Testing Safety Information

Warning

Perform all leakage tests any time the unit is opened.

AC mains voltage is present on the applied part terminals during this test. Exercise caution to avoid electrical shock hazard.

Note

The monitor must be placed in **Diagnostic Mode**, with the NBP test screen active for each of the NBP tests.

If the test fails, ensure the integrity of the cuff and tubing, then test again. If the test fails again, verify the integrity of all the pneumatic tubing inside the monitor.

Before beginning the Battery Performance test, ensure that the monitor is disconnected from the AC power source.

Objectives

In order to meet this chapter's objectives, you should be able to test the monitor through the following types of tests:

- Performance Assurance Check List
- Accuracy, Calibration and Performance Procedures
- Patient Safety Checks

For inspection procedures; preventative maintenance procedures; cleaning procedures; and battery maintenance, refer to this chapter and *Chapter 2, "Site Preparations"*.

Concepts

Functionality Assurance

This refers to the combined Performance Assurance Test and Functionality Testing Procedures found in this chapter. These tests verify correct monitor functionality in general terms.

Preventative Maintenance

Preventative Maintenance refers specifically to the service calibration tests required to ensure the monitor measurement results are accurate. When authorized Philips personnel service the monitor, they report these results back to Philips. The collected data forms a database to be used in product development. These specific tests are required for the NBP parameter. It is not necessary for hospital personnel to report results.

Performance and Safety Tests

This concept refers to all the remaining accuracy and performance tests available on the monitor, including safety tests and checks for the monitor.

Testing Checklist

The tests described in this chapter are listed in the table below. Use this table as a checklist.

Topics	See...	Check Here if Completed	Date Completed
Functionality Assurance Tests			
Performance Assurance Test	*page 4-11*		
Power-On Self-Test	*page 4-11*		
Alarm Test	*page 4-12*		
Volume Control Test	*page 4-12*		
Preventive Maintenance Tests			
NBP	*page 4-14*		
Performance Procedures			
Battery Performance Test	*page 4-22*		
Temperature Test	*page 4-23*		
ECG Performance	*page 4-25*		
Respiration Performance	*page 4-25*		
SpO_2 Performance	*page 4-27*		
CO_2 Performance	*page 4-29*		
Serial Interface and Nurse Call Signal Test	*page 4-36*		
ECG Sync Performance Test	*page 4-38*		
Patient Safety Tests			
S(1) Ground Integrity	*page 4-39*		
S(2) Electrical Leakage	*page 4-41*		
S(3) Earth Leakage Current	*page 4-41*		
S(4) Enclosure Leakage Current	*page 4-42*		
S(5) Patient Leakage Current	*page 4-43*		
S(6) Patient Leakage Current with Mains	*page 4-44*		

Test Reporting

The following table shows what must be recorded on the Service Record after completing the tests in this chapter.

Test	What to Record
Functionality Assurance Tests	
Visual	V:P or V:F
Power **O**n	PO:P or PO:F
Preventive Maintenance Tests	
P NBP	PN:P/X1/X2/X3/X4/X5 or PN:F/X1/X2/X3/X4/X5 See page 4-15 for details
Performance Procedures	
CO_2 Performance	PCO_2: P/X1/X2/X3/X4/X5/X6/X7 or PCO_2: F/X1/X2/X3/X4/X5/X6/X7 See page 4-30 for details
Patient Safety Tests	
Safety(1) Ground Integrity	S(1):P or S(1):F
Safety(2) Earth Leakage Current	S(2):P or S(2):F
Safety(3) Enclosure Leakage Current	S(3):P or S(3):F
Safety(4) Patient Leakage Current	S(4):P or S(4):F
Safety(5) Patient Leakage Current with Mains	S(5):P or S(5):F

Where P = Pass, F = Fail and X is the measured value as defined in the tests described in this chapter.

Recommendations for Testing Frequency

The testing checklist appears in the next section of this chapter. Perform the procedure as indicated in the suggested testing timetable. These timetable recommendations do not supersede local requirements.

Suggested Testing	Frequency
Functionality Assurance • Performance Assurance Test • System Self-Test	When functional defects in the measurements are suspected, after any repairs, if the monitor has been dropped or opened.
Preventative Maintenance Tests (NBP)	Every year, or as needed.
Performance Tests • Battery Performance • Temperature Accuracy • ECG Performance • Resp Performance • SpO_2 Performance • CO_2 Performance • Serial Interface and Nurse Call Signal Test • ECG Sync Performance[a]	The battery performance test must be performed every two years, before monitor repairs, or whenever the battery is suspected as being the source of the problems. All other test must be performed at least once every year, if the monitor has been opened, or if you suspect defects in the measurements.
Safety Checks (in accordance with IEC 60601-1) • Ground Integrity • Electrical Leakage • Earth Leakage Current • Enclosure Leakage Current • Patient Leakage Current • Patient Leakage Current with Mains Voltage on the Applied Part	At least once every 2 years, after any repairs, if the monitor has been dropped or opened.

a. Only when in use as part of hospital protocol safety checks.

Test Map

The Test Map shows which tests are required in which situations.

Service Event (When performing...)	**Test Block Required (...complete these test)**
Installation	• Visual • Power On
Monitor exchange	• Visual • Power On
Monitor opened	• Power On • Pneumatic Leakage Test • All Safety tests
Battery replacement	• Power On • Battery Performance • All Safety tests
Speaker replacement	• Power On • Pneumatic Leakage Test • All Safety tests
Backlight tube replacement	• Power On • Pneumatic Leakage Test • All Safety tests
NBP pump replacement	• Power On • Pneumatic Leakage Test • All Safety tests • Preventative Maintenance Tests
SpO_2 module replacement	• Power On • Pneumatic Leakage Test • All Safety tests • SpO_2 Tests
CO_2 module replacement	• Power On • Pneumatic Leakage Test • All Safety tests • CO_2 Tests
Power supply module replacement	• Power On • Pneumatic Leakage Test • Safety Tests
Patient monitoring I/O module replacement	• Power On • Pneumatic Leakage Test • All Safety tests • All Performance tests
Communications module replacement	• Power On • Pneumatic Leakage Test • All Safety tests

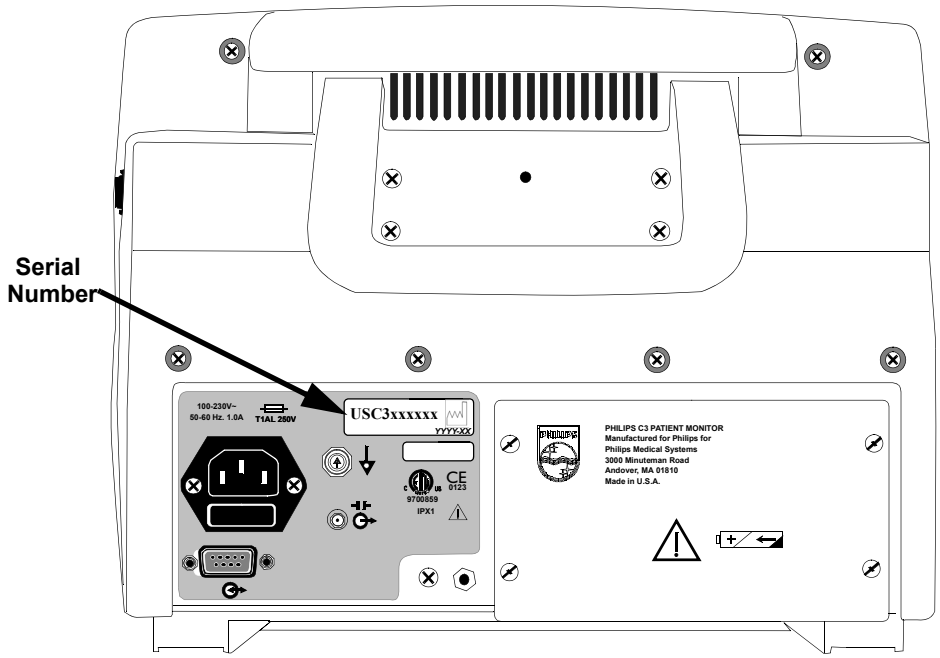
Equipment

The following table lists the equipment required for performance verification.

