VS-600

**Vital Signs Monitor** 

**Service Manual** 

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# **Revision History**

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

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# Preface Manual Purpose

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

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

Observance of the manual is a prerequisite for proper equipment maintenance and prevents equipment damage and personnel injury.

### **Intended Audience**

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

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### FOR YOUR NOTES

# 1.1 Information of This Manual

A detailed revision history of this manual is recorded in the table below:

Version	Revision History
1.0	New

# 1.2 Safety Information

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

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

• 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.

### 1.2.1 Dangers

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

### 1.2.2 Warnings

## 

- All installation operations, expansions, changes, modifications and repairs of this product are conducted by Mindray authorized personnel.
- There is high voltage inside the equipment. Never disassemble the equipment before it is disconnected from the AC power source or the battery.
- 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.
- Disposal of the packaging material should observe the applicable waste control regulations and keeping it out of children's reach.

## 1.2.3 Cautions

# 

- 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 receiver to the power line, check that the voltage and frequency ratings of the power line are the same as those indicated on the unit's label or in this manual.
- Protect the equipment from damage caused by drop, impact, strong vibration or other mechanical force during servicing.

### 1.2.4 Notes

NOTE

• Refer to Operator's Manual for detailed operation and other information.

# **1.3 Equipment Symbols**

### NOTE

• Not all the symbols listed below are applied to your equipment.

$\triangle$	Caution: Consult accompanying documents(this manual)	•/_	Neonate
⊙/Ò	Power ON/OFF	Ť	Pediatric
С	Clear	İ	Adult
$\sim$	Alternating current (AC)	$\bigtriangledown$	Equipotentiality
- +	Battery indicator	ᢙ	Input/Output
┥	DEFIBRILLATION -PROOF TYPE CF APPLIED PART	[m]	Date of manufacture
<b>*</b>	NIBP Start/Stop key		Manufacturer
SN	Serial number		Insertion Direction
$\bigotimes$	No alarming system	IPX1	Protection against fluid ingress
	The following definition of the WEEE label applies to EU member states only. This symbol indicates that this product should not be treated as household waste. By ensuring that this product is disposed of correctly, you will help prevent bringing potential negative consequences to the environment and human health. For more detailed information with regard to returning and recycling this product, please consult the distributor from whom you purchased it. * For system products, this label may be attached to the main unit only.		

## 2.1 Overview

The monitor is intended for spot-check monitoring physiologic parameters, including  $SpO_2$ , PR, NIBP and TEMP, on adult, pediatric, and neonatal patients in healthcare facilities by clinical physicians or appropriate medical staff under the direction of physicians.

# 2.2 Connectors for Peripheral Devices



1. Input/Output connect (RS-232 connector)

This connector is used for software upgrade and DIAP communication.

- 2. AC power input
- 3. Equipotential grounding terminal:

When the equipment and other devices are to be used together, their equipotential grounding terminals should be connected together to eliminate the potential difference between them.

# 2.3 Main Unit

The main unit of the vital signs monitor consists of three parts:

- Front housing assembly, consisting of main board, segment-code display, and Power On/Off keypad;
- Rear housing assembly: power module (AC/DC), power management and interface board (including SpO<sub>2</sub> isolation power), battery, NIBP module, and SpO<sub>2</sub> board (including three types of configuration, i.e. Mindray, Masimo, and Nellcor); and,
- External module: Temp module.

The following figure shows the main unit architecture of the vital signs monitor.



# 2.4 Front Housing Assembly



#### **Main Board**

The main board is the control center of the equipment. It provides communication and display functions, including:

- Communication with SpO<sub>2</sub> board, and NIBP module through serial ports, starting parameter measurement, and reading measured results;
- Communication with Predictive/IR (Infrared Radiation) Temp module through serial ports;
- Communication with power management board through serial ports;
- Extending an RS232 serial port;
- Control over the Segment-code LCD display through I2C;
- Providing backlight drive for segment-code display;
- Recognition of keypad actions, and providing corresponding response;
- Control over the beeper through IO port; and,
- Providing 24 hour timing via the inner RTC.

### Keypad

The keypad consists of elements like keypad and AC/Battery indicator etc.

# 2.5 Rear Housing Assembly



Rear housing assembly consists of power module (AC/DC), power management and interface board (including  $SpO_2$  isolation power), battery compartment, NIBP module, and  $SpO_2$  board (including three types of configuration, i.e. Mindray, Masimo, and Nellcor).

#### **AC/DC Power Module**

The AC/DC power board transforms the input AC into DC power, which is the power source for all voltages in the equipment.

#### Power management and interface board

The power management interface board mainly provides the following functions:

- Charge and discharge of battery and charge detection;
- DC/DC conversion: outputs 12V and 5V DC power;
- Control over power On/Off key and AC, BAT indicator;
- Communication transmission among parameter modules;

- Providing isolation power for Mindray/OEM SpO<sub>2</sub> module; and,
- Providing external connectors, and also filter and protection for these connectors.

#### **NIBP Module**

The NIBP module consists of blood pressure measurement board and pump and valve assembly, providing measurement acquisition of blood pressure data. The main functions of the NIBP module are:

- NIBP measurement; and,
- Data exchange with the main board through the serial ports.

### SpO<sub>2</sub> board

The independently developed Mindray SpO<sub>2</sub> board provides SpO<sub>2</sub> measurement as good as other boards but with smaller size and lower consumption. The power management and interface board is also compatible with Nellcor NELL-1 SpO<sub>2</sub> board and Masimo MS-2013 SpO<sub>2</sub> board.

