# **T1 Patient Monitor**

**Service Manual** 

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• Federal Law (USA) restricts this device to sale by or on the order of a physician.

#### NOTE

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

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- Others not caused by instrument or part itself.

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1. Obtain a return authorization.

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#### 2. Freight policy

The customer is responsible for freight charges when this product is shipped to Mindray 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.

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# Preface

# **Manual Purpose**

This manual provides detailed information about the assembly, disassembly, and testing 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 a necessary for proper equipment maintenance and will help eliminate equipment damage and personnel injury.

# **Intended Audience**

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

Contact your local Mindray 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. The passwords are listed below:

- User maintenance: 888888
- Configuration mode: 315666

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

#### FOR YOUR NOTES

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# **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.

#### 1.1.1 Warnings

#### WARNING

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

#### 1.1.2 Cautions

#### CAUTION

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

#### 1.1.3 Notes

#### NOTE

• Refer to Operation Manual for detailed operation and other information.

# **1.2 Equipment Symbols**

⊙/Ò	ON/OFF for a part of equipment		Direct current
<b>-</b> +	Battery indicator	墨	Network connector
MP1 ↔	Multifunctional connector	SN	Serial number
1	Unlocking	$\bigtriangledown$	Equipotentiality
$\rightarrow$	VGA connector	0° 75 − ↓ / /	Direction and angle of rotation
u → ↓ →	Lock; tighten	$\sim$	Alternating current
[m]	Date of Manufacture		Symbol for "MANUFACTURER"
$\leftrightarrow$	Input/output	● <del>· · · ·</del> · · · · · · · · · · · · · · ·	USB connector
IPX1	Protected against vertically falling water drops per IEC 60529	IPX2	Protected against vertically falling water drops when ENCLOSURE tilted up to 15° per IEC 60529
H <b>W</b> H	Defibrillation-proof Type CF applied part	l 🖈 ŀ	Defibrillation-proof Type BF applied part
	General warning sign	8	Refer to instruction manual/booklet
ETL CLASSIFIED	The presence of this label indicates the machine was certified by ETL with the statement:		
<b>A</b>	Conforms to AAMI Std ES 60601-1, IEC 60601-1-6, IEC Std 60601-1-8, IEC Std 60601-2-25, IEC Std 60601-2-25, IEC Std 60601-2-27, IEC Std 80601-2-27,		
	80601-2-56, ISO Std 80601-2-61		, 2 30, 130 310 000 1 2 33, 130 310
Intertek	Certified to CSA Std C22.2 NO. 60601-1,	NO. 60601-1-6, NO. 6060	1-1-8, NO. 60601-2-25, NO. 60601-2-27,
3191955	NO. 60601-2-34, NO. 60601-2-49, NO. 80601-2-30, NO. 80601-2-55, NO. 80601-2-56, NO. 80601-2-61		

#### FOR YOUR NOTES

## **2.1 Introduction**

The T1 is intended to be used for monitoring, displaying, reviewing, storing and transferring of multiple physiological parameters including ECG, respiration (Resp), temperature (Temp), SpO<sub>2</sub>, pulse rate (PR), non-invasive blood pressure (NIBP), invasive blood pressure (IBP), and carbon dioxide (CO<sub>2</sub>) of the patient.

## 2.2 T1 Main Unit

### 2.2.1 Front View



1. Alarm lamp

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

- 2. Display Screen
- 3. Ambient light sensor

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

- 4. External power supply indicator
  - On: when external DC power supply is connected.
  - Off: when external DC power supply is not connected.
- 5. Battery indicator
  - On: when the battery is installed and the external DC power supply is connected.

- Off: when no battery is installed, or the installed battery is malfunctioning, or no external DC power supply is connected when the patient monitor is power off.
- Flash: when the patient monitor is operating on battery power.
- 6. Power On/Off Switch
  - When the monitor is off, pressing this switch turns the patient monitor on.
  - When the monitor is on, pressing and holding this switch turns the monitor off.

An indicator is built into this switch. It turns on when the patient monitor is on and turns off when the patient monitor is off.

- 7. Lock/unlock switch:
  - When the T1 is not connected with the external display, sliding this switch to the right locks/unlocks the touch screen.
  - When the T1 is connected to the external display, sliding this switch to the right switches screen display between T1 and the external display.

### 2.2.2 Left View



- 1. External DC power supply connector
- 2. Main unit multi-pin connector: Connects T1 to the T1 handle or the T1 Docking Station.
- 3. Infrared filter: used for communication between the T1 and host monitor.
- 4. Contacts: connect power to the T1 from the T1 docking station or the host monitor.

#### NOTE

• To ensure proper operation, clean the infrared filter and contacts regularly. When cleaning the contacts, wipe them with cotton, dampened with alcohol.

## 2.2.3 Right View



- 1. Connector for Temp probe 1
- 2. Connector for Temp probe 2
- 3. Connector for IBP cable
- 4. Connector for NIBP cuff
- 5. Connector for ECG cable
- 6. Connector for SpO<sub>2</sub> cable
- 7. Multifunctional connector: outputs analog and defibrillation synchronization signals.
- 8. Speaker

### 2.2.4 Bottom View



- 1. Latch: locks T1 when T1 is in use with a Passport 12M or 17M patient monitor, T1 docking station, or T1 handle. Pressing here releases T1 so that you can take it out from the host monitor, T1 docking station, or T1 handle.
- 2. Battery door

## 2.3 T1 handle

## 2.3.1 Left View



- 1. Release button: pressing this button releases the T1 handle from the T1 docking station.
- 2. T1 handle multi-pin connector 1: connects the T1 handle and T1 docking station.

## 2.3.2 Right View



- 1. T1 handle multi-pin connector 2: connects the T1 handle and T1.
- 2. Infrared filter: used for communication between the T1 handle and external parameter module.
- 3. Contact: power input connector of the external parameter module.

# 2.4 T1 Docking Station

## 2.4.1 Left View



- 1. Symbol: indicates the direction and angle that T1 docking station can rotate when T1 docking station is fixed onto a transverse or a vertical rod.
- 2. USB connector: connects USB devices, including the USB drive, mouse and keyboard.
- 3. Network connector: a standard RJ45 connector that connects the patient monitor to the CMS or CIS.

### 2.4.2 Right View



- 1. T1 docking station multi-pin connector: power input and communication connector of T1
- 2. Connection status indicator: it is on when the T1 is properly connected to the T1 docking station.
- 3. External power supply indicator: it is on when the external AC power supply is connected.

#### 2.4.3 Rear View



- 1. AC power input
- 2. Equipotential grounding terminal
- 3. VGA connector: connects the external display
- 4. External device connector: connects T1 to the host monitor through the T1 docking station cable (P/N 009-003591-00 (1 meter) or P/N 009-003592-00 (4 meters)).
- 5. USB connector: connects USB devices, including the USB drive, mouse and keyboard.
- 6. Network connector: a standard RJ45 connector that connects the patient monitor to the CMS or CIS.

## 2.5 System Structure



A complete solution consists of four parts: T1, T1 Docking Station, T1 Handle, and an external display, wherein:

- T1 is the core of the entire solution, providing functions of displaying, controlling, parameter measurement and printing. It supports:
  - basic measurements of parameters including ECG, SpO<sub>2</sub>, Temp, NIBP, and IBP.
  - connection with CO<sub>2</sub> modules, providing display and storage of measurement results and alarm functions.
  - working as a module of Passport 12M and 17M patient monitors.
  - installation in a T1 docking station to support patient transferring and data transmission to the docking station.
  - output analog signals (ECG/IBP) and Sync Defib signals.
  - DC power source and smart battery.
  - Wi-Fi communication.
- T1 Docking Station can be fixed to the bedside for the docking of T1. It provides power for T1 or charging of the installed battery. It can be connected to an external display, mouse, keypad, USB flash memory, Passport 12M or 17M patient monitors, and a wired network.
- **T1 Handle** connects T1 to the external CO<sub>2</sub> module. It is portable and convenient for patient transferring in hospitals.

### 2.5.1 Main Unit

The following figure shows the main unit architecture of T1.