Equipment	Description
Digital multimeter (DMM)	Fluke model 87 or equivalent
Defib Sync Cable and Switchcraft 3.5 mm phone plug	M4820A (see page 4-38 to use a substitute cable) Switchcraft 750 or equivalent
SpO_2 adapter cable	M1943A
SpO_2 reusable sensor, adult finger	M1191A
ECG trunk cable	M1540C (ICU, AAMI) or M1550C (ICU, IEC)
ECG electrodes	Standard
ECG lead sets	M1605A (AAMI) or M1615A (IEC)
NBP tubing	M1599B
NBP reusable cuff, adult	40401C
Pulse oximeter tester	Clinical Dynamics Corp - SmartSat simulator with Nellcor simulator cable
ECG simulator	Dynatech Nevada medSim 300 or equivalent
NBP simulator	Bio-Tek BP Pump 2 or equivalent
Temperature simulator	MedSim 300 or equivalent
Respiration simulator	MedSim 300 or equivalent
Safety analyzer	Bio-Tek 601 Pro or equivalent
Stopwatch	Manual or electronic
Screwdriver	flathead and philips
Tweezers	any model
Electronic flowmeter	M1026-60144
Cal 1 gas (5% CO_2)	15210-64010
Cal 2 gas (10% CO_2)	15210-64020
Cal gas flow regulator	M2267A
Cal tube	13907A

Serial Numbers

When recording test results, these are always associated with a particular monitor by means of the serial number. The serial number is 10 characters and is located on the back of the monitor.



Passwords

Some of the test may require that you enter the **Power-Up Default Menu** located in the **Setup Menu**. To access **Power-Up Default Menu** you must enter a password. The password is:

2 - 1 - 5

Visual Test

Inspect the system for obvious signs of damage. Also check external leads and accessories.

What to record on the service record:

V:P or V:F

Power On Test

Step	Action
1	Switch the monitor On.
2	Observe whether the system boots up successfully without displaying any error codes. The main monitoring screen should display.

What to record on the service record:

PO:P or PO:F

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Functionality Assurance Tests

The following assurance checks are recommended to verify proper operation daily before the monitor is used to monitor a patient.

During functionality assurance checks, verify the overall operation by completing the following Performance Assurance Tests.

Performance Assurance Test

To verify your monitor works properly, perform the following test:

Step	Action
1	Using the supplied AC power cord, connect the monitor to the AC power source.
2	Verify that the AC LED is lit.
3	Do not connect any patient monitoring input connectors or cables to the monitor. If there are any such connections, disconnect them.
4	If the monitor is Off, press the **On/Standby** button. The monitor must perform the following sequence: a. The screen backlight illuminates. b. Three consecutively higher pitched "chimes" sound while the version numbers of the boot and operational software display. c. After successful completion, the main monitoring screen displays. No vital sign numeric values or waveforms display.
5	If any error codes display, or the screen remains blank, refer to *Chapter 6, "Troubleshooting"*.

Power-On Self-Test

After you first press the **On/Standby** button, the monitor displays a startup screen and conducts a set of self-diagnostic test routines.

Alarm Test

Tools Needed:

- SpO_2 adapter cable (M1943A)
- Clinical Dynamics Corp - SmartSat simulator (with Nellcor simulator cable)

Step	Action
1	Connect SpO_2 simulator cable to the SpO_2 adapter cable. Connect the cable to the SpO_2 patient monitoring input connector.
2	Set the simulator as follows: **Item** — **Setting** Oximeter — Nellcor SpO_2% — 81 BPM — 36 Pulse Mod — 0.50%
3	Press the **On/Standby** button to turn the monitor On.
4	After the normal power-up sequence, verify that the SpO_2% display initially indicates zero, or is blank.
5	Verify that the following monitor reaction occurs: a. After approximately 45 seconds, the monitor displays saturation and heart rate as specified by the tester. Verify that the values are within the following tolerances: – Oxygen Saturation Range 79% to 83% – Heart Rate Range 33 to 39 bpm b. The audible alarm sounds and both the SpO_2% and Heart Rate (HR) displays flash, indicating both parameters have violated the default alarm limits. c. The HR tone is heard. For this test, the HR tone source must be set to SpO_2 from the **Heart Rate Menu**.
6	Press the **Alarm Silence** button to temporarily silence the audible alarm.
7	Verify the following: a. The audible alarm remains silenced. b. The crossed-out bell icon displays in each numeric frame on the screen. c. The SpO_2% and HR displays continue flashing. d. The HR tone remains audible. e. The audible alarm returns in approximately 120 seconds.

Volume Control Test

Tools Needed:

- SpO_2 adapter cable (M1943A)
- Clinical Dynamics Corp - SmartSat simulator (with Nellcor simulator cable)

Step	Action
1	Connect SpO_2 simulator cable to the SpO_2 adapter cable. Connect the cable to the SpO_2 patient monitoring input connector.
2	Set the simulator as follows: **Item** — **Setting** Oximeter — Nellcor SpO_2% — 81 BPM — 70 Pulse Mod — 5.00%
3	a. Power the monitor On. Verify that the values are within the following tolerances: – Oxygen Saturation Range 79% to 83% – Heart Rate Range 67 to 73 bpm
4	Press the **Alarm Silence** button to temporarily silence the audible alarm.
5	Verify that the heart rate tone source, found in the **Heart Rate Menu**, is set to SpO_2.
6	Press the **Volume** button on the monitor's front panel. Within 3 seconds of having pressed the button, rotate the navigation wheel clockwise to verify that the beeping heart rate tone sound level increases.
7	Wait 3 seconds. Press the **Volume** button and rotate the wheel counter-clockwise and verify that the beeping heart rate tone decreases until it is no longer audible. Rotate the wheel clockwise to return the beep volume to a comfortable level. After 3 seconds with no wheel activity, the volume adjust function terminates.

Preventative Maintenance Tests

Preventative maintenance refers specifically to the service tests required to make sure the monitor measurement results accurate. In cases where the performance of NBP is in question or could have been configured during repair, the complete set of NBP tests described in this service manual should be used.

The tests in this section verify the functionality of the monitor's pneumatic system. All of these tests, which the exception of the Basic Pneumatic Leakage (BPL) Test, require the use of an NBP simulator.

