Solar® SpO_2 Module with Masimo SET®

Service Manual

2004407-001 Revision A

GE Medical Systems
Information Technologies

gemedicalsystems.com

NOTE: Due to continuing product innovation, specifications in this manual are subject to change without notice.

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1 Introduction

For your notes

Manual Information

Revision History

Each page of the document has the document part number and revision letter at the bottom of the page. The revision letter changes whenever the document is updated.

Revision	Date	Comment
A	15 December 2000	Initial release.

Purpose

This manual provides technical information for maintaining the equipment. Use it as a guide for maintenance and electrical repair of parts considered field repairable.

Intended Audience

Users of this manual are expected to have a background in electronics, including analog and digital circuitry with RF and microprocessor architectures. It is intended for service representatives and technical personnel who maintain, troubleshoot, or repair this equipment.

Safety Information

Responsibility of the Manufacturer

GE Medical Systems *Information Technologies* is responsible for the effects of safety, reliability, and performance only if:

- assembly operations, extensions, readjustments, modifications, or repairs are carried out by persons authorized by GE Medical Systems *Information Technologies*, Inc;
- the electrical installation of the relevant room complies with the requirements of the appropriate regulations; and
- the device is used in accordance with the instructions for use.

Intended Use

This device is intended for use under the direct supervision of a licensed health care practitioner.

This device is not intended for home use.

Federal law restricts this device to be sold by or on the order of a physician.

Contact GE Medical Systems *Information Technologies* for information before connecting any devices to the equipment that are not recommended in this manual.

Parts and accessories used must meet the requirements of the applicable IEC 60601 series safety standards, and/or the system configuration must meet the requirements of the IEC 60601 medical electrical systems standard.

Periodically, and whenever the integrity of the device is in doubt, test all functions.

The use of ACCESSORY equipment not complying with the equivalent safety requirements of this equipment may lead to a reduced level of safety of the resulting system. Consideration relating to the choice shall include:

- use of the accessory in the PATIENT VICINITY; and
- evidence that the safety certification of the ACCESSORY has been performed in accordance to the appropriate IEC 60601-1 and/or IEC 60601 harmonized national standard.

If the installation of the equipment, in the USA, uses 240V rather than 120V, the source must be a center-tapped, 240V, single-phase circuit.

Definitions of Warnings, Cautions, and Notes

Warnings, cautions, and notes are used throughout this manual to designate a degree or level of hazardous situations. Hazard is defined as a source of potential injury to a person.

DANGER
indicates an imminent hazard which, if not avoided, will result in death or serious injury.

WARNING
indicates a potential hazard or unsafe practice which, if not avoided, could result in death or serious injury.

CAUTION
indicates a potential hazard or unsafe practice which, if not avoided, could result in minor personal injury or product/property damage.

NOTE: provides application tips or other useful information to assure that you get the most from your equipment.

Equipment Symbols

The following symbols appear on the equipment.

ATTENTION: Consult accompanying documents before using the equipment.

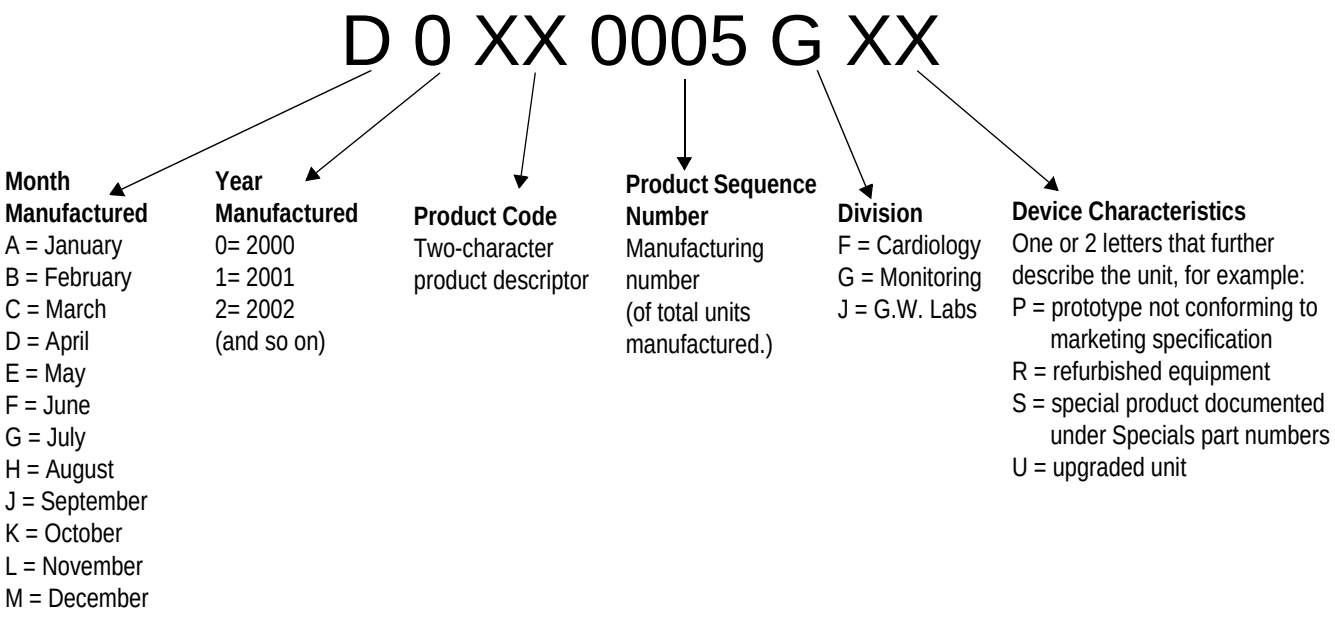
Service Information

Service Requirements

- Refer equipment servicing to GE Medical Systems *Information Technologies* authorized service personnel only.
- Any unauthorized attempt to repair equipment under warranty voids that warranty.
- It is the user's responsibility to report the need for service to GE Medical Systems *Information Technologies* or to one of their authorized agents.
- Failure on the part of the responsible individual, hospital, or institution using this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.
- Regular maintenance, irrespective of usage, is essential to ensure that the equipment will always be functional when required.

Equipment Identification

Every GE Medical Systems *Information Technologies* device has a unique serial number for identification. The serial number appears on the product label on the base of each unit.