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

#### 2.5.1.1 Main Board

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

- Implementing display drive, audio drive, Wi-Fi drive, and touch screen drive;
- Implementing network communication, data storage, serial port extension, button scanning, and DC/DC conversion;
- Controlling power on/off, alarm indicating lamp, backlight, and fan;
- Managing multi-parameter subsystem and smart battery;
- Detecting whether the battery is installed;
- Exchanging data with the infrared communication backboard;
- Controlling the power supply to peripheral devices, such as screen backlight, digital drive of the screen, and Wi-Fi; turning off these devices individually or switching them into low power consumption mode.

#### 2.5.1.2 Multi-parameter Board

The multi-parameter board provides the following functions:

- ECG and Resp measurement
- SpO<sub>2</sub> measurement
- NIBP measurement
- 2-channel TEMP measurement
- 2-channel IBP measurement
- Isolating the parameter modules, except NIBP, from the earth
- Isolating ECG from other parameters
- Analog output (one channel for ECG and two channels for IBP)
- Defib sync output
- Data exchange with the main board through the serial ports

#### 2.5.1.3 Parameter Connector Board

The parameter connector board provides the following functions:

- ECG signal isolation and transmission
- SpO<sub>2</sub> signal transmission
- TEMP signal transmission
- IBP signal transmission
- Speaker transmission
- Analog output transmission

#### 2.5.1.4 Infrared Communication Backboard

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

#### 2.5.1.5 Wi-Fi Module

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

### 2.5.2 T1 Docking Station and T1 Handle



The figure above shows the connection and relation among T1, T1 Docking Station and T1 Handle. They can be mutually connected through 54-pin connectors. T1 is the core of the system, while T1 Handle and T1 Docking Station provide extension of many functions.

When T1 is used with the T1 Handle alone, it can communicate with external parameter modules, and its interaction with external modules is realized through the T1 handle converter board and T1 handle NIOS board.

When T1 is installed to the T1 Docking Station, it is connected to the T1-Dock interface power board through the T1-Dock converter board, thus getting power from the T1-Dock interface board. Besides, T1 can be connected with external devices through the USB connector, external device connector (Mini DB15), VGA, and network connector on the Docking Station.

When T1, the T1 Docking Station and the T1 Handle are used together, all the functions described above are provided.

## 2.5.3 External Parameter Modules

T1 can be configured with the following external modules:

- Sidestream CO<sub>2</sub> module
- Microstream CO<sub>2</sub> module

T1 is connected with the external modules through the T1 Handle.



If T1 and an external module are both installed to the T1 handle, the external module is connected to the T1 handle converter board through the T1 handle NIOS board gets power from the battery installed in T1. The T1 handle converter is connected to T1 through the 54 pin connector. The T1 Handle can be installed to the T1 Docking station and be powered by the Docking Station.

#### FOR YOUR NOTES

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

#### WARNING

- The equipment shall be installed by personnel authorized by Mindray.
- The software copyright of the equipment is solely owned by Mindray. No organization or individual shall resort to altering, copying, or exchanging it or to any other infringement on it in any form or by any means without due permission.
- Devices connected to the equipment must meet the requirements of the applicable IEC standards (e.g. IEC 60950 safety standards for information technology equipment and IEC 60601-1 safety standards for medical electrical equipment). The system configuration must meet the requirements of the IEC 60601-1-1 medical electrical systems standard. Any personnel who connect devices to the equipment's signal input/output port is responsible for providing evidence that the safety certification of the devices has been performed in accordance to the IEC 60601-1-1. If you have any question, please contact Mindray.
- If it is not evident from the equipment specifications whether a particular combination with other devices is hazardous, for example, due to summation of leakage currents, please consult the manufacturers or an expert in the field. A determination must be made that the proposed combination will not negatively affect the devices themselves or the patient's safety.

## 3.1 Unpacking and Checking

Before unpacking, examine the packing case carefully for signs of damage. If any damage is detected, contact the carrier or Mindray.

If the packing case is intact, open the package and remove the equipment and accessories carefully. Check all materials against the packing list and check for any mechanical damage. Contact Mindray in case of any problem.

### WARNING

- When disposing of the packaging material, be sure to observe the applicable waste control regulations and keep it out of children's reach.
- The equipment might be contaminated during storage and transport. Before use, please verify whether the packages are intact, especially the packages of single use accessories. In case of any damage, do not apply it to patients.

• Save the packing case and packaging material as they can be used if the equipment must be reshipped.

## 3.2 Preparation for Installation

#### 3.2.1 Preparation for Installation Site

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

# riangleq warning

• Use only the power cord or DC adapter provided with the system.

#### **Environmental Requirements**

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

The environmental specification is as follows:

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

Microstream CO <sub>2</sub> module			
Item	Operating conditions	Storage conditions	
Temperature (°C)	0 to 40	-20 to 60	
Relative humidity (noncondensing)	15% to 95%	10% to 95%	
Barometric (kPa)	57.3 to 105.3	57.3 to 105.3	

Sidestream CO <sub>2</sub> module		
Item	Operating conditions	Storage conditions
Temperature (°C)	5 to 40	-20 to 60
Relative humidity (noncondensing)	15% to 95%	10% to 95%
Barometric (kPa)	57.3 to 105.3	57.3 to 105.3

Battery charger, T1 Docking Station, and T1 Handle			
Item	Operating conditions	Storage conditions	
Temperature (°C)	0 to 40	-20 to 60	
Relative humidity (noncondensing)	15% to 95%	10% to 95%	
Barometric (kPa)	57.0 to 107.4	16.0 to 107.4	

#### NOTE

• The environmental requirements of unspecified parameters are the same as those of the main unit.

#### **3.2.2 Electrical Requirements**

T1 can be connected to AC power source through the T1 Docking Station or connected to external power through a DC adapter. Only power sockets with protective grounding can be used. Make sure that:

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

#### The electrical specification of the DC adapter is as follows:

Line voltage	100 to 240 VAC (±10%)
Current	0.6 to 0.4 A
Frequency	50/60 Hz (±3 Hz)

The electrical specification of the T1 Docking Station is as follows:

Line voltage	100 to 240 VAC (±10%)		
Current	0.65 to 0.35 A		
Frequency	50/60 Hz (±3 Hz)		

Preparation for Power On:

- 1. Before you begin taking measurements, check the patient monitor for any mechanical damage, and make sure that all external cables, plug-ins and accessories are properly connected.
- 2. If you run T1 on external DC power, connect T1 with the DC adapter. If you run T1 on battery power, ensure that the battery is sufficiently charged. If you run T1 on T1 Docking Station, connect the power cord of the Docking Station to AC power and check if the power indicator on the Docking Station lights up.
- 3. Press the power on/off switch on the monitor's front.

# 3.2.3 Wireless Network Specification

Network Standard	IEEE 802.11b/g/n @ 2.4 GHz		
Modulation Mode	DSSS and OFDM		
Device Baud Rate (data	IEEE 802.11b: 1 - 11 Mbps		
rate)	IEEE 802.11g: 6 - 54 Mbps		
	IEEE 802.11n: 6.5 - 65 Mbps		
Network Latency	Total delay of T1 transmitting data to the central station: $\leq 2s$		
	Total delay of theT1 transmitting data to other monitors: $\leq 2s$		
Output Power	< 30 dBm (FCC requirement: detection mode – peak power)		
	< 20 dBm (CE requirement: detection mode – RMS)		
Operating Mode	Infrastructure		
Data Security	WPA2-PSK encryption supported		
Data Integrity	Code error rate (UDP Layer) <3%		
Priority	All communication data types shall have the same priority		
Roaming	Network switchover is automatically implemented when T1 moves from the coverage area of AP1		
	that of AP2		
System Capacity	Number of T1 monitors supported by a single AP: $\leq$ 16.		
	Each T1 can communicate with the Central Station and connect to two other monitors at the same		
	time. When reconnected at the same time, at most two T1 monitors can transmit history data to		
	the DPM Central Station (the Panorama Central Station does not support transfer of historical data)		
	simultaneously. The wireless function of all T1 monitors is normal under these conditions.		
Susceptibility to wireless	When the distance between interfering devices (including wireless devices at the frequency of		
nterference 2.4GHz such as cellular mobile communication networks, microwave ovens, interphones,			
	phones and electro-surgical units, excluding Wi-Fi) and T1 is greater than 20 cm, the wireless		
	functions of T1 are normal.		
Network Interruption	When the network is reconnected, wireless connection recovers automatically		
FCC Approval	ZLZWM1010BGN10		

### 3.2.4 Setting up the Wireless Network

The patient monitors can be connected to a wireless network via a built-in Wi-Fi module. To set up the wireless network:

- Select [Main Menu]→[Maintenance>>]→[User Maintenance>>]→enter the required password→[Network Setup >>]
  →[Monitor Network Setup >>].
- 2. Set the [Network Type] to [WLAN].
- 3. Configure the [Network Name (SSID)], and [Password].
- 4. Click [**Ok**] to confirm the setting.