Note

The monitor must be placed in **Diagnostic Mode**, with the NBP test screen active for each of the NBP tests. To place your monitor into this mode see page 4-9.

Tools Needed for NBP Testing:

- NBP cuff (40401C)
- NBP tubing (M1599B)
- Bio-Tek BP Pump 2 simulator or equivalent, with an internal test volume of 310 ml.

Documenting NBP Test Results

The following table lists the tests that should be documented and summarizes how to document the NBP test results.

Test	Expected Test Results	What to record on service record
Pressure Transducer Accuracy Test	X1 = difference between the pressure on the monitor and on the simulator Difference less than or equal to 5 mmHg (0.7 kPa)	PN:P/X1/X2/X3/X4/X5 or PN:F/X1/X2/X3/X4/X5 P = passed, F = failed
Pneumatic Leakage Test	X2 = difference between the pressure at the start (P1) and after one minute (P2) Difference less than or equal to 6 mmHg (0.8 kPa)	
Inflation Rate Test	X3 = number of seconds for the monitor to inflate Rate between 1 and 6 seconds	
Over-Pressure Test	X4 = peak value Peak value between 270 and 330 mmHg (36 kPa and 44 kPa)	
Deflation Rate Test	X5 = mmHg (kPa) per second to deflate 1.8 mmHg/s to 4.8 mmhg/s	

Pneumatic System Functionality

The following tests must be performed to verify pneumatic system functionality. Perform these tests in the following order:

1. Pressure Transducer Accuracy
2. Pneumatic Leakage
3. Inflation Rate
4. Over-Pressure
5. Deflation Rate

Note

The pneumatic system includes an over-pressure safety limit function and a safety period time-out function. These safety functions may interfere with NBP tests described in this section. In order to avoid activating these safety functions, do not pressurize the system above 270 mmHg (36 kPa) and do not pressurize the system for time periods that exceed 150 seconds.

To Zero the Simulator

If the simulator does not display a "0" before starting a test, use the following procedure to zero the simulator:

1. Disconnect the hose from the simulator.
2. Press **Home**.
3. Press **SETUP**.
4. Press **MORE**.
5. Press **MORE** again
6. Press **ZERO PRESSURE**.
7. Press **ZERO**.
8. Press **Home** to return to main menu.
9. Reconnect the hose.

Before beginning the above test sequence, perform the following three steps:

Step	Action
1	Turn the NBP simulator On.
2	Perform the following sequence: a. Press the **Home** button. b. Press the **Pressure Tests** button. c. Press the **Pressure Leak Test** button. d. Press the **Setup** button. e. Press **2**, **5**, **0**, then Enter. f. Set the Cuff to **Internal**.
3	Connect the simulator tubing to the NBP patient monitoring input connector.
4	Place the monitor in **Diagnostic Mode** with the NBP test screen active.

Pressure Transducer Accuracy Test

This test verifies the pressure accuracy of the monitor's pressure transducer.

Step	Action
1	Confirm that the simulator displays "Leak Test" (see steps 1 and 2, in the previous table).
2	Press the **Volume** button to ensure that both valves are closed.
3	Perform an offset adjustment so that the simulator and monitor both display a pressure of 0 mmHg or kPa by doing the following: a. Press the **Contrast** button on the monitor's front panel. b. If needed, zero the simulator (see "To Zero the Simulator" on page 4-16).
4	Press **Start** on the simulator.
5	Allow 15-20 seconds for the pressure to stabilize. The pressure displayed on the monitor and on the simulator should be within 5 mmHg (0.7 kPa) of one another. Document the difference between the simulator value and the monitor value (X1).
6	Press the **Stop** button on the simulator to stop the test.
7	Press and hold the **Volume** button until the monitor displays a pressure of 0 mmHg or kPa.
8	If no further NBP tests are to be conducted, turn the monitor Off. Normal monitoring operation returns the next time the monitor is turned On.

Pneumatic Leakage Test

This test verifies the integrity of the pneumatic system.

Step	Action
1	Turn the simulator on.
2	Perform the following sequence: a. Press the **Home** button. b. Press the **Pressure Tests** button. c. Press the **Pressure Leak Test** button. d. Press the **Setup** button. e. Press **3**, **0**, **0**, then **Enter**. f. Set the **Cuff** to **Internal**.
3	Confirm that the simulator test screen is active and displays "Leak Test".
4	Press the **Volume** button to ensure that both valves are closed.
5	Perform an offset adjustment so that the simulator and monitor both display a pressure of 0 mmHg or kPa by doing the following: a. Press the **Contrast** button on the monitor's front panel. b. If needed, zero the simulator (see "To Zero the Simulator" on page 4-16).
6	Press the **NBP** button on the monitor's front panel to activate the pump. Hold the button until the monitor displays a pressure of approximately 250 mmHg (33.3 kPa).
7	Allow 15-20 seconds for the pressure to stabilize. Record the pressure displayed on the monitor (P1).

Step	Action
8	Start a one minute timer. After one minute, record the pressure displayed again (P2). The pressure should drop by no more than 6 mmHg (0.8 kPa) during the one minute period. Calculate (P1 - P2) and document the leakage test value (X2).
9	Press and hold the **Volume** button until the monitor displays a pressure of 0 mmHg or kPa.
10	If no further NBP tests are to be conducted, turn the monitor Off. Normal monitoring operation returns the next time the monitor is turned On.

Inflation Rate Test

This test verifies the inflation rate of the monitor.

Step	Action
1	Turn the simulator on.
2	Perform the following sequence: a. Press the **Home** button. b. Press the **Pressure Tests** button. c. Press the **Pressure Leak Test** button. d. Press the **Setup** button. e. Press **3**, **0**, **0**, then **Enter**. f. Set the **Cuff** to **Internal**.
3	Press the **Volume** button to ensure that both valves are closed.
4	Perform an offset adjustment so that the simulator and monitor both display a pressure of 0 mmHg or kPa by doing the following: a. Press the **Contrast** button on the monitor's front panel. b. If needed, zero the simulator (see "To Zero the Simulator" on page 4-16).
5	Press the **NBP** button on the monitor's front panel to activate the pump, and simultaneously start the timer. Hold the button until the monitor displays a pressure of 250 mmHg (33.3 kPa), then stop the timer. The inflation rate should be between 1 and 6 seconds. Document the number of seconds (X3).
6	Press and hold the **Volume** button until the monitor displays a pressure of 0 mmHg or kPa.
7	If no further NBP tests are to be conducted, turn the monitor Off. Normal monitoring operation returns the next time the monitor is turned On.

Note

The over-pressure relief may activate and automatically deflate the cuff. For more information on the NBP safety functions, see page 4-16.

Over-Pressure Test

This test verifies the functionality of the over-pressure relief system of the monitor.

