BIS VISTA™ Monitoring System

SERVICE INFORMATION MANUAL

Aspect Medical Systems, Inc.

Bispectral Index™ (BIS™) Monitoring System

Rx only

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ABOUT THIS MANUAL

This manual contains information necessary for the customer to install, maintain, service, identify and prepare for use Aspect Medical Systems' BIS VISTA™ Monitoring System. Also included are directions to diagnose, troubleshoot, and repair the system. A spare parts and accessories list and system specifications are included.

This manual is intended to be used in combination with the BIS VISTA Monitoring System Operating Manual.

The BIS VISTA Monitoring System is designed and manufactured using state-of-the-art components and manufacturing processes. Field repair or customer repairs are therefore limited by design to replacement of major component assemblies such as the Patient Interface Cable (PIC), BISx™, or the power supply and battery of the BIS VISTA monitor.

This manual, in conjunction with the BIS VISTA Monitoring System Operating Manual, contains the maintenance and diagnostic troubleshooting information necessary for customer qualified technical personnel to test and replace those parts of the equipment that are replaceable by the customer. Aspect does not authorize nor provide information to service or repair the internal components of the BIS VISTA monitor, with the exception of the power supply and battery.

Before attempting to set up or service the BIS VISTA Monitoring System, please familiarize yourself with the safety information provided in Section 1 of this manual.

SECTION 1

1 SAFETY PRECAUTIONS

INTRODUCTION:

Caution:

Carefully read the BIS VISTA Monitoring System Operating Manual entirely before using the monitor in a clinical setting.

WARNINGS, CAUTIONS, AND NOTES

The terms warning, caution, and note have specific meanings in this manual.

- A **WARNING** advises against certain actions or situations that could result in personal injury or death.
- A **CAUTION** advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure, although personal injury is unlikely.
- A **NOTE** provides useful information regarding a function or procedure.

KEY TO SYMBOLS

A key to the symbols used on the BIS VISTA Monitoring System appears at the end of this section.

1.1 Warnings

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**
- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 60601-1 AND/OR IEC 60601-2-26 HARMONIZED NATIONAL STANDARD.**

WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC 60601-1 LIMIT.

EXPLOSION HAZARD: DO NOT USE THE BIS VISTA SYSTEM IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

MONITOR IS NOT DESIGNED FOR USE IN MRI ENVIRONMENT.

FOR PROPER GROUNDING, THE POWER RECEPTACLE MUST BE A THREE-WIRE GROUNDED OUTLET. A HOSPITAL GRADE OUTLET IS REQUIRED. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.

IF THE INTEGRITY OF THE EXTERNAL PROTECTIVE EARTH GROUND IS IN DOUBT, THE BIS VISTA SYSTEM SHALL BE OPERATED FROM ITS INTERNAL BATTERY POWER SOURCE ONLY.

FOR BIS VISTA SYSTEMS USED OUTSIDE OF NORTH AMERICA: A HARMONIZED LINE CORD WITH CONDUCTORS HAVING A CROSS SECTIONAL AREA GREATER THAN 0.75 mm^2 MUST BE USED.

BE SURE THE MONITOR IS MOUNTED SECURELY IN PLACE TO AVOID PERSONAL OR PATIENT INJURY.

UNIVERSAL PRECAUTIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. PLACE CONTAMINATED MATERIALS IN REGULATED WASTE CONTAINER.

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

DO NOT MIX DISINFECTING SOLUTIONS (e.g., BLEACH AND AMMONIA), AS HAZARDOUS GASES MAY RESULT.

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.

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.

POWER SUPPLY IS INTERNALLY FUSED. REPLACE POWER SUPPLY ONLY WITH ASPECT MEDICAL SYSTEMS BIS VISTA POWER SUPPLY.

ENSURE THAT THE BISx DOES NOT COME INTO PROLONGED CONTACT WITH PATIENT'S SKIN, AS IT MAY GENERATE HEAT AND CAUSE DISCOMFORT.

THE CONDUCTIVE PARTS OF ELECTRODES OR SENSOR AND CONNECTORS, INCLUDING THE NEUTRAL ELECTRODE, SHOULD NOT CONTACT OTHER CONDUCTIVE PARTS, INCLUDING EARTH.

TO REDUCE THE HAZARD OF BURNS IN THE HIGH-FREQUENCY SURGICAL NEUTRAL ELECTRODE CONNECTION, THE SENSOR OR ELECTRODES SHOULD NOT BE LOCATED BETWEEN THE SURGICAL SITE AND THE ELECTRO-SURGICAL UNIT RETURN ELECTRODE.

THE SENSOR MUST NOT BE LOCATED BETWEEN DEFIBRILLATOR PADS WHEN A DEFIBRILLATOR IS USED ON A PATIENT CONNECTED TO THE BIS VISTA SYSTEM.

TO MINIMIZE THE RISK OF PATIENT STRANGULATION, THE PATIENT INTERFACE CABLE (PIC) MUST BE CAREFULLY PLACED AND SECURED.

SHOCK HAZARD: DO NOT ATTEMPT TO DISCONNECT THE POWER CORD WITH WET HANDS. MAKE CERTAIN THAT YOUR HANDS ARE CLEAN AND DRY BEFORE TOUCHING THE POWER CORD.

CONSIDERATIONS WHEN USING ELECTRO CONVULSIVE THERAPY (ECT) EQUIPMENT DURING BIS™ MONITORING:
SEPARATE ECT ELECTRODES FROM THE BIS SENSOR AS MUCH AS POSSIBLE TO MINIMIZE THE EFFECT OF INTERFERENCE.
CERTAIN ECT EQUIPMENT MAY INTERFERE WITH THE PROPER FUNCTION OF THE BIS MONITORING SYSTEM. CHECK FOR COMPATIBILITY OF EQUIPMENT DURING PATIENT SETUP.

1.2 Cautions

Read this entire manual carefully before using the monitor in a clinical setting.

To turn off all A/C power, disconnect power cord from A/C outlet. Battery can be removed to shut down unit completely.

Continuous impedance checking may need to be disabled if the 1 nanoampere 128 Hz impedance check signal interferes with other equipment (e.g., evoked potential monitors).

Do not autoclave the BISx or Monitor. Autoclaving will seriously damage both components.

Avoid liquid ingress to the Patient Interface Cable. Contact of fluids with the PIC sensor connector can interfere with PIC performance.

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.

All repairs to the BIS VISTA Monitoring System should be made only by a qualified Biomedical Engineering Technician or other authorized personnel.

Use only the parts and tools specified. Use of any others may damage the instrument.

Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the BIS VISTA Monitoring System.

The BIS VISTA Monitor should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BIS VISTA monitor should be observed to verify normal operation in the configuration in which it will be used.

Do not block ventilation inlet holes on the underside of monitor.

Do not open the BISx for any reason. The seal to prevent liquids from entering the BISx may be damaged if opened. Service or repairs must be performed only by qualified biomedical technicians.

The BIS VISTA system has been designed to operate with a BIS Sensor. The sensor is a silver/silver chloride electrode array that utilizes Aspect's patented Zipprep™ technology and uses a proprietary connector. Use of other electrodes is not recommended.

Do not disconnect the BISx during the software upgrade.

The BIS VISTA system complies with the electromagnetic compatibility requirements of EN60601-1-2. Operation of this device may affect or be affected by other equipment in the vicinity due to electromagnetic interference (EMI). If this occurs:

- **Increase separation between devices**
- **Re-orient device cabling**
- **Plug devices into separate outlet circuit branches**

Refer to Section 9.2 "Electromagnetic Compatibility Specifications."

When connecting or disconnecting BISx, take care not to touch the exposed contacts of either connector. Damage due to electrostatic discharge may result.

All work involving opening the instrument case must be performed in a static-safe environment to prevent damage to electronic components and assemblies. This environment includes the operator, work area and tools, and any other test or storage items that might touch the monitor or BISx assemblies.

Important:
The BIS VISTA systems comply with the European Medical Device Directive (MDD) and applicable regulatory requirements of the country distributed to and carry the CEXXXX Marking. Declarations of Conformity provided upon request where appropriate.

1.3 Key to Symbols

Manufacturer

Authorized Representative in the European Community

Conformité Européenne (CE) Marking of Conformity to European Medical Device Directive. CE_{xxxx} represents the Notified Body number

Classified by Underwriters Laboratories Inc.® with respect to electric shock, fire and mechanical hazards only, in accordance with UL 60601-1 and IEC60601-2-26

Recognized under the Component Recognition Program of Underwriters Laboratories Inc.

Latex-free product

Type BF Equipment

Type BF Equipment Defibrillator-proof

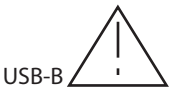
Crossed out wheelie bin indicates separate treatment from general waste at end of life

Attention, Consult Accompanying Documents

Attention, Data I/O, RS-232 Serial Port, Consult Accompanying Documents

Figure 1 - Symbol Key (page 1 of 3)

Attention, USB-A, Host. Consult Accompanying Documents



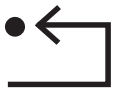
Attention, USB-B function. Consult Accompanying Documents

Caution: Hot Surface

Alternating Current

D/C Current

Battery Location



Reset Button

Packaging Labelling:
Storage Temperature Limits, Fragile, Do Not Get Wet, and This Side Up

Monitor Power ON

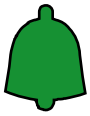
Monitor Power OFF or Standby Mode

Figure 1 - Symbol Key (page 2 of 3)

Operating on Battery

No Battery is Installed in Monitor

Ringing Bell Icon - Alarm Sounding



Green Bell Icon - Alarms Active

Yellow Bell with Dotted Line 'X' - Alarms Paused

Red Bell with 'X' - Alarms Silenced

A green box denotes ON or active condition.

A red box with an 'X' denotes OFF or cancel.

Figure 1 - Symbol Key (page 3 of 3)

SECTION 2

2 BIS VISTA MONITORING SYSTEM OVERVIEW

2.1 Introducing the BIS VISTA Monitoring System

The BIS VISTA Monitoring System is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in its proper use. The BIS VISTA Monitor is intended for use on adult and pediatric patients within a hospital or medical facility providing patient care to monitor the state of the brain by data acquisition of EEG signals.

The BIS may be used as an aid in monitoring the effects of certain anesthetic agents. Use of BIS monitoring to help guide anesthetic administration may be associated with the reduction of the incidence of awareness with recall in adults during general anesthesia and sedation.

The BIS VISTA Monitoring System processes raw EEG signals to produce a single number, called the Bispectral Index™, or BIS, which correlates to the patient's level of hypnosis. It operates from an AC power source of 100V to 240V, 50/60Hz, and provides approximately 45 minutes of automatic back-up battery power.

The monitor is menu-driven with on-screen touch keys. A detailed description of how the BIS VISTA Monitoring System works is included in the BIS VISTA Operating Manual. Please refer to the BIS VISTA Operating Manual for additional information.

Figure 2- The BIS VISTA Monitoring System

2.2 Principal Components

The system is composed of a monitor, a BISx, a Patient Interface Cable (PIC), and BIS sensor.

2.2.1 The BIS VISTA Monitor

The front panel of the BIS VISTA monitor contains the Touch Screen, BISx port and the ON/Standby button. See Figure 2.

Touch Screen

The BIS VISTA monitor is designed so that all controls (with the exception of the ON/Standby button) are accessible by touching a designated area on the monitor screen. This area is called a touch key. The touch keys are designed to function even when the user is wearing examination gloves.

ON/Standby button

The ON/Standby button is located in the lower right corner of the monitor and is used to put the monitor in ON or in Standby mode. When the small LED light to the right of the ON/Standby button is green, the unit is running and providing power to the BISx. When it is yellow, the battery is charging and the system is in Standby mode. When it is not lit, no A/C power is available to the unit; pressing the ON/Standby button will start up the monitor using the battery.

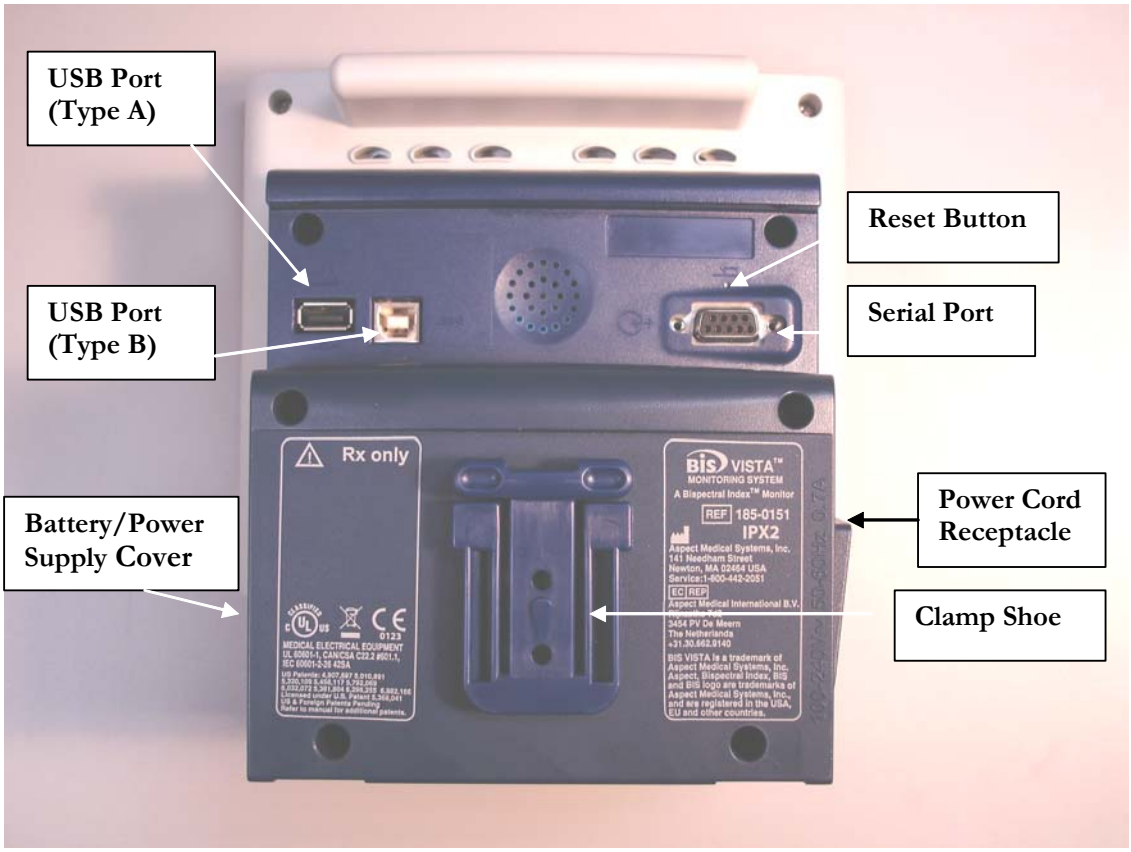


Figure 3 - Rear Panel

Rear Panel

The rear panel components are pictured in Figure 3. They include: two USB ports (Type A and B), the clamp shoe, an RS-232 port, the Reset button, the Battery/Power Supply cover, and the power cord receptacle.

