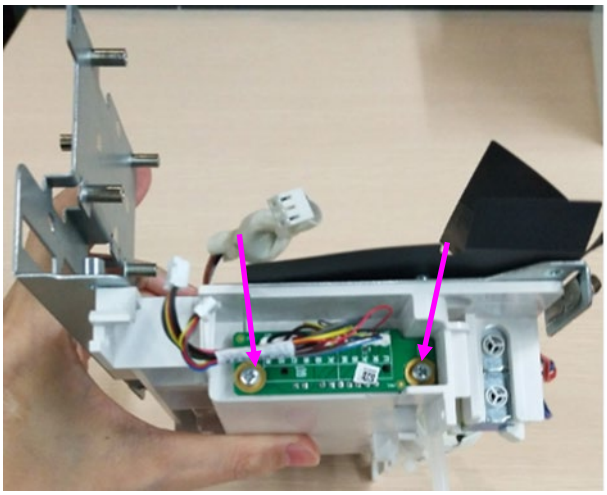


6. As shown in the following figure, loosen the nuts or screws on the rear of the main control board, and take the studs out.

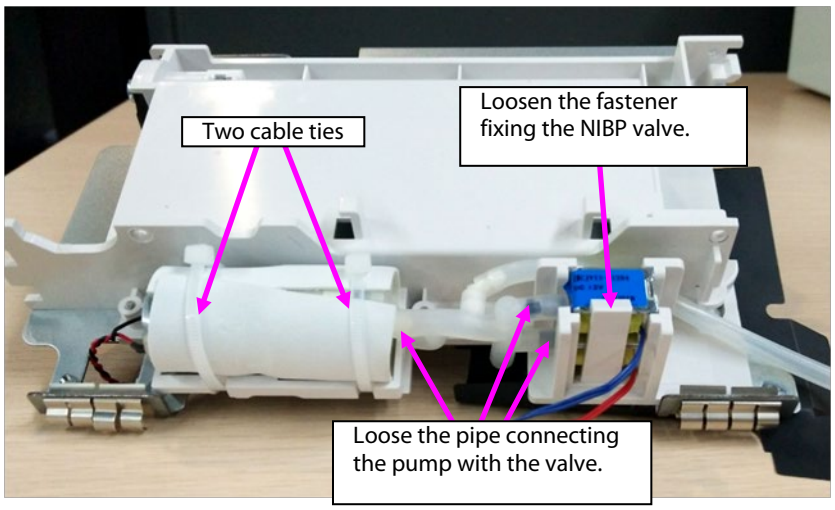


6.3.13 Disassembling Power Transition Board and NIBP Pump/Valve

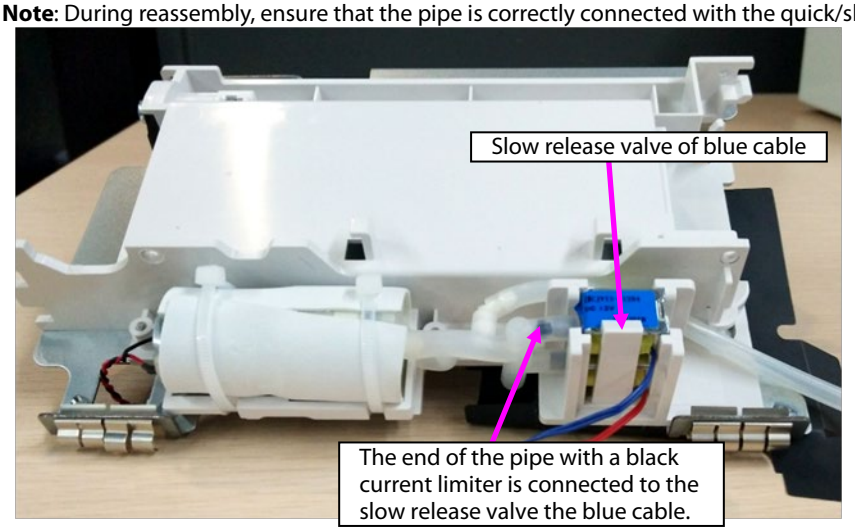
1. As shown in the following figure, loosen the two ST3.3X8 screws, and take the battery transition board out.



2. Loosen the pipe connecting the NIBP pump/valve.
3. Loosen the fastener fixing the NIBP valve, and take the NIBP valve out.
4. Loosen the two cable ties fixing the NIBP pump, and take the NIBP pump out.



