

6.2.1 Monitor Checkout Procedure

The successful completion of this test will verify that the monitor is functioning and that all operator input (touch keys) and output (display and audio alarm) are OK.

IF ANY FAILURES ARE NOTED, SEE SECTION 7.3, "BIS VISTA System Messages And Corrective Actions".

1. Disconnect the BISx from the monitor.
2. Connect power cord to monitor. Plug power plug into appropriate wall outlet.
 - Verify that the light to the right of the ON/Standby button is yellow.
3. Start up monitor by pressing the ON/Standby button (lower right corner).
 - Verify that the light to the right of the ON/Standby button is green.
 - Verify all self-tests complete successfully. A beep tone sounds.
 - Verify next screen says "Connect BISx."
4. Connect BISx to monitor with PIC and sensor.
 - Verify screen says, "BISx Initialization Complete."
 - Verify SENSOR CHECK begins.
5. Disconnect power cord from rear of monitor.
 - Verify 'OPERATING ON BATTERY BACKUP' is displayed.
 - Verify battery icon displays below BIS number.

NOTE:

Since the BIS VISTA monitor has a built in battery backup, the monitor will power up with or without AC power applied. This step assures that this part of the test is performed under battery power

6. Reconnect power cord.
 - Verify battery icon is not displayed below BIS number.
 - Verify 'OPERATING ON BATTERY BACKUP' is not displayed.

NOTE:

Since the BIS VISTA monitor has a built-in battery backup, the monitor will power up with no AC power applied. This step assures that this part of the test is performed in AC operation.

IF ANY FAILURES ARE NOTED:

- Verify AC power outlet (wall outlet) is supplying AC Volts of 110vac to 240vac at a frequency of 50hz to 60hz. Move power cord to known good outlet.
- Verify AC power cord is good. Swap power cord with known good one.

- If monitor runs on battery when it is plugged in to AC power, the power supply may need replacement.
- If failure continues after above actions, the monitor will need to be serviced, see section 8.12, “What To Do With a Component That Requires Service.”

7. End of monitor checkout.

6.2.2 BISx Checkout Procedure

Periodically the BISx and associated cables and connectors should be inspected for physical damage and verification that the BISx will pass the DSC Self Test. Begin this procedure with the system components disconnected. The successful completion of this test verifies that the BISx circuits are functioning properly and that it is recognized by and communicates with the monitor.

IF ANY FAILURES ARE NOTED, SEE SECTION 7.3, “BIS VISTA System Messages And Corrective Actions”.

1. Using a known good BIS VISTA monitor (see Section 6.2.1 “Monitor Checkout Procedure”), start up the monitor with the BISx disconnected.
 - Verify that the screen message “Connect BISx” displays.
2. Connect the BISx that you are testing.
 - Verify that the screen message “Connect sensor or cable” displays.
3. Press the **[MENU]** touch key to access menu options.
4. Press **[Next]** twice until the “Diagnostics” option is displayed.
5. Press **[Diagnostics]**.
6. Press **[DSC Self Test]** to initiate the test.
 - Verify that the display shows “DSC Self Test Results: PASS.” This takes approximately 20 seconds. Note that test results are posted in 4 tests for 2 channels. If a test fails, the failed test displays either “***” or the word, “FAIL.”
7. Press **[Return to Previous Menu]** and repeat the DSC Self Test while flexing cables to see if intermittent opens or shorts exist.

IF ANY FAILURES ARE NOTED:

- Swap BISx with known good one to verify that problem does not exist with the monitor.
- If failure is isolated to this BISx, it will need to be serviced. See section 8.12 “What To Do With a Component That Requires Service.”

8. Press **[HOME]** to exit. If PIC and Sensor are available, perform PIC Checkout Procedure. See section 6.2.3 “Patient Interface Cable (PIC) Checkout Procedure.”

6.2.3 Patient Interface Cable (PIC) Checkout Procedure

The successful completion of this test will verify function of the BIS VISTA system from the BISx circuits to the patient connector. Since the conductors used are located both in the BISx and the PIC, use a swapping technique to isolate the faulty component.