2 Equipment Overview

For your notes

System Components

Solar SpO_2 Module with Masimo SET

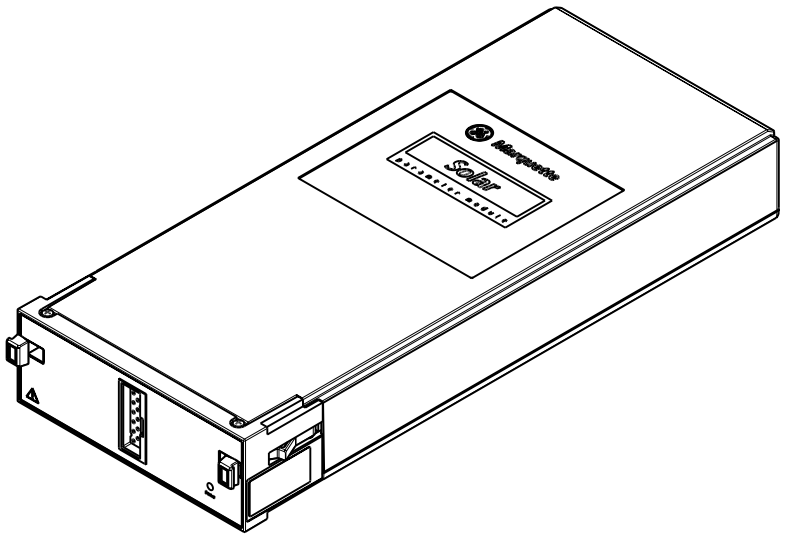
The Solar SpO_2 module with Masimo SET, hereafter called the Masimo module, and accessories is intended for continuous noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate (measured by an SpO_2 sensor) for adult, pediatric, and neonatal patients in hospitals and hospital-type environments. The Masimo module provides all the necessary patient isolation. The Masimo module is compatible with GE Medical Systems *Information Technologies* Solar 7000, 8000, and 8000M modular products including Tram-rac 4A. The device is housed in a standard single-high 7000 series module enclosure.

The Masimo module uses spectrophotometric analysis to determine the percent of oxygen saturation of hemoglobin in arterial blood also known as pulse oximetry. When inserted into a Tram-rac 4A housing connected to any Solar-based patient monitor, the module provides monitoring of peripheral oxygen saturation and pulse rate for an adult, pediatric, or neonatal patient.

It uses Masimo LNOP cables. Other hardware functions include power conditioning (soft-start live-insertion capability, short-circuit protection) and isolation of the patient connected circuitry from earth ground.

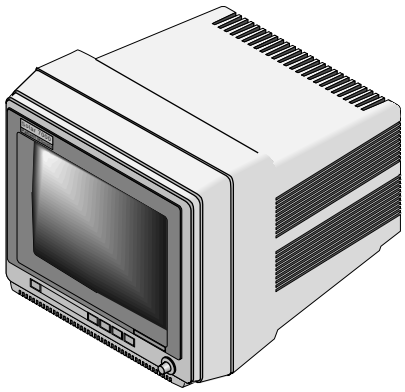
Software may be updated using a laptop computer connected to any compatible Solar based patient monitor.

The Masimo module shown below monitors pulse oximetry.



Solar 7000 Patient Monitor

One Solar based patient monitor used with the Masimo module is the Solar 7000 patient monitor (software version 3C, 4B, or later). It is an intelligent terminal, containing the display, all of the user controls, and processors to communicate with patient monitor peripherals and analyze patient data. It is capable of displaying up to six or eight different waveforms at one time. System software may be updated by a laptop computer at the monitor or through the Unity Network using a central station.



Solar 8000 Patient Monitor

The Solar 8000 patient monitor system (software version 3C, 4B, or later) consists of a Solar 8000 processing unit with a compatible display. The processing unit provides the user controls, processors to communicate with patient monitor peripherals, and analyzes patient data. It is capable of displaying up to six or eight different waveforms at one time on the compatible 12, 15, 17, or 19-inch display. System software may be updated using a laptop computer connected to the Solar 8000 processing unit or through the Unity Network using a central station.

Solar 8000M Patient Monitor

The Solar 8000M patient monitor (software version 1A or later) consists of a Solar 8000M processing unit with compatible display.

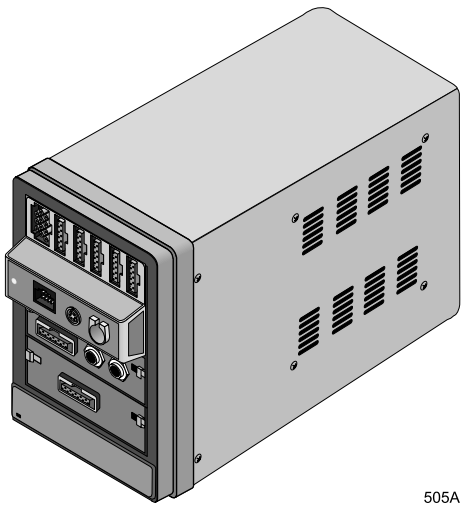
The processing unit is the center of the Solar 8000M Patient Monitoring system. It provides the user controls, the processors to communicate with various patient monitoring modules, and it analyzes patient data. It can display up to eight different waveforms at one time. System software may be updated using a laptop computer connected to the Solar 8000M processing unit or from a central station on the Unity Network.

Tram-rac Housing

The Tram-rac housing (remote acquisition case) acquires patient data for the patient monitor. The Tram-rac Housing Service Manual has more information.

Only compatible Solar based monitors and the Tram-rac 4A (software version 6C or later) housing support the Masimo module.

Shown below is a Tram-rac 4A housing.



505A

Technical Specifications

NOTE

Nellcor, GE Medical Systems *Information Technologies*, and Masimo pulse oximetry is calibrated to display functional saturation. Ohmeda pulse oximetry is calibrated to display fractional saturation.

Performance Specifications	
Item	**Description**
Display Messages	*ARTIFACT DETECTED, LOW QUALITY, PROBE IS OFF THE PATIENT, PROBE OR MODULE MALFUNCTION, POOR SIGNAL QUALITY DETECTED, PULSE SEARCH*
Measurement Range Saturation Pulse Rate Perfusion	 1 to 100% SpO_2 25 to 240 bpm 0.02 to 20%
Accuracy Saturation, no motion Saturation, motion Pulse Rate, no motion Pulse Rate, motion	 SpO_2 over the range 70 to 100%, below 69% is unspecified ±2 digits for adults and pediatrics, ±3 digits for neonates SpO_2 over the range 70 to 100%, below 69% is unspecified ±3 digits for adults, pediatrics, and neonates 25 to 240 bpm, ±3 bpm 25 to 240 bpm, ±5 bpm

Power Requirements	
Item	**Description**
Maximum Power Consumption (non-isolated)	+16.5V, 150mA +5V, 150mA

Environmental Specifications	
Item	**Description**
Operating Conditions Temperature Relative Humidity	 0°C to 40°C (32°F to 104°F) 15 to 90% (non-condensing)
Storage Conditions Temperature Relative Humidity	 –40°C to +70°C (–40°F to +140°F) 0 to 95% (non-condensing)
Altitude	-305 to 1830m (-1000 to 6,000ft.)
Atmospheric Pressure	645 to 795mmHg (860 to 1060hPa)

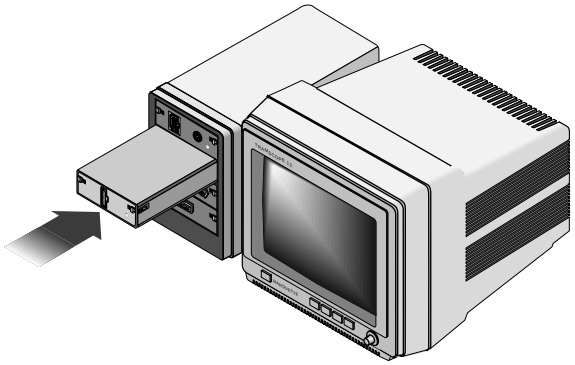
Alarm Specifications	
Item	**Description**
Alarm Limit Range	SpO2: 1% to 105% Pules: 40 BPM to 235 BPM
Type	Audible Visual

Physical Specifications	
Item	**Description**
Height	4.0 cm (1.6 in)
Width	11.4 cm (4.5 in)
Depth	28.6 cm (11.25 in)
Weight	0.50 Kg (1.11 lb)
Cooling Method	Natural convection
Heat Dissipation	8.75Btu/Hr (2.5W), maximum

Certification	UL 2601-1 Classified. UL Classified for CAN/CSA C22.2 No. 601.1. CE Marking for the 93/42/EEC medical Device Directive. IEC 60601-1 Certified.
Warranty	One year (accessories may differ)

Insert Module

1. Insert the module in one of the bottom two slots of a Tram-rac 4A housing.



2. Connect the patient cable assembly to the SpO_2 connector on the module.

   Make sure the following events take place.