The SpO<sub>2</sub> board collects SpO<sub>2</sub> signals, processes SpO<sub>2</sub> algorithm and sends measurement results to the main board. The power management interface board provides isolation power for it.

# 2.6 External Module

An external Temp module can be extended on the monitor.

The independently developed Mindray Temp module consists of an isolation power board, Temp measurement board, and probes. The Temp measurement board collects Temp signals, processes algorithm and sends measurement results to the main board.

### FOR YOUR NOTES

# 3.1 Unpacking the Equipment

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

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

## 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 equipment needs to be connected to network.

## **3.2.2 Environmental Requirements**

To avoid explosion hazard, do not use the equipment in the presence of flammable anesthetics, vapors or liquids. The environment where the equipment will be used should be reasonably free from vibration, dust and corrosive substances. If these conditions are not met, the system may not function normally.

The environmental specification is as follows:

Main Unit			
ltem	Temperature (°C)	Relative humidity (noncondensing)	Altitude (kPa)
Operating environment	0 to 40 (without Temp module) 5 to 40 (with Temp module)	15% to 95%	57.0 to 107.4
Storage environment	-30 to 70	10% to 95%	16.0 to 107.4

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

### **3.2.3 Electrical Requirements**

Check that the system cables, power cords, and power plugs are not damaged, and that the pins are not loose. In case of any damage, remove it from use.

 $m \hat{/}$  warning

- Only power sockets with protective grounding can be used.
- Use the supplied power cord only!
- If you doubt the completeness of the installation and cabling of the external protective cables, disconnect the equipment from the power line and operate it on battery. Otherwise, patient or operator might be shocked.

Voltage	100 to 240V AC
Current	0.9 to 0.5A
Frequency	50/60 Hz

## 3.3 Equipment Installation

Follow the procedure below to install the equipment:

- 1. Check the quantity of equipment and accessories as per the packing list.
- 2. Check for mechanical damages on the equipment and accessories.
- 3. Install the battery (optional). For detailed operations, please refer to the Operator's Manual of the vital signs monitor.
- 4. Connect AC power.
- 5. Connect the accessories.

The vital signs monitor can be mounted on a wall bracket or on a trolley support. The wall bracket or trolley support can be ordered optionally. Each type of mounting bracket is delivered with a complete set of mounting hardware and instructions. For detailed installation information, please refer to *Wall-mount Bracket Instructions for Use (PN: 0010-20-42933)* and *Rollstand Instructions for Use (PN: 0010-20-42934)*.

## 

- Use mounting brackets we supply or approve. If other compatible mounting bracket is used, be sure it can be safely used on the vital signs monitor.
- The mounting bracket should be installed by our qualified service personnel, or engineers who have adequate knowledge on it.
- If other mounting solution is used, the installation personnel and the customer should verify if it can be safely used on the equipment, and the customer assume the responsibility for any risk resulting from that.

# 3.4 Preparation for Power on

- 1. Before you start to make measurements, check the equipment for any mechanical damage and make sure that all external cables, plug-ins and accessories are properly connected.
- 2. Plug the power cord into the AC power source. If you run the equipment on battery power, ensure that the battery is sufficiently charged.



3.

Press the  $\bigcirc$  button on the front panel to turn on the equipment.

### FOR YOUR NOTES

## 4.1 Introduction

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

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

# 

- All tests should be performed by qualified service personnel only.
- Service personnel should acquaint themselves with the test tools and make sure that test tools and cables are applicable.

## 4.1.1 Test Equipment

See the following sections.

## 4.1.2 Test Report

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

## 4.1.3 Preventative Maintenance

Below are preventative maintenance tests which need to be performed on the monitor. The recommended frequency of preventative maintenance is at least once per year. See the following sections for detailed maintenance procedures.

- Visual Inspection
- NIBP test and calibration

## 4.1.4 Recommended Frequency

Check/Maintenance Item		Recommended Frequency	
Preventative Mai	ntenance		
Visual Inspection		When first installed or reinstalled.	
Performance test			
SpO <sub>2</sub> test		1. If the user success to the the measurement is	
	Pressure check	incorrect.	
NIBP test and	Leakage test	2. Following any repairs or replacement of relevant	
calibration Module Calibration		3. At least once every two years.	
TEMP test		Note: At least once a year is recommended for NIBP.	
Electric safety tests			
For details, refer to Appendix <b>A</b> Electrical Safety Inspection.		1. Following any repair or replacement.	
		2. After the monitor drops.	
		3. At least once every two years.	
Other tests			
		1. When first installed or reinstalled.	
Power-on test		2. Following any repairs or replacement of any main unit parts.	
Battery check	Functional text	1. When first installed.	
	Functional test	2. Whenever a battery is replaced.	
	Performance test	Once per year or if the battery run time reduced significantly.	

# 4.2 Visual Inspection

Perform an overall inspection on the appearance of the equipment. The test is passed if the equipment has no obvious signs of damage. Follow these guidelines when inspecting the equipment:

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

## 4.3 Power-on Test

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

1. Insert the battery in the battery compartment, and connect the equipment to the AC mains. The AC mains indicator and battery indicator light up.



- 2. Press the button on the front panel to turn on the equipment. The work status indicator lights up inside the Power button.
- 3. The screen lights up.
- 4. The main interface is displayed. Now the equipment is correctly started.