Step	Action
1	Turn the simulator on.
2	Perform the following sequence: a. Press the **Home** button. b. Press the **Pressure Tests** button. c. Press the **Pressure Relief** button. d. Press the **Setup** button. e. Press **3**, **3**, **5**, then **Enter**.
3	Confirm that the simulator is active and displays "Relief Valve Test".
4	Press the **Volume** button to ensure that both valves are closed.
5	Perform an offset adjustment so that the simulator and monitor both display a pressure of 0 mmHg or kPa by doing the following: a. Press the **Contrast** button on the monitor's front panel. b. If needed, zero the simulator (see "To Zero the Simulator" on page 4-16).
6	Press the **Start** button on the simulator. The peak value (X4) shown on the simulator should be between 270 mmHg and 330 mmHg (35.9 kPa and 43.9 kPa). The pressure should return to 0 automatically on the monitor and simulator). Both conditions should be true for the monitor to pass this test.
7	If no further NBP tests are to be conducted, turn the monitor Off. Normal monitoring operation returns the next time the monitor is turned On.

Deflation Rate Test

This test verifies the deflation rate of the monitor.

Step	Action
1	Turn the simulator on.
2	Perform the following sequence: a. Press the **Home** button. b. Press the **Pressure Tests** button. c. Press the **Pressure Leak Test** button. d. Set the **Cuff** to **Internal**.
3	Confirm that the simulator is active and displays "Leak Test".
4	Press the **Volume** button to ensure that both valves are closed.
5	Perform an offset adjustment so that the simulator and monitor both display a pressure of 0 mmHg or kPa by doing the following: a. Press the **Contrast** button on the monitor's front panel. b. If needed, zero the simulator (see "To Zero the Simulator" on page 4-16).
6	*Note*—Complete steps 6-9 within 150 seconds. Press and hold the **NBP** button on the monitor's front panel and inflate to 250 ±10. Don't go over 270, or safety deflation may occur. (Slow the inflation rate by pulsing the button when the pressure is over 200).
7	Allow 15-20 seconds for the pressure to stabilize. Record the pressure displayed on the monitor (P1).
8	Press and hold the "Alarm off" button on the monitor to release the pressure in steps of 3 mmHg (.4 kPa). Simultaneously, start the timer.
9	Stop the timer when the pressure drops below 150 mmHg (20 kPa). Calculate the deflation rate (X5): (starting pressure - 150)/# of seconds. The deflation rate should be 3.3 mmHg/s ±1.5 mmHg/s (0.44 kPa/s ± 0.2 kPa/s).
10	Press and hold the **Volume** button until the monitor displays a pressure of 0 mmHg or kPa.
11	If no further NBP tests are to be conducted, turn the monitor Off. Normal monitoring operation returns the next time the monitor is turned On.

Basic Pneumatic Leakage (BPL) Test

The purpose of this test is to verify the integrity of the NBP pneumatic system after the monitor has been opened. This includes all external and internal tubing connections.

No simulator is required for this test, and results are not required to be reported.

Step	Action
1	Attach the NBP cuff to the NBP tubing and the tubing to the NBP patient monitoring input connector.
2	Wrap the cuff around itself and place it on a table for the test. DO NOT place the cuff on your arm.
3	Turn the monitor On and enter the NBP test screen located within **Diagnostic Mode**.
4	Press the **Volume** button to close valves.
5	a. Press and hold the **NBP Start/Stop** switch until the monitor's screen reads "250 mmHg" or "33.3 kPa". b. Wait 15-20 seconds to allow the pressure to stabilize.
6	a. Note the value on the screen (P1), then start a timer. b. After one minute, note the value on the screen (P2). c. Calculate the difference between the two values (P1 - P2). The value should be less than or equal to 6 mmHg (0.8 kPa).
7	Press and hold the **Volume** button until the screen shows the pressure has released and the value is 0 mmHg or kPa.
8	Turn the monitor Off.

Note

If the test fails, ensure the integrity of the cuff and tubing, then test again. If the test fails again, verify the integrity of all the pneumatic tubing inside the monitor.

Performance Procedures

The following accuracy and performance procedures are designed to be completed to verify the accuracy and performance of the monitor. They must be performed, according to the frequency specified in the section titled, *"Recommendations for Testing Frequency" on page 4-6*.

Battery Performance Test

The battery performance test should be performed every two years, before monitor repairs, or whenever the battery is suspected as being a source of the problems. Before performing the battery performance test, verify that the battery is fully charged (see *"Charging the Battery" on page 3-9*).

Note

Before beginning this test, ensure that the monitor is disconnected from the AC power source.

Tools Needed:

- SpO_2 adapter cable (M1943A)
- Clinical Dynamics Corp - SmartSat simulator (with Nellcor simulator cable)
- NBP tubing (M1599B)
- Bio-Tek BP Pump 2 simulator or equivalent, with an internal test volume of 310 ml

Note

The instructions below apply to the Bio-Tek BP Pump 2 simulator.

Step	Action
1	Connect SpO_2 simulator cable to the SpO_2 adapter cable. Connect the cable to the SpO_2 patient monitoring input connector.
2	Connect the NBP simulator to the monitor via the NBP tubing.
3	Set the SpO_2 simulator switches as follows: **Item** — **Setting** Oximeter — Nellcor SpO_2% — 81 BPM — 36 Pulse Mod — 0.50%
4	Set the NBP simulator to a pressure setting of 120/80 mmHg (16/11 kPa), and a heart rate of 80 bpm.

Step	Action
5	With the monitor Off, press the **On/Standby** button. (When the monitor is turned on, the battery icon may initially indicate a higher charge then it actually holds - wait 5 minutes or until after an NBP measurement for an accurate battery reading.)
6	Verify that the monitor is responding to the SpO_2 simulator signal and that the audible alarm is sounding. Use the navigation wheel to select the **SpO_2 Menu** and permanently silence the SpO_2 audible alarm. Select the **Heart Rate Menu** and silence the Heart Rate alarm.
7	Use the navigation wheel to select the **NBP Menu** and set the **Automatic Interval Mode** option to 15 minutes. Select **Return** to exit the menu.
8	Press the **NBP** button on the monitor's front panel to start the first NBP measurement. Subsequent NBP measurements are taken automatically every 15 minutes.
9	Verify that the battery icon displays at the bottom of the display. Note the time. (At least one segment of the battery icon should be filled.)
10	Keep the monitor On until the low battery warning alarm occurs. Note the time. Verify that alarm sounds 15-30 minutes before the battery fully discharges.
11	Keep the monitor On until it automatically powers down due to low battery condition. Verify that the audible alarm sounds when the monitor automatically shuts down. Note the time. **Press any front panel button, on the monitor, to terminate this audible alarm.**
12	If the monitor passes this test, immediately recharge the battery. If it fails the test, replace the battery. (See *"Removing the Battery" on page 7-4* for more information).

Temperature Test

The accuracy of the monitor's temperature measurements is ±0.1°C (±0.2°F). In the procedure below, add the tolerance of the simulator to the acceptable range of readings.

Tools Needed:

- Dynatech Nevada MedSim 300 or equivalent simulator
- Temperature cable (supplied with the temperature simulator)

Note

The instructions below apply to the Dynatech Nevada MedSim 300.

Step	Action
1	Verify the monitor is turned Off. Connect the temperature cable to the appropriate connector on the temperature simulator.
2	Connect the temperature cable to the Temperature patient monitoring input connector.