The clamp shoe allows the monitor to slide into the pole clamp so that it can be attached to a ½" – 1 ½" diameter vertical pole.

2.2.2 The BISx and Patient Interface Cable (PIC)

The BISx receives, filters, and processes patient EEG signals. It is located close to the patient's head where the EEG signal is less subject to interference from other medical equipment.

Figure 4 - The BISx and PIC

The BISx is shown in Figure 4. Its long flexible **Monitor Interface Cable** connects to the front of the monitor. The **Patient Interface Cable (PIC)** connects the BIS sensor to the BISx.

The attachment clip on the BISx is used to secure it in a convenient location near the patient's head.

2.3 Instrument Identification

BIS VISTA Monitor

Monitor identification information is permanently marked on the rear panel. This information includes instrument model and serial numbers, power ratings, cautions, and the Aspect Medical Systems shipping address.

BISx

The BISx identification information is permanently marked on its rear panel. This information includes instrument model and serial numbers and cautions.

The PIC

The Patient Interface Cable lot number is stamped on the cable itself.

Software Revision Numbers

Software revision numbers may be displayed by pressing the "Configuration Information" touch key in the menu system.

2.4 Proprietary Information and Devices

 Portions of the BIS VISTA Monitoring System design are proprietary and are the subject of patents and patents pending. See the BIS VISTA Operating Manual for details.

SECTION 3

3 PRINCIPLES OF OPERATION

INTRODUCTION

This section includes:

- How the BIS VISTA Monitoring System works
- The architecture of the BIS VISTA monitor and BISx
- System Features

3.1 How the BIS VISTA Monitoring System Works

The BIS VISTA Monitoring System consists of:

- The BIS monitor with built-in battery backup and detachable power cord
- The BISx
- Aspect's Patient Interface Cable (PIC) and BIS sensor.

A sensor placed on the patient's head transmits EEG signals to the BISx. The BISx filters the data, analyzes it for artifact and processes it using digital signal processing techniques, then sends the data to the monitor for display. The purpose of processing the EEG waveform data is to extract characteristic features from the complex signal in order to provide easier pattern recognition of changes over time during the recording.

3.2 System Architecture

Hardware is divided into three main components: the monitor, the BISx, and the Patient Interface Cable (PIC) with BIS sensor. The BISx contains the circuits that acquire and digitize the EEG signals, digitally process the EEG data, and compute the processed parameters. The BIS VISTA monitor contains the circuits to display the waveforms and processed parameters. The PIC and BIS sensor are the patient connection for EEG signal acquisition.

A block diagram depicting the monitor subassemblies appears in Figure 5. A data flow diagram appears in Figure 6.

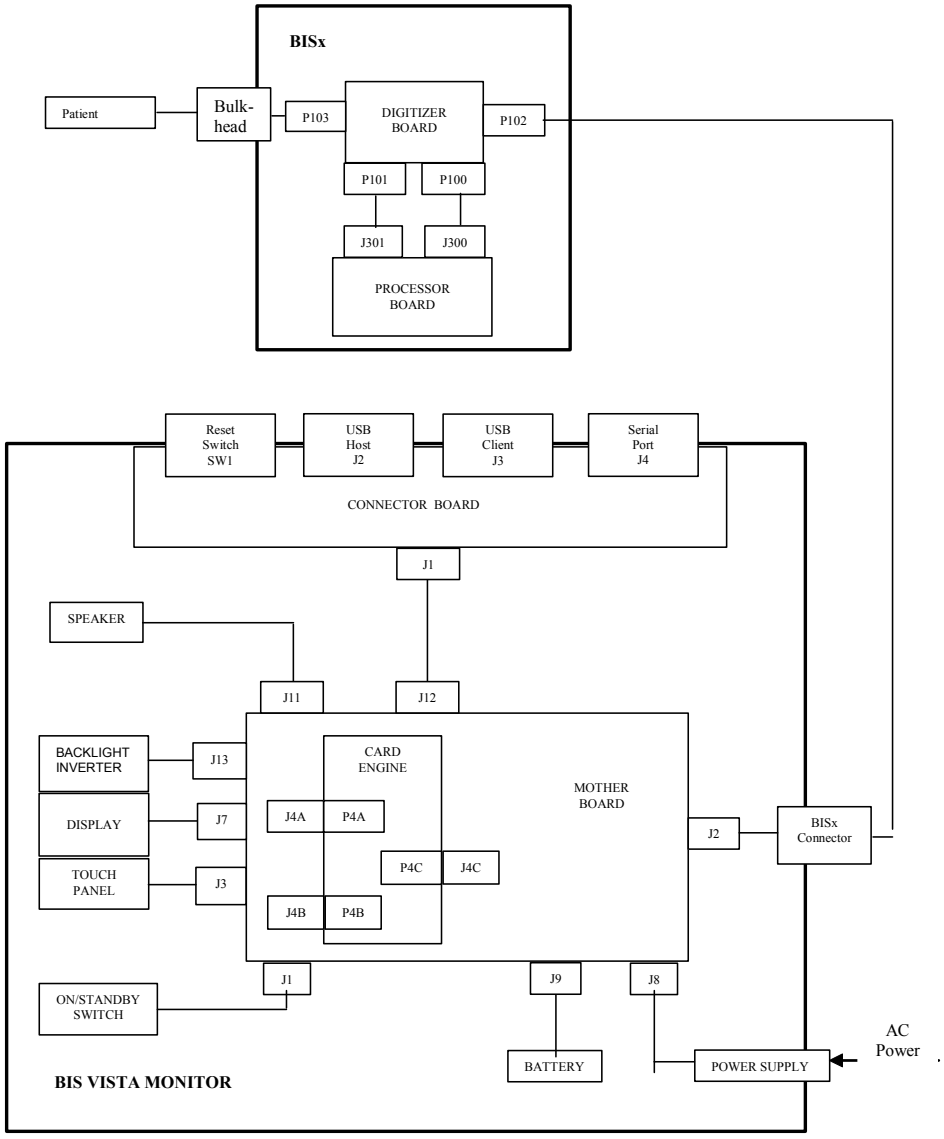


Figure 5 - The BIS VISTA System Block Diagram

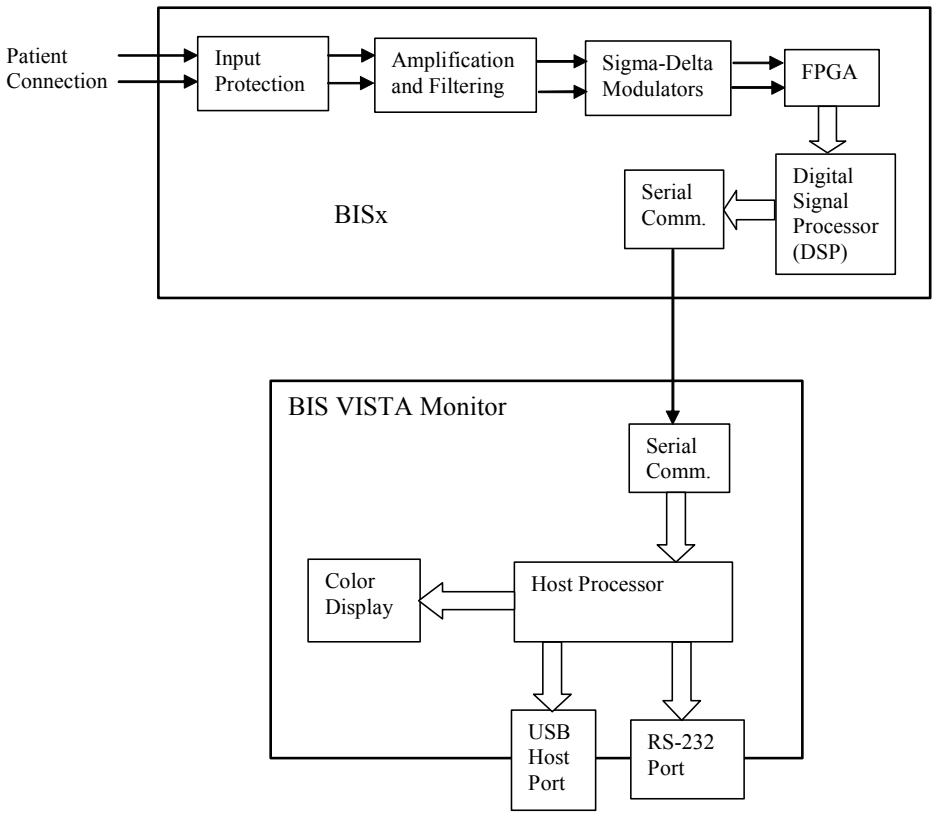


Figure 6 - The BIS VISTA Data Flow Diagram

After passing through input protection circuits, the EEG signals are differentially amplified and filtered to remove DC and high frequency components. The signals are digitized by separate one bit sigma-delta analog to digital converters and sent to the Digital Signal Processor (DSP). The DSP filters the signals and computes the processed variables. The results are passed to the monitor for display.

3.2.1 The BISx

The BISx contains the inputs, amplifiers, and digitizers for two channels of EEG, and contains the circuits to digitally process the EEG data and compute the processed parameters. It has a single point connection that connects via a Patient Interface Cable (PIC) to a BIS sensor. The sensor and PIC contain circuits for identifying them to the monitor. This permits the monitor to configure automatically.

The BISx contains circuits for injecting self-test voltages into the amplifier inputs. It constantly monitors the combined source impedance from the sensor electrodes and is able to measure the individual impedance of the channel and ground electrodes.

3.2.1.1 BISx Signal Conditioning

The input protection circuits are designed to protect the input from destruction by electric shock from sources such as electrostatic discharge (ESD) or defibrillation. The protection circuits also reduce the effects of high frequency ambient noise from sources such as electro-cautery and other devices.

Input signals are amplified by instrumentation amplifiers, which have a fixed gain. The amplifiers have DC servos, which remove the signals below high pass cutoff frequency. In the event of amplifier overload, the servos are changed to a higher frequency to facilitate fast recovery (blocking) under control of the host processor.

Each channel is further amplified to the level required by the A/D converters. The amplifiers also serve as filters to prevent aliasing by the converters.

3.2.1.2 BISx Impedance Testing

In the default state of the BISx the combined channel electrodes' impedance is continuously checked. A small current (approximately 1 nanoampere) is injected into each electrode at 128 Hz, just above the EEG band. The resulting voltages are measured. Equal but opposite currents are injected into the (+) and (-) electrodes simultaneously while the digital signal processor measures the resulting voltage. BIS monitoring is performed while combined impedance is checked.

The BISx measures the individual electrode impedance during a sensor check by injecting current into the REF electrode only. Individual electrode impedance is derived by subtracting the resulting value from the combined value. BIS monitoring is interrupted while individual impedance is checked.

The ground electrode impedance is also measured while injecting current into the REF electrode. BIS monitoring is interrupted while the ground impedance is checked. Ground impedance checking occurs when a sensor check is performed and thereafter on a 10-minute schedule during patient monitoring.

The impedance check signal can occasionally interfere with other monitoring equipment connected to the patient. Evoked potential monitors are particularly susceptible because they use a wide bandwidth. The automatic impedance check feature can be turned off by selecting "Impedance Checking – OFF." (See Operating Manual for specific instructions).

3.2.1.3 BISx Processor and Communications Circuits

The BISx contains: an analog to digital (A/D) converter for each channel, the monitor interface, the sensor interface and the power supply circuits. A crystal controlled BISx master clock is on this board. This clock is the system's BIS processing clock.

A/D Conversion

There are two independent sigma-delta modulators for the two channels. These run at 16384 samples per second.

Test Signal
A calibrated test signal is generated during the DSC Self Test. The signal is a 2 Hz square wave of approximately +/-50μV. It is applied to the inputs of the differential amplifiers, resulting in a test of the entire signal path except for the input connections and protection circuits. During the Self Test, noise, gain and frequency response are checked.

Interface to the Monitor
Output from the two channels are multiplexed in a field programmable gate array (FPGA). Multiplexed with the EEG data is status information such as BISx identification, "lead off" indication, and power supply faults.

The BISx decodes the control information coming from the monitor via a command line. Commands such as "block" amplifier saturation and conduct impedance tests are transmitted.

BISx Power Supply (Patented technology)
The BISx derives power from the monitor. Power supply circuitry produces the necessary voltages for operation. Power for patient-connected circuits is provided through a transformer. These circuits are isolated for patient safety.