Note: During reassembly, ensure that the pipe is correctly connected with the quick/slow release valve.

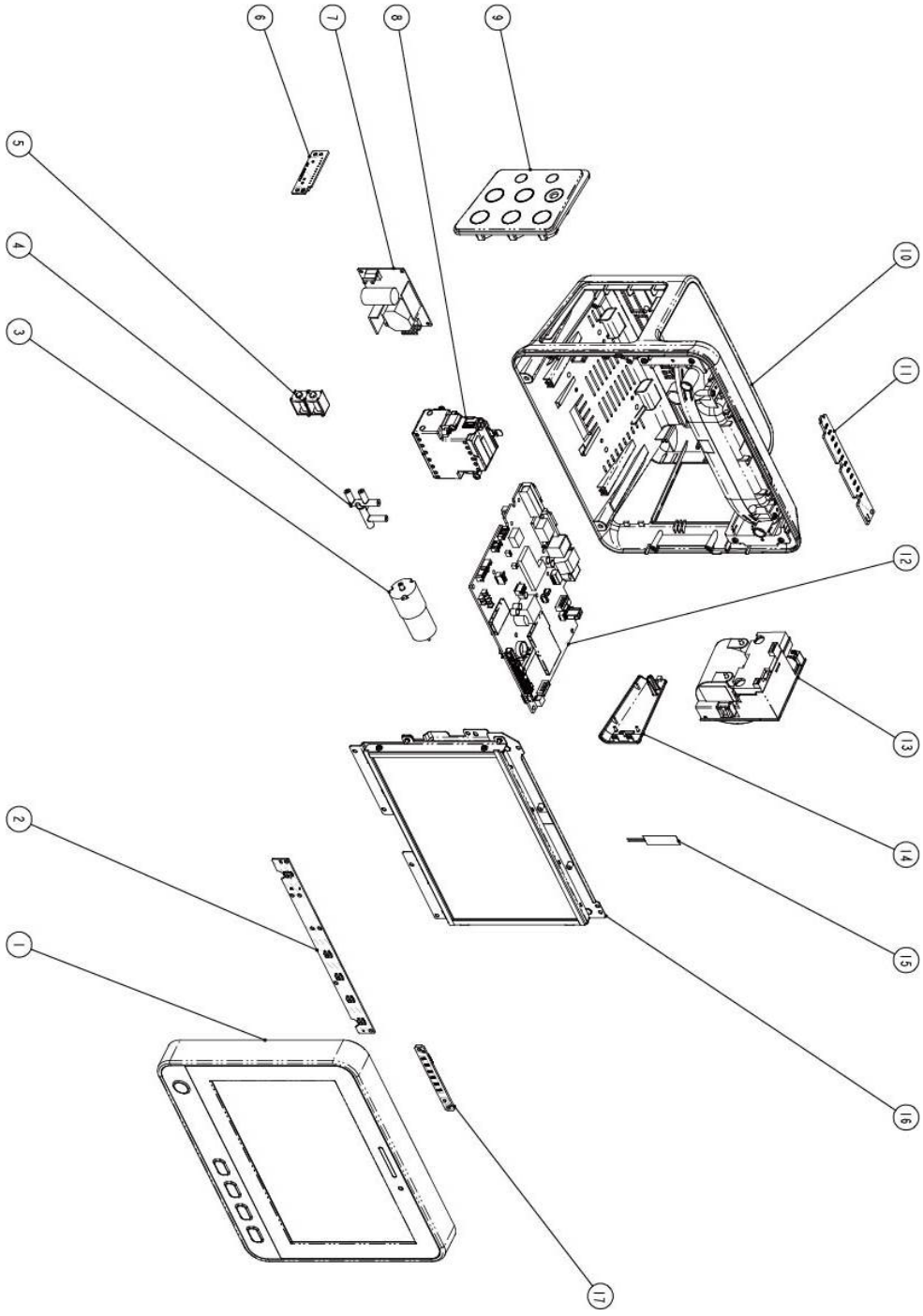


7 Parts

This chapter lists the exploded views and material codes of the parts including the monitor's main unit, SMR and parameter module. It helps the engineer to identify the parts during disassembly of the patient monitor and spare parts replacement.