# 4.4 Module Performance Tests

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

#### Test Method 1

Tool required:

None

**Test Procedures** 

1. Connect SpO<sub>2</sub> sensor for adult to the SpO<sub>2</sub> connector of the monitor. Press (

set the patient category to

- 2. Apply the SpO<sub>2</sub> sensor to your ring finger (assume that you stay healthy).
- 3. Check the PR reading on the screen and make sure that the displayed SpO $_2$  is within 95% and 100%.
- 4. Remove the SpO<sub>2</sub> sensor from your finger and make sure that an alarm of SpO<sub>2</sub> Sensor Off is triggered.

#### **Measurement validation**

The SpO<sub>2</sub> accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, and only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements.

#### NOTE

• The SpO<sub>2</sub> simulator can only be used to verify that the pulse oximeter operates properly. It cannot be used to verify the accuracy of the pulse oximeter or the SpO<sub>2</sub> sensor. To verify the accuracy, clinical tests are required.

#### **Test Method 2**

Tool required:

■ SpO<sub>2</sub> simulator, Index-2 recommended

**Test Procedures:** 

- 1. Connect the SpO<sub>2</sub> sensor to the SpO<sub>2</sub> simulator.
- 2. Selected the model and manufacturer of the SpO<sub>2</sub> module to be tested on the simulator, and set the simulator as follows: SpO<sub>2</sub> to 96% and PR to 80 bmp.
- 3. Set the patient type to adult, pediatric and neonate respectively. Observe the monitor and make sure the displayed SpO<sub>2</sub> and PR value fall in the following range.

Manufacturer	SpO <sub>2</sub>	PR
Mindray	96% $\pm$ 2% (Adult, pediatric) 96% $\pm$ 3% (Neonate)	80 ± 3 bpm
Nellcor	96% $\pm$ 2% (Adult, pediatric) 96% $\pm$ 3% (Neonate)	80 ± 3 bpm
Masimo	96% $\pm$ 2% (Adult, pediatric) 96% $\pm$ 3% (Neonate)	$80 \pm 3$ bpm

### 4.4.2 NIBP Test

#### 4.4.2.1 Leakage Test

NOTE

• Perform NIBP leakage test before any other NIBP concerned test and calibration.

Tools required:

- NIBP cuff for adult patient
- Air tubing
- Cylinder

Follow this procedure to perform the leakage test:

- 1. Press to set the patient category to
- 2. Connect the NIBP cuff to the NIBP connector on the monitor.
- 3. Apply the cuff to the cylinder as shown below.



- 4. Start the monitor. Within 10 s after you hear a beep, press and hold to enter the maintenance mode.
- 5. Press C to enter the NIBP leakage test interface. In the PR parameter area, code 550 is displayed.

	(	)	
		•	1
PR bpm	550		

6. Press to start leakage test. The real-time pressure is displayed in the mean pressure area.



7. When the leakage test is completed, the cuff releases gas automatically.



the system has no leakage. If is displayed, it indicates the system may have a leakage. Check the tubing and connections for leakages. If you ensure that the tubing and connections are all correct, perform a leakage test again. If the problem persists, contact your service personnel.

You can either perform a manual leakage test:

- 1. Perform steps 1 4 as described in Section 4.4.2.2 NIBP Accuracy Test.
- 2. Raise the pressure in the rigid vessel to 250 mmHg with the balloon pump. Then, wait for 5 seconds to let the measured values becoming stable.
- 3. Record the current pressure value, and meanwhile use a time counter to count the time. Then, record the pressure value after 60 s.
- 4. Compare the two pressure values and make sure the difference should not be greater than 6 mmHg.

### 4.4.2.2 NIBP Accuracy Test

Tool required:

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

Follow this procedure to perform the accuracy test:

1. Connect the equipments as shown below.



- 2. Before inflation, check that the reading of the manometer is 0. If not, open the balloon pump to let the whole airway open to the atmosphere. Close the balloon pump after the reading is 0.
- Start the monitor. Within 10 s after you hear a beep, press and hold c to enter the maintenance mode. Then press c to display the NIBP accuracy test interface. In the PR parameter area, the code 555 is displayed.



4. Press to start accuracy test. The real-time pressure is displayed in the mean pressure area.

In this process, you can press to terminate the current accuracy test. An invalid value is displayed in the mean pressure area.

- 5. Check the manometer values and the monitor values. Both should be 0 mmHg.
- 6. Raise the pressure in the metal vessel to 50 mmHg with the balloon pump. Then wait for 10 s to let the measured values become stable.
- 7. Compare the manometer values with the monitor values. The difference between the manometer and displayed values should be ± 3 mmHg.
- 8. Raise the pressure in the metal vessel to 200 mmHg with the balloon pump. Then wait for 10 s to let the measured values become stable. Repeat step 7.

If the difference between the manometer and displayed values is greater than 3 mmHg, contact your service personnel.

#### NOTE

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

#### 4.4.2.3 NIBP Calibration

Contact the service personnel for NIBP calibration.

## 4.4.3 Temp Test

Tool required:

- Resistance box (with accuracy above 0.1 Ω)
- 1. Connet the Temperature probe to Monitor. Connect the two wires (orange wires) of Temp probe connector to the two ends of the resistance box.
- 2. Set the resistance box to 9882.0  $\Omega$  (corresponding temperature is 25.3 °C).
- 3. Verify displayed tempreture value on monitor is within  $25.3 \pm 0.1$  °C.
- 4. Set the resistance box to 6037.1  $\Omega$  (corresponding temperature is 37.0 °C).
- 5. Verify displayed tempreture value on monitor is within  $37.0\pm0.1$  °C.
- 6. Set the resistance box to 4619.2  $\Omega$  (corresponding temperature is 43.7 °C).
- 7. Verify displayed tempreture value on monitor is within  $43.7 \pm 0.1$  °C.