   - The front panel LED of the module illuminates steady green after all self-tests of the processor are complete.
   - The module identifies itself on the monitor screen with a patient parameter box.

NOTE
The module will not identify itself on the monitor if the patient cable assembly is not connected.

NOTE
When used with a powered Tram-rac, the patient isolated circuitry voltage is enabled by the host monitor as indicated by the **PWR** LED.

3. If the module does not identify itself on the screen and the patient cable assembly is connected, refer to chapter 4, Troubleshooting. Otherwise, go to chapter 3, Maintenance and perform the Checkout Procedures and Safety Tests.

3 Maintenance

For your notes

Maintenance Schedule

Recommended Maintenance

A regular equipment maintenance program helps prevent unnecessary equipment failures and also reduces possible health hazards. This chapter contains instructions for the following recommended maintenance:

- Inspecting and cleaning the module
- Checkout procedure to verify the unit is working properly
- Leakage tests to verify the equipment does not propose a safety hazard

Recommended Frequency

To help you establish a systematic maintenance routine, GE Medical Systems *Information Technologies* recommends that you perform all maintenance procedures presented in this chapter

- upon receipt of the module,
- every twelve months thereafter,
- each time a circuit board is removed or replaced, and
- record the results on the Repair Log included at the end of this chapter.

Safety Tests

It is recommended that all safety tests be performed if a unit has been opened for any reason or repaired. Listed below are the safety tests recommended.

- All leakage tests described in this chapter,
- All hi-pot tests described in this chapter,

WARNING
Failure to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards. Unless you have an Equipment Maintenance Contract, GE Medical Systems *Information Technologies* does not in any manner assume the responsibility for performing the recommended maintenance procedures. The sole responsibility rests with the individual or institution using the equipment. GE Medical Systems *Information Technologies* service personnel may, at their discretion, follow the procedures provided in this manual as a guide during visits to the equipment site.

Inspection and Cleaning

Visual Inspection

Remove module before making an inspection or cleaning the module.

- Check the case for cracks or other damage.
- Regularly inspect cables for fraying or other damage.
- Inspect all plugs, cables, and connectors for bent prongs or pins.
- Verify that all cables and connectors are securely seated. Note that replacement of components should be performed only by qualified service personnel.

Cleaning Precautions

Recommended cleaning supplies:

- ammonia (diluted), or
- Cidex solution, or
- sodium hypochlorite bleach (diluted), or
- mild soap (diluted), and
- lint-free cloth, and
- dust remover (compressed air)

To avoid damage to the equipment surfaces, do not use the following cleaning agents:

- organic solvents,
- ammonia based solutions,
- acetone solution,
- alcohol based cleaning agents,
- Bentadine solution,
- a wax containing a cleaning substance, or
- abrasive cleaning agents.

Exterior Cleaning

Clean the exterior surfaces with a clean, lint-free cloth and one of the cleaning solutions listed above.

- Wring the excess water from the cloth. Do not drip any liquid into open vents, plugs, or connectors.
- Dry the surfaces with a clean cloth or paper towel.

Checkout Procedure

General

This procedure tests the functions of the module. The checkout procedures consist of the SpO_2 tests.

These procedures are based on the assumption that the module under test is used with known good cables and known good test equipment. It also assumes that you are at least somewhat familiar with the operation of all devices required for the procedures. For more information concerning the operation of these components, consult the appropriate operator's manuals.

Required Tools/Equipment

The following lists the test equipment, adapters, and cables necessary to complete the checkout procedures.

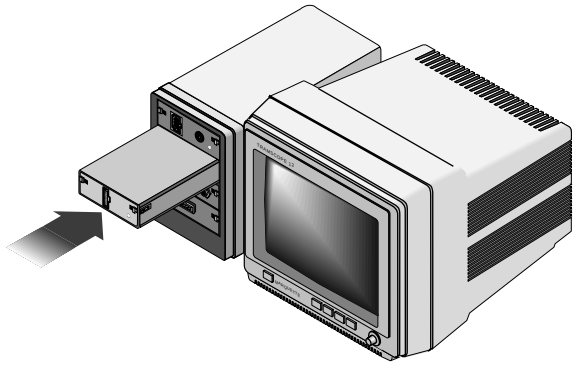
- Compatible Solar monitor and a Tram-rac 4A housing to power the module.
- Simulators and cables listed below provide waveforms and patient vital signs.

Required Simulators and Cables	
Item	**Manufacturer and Part Number/Model**
SpO_2 Simulator	408610-001 or equivalent
SpO_2 Simulator Cable	2006011-001 or equivalent

- Any patient cable or leadwire set that you would usually use on patients.

Preparation

1. Install the module in a Tram-rac 4A housing.



2. Apply power to the monitor by turning the rear panel power switch to the ON position.
3. Turn the display ON by pressing the **DISPLAY ON/OFF** or **POWER** key on the front panel of the monitor.
4. Ensure that the power indicator of the monitor is on.
5. Ensure that the power indicator of the module is illuminated green.

SpO_2 Test

NOTE
Do not connect the simulator to an AC power supply for these tests. Operate the simulator on battery power.

1. Turn the SpO_2 simulator power switch **OFF**.
2. Connect the simulator cable to the module.
3. Set the simulator as follows:

   NOTE
   Use the white-colored values on the simulator.

   - Set the MODE to **NELLCOR**.
   - Set the SpO_2% to **99**.
   - Set the PRR to **70** beats/minute.
   - Turn the power **ON**.

4. Verify the following are displayed at the monitor: (It might be necessary to turn the SpO_2 parameter on.)

   - A waveform with an SpO_2 label.
   - An SpO_2% reading between 97 - 100%.
   - A PRR reading between 67 and 72 beats per minute.

5. Test the accuracy of these SpO_2% settings.

SpO_2 Settings	
Simulator Setting	**Displayed Value**
99%	96 - 100%
90.6%	87 - 94%
80.3%	77 - 83%

6. Test the accuracy of these PPR settings.

PPR Settings	
Simulator Setting	**Displayed Value**
70	67 – 73
100	97 – 103

7. Return the simulator to these conditions:
   - Set the SpO_2% to **99**.
   - Set the PPR to **70** beats/minute.
8. Set these alarms on the monitor:
   - Set SpO_2% LO to **90**.
   - Set PPR HI to **90**.
9. Set PPR on the simulator to **100**.
10. Make sure the PPR value on the monitor flashes, and it sounds an alarm.
11. Return PPR on the simulator to **70**.
12. Set SpO_2% on the simulator to **80.3**.
13. Make sure the SpO_2% value on the monitor flashes, and it sounds an alarm.
14. Disconnect the simulator cable from the module.