To test the availability of the wireless network, follow this procedure:

- 1. Select [WLAN Test >>] in the [Monitor Network Setup] menu.
- 2. Enter the [IP Address] of the wireless AP in the [WLAN Test >>] menu.
- 3. Click [Connection Test].

If the designated IP can be successfully connected, the reply time is displayed. If the connection fails, the reply is timeout.

The Wi-Fi device used in the monitor is in compliance with IEEE 802.11b/g/n.

#### 3.2.5 Setting the IP Address, Subnet Mask and Gateway

In the [Network Setup >>] $\rightarrow$ [Monitor Network Setup] menu, you can set the IP address, subnet mask and gateway. You should not change the patient monitor's IP address randomly. For the detailed information regarding IP address setup, contact the technical personnel in charge of the CMS.

#### NOTE

- The design, installation, construction and maintenance of the wireless network shall be performed by authorized Mindray service personnel.
- Certain obstacles, such as walls, may impact data transmission and possibly cause network interruption.

#### FOR YOUR NOTES

## 4.1 Hardware Upgrade

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

## 4.1.1 Upgrade Package

Upgrade	Monitor configuration	Description of upgrade package	PN of upgrade package
package	before upgrade		
IBP	Nellcor SpO <sub>2</sub> +5-lead	IBP upgrade package (Nellcor SpO <sub>2</sub> +5-lead	801-9281-00014-00
	Mindray ECG algorithm	Mindray ECG algorithm)	
	Masimo SpO <sub>2</sub> +5-lead	IBP upgrade package (Masimo	801-9281-00015-00
	Mindray ECG algorithm	SpO <sub>2</sub> +5-lead Mindray ECG algorithm)	
	Nellcor SpO <sub>2</sub> 12-lead	IBP upgrade package (Nellcor SpO <sub>2</sub>	801-9281-00017-00
	Mindray ECG algorithm	12-lead Mindray ECG algorithm)	
	Masimo SpO <sub>2</sub> +12-lead	IBP upgrade package (Masimo	801-9281-00018-00
	Mindray ECG algorithm	SpO <sub>2</sub> +12-lead Mindray ECG algorithm)	
12-lead ECG	/	12-lead Mindray ECG algorithm upgrade	801-9281-00022-00
		package	
IBP+12-lead	Nellcor SpO <sub>2</sub>	IBP+12-lead Mindray ECG algorithm	801-9281-00020-00
ECG		upgrade package (Nellcor SpO $_2$ )	
	Masimo SpO <sub>2</sub>	IBP+12-lead Mindray ECG algorithm	801-9281-00021-00
		upgrade package (Masimo $SpO_2$ )	
Wi-Fi	/	Wi-Fi upgrade package	801-9281-00023-00

### 4.1.2 Hardware Upgrade Method

## 4.1.2.1 Upgrading the Monitor to Have IBP Function

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

- 1. Refer to **7.3.2.2** *Disassembling the parameter board* and **7.3.3.2** *Removing the Parameter Connector Panel Assembly* to remove the parameter board and parameter connector panel assembly.
- 2. Use the parts in the upgrade package to replace the original parameter board and parameter connector panel assembly.
- 3. Reassemble the monitor.
- 4. Turn on the monitor, and then select [Main Menu]→[Maintenance>>]→[Factory Maintenance>>]→enter the required password→[Device Configuration], and then select[IBP1/IBP2].
- 5 Refer to **5.3.8IBP Performance Test** to test the monitor.

## 4.1.2.2 Upgrade the Monitor to Have 12-lead ECG Function

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

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

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

## 4.1.2.4 Upgrade the Monitor to Have Wi-Fi Function

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

- 1. Refer to **7.3.3** *Disassembling the Front Housing Assembly* to separate the front housing assembly and the main frame assembly.
- 2. Insert the antenna in the antenna slot in the main frame, and then apply the protective tape onto the antenna.

The antenna should be inserted into the antenna slot as indicated in the following picture. Protect the antenna from being damaged during assembly. The antenna should not bend or twist in the slot. When the antenna is in place, press the protective tape down firmly to make sure the antenna is secured onto the main frame.


3. Route the antenna cables and secure the cables in the cable holder. Separate the two cables and use tape to secure the cables onto the main frame. Press the tape down firmly to make sure the cables are tightly secured onto the main frame.



Separate the two cables and use tape to secure the cables onto the main frame

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



5. Insert the antenna plugs into the Wi-Fi sockets (socket on the left for the cable on the left and socket on the right for the cable on the right). Secure the antenna plug with tape.



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

# 4.2 Software Upgrade

Software upgrades must be performed by Mindray, NA authorized service provider. Call Service Dispatch 1 800 288-2121 ext: 7875.

# **5.1 Introduction**

To ensure the patient monitor always functions properly, qualified service personnel should perform regular inspections, maintenance and testing. This chapter provides a checklist of the testing procedures for the patient monitor with recommended test equipment and inspection schedule.

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

## CAUTION

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

# **5.2 Preventative Maintenance**

Preventative maintenance refers specifically to actions taken to prevent inaccurate results in the equipment. The following sections provide a list of recommended preventative maintenance procedures and their recommended frequencies.

## **5.2.1 Preventative Maintenance Frequency**

Check/Maintenance Iten	n	Frequency
Sidestream and	Leakage test	1. If the user suspects that the measurement is incorrect.
microstream CO <sub>2</sub> tests and calibration	Performance test Calibration	<ol> <li>Following any repairs or replacement of relevant module.</li> <li>Once a year.</li> </ol>

### 5.2.2 CO<sub>2</sub> Leakage test

Follow this procedure to perform the test:

- 1. Connect the CO<sub>2</sub> module.
- 2. Wait until CO<sub>2</sub> warmup is finished and then completely block the gas inlet of the module or watertrap. The sidestream and microstream CO<sub>2</sub> modules should have as follows:
  - Sidestream: The alarm message [**CO2 FilterLine Err**] is displayed on the screen after a short time. Block the gas inlet for another 30 s. If the alarm message does not disappear, it indicates that the module does not leak.
  - Microstream: The alarm message [CO2 Purging] is displayed on the screen after a short time. Block the gas inlet for another 30 s. If alarm message [CO2 FilterLine Err] is shown, it indicates that the module does not leak.

### 5.2.3 CO<sub>2</sub> Accuracy Test

Tools required:

- A steel gas cylinder with 5±0.03% CO<sub>2</sub>, 21.0% O<sub>2</sub> and balance gas N<sub>2</sub> (P/N 0075-00-0033-01), or a steel gas cylinder with:
  - ◆ CO<sub>2</sub> concentration 3% 7%
  - $a/c \leq 0.01$  (where a = absolute gas concentration accuracy, c = gas concentration)
  - balance gas N<sub>2</sub>
- T-shape connector
- Tubing

Follow this procedure to perform the test:

- 1. Connect the CO<sub>2</sub> module.
- 2. Wait until the CO<sub>2</sub> module warmup is finished. Check the airway for leak.
- Select [Main Menu]→ [Maintenance>>]→[User Maintenance>>]→enter the required password→ [Module Maintenance>>]→ [Maintain CO2>>]→[Calibrate CO2>>].
- 4. Connect the test system as follows:



- 5. Open the valve to flow CO<sub>2</sub> and make sure that there is flow sufficient to vent to atmosphere.
- 6. Verify the realtime  $CO_2$  value is within 5.0±0.3% in the [**Calibrate CO2**] menu.