Please contact our service personnel if the Temp test fails.

### NOTE

• Due to the different application environment and the test object in vivo and vitro conditions, there is deviations in the measurement result. The maximum deviation of 2.5° may exist in predictive Temp measurement by liquid bath techniques.

## 4.5 Electric safety tests

For details about electric safety tests, refer to Appendix *A Electrical Safety Inspection*.

# 4.6 Battery Check

Tool required:

None

#### **Functional Test**

- 1. If the equipment is installed with a battery, remove the battery first.
- 2. Verify that the equipment works correctly when running powered form an AC source.
- 3. Insert the battery per the procedures provided in the Operator's Manual.
- 4. Remove the AC power cord and verify that the equipment still works correctly.

#### Performance Test

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

# 4.7 Maintenance Mode

## 4.7.1 Entering/Quitting Maintenance Mode

- 1. Start the monitor. Within 10 s after you hear a beep, press and hold the maintenance mode.
- 2. Press <u>c</u> repeatedly to switch to different settings, including NIBP unit setup, Temp unit setup, system time setup, NIBP leakage test, NIBP accuracy test, version information, restoring factory configuration, work time information, screen brightness adjustment and DIAP communication setup.
- Press and hold () to turn off the equipment. When the equipment is started next time, the changed settings take effect.

## 4.7.2 Checking Version Information

- 1. Enter maintenance mode.
- 2. Press C and switch to version information.
- 3. Press to toggle version information.

The following information is displayed on the monitor:

- System software version;
- NIBP module version;
- SpO<sub>2</sub> module version;
- Temp module version; and
- Power management software version.

The indications of codes are listed below:

Version	Screen display	Indication of codes
System software	***	"030 000" indicates version
version	030 000	03.00.00

NIBP module hardware version		"540" indicates version 05.04.00
Mindray SpO₂ module version	SpO <sub>2</sub>	"223" indicates version 2.2.3
Masimo、Nellcor SpO <sub>2</sub> 模块版本	SpO <sub>2</sub>	"1210" indicates version 1.2.1.0
Temp module version	Тетр	"502" indicates version 5.0.2
Power management software version		"011" indicates version 01.01

## 4.7.3 Restoring Factory Default Configuration

- 1. Enter maintenance mode.
- 2. Press c and switch to restore factory default configuration interface. In the PR parameter area, code 000 is displayed.



3. Press to change settings. If indicates that the current settings are restoring to the factory default configuration while means to remain the current setting.

The default settings are:

- NIBP unit: mmHg
- Temp unit: °C
- Patient category: Adult
- Beat sound: On
- Temp position: oral
- Brightness: 5

#### **Maintenance and Test Report**

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

Customer name		
Customer address		
Servicing person		
Servicing company		
Equipment under test (EUT)		
Model of EUT		
SN of EUT		
Hardware version		
Software Version		
Test equipment	Model/No.	Expiration Date for Calibration

Test Contents	Test Record	Test Result (Pass/Fail)
Visual Inspection		
The case, display screen, buttons, power cord, wall mount, and accessories have no obvious signs of damage.		
The external connecting cables are not frayed and the connector pins are not loose and 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 works correctly and the monitor starts up properly.		
Performance test		
SpO <sub>2</sub> test		
Measure SpO <sub>2</sub> on a healthy person's finger and a PR value is displayed. The displayed SpO <sub>2</sub> value is within 95% and 100%.		
NIBP test		
The difference is within $\pm 3$ 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 displayed Temp value on the monitor is within $37 \pm 0.1$ °C.		
Electric safety tests		
Refer to Appendix <i>A Electrical Safety Inspection</i> .		
Battery Check		
The monitor can operates correctly from battery power when an AC power failure accidentally occurs.		
The monitor can operate independently on a single battery.		

Test conclusion:

Tested by:

Test date:

## 5.1 Overview

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

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

## **5.2 Parts Replacement**

Printed circuit boards (PCBs), major parts and components in the monitor are replaceable. Once you isolate a PCB you suspect defective, follow the instructions in chapter **6** Disassembly and Repair to replace the PCB with a known good one and check that the trouble disappears or the equipment passes all performance tests. Defective PCB can be sent to us for repair. If the trouble remains, exchange the replacement PCB with the original suspicious PCB and continue troubleshooting as directed in this chapter.

To obtain information on replacement parts or order them, refer to chapter 7 Parts.

# 5.3 Troubleshooting Guide

## 5.3.1 Power On/Off Failure

Symptoms	Possible Cause	Troubleshooting
The monitor fails to start.	AC mains not connected or battery too low	Check that AC mains is properly connected or battery capacity is sufficient.
		1. Check that the cable between the keypad board and main board is correctly connected.
	Cable defective	<ol> <li>Check that the cable between the power board and power management board is correctly connected.</li> </ol>
		<ol> <li>Check that the cable between the main board and power management board is correctly connected.</li> </ol>
	Power board defective	Replace the power board.
	Power management board defective	Replace the power management board.
	The main board failed.	Replace the main board.

## 5.3.2 Display Failures

Symptoms	Possible Cause	Troubleshooting
The display is blank or black.	Cable defective	<ol> <li>Check if the cable between the display and main board and the backlight cable are correctly connected.</li> </ol>
		<ol><li>Check that the cables and connectors are not damaged.</li></ol>
	Main board defective	Replace the main board.
	Display defective	Replace the display.
lmages overlapped or distorted	Main board error	Replace the main board, or upgrade the main board with the upgrade software.
	Cable defective	Check if the cable between the display and main board and the backlight cable are correctly connected.