Electrical Safety Tests

Electrical safety tests provide a method of determining if potential electrical safety hazards to the patient or operator of the device exist.

Recommendations

GE Medical Systems *Information Technologies* recommends electrical safety tests be performed:

- upon receipt of the module,
- every twelve months thereafter, and
- each time the module is opened or repaired.

Record the date and results on the Repair Log included at the end of this chapter.

Required Tests

To help you establish a systematic maintenance routine, GE Medical Systems *Information Technologies* recommends that you perform all safety tests presented in this chapter.

These instructions are intended for every module in the system. The Tram-rac housing should remain connected to the host during the safety tests. Listed below are the safety tests.

- Hi-Pot Tests

  These tests are mandatory when a module is opened or repaired.

- Leakage Current Tests

  These tests are performed after the hi-pot tests.

If a module under test fails the leakage tests, call Tech Support for assistance. (Refer to “How to Reach Us” in front of this manual.)

Test Conditions

All electrical safety tests may be performed under normal ambient temperature, humidity, and pressure conditions with the module inserted in a Tram-rac 4A.

AC Hi-Pot Test

Hi-pot (high-potential) tests protect the patient from possible electrical safety hazards. They are recommended for any repaired patient-connected devices to ensure patient isolation after the repair.

Test Frequency

This test is required each time the module is opened or repaired.

WARNING
Failure to perform hi-pot tests may cause undue equipment failure and possible health hazards. GE Medical Systems *Information Technologies* does not in any manner, unless an Equipment Maintenance Contract exists, assume the responsibility for performing this recommended health test. The sole responsibility rests with the individual or institution using the equipment.

Required Tools/Equipment

Equipment required to perform the test is listed below. Equivalent equipment may be substituted.

Required Tools/Equipment	
Item	**Specifications or Part Number**
AC Hi-Pot Generator	0 - 5000 Vac
Masimo Test Body Cable Assembly	2006036-001

Procedures

WARNING
Shock hazard. DO NOT perform this test on any of the other connectors.

1. Install the Masimo test body in the SpO_2 connector of the module.
2. Connect the hi-pot generator output lead to the exposed lead of the test body and connect the hi-pot return to any connector shell on the back of the Tram-rac.
3. Set the HIGH VOLTAGE switch to **ON**.
4. Slowly increase output voltage to 4000 volts.

5. Wait for 60 seconds. There should be no indication of breakdown (warning lamp or buzzer).
6. Turn off the hi-pot tester and disconnect the leads.
7. If your module fails this test, contact GE Medical Systems *Information Technologies* Tech Support.

Current Leakage Tests

Preparation

The leakage current tests are safety tests to ensure that the equipment poses no electrical safety hazards. It is recommended after performing the hi-pot tests.

NOTE

These procedures test the integrity of this module only, not the entire system.

WARNING

Failure to perform leakage tests may cause undue equipment failure and possible health hazards. GE Medical Systems *Information Technologies* does not in any manner, unless an Equipment Maintenance Contract exists, assume the responsibility for performing this recommended health test. The sole responsibility rests with the individual or institution using the equipment.

The module must be installed in a Tram-rac 4A housing. Equipment and tools are listed below.

Required Tools/Equipment	
Item	**Specifications or Part Number**
Leakage Current Tester	Equivalent to the circuits shown below
Digital Multimeter (DMM)	0 - 200 AC millivolts
Masimo Test Body Cable Assembly	2006036-001

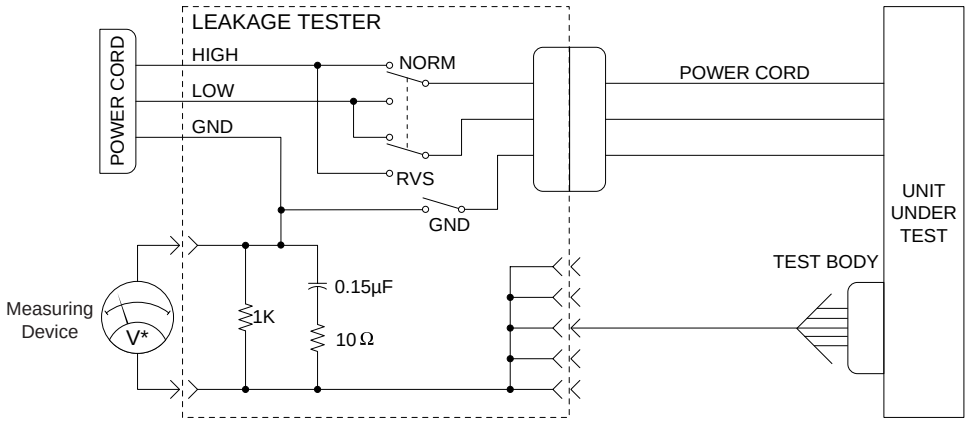
Use the table below to determine the maximum allowable leakage currents. For international leakage limits, refer to the internal standards agencies of the particular country.

Maximum Allowable Leakage Currents	
Test	**Maximum Current**
Patient (Source) leakage current Ground closed, normal & reverse polarity	10 µA
Patient (Source) leakage current Ground open, normal & reverse polarity	50 µA
Patient (Sink) leakage current Ground closed, normal & reverse polarity	50 µA

Patient (Source) Leakage Current Test

This test checks leakage current from the patient cable connector of the module to ground.

1. Prepare the system according to instructions on page 3-6.
2. Configure the leakage tester like the circuit shown below.



1-mV meter reading = 1-µA leakage current

3. Connect the host power cord to the power outlet on the leakage tester.
4. With the power switch of the leakage tester off, connect the power cord of the leakage tester to a correctly wired and properly grounded ac power outlet.
5. Set leakage tester switches as follows:
   - Set the GND switch to **GND OPEN**.
   - Set the polarity switch to **NORM/FORWARD**.
   - Set the power switch to **OFF**.
6. Set the leakage tester power switch to **ON**.

7. Set the host rear panel power switch to **ON**.
8. Read the leakage current indicated on the measuring device.
9. Change the leakage tester polarity switch to the **REVERSE** position.
10. Read the leakage current indicated on the measuring device.

NOTE

If either reading is greater than 50 µA, the module fails this test. Contact GE Medical Systems *Information Technologies* Tech Support.

11. Change the GND switch to the **CLOSED** position.
12. Read the leakage current indicated on the measuring device.
13. Change the leakage tester polarity switch to the **REVERSE** position.
14. Read the leakage current indicated on the measuring device.
15. Set the power switch of the leakage tester to **OFF**.

If either reading is greater than 10 µA, the module fails this test. Contact GE Medical Systems *Information Technologies* Tech Support.