## 5.2.4 CO<sub>2</sub> Calibration

Tools required:

- A steel gas cylinder with 5±0.03% CO<sub>2</sub>, 21.0% O<sub>2</sub> and balance gas N<sub>2</sub> (P/N 0075-00-0033-01), or a steel gas cylinder with:
  - ◆ CO₂ concentration 3% 7%
  - $a/c \leq 0.01$  (where a = absolute gas concentration accuracy, c = gas concentration)
  - ♦ balance gas N<sub>2</sub>
- T-shape connector
- Tubing

Follow this procedure to perform a calibration:

- 1. Make sure that the sidestream or microstream CO<sub>2</sub> module is warmed up.
- 2. Check the airway for leaks.
- Select [Main Menu]→ [Maintenance>>]→ [User Maintenance>>]→ enter the required password→ [Module Maintenance>>]→[Maintain CO2>>]→ [Calibrate CO2>>].
- 4. In the [Calibrate CO2] menu, select [Zero].
- 5. After the zero calibration is finished successfully, connect the equipment as follows:



- 6. Open the valve to flow CO<sub>2</sub> and make sure that there is flow sufficient to vent to atmosphere.
- 7. In the [Calibrate CO2] menu, enter the CO<sub>2</sub> concentration in the [CO2] field.
- 8. In the [Calibrate CO2] menu, the measured CO<sub>2</sub> concentration is displayed. After the measured CO<sub>2</sub> concentration becomes stable, select [Calibrate CO2] to calibrate the CO<sub>2</sub> module.

If the calibration is completed successfully, the message [Calibration Completed!] is displayed in the [**Calibrate CO2**] menu. If the calibration failed, the message "**Calibration Failed!**" is displayed. If the initial calibration fails, perform a second calibration. If that attempt fails, contact Mindray Technical Support for assistance.

# **5.3 Performance Tests**

Performance test are designed to ensure that measurement results are accurate. The following sections provide a list of performance and accuracy tests and their recommended frequencies.

## 5.3.1 Performance Test Frequencies

Visual Inspection		1. When first installed or reinstalled.
ECG test	Performance test	1. If the user suspects that the measurement is incorrect.
	Verification	2. Following any repairs or replacement of relevant module.
Resp performance test		3. Once a year for NIBP and $CO_2$ tests.
SpO <sub>2</sub> test		4. Once every two years for other parameter module performance tests.
NIBP test	Pressure check	
	Leakage test	
Temp test		
IBP performance test		
CO <sub>2</sub> tests and	Leakage test	
calibration	Performance test	
	Calibration	
Analog output performa	nce test	If the user suspects that the analog output does not work.

### 5.3.2 Visual Inspection

Inspect the equipment for obvious signs of damage. Follow these guidelines when inspecting the equipment:

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

#### 5.3.3 ECG Tests

### 5.3.3.1 ECG Performance Test

Tool required:

Fluke Medsim 300B patient simulator or equivalent equipment

Follow this procedure to perform the test:

- 1. Connect the patient simulator with the ECG connector using an ECG cable.
- 2. Set the patient simulator as follows: ECG sinus rhythm, HR=80 bpm with the amplitude as 1mV.
- 3. Check the ECG waves are displayed correctly without noise and the displayed HR value is within 80 ± 1 bpm. If the value is not within 80 +/-1 then contact Mindray Technical Support

- 4. Disconnect each of the leads in turn 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.

#### 5.3.3.2 ECG Verification

Tool required:

Vernier caliper

Follow this procedure to perform verification:

- 1. Select the ECG parameter window or waveform area→ [Filter]→ [Diagnostic].
- Select [Main Menu] → [Maintenance >>] → [User Maintenance >>] → enter the required password → [Module Maintenance>>].
- 3. Select [Calibrate ECG]. A square wave appears on the screen and the message [ECG Calibrating] is displayed.
- 4. Compare the amplitude of the square wave with the wave scale. The difference should be within 5%. If the difference is not within 5% contact Mindray Technical Support.
- 5. After completing the verification, select [Stop Calibrating ECG].

### 5.3.4 Resp Performance Test

Tool required:

■ Fluke Medsim 300B patient simulator or equivalent equipment

Follow this procedure to perform the test:

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

### 5.3.5 SpO<sub>2</sub> Test

Tool Required:

None.

Follow this procedure to perform the test:

- 1. Connect SpO<sub>2</sub> sensor to the SpO<sub>2</sub> connector of the monitor. Set [**Patient Cat.**] to [**Adu**] and [**PR Source**] to SpO<sub>2</sub> on the monitor.
- 2. Apply the SpO<sub>2</sub> sensor to the ring finger of a healthy person.
- 3. Check the Pleth wave and PR reading on the screen and make sure that the displayed SpO2 is within 95% and 100%. If you are unable to get the SPO<sub>2</sub> between 95% and 100%, contact Mindray Technical Support.
- 4. Remove the SpO<sub>2</sub> sensor from the finger and make sure that an alarm of SpO<sub>2</sub> Sensor Off is triggered.

### NOTE

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

### 5.3.6 NIBP Tests

#### 5.3.6.1 NIBP Accuracy Test

Tools required:

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

Follow this procedure to perform the test:

1. Connect the equipment as shown below.



- 2. Before inflation, the reading on the manometer should be zero. If not, disconnect the squeeze bulb to release any pressure. Reconnect the squeeze bulb and verify that the pressure reading is zero.
- 3. Select [Main Menu] → [Maintenance >>] → [User Maintenance >>] → enter the required password → [Module Maintenance>>]. → [NIBP Accuracy Test].
- 4. Check the manometer values and the monitor values. Both should be 0 mmHg.
- 5. Raise the pressure in the rigid vessel to 50 mmHg with the squeeze bulb. Then, wait for 10 seconds until the measured values become stable.
- 6. Compare the manometer values with the monitor values. The difference should be within ±3 mmHg.
- 7. Raise the pressure in the rigid vessel to 200 mmHg with the squeeze bulb. Then, wait for 10 seconds until the measured values become stable and repeat step 6.

#### NOTE

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

#### 5.3.6.2 NIBP Leakage Test

#### NOTE

• You should perform the NIBP leakage test before any other NIBP test.

Tools required:

- NIBP cuff for adult patient
- Appropriate tubing
- Rigid cylinder

Follow this procedure to perform the test:

- 1. Set [Patient Cat.] to [Adu].
- 2. Connect the NIBP cuff to the NIBP connector on the monitor.
- 3. Wrap the cuff around the cylinder as shown below.



- Select [Main Menu]→ [Maintenance >>]→ [User Maintenance >>]→ enter the required password→ [Module Maintenance>>]→[NIBP Leakage Test]. The message [Leakage Testing...] is displayed in the NIBP parameter area.
- 5. The cuff automatically deflates after 20s, which means NIBP leakage test is completed.

If no message is displayed in the NIBP parameter area, it indicates that the system does not leak. If the message [**NIBP Pneumatic Leak**] is displayed, it indicates that the system may have a leak. In this case, check to make sure the NIBP cuff, hose and connectors are not leaking and perform the test again.

You can also perform a manual leak test:

- 1. Perform procedures steps 1 to 4 in the *NIBP Accuracy Test*.
- 2. Raise the pressure in the rigid vessel to 250 mmHg with the squeeze bulb. Then, wait for 5 seconds to let the measured values becoming stable.
- 3. Record the current pressure value, and then, record the pressure value after 60s.
- 4. Compare the two pressure values and make sure the difference is not greater than 6 mmHg.

### 5.3.7 Temp Test

Tool required:

**\blacksquare** Resistance box (with accuracy above 0.1 $\Omega$ )

Follow this procedure to perform the test:

- 1. Connect the two pins of any Temp connector of a module to the two ends of the resistance box using 2 wires.
- 2. Set the resistance box to  $1354.9\Omega$  (corresponding temperature is  $37^{\circ}$ C).
- 3. Verify that the displayed value is within  $37 \pm 0.1$  °C. If the temperature is not within  $37 \pm 0.1$  °C, contact Mindray Technical Support.
- 4. Repeat steps 1 to 3 and verify another temperature channel.

### 5.3.8 IBP Performance Test

Tools required:

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

Follow this procedure to perform the test:

- 1. Connect the patient simulator to the monitor's IBP connector.
- 2. Verify the patient simulator output to the IBP channel is zero.
- 3. Select IBP Zero in the IBP setup menu to make a zero calibration.
- 4. Configure the patient simulator as P (static) = 200 mmHg.
- 5. The displayed value should be within  $200 \pm 4$  mmHg. If the error is beyond  $\pm 4$  mmHg, return the IBP module to the factory for repair.
- 6. Set the patient simulator output to 120/80 mmHg ART signal and 120/0 mmHg LV signal to the IBP channel and check that the IBP wave is displayed correctly.
- 7. Repeat the steps above for all the IBP channels.