3.2.1.4 The BISx Mechanicals

The BISx is contained in a small custom designed plastic case (see Figure 4). It is connected to the monitor via the Monitor Interface Cable and connects to the BIS sensor via the Patient Interface Cable (PIC). Both cables are strain relieved. The cables and the BISx Bulkhead Connector (used to attach the PIC to the BISx) can be replaced, if necessary, by the user. The attachment clip on the back of the BISx may be used to secure it to a convenient location near the patient's head.

There are no ventilation holes in the BISx case. It will not leak when splashed with liquids. The case is electrically shielded both to prevent spurious emissions from the BISx and to prevent externally caused interference with the BISx circuits.

3.2.2 The BIS VISTA Monitor

The BIS VISTA monitor contains the circuits to enable the touch screen, to receive processed parameters from the BISx, to display the data on the screen, and to communicate with other devices via USB and RS-232 ports.

The monitor also contains the circuits for powering the monitor and the BISx. An on board annunciator generates alarm sounds.

A block diagram depicting the monitor subassemblies appears in Figure 5. A data flow diagram appears in Figure 6. The signals are acquired, digitized, filtered, and processed by the BISx. The BISx multiplexes the signals onto the BISx communications line. The data are de-multiplexed in the monitor for display.

The Main board controls all input and outputs, power, data memory, and clock functions. The Card Engine controls the screen display.

The Connector board connects the reset button, USB and serial ports to the main board. There are two USB ports. The USB Type A port is used to export data to a removable drive. It is also used to upgrade monitor and BISx software. The RS-232 serial port can be used to transfer data from the monitor.

3.2.2.1 The BISx Interface

The BISx interface is composed of two unidirectional bi-phase encoded serial lines, one going to the BISx and another bringing data from the BISx.

The power to the interface is under software control. An overcurrent detector circuit monitors current to the BISx. If the current exceeds the expected value, the power is shut off to the BISx by the hardware and the user is notified.

3.2.2.2 The Interconnect Board

The Interconnect board provides the physical mounting and electrical connections for the serial and USB ports. Its mechanical construction includes ESD protection.

3.2.2.3 The Power Supply

The power supply operates on AC power from 100-240 VAC, 50-60 Hz, with output of 12 VDC, 24 watt maximum. It charges the battery; 7.2 V (nominal), 2150 mA hr. Signals are provided to the processor to indicate AC FAIL, RESET, and LOW BATTERY. The power supply contains internal fuses.

Caution:

To turn off all A/C power, disconnect power cord from A/C outlet. Battery can be removed to shut down unit completely.

3.2.2.4 The Battery

The battery is for backup use only. The battery includes temperature and current control elements, and has a nominal output of 7.2 volts DC. The battery charges whenever the BIS VISTA monitor is plugged into A/C power. It is capable of supporting monitor operation for approximately 45 minutes.

Note:

The BIS VISTA monitor may not power up entirely if battery power is low. If that should occur, connect unit to wall power and press the Reset button. (Refer to Section 8.10 "Using the Reset Button").

3.3 System Features

3.3.1 System Self Checks

The BIS VISTA monitor has several self-checking features to ensure that the system is operating properly. These include:

3.3.1.1 System Check

Software image checksums and trend data memory are tested and repaired if necessary when the system is powered up for the first time, after a new battery or power supply are installed, or after the system has been reset.

3.3.1.2 Equipment and Connection Checks

The system checks continuously to be sure that the BISx, the PIC, and patient sensors are operating properly and have not become disconnected.

3.3.1.3 DSC Self Test

The DSC Self Test tests the digital signal acquisition and conversion functions of the BISx. It is a thorough test of the entire signal processing chain. The DSC Self Test may be initiated from the Diagnostics Menu (See Section 6.2.2., "The BISx Checkout Procedure")

3.3.1.4 Sensor Integrity Check

This test begins each time that a sensor is connected to the PIC. It checks to make certain that a valid, unexpired sensor is in use.

3.3.1.5 Impedance Check (Sensor Check)

Electrode impedance is tested when the BISx and PIC are connected and is monitored continuously unless the user has turned impedance checking off in the menu system.

Caution:

Continuous impedance checking may need to be disabled if the 1 nanoampere 128 Hz impedance check signal interferes with other equipment, e.g., evoked potential monitors.

3.3.2 Diagnostic Codes

The BIS VISTA monitor provides diagnostic codes to assist the user in tracing the source of any problems that may occur. Codes are displayed in the Message Region only if the user has requested them in the Diagnostics Menu.

3.3.3 Monitor Data Memory

The monitor stores recorded trend data with time and date of acquisition. The duration of trend data stored is approximately 72 hours. Trend memory can be viewed on the screen by pressing the **[Trend Review]** key or, while a case is in progress, by using the Review arrow key **[◄]** .

Information on the current sensor can be viewed in the "Configuration Information" Screen.

When the memory is full, the oldest data are automatically erased as new data are stored. Memory will be retained even if the battery has been discharged and remains when the monitor is in the power off condition.

3.3.4 BISx Data Memory

The BISx stores processed EEG parameters, including the BIS value, with time and date of acquisition. History data stored in the BISx can be accessed by exporting it to a removable drive using the "Export Data" function. The duration of BISx data stored is approximately 1200 hours.

To view BISx history for a specific case, the user must first identify which BISx was in use during the case by looking up the BISx serial number in the Maintenance Menu's "BISx Connection History." The appropriate serial number BISx can then be connected to any monitor to export its History Data.

When the BISx memory is full, the oldest data are automatically erased as new data are stored. Memory will be retained even if the monitor battery has been discharged and remains when the monitor and BISx are powered off.

3.3.5 Saved Settings

Whenever the monitor is started up from Standby mode, it reverts to user settings that have been set up and then saved using the **[Save Settings]** touch key. Settings are saved to the current Monitor Mode (I, II, III, or IV).

The "Save Settings" option is disabled when in Battery Backup-Low Power condition. The following settings are not saved by the Save Settings option: Impedance Checking (always returns to ON), Filters (returns to ON), and Display Type (returns to BIS).

To restore factory settings to the current Monitor Mode, use the **[View/Save Settings]** function. To restore the factory settings to all modes, press **[Restore Default Settings for All Modes]** in the Maintenance Menu.

3.3.6 Battery Operation

In the event of a power failure or interruption of power during a procedure, the monitor automatically switches to back-up battery operation. A fully charged battery will provide approximately 45 minutes of operation. When the system is running on battery, a battery icon displays next to the BIS number, indicating the battery status. When the battery reaches a low power condition, the monitor beeps and the battery symbol displayed on the screen changes color from green to orange. In addition, a "Battery Power Low" message blinks continuously in the Message area of the screen.

The Save Settings feature is disabled when the battery power is low. Battery recharge time is approximately 6 hours.

Caution:
To turn off all A/C power, disconnect power cord from A/C outlet.
Battery can be removed to shut down unit completely.

3.3.7 Data Transfer and Software Updates

Three ports on the rear of the BIS VISTA monitor facilitate data transfer. The USB (Type A) port is used to export data to a removable drive. It is also used to update the monitor and BISx software. BIS values and other EEG data may also be acquired from the monitor using the RS-232 serial port. To connect to a personal computer, please contact Aspect Medical Systems Technical Service for instructions. (See back cover for contact information.)

WARNINGS

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**
- **EVIDENCE THAT THE SAFETY CERTIFICATION OF THE ACCESSORY HAS BEEN PERFORMED IN ACCORDANCE TO THE APPROPRIATE IEC 60601-1 AND/OR IEC 60601-2-26 HARMONIZED NATIONAL STANDARD.**

WHEN CONNECTING EXTERNAL EQUIPMENT (e.g., DATA CAPTURE COMPUTER), THE SYSTEM LEAKAGE CURRENT MUST BE CHECKED AND MUST BE LESS THAN THE IEC 60601-1 LIMIT.

NOTE:

When software is updated, all previously recorded data and monitor configuration settings will be lost. Therefore, configuration settings should be recorded before the software update is performed.

SECTION 4

4 PREPARATION FOR USE AND INSTALLATION

INTRODUCTION

This section provides an overview of installation information for service personnel working with the Aspect BIS VISTA Monitoring System. Please see the BIS VISTA Monitoring System Operating Manual for full installation instructions.

- Environment
- Instrument connections
- Installation and verification procedure

4.1 Environment

4.1.1 Shipping and Storage Environment

The monitor and its accessories can be stored or shipped within the following environmental limits. Note that these limits apply to non-operational storage and shipping situations.

Temperature	-10°C to +60°C
Humidity	15% to 95% (non-condensing)
Pressure	360 mmHg to 800 mmHg

Protect the monitor from sudden temperature changes that can lead to condensation within the instrument. To minimize condensation, avoid moving the system between heated buildings and outside storage. Once moved inside, allow the monitor to stabilize in the unopened shipping container at the inside ambient temperature before unpacking and placing into service. Before operation, wipe down all visible condensation and allow the system to reach equilibrium at room temperature.

4.1.2 Operating Environment

The BIS VISTA Monitoring System is not designed for use in areas containing flammable gases or vapors.

WARNING!

EXPLOSION HAZARD: DO NOT USE THE BIS VISTA SYSTEM IN A FLAMMABLE ATMOSPHERE OR WHERE CONCENTRATIONS OF FLAMMABLE ANESTHETICS MAY OCCUR.

MONITOR IS NOT DESIGNED FOR USE IN MRI ENVIRONMENT.

Temperature: The BIS VISTA monitor is designed to operate safely at a room temperature of 0°C to 40°C. Conditions that exceed these limits could affect reliability.

Humidity: The monitor is designed to operate within specifications at a relative non-condensing humidity of 15% to 95%.

Pressure: The monitor will operate satisfactorily at or above sea level, and is unaffected by extremes or changes in altitude within atmospheric pressures of 360 mmHg to 800 mmHg.

4.1.3 Power Requirements and System Grounding

The BIS VISTA Monitoring System requires a power source of 100-240 VAC, 50-60Hz. Current consumption is 0.7 ampere maximum.

To protect operating personnel and patients, the monitor must be properly grounded. Accordingly, the monitor is equipped with a hospital grade line cord. The power cord grounds the system to the power line ground when plugged into an appropriate three-wire receptacle.

WARNING!

FOR PROPER GROUNDING, THE POWER RECEPTACLE MUST BE A THREE-WIRE GROUNDED OUTLET. A HOSPITAL GRADE OUTLET IS REQUIRED. NEVER ADAPT THE THREE-PRONG PLUG FROM THE MONITOR TO FIT A TWO-SLOT OUTLET. IF THE OUTLET HAS ONLY TWO SLOTS, MAKE SURE THAT IT IS REPLACED WITH A THREE-SLOT GROUNDED OUTLET BEFORE ATTEMPTING TO OPERATE THE MONITOR.

IF THE INTEGRITY OF THE EXTERNAL PROTECTIVE EARTH GROUND IS IN DOUBT, THE BIS VISTA MONITOR SHALL BE OPERATED FROM ITS INTERNAL BATTERY POWER SOURCE ONLY.

FOR BIS VISTA SYSTEMS USED OUTSIDE OF NORTH AMERICA - A HARMONIZED LINE CORD WITH CONDUCTORS HAVING A CROSS SECTIONAL AREA GREATER THAN 0.75 mm^2 MUST BE USED.

4.1.4 Site Preparation: Mounting the Monitor

Aspect Medical Systems, Inc. strongly recommends permanent mounting of the BIS VISTA monitor to the anesthesia machine to enhance safety and facilitate ease-of-use. Please contact your local representative or Aspect to discuss mounting options.

WARNING!

BE SURE THE MONITOR IS MOUNTED SECURELY IN PLACE TO AVOID PERSONAL OR PATIENT INJURY.

4.1.4.1 Mounting the Monitor using the Pole Clamp

To mount the monitor to a secure vertical pole (1/2" - 1½" in diameter):

1. Place pole within clamp bracket and tighten screw using the black finger knob. Make sure that there is enough space above the clamp so that you have a few inches to slide the monitor in from above.
2. Line up the clamp shoe (on back of monitor) with the slot on pole clamp and slide monitor down to fit. The bottom of the clamp shoe should be seen well below the bottom of the pole clamp, and the monitor should snap securely into place.

Figure 7 - Pole Clamp

To remove the monitor, press tab on top of clamp shoe before sliding monitor up.

The pole clamp may be locked onto the monitor so that the two do not get separated. To do this:

1. Line up the clamp shoe (on back of monitor) with the slot on pole clamp and slide monitor down to fit. The bottom of the clamp shoe should be seen well below the bottom of the pole clamp and the monitor should snap securely into place.
2. Make sure that set screw hole on pole clamp aligns with corresponding hole on clamp shoe.
3. Remove black knob screw from pole clamp.

4. Using the Allen wrench supplied, secure pole clamp to monitor with the set screw provided.
5. Replace black knob screw.
6. To attach to pole, place pole within clamp bracket and tighten screw using the black finger knob.

4.1.4.2 Optional Mounting Accessories

For information on optional mounting accessories, request Aspect's "Monitor Mounting Solutions" booklet (part number 070-0031).

4.2 Instrument Connections

Detailed connection instructions are provided in the BIS VISTA Operating Manual.

4.2.1 Connecting the BISx

1. **Connect the BISx to the monitor**
   Holding the cylindrical connector with the flat side up, plug the BISx Monitor Interface Cable into the BISx port on the front of the monitor.

   Once connected, the BISx need not be disconnected again. However, if you wish to disconnect the BISx cable from the monitor, carefully grasp the connector and pull. DO NOT pull on the cable.

2. **Connect the PIC to the BISx**
   Attach the gray connector of the Patient Interface Cable to the BISx.