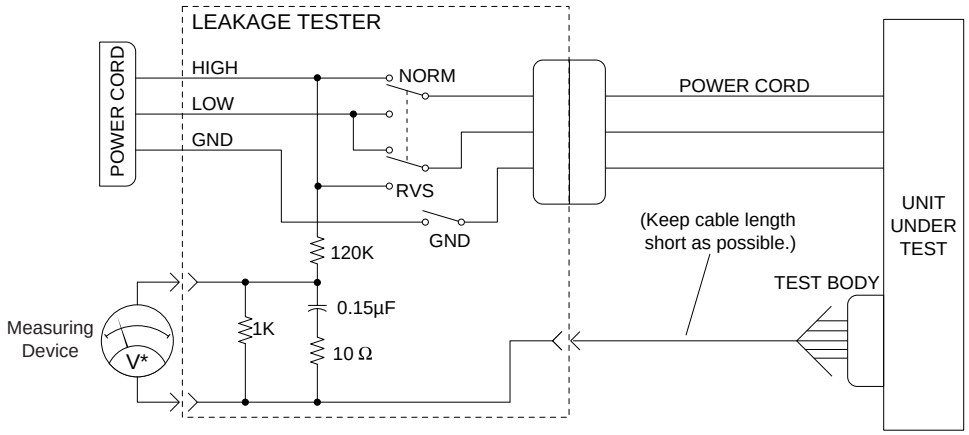
NOTE

The AAMI and IEC single fault condition (ground open) limit is 50 µA, whereas the normal condition (ground closed) limit is 10 µA.

Patient (Sink) Leakage Current Test

This tests the patient cable leakage current from a 115 or 220V ac source into the SpO_2 connector of the module.

1. Prepare the system according to instructions on page 3-6.
2. Configure the leakage tester like the circuit shown below.



1-mV meter reading = 1-µA leakage current

3. On the leakage tester, leave the GND switch set to **CLOSED** and set the polarity switch to **NORM/FORWARD**.

WARNING
Shock hazard. The following step causes high voltage at the test body. Do not touch the test body.

4. Set power switch on the leakage tester to **ON**.
5. Read leakage current indicated on measuring device.
6. Change the leakage tester polarity switch to the **REVERSE** position.
7. Read the leakage current indicated on the measuring device.
8. Set the power switch on the leakage tester to **OFF**.

   If either reading is greater than 50 µA, the module fails this test. Contact GE Medical Systems *Information Technologies* Tech Support.

Completion

1. Disconnect all test equipment from the module.
2. Disconnect the host power cord from leakage tester.
3. Disconnect the tester from the power outlet.

PM Form

Due to continuing product innovation and because specifications in this manual are subject to change without notice, a PM form is not included with this manual. For the latest PM form regarding this product, contact a GE Medical Systems *Information Technologies* service representative.

On the following pages is a repair log to record the repair history of this product.

Repair Log

Unit Serial Number:

Institution Name:

Date	Maintenance/Repair	Technician

4 Troubleshooting

For your notes

General Fault Isolation

First Things to Ask

If the unit is not working properly ask these basic questions.

- Is the module seated correctly?
- Is the monitor and Tram-rac housing power cord connected?
- Is the monitor turned ON at the rear of the monitor?
- Is the display LED illuminated? Are all the communication cables firmly connected?
- Were there any changes in the use, location, or environment of the equipment that could cause the failure?
- Has the unit been modified in any way, either in software or hardware?

Is operator error the cause of the problem? Try to repeat the user's scenario exactly and compare that to the proper operation of the equipment. Check the operator's manual as necessary.

Visual Inspection

A thorough visual inspection of the equipment can save time. Small things—disconnected cables, foreign debris on circuit boards, missing hardware, loose components—can frequently cause symptoms and equipment failures that may appear to be unrelated and difficult to track.

Take the time to make all the recommended visual checks (refer to the visual inspection chart on the next page) before starting any detailed troubleshooting procedures.

Visual Inspection List	
Area	**Look for the following problems:**
I/O Connectors and Cables	■ Fraying or other damage ■ Bent prongs or pins ■ Cracked housing ■ Loose screws in plugs
Interface Cables	■ Excessive tension or wear ■ Loose connection ■ Strain reliefs out of place
Circuit Boards Note: If module is opened, perform Electrical Safety Tests in chapter 3, Maintenance.	■ Moisture, dust, or debris (top and bottom) ■ Loose or missing components ■ Burn damage or smell of over-heated components ■ Socketed components not firmly seated ■ Solder problems: cracks, splashes on board, incomplete feedthrough, prior modifications or repairs
Ground Wires/Wiring	■ Loose wires ■ Faulty wiring ■ Wires pinched or in vulnerable position
Mounting Hardware	■ Loose or missing screws or other hardware
Power Source	■ Faulty connection between PCBs ■ Power source problems may cause static discharge, resetting problems, and noise.)

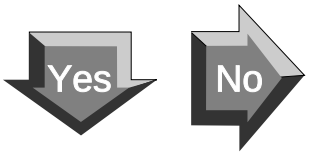
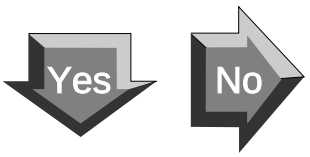
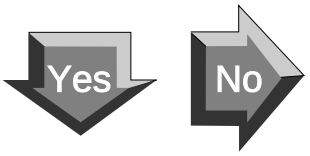
WARNING

Solder multilayer and surface mount PCB assemblies at your own risk! Improper repair methods can damage the PCB assemblies even further. Only qualified service personnel with the proper laboratory equipment should attempt to repair PCB assemblies.

Troubleshooting Procedure

To use this troubleshooting procedure, read through the steps in the table until you find a similar problem to the one you are having. Do not perform any invasive procedures listed in this procedures unless you are a trained field or bio-medical engineer.

WARNING
This procedure is intended for use by service personnel with advanced troubleshooting skills. The consequences of the following steps may cause loss of patient data and disruption of the entire Unity Network.

Troubleshooting Chart	
Is LED on front panel green? 	This problem has many sources, so try one or more of the following solutions.
	1. Verify Tram-rac 4A housing is functional. ■ Verify Tram-rac power LED is ON. ■ Check for a loose or faulty cable from the patient monitor to the Tram-rac housing. ■ Power cycle Tram-rac 4A housing if it has an external power supply. ■ Swap Tram-rac 4A housing with a known good one.
	2. If module LED is off or *PROBE OR MODULE MALFUNCTION* displays on the screen, there is a hardware problem with the module. ■ Reseat Solar SpO_2 module in the Tram-rac 4A housing. ■ Remove the sensor from the module, then reseat the Masimo module in the Tram-rac housing. ■ Verify Tram-rac housing is a Tram-rac 4A housing and turned ON. ■ Verify the host is a Solar-based monitor and turned ON. ■ Verify Solar-based monitor is running V2A or later software. ■ Verify Solar-based monitor is not resetting itself. ■ Swap module with a known good one.
Is patient data displayed at the monitor? 	Try one of the following solutions.
	1. Verify correct patient or simulator leadwire connections to module.
	2. Contact GE Medical Systems *Information Technotogies* Tech Support.
Is the parameter box displayed at the monitor? 	Verify that the patient cable is connected.
End	This is the extent of troubleshooting steps.

System OK LED

The system LED, DS1, is red and is located inside the module. This LED indicates whether the software is operating normally. The status of the LED toggles each time the module completes transmitting a packet to the host patient monitor.

MS-3 Communications OK LED

The MS-3 communications LED, DS2, is yellow and is located inside the module. This LED indicates whether communications between the Masimo MS-3 analyzer and the system processor are operating normally. The LED toggles if a complete data packet is received from the Masimo MS-3 analyzer pcb.