## 5.3.9 CO<sub>2</sub> Tests

See 1.1.1.

### 5.3.10 Analog Output Performance Test

Tool required:

- Medsim300B Patient simulator, or MPS450, or equivalent equipment
- Oscilloscope
- 1. Connect the patient simulator to the monitor using an ECG or IBP cable.
- 2. Connect the oscilloscope to the monitor's multifunctional connector.
- 3. Verify that the waves displayed on the oscilloscope are identical with those displayed on the monitor.

# 5.4 Electrical Safety and Other Tests

### 5.4.1 Electrical Safety and Other Test Frequencies

Check/Maintenance Item		Frequency	
Electrical safety tests		Refer to Appendix A Electrical Safety Inspection.	
Power on test		1. When first installed or reinstalled.	
		2. Following any maintenance or the replacement of any main unit parts.	
Touchscreen calibration/		1. When the touchscreen accuracy diminishes.	
		2. After the touchscreen is replaced.	
Battery check	Function test	1. When first installed.	
		2. Whenever a battery is replaced.	
Performance test		Once a year or if the battery run time is significantly reduced.	

### 5.4.2 Electrical Safety Test

See Appendix A Electrical Safety Inspection for electrical safety tests.

### 5.4.3 Power On Test

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

#### When T1 is powered by battery:

- 1. Insert the battery in the battery compartment.
- 2. Press the power on/off switch to switch on T1. The battery indicator lights up.

#### When T1 is powered through DC adapter:

- 1. Insert the battery in the battery compartment and connect T1 to the AC to DC adapter. Verify the external power supply indicator and battery indicator light up.
- 2. Press the power on/off switch to switch on T1.

#### When T1 is powered through T1 Docking Station

- 1. Insert the battery in the battery compartment and install T1 to the T1 Docking Station. Then connect the Docking Station with AC power. The power indicator on the Docking Station and the battery indicator on T1 light up.
- 2. Press the power on/off switch to switch on T1.

T1 performs a self-test as soon as being powered on. During the self-test, the alarm lamp turns yellow and red, and then turns off; T1 beeps once. This indicates that the visual and audible alarm indicators operate properly.

## 5.4.4 Touchscreen Calibration

Tools required:

- None.
- 1. Select [Main Menu] → [Maintenance >>] → [Cal. Touchscreen]. The 🕒 symbol will appear at different positions of the screen.
- 2. Touch, in turn, the central point of the 🛨 symbol. After the calibration is completed, the message [Screen Calibration Completed!] is displayed.
- 3. Select [**Ok**] to confirm the completion of the calibration.

### 5.4.5 Battery Check

Tools required:

None.

### 5.4.5.1 Battery Function Test

- 1. Remove the battery from T1's battery compartment.
- 2. Verify that T1 works correctly when running on the external power supply.
- 3. Reinstall the battery.
- 4. Disconnect the external power supply and verify that T1 still works properly.

#### 5.4.5.2 Battery Performance Test

- 1. Turn off the monitor. Disconnect the monitor from the external power supply if DC adapter or T1 docking station is connected.
- 2. Install the battery in the monitor. Connect the external power supply and allow the battery to be charged uninterruptedly till it is fully charged.
- 3. Disconnect the external power supply. Remove the battery from the monitor. Keep the battery in room temperature for two hours.
- 4. Allow the monitor to run from the battery until the battery is completely depleted and the monitor automatically shuts off.

The operating time of the batteries reflects their performance directly. If the operating time of a battery is noticeably shorter than that stated in the specifications, replace the battery.

## 5.4.6 Network Print Test

#### Note

• Use the recommended printers specified in the operator's manual (PN: 046-006734-00).

Tools required:

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



- 2 Set IP address as follows: Select [Main Menu] → [Maintenance >>] → [User Maintenance >>] → enter the required password → [Network Setup >>] → [Monitor Network Setup >>], set the IP address of the patient monitor in the same network segment with that of the network printer. (See the instructions for use accompanying the printer)
- 3 Search for printer by selecting [Main Menu] → [Print Setup >>] → [Printer Setup >>] → [Search Printer]. After a while, the printer's model and IP address will appear in the box beside [Printer].

### **5.4.7 Print Function Test**

- 1 Enter the Demo mode of the patient monitor.
- 2 Select [Main Menu] → [Print Setup >>] → [Realtime Reports >>] → [Normal Report] and then select [Print]. The network printer should print out the report correctly.

# 5.5 Factory Maintenance

### 5.5.1 Accessing Factory Maintenance Menu

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

## 5.5.2 Drawing Waves

In the [Factory Maintenance>>] menu, select [Draw Wave] to define the method to draw waves. There are two methods to draw waves:

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

### 5.5.3 Checking Software Version

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

### 5.5.4 Checking Monitor Information

In the [Factory Maintenance] menu, select [Monitor Information] to show the status of the patient monitor.

#### FOR YOUR NOTES

## 6.1 Introduction

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

For more information on troubleshooting, contact Mindray Technical Support Department.

# 6.2 Part Replacement

Printed circuit boards (PCBs), major parts and components in patient monitors are replaceable. Once you isolate a PCB you suspect defective, follow the instructions in 7 Disassembly and repair to replace the PCB with a known good one. Verify proper operation and that the patient monitor passes all performance tests.

To obtain information on replacement parts, refer to 8 Parts.

# **6.3 Checking Patient Monitor Status**

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

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

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

# **6.4 Checking Software Version**

Some troubleshooting may involve software compatibility. This requires you to know your monitor configuration and software version. For detailed information on version compatibility, please contact our Technical Support Department.

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

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

# 6.5 Checking Technical Alarms

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

For detailed information on technical alarm messages, possible causes and corrective actions, refer to the T1 Operator's Manual.

# 6.6 Troubleshooting Guide

Symptoms	Possible Cause	Correction Action
T1 fails to start	Adapter failure	Check if T1 works properly when inserted in Passport 12M/17M series
when connected to		patient monitor or installed to the T1 Docking Station. If so, replace the
the external DC		adapter.
power	Power management failure	If the AC power indicator or power on/off indicator does not light up,
		replace the main control board.
	Display defective	Check the power indicators, lock/unlock button, and verify you hear an
		audible tone when you touch the screen. If they all work normally,
		replace the display.
	Main control failure	Check the backlight. If there is no light, the backlight drive circuit on the
		main control board is faulty. Replace the main control board.
		If the power on/off indicator lights up, but there is no audible tone after
		touching the screen or sliding the lock/unlock key, replace the main
		control board.
T1 fails to start	Low charge or battery	Charge the battery properly and test for proper voltage reading. If the
when running on	defective	battery does not charge properly, replace it.
battery	The Infrared board is defective	If the battery works properly, and T1 works properly when connected to
		the external power source, verify the infrared board is installed. If
		properly installed but not working, replace the infrared board.

## 6.6.1 Power On/Off Failure

## 6.6.2 Display Failures

Symptoms	Possible Cause	Correction Action
The display is blank or black.	The display connection cable is	Properly connect the display connection cable.
	loose	
	Display is defective	Replace the front housing assembly.
Vertical or horizontal line displayed	Display is defective	Replace the front housing assembly.
Touchscreen does not respond.	Display is defective	Replace the front housing assembly.
Touchscreen accuracy is off	Touchscreen needs to be calibrated	Calibrate the touchscreen.

# 6.6.3 Alarm Problems

Symptoms	Possible Cause	Correction Action
The alarm LED does not	Main board is defective	Replace the main board.
light.		
No alarm sound is issued.	Audible alarm is disabled	1. Check if the " <mark></mark> " icon is displayed. If yes, the
		audible alarm is disabled.
		2. Check if the " icon is displayed. If yes, the
		alarm is paused or turned off.
	Connection between the main control	Verify the connection.
	board and the parameter connector board	
	or the connection between the parameter	
	connector board and the speaker is	
	defective	
	Speaker is defective	Replace the speaker.
	Main board is defective	Replace the main board.