## 5.3.3 Button Failures

Symptoms	Possible Cause	Troubleshooting
Buttons do not work	Cable defective	Check that the cable between the keypad board and main board is correctly connected.
	Keypad board failure	Replace the keypad board.

## 5.3.4 Battery Failures

Symptoms	Possible Cause	Troubleshooting
Battery cannot be charged	Battery defective	Replace the battery.
	Cable defective	Check that the cable between the battery interface board and power management board is correctly connected.
	Power management board defective	Replace the power management board.
	Battery interface board defective	Replace the battery interface board.

#### NOTE

- When the battery module has a failure, it may cause problems to other components. In this case, troubleshoot the battery module per the procedure described in the table above.
- Components of the main unit are powered by the power module. In the event that a component malfunctions, check if the operating voltage is correct.
#### 5.3.5 Module defective

Symptoms	Possible Cause	Troubleshooting
	Module defective	<ol> <li>Check that the cable between the external converter board inside the module and the converter board is correctly connected.</li> <li>Replace the converter board</li> </ol>
Failed to load		
modules	Main unit defective	1. Check that the cable between the main board and power management board is correctly connected.
		2. Replace the power management board.
		3. Replace the main board.
Module loading	Cable defective inside the module	Check the cables connecting the converter board and corresponding parameter module.
succeeds but parameters do not function	Parameter module defective	Replace the corresponding module.
	Converter board defective inside the module	Replace corresponding converter board.

#### 5.3.6 Software Upgrade Problems

Symptoms	Possible Cause	Troubleshooting
Boot file upgrade fails	Power failure or unintended power off during boot file upgrade	Replace the main board.
	Incorrect network connection	Check if the monitor is correctly connected with the PC.
Program upgrade fails	Incorrect upgrade or unmatched program package	Select the program to be upgraded and corresponding software, and then perform upgrade as described in <b>8.2 Software Upgrade</b> .
Battery abnormal after upgrading the power management program	Fails to power cycle the monitor after upgrading the power management program	Upgrade the power management software again and then power cycle the monitor.

# 5.4 Error codes

Error codes are displayed on the monitor if a failure is detected. For detailed failure description, cause and solutions, please refer to Appendix *D* Error codes in the Operator's Manual.

#### FOR YOUR NOTES

# 6.1 Tools Required

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

- Philips screwdrivers
- Tweezers
- Sharp nose pliers
- Clamp

# 6.2 Preparations for Disassembly

Before disassembling the equipment, finish the following preparations:

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

# 🖳 WARNING

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

# 6.3 Disassembling the Main Unit

NOTE

- To disassemble the equipment, place the equipment on a work surface free from foreign material, avoiding damaging the screen.
- All the operations should be performed by qualified service personnel only. Make sure to put on the insulating gloves during service operations.
- Operations relating to optional parts may not apply to your equipment.

#### 6.3.1 Disassembling the Temp Module (Optional)

Lay the monitor on a table as shown below. Unscrew the two M3 $\times$ 6 screws, pull the Temp module up, and disconnect the Temp cable.



#### 6.3.2 Separating the Front and Rear Half of the Monitor

1. Lay the monitor on a table as shown below. Unscrew the four M3 screws.



2. Stand the monitor and separate the front housing assembly and rear housing assembly with caution. Disconnect the cable between the main board and power management board and then take off the front panel.



#### NOTE

• When reassembling the equipment, be sure to check if the front housing waterproof strip is correctly placed.

#### 6.3.3 Removing the Parameter Connector Panel Assembly

Lay the rear housing assembly on the table, disconnect the  ${\rm SpO}_2$  cable and connector panel connecting tube, and then take out the parameter connector panel.



# 6.3.4 Disassembling the Main Bracket Assembly

Unscrew the four PT3 $\times 8$  screws as indicated below. Then take out the main bracket assembly.



# 6.3.5 Removing the Parameter Board (SpO<sub>2</sub> Optional) and Power Management Board

1. Unscrew the two M3×6 screws and two external hexagon screws, and take the power management board assembly out from the main bracket assembly.



2. Unscrew the two M3×4 screws and take the parameter board out from the power management board assembly.



3. Unscrew the two M3×6 screws and take out the power management board assembly.



#### 6.3.6 Disassembling Pumps and Valves (NIBP optional)

1. Cut the two cable ties and take out the gas pump.



2. Unscrew the two M3×6 screws as indicated and take out the valve.



# 6.3.7 Disassembling AC/DC Power Board and Battery Converter Board

1. Unscrew the four M3×6 screws as indicated and take out the AC/DC power board.



2. Unscrew the two M3 nuts to take out the battery interface board.



# 6.4 Disassembling the Front Housing Assembly

#### NOTE

- To disassemble the equipment, place the equipment on a work surface free from foreign material, avoiding damaging the screen.
- Remember to install the screen support pad properly during reassembly.
- Operations relating to optional parts may not apply to your equipment.

#### 6.4.1 Removing the Main Board

Disconnect the cable between the main board and keypad board. Unscrew the four  $M3 \times 6$  screws and take out the main board, as shown below:



### 6.4.2 Removing the Display

Unscrew the four M3×8 screws as indicated below. Take out the display assembly. Then unscrew the four PT2×6 and take out the display.



#### 6.4.3 Removing the Keypad

Unscrew the Two PT3×8 screws indicated below and take out the keypad.



# 6.5 Disassembling the Temp Module (Optional)

#### 6.5.1 Removing the Temp Module PCBA and Temp Module Power Board PCBA

Unscrew the 2 M3 screws indicated below and take out the metal sheet. Disconnect the Temp board cable and the cable between Temp isolation power board and Temp board. Unscrew the four M3×6 screws, you can take out the Temp module PCBA. Then unscrew the three M3×6 screws, you can take out the Temp module power board PCBA.