Step	Action
3	Set the temperature simulator as follows: a. Temperature: 37°C (98.6°F). b. Probe Type: YSI 400 Series
4	Press the **On/Standby** button to turn the monitor On.
5	After the power-up sequence, verify the temperature reads 37°C ±0.1°C (98.6°F ±0.2°F if Fahrenheit is selected as the temperature unit).
6	Turn the monitor Off.

ECG/ Respiration Performance

This section includes tests for both ECG and Respiration.

Tools Needed for both ECG and Respiration testing:

- ECG leads - M1605A (AAMI) or M1615A (IEC)
- ECG trunk cables - M1540C (ICU, AAMI) or M1550C (ICU, IEC)
- Dynatech Nevada MedSim 300 or equivalent simulator

ECG Test

The accuracy of the monitor's ECG measurements is ±5 bpm. In the following procedure, add the tolerance of the simulator to the acceptable range of readings.

Step	Action
1	Verify that the monitor is turned Off. Connect the ECG leads to the appropriate jacks on the ECG simulator.
2	Connect the leads to the ECG trunk cable. Connect the cable to the ECG patient monitoring input connector.
3	Set the ECG simulator as follows: **Set...** — **To...** Heart Rate (HR) — 30 bpm Lead select — II
4	Press the **On/Standby** button to turn the monitor On.
5	After the power-up sequence, verify the following monitor reactions: a. After at least five heartbeats, the monitor displays a heart rate of 30 ±5 bpm. b. The audible alarm sounds and the Heart Rate frame flashes, indicating heart rate is below the default lower alarm limit.
6	Press the **Alarm Silence** button twice (on the monitor's front panel) to invoke the Silence/Reset mode.
7	Increase the heart rate setting on the ECG simulator to 240 bpm. After at least five heartbeats, verify that the monitor displays a heart rate of 240 ±5 bpm.
8	Verify that the audible alarm sounds and the Heart Rate frame flashes, indicating that the heart rate is above the default upper alarm limit.
9	Press the **Alarm Silence** button twice (on the monitor's front panel) to invoke the Silence/Reset mode.
10	Decrease the heart rate setting on the ECG simulator to 120 bpm. After at least five heartbeats, verify that the monitor displays a heart rate of 120 ±5 bpm.
11	Disconnect the LL lead from the ECG simulator. Verify that the Leads Off alarm message displays. -?- displays in the Heart Rate frame, and the low priority "Leads Off" INOP sounds.
12	Reconnect the LL lead to the ECG simulator. Verify that the Leads Off alarm message no longer displays and the audible alarm is silenced.
13	Repeat steps 11 and 12 for LA and RA leads, then turn your monitor Off.

Respiration Test

The accuracy of the monitor's respiration measurements is ±3 breaths per minute. In the procedure below, add the tolerance of the simulator to the acceptable range of readings.

Step	Action
1	Verify that the monitor is turned Off. Connect the ECG leads to the appropriate jacks on the ECG simulator.
2	Connect the ECG leads to the ECG trunk cable.
3	Connect the cable to the ECG patient monitoring input connector.
4	Set the simulator for a respiration rate of 120 breaths per minute.
5	Press the **On/Standby** button to turn the monitor On.
6	After the power-up sequence, verify the following monitor reactions: a. The monitor displays a respiration rate of 120 ±3 breaths per minute. b. The audible alarm sounds and the Respiration Rate frame flashes, indicating the respiration rate is above the default upper alarm limit.
7	Press the **Alarm Silence** button to silence the alarm.
8	Decrease the respiration rate setting on the respiration simulator to 20 breaths per minute. Verify that the monitor displays a respiration rate of 20 ±3 breaths per minute.

SpO_2 Performance

SpO_2 testing includes the following tests:

- Dynamic Operating Range
- LED Excitation Test

Tools Needed for SpO_2 Tests:

- Clinical Dynamics Corp - SmartSat simulator (with Nellcor simulator cable)
- SpO_2 adapter cable (M1943A)
- SpO_2 reusable sensor, adult finger (M1191A)

Dynamic Operating Range Test

The following test sequence verifies proper monitor operation over a range of input signals.

Step	Action
1	Connect SpO_2 simulator cable to the SpO_2 adapter cable. Connect the cable to the SpO_2 patient monitoring input connector.
2	Set the simulator as indicated in the table below. Verify that the monitor readings are within the indicated tolerances. Allow the monitor several seconds to stabilize the readings.
3	Turn the monitor Off.

Table 4-1. Settings and Monitor Indications

Simulator Settings					Monitor Indications	
SpO_2%	Pulse Rate	Ambient Light Freq	Ambient Light Ac Level	Modulation	SpO_2	Pulse Rate
81	36	120	200	0.50%	79-83*	33-39*
81	112	120	200	5.00%	79-83*	109-115
81	201[a]	120	10	0.50%	79-83*	195-207*
81	201[a]	120	200	5.00%	79-83*	195-207*

An * indicates values that produce an alarm. Press the **Alarm Silence** button to temporarily silence the audible alarm.

a. For the pulse rate setting of 201 bpm, the pulse rate tolerance of 195 to 207 bpm is greater than ±3 bpm accuracy specification on the monitor, due to the performance characteristics of the simulator.

LED Excitation Test

This procedure uses normal system components to test circuit operation. A SpO2, adult finger, reusable sensor is used to examine LED intensity control. The red LED is used to verify intensity modulation caused by the LED intensity control circuit.

Step	Action
1	Connect an SpO_2 sensor to the monitor.
2	Press the **On/Standby** button to turn the monitor On.
3	After the monitor completes its normal power-up sequence, verify that the sensor LED is brightly lit.
4	Slowly move the sensor LED in proximity to the photo detector element of the sensor. Verify, as the LED approaches the optical sensor, that the LED intensity decreases.
5	Open the sensor and take note that the LED intensity increases.
6	Repeat Step 5 and the intensity again decreases. This variation is an indication that the micro-processor is in proper control of LED intensity.
7	Turn the monitor Off.

CO_2 Performance

This test checks the performance of your CO_2 measurement for the monitor. This test uses calibration equipment that can be ordered (contact your Philips representative). Refer to the documentation accompanying the equipment for detailed instructions. The procedure is summarized in the following steps:

- Barometric Pressure Check and Calibration, if required
- Leakage Check
- Pump Check
- Flow Check and Calibration, if required
- CO_2 Cal Check and Calibration, if required
- CO_2 Cal Verification using Cal 2 gas

Note

Allow 5 seconds between individual service procedures in order to ensure stable equipment conditions.

Tools Needed for CO_2 Tests:

- Screwdriver
- Tweezers
- Cal 1 gas (5% CO_2)
- Cal 2 gas (10% CO_2)
- Cal gas flow regulator
- Cal tube

You also need a local barometric pressure rating received from a reliable local source, such as an airport, regional weather station, or hospital weather station. The pressure rating must be located at the same altitude as the hospital.

Note

All steps must be performed in the same session.

Documenting CO_2 Test Results

The following table lists the CO_2 tests and summarizes how to document the test results.