Isolated Power Supply OK LED

The isolated power supply LED, DS3, is green and is located on the front panel of the module. This LED indicates whether the isolated power supply is operating normally. The LED is illuminated if power is applied to the Masimo MS-3 analyzer pcb.

Theory of Operation

Hardware Functions

The Masimo SET SpO_2 Module, hereafter referred to as the Masimo module, provides all the hardware necessary to communicate with a host patient monitor and continuously monitor the functional oxygen saturation of arterial hemoglobin (SpO_2) and pulse rate. The hardware features include the following items:

- Bedside communications using the Synchronous Serial Shift Register Interface protocol.
- Masimo MS-3 analyzer communications and control
- Input power conditioning and soft-start current limiting
- Code download - from host or BDM
- 4000 Volt patient isolation

Software Functions

The Masimo module PCB performs the communications with the Masimo MS-3 Analyzer PCB and host bedside communications. The device performs the following functions under software control:

- Bedside communications and error detection
- Masimo MS-3 Analyzer communications and control
- SpO_2 value calculation
- Respiration rate calculation
- Error detection and alarm indication
- Initialization and self test

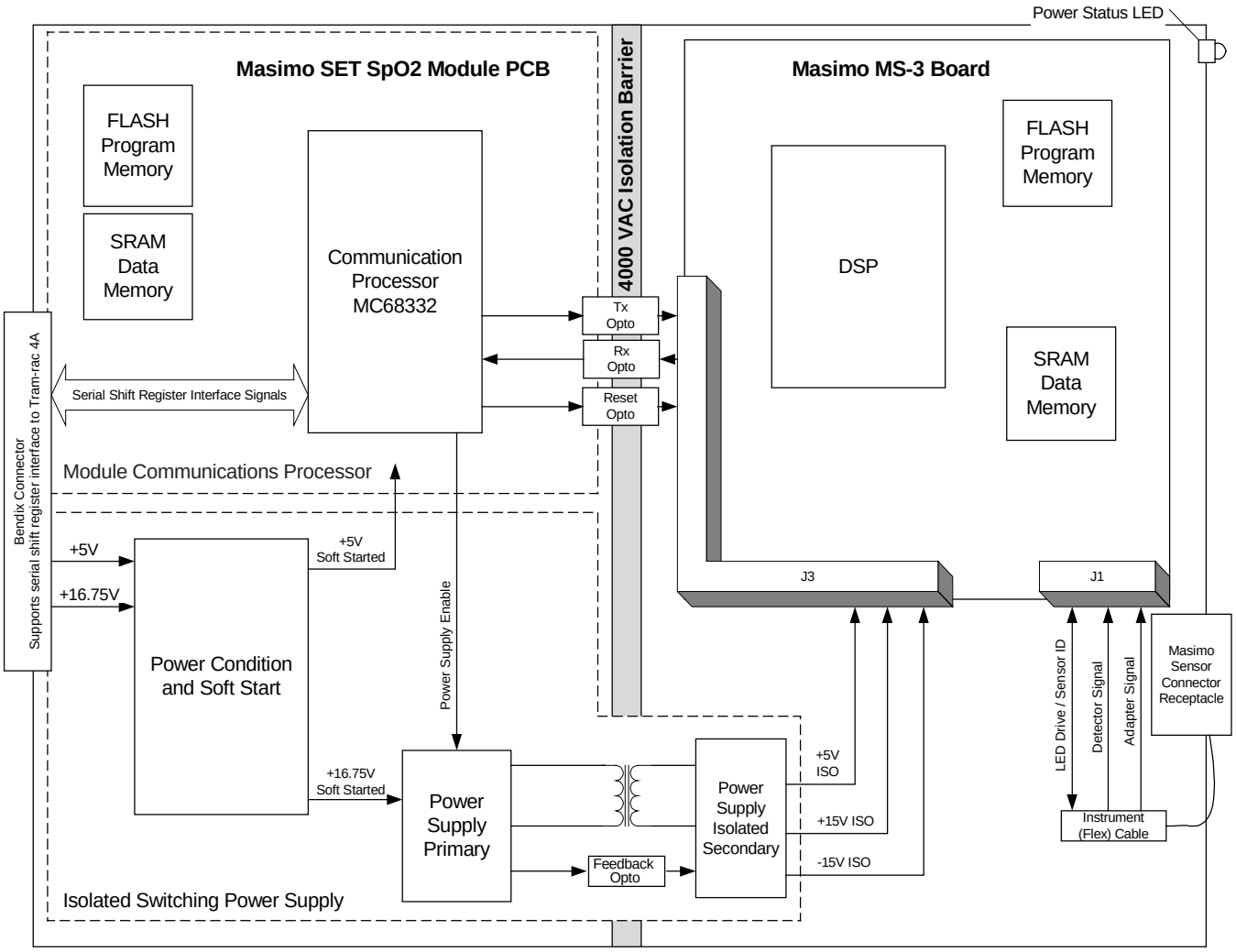
System Processor

The system processor uses external memory for operation. There is a 512K x 8 static RAM for temporary data storage.

NOTE The static RAM is not battery backed-up, therefore this device is not a transportable patient monitor such as the TRAM module.

The static RAM is also used as temporary storage of Masimo MS-3 program code during program download of the MS-3 software. The program code is stored in a 128K x 8 sectored FLASH EPROM. This device can be erased on an individual sector basis. The first sector of FLASH is used for storing the BOOT code. This insures that even if a download of code fails the module still attempts another download of code. The other seven sectors of FLASH store the MAIN code. The MAIN code operates during normal operation of the module. This code can be updated using the host patient monitor.

Below is the overall block diagram for the Masimo module.



Masimo MS-3

The principles of operation of the Masimo MS-3 pulse oximeter is that oxyhemoglobin and deoxyhemoglobin differ in their absorption of red and infrared light (spectrophotometry), the volume of arterial blood in tissue (and hence, light absorption by that blood) changes during the pulse (plethysmography), and that arterio-venous shunting is highly variable and that fluctuating absorbance by venous blood is a major component of noise during the pulse. Because oxyhemoglobin and deoxyhemoglobin differ in light absorption, the amount of red and infrared light absorbed by the blood is related to hemoglobin oxygen saturation. The Masimo MS-3 pulse oximeter decomposes the red and infrared pulsatile absorbance signal into an arterial signal plus a noise component and calculates the ratio of the arterial signals without noise. The ratio of the two arterial pulse-added absorbance signals and its value is used to find the SpO_2 saturation in an empirically derived equation into the Masimo MS-3's software.

Host Patient Monitor Communications

The Masimo module communicates with the host patient monitor using the synchronous Serial Shift Register Interface Signals. The communication processor performs this function, operating in slave mode it receives clock and enable signals from the host patient monitor.

All integrated circuits with signals connected to the backplane are powered directly from the backplane +5 volts not the soft-started power supplies. This is so the signals won't load down the synchronous Serial Shift Register Interface Signals upon insertion of the module.

Power Condition and Soft Start

The Masimo module receives power from the host Tram-rac. The module is designed for insertion into a live Tram-rac. All the power supply pins incorporate soft-start circuitry to limit inrush currents. This module uses the +5V and +16.5V power supplies from the host patient monitor.