#### 6.5.2 Disassembling the Temp On-Position Detection Board PCBA

1. Unscrew the four M3×6 screws as indicated and take out the temp module housing.



2. Unscrew the four M2 screws as indicated below and take out the Temp on-position detection board PCBA.



#### NOTE

• Remember to assemble the silicon button for the Temp on-position detection switch during reassembly.

# 7.1 Introduction

This section contains the exploded views and parts lists of the main unit. It helps the engineer to identify the parts during disassembling the monitor and replacing the parts. This manual is based on the maximum configuration. Your equipment may not have same parts and the quantity of the screws or stacking sleeves etc. may be different with those included in the parts lists.

#### NOTE

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



# 7.2.2 Parts List

SN	PN	Description FRU part number		Remarks
1	/	Rear housing for VS-600	115-018253-00	/
2	115-017682-00	Parameter connector panel assembly for VS-600	115-017686-00	with no SpO <sub>2</sub>
2	1	Power management	051-001458-00	Mindray/Nellcor
3	/	VS-600	051-001360-00	Masimo
4	115-017679-00	NIBP valve assembly	115-017679-00	/
5	/	Screw, pan head	/	1
6	/	Screw assembly	/	/
7	/	Pump		
8	/	Shock absorption cushion for pump	801-9261-00040-00	/
/	/	Fixing strip		
9	/	Front housing assembly for VS-600	115-018250-00	front cover FRU
10	/	Main bracket assembly for VS-600	/	/
11	/	FOOT, "ENDEAVOUR"	/	/
12	/	Rubber foot	/	1
13	/	Battery door assembly for VS-600	115-018252-00	/
14	115-017687-00	Predictive Temp module for VS-600	115-017687-00	/
15	/	Screw, pan head, Phillips M3X8	/	/
/	009-003238-00	Cable between NIBP module and power management board	009-003238-00	/
/	009-003248-00	Cable between the main board and power management board	009-003248-00	/

# 7.3 Front Housing Assembly 7.3.1 Exploded View



#### 7.3.2 Parts List

SN	PN Description FRU		FRU part number	Remarks
1	/	Waterproof strip for front and rear housing		
2	/	Front housing for VS-600	115-018250-00	/
6	/	Display lens for VS-600		
3	051-001358-00	Keypad PCBA for VS-600	051-001358-00	/
4	/	Keypad board cushion	047-010363-00	/
5	/	Keypad board adjusting sleeve	043-003153-00	
7	/	Short poron cushion		
8	/	Long poron cushion	115-018251-00	/
9	/	Segment-code display		
10	/	Display metal sheet for VS-600	/	/

SN	PN Description		FRU part number	Remarks
11	/	Screw, PT2X6	/	/
12	/	Screw, PT3X10	/	/
13	/	Screw, pan head cross recessed M3X6	/	/
14	051-001363-00	Main board PCBA (VS-600)	051-001363-00	/
/	049-000573-00	Silicon buttons for VS-600	049-000573-00	/

# 7.4 Main Bracket Assembly 7.4.1 Exploded View



# 7.4.2 Parts List

SN	PN	Description	FRU part number	Remarks
1	1	6301 battery interface PCBA	051-001460-00	With cable
2	/	Screw, Pan head w/washer	/	/
3	/	Battery spring	/	/
4	/	Nut with lock washer	/	/
5	0380-00-0593	Knob, Battery latch	0380-00-0593	/
6	/	Battery spring	/	/
7	/	Battery hook binder plate	/	/
8	/	Screw, pan head	/	/
9	009-003241-00	AC input receptacle and cable	009-003241-00	/
10	/	Grounding pole	/	/
11	/	Lock washer	/	/
12	/	Grounding pole pad	/	/
13	047-010575-00	Power board shield	047-010575-00	
14	022-000125-00	Power board	022-000125-00	/
15	047-010364-00	Power board insulator	047-010364-00	/
16	/	Battery compartment support	/	
17	/	Spring	/	/
/	009-003237-00	Cable between the power management board and power board	009-003237-00	/

# 7.5 Power Management Board Assembly 7.5.1 Exploded View



#### 7.5.2 Parts List

SN	PN	Description	FRU part number	Remarks
1 /	/	PCBA, Power management/interface board	051-001458-00	Power management board service kit (without Masimo receptacle)
			051-001360-00	Power management board service kit (with Masimo receptacle)
2	1	Power management board bracket	/	/
3	/	Spring	1	/
4	/	SpO2 shield	047-010576-00	/
			115-018383-00	SpO2 board service kit, 9008 V2.0
5	1	SpO2 board	0671-00-0102-01	Nellcor SpO₂ board (MDU)
			040-001149-00	SpO2 board, Masimo MS-2013
6	1	Screw assembly	/	/

# 7.6 Parameter Connector Panel Assembly

# 7.6.1 Exploded View



#### 7.6.2 Parts List

SN	PN	Description	FRU part number	Remarks	
1	043-003156-00	Parameter receptacle cover	115 017696 00	VS-600 panel	
3	/	NIBP gas nozzle assembly	113-017080-00	assembly(wo SpO2)	
			009-003371-00	Mindray (6011)	
2	/	/ SpO2 signal cable	009-003372-00	Masimo (6011)	
			009-003373-00	Nellcor (6011)	