Use a Sensor Simulator or make a Test Sensor for this test. See Section 10.3 “Test Sensor” for details.

IF ANY FAILURES ARE NOTED, SEE SECTION 7.3, “BIS VISTA System Messages And Corrective Actions”.

1. Using a known good BIS VISTA monitor (see section 6.2.1 “Monitor Checkout Procedure) and a known good BISx (see section 6.2.2 “BISx Checkout Procedure) connect the PIC that you are testing to the BISx, and connect the BISx to the BIS VISTA monitor.
2. Press the monitor’s ON/Standby button to start up the monitor and BISx. At the completion of the power up self-test, verify that the screen message “Connect sensor or cable” displays.
3. Connect a Sensor Simulator (see Section 10.2) or Test Sensor (see Section 10.3) to the PIC cable.
4. A sensor check is initiated automatically when the sensor and PIC are connected to the BISx. (It may also be initiated by pressing the **[SENSOR CHECK]** touch key.) The message, “Sensor Check in Progress” appears. When the sensor successfully passes the test, the BIS Trend screen displays.
5. **If the Sensor Check is not immediately successful**, the Sensor Check Graphic Screen displays automatically. This screen shows a sensor with each electrode numbered. Colors indicate the status of each electrode.
 - White hollow circle – No status is available (Lead is off).
 - Green circle – The electrode impedance is within the acceptable range.
 - Red blinking circle – The electrode impedance is not within the acceptable range.

The impedance value for each electrode, in kilo ohms, appears on the screen along with its status:

- PASS - An electrode passes if the impedance for that electrode is less than 7.5 kilo ohms. The ground electrode (element #2) must be less than 30 kilo ohms to pass.
- HIGH - An electrode is labeled “HIGH” if its impedance value is above 7.5 kilo ohms. As long as the combined impedance of electrodes #1 and #3 and the combined impedance of electrodes #1 and #4 are less than 15 kilo ohms, the sensor check will be considered successful.
- NOISE - If the signal from the electrode goes beyond the measurable range, the label “NOISE” displays.
- LEAD OFF - If the impedance check indicates that the electrode is not in contact with the patient, the label “LEAD OFF” displays.

6. If the **Sensor Check** is successful, repeat the test by pressing the [**SENSOR CHECK**] touch key. The Sensor Check Graphic Screen displays. During the test sequence, flex the cable and connections at the PIC/SENSOR, and PIC/BISx connections. Note that gentle flexing of these cables and connectors should not cause the Sensor Check to fail.

NOTE:

Sensor Check is used in clinical application as an indicator of the patient's skin conductivity. When used with a Sensor Simulator or Test Sensor, the Sensor Check serves to test the cable conductors of the BISx and PIC, and the status indications noted above indicate the ability of the BISx and PIC to conduct the sensor check signal. Values that are too high indicate a need to investigate and possibly replace the PIC or BISx.

Expected Impedance Values

| Sensor Simulator Values | | | Test Sensor Values | | |
|--------------------------------|-----------|-------------|---------------------------|----------|------------|
| Electrode # | Typical | Range | Electrode # | Typical | Range |
| 1 | 5 K Ohms | 4-6 K Ohms | 1 | 1 K Ohms | 1-2 K Ohms |
| 2 | 10 K Ohms | 8-17 K Ohms | 2 | 1 K Ohms | 1-3 K Ohms |
| 4 | 4 K Ohms | 3-5 K Ohms | 4 | 1 K Ohms | 1-2 K Ohms |
| 3 | 3 K Ohms | 2-4 K Ohms | 3 | 1 K Ohms | 1-2 K Ohms |

6.3 Checking the Battery

The battery must be tested periodically to verify that the BIS VISTA Monitoring System will continue to operate during power outages. To test:

1. Charge the BIS VISTA monitor by leaving it plugged into A/C power for at least 6 hours. The monitor charges while in either Standby mode (yellow light) or ON (green light).
2. Disconnect the A/C cord from the wall supply.
3. Verify that the BIS VISTA Monitoring System operates reliably for 45 minutes.
4. Recharge the battery.

WARNING

ELECTRICAL SHOCK HAZARD: DO NOT REMOVE MONITOR COVERS DURING OPERATION OR WHILE POWER IS CONNECTED TO MONITOR.