7.1 Guardian/GT Series Parts

Exploded View



Parts List

No.	Name and Specification	Qty	Material Code
1	Front cover&screen FRU(Guardian/GT Series/All)	1	115-091132-00
2	10'Funtion key PCBA FRU	1	115-067901-00
3	NIBP Pump FRU	1	115-059743-00
4	NIBP internal tube FRU	1	115-059737-00
5	NIBP Valve FRU	1	115-059742-00
6	5600mAh Battery Connector PCBA FRU	1	115-059753-00
	2600&4500mAh Battery Connector PCBA FRU	1	115-059754-00
7	AC-DC Power Module FRU	1	115-059799-00
8	M02D module wire(Guardian/GT Series type C)	1	009-009042-00
	Microstream CO2 Kit FRU	1	115-059956-00
9	Parameter Panel Kit（Support CO2）	1	115-059952-00
	Parameter Panel Kit（Not Support CO2）	1	115-059951-00
10	10'Back Housing FRU(Integrated Type)	1	115-065379-00
	10'Back Housing FRU(Integrated Type)	1	115-065380-00
11	Back alarm lamp FRU(Integrated Type)	1	115-059941-00
12	3/5 lead/OEM spo2 Main Board FRU(ALL)	1	115-059987-00
13	Recorder kit FRU	1	115-059807-00
14	10/12'Battery door FRU(Integrated Type)	1	115-059971-00
15	10'Innolux display screen FRU	1	115-059828-00
16	Front alarm lamp FRU	1	115-059746-00
	Front alarm lamp FRU(Light sensor)	1	115-059747-00

A Electrical Safety Inspection

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

All tests can be performed using commercially available safety analyzer test equipment. These procedures assume the use of a 601PROXL International Safety Analyzer or equivalent safety analyzer. Other popular testers complying with IEC 60601-1 used in Europe and North America 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

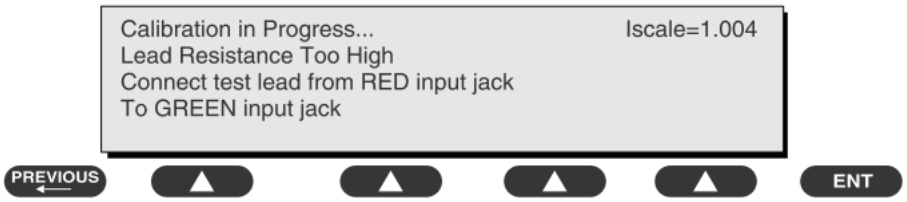
A.4 Protective Earth Resistance

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

3. First select the test current that will be used for performing the Protective Earth Resistance test by pressing AMPERES (SOFT KEY 3).
4. Connect the test lead(s) between the RED input jack and the GREEN input jack.
5. 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.



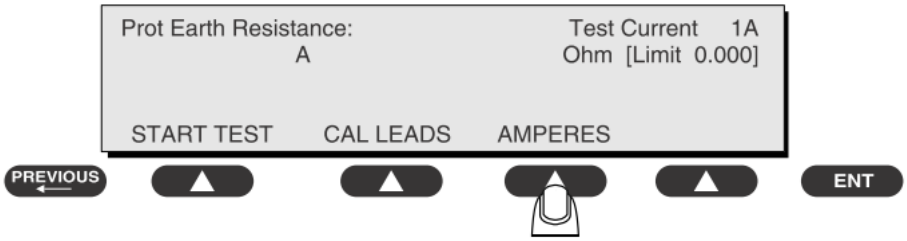
If the calibration fails, the previously stored readings will be used until a passing calibration has occurred.

⚠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

6. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet.
7. Attach the 601PRO RED input lead to the device's Protective Earth terminal or an exposed metal area.
8. Press shortcut key 3. The Protective Earth Resistance test is displayed.
9. 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.