Note:

Connect with the BIS logo facing up for proper pin alignment. To disconnect the PIC, grasp the connector housing and pull firmly. DO NOT pull apart by the cable wire.

4.2.2 Power Cord Connections

The BIS VISTA Monitoring System is designed to use only 3-conductor IEC hospital-grade power cords. Cords must be type SJE, SJT, or SJO. Check for a firm connection.

4.3 Installation and Verification Procedure

1. Open packages and inspect for all components:
   - Monitor
   - Power cord
   - Pole clamp
   - BISx
   - PIC (Patient interface cable, connects BISx to patient)

2. Connect power cable to monitor, plug power plug into appropriate wall outlet.

- Verify that light to right of ON/Standby button is yellow.

3. Start up monitor by pressing the ON/Standby button (lower right corner).
   - Verify that light to right of 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. Connect PIC and sensor to BISx.
   - 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.

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

7. End of install.

SECTION 5

5 CARE AND CLEANING

INTRODUCTION

This section describes:

- Care and cleaning procedures
- Preventive maintenance

5.1 Care and Cleaning

WARNING!

UNIVERSAL PRECAUTIONS SHALL BE OBSERVED TO PREVENT CONTACT WITH BLOOD OR OTHER POTENTIALLY INFECTIOUS MATERIALS. PLACE CONTAMINATED MATERIALS IN REGULATED WASTE CONTAINER.

5.1.1 Cleaning the Monitor and BISx

Clean any spillage of blood or solutions on either the monitor or BISx as soon as possible. Dried blood is very difficult to remove. Use lint-free absorbent towels for spill cleanups. Dampen the towel with detergent and lukewarm water to aid in cleaning. After cleaning, wipe the PIC connector ends with alcohol and allow to dry completely. Residual moisture inside the connector may affect BISx performance.

5.1.2 Disinfecting the Monitor and BISx

Use lint-free absorbent towels dampened with a 10% bleach solution, or a commercial disinfectant (e.g. Lysol® Professional Disinfectant Foam Cleaner Spray or PDI Germicidal Disposable Wipes).

After cleaning, dry all areas except the monitor display screen (see below) with a lint-free absorbent paper towel. Wipe the BISx and PIC connector ends with alcohol and allow to dry completely.

WARNING!

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

DO NOT MIX DISINFECTING SOLUTIONS (e.g., BLEACH AND AMMONIA) AS HAZARDOUS GASES MAY RESULT.

Caution:

Do not autoclave the BISx or Monitor. Autoclaving will seriously damage both components.

Avoid liquid ingress to the Patient Interface Cable. Contact of fluids with the PIC sensor connectors can interfere with PIC performance.

5.1.3 Cleaning the Monitor Display

Clean the monitor display screen with a mild solution of detergent and warm water or a commercial display screen cleaner, available through personal computer dealers. To avoid scratching the screen, never use abrasive cleaners.

SECTION 6

6 PREVENTIVE MAINTENANCE

INTRODUCTION

The BIS VISTA system is designed so that no periodic adjustment or calibration is required. Suggested routine maintenance covered in this section includes:

- Periodic checking of cable integrity
- System checkout
- Checking the battery
- Checking leakage current

Instructions on replacing cables, connectors, the battery, the power supply and the clamp shoe are included in Section 8, "Servicing the BIS VISTA System" if replacement is necessary. In the event that the touch screen needs calibration, follow the instructions in Section 8.9, "Calibrating the Touch Screen."

6.1 Physical Integrity Inspection

Periodically check the system (BIS VISTA monitor, BISx, PIC) for physical damage to cases and associated cables and connectors.

1. Inspect the cases of the monitor and the BISx to ensure that plastic is not cracked or broken.
2. Inspect the gasket seal around the case joining surfaces to insure the integrity of the splash resistance seal.
3. Inspect the cables and strain relief mechanisms.
4. Inspect the connectors for damage, faulty strain relief or contamination.

6.2 System Checkout

A system checkout should be done periodically to verify that all system components are in working order. To test the system from the BISx to the BIS sensor, you will need a Sensor Simulator (Part Number 186-0137) or a Test Sensor (See Appendix I for more information). Follow the instructions below for System Checkout.

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 Section6.2.1 "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.

SECTION 7

7 DIAGNOSTICS AND TROUBLESHOOTING

INTRODUCTION

This section explains:

- General troubleshooting using built in diagnostic tools
- BIS VISTA Monitoring System troubleshooting procedure.
- Status messages, causes, and corrective actions

7.1 General Troubleshooting

The BIS VISTA Monitoring System has both automatic and manual diagnostic features. These features check the BIS VISTA Monitoring System's operability and status, and report software and hardware malfunctions.

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

The **power-up** diagnostics run automatically the first time the unit is powered on, after the battery or power supply have been replaced, or after the Reset button has been pressed. Software image checksums and trend data memory are tested and repaired if necessary.

The **automatic** diagnostics run continuously in the background while the unit operates. These procedures check the BISx for the following conditions: interface faults, disconnect, lead off, and power faults.

The **manual** diagnostics are operator initiated using the monitor touch keys and menu choices. These procedures check the digital signal converter function within the BISx.

NOTE:

The manual diagnostics can be run safely while the patient is connected to the BIS VISTA Monitoring System; however, running the diagnostics will temporarily disrupt monitoring. Do not run the DSC Self Test during electro-cautery as it may erroneously indicate a failure of the BISx.

7.2 BIS VISTA Monitoring System Troubleshooting Procedure

The BIS VISTA Monitoring System consists of three major components: Monitor, BISx, and PIC/Sensor. By using the three-step Checkout Procedure and a component swapping technique, the component at fault can easily be determined.

Use the Checkout procedures in Section 6.2 "System Checkout" to test function of each component. The steps of this checkout procedure include:

- Monitor; test monitor and battery power functions
- BISx; recognition and DSC Self Test
- PIC and Sensor; recognition and Sensor Check test

Consult Section 7.3 "BIS VISTA System Messages and Corrective Actions" for messages that may occur and the appropriate action to take.

Consult Section 8 "Servicing the BIS VISTA System" for directions on replacing components and handling components that require service.

BISx Cable Problem Isolation

Note:

This BIS VISTA Monitoring System Service Information Manual contains the maintenance and diagnostic troubleshooting information necessary for qualified technical personnel to test and replace those parts of the equipment that are replaceable by the customer. Aspect does not authorize nor provide information to service or repair the internal electronic components of the BISx or the BIS VISTA monitor.

The qualified user may replace the BISx cables by following the procedures in Section 8 "Servicing the BIS VISTA System." If the cables or connectors are physically damaged, they will need to be replaced. If cables are suspect, the following may be of aid in determining which cable is defective.

The **Monitor Interface Cable** (monitor connector to BISx) is an 11-conductor cable that handles all communications to/from the BISx. It uses two twisted pair and a ground for digital data transmission and for the clock transitions that are used to generate power in the BISx housing. Therefore, failure in this cable is usually seen as failure to recognize the BISx ("Connect BISx" message).

The **Patient Interface Cable (PIC)** is a 10-lead conductor that brings in the patient's EEG signal and also provides information about the sensor connected. If this cable fails, the system may indicate that the sensor is not connected or is illegal, or the Sensor Check may fail or restart on its own.

Problem Isolation Procedure: Use the following sequence to determine the most probable cable:

1. With no sensor connected, run DSC Self Test (see Section 7.2.2 "BISx Checkout Procedure):
   - If test fails or will not start, or the BISx is not recognized, the Monitor cable is likely suspect. This failure may also be related to a PCB problem in the BISx in which case the BISx must be replaced.
   - If test indicates PASS, continue to step 2.

2. Connect Sensor Simulator or Test Simulator. Run Sensor Check (see Section 7.2.3 "PIC Chekcout Procedure)
   - If failure is noted, swap PIC with known good PIC cable and run again.
   - If failure repeats, the BISx or the BISx Bulkhead Connector is suspect. This failure may also be related to a PCB problem in the BISx in which case the BISx must be returned to Aspect for service.

7.3 BIS VISTA System Messages and Corrective Actions

When an alarm is triggered, a message appears in the Message Region of the screen. Possible messages and the recommended operator actions are listed below:

BIS VISTA Messages and Operator Actions

Status Messages:	Causes:	Corrective Actions:
01 **Connect BISx**	1. BISx disconnected. 2. Defective BISx cable. 3. Defective BISx. 4. Defective monitor.	1. Connect BISx. Verify all cable connections. 2. Replace Monitor Interface Cable. 3. Replace the BISx. 4. Replace monitor.
13 **Re-prep Sensor**	1. Incorrect sensor application. 2. Poor sensor connections. 3. Sensor Check fails 4. Defective PIC. 5. Defective BISx.	1. Read Instructions on sensor package and re-prep sensor. 2. Check sensor connections. 3. Re-prep again or replace sensor. Verify Sensor Check passes. 4. Replace the PIC. 5. Replace BISx Bulkhead Connector or replace BISx.
14 **Sensor Disconnected**	1. Disconnected sensor. 2. Poor or contaminated connection between sensor and PIC. 3. Disconnected PIC. 4. Defective PIC. 5. Defective BISx.	1. Connect the Sensor. 2. Connect/clean connection between sensor and PIC. 3. Connect the PIC. 4. Replace the PIC. 5. Replace BISx Bulkhead Connector or replace BISx.

Status Messages:	Causes:	Corrective Actions:
16 **Last Sensor Check Failed**	1. At least one element of sensor has too high impedance, and EXIT pressed (before sensor check completes). 2. Incorrect sensor application. 3. Poor sensor connection. 4. Defective PIC. 5. Defective sensor. 6. Defective BISx.	1. Verify Sensor Check passes. 2. Read Instructions on sensor package and re-apply sensor. 3. Check sensor connection. 4. Replace the PIC. 5. Replace sensor. 6. Replace BISx Bulkhead Connector or replace BISx.
27 **Excessive Artifact Detected in Signal**	The Signal Quality is less than half of the level desirable for optimal monitoring conditions. This may occur as the result of artifact such as those generated from motion or eyeblinks. 1. Artifact, such as those generated by motion or eyeblinks, is causing loss of EEG recognition. 2. EMG Bar indicates electrical activity that may be interfering with EEG recognition. 3. PIC is defective. 4. BISx is defective. **Note:** This message may occur as the results of artifact (non-EEG signal) such as those generated from motion (patient movement or eyeblinks) or the presence of electro-cautery, warming blankets, or other devices	1. If ARTIFACT label appears above the EEG waveform box, attempt to identify and eliminate artifact source. 2. If EMG bar is illuminated, attempt to determine and eliminate cause. 3. Verify Sensor Check passes. If not, replace PIC. 4. Replace BISx Bulkhead Connector or replace BISx.

Status Messages:	Causes:	Corrective Actions:
28 **Data unavailable due to poor signal quality**	The signal quality is too low to accurately calculate a BIS value. The BIS value and other trend variables that are adversely affected by artifact are not displayed 1. Artifact, such as those generated by motion or eyeblinks, is causing loss of EEG recognition. 2. EMG Bar indicates electrical activity that may be interfering with EEG recognition. 3. PIC is defective. 4. BISx is defective. **Note**: This message may occur as the results of artifact (non-EEG signal) such as those generated from motion (patient movement or eyeblinks) or the presence of electro-cautery, warming blankets, or other devices.	1. If ARTIFACT label appears above the EEG waveform box, attempt to identify and eliminate artifact source. 2. If EMG bar is illuminated, attempt to determine and eliminate cause. 3. Verify Sensor Check passes. If not, replace PIC. 4. Replace BISx Bulkhead Connector or replace BISx.
BIS Out of Target Range **29 – Low** **30 – High**	The BIS has fallen outside the target range set by the user.	1. Check patient. 2. Take note of BIS at limit set by user.

Status Messages:	Causes:	Corrective Actions:
31 **Isoelectric EEG Detected**	No discernible EEG activity is detected for several minutes; SR=100. **Note:** This message notifies user of a flatline EEG. This is a normal condition when Sensor Simulator or Test Sensor is connected.	If unintended: 1. Check patient vital signs, dosage, etc. 2. Check leads for proper connection and possible shorts. 3. Verify Sensor Check passes. 4. Verify DSC Self test passes. 5. Verify PIC. Use Test Sensor or Sensor Simulator and Sensor Check.
33 **Operating On Battery Backup**	The AC power has been lost and the monitor is running on the battery. The battery keeps the monitor operating for approximately 45 minutes (when the battery is fully charged).	1. Restore the AC power. 2. Verify power cord. 3. Replace power supply.
34 **Battery Power Low**	There are only a few minutes of battery life left.	Restore AC power to avoid automatic shutdown.
92, 93 **Sensor Ground Fault**	Problem is detected relating to sensor ground electrode.	1. Disconnect and examine sensor connection. Clean any contamination present. 2. Replace sensor if necessary. 3. Replace PIC. 4. Replace BISx Bulkhead Connector or replace BISx.
94 **Sensor Overcurrent**	Sensor is using too much current.	1. Disconnect and examine sensor connection. Clean any contamination. 2. Replace sensor if necessary. 3. Replace PIC. 4. Replace BISx Bulkhead Connector or replace BISx.
95 **No more Uses for this Sensor**	Sensor has been connected and disconnected too many times.	Replace the sensor.