Test	Expected Test Results	What to record on service record
Barometric Pressure Check	X1 = difference between the reference pressure and the measured ambient pressure displayed on the monitor (-12 mmHg < X1 < +12 mmHg)	PCO_2: P/X1/X2/X3/X4/X5/X6/X7 or PCO_2: F/X1/X2/X3/X4/X5/X6/X7 P = passed, F = failed X1: xx (two digits) X2: x.x X3: x.x X4: xxx X5: x.x X6: x.x X7: x.x
Leakage Check parts 1 and 2	X2 = value of part 1 leakage check on flowmeter (X2 </= 4.0 ml/min) X3 = value of part 2 leakage check on flowmeter (X3</= 4.0 ml/min)	
Pump Check	X4 > 120 mmHg below the ambient pressure	
Flow Rate Check	X5 = CO_2 flow rate (42.5 ml/min <X5 <65 ml/min).	
CO_2 Gas Measurement Calibration Check	X6 = difference between measured CO_2 value and calculated value, based on 5% CO_2 cal. gas (X7<2.6 mmHg, or 0.35 kPa)	
Calibration Verification	X7 = difference between measured CO_2 value and calculated value, based on 10% CO_2 cal. gas. (X7±{0.07 x value calculated})	

Barometric Pressure Check and Calibration

Check the barometric pressure value in the CO_2 module as follows:

Step	Action
1	Enter the **Power-Up Defaults Menu** (see "*"Power-Up Defaults Menu" on page 5-3*"for instructions on accessing this menu).
2	Select the **Enter Diagnostic Mode?** option.
3	From the popup menu, select **Yes**. The **Diagnostic Menu** displays.
4	Select the **CO_2 Test** option.
5	Connect a FilterLine to the CO_2 patient monitoring input connector. This activates the pump in the CO_2 module.
6	Check the status line at the top of the screen. It will display "CO_2 pressure in mmHg (ambient/cell) xxx/yyy" where xxx is the ambient pressure and yyy is the measured cell pressure. The values are displayed with a resolution of 2 mmHg (0.3 kPa) up to 475 mmHg (63.2 kPa) and a resolution of 1 mmHg (0.1 kPa) from 475 mmHg (63.2 kPa) to 825 mmHg (109.7 kPa). Check whether the ambient pressure (X1) matches (within the acceptable tolerance of ±12 mmHg) the reference value you have received. If so, proceed to the *"Leakage Check"*. If the value is not correct, calibrate as follows.
7	Select **Set Barometric Pressure (mmHg)**. An adjustable value in mmHg is activated.
8	Select the value that matches the reference value received from a reliable local source, such as an airport, regional weather station or hospital weather station.
9	If the selected value is not with ±12mmHg (1.6 kPa) of the current measured ambient pressure, verify the reference value by getting another reading from a different source. If the ambient pressure displayed also differs from the new reference by more than ±12mmHg (1.6 kPa), the CO_2 module should be replaced.
10	Confirm the barometric pressure setting by clicking on the adjusted value so that it is no longer highlighted.
11	Check that the ambient pressure displayed in the CO_2 Pressure line at the top of the screen is the same as the value that you selected from the list in Step 8.

Leakage Check

The Leakage Check consists of two parts:

- Part 1 - Checking the tubing between the pump outlet and the CO_2 module outlet.
- Part 2 - Checking the tubing between the pump inlet and the FilterLine inlet.

Note

Check the flowmeter's user guide for details on how to make a correct flow reading.

Part 1

Step	Action
1	Check the ambient and cell pressure shown in the status line on the screen. The cell pressure should be approximately 20 mmHg (2.7 kPa) lower than the ambient pressure.
2	Connect the flowmeter outlet to the FilterLine inlet using a flexible connecting tube.
3	Block the CO_2 module outlet using your fingertip and observe the flowmeter display. The value on the flowmeter (X2) should decrease to between 0 and 4 ml/minute. If the value is not within the tolerance limits, there is a leakage between the pump outlet and the CO_2 module gas outlet.
4	If a leakage is found in Step 3, open the CO_2 module and check the tubing connections at the pump outlet and the module CO_2 gas outlet. If the connections are good, then there is leakage in the module and the CO_2 module must be exchanged.

Part 2

Step	Action
1	Disconnect the flowmeter from the Part 1 setup and connect the flowmeter inlet to the CO_2 module gas outlet.
2	Leave the FilterLine connected to the CO_2 module inlet.
3	Block the inlet of the FilterLine using your fingertip and observe the flowmeter display. The value on the flowmeter (X3) should decrease to between 0 and 4 ml/minute. If the value is within the tolerance limits, there are no leakages and the leakage check is completed. You can proceed to the *"Pump Check"*.
4	If the value is not within the tolerance limits, there is a leakage between the FilterLine inlet and the pump inlet.
5	Check the FilterLine connections and open the monitor to check the tubing connections at the pump inlet and the CO_2 module gas inlet. If the connections are good, try replacing the FilterLine and repeating the leakage check. If the situation remains, there is a leakage in the tubing and the CO_2 module must be exchanged.

Pump Check

Step	Action
1	Connect the flowmeter inlet to the CO_2 module gas outlet.
2	Connect the FilterLine to the CO_2 module inlet.
3	Block the inlet of the FilterLine using your fingertip and observe the cell pressure to the right of the slash symbol on the top row of the CO_2 Test display screen. The cell pressure (X4) should be more than 120 mmHg below the ambient pressure shown. If the pressure difference is less than 120 mmHg, the pump is not strong enough and should be replaced (regardless of the Pump Op Time).

Flow Rate Check and Calibration

Step	Action
1	Connect the flowmeter to the CO_2 FilterLine.
2	On the flowmeter, check the flow that the CO_2 Pump draws (X5). The nominal value is 50; the acceptable limits are 42.5 and 65 ml/minute. If the value is within these limits, proceed to the CO_2 Gas calibration check. If not within the limits, calibrate as follows.
3	Select **Flow Rate Check and Calibration**. Adjust the flow in the monitor by selecting **Increase Flow** or **Decrease Flow** until it is as close as possible to 50 ml per minute as indicated on the flowmeter gauge. The pump voltage displayed on the second row of the CO_2 Test screen will vary as the flow is changed.
4	When you are satisfied that the flow is set as close as possible to 50 ml per minute, select **Store Flow** to confirm the setting

Note

If the adjusted flow is not stored within 60 seconds of the adjustment, the old flow setting is restored. If the flow cannot be adjusted to within tolerance, the pump should be replaced. If the flow adjustment still cannot be made, this indicates a fault in the CO_2 module, which must be replaced.

CO_2 Gas Measurement Calibration Check

After switching the monitor on, or after turning on the etCO_2 On/Off setting in the etCO_2 frame, wait at least 20 minutes before checking the calibration.