# 7.7 Predictive Temp Assembly 7.7.1 Exploded View



#### 7.7.2 Parts List

SN	PN	Description	FRU part number	Remarks
1	/	Screw, Pan head w/washer	/	/
2	M09A-30-62080	Predictive Temp module power board PCBA	801-6006-00043-00	
3	/	Temp module insulator	/	/
4	/	FOOT, "ENDEAVOUR"	/	/
5	043-003152-00	Predictive Temp housing	043-003152-00	/
6	051-001419-00	Temp on-position detection board PCBA	051-001419-00	/
7	/	Chassis	/	/

SN	PN	Description	FRU part number	Remarks
8	043-003312-00	External compartment for Temp module (VS)	043-003312-00	/
9	049-000547-00	Temp cover for VS-600	049-000547-00	/
10	M09A-20-62064	Silicon buttons	M09A-20-62064	/
11	051-001435-00	Predictive Temp module PCBA	051-001435-00	/
12	/	Screw, pan head cross recessed M2X6	/	/
13	/	Temp module support for VS-600	/	/
14	/	Screw, Flat Head Phillips, M3X8	/	/
15	/	Screw, pan head cross recessed M3X6	/	/
/	009-003368-00	VS-900 predictive Temp board cable	009-003368-00	/
/	009-003239-00	VS-900 Cable between the Temp module and power management board	009-003239-00	/
/	009-003240-00	VS-900 Cable between the isolation power board and Temp board	009-003240-00	/

#### FOR YOUR NOTES

# 8.1 Hardware Upgrade

The vital signs monitor supports upgrade of NIBP,  $\mathsf{SpO}_2$  and Temp functions.

#### 8.1.1 Upgrade Package

Upgrade package         Description of upgrade         PN           package         pa		PN of upgrade package	Remarks
	VS-600 Mindray SpO <sub>2</sub> upgrade kit	115-018265-00	/
SpO <sub>2</sub>	VS-600 Masimo SpO₂ upgrade kit	115-018266-00	/
	VS-600 Nellcor SpO <sub>2</sub> upgrade kit	115-018267-00	/
Temp	VS-600 Temp module	115-017687-00	/

Note: measurement accessories are not included in the above upgrade packages.

### 8.1.2 Upgrading Parameter Modules

#### 8.1.2.1 Upgrading Mindray SpO<sub>2</sub> and Nellcor SpO<sub>2</sub>

List of upgrade package:

- A Mindray SpO<sub>2</sub> board or Nellcor SpO<sub>2</sub> board; and,
- A connector panel assembly of the same SpO<sub>2</sub> board.
- 1. Disassemble the power management board and parameter connector panel assembly as described in **6.3 Disassembling the Main Unit**.
- Remove the SpO<sub>2</sub> board from the disassembled power management board assembly as described in 6.3.5Removing the Parameter Board (SpO2 Optional) and Power Management Board, and assemble the SpO<sub>2</sub> board in the upgrade kit.
- 3. Install the power management board assembly with the SpO<sub>2</sub> board and the connector panel assembly in the service kit into the main unit as described in **6.3 Disassembling the Main Unit**.

#### 8.1.2.2 Upgrading Masimo SpO<sub>2</sub>

List of upgrade package:

- A Power Management Board Assembly; and,
- A parameter connector panel assembly.

- 1. Remove the power management board assembly and connector panel assembly as described in *6.3 Disassembling the Main Unit*.
- 2. Install the power management board assembly and the connector panel assembly in the service kit into the main unit as described in **6.3 Disassembling the Main Unit**.

#### 8.1.3 Upgrading Temp

List of upgrade package:

- A Temp module with cables; and,
- Two M3×6 screws.

Remove the decorative cover from the Temp module connector. Install the Temp module onto the main unit as described in *6.5 Disassembling the Temp Module (Optional)*.

#### 8.1.4 Enabling Parameter Functions

1. Turn on the monitor. Within 10 s after you hear a beep, press and hold

keys simultaneously, and the system starts to identify the currently configured modules.

The labels of parameters start to flash till the end of module identification. Then the results are displayed in corresponding parameter areas,

- NIBP and Temp parameter areas: means "this module is configured on this equipment" while means the contrary.
- ◆ SpO₂ parameter area: Number "1" means MindraySpO₂ module, "2" means MindraySpO₂ module, "3" means NellcorSpO₂ module.
- PR parameter area: means "SpO<sub>2</sub> module is configured on this equipment" while means the contrary.
- 2. Restart the monitor.

# 8.2 Software Upgrade

A download tool is adopted for the upgrade of 6011 products, i.e. *Parameter Module Upgrade and Download tool* (PN: G-0010-30-43088).

No.	PN	Description
1	110-002528-00	Main control function program VS600
2	110-002525-00	Power management program
3	110-000889-00	NIBP module software (LPC2136)
4	110-001842-00	Software for Mindray SpO <sub>2</sub> module
5	110-002595-00	TEMP module software (New Vital signs)

Upgradeable Download Software for VS-600

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- Disconnect the equipment from the patient.
- Do not shut down or power off the equipment during upgrade. Otherwise, it may cause the equipment to break down.
- Software upgrade should be performed by qualified service personnel only.

#### 8.2.1 Upgrade program installation

- 1. Run the installation file "setup.exe" on your PC.
- 2. Click "Next".
- 3. Enter "User name" "Company" and correct CD-KEY" (36729683225), and then click "Next".
- 4. Select the path and click "Next".
- 5. Click "Finish" to finish the installation.

#### 8.2.2 Upgrading software

- 1. Connect PC with monitor's RS232 port with standard serial port extentd cable, and remember the COM comber, such as COM1.
- 2. Run the upgrade program on your PC through click "Start" → "All Programs" → "Mindray icare upgrade program" → "icare".