Status Messages:	Causes:	Corrective Actions:
96 **Sensor Invalid**	1. Poor or contaminated connection between sensor and PIC. 2. Defective sensor. 3. Defective PIC. 4. Defective BISx.	1. Connect/clean connection between sensor and PIC. 2. Replace the sensor. 3. Replace the PIC. 4. Replace BISx Bulkhead Connector or replace BISx.
109 **Sensor Used for Over 24 Hours**	Sensor has been sending data for more than 24 hours	Replace sensor
202 **Sensor Expired**	1. Sensor expiration date has passed 2. Time and date are incorrect	1. Replace Sensor 2. Verify current time and date; Reset if necessary
1000-1999 **Unrecoverable BISx Error**	1. Poor connection between BISx monitor cable and monitor. 2. Defective BISx 3. Defective monitor.	1. Unplug BISx from monitor and plug in again. 2. Replace the BISx or the Monitor Interface Cable. 3. Replace the monitor
2000-2999 **Unrecoverable Monitor Error**	A system error has occurred. The monitor may stop operating.	1. Turn the monitor off, then on again. 2. Reset monitor. 3. Replace monitor.
3000-3999 **Data Export Error**	The data export was not successful. 1. Removable drive is not connected properly to USB(A) port. 2. Drive is incompatible or defective. 3. Drive is full.	1. Check connection. 2. Replace drive. 3. Replace drive.
4000-4999 **Software Update Error**	A software error has occurred.	1. Restart monitor. 2. Reset monitor. 3. Replace monitor.
5000-5999 **Trend Memory Error**	A memory error has occurred.	1. Restart monitor. 2. Reset monitor. 3. Replace monitor.

Status Messages:	Causes:	Corrective Actions:
6000-6999 **Snapshot Error**	Operating system has noted that the snapshot process has not completed correctly.	1. Retry snapshot. 2. Restart monitor. 3. Reset monitor. 4. Replace monitor.

SECTION 8

8 SERVICING THE BIS VISTA SYSTEM

INTRODUCTION

This section provides instructions for replacing the PIC, BISx, and the monitor, and for removing and replacing parts of the monitor and the BISx. If a component needs to be serviced, please consult Sections 8.12 and 8.13 for instructions on packaging and shipping.

The BIS VISTA Monitoring System is designed to be easily serviced by using the built in diagnostic routines (see Section 7 "Diagnostics and Troubleshooting") and the major component swapping techniques described below. Replacement part numbers are listed in Section 10.1, "Accessories and Spare Parts List."

8.1 Replacing the PIC

Parts Required:	Tools Required:
Patient Interface Cable (PIC Plus) P/N 186-0107	None

To replace the PIC, unplug the PIC cable from the BISx Bulkhead Connector by grasping the connectors (NOT the cable!) and firmly pulling the two sections apart.

To attach the replacement PIC cable to the BISx, align and press the PIC and BISx connectors together firmly.

8.2 Replacing the BISx

Parts Required:	Tools Required:
BIS VISTA BISx with Patient Interface Cable; P/N 185-0145-AMS	None

To replace the BISx:
Disconnect the BISx from the front of the monitor. To do this, carefully grasp the connector on the BISx Monitor Interface Cable and pull. DO NOT twist or pull on the cable.

If necessary, unplug the PIC cable from the BISx by grasping the connector (NOT the wires!) and firmly pulling it out of the BISx Bulkhead Connector.

To install the replacement BISx, hold the cylindrical connector with the flat side up (at 12 o'clock position) and insert firmly into BISx port on front of monitor.

To re-attach the PIC cable, align the PIC and BISx connectors and press together firmly.

8.3 Replacing the Monitor

Parts Required:

BIS VISTA Monitor P/N 185-0151

Tools Required:

None

To replace the monitor:

1. Put monitor in Standby mode by pressing the ON/Standby button. The light to the right of the button should be yellow or off.
2. Unplug the power cable from the wall and remove it from its receptacle in the rear of the monitor.
3. Disconnect the BISx from the front of the monitor. To do this, grasp the connector on the BISx Monitor Interface Cable and pull. DO NOT twist or pull on the cable.
4. If necessary, dismount monitor from pole clamp by removing set screw from clamp, then depressing top of clamp shoe (blue plastic clip at top of aluminum pole clamp) and slide the monitor up and off of the clamp.
5. To install the replacement monitor, insert power cord into receptacle on rear of monitor.
6. To install the BISx, hold the cylindrical connector with flat side up (at 12 o'clock position) and insert firmly into BISx port on front of monitor.
7. Re-mount pole clamp assembly.

8.4 Replacing the Battery

Parts Required:

Battery Replacement Kit P/N 186-0208

Tools Required:

Philips #2 screwdriver

Caution:

All repairs to the BIS VISTA Monitoring System should be made only by a qualified Biomedical Engineering Technician or other authorized personnel.

To replace the battery, you will need a Philips #2 screwdriver. Follow the instructions below:

1. Unplug A/C line cord from the monitor.
2. Lay monitor screen-side-down on a scratch-free work surface so that the Battery/Power Supply cover is accessible.

3. Remove 4 screws from the Battery/Power Supply cover and remove the cover. Note the position of the battery cable.

4. Squeeze the battery connector latch to disengage it from the back of the monitor and remove the old battery.

5. Lay the new battery in the recess with the wires at the top, and plug in the connector.
6. Replace the cover and four screws (hand-tighten only) and reconnect the A/C power cord.

8.5 Replacing the Power Supply

Parts Required:

Power Supply Replacement Kit P/N 186-0216

Tools Required:

Philips #2 screwdriver

Caution:

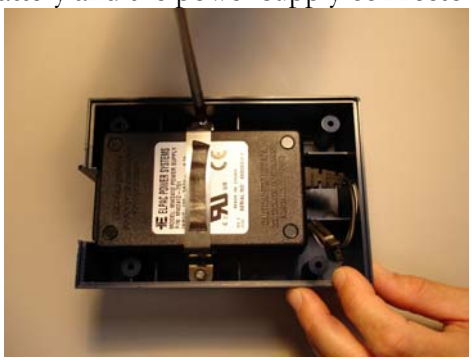
All repairs to the BIS VISTA Monitoring System should be made only by a qualified Biomedical Engineering Technician or other authorized personnel.

WARNING:

POWER SUPPLY IS INTERNALLY FUSED. REPLACE POWER SUPPLY ONLY WITH ASPECT MEDICAL SYSTEMS BIS VISTA POWER SUPPLY.

To replace the power supply, you will need a Philips #2 screwdriver. Follow the instructions below:

1. Unplug A/C line cord from the BIS VISTA monitor.
2. Lay the monitor screen-side-down on a scratch-free work surface so that the Battery/Power Supply cover is accessible.
3. Remove 4 screws from the Battery/Power Supply cover and remove the cover. The power supply is located inside the cover.
4. Unplug (squeeze and pull to remove) the battery and the power supply connectors.



5. Remove screws from the power supply bracket and remove the old power supply.
6. Insert new power supply into the cover, lining up the A/C power receptacle with the cutout in the cover.
7. Reconnect the power supply.
8. Reconnect the battery.
9. Replace the cover and 4 screws (hand-tighten only) and reconnect the A/C power cord.

8.6 Replacing the Clamp Shoe

Parts Required:

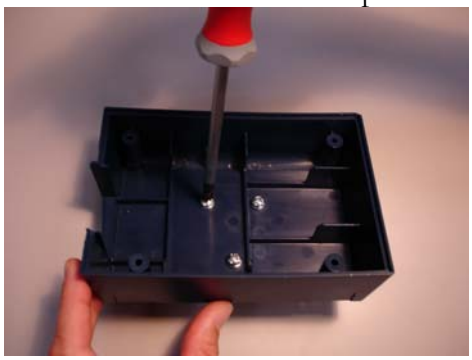
Shoe Clamp Replacement Kit P/N 186-0217

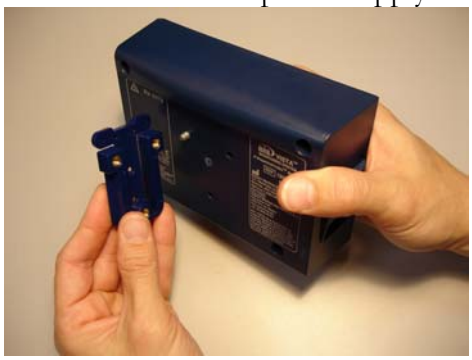
Tools Required:

Philips #2 and #8 screwdrivers

To replace the Clamp Shoe, you will need Philips #2 and #8 screwdrivers. The power supply must be removed to access the Clamp Shoe screws. Follow the instructions below:

1. Unplug A/C line cord from the BIS VISTA monitor.
2. Lay the monitor screen-side-down on a scratch-free work surface so that the Battery/Power Supply cover is accessible.
3. Remove 4 screws from the Battery/Power Supply cover and remove the cover. The power supply is located inside the cover.
4. Unplug (squeeze and pull to remove) the power supply connector.
5. Remove screws from the power supply bracket and remove the power supply.





6. Remove the three screws that attach the Clamp Shoe to the back panel.
7. Replace the Clamp Shoe and attach it to the back panel with the three new screws provided in the kit (hand-tighten only).
8. Insert power supply into the cover, lining up the A/C power receptacle with the cutout in the cover.
9. Reconnect the power supply.
10. Replace the cover and 4 screws (hand-tighten only) and reconnect the A/C power cord.

8.7 Replacing the Monitor Interface Cable

Caution:

All repairs to the BIS VISTA Monitoring System should be made only by a qualified Biomedical Engineering Technician or other authorized personnel.

Use only the parts and tools specified. Use of any others may damage the instrument.

8.7.1 Parts and Tools Required

Parts Required:

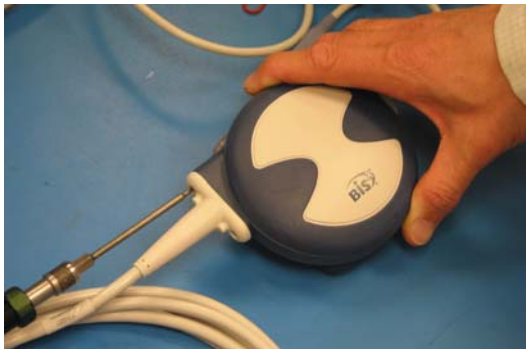
BIS VISTA Host Cable Replacement Kit; P/N 186-0201-AMS includes:

- BISx Monitor Interface Cable P/N 175-0061-GA
- Gasket, P/N 150-0187
- Torx head screws, P/N 606-0008

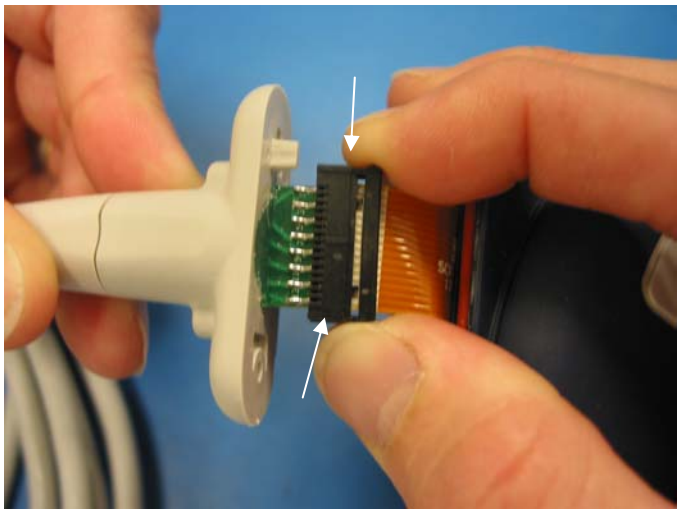
Tools Required:

Torque screwdriver with Torx bit size T-7.

8.7.2 Procedure:



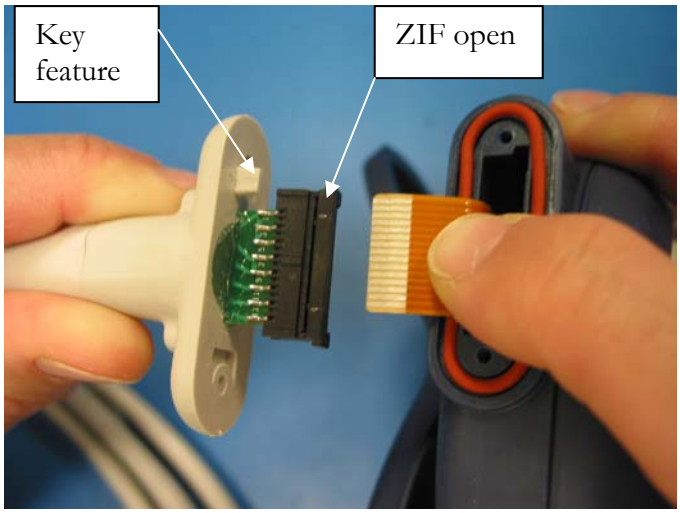
1. Disconnect BISx from the monitor.
2. Remove screws from the bulkhead of the old Monitor Interface Cable.



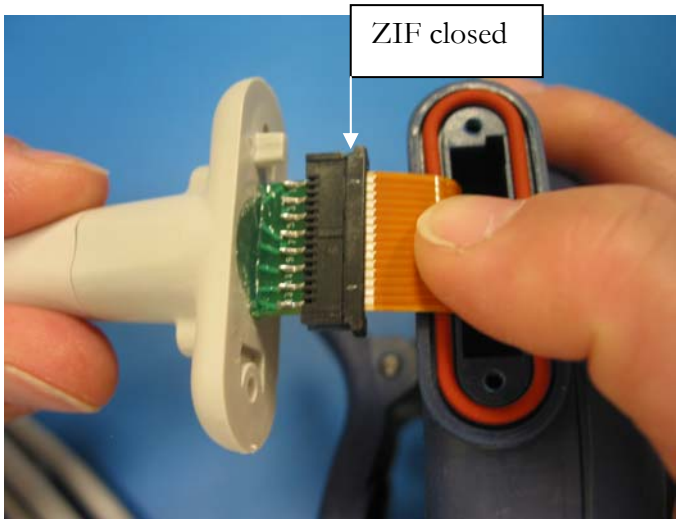
3. Open the ZIF connector by pulling away from the bulkhead.