## 6.6.4 Button Failures

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

# 6.6.5 T1 Docking Station and T1 Handle Failure

Symptoms	Possible Cause	Correction Action
Failed to identify parameter	T1 handle NIOS board defective	Replace the T1 handle NIOS board
modules	T1 handle converter board	Check the connection between the T1 handle
	defective	converter board and the T1 handle NIOS board. If
		properly connected, replace the T1 handle converter
		board.
	Main board defective	Replace the main board
No video output	Dock interface board defective	Replace the Dock interface board.
	Dock converter board defective	Replace the Dock converter board.
	Main board defective	Replace the main board of the Docking Station
Fail to connect Passport 12M or	Dock interface board defective	Replace the Dock interface board.
17M patient monitor		
No power output from the T1	Dock power board defective	Replace the Dock power board.
Docking Station		
Unable to connect the preset	External display incompatible	Replace the screen.
CMS or correctly display bed		
number or department		
The external display turns black	Error caused by hot plug	Reinstall T1.

Symptoms	Possible Cause	Correction Action
when T1 is installed to the T1	Incorrect connection sequence	Connect the external display and T1 Docking Station
Docking Station		first and then install or start T1.
The touchscreen of the external	USB connection error	Reinstall or restart T1.
display does not work		

# 6.6.6 System Running Failure

Symptoms	Possible Cause	Correction Action
The equipment does not respond	System program failure	Reinstall the system software,
	Main board is defective	Replace the main board.
No connection when inserted into Passport	Infrared communication board	Replace the infrared communication board
12M or 17M patient monitor	defective	
Connected but no data transmitted with	Main board defective	Replace the main board.
Passport 12M or 17M patient monitor		
System time is being reset	Backup battery failure	Replace the backup battery
	The charging circuit for the	Replace the infrared communication board.
	backup battery is faulty	
	Main board is defective	Replace the main board.

# 6.6.7 Input/output Interface Failure

Symptoms	Possible Cause	Correction Action
No analog out signal or	Parameter board failure	Replace the parameter board.
defib. Sync signal	Main board defective	Replace the main board.
	Parameter connector board failure	Replace the parameter connector board.
	Connection failure	Check that the connection between the main board and the
		parameter connector board is not damaged.
	Analog out cable or defib sync.	Replace the cable
	cable failed	

# 6.6.8 Storage Failure

Symptoms	Possible Cause	Correction Action
Failure to store history data or	SD card defective	Enter the User Maintenance menu to format the SD card, or
resting ECG waveform		replace the SD card.
	Main board defective	Replace the main board.
Storage Card Err is reported	SD card error	Restart T1. If the problem persists, format the SD card.

## 6.6.9 Power Supply Failures

Symptoms	Possible Cause	Correction Action
Battery cannot be fully	Battery is defective	Replace the battery.
charged.	Main board failure	Replace the main board.
Battery cannot be	Battery is defective	Replace the battery.
recharged.	Main board is defective	Replace the main board.
No +5 VDC/+12 VDC	Main board failure	1. Restart T1.
output		2. If T1 does not turn on, replace the main board.
Power Communication	Main board failure	Replace the main board.
error is reported		

## NOTE

• When the power module fails, it may cause problems to other components, e.g. the monitor shuts off during start-up. In this case, troubleshoot the power module per the procedure described in the table above.

# 6.6.10 Wi-Fi Related Problems

Symptoms	Possible Cause	Corrective Action
The monitor is frequently off	The Wi-Fi signal is unstable in the	1. Check if the Mindray recommended wireless AP is used. If
line or disconnects from the	operating area.	not, verify the AP effective transmission rate meets the
Wi-Fi network. The		throughput requirements of the connected devices.
transmission delay is too long.		2. Verify the AP channel bandwidth is 20 MHz.
		3. Verify where the monitor is located, the wireless AP signal
		strength is no less than -65 dBm.
		4. Verify where the monitor is located, the signal strength of
		other Wi-Fi devices at the same channel is no greater than
		-85 dBm.
		5. Verify where the monitor is located, the signal strength of
		other Wi-Fi devices of adjacent channels is no greater than
		-50 dBm.
		6. Verify that the recommended distance between the
		monitor and other non-Wi-Fi wireless devices, including
		wireless devices at the frequency of 2.4GHz, cellular mobile
		communication networks, microwave ovens, intercoms,
		cordless phones and electro-surgical units, is no less than
		20 cm.
		7. Verify that no unauthorized devices are connected to the
		wireless AP.

Symptoms	Possible Cause	Corrective Action
	The monitor's Wi-Fi antenna is	Disassemble the monitor and properly attach the Wi-Fi
	detached from or not properly	antenna.
	connected with the Wi-Fi	
	module.	
	Wi-Fi antenna defective	Replace the Wi-Fi antenna.
	Wi-Fi module defective	Replace the Wi-Fi module.
Unable to connect to the Wi-Fi	The Wi-Fi signal is unstable in the	1. Verify that the network is available.
network.	operating area.	2. Check if the network type is correctly set. For example, if
		LAN is used, set network type to LAN and connect the
		patient monitor to the network; if WLAN is used, set the
		network type to WLAN and connect the patient monitor to
		the network.
		3. Check that the SSID and password of the monitor are
		consistent with those of the wireless AP.
		4. Check for IP address conflicts. If any, set the IP addresses
		correctly.
		5. Check if Mindray recommended wireless AP is used. If
		not, verify the AP effective transmission rate meets the
		throughput requirements of the connected devices.
		6. Verify the AP channel bandwidth is 20 MHz.
		7. Verify where the monitor is located, the wireless AP signal
		strength is no less than -65 dBm.
		8. Verify where the monitor is located, the signal strength of
		other Wi-Fi devices at the same channel is no greater than
		-85 dBm.
		9. Verify where the monitor is located, the signal strength of
		other Wi-Fi devices of adjacent channels is no greater than
		-50 dBm.
		10. Verify that the recommended distance between the
		monitor and other non-Wi-Fi wireless devices, including
		wireless devices at the frequency of 2.4GHz, cellular mobile
		communication networks, microwave ovens, intercoms,
		cordless phones and electro-surgical units, is no less than
		20 cm.
	The monitor's Wi-Fi antenna is	Properly attach the Wi-Fi antenna.
	detached from or not connected	
	to the Wi-Fi module.	
	Wi-Fi antenna defective	Replace the Wi-Fi antenna.
	Wi-Fi module defective	Replace the Wi-Fi module.
	Main board defective	Replace the main board.

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

# 6.6.11 Wired Network Related Problems

# 6.6.12 Software Upgrade Problems

Symptoms	Possible Cause	Correction Action
Program	Incorrect network	1. Check the network connector on the patient monitor.
upgrade	connection	2. Make sure that the hub or switch is operating correctly. Check that correct
fails		network cable is in use and has been connected correctly.
	Wrong upgrade package	Upgrade package shall be .pkg files. Select the correct .pkg file for your application.
	has been downloaded	
	Incorrect IP address setting	Configure a fixed IP address in range C as specified for the patient monitor. We
		recommend not performing software upgrade whenT1 is connected to a network
		having multiple PCs.
	Main board defective	Replace the main board.

#### FOR YOUR NOTES

# 7.1 Tools Required

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

- Number 2 Philips screwdriver
- 3 mm hex driver
- Tweezers
- Needle nose pliers

# 7.2 Preparations for Disassembling

Before disassembling the equipment, do the following:

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

### CAUTION

- Before disassembling the equipment, be sure to eliminate any static charges first. When disassembling the PCBAs and parts labeled with static-sensitive symbols, make sure you are wearing electrostatic discharge protection such as an anti-static wristband or gloves to avoid damaging the equipment.
- Properly connect and route the cables and wires when reassembling the equipment to avoid short circuits.
- Select appropriate screws to assemble the equipment.
- Follow the proper sequence when disassembling the equipment.
- Disconnect all the cables before disassembling any parts. Be careful not to damage any cables or connectors.
- Place removed screws and disassembled parts properly, preventing them from being lost or contaminated.
- Place the screws and parts from the same module together to facilitate reassembling.
- To reassemble the equipment, first assemble the assemblies, and then the main unit. Carefully route the cables.
- Make sure all O rings and seals are installed during reassembling.