GROUND WIRE LEAKAGE CURRENT MUST BE CHECKED WHENEVER INSTRUMENT CASE IS OPENED BY A QUALIFIED BIOMEDICAL ENGINEERING TECHNICIAN.

Caution:

Check the battery periodically by operating a BIS VISTA monitor that has been disconnected from the wall socket and that has been charged to full capacity (at least 6 hours of charge time). After long periods of

storage (e.g., more than 1 month) it may be necessary to cycle (charge, then discharge) the battery a few times to get full charge capacity. If the BIS VISTA monitor fails to operate reliably from the battery for approximately 45 minutes, battery replacement is required.

The BIS VISTA monitor contains an internal lithium ion battery. The battery must be removed by a qualified service technician and disposed of or recycled in accordance with the national laws of the country. Contact Aspect Medical Systems, Inc. or the local distributor for a replacement battery: Aspect part number 186-0208.

If the battery requires replacement, see Section 8.4, “Replacing the Battery”.

6.4 Checking Leakage Current

Leakage current is a primary indicator of electrical shock hazard to personnel making contact with any exposed outer surface of the equipment. Each BIS VISTA system is carefully checked at the factory to verify that leakage current meets the UL60601-1 and IEC60601-1 safety standards.

The BIS VISTA monitor should be checked routinely for leakage current at least once a year. Always have the leakage current checked after a saline or blood spill, or immediately after a major surge in the house electrical system and after every time the monitor case has been opened. Keep in mind that liquids such as saline and Ringer’s as well as blood are all excellent conductors of electricity. Avoid touching any part of the system with wet hands. Always work with clean, dry hands.

WARNING!

ELECTRICAL SHOCK HAZARD: THE MANUFACTURER’S INSPECTION OF THIS APPARATUS VERIFIED THAT THE GROUND LEAKAGE CURRENT AND THE PATIENT SAFETY CURRENT WERE LESS THAN THE SPECIFIED LIMITS ESTABLISHED BY THE APPLICABLE SAFETY STANDARDS. AS A MATTER OF SAFE PRACTICE, THE INSTITUTION SHOULD CONDUCT PERIODIC TESTS TO VERIFY THESE CURRENTS.

WHENEVER AN EVENT SUCH AS SPILLAGE OF BLOOD OR SOLUTIONS OCCURS, RE-TEST BEFORE FURTHER USE.

Leakage Current testing should be performed by a qualified Biomedical Engineering Technician or authorized personnel only.

The BIS VISTA Monitoring unit **does not** contain a *Protective Earth Stud (GND Stud)*. Since the exposed metal parts on the rear of the BIS VISTA Monitor (Communication serial port and USB ports) are separated from live parts by double insulation, a ground continuity test does not apply to these parts. The components of the BIS VISTA Monitor that are connected to protective earth are contained within its enclosure and are not accessible to the

user of the equipment. However, as stated in the operating manual, an enclosure leakage current test should be performed on the exposed metal parts and should be checked periodically to ensure that the integrity of the equipment's insulation system is maintained. The leakage current test should include measurement of ground wire leakage, enclosure leakage, and patient leakage.

Ground wire leakage typically can be performed automatically by connecting the A/C power cord of the BIS VISTA Monitor into a safety tester. The enclosure leakage may be measured by any safety test equipment that is capable of connecting to isolated conductive parts and measuring the current from those parts to earth. The patient connection terminals of many safety testers can be used for this purpose. The patient leakage current of the BISx can be measured by connecting the patient connection terminals of a safety tester to a Sensor Simulator that is connected to the PIC.

To check BISx patient isolation:

1. Connect the Sensor Simulator to the PIC in place of a sensor. (See Section 10.2 "Sensor Simulator P/N 186-0137".)
2. Short the two circular terminals at the end of the simulator using conventional methods such as jumpers or alligator clips. Wire attached with screws will work also.
3. Connect the test lead to the shorted terminals. Make sure that you are not touching the simulator beyond this point.
4. Proceed to test instrument for leakage current as per established facility protocols and procedures for safety testing of medical devices.