4. Disconnect from the flex cable. Discard the old gasket.

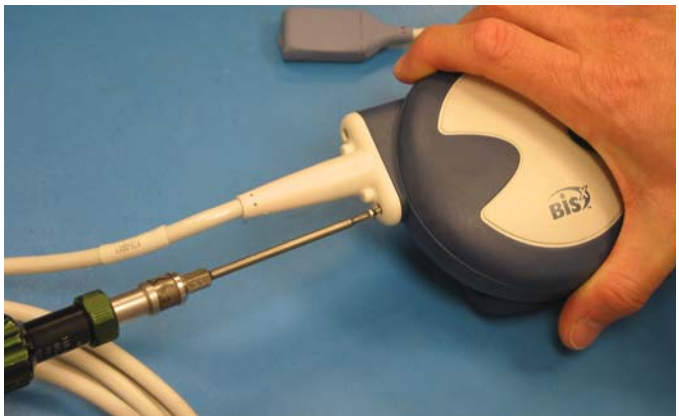
5. Set the new gasket in the groove of the BISx housing.



6. Align the key feature on the bulkhead and the BISx unit. Attach the flex cable from the BISx to the ZIF connector on the replacement cable.



7. Ensure that the flex cable is fully inserted into the ZIF and close the ZIF connector by pushing toward the bulkhead. Carefully feed the flex cable into the housing and seat the cable bulkhead to the BISx housing.



8. Set the screws in the holes. Slowly tighten to 45 in-oz.

8.8 Replacing the BISx Bulkhead Connector

Caution:

All repairs to the BIS VISTA Monitoring System should be made only by a qualified Biomedical Engineering Technician or other authorized personnel.

Use only the parts and tools specified. Use of any others may damage the instrument.

8.8.1 Parts and Tools Required

Parts Required:

BISx Bulkhead Replacement Kit P/N 195-0052 includes:

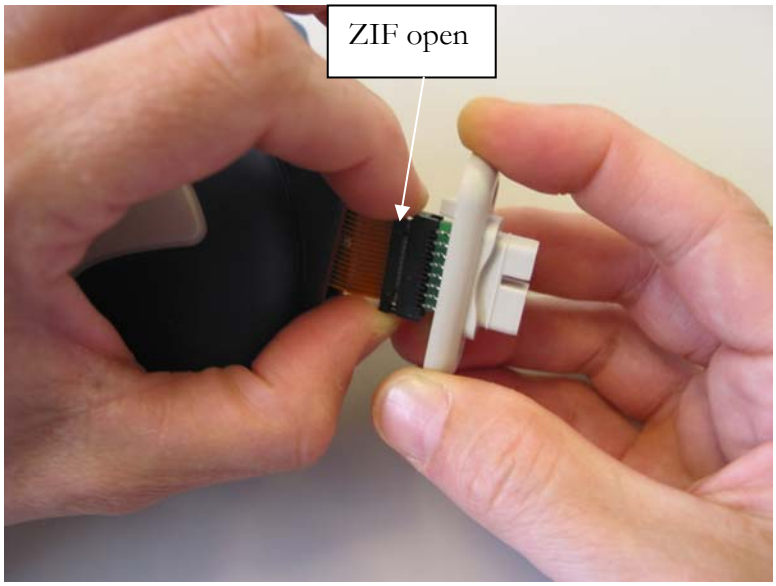
BISx Bulkhead,
P/N 175-0052
Gasket, P/N 150-0187
Torx head screws, P/N 606-0008

Tools Required:

Torque screwdriver with Torx bit size T-7.

8.8.2 Procedure:

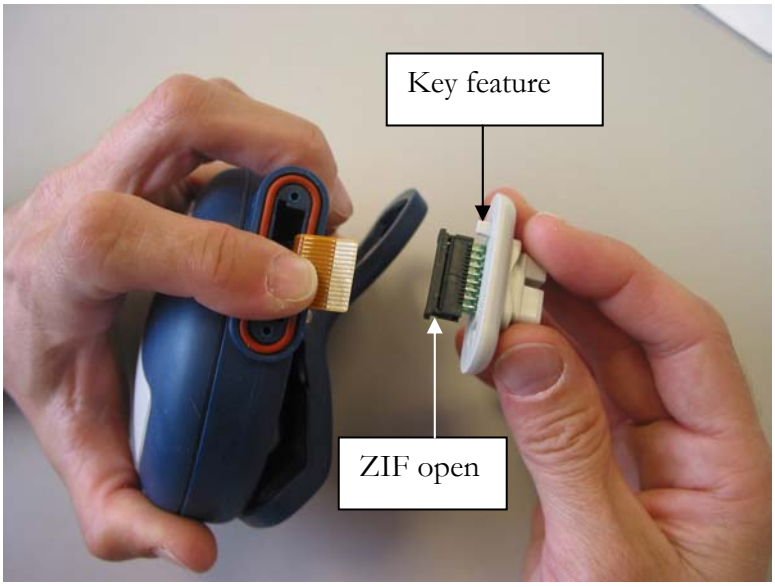
1. Disconnect BISx from the monitor and remove Patient Interface Cable from BISx.
2. Remove screws from the bulkhead.



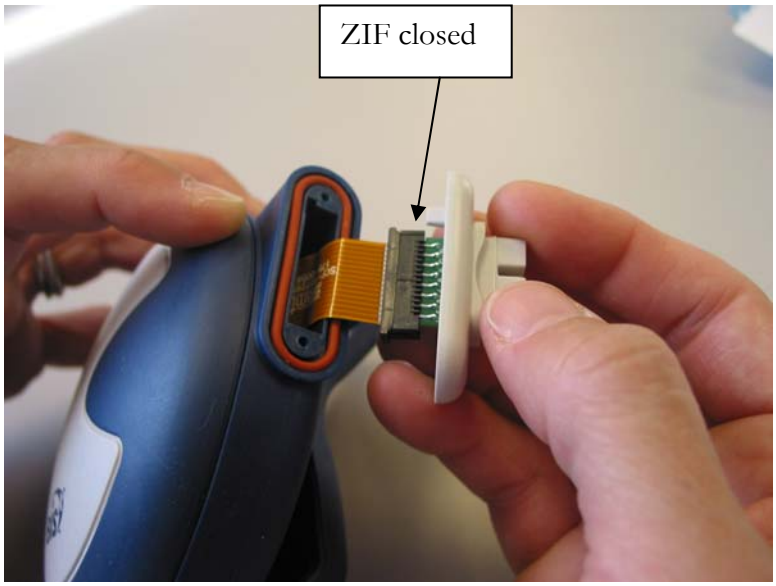
3. Open the ZIF connector by pulling away from the bulkhead.

4. Disconnect from the flex cable. Discard the old gasket.

5. Set the new gasket in the groove of the BISx housing.



6. Align the key feature on the bulkhead and the BISx unit. Attach the flex cable from the BISx to the ZIF connector on the replacement bulkhead.



7. Ensure that the flex cable is fully inserted into the ZIF and close the ZIF connector by pushing toward the bulkhead. Carefully feed the flex cable into the housing and seat the bulkhead to the BISx housing.

8. Set the screws in the holes. Slowly tighten to 45 in-oz.

8.9 Calibrating the Touch Screen

The Touch Screen is calibrated at the factory and does not need to be re-calibrated on a regular basis. However, if necessary, the touch screen may be calibrated by selecting **[Calibrate Touch Screen]** from the Maintenance Menu. Follow the on-screen instructions.

8.10 Using the Reset Button

The Reset button is located on the back panel of the monitor. If necessary, the software can be reset by accessing this button with a ballpoint pen, paper clip or other similar tool.

8.11 BISx Checkout and Safety Tests

1. Perform DSC Self Test. See Section 7.2.2 "The BISx Checkout Procedure" or refer to the BIS VISTA Monitoring System Operating Manual.
2. Verify that all test sections PASS.
3. Install a known good PIC cable.
4. Connect a Sensor Simulator or Test Sensor tool as described in Section 10 "Appendix I."
5. Perform a Patient Interface Cable (PIC) Checkout Procedure as described in Section 7.2.3. "PIC Checkout Procedure." For more detail, refer to the BIS VISTA Monitoring System Operating Manual.
6. Perform a leakage (electrical safety test) according to the appropriate institution requirements.
7. If appropriate, perform a Hipot test according to institution requirements.
8. End of Procedure.

8.12 What to do with a Component that Requires Service

Contact your local distributor to determine where servicing will occur. Aspect's Technical Service Department will assist you in isolating the problem to a specific component. Have the equipment available when you call so that you can supply the appropriate serial numbers and a detailed description of the problem. If it becomes necessary to return a unit directly to Aspect Medical Systems, follow the procedure below:

- Contact Aspect's Technical Service Department to obtain a Returned Materials Authorization (RMA) number. (The Technical Service phone number is printed on the back cover of this manual.) The RMA number must appear on the outside of the shipping container.

- Use the original shipping container, if available, or equivalent packaging to protect the product. Seal the package with plastic shipping tape rather than masking tape. Mark shipping or storage container FRAGILE.

- If the repair or replacement is covered by the warranty, Aspect will bear the costs of shipping the repaired or replacement product back to the user. All other shipping costs shall be paid by the user.

8.13 Repackaging for Shipping and Storage

If it becomes necessary to return the monitor to the factory, use the original shipping container to protect the product. Seal the package with reinforced packing tape rather than plastic or masking tape. Mark shipping container FRAGILE.

SECTION 9

9 SPECIFICATIONS AND WARRANTY

INTRODUCTION

This section includes:

- General specifications of the BIS VISTA monitor and accessories
- Electromagnetic compatibility specifications
- Warranty

9.1 General Specifications

This section lists specifications for the BIS VISTA Monitoring System.

General Specifications:

Product Description:	BIS (Bispectral Index) monitoring system for display of processed data and real-time EEG waveforms
Monitor Weight:	4.5 lbs (2 kg)
Monitor Dimensions:	7.5 in wide x 8 in high x 5 in deep (19 cm x 20.3 cm x 12.7 cm)
Display Size:	4 in high x 5.25 in wide (10 cm x 13 cm)
Digital Output:	USB ports A, B, RS232 serial port
Power Requirements:	100-240 VAC, 50-60 Hz, 0.7 ampere max.
Electrical Safety:	Conforms to: UL 60601-1, IEC 60601-2-26, CAN/CSA-C22.2#601.1
Battery Backup:	45 minutes at full operation Recharge Time: 6 hours
Software Updates:	User-via USB port (Type A)

EEG Specifications:

Epoch Duration:	2 seconds
Artifact Rejection:	Automatic
EEG Scales:	25 μV/div (+/- 1 mV Full Scale)
EEG Sweep Speeds:	25 mm/sec
Computed Parameters:	Bispectral Index, Suppression Ratio, EMG, Signal Quality Index, and Burst Count
User-defined Displays:	Trend and real-time EEG waveforms
Update Rate:	1 second for BIS number, 10 seconds for Trend
Event Markers:	User selected
Alarms:	Auditory and visual, user adjustable limits
Filters:	ON (2 – 70 Hz with notch) or OFF (.25 – 100 Hz)
Mode:	Sensor automatically selects mode.

BISx Specifications:

BISx:

Weight:	10.0 oz (0.284 kg) including integral cable
Dimensions:	3.75 in wide x 2.5 in high (9.5 cm x 6.3 cm)
Cable Length:	9 ft (2.7 m) Integral BISx Cable 4 ½ ft (1.4 m) from BISx to sensor connector
Analog to Digital Converter:	Noise-shaped sigma-delta
Sampling Rate:	16,384 samples/second
Resolution:	16 Bits at 256 samples/second
Input Impedance:	50 Mohms typical
Noise:	< 0.3 μV RMS (2.0 μV peak-to-peak); 0.25 Hz to 50 Hz
Common Mode Rejection: (Isolation mode)	110 dB at 50/60 Hz to earth ground
Frequency/Bandwidth:	0.16 – 450 Hz

Type of Protection against Electric Shock of the System:
Class 1: Equipment in which protection against electric shock does not rely on basic insulation only, but which includes an additional safety precaution. Means are provided for the connection of the equipment to the protective earth conductor in the fixed wiring of the installation in such a way that accessible metal parts cannot become live in the event of a failure of the basic insulation.

Degree of Protection against Electric Shock of the System:
Type BF: Equipment providing a degree of protection against electric shock regarding allowable leakage currents and reliability of the protective earth ground connection with an F-type applied part. An F-type applied part is isolated from all other parts of the equipment to such a degree that the patient leakage current allowable in single fault condition is not exceeded when a voltage equal to 1.1 times the highest rated AC supply voltage is applied between the applied part and earth. The circuitry inside the BIS VISTA monitor is isolated from the mains in accordance with UL60601-1. Patient isolation is accomplished within the BISx.

Degree of Protection against effects of Cardiac Defibrillation:
The BIS VISTA system provides protection for the operator and patient during cardiac defibrillation. This protection is achieved via the isolation barrier within the BISx.

Degree of Protection against the Ingress of Water:
Monitor degree of protection rating: IPX2 (ingress of water vertically dripping).
BISx degree of protection rating: IPX4 (splash proof).

Mode of Operation of the System:
Continuous: Operation under normal load for a normal period without exceeding the specified limits of temperature.

Classification:

MEDICAL ELECTRONIC EQUIPMENT

CLASSIFIED BY UNDERWRITERS LABORATORIES INC.® WITH RESPECT TO ELECTRIC SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1, IEC 60601-1, IEC 60601-2-26, CAN/CSA-C22.2#601.1.

9.2 Electromagnetic Compatibility Specifications

The BIS VISTA Monitoring System requires special precautions regarding Electromagnetic Compatibility (EMC). The BIS VISTA system must be installed and put into service according to the EMC guidance information provided in this section.