# 7.3 Disassembling T1 Main Unit

## 7.3.1 Removing the Battery Door and Battery

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



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



### 7.3.2 Disassembling the Rear Housing Assembly

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



2. Carefully separate the front housing from the rear housing. Press the battery door tether to remove the battery door from its tether. This will allow separation of the rear housing from the main frame.



#### 7.3.2.1 Disassembling the Infrared Communication Board

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



### NOTE

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

#### 7.3.2.2 Disassembling the parameter board

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



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



3. Loosen the parameter board latch and slide the parameter board to the right to remove it from the main frame.



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



 Remove the insulating plate. Unscrew the two plastic M3 hex nuts and the two M3×12 plastic double-screw bolts. Detach the tubing.



## 7.3.3 Disassembling the Front Housing Assembly

 Unscrew the four PT3×10 screws that secure the front housing assembly and remove the front housing assembly from the main frame. Make sure to disconnect the connectors for the Wi-Fi antenna, analog output cable, fan cable, DC-IN cable, and analog signal cable. See the pictures below for details.





Cut the adhesive tape and remove the Wi-Fi antenna connector

Disconnect the fan cable from this socket

Analog Output cable

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

- 1. Loosen the latch securing the Wi-Fi module PCBA and remove the Wi-Fi module PCBA from the main board.
- 2. Cut the adhesive tape, and then depress the SD card release button to allow removal from the main board.
- 3. Remove the tape, loosen the socket retaining clip, and then detach the LCD cable from the main board connector. Remove the main board from the front housing assembly frame, as shown in the figure below.

<text><text><image><text>

### NOTE

- Make sure to set the language to what the customer requires after repairing the main board. Refer to the operator's manual for how to set the language.
- Use tape to secure the Wi-Fi antenna back in its original location after replacing the antenna.
- When reinstalling the SD card, be sure to secure the SD card on the tray by using the adhesive tape. See the pictures below.



## 7.3.3.2 Removing the Parameter Connector Panel Assembly

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



Withdraw the analog out cable from the hole beside the fan



Disconnect the NIBP tubing

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



## 7.3.3.3 Removing the Backup Battery

Loosen the retaining clip to remove the backup battery from the main frame.



Loosen the retaining clip to remove the backup battery

#### 7.3.3.4 Disassembling the Pump, the Dump Valve and the Linear Valve

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



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



3. Disconnect the air tubing connecting the pump, the dump valve and the linear valve.



pump and the valves

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



### 7.3.3.5 Removing the Fan

Loosen the fan by simultaneously pushing the two retaining clips outwards, and then push the fan up. Take care not to damage the fan core.

Loosen the retaining clips to take out the fan Do not press on the fans core. A fan mounting pads on bottom

# 7.4 Disassembling the T1 Docking Station

- 1. Removing the Bottom Board
- 2. Unscrew the four M3×8 screws that attach the bottom board, and remove the bottom board as shown below:



## 7.4.1 Disassembling the Right Housing Assembly

Remove the four white covers over the screws, unscrew the four M3×8 screws and take out the right housing assembly.


#### 7.4.1.1 Removing the Rotating Plate

Unscrew the four  $M3 \times 8$  screws and take out the right housing strengthen board. Then remove the rotating plate from the right housing.



### 7.4.2 Removing the Converter Board

Unscrew the six  $M3 \times 6$  screws that attach the converter board pressing plate and then take it out.



#### 7.4.2.1 Removing the Converter Board PCBA

Take out the converter board PCBA cable and converter board PCBA from the top housing. Then remove the connector from the socket of converter board PCBA.



Remove the connector from the socket of converter board PCBA.

#### 7.4.3 Disassembling the Connector Assembly

Unscrew the two  $M3 \times 6$  screws indicated below. Slide the connector assembly slightly downward as shown below and then lift the assembly to take it out from the top housing. Then disconnect the indicator cable from the connector assembly.



#### Note

• When reassembling the assembly, make sure the silicon jacket is installed in place.

#### 7.4.3.1 Removing Connector Board PCBA

Disconnect the power board cable from the connector board, unscrew the two  $M3 \times 6$  screws and take out the connector board PCBA.



Disconnect the power board cable from the connector board

#### 7.4.3.2 Removing the Power Board

Disconnect the cable from the socket on the power board, unscrew the four  $M3 \times 6$  screws indicated below and take out the power board.



### 7.4.4 Disassembling the Top Housing Assembly 7.4.4.1 Removing the Locating Pin



Unscrew the two M3×6 screws, remove the locating pin pressing plate and take out the locating pin and locating pin spring.

#### 7.4.4.2 Removing the Indicator

Slide the LED bracket upward to remove the top housing. Then remove the indicator. The yellow cable is for AC power indicator while the black one is for T1 connection indicator.



# 7.5 Disassembling the T1Handle

### 7.5.1 Removing the Handle

1. Take out the five white covers over the screws, unscrew the five  $M3 \times 8$  screws and then take out the handle.



Unscrew the M2.5  $\times$  8 screw and take out the unlock lever, module A button, and the spring. 2.



Unscrew the M2.5

### 7.5.2 Removing the Infrared Board

Unscrew the M3  $\times$  8 screw, Loosen the retaining clip and remove the flexible cable from the PCBA socket.



## 7.5.3 Removing the Converter Board

1. Unscrew the two PT3  $\times$  10 screws and take out the T1 handle socket bracket.



2. Unscrew the two M2×8 screws, take out the waterproof sheath of the connector, and remove the converter board PCBA from the T1 handle socket bracket.



### 7.5.4 Removing Contact Screws

Press on the contact screw with your hand, and unscrew the M3 hexagon nut. Then take out the contact screw and spring.



#### FOR YOUR NOTES

## 8.1 Introduction

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

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



#### NOTE

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

## 8.2 Main Unit

# 8.2.1 Exploded View



## 8.2.2 Parts List

SN	Description	FRU part number	Remark
1	Display assembly	115-024223-00	/
2	Lithium battery	115-018016-00	/
3	Power supply waterproof sheath	/	/
4	DC-IN plug	009-003302-00	/
5	Infrared Communication Backboard	051-000821-01	/
6	Phillips screw, pan head, M3×8	/	/
7	Battery door	115-018386-00	The battery door is included in
			the rear cover assembly
8	Rear cover assembly	115-018386-00	/
9	Screw hole cover	/	/
10	Parameter assembly	051-001969-00	Without 12 lead ECG
		051-001970-00	With 12 lead ECG
11	Crosshead tapping screw, pan head,	/	/
	PT3×10		

SN	Description	FRU part number	Remark
12	Trestle module	115-021319-00	/
13	Parameter connector assembly	115-010239-01	Nellcor SpO2
		115-010240-01	Masimo SpO2

# 8.3 Front Cover Assembly (115-022667-00)

# 8.3.1 Exploded View



## 8.3.2 Parts List

SN	Description	FRU part number
1	LCD, TFT 5-inch	115-024223-00
2	Front Cover	
3	Power button	
4	Silicone base for power button	
5	9281 Main board	115-024222-00
6	SD storage card (SLC)	023-000755-00
7	T1 handle Waterproof cover	/
8	Silicone seal	/

SN	Description	FRU part number
9	Screen lock/unlock button	
10	Spring	
11	Screen lock/unlock slider	
12	Lens for alarm LED	
13	Lens for indicating LED	
14	LED cover	

# 8.4 Rear Cover Assembly

# 8.4.1 Exploded View



### 8.4.2 Parts List

SN	Description	FRU part number
1	Rear cover	115-018386-00
2	Slot cover	

SN	Description	FRU part number
3	Guide strip	
4	Infrared lens	
5	Contact nut	
6	Contact screw	
7	Handle	

# 8.5 Main Frame Assembly

# 8.5.1 Exploded View



## 8.5.2 Parts List

SN	Description	FRU part number	Remark
1	Shock absorption block	801-9281-00004-00	/
2	Backup lithium battery	801-9281-00025-00	/
3	Main frame (with tether)	115-021319-00	1
4	Battery direction label		
5	Air valve	801-9281-00004-00	/
6	Shock absorption cushion for pump	801-9281-00003-00	1
7	Screw, pan head, Phillips M3×8	/	/
8	NIBP mounting board	043-001737-00	/