3. Choose "VS-600" from the poped-up menu.

Pulse Oximeter Type Selection	
Machine Type	
O ICARE	
₢ VS-600	
Display this dialog box at the startup	

4. Click "ok" and then enter "Password" (8593210) in the poped-up menu.

Passw	ord	
	Please enter password	
	Password:	
	OK	

<ol><li>Click "ok", "VS-600 Update Tool" menu</li></ol>
---

Make package	Select Package	Package Path:					
Port	Status	Percent	Time (s)	]			
				Port:	COM 1	•	Start
				Port:	COM 1	•	Start
				Port:	COM 1	•	Start
				Port:	COM 1	•	Start
				Port:	СОМ 1	•	Start
				Port:	COM 1	•	Start
				Port:	СОМ 1	•	Start
				Port:	COM 1	•	Start

6. Click "Select Package" and choose "Path" from the poped-up menu by clcik "

Path:	D:\luhx\s	oftware packgage\syste		
Made time:	2013-04-	25 01 59 12		
Check sum:	20 D2 72	00		
Module		Checksum	Version	Note
System pro	ogram	DB 89 72 00		

注意

- Upgrade package shall be .pkg files. Select package according to system requirement.
- The package files are made and supplied by our company. You do not need to make package by yourself.

4. Click "Yes" to finsih the package selection. The below figure displays.

Make package	Select Package	D:\luh×\software p	oackgage\syste	em.pkg		
Port	Status	Percent	Time (s)	]	2	
				Port: CON	41 💌	Start
				Port: COM	<b>41</b>	Start
				Port: COM	41 💌	Start
				Port: COM	41 <u>·</u>	Start
				Port: COM	41 💌	Start
				Port: COM	<b>41</b>	Start
				Port: COM	<b>41</b>	Start
				Port: COM	41 💌	Start

5. Set "Port" to "COM1". And then click "Start".

Make pac	kage Select Package	D:\luhx\software p	ackgageVNIBP	.pkg		
Port	Status	Percent	Time (s)	]		
1	Start connection			Pert COM	1 .	Stop
				Port COM	11 💌	Start
				Port COM	1 .	Start
				Port COM	11 ·	Start
				Pert COM	11 •	Start
				Pert: COM	1 •	Start
				Port: COM	1 .	Start
				Port: COM	11 •	Start
					Eule	4

6. Make sure the monitor is power off, press and hold three buttons C, and

firstly, and then press  $\begin{pmatrix} 0/0 \\ 0 \end{pmatrix}$  button at the same time, after about 2 seconds, release the three buttons, the monitor enters upgrade mode and starts software

upgrade automatically, the display screen is black while the indocator built in (0,0) button lights green.

The corresponding prompt messages are displayed on PC. When software upgrade is finished, prompt "Update succed" displays. Restart the monitor and check if the software is correctly upgrade.

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

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

he electrical safety inspection should be periodically performed every two years .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 plug body	No physical damage to the plug body.		
The power 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.1.1 The Power Plug

# A.2 Device Enclosure and Accessories

#### A.2.1 Visual Inspection

Test Item	Acceptance Criteria
	No physical damage to the enclosure and accessories.
The opelocure and accessories	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 Protective Earth Resistance

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

The following conditions apply: L1 and L2 Open.

#### Preparation

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



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

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

#### **To Perform the Test**

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



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

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

#### In Case of Failure

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

#### LIMITS

ALL COUNTRIES R = 0.2  $\Omega$  Maximum

#### A.5 Earth Leakage Test

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

Leakage current is measured the following ways:

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

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

#### **To Perform the Test**

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



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

- SOFT KEY 4 toggles the AP to Earth to No AP to Earth.
- 4. Press the print data key at any time to generate a printout of the latest measurement.

#### In Case of Failure

- Check any broken of the enclosure. Replace any defective part.
- Inspect wiring for bad crimps, poor connections, or damage.
- Test the wall outlet; verify it is grounded and is free of other wiring abnormalities. Notify the user or owner to correct any deviations. As a work around, check the other outlets to see if they could be used instead.
- Change another probe to confirm if the fail is caused by console.
- 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 UL60601-1,

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

For IEC60601-1,

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

# A.6 Patient Leakage Current

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

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

#### To Perform the Test

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



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

#### In Case of Failure

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

#### LIMITS

For CF 💌 applied parts

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



- 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).

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



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

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

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

#### To Perform the Test

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



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

#### NOTE

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

#### In Case of Failure

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

#### LIMITS

- For CF applied parts: 50 μA
## ELECTRICAL SAFETY INSPECTION FORM

## **Overall assessment**

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

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) Single Fault condition(SFC)	μΑ μΑ		Max: NC: 300μA(refer to UL60601-1) * NC: 500μA(refer to IEC60601-1) * SFC: 1000μA
6	Patient Leakage Current	Normal condition(NC) Single Fault condition(SFC)	□ BFμA □ CFμA □ BFμA □ CFμA		Max: CF applied part: NC:10µA, SFC: 50µA BF applied part: NC:100µA, SFC: 500µA
7	Mains on Applied Part Leakage		□BFμA □CFμA		Max: CF applied part: 50µA BF applied part: 5000µA

Note: The equipment which sell to America shall comply with the requirement of UL60601-1, others shall comply with the requirement of IEC60601-1.

Name/ Signature: \_\_\_\_\_\_ Date: \_\_\_\_\_\_

## FOR YOUR NOTES

PN: 046-004927-00 (1.0)