Step	Action
1	Check that the 5% calibration gas and flow regulator are connected.
2	Calculate the expected measurement value in mmHg as follows: 0.05 x (ambient pressure) / 1.03 = value mmHg i.e. 0.05 x 736 mmHg / 1.03 = 35.7 mmHg (with an ambient pressure of 736 mmHg) *Note: Dividing by 1.03 compensates for the dry calibration gas at room temperature, relative to breath gases containing water vapor and at body temperature.*
3	Select **CO_2 Calibration**. Wait for the status message "CO_2 module reset in progress" to disappear. Open the valve on the flow regulator to allow 5% CO_2 gas to flow into the monitor. Allow the displayed CO_2 value (third row of **CO_2 Test** menu) to stabilize.
4	Check that the CO_2 value on the monitor matches the calculated mmHg value ±2.6 mmHg. If the value is outside the tolerance, calibrate as described in Step 9 to 13.
5	Disconnect the 5% calibration gas and connect the 10% calibration gas.
6	Calculate the expected measurement value and tolerance in mmHg as follows: 0.1 x (ambient pressure) / 1.03 = value mmHg ±0.07 x (value mmHg) = tolerance i.e. 0.1 x 737 mmHg / 1.03 = 71.6 mmHg (with an ambient pressure of 737 mmHg) ±0.07 x 71.6 mmHg = ±5.01 mmHg tolerance
7	Open the valve on the flow regulator to allow 10% CO_2 gas to flow into the monitor. Allow the value to stabilize.
8	Check that the value on the monitor (X6) matches the calculated mmHg value within the calculated tolerance. If so, the CO_2 module is correctly calibrated. If the value is outside the tolerance, calibrate as follows.
9	If not already connected, connect the 5% calibration gas.
10	Select **CO_2 Calibration** to enter the Calibration sub-menu. Wait for the status message "CO_2 module reset in progress" to disappear.
11	Select the value for the calibration gas (The default value is 5%).
12	Select **Start Calibration** and open the valve on the calibration gas to allow CO_2 gas to flow into the monitor. Allow the value to stabilize before the start of the calibration. Leave the valve open until the monitor gives a prompt that the gas can be removed.
13	The CO_2 module calibrates and prompts when calibration is successful.

Calibration Verification

Step	Action
1	Reopen the 5% gas valve and allow the value to stabilize.
2	Check that the value displayed on the monitor is correct and within the tolerance (see Step 2 in above section).
3	Disconnect the 5% calibration gas and connect the 10% calibration gas.
4	Open the valve on the flow regulator to allow 10% CO_2 gas to flow into the monitor. Allow the value to stabilize.
5	Check that the value displayed on the monitor (X7) is correct and within the tolerance (see Step 6 above). If one or both values are not within tolerances, the CO_2 module must be exchanged.

Reset Pump Operating Time Counters

If the pump in the CO2 module is replaced, the Pump Operating Time counter should be reset to start counting operating time for the new pump.

Step	Action
1	In the CO2 Test menu, select Pump Op Time.
2	Select **Reset to Zero**.

Note

When the Pump Op Time has been reset a "CO2 Equipment Malfunction" INOP will be generated on restarting the monitor. To clear this INOP you must perform a flow check and store the flow in **Diagnostic Mode** (select **Store Flow**).

Serial Interface and Nurse Call Signal Test

Perform the following procedure to test the serial port voltages. The test is qualitative and only verifies that the serial interface port is powered correctly, and that the Nurse Call signal is operational. The serial connector is a male DB-9 located on the monitor's rear panel, identified by the RS-232 symbol.

Tools Needed:

- Clinical Dynamics Corp - SmartSat simulator (with Nellcor simulator cable)
- SpO_2 adapter cable (M1943A)

Step	Action
1	Turn the monitor On.
2	Set up the DMM with the function set to VDC at a range of 10 volts.
3	Connect the DMM negative lead to connector pin 5 (GND), or the shell of the RS-232 connector.
4	Referring to *Table 4-2, Serial Interface Voltages*, connect the DMM positive lead to each pin in turn, and verify the voltage values listed. Voltage for pin 9 is that listed from the No Alarm condition.
5	Connect SpO_2 simulator cable to the SpO_2 adapter cable. Connect the cable to the SpO_2 patient monitoring input connector.
6	Set the simulator switches as follows: **Item** — **Setting** Oximeter — Nellcor SpO_2% — 81 BPM — 36 Pulse Mod — 0.50%
7	Verify that the monitor is responding to the SpO_2 simulator signal and the audible alarm is sounding. If desired, press the **Alarm Silence** button to temporarily silence the audible alarm.
8	Connect the DMM positive lead to pin 9 and verify the voltage value listed in *Table 4-2, Serial Interface Voltages*. The voltage for pin 9 is that listed for the Alarm Underway condition.

Table 4-2. Serial Interface Voltages

Pin	Signal	Direction	Measurement (V)		
			Min.	Typical	Max.
1	not used		-0.4	0.0	0.4
2	RXD <<<	input	-0.4	0.0	0.4
3	TXD<<<	output	-5.0	-7.0	-15.0
4	DTR<<<	output	5.0	7.0	15.0
5	GND		-0.4	0.0	0.4
6	DSR<<<	input	-0.4	0.0	4.0
7	RTS>>>	output	5.0	7.0	15.0

Pin	Signal	Direction	Measurement (V)		
8	CTS<<<	input	-0.4	0.0	0.4
9	Alarm Out>>> (no alarm)	output	-5.0	-7.0	-15.0
9	Alarm Out>>> (alarm underway)	output	5.0	7.0	15.0

ECG Sync Test

This test checks the performance of ECG synchronization between the monitor and a defibrillator. The ECG sync performance test is required once every year and when the monitor is repaired or when the monitor's parts are replaced.

Tools Needed:

- Dynatech Nevada MedSim 300 or equivalent simulator
- Defib Sync Cable (M4820A) or Switchcraft 850
- Switchcraft 750

Two sections are needed to complete the connection from the monitor to the simulator.

1. If a Defib Sync Cable is available, connect it the ECG Sync output on the monitor, then to the Switchcraft 750.
   or
   If a Switchcraft 850 is available, connect it the ECG Sync output on the monitor, then to the Switchcraft 750.

2. Connect the Switchcraft 750 to the SYNC/A PACE input on the simulator

Connect to the monitor	Connect to the simulator
Defib Sync Cable	Switchcraft 750
Switchcraft 850	Switchcraft 750

Step	Action
1	Connect the ECG leads and trunk cables between the monitor and the simulator (as described above).
2	Turn on the monitor and the simulator
3	On the simulator main menu select **DEFB**, then **CARD** to set the simulator to Defibrillator Tests/Cardioversion.
4	Press **Start** to begin the test. If the monitor is working properly, the following sequence of text messages will appear on the simulator over a period of approximately 3 seconds: "cardioversion: afib", "cardioversion: sync ok", and "cardioversion: converted" (this message will persist on the simulator)
5	If the monitor isn't working properly, messages such as the following may appear: "cardioversion: vfib", "cardioversion: late".

Patient Safety Tests

Philips safety tests meet the standards of, and are performed in accordance with IEC 60601-1, Clause 19 (EN60601-1, Second Edition, 1988; Amendment 1, 1991-11, Amendment 2, 1995-03).

The C3 patient monitor is a Class I device. It requires a protective earth (ground) wire. Keep this in mind when performing the following test procedures.