Isolated Power Supply

The Masimo module uses an isolated power supply to power the Masimo MS-3 board. The power supply is designed to provide 4000 volts of patient isolation from the host patient monitor. The isolated power supply generates +5V, +15V, and -15V and is controlled by the system processor.

The system processor monitors signal PS_FAULT which indicates a fault condition with the power supply. If this signal is active (logic high) for more than 200ms, the system processor shuts down the isolated power supply. The system processor does not monitor this line for the first 100ms after the power supply is enabled allowing the isolated power supply time to stabilize.

Patient Connector Flex Circuit

The flex circuit assembly provides the connection from the Masimo MS-3 analyzer to the patient receptacle on the front panel of the module. The Masimo Flex PCB includes a ferrite core to reduce electromagnetic emissions/susceptibility and a shield around the front panel connector to reduce susceptibility to external interference.

External Connectors

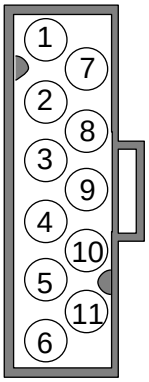
Pin-by-pin descriptions and the signal names for each connector on the front panel of the module are described in this section.

SpO_2 Signals

The SpO_2 patient cable attaches to the front panel 11-pin Blue Nicolay SpO_2 connector.

SpO_2 Connector

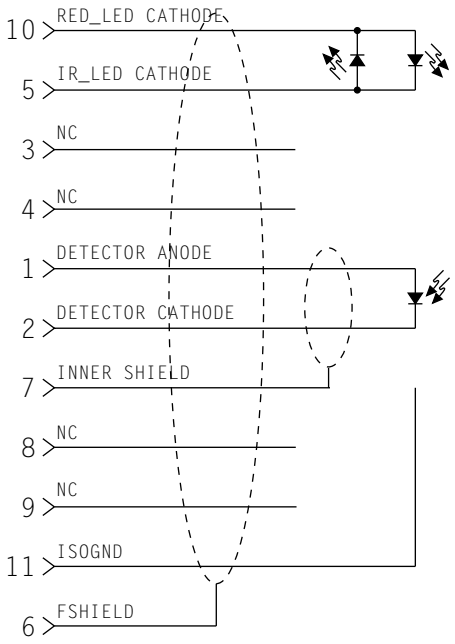
Signal Name	Pin	Type	Description
Detector Anode	1	I	Detector Anode
Detector Cathode	2	I	Detector Cathode
NC	3	X	No connection
NC	4	X	No connection
IR LED Cathode	5	O	IR LED Cathode/Red LED Anode
Outer Shield	6	O	Outer shield of patient cable
Inner Shield	7	O	Inner shield (shield around detector wires of patient cable)
NC	8	X	No connection
NC	9	X	No connection
RED LED Cathode	10	O	Red LED Cathode/IR LED Anode
Outer Shield	11	O	Outer shield of patient cable



Front View of Module

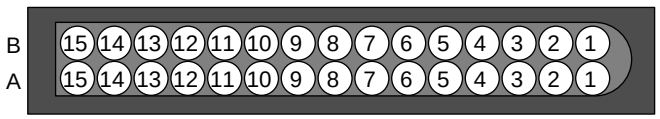
Probe Schematic Diagram

The schematic diagram of the Nellcor probe sensor is presented below.



Host Patient Monitor Connector

The Masimo module uses a 2 x 15 pin female Bendix connector with bristle brush pins to mate with the Tram-rac housing. The following table lists signal names, input pins, type, and descriptions. Signals with an asterisk (*) indicate a low signal.



Signal Name	Pin	Type	Description
GND	A1	I	+16.5 volt power supply return
WF_A	B1	O	Not Used
MOD_EN_B	A2	I	Not Used
MOD_EN_A	B2	I	MODULE CHANNEL A ENABLE: This signal is the enable for this module. This signal is asserted high to enable the module to communicate via the synchronous serial shift register interface.
AGND	A3	I	Not Used
WF_B	B3	O	Not Used
SNYC_ECG	A4	I	Not Used
+16.5V	B4	I	+16.5 volt power supply
MOD_DATA_CLK*	A5	I	MODULE DATA CLOCK*: This signal is the 7000-series module data clock used in the synchronous serial shift register interface. The falling edge is used to shift data both into and out of the module.
PWRBUS	B5	I/O	Not Used
MOD_DATA_IN*	A6	I	MODULE LOAD, MODULE DATA IN: The module load function is used in the synchronous serial shift register interface to pre-load the module's output shift register prior to transferring data out of the module to the Tram-rac. When this interface is used, active-low binary input data is transferred to the module's input serial shift register on this signal with the falling edge of the module data clock signal.
WF_OUT1	B6	I/O	Not Used
MOD_DATA_OUT*	A7	O	MODULE DATA OUT*: When the 7000-series synchronous serial shift register interface is used, active-low binary output data is transferred from the module's output shift register on this signal with the falling edge of the module data clock signal.
WF_OUT2	B7	I/O	Not Used
MOD_DATA_LAT*	A8	I	MODULE DATA LATCH*: This signal is the 7000-series module data latch strobe used in the synchronous serial shift register interface. After 8 data bits of input data have been shifted into the module using the module data clock signal, this signal strobes the input data into the modules latch.
WF_OUT3	B8	I/O	Not Used
AGND	A9	I	Not Used

Signal Name	Pin	Type	Description
123KHZ	B9	I	Not Used
CALIBRATE*	A10	I	Not Used
WF_OUT5	B10	O	Not Used
GND	A11, B11	I	GROUND: These pins are the logic reference and the +5V power supply return lines.
TN_ENA*	A12	O	TRAMNET ENABLE*: When high this signal identifies the device's communication protocol as the synchronous serial shift register interface. When low this signal identifies the device's communication protocol as Tramnet.
+5	B12	I	+5V DIGITAL POWER: +5V power supply to the module for the device digital circuitry.
+15V	A13, B13	I	Not Used
-15V	A14, B14	I	Not Used
AGND	A15, B15	I	Not Used

Software Updates

Two types of downloading procedures are available for the Masimo module. Software may be downloaded from a programmed software diskette using a patient monitor by either of the following two ways:

- from a laptop personal computer or terminal, or
- across the Unity Network from a central station.

These procedures are explained in detail in the software upgrade kit. Contact your GE Medical Systems *Information Technologies* service representative for information.

For your notes

5 Parts Lists and Drawings

For your notes

Ordering Parts

General

The parts lists and assembly drawings in this chapter supply enough detail for you to order parts for the assemblies considered field serviceable. If you require additional information or troubleshooting assistance, contact Tech Support.

To order parts, contact Service Parts at the address or telephone number listed on the "How to Reach Us...," page found at the front of this manual.

Field Replaceable Units

The tables below list the most commonly replaced assemblies ordered in the service spare circuit board kits.

Field Replaceable Units	
Item	**Part Number**
Masimo SET SpO_2 Module PCB	2001857-001
Masimo SET SpO_2 Module Flex PCB	2001861-001
Masimo SET SpO_2 MS-3 PCB	2002271-001

The following is a list of all accessories available for the Masimo SET SpO2 Module.