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SN	Description	FRU part number	Remark
9	Pump, Pl6B07	801-9281-00003-00	1
10	630F reducer	801-9281-00005-00	/
11	4-channel silicone tube		1
12	Connector		
13	Silicone tube		/
14	Connector		1
15	Antenna	115-010234-00	/
16	Electromagnetic insulating tape	/	Used only when Masimo SpO2
			kit is configured
17	Module fan cushion	115-016289-00	/
18	Fan	]	/
19	Fan cushion		/

# 8.6 Parameter Connector Assembly

# 8.6.1 Exploded View



### 8.6.2 Parts List

SN	Description	FRU part number	Remark
1	Parameter panel	115-010238-01	Refer to the equipment's parameter

SN	Description	FRU part number	Remark
2	Speaker	115-010239-01	module configuration to choose
3	Speaker cushion	115-010240-01	correct FRU part number, see <b>8.2.2</b>
4	Connector fastening plate		Parts List.
5	Multifunctional connector socket, 9281		
6	Screw, self-tapping, PT2.6×6		
7	Connector board PCBA		
8	TEMP connector housing		
9	IBP connector housing		
10	ECG connector housing		
11	NIBP external pedestal		
12	SpO2 connector housing		
13	Silicon jacket		
14	Steal ball, $\Phi$ 2.5	]	
15	NIBP internal pedestal (hexagon)		

# 8.7 Parameter Assembly

# 8.7.1 Exploded View



### 8.7.2 Parts List

SN	Description	FRU part number	Remark
1	3-channel silicone tube	801-9281-00005-00	/
2	Plastic connector		/
3	Silicone tube		1
4	Plastic hex bolt	/	/
5	Phillips screw, pan head, M3×4	/	1
6	SpO <sub>2</sub> board	115-022691-00	Masimo SpO2
		115-010243-00	Nellcor SpO2
7	Multi-parameter module	051-000974-01	5-lead ECG
		051-000975-01	12-lead ECG
8	Plastic hex nut, M3×0.5	/	/
9	SpO2 board insulator	/	/

# 8.8 T1 Handle (115-028440-00)

# 8.8.1 Exploded View







### 8.8.2 Parts List

SN	Description	FRU part number
1	T1 handle front housing	/
2	Elastic clip	/
3	Contact screw	/
4	Washer-Grade A GB/T96.1-2002	/
5	Washer for hexagonal nut	/
6	Infrared lens	/
7	Contact spring	/
8	T1 handle male plug cover	/
9	T1 handle converter board PCBA	051-001366-00
10	T1 handle receptacle bracket	/
11	Screw, GB/T818-2000 M2×8	/
12	T1 handle female plug cover	/
13	T1 handle NIOS board	051-001367-00
14	Screw, PT3×10	/
15	Screw, GB/T818-2000, M3×8	/
16	Handle	115-021127-00

SN	Description	FRU part number
17	Release button	
18	T1 handle compression spring	
19	T1 handle unlock lever	
20	Screw, GB/T818-2000, M2.5×8	
21	Decorative label	/
22	Screw Cover	/

# 8.9 T1 Docking Station (115-028323-00/115-023300-00)

### 8.9.1 Main Unit

8.9.1.1 Exploded View



#### 8.9.1.2 Parts List

SN	Description	FRU part number
1	Screw cover 2	/
2	Screw, M3×8, NI-P	/
3	Dock Right housing assembly	/

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SN	Description	FRU part number
4	ESD insulator	1
5	Screw, M3×6, NI-P	1
6	Press plate for Dock converter board	1
7	T1 Dock converter board PCBA	051-001368-00
8	T1 handle male plug cover	1
9	Dock top housing assembly	115-030316-00
10	Power cable hook	1
11	VGA socket cover	1
12	Dock connector assembly	009-003698-00
13	Dock bottom housing	/
14	Handle pad	/
15	T1 Docking label (CE)	/

# 8.9.2 Dock Top Housing Assembly (115-028363-00)



#### 8.9.2.2 Parts List

SN	Description	FRU part number
1	Dock indicator connection cable	009-003299-00
2	Screw, M3×6, NI-P	/
3	T1 handle locating pin plate	/
4	T1 handle locating pin waterproof pad	/
5	Pin spring	/
6	T1 handle locating pin	043-003181-00
7	Dock top cover	/
8	Dock decorative label	/
9	LED bracket	1

# 8.9.3 Dock Right Housing Assembly (115-028364-00)

8.9.3.1 Exploded View



#### 8.9.3.2 Parts List

SN	Description	FRU part number
1	Dock rotating plate label	/
2	Dock rotating plate	/
3	Dock right housing	/
4	Dock right housing bracket	/
5	Combination bolt, M3×8	/

# 8.9.4 Dock Connector Assembly (115-020747-00/115-018067-00)

### 8.9.4.1 Exploded View



#### 8.9.4.2 Parts List

SN	Description	FRU part number
1	T1 Dock interface board PCBA	051-001369-00/051-001509-00
2	Dock interface board bracket	/
3	Network connector insulator	/
4	Grounding terminal	/
5	Lock washer, #6	/
6	AC inlet and cable	009-003698-00
7	Power board insulator	/
8	Thermal pad	/
9	Power board, 12V 40W	022-000137-00
10	Screw, M3×6, NI-P	/
11	Screw, M4×8	/
12	Socket waterproof cushion	/

# 8.10 Other Replaceable Parts

SN	Description	FRU part number
1	Analog out cable	009-002208-00
2	T1 adapter cable	009-003302-00
3	Cable, transfer board to interface board	009-003300-00
4	T1 network upgrade cable	009-003726-00
5	T1 network upgrade tool assembly	115-020584-00
6	Adhesive tape, for SD card	047-011750-00
7	Masimo SpO2 upgrade kit	115-023940-00
8	Nellcor SpO2 upgrade kit	115-023941-00

FOR YOUR NOTES

A Electrical Safety Inspection

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

All tests can be performed using commercially available safety analyzer test equipment. Please follow the instructions of the analyzer manufacturer.

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

# A.1 Power Cord Plug

Test Item		Acceptance Criteria	
	The power plug pins	No broken or bent pin. No discolored pins.	
The power	The plug body	No physical damage to the plug body.	
plug	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	
	No physical damage to the enclosure and accessories.	
<b>T</b> he second sec	No physical damage to meters, switches, connectors, etc.	
The enclosure and accessories	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	
	No unusual noises (e.g., a rattle inside the case).	
The enclosure and accessories	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 Scheduled Electrical Safety Inspection

For scheduled electrical safety inspection, perform all the test items listed in A.6ELECTRICAL SAFETY INSPECTION.

## A.5 Electrical Safety Inspection after Repair

The following table specifies test items to be performed after the equipment is repaired. Refer to **A.6 ELECTRICAL SAFETY INSPECTION** for the description of the test items.

Repair with main unit not disassembled		Test items: 1, 2, 3
Repair with	When neither power supply PCBA nor patient	Test items: 1, 2, 3, 4
main unit	electrically-connected PCBA is repaired or	
disassembled replaced		
	When power supply PCBA is repaired or	Test items: 1, 2, 3, 4, 5
replaced		
When patient electrically-connected PCBA is		Test items: 1, 2, 3, 4, 6, 7, 8
repaired or replaced		
	When both power supply PCBA and patient	Test items: 1, 2, 3, 4, 5, 6, 7, 8
	electrically- connected PCBA are repaired or	
	replaced	

# A.6 ELECTRICAL SAFETY INSPECTION TEST

Inspection and Testing		Limit	
1	Power Cord Plug		
2	Device Enclosure and Acce	essories	/
3	Device Labeling		/
4	Protective Earth Resistance	2	Max 0.2 Ω
5	Earth Leakage	Normal condition(NC)	Max:
			NC: 300µA(refer to UL60601-1)
		Single Fault condition(SFC)	SFC: 1000µA
6	Patient Leakage Current	Normal condition(NC)	Max:
			CF applied part:
			ΝC:10μΑ, SFC: 50μΑ
		Single Fault condition(SFC)	BF applied part:
			NC:100μΑ, SFC: 500μΑ
7	7 Mains on Applied Part Leakage		Max:
			CF applied part: 50µA
			BF applied part: 5000μA
8	Patient Auxiliary Current	Normal condition(NC)	Max:
			CF applied part:
			NC:10μΑ, SFC: 50μΑ
			BF applied part:
			NC:100µA, SFC: 500µA

#### FOR YOUR NOTES