Portable and mobile radio frequency communications equipment can affect the operation of the BIS VISTA Monitoring System. Refer to the EMC guidance information and Cautions provided in this manual.

9.2.1 Accessories

The BIS VISTA Monitoring System complies with the requirements of IEC 60601-1-2:2001 when used with the accessories listed in Section 2 of the Operating Manual. In addition, the BIS VISTA system must be used only with the power cord provided.

When using the Software Upgrade Device to load new versions of software into the BIS VISTA monitor, no cables or other accessories should be connected to the device. The BIS VISTA monitor should be connected to the mains through the appropriate power cord, and the Software Upgrade Device should be plugged into the USB-A connector on the back of the device.

Caution:
Using accessories other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the BIS VISTA Monitoring System.

9.2.2 IEC 60601-1-2:2001 Electromagnetic Compatibility Guidance

This section provides the appropriate specification tables for the BIS VISTA Monitoring System as per IEC 60601-1-2.

Guidance and Manufacturer's Declaration - Electromagnetic Emissions

The BIS VISTA Monitoring System is intended for use in the electromagnetic environment specified below. The customer or user of the BIS VISTA system should assure that it is used in such an environment		
Emissions test	**Compliance**	**Electromagnetic Environment - Guidance**
RF Emissions CISPR 11	Group 1	The BIS VISTA Monitoring System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The BIS VISTA Monitoring System is suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

Caution:

The BIS VISTA system should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BIS VISTA monitor should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The BIS VISTA system is intended for use in the electromagnetic environment specified below. The customer or user of the BIS VISTA system should assure that it is used in such an environment			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines. ±1 kV for input/output lines.	±2 kV for power supply lines. ±1 kV for input/output lines.	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines. IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycle. 40% UT (60% dip in UT) for 5 cycles. 70% UT (30% dip in UT) for 25 cycles. <5% UT (>95% dip in UT) for 5 sec.	<5% UT (>95% dip in UT) for 0.5 cycle. 40% UT (60% dip in UT) for 5 cycles. 70% UT (30% dip in UT) for 25 cycles. <5% UT (>95% dip in UT) for 5 sec.	Mains power quality should be that of a typical hospital environment. If the user of the BIS VISTA system requires continued operation during power mains interruptions longer than 45 minutes, it is recommended that the BIS VISTA monitor be powered by an uninterruptible power supply or an additional battery.
Power frequency (50/60 Hz) magnetic field. IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in a typical hospital environment.

NOTE: UT is the AC mains voltage prior to the application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Immunity

The BIS VISTA Monitoring System is intended for use in the electromagnetic environment specified below. The customer or user of the BIS VISTA system should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the BIS VISTA system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$, 80 MHz to 800 MHz $d = 2.3\sqrt{P}$, 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by electromagnetic site survey[a], should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BIS VISTA system is used exceeds the applicable RF compliance level above, the BIS VISTA system should be observed to verify normal operation. If abnormal performance is observed, additional measures may by be necessary, such as reorienting or relocating the BIS VISTA system[b]
Over the frequency ranges 150kHz to 80 MHz field strength should be less than 3 V/m.

Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the BIS VISTA Monitor

The BIS VISTA Monitoring System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the BIS VISTA system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BIS VISTA system as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of equipment **W**	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency ranges applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

9.3 Warranty

Aspect warrants to the initial Purchaser that the BIS VISTA monitor and the BISx ("Warranted Product") will be free from defects in workmanship or materials, when given normal, proper, and intended usage for a period of one year ("Warranty Period") from the date of its initial shipment to Purchaser. Excluded from this warranty are expendable components and supply items such as, but not limited to, electrodes, cables, and prep solutions. Aspect's obligations under this warranty are to repair or replace any Warranted Product (or part thereof) that Aspect reasonably determines to be covered by this warranty and to be defective in workmanship or materials provided that the Purchaser has given notice of such warranty claim within the Warranty Period and the Warranted Product is returned to the factory with freight prepaid. Repair or replacement of Products under this warranty does not extend the Warranty Period.

To request repair or replacement under this warranty, Purchaser should contact Aspect directly (see contact information on the back cover of this manual). Aspect will authorize Purchaser to return the Warranted Product (or part thereof) to Aspect. Aspect shall determine whether to repair or replace Products and parts covered by this warranty and all Products or parts replaced shall become Aspect's property. In the course of warranty service, Aspect may but shall not be required to make engineering improvements to the Warranted Product or part thereof. If Aspect reasonably determines that a repair or replacement is covered by the warranty, Aspect shall bear the costs of shipping the repaired or replacement Product to Purchaser. All other shipping costs shall be paid by Purchaser. Risk of loss or damage during shipments under this warranty shall be borne by the party shipping the Product. Products shipped by Purchaser under this warranty shall be packaged in the original shipping container or equivalent packaging to protect the Product. If Purchaser ships a Product to Aspect in unsuitable packaging, any physical damage present in the Product on receipt by Aspect (and not previously reported) will be presumed to have occurred in transit and will be the responsibility of Purchaser.

This warranty does not extend to any Warranted Products or part thereof: that have been subject to misuse, neglect, or accident; that have been damaged by causes external to the Warranted Product, including but not limited to failure of or faulty electrical power; that have been used in violation of Aspect's instructions; that have been affixed to any nonstandard accessory attachment; on which the serial number has been removed or made illegible; that have been modified by anyone other than Aspect; or that have been disassembled, serviced, or reassembled by anyone other than Aspect, unless authorized by Aspect. Aspect shall have no obligation to make repairs, replacements, or corrections which result, in whole or in part, from normal wear and tear. Aspect makes no warranty (a) with respect to any products that are not Warranted Products, (b) with respect to any products purchased from a person other than Aspect or an Aspect-authorized distributor or (c) with respect to any product sold under a brand name other than Aspect Medical Systems, Inc.

THIS WARRANTY IS THE SOLE AND EXCLUSIVE WARRANTY FOR ASPECT'S PRODUCTS, EXTENDS ONLY TO THE PURCHASER, AND IS EXPRESSLY IN LIEU OF ANY OTHER EXPRESS OR IMPLIED WARRANTIES INCLUDING WITHOUT LIMITATION ANY WARRANTY AS TO MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. ASPECT'S MAXIMUM LIABILITY ARISING OUT OF THE SALE OF THE PRODUCTS OR THEIR USE, WHETHER BASED ON WARRANTY, CONTRACT, TORT, OR OTHERWISE, SHALL NOT EXCEED THE ACTUAL PAYMENTS RECEIVED BY ASPECT IN CONNECTION THEREWITH. ASPECT SHALL NOT BE LIABLE FOR ANY INCIDENTAL, SPECIAL, OR CONSEQUENTIAL LOSS, DAMAGE OR EXPENSE (INCLUDING WITHOUT LIMITATION LOST PROFITS) DIRECTLY OR INDIRECTLY ARISING FROM THE SALE, INABILITY TO SELL, USE OR LOSS OF USE OF ANY PRODUCT. EXCEPT AS SET FORTH HEREIN, ALL PRODUCTS ARE SUPPLIED "AS IS" WITHOUT WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED.

SECTION 10

10 APPENDIX I

10.1 Accessories and Spare Parts List

MAJOR COMPONENTS AND SENSORS:	
185-0151	BIS VISTA Monitor
185-0145-AMS	BISx
186-0107	PIC+, for BISx
186-0106	BIS Quatro Sensor
186-0200	BIS Pediatric (XP) Sensor
186-0160	BIS Extend Sensor
536-0047	Power Cord 10' North America
MANUALS:	
070-0031	Mounting Options Manual
070-0069	BIS VISTA Monitoring System Operating Manual (English)
075-0015	BIS VISTA Service Information Manual (English)
080-0233	Clinician's Guide to the Bispectral Index
ACCESSORIES:	
150-0037	Pole Clamp Assembly
150-0058	BIS VISTA Monitor Stand
186-0104	BIS Sensor Dispenser
186-0137	Sensor Simulator
817-0014	GCX 12" Pivot Support Arm w/7" Up-Post
817-0015	GCX 16" Pivot Support Arm w/7" Up-Post
817-0011	GCX 7" Channel & Adapter for Draeger Narkomed
817-0012	GCX 7" Channel w/Dovetail Attachment for Ohmeda
PARTS:	
186-0208	Battery Replacement Kit
186-0216	Power Supply Replacement Kit
186-0217	Shoe Clamp Replacement Kit
186-0201-AMS	BIS VISTA Host Cable (Monitor Cable) Replacement Kit
195-0052	BISx Bulkhead Replacement Kit
151-0009	Battery/ Power Supply Cover Assembly with Shoe Clamp
675-0022	Cable wrap (Blue, hook & loop)
194-0039	Label "DO NOT DISCARD"

MISCELLANEOUS:	
180-0085	Empty carton, with foam, BIS VISTA
536-0044	RS-232 Cable, approx 6 ft. length
186-0170	J-Hooks

10.2 SENSOR SIMULATOR: P/N: 186-0137

Description of device:

The Sensor Simulator is a service tool that allows for the verification of proper impedance values being detected by the BIS VISTA Monitoring System during the Sensor Check. This test is part of the initial test that each system performs. The simulator also allows for safety testing of the system in the field by allowing connection of the test equipment to the monitor via the Patient Interface Cable (PIC).

NOTE:

The life expectancy of the Sensor Simulator is 25 connect / disconnect cycles.

S1 – S4 connect to 4 input signal pins on the PIC. The Inputs (+ and -) are where one connects the test signals to test the BIS VISTA system.

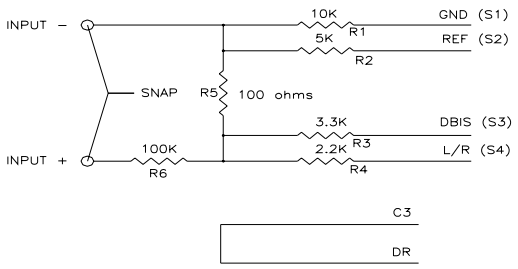


Figure 8 - Schematic of Sensor Simulator Circuit

Test types allowed:

Sensor Check:

The Sensor Check tests and verifies that the monitor is reporting the proper impedance values provided by the Sensor Simulator. This procedure verifies functionality of the BIS VISTA Monitoring System. See Section 7.2.3 "PIC Checkout Procedure" for instructions.

Safety Testing: Leakage Current

Leakage Current testing should be performed by a qualified Biomedical Engineering Technician or authorized personnel only. See Section 6.4 "Checking Leakage Current" for instructions.

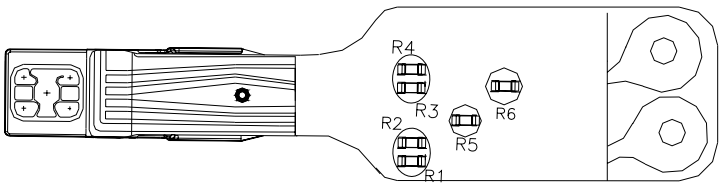


Figure 9 - Sensor Simulator

10.3 Test Sensor

Use the following procedure to make a Test Sensor:

1. Remove a new sensor from its plastic carrier sheet and place on flat surface with the adhesive facing up.

   NOTE:

   Be careful that gel does not leak onto hands or connector during this procedure.

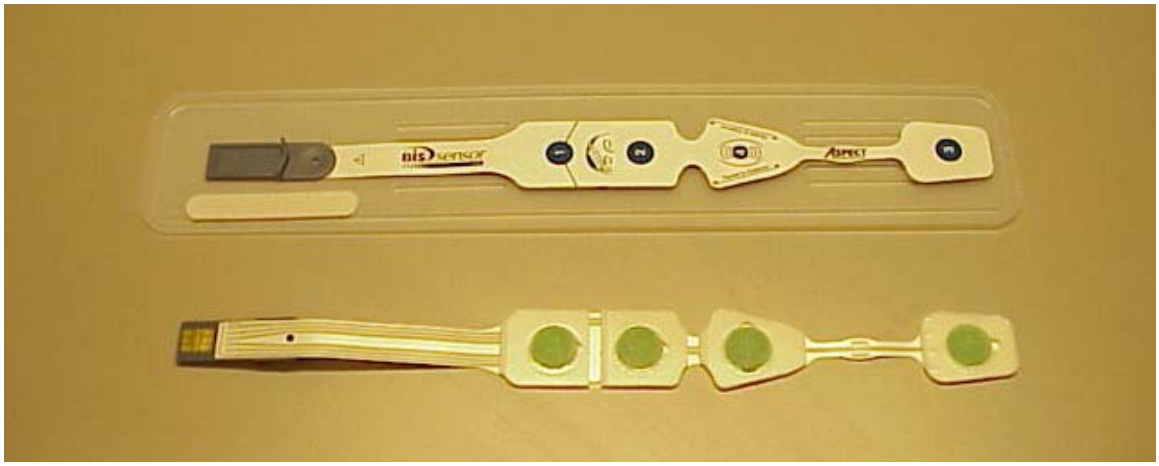


Figure 10 - BIS Sensor

2. Place the end of a small paper clip at the midpoint of electrode #2 then lay it across electrode #4. (See Figure 11.)

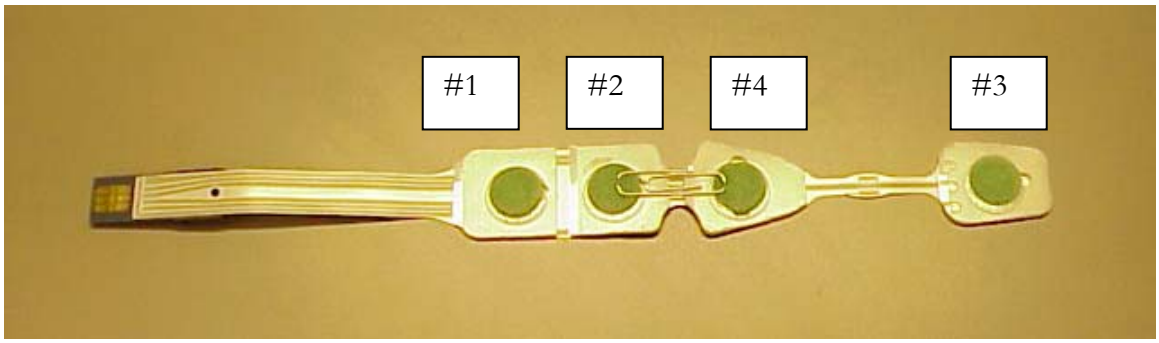


Figure 11 - Connecting electrodes #2 and #4.