Accessories	
Description	**Part Number**
Cable Assy Patient Adapter Masimo SpO2 12 FT	2002592-001
Cable Assy Patient Adapter Masimo SpO2 8 FT	2002592-002
Kit Samples Masimo Adult/Pediatric Sensors	2002797-001
Masimo LNOP Adt Adult Sensor	N/A
Masimo LNOP Pdt Pediatric Sensor	N/A
Kit Samples Masimo Neonatal Sensors	2002798-001
Masimo LNOP Neo Neonatal Sensor	N/A
Masimo LNOP NeoPt Neonatal Sensor	N/A
Masimo LNOP DC1P Reusable Finger Sensor Pediatric	2002799-001
Masimo LNOP DC1 Reusable Finger Sensor Adult	2002800-001

Disassembly Procedures

Refer to the exploded view that follows these procedures for part location.

Assembly Housing

1. Remove 2 screws from the module top and 2 screws from the module bottom.
2. Slide the housing away from the bezel.

Masimo SET SpO_2 MS-3 PCB

1. Remove the assembly housing according to the steps above.
2. Remove 3 screws from the MS-3 PCB and pull the PCB up and away from the spacers.
3. Disconnect the Masimo module flex PCB from the MS-3 PCB and remove the MS-3 PCB.

Masimo SET SpO_2 Module Flex PCB

1. Remove the assembly housing and the Masimo module MS-3 PCB according to the steps above.
2. Disconnect ends of the flex assembly and remove.

Masimo SET SpO_2 Module PCB

When the assembly housing, the MS-3 PCB, and the flex PCB are removed according to the steps above, the Masimo module PCB is loose and can be removed.

Reassembly

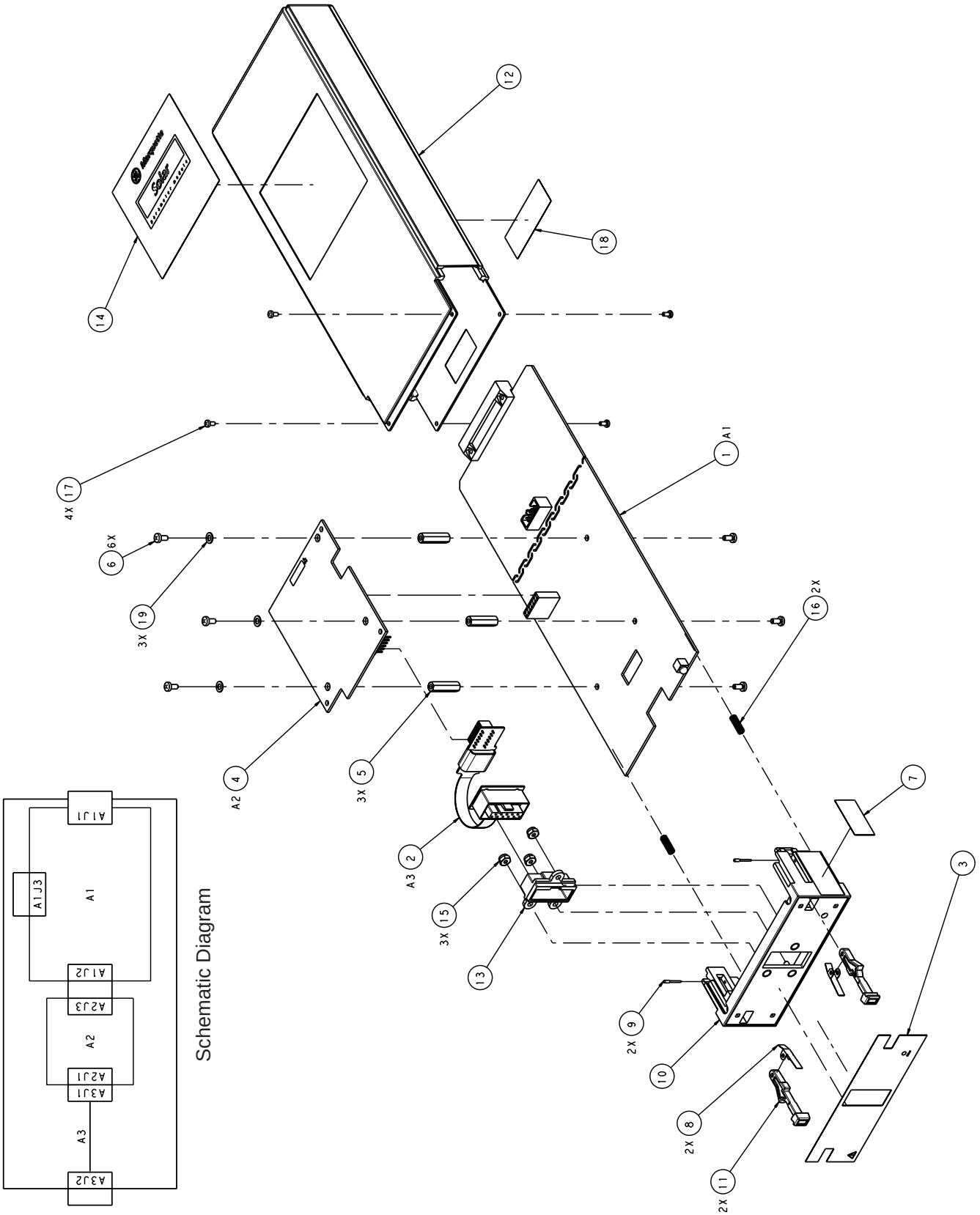
Reverse the above steps to reassemble the Masimo module.

Testing

Perform the Electrical Safety Tests described in chapter 3, Maintenance.

Solar SpO_2 Module with Masimo SET 2001891-001A

Find Number	Item Number	Item Description	Qty
1	2001857-001	PCB MASIMO SET SPO2 MODULE	1
2	2001861-001	PCB FLEX MASMO SET SPO2 MODULE	1
4	2002271-001	PCB MS-3 MASIMO SET SPO2	1
5	2002326-001	SPACER 5.5MM HEX M3 F/F 20.1LG NYLON	3
6	45209-411	SCREW PH M3 X 8MM	6
7	404525-008	LABEL BLANK 1.2IN X .6IN	1
8	406019-001	LATCH SPRING TRAM	2
9	406037-001	LATCH PIN TRAM	2
10	410124-020	MDL FR BEZEL NICOLAY SGL 11P	1
11	410337-001	LATCH MODULE	2
12	412669-001	ASSY MODULE HOUSING	1
13	414536-001	ADAPTER CONN NICOLAY 11P	1
14	2004668-001	LABEL MODULE COVER SOLAR	1
15	4521-304	NUT,ESNA,4-40,	3
16	4551-312	SPRING COMPRESSION .50 LG	2
17	4760-014	SCREW PH 2-56X3/16 COATED	4
18	404525-001	LABEL BLANK 2 X 3/4	1
19	4550-014	WASH NYL .28 OD .12 ID .03THK	3
24	2004407-001	MNL SVCE MASIMO SET SPO2 MODULE ENG	.25


12
18
14
4X 17
6X 6
3X 19
1 A1
16 2X
A2 4
3X 5
A3 2
3X 15
13
7
3
2X 9
10
2X 8
2X 11
A1J1
A1J3
A1
A1J2
A2J3
A2
A2J1
A3J1
A3
A3J2
Schematic Diagram

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