10. Press START TEST to start the test. The test current is applied while resistance and current readings are taken. This takes approximately 5 seconds.
11. 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 limit, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

Limits = 0.2 Ω Maximum

A.5 Earth Leakage Test

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

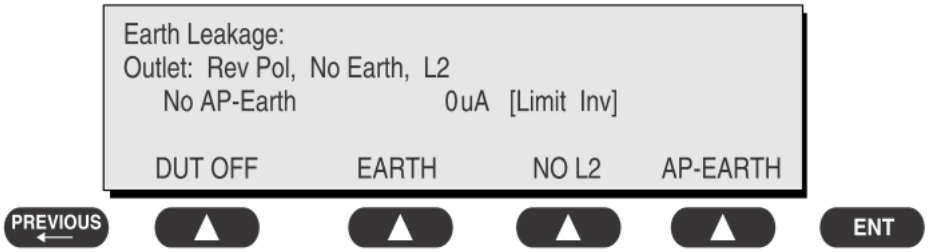
Leakage current is measured the following ways:

- 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

12. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet, and turn on the device.
13. Attach the device's applied parts to the 601PRO applied part terminals if applicable.
14. 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.

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

In Case of Failure

- Check if there are any broken parts of the enclosure. Replace any defective parts.
- 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.
- Use another probe to confirm if the failure is caused by the 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 IEC60601-1,

- 5mA in Normal Condition
- 10mA in Single Fault Condition

A.6 Patient Leakage Current

Patient leakage currents are measured between a selected applied part and mains earth. All measurements have a true RMS 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

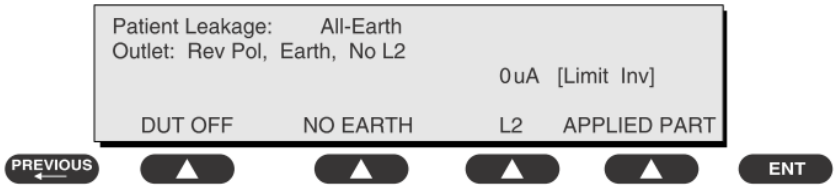
- Normal Polarity, L2 Open, Outlet ON Reversed Polarity, Outlet ON
- Reversed Polarity, Earth Open, Outlet ON Reversed Polarity, L2 Open, Outlet ON

⚠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

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



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

In Case of Failure

- Check if there are any broken parts of the enclosure. Replace any defective parts.
- 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.
- Use another probe to confirm if the failure is caused by the console.
- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

For CF applied parts

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

For BF applied parts

- 100µA in Normal Condition
- 500µA 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.

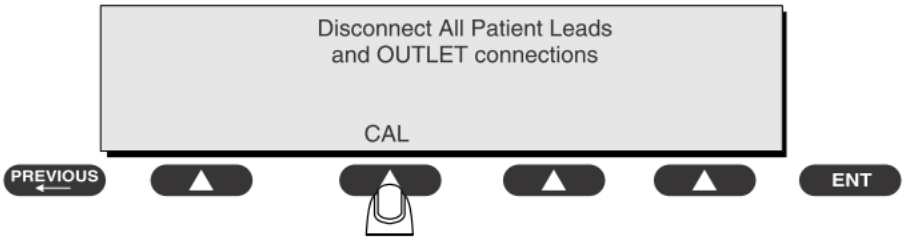
The following outlet conditions apply when performing the Mains on Applied Part test.

- Normal Polarity;
- Reversed Polarity

Preparation

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

22. Disconnect ALL patient leads, test leads, and DUT outlet connections.
23. 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.

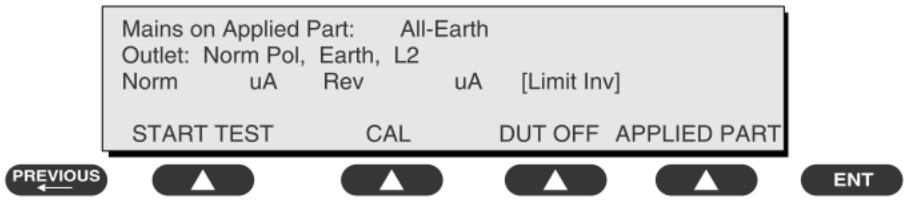
24. When the calibration is finished, the Mains on Applied Part test will reappear.