There are two categories of safety tests:

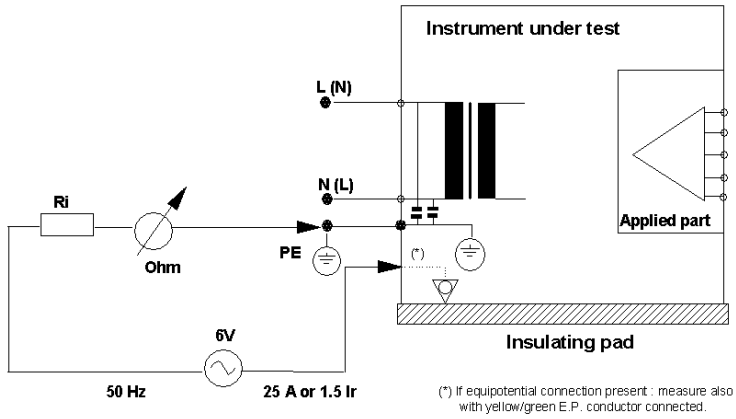
- Ground Integrity
- Electrical Leakage

Ground Integrity

Table 4-3. Ground Integrity

Test or "Inspection" to Perform	Expected Test Results
Protective Earth See *"Safety Test Diagram - Protective Earth" on page 4-40.*	With mains cable: Maximum impedance = x <= 100 mOhms

Figure 4-1 Safety Test Diagram - Protective Earth

Test or Inspection to Perform

Measures impedance of Protective Earth (PE) terminal to all exposed metal parts of IUT, which are for safety reasons connected to the Protective Earth (PE). Max. 100 mOhm. Test current 25 Amps applied for 5 to 10 seconds. We recommend to flex the main cable during the test in order to identify potential **bad** contact or damage of the earth wire. *Safety test according to EN60601-1 (Clause 18).* Report largest value.

What to record on this service record:

S(1): P or S(1): F

Electrical Leakage

The following tests verify the electrical leakage of the monitor:

- Earth Leakage Current
- Enclosure Leakage Current
- Patient Leakage Current
- Patient Source Current, with Mains Voltage on the Applied Part

Warning

Perform all leakage tests any time the unit is opened.

Earth Leakage Current

This test is in compliance with IEC 60601-1 (Earth Leakage Current). In locations where mains voltage is 100-120 volts, the applied voltage is 132 volts. In locations where mains voltage is 220-240 volts, the applied voltage is 264 volts. The applied AC frequency should be the same as the local mains (50 or 60 Hz).

All measurements shall be made with the power switch in both On and Off positions.

1. Connect the monitor AC plug to the electrical safety analyzer as recommended by the analyzer operating instructions.
2. Perform test as recommended by analyzer operating instructions.

Earth leakage current is measured under various conditions of the AC mains and protective earth conductor. For each condition, the measured leakage current must not exceed that indicated below.

Table 4-4. Earth Leakage Current Values

Test Condition	Polarity	Allowable Leakage Current
Normal	Normal	300 µA
	Reversed	300 µA
S.F.C[a]	Normal	1000 µA
Open Supply	Reversed	1000 µA

a. S.F.C = Single Fault Condition

What to record on the service record:

S(2): P or S(2): F

Enclosure Leakage Current

This test is compliance with EN60601-1 (Enclosure Leakage Current). Test at 110% of the nominal line voltage.

Step	Action
1	Connect the AC mains power cord to the analyzer as recommended by the analyzer operating instructions.
2	Using the appropriate test cable, connect the analyzer to either of the screws on the back of the monitor, next to the handle.
3	Turn the monitor on.
4	Perform the test as recommended by the analyzer operating instructions.

The analyzer leakage current indication must not exceed the values listed below.

Table 4-5. Enclosure Leakage Current

EN60601-1 (1990 + A1, A2, A11, A12, A13) and UL2601 (2nd Ed. 1997) US Deviations

Test Condition	Polarity	Allowable Leakage Current
Normal	Normal	100 µA
	Reversed	100 µA
S.F.C[1] Open Protective Earth	Normal	300 µA
	Reversed	300 µA

What to record on your service record:

S(3): P or S(3): F

Patient Leakage Current

This test measures patient leakage current in accordance with EN60601-1, Clause 19, for Class I, type CF equipment. Patient leakage current in this test is measured from any individual patient connection to earth (power ground).

This test requires a sample patient cable for each device parameter. These must be configured as recommended by the safety analyzer operating instructions.

Step	Action
1	Configure the electrical safety analyzer as recommended by the analyzer operating instructions.
2	Connect the monitor's AC mains power cord to the analyzer as recommended by analyzer operating instructions.
3	Connect the ECG test cable between the ECG connector on the monitor and the appropriate input connector on the analyzer.
4	Turn the monitor On.
5	Perform the test as recommended by the analyzer operating instructions. Patient leakage current is measured under various conditions of the AC mains and protective earth conductor. For each condition, the measured leakage current must not exceed that indicated below.
6	Repeat the test for SpO_2 and temperature patient connections, using appropriate test cables.

Table 4-6. Patient Leakage Current Values

Test Condition	Polarity	Allowable Leakage Current (Max.)
		Type CF
Normal	Normal	10 µA
	Reversed	10 µA
S.F.C.(Open Earth/Ground)	Normal	50 µA
	Reversed	50 µA

What to record on the service record:

S(4): P or S(4): F

Patient Leakage Current, with Mains Voltage on the Applied Part

This test measures patient leakage current in accordance with EN60601-1, Clause 19, for Class I, type CF equipment. In this test, 110% of mains voltage is applied between each patient connection and earth (power ground). Patient leakage current is then measured from any individual patient connection to earth.

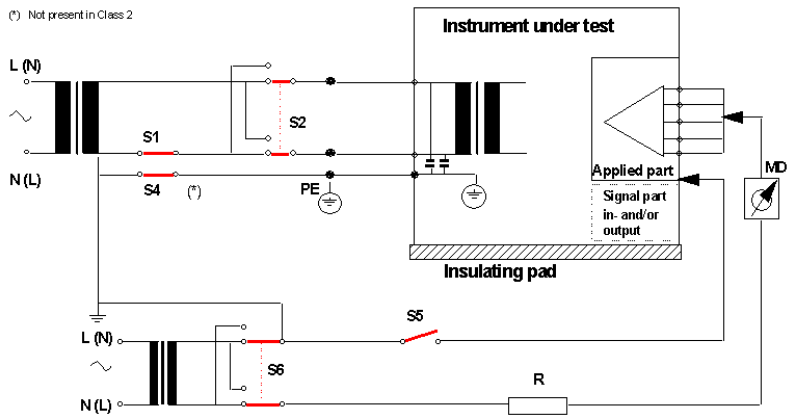
Warning

AC mains voltage is present on the applied part terminals during this test. Exercise caution to avoid electrical shock hazard.

Table 4-7. Safety Tests - Patient Leakage Current, with Mains Voltage on the Applied Part

Test or "Inspection" to Perform	Expected Test Results
Patient Leakage Current - AC See *"Safety Test Diagram - Patient Leakage Current - AC" on page 4-44*	Maximum leakage current = x <= 50 µA @ 250V (IEC601-1 or UL2601-1) Test at 110% of the nominal line voltage.

Figure 4-2 Safety Test Diagram - Patient Leakage Current - AC

Test or Inspection to Perform

Measures patient leakage current from Applied Part to earth caused by external mains voltage on Applied Part with switch S5 open and closed. Each polarity combination possible is tested using S2 and S6. *Safety test according to EN60601-1 (Clause 19.4.h).* Report largest value.

What to record on the service record:

S(5): P or S(5): F