3. Fold electrode #3 over onto electrode #4, pressing adhesive surfaces together and making sure the paper clip remains in place.
4. Fold electrode #1 over onto electrode #2.

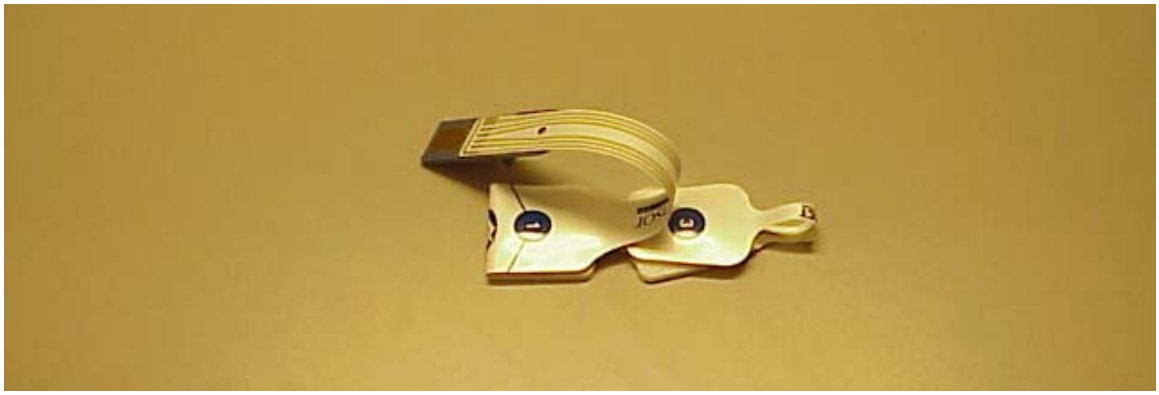


Figure 12 - Connecting electrode #3 with #4, and #1 with #2.

5. Connect this Test Sensor to the PIC. All impedance tests should complete successfully, with low impedance values. Typical values using this alternative Test Sensor are less than 5 K ohms.

The following chart shows expected Test Sensor values:

Test Sensor Values		
Electrode #	**Typical**	**Range**
1	1 K ohm	1-2 K ohms
2	1 K ohm	1-3 K ohms
4	1 K ohm	1-2 K ohms
3	1 K ohm	1-2 K ohms

10.4 Safety Tester Connection with PIC

This procedure describes a method to connect an BIS VISTA Monitoring System to a safety tester. It uses a current date sensor to provide a contact point for the safety tester leads that correspond to the patient contact points of the BIS VISTA system.

1. Connect BISx (Digital Signal Converter) cable to BIS VISTA monitor.
2. Connect PIC (Patient Interface Cable - sensor) cable to other end of BISx.
3. Verify sensor for test is of current date code. Connect sensor to PIC cable.
4. Remove gel and green pad from each sensor contact point.
5. Connect safety tester leads per tester instructions to sensor contact point pads (i.e. via alligator clips).
6. Apply power to the BIS VISTA system per safety tester instructions. Make required leakage measurements.
7. Disconnect and dispose of sensor. NOTE: DO NOT discard PIC or BISx. These are re-usable components.

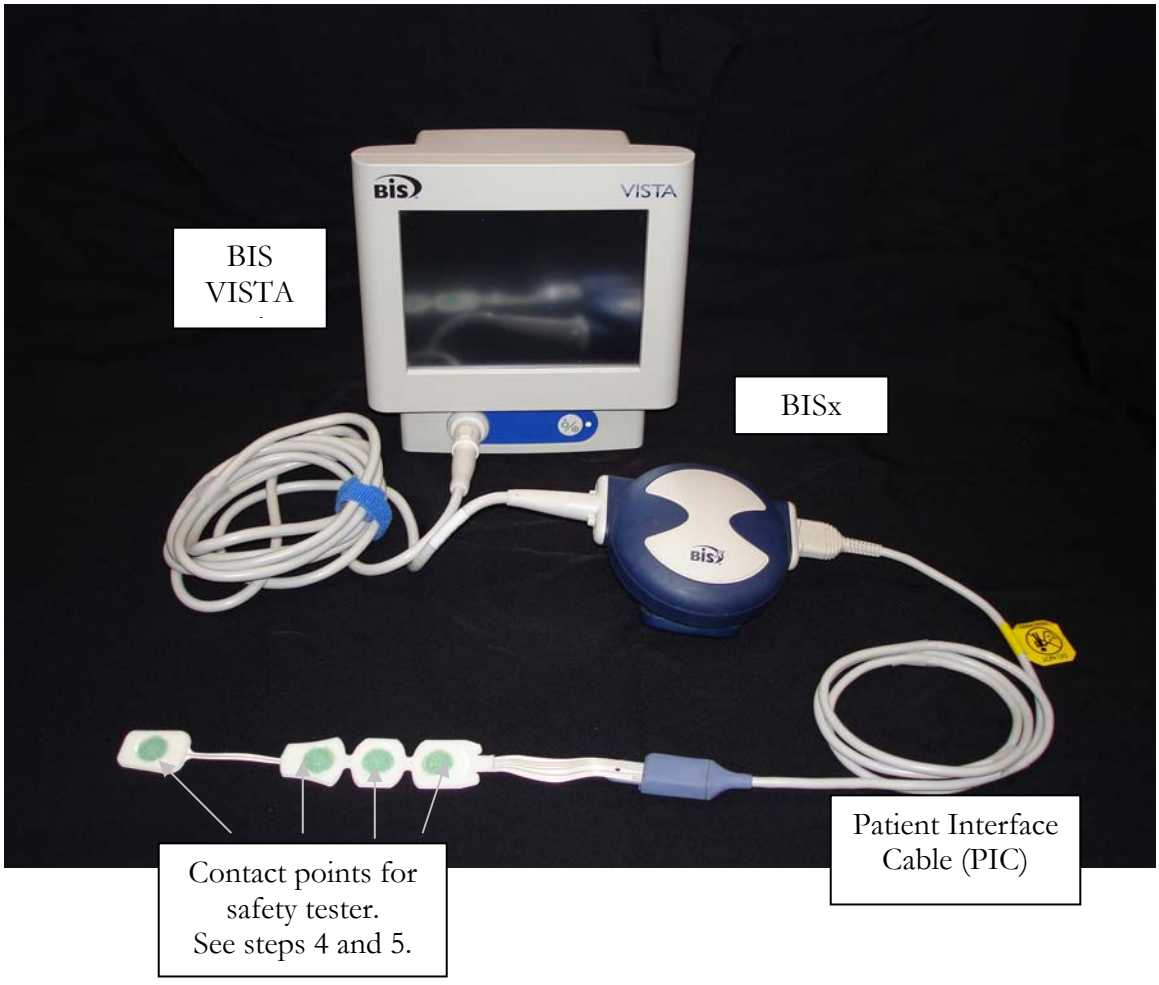
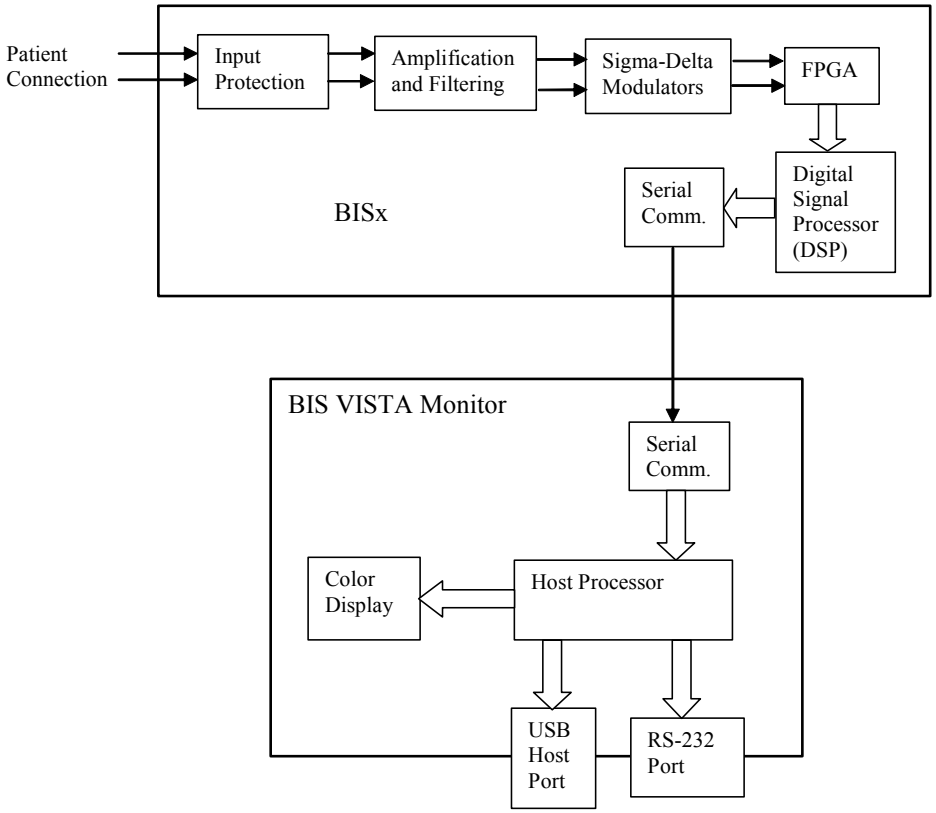


Figure 13 - Safety Tester Contact Points

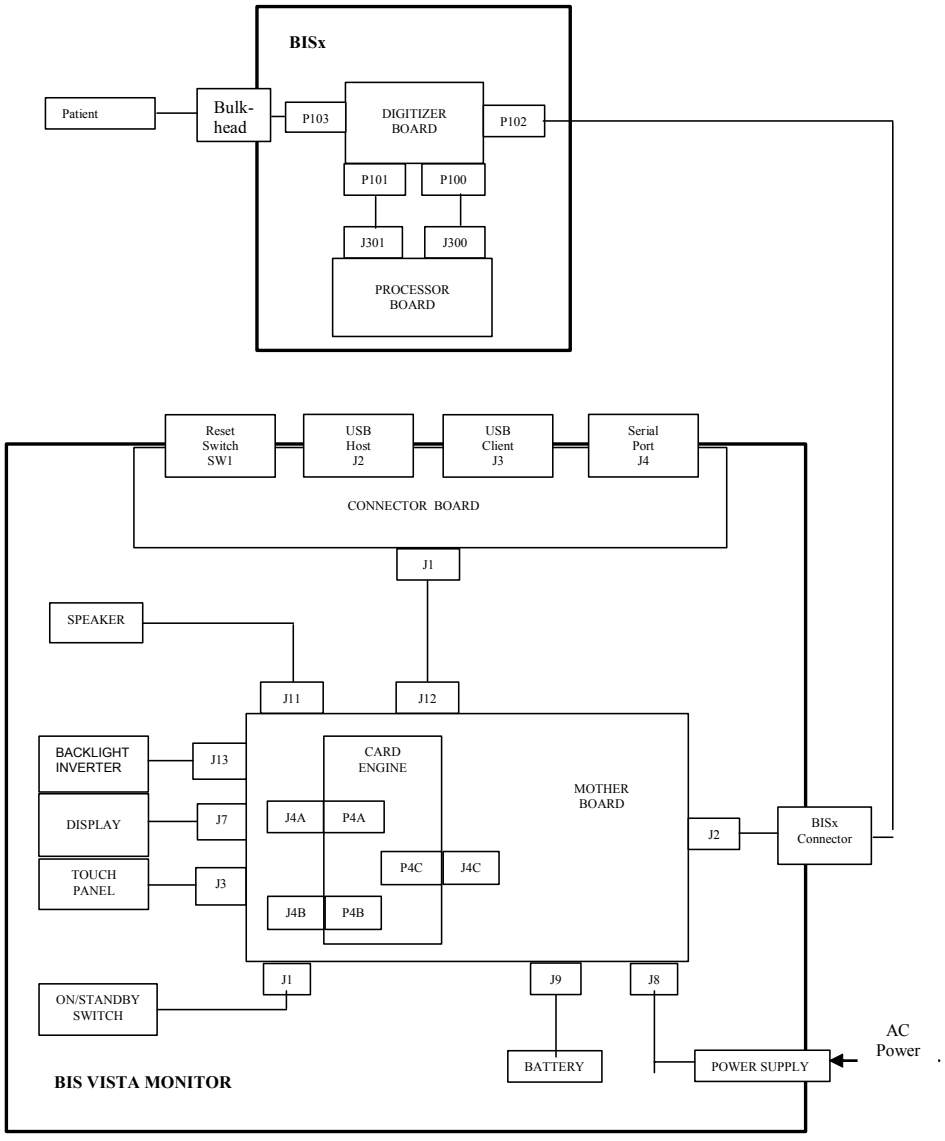
SECTION 11

11 APPENDIX II

11.1 Data Flow Diagram



11.2 Block Diagram



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