⚠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

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



29. Select the desired outlet configuration and applied part to test using the appropriate SOFT KEYS:
30. Press START TEST (SOFT KEY 1) to begin the test.
31. 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 if there are any broken parts of the enclosure. Replace any defective parts.
- 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.
- Use another probe to confirm if the failure is caused by the 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

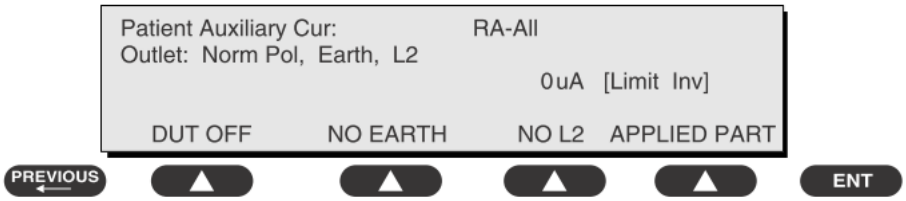
- For CF  applied parts: 50 µA
- For BF  applied parts: 5000 µA

A.8 Patient Auxiliary Current

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

Preparation

32. From the MAIN MENU, or with the outlet unpowered, plug the DUT into the 601PRO front panel outlet, and turn on the device.
33. Attach the patient leads to the 601PRO ECG jacks.
34. Define the Lead Types from the View Settings Option (refer to: Lead Type Definitions in Section 5 of this chapter).
35. 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.



36. Press SOFT KEYS 1-4 to select leakage tests

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

In Case of Failure

- Check if there are any broken parts of the enclosure. Replace any defective parts.
- 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.
- Use another probe to confirm if the failure is caused by the console.
- If the leakage current measurement tests fail on a new unit and if situation can not be corrected, submit a Safety Failure Report to document the system problem. Remove unit from operation.
- If all else fails, stop using and inform the Customer Service Engineer for analysis and disposal.

LIMITS

For CF  applied parts,

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

For BF  applied parts,

- 100µA in Normal Condition
- 500µA in Single Fault Condition

ELECTRICAL SAFETY INSPECTION FORM

Overall assessment:

Scheduled inspection	Test item: 1, 2, 3, 4, 5, 6, 7, 8

Location:				**Technician:**	
Equipment:				**Control Number:**	
Manufacturer:		**Model:**		**SN:**	
Measurement equipment /SN:				**Date of Calibration:**	
INSPECTION AND TESTING				**Pass/Fail**	**Limit**
1	Power Cord Plug				
2	Device Enclosure and Accessories				
3	Device Labeling				
4	Protective Earth Resistance		Ω		Max 0.2 Ω
5	Earth Leakage	Normal condition(NC)	____μA		Max: NC: 5mA SFC: 10mA
		Single Fault condition(SFC)	____μA		
6	Patient Leakage Current	Normal condition(NC)	□BF____μA		Max: CF applied part: NC:10μA, SFC: 50μA BF applied part: NC:100μA, SFC: 500μA
			□CF____μA		
		Single Fault condition(SFC)	□BF____μA		
			□CF____μA		
7	Mains on Applied Part Leakage		□BF____μA		Max: CF applied part: 50μA BF applied part: 5000μA
			□CF____μA		
8	Patient Auxiliary Current	Normal condition(NC)	□BF____μA		Max: CF applied part: NC:10μA, SFC: 50μA BF applied part: NC:100μA, SFC: 500μA
			□CF____μA		
		Single Fault condition(SFC)	□BF____μA		
			□CF____μA		

Name/ Signature: _____ Date:_____

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

Location:	**Technician:**

Equipment:				**Control Number:**	
Manufacturer:		**Model:**		**SN:**	
Measurement equipment /SN:				**Date of Calibration:**	
INSPECTION AND TESTING				**Pass/Fail**	**Limit**
1	Power Cord Plug				
2	Device Enclosure and Accessories				
3	Device Labeling				
4	Protective Earth Resistance		Ω		Max 0.2 Ω
5	Earth Leakage	Normal condition(NC)	____μA		Max: NC: 5mA SFC: 10mA
		Single Fault condition(SFC)	____μA		
6	Patient Leakage Current	Normal condition(NC)	□BF____μA		Max: CF applied part: NC:10μA, SFC: 50μA BF applied part: NC:100μA, SFC: 500μA
			□CF____μA		
		Single Fault condition(SFC)	□BF____μA		
			□CF____μA		
7	Mains on Applied Part Leakage		□BF____μA		Max: CF applied part: 50μA BF applied part: 5000μA
			□CF____μA		
8	Patient Auxiliary Current	Normal condition(NC)	□BF____μA		Max: CF applied part: NC:10μA, SFC: 50μA BF applied part: NC:100μA, SFC: 500μA
			□CF____μA		
		Single Fault condition(SFC)	□BF____μA		
			□CF____μA		

Name/ Signature: _____ Date:_____

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