BIS VISTA™ Monitoring System
BILATERAL MONITORING ADDENDUM

Rx only

Aspect Medical Systems, Inc.
One Upland Road
Norwood, MA 02062
U.S.A.
(Tel) 617-559-7000
(Tel) 888-BIS INDE(X) (U.S. only)
(Fax) 617-559-7400
bis_info@aspectms.com
www.aspectmedical.com

Aspect Medical Systems International B.V.
Rijnzathe 7d2
3454 PV De Meern
The Netherlands
Tel: +31.30.662.9140
Fax: +31.30.662.9150
amsint@aspectms.com

070-1024 1.01
BIS VISTA™ Monitoring System

BILATERAL MONITORING ADDENDUM
# TABLE OF CONTENTS

## ABOUT THIS DOCUMENT

1. The BIS Bilateral System
   1.1 Overview
   1.2 Required Equipment and Supplies

2. Using the BIS Bilateral System
   2.1 Sensor Check
   2.2 Screen Displays
      2.2.1 BIS Number Display/Bilateral Touch Key
      2.2.2 Main Display and Small Display
         2.2.2.1 Density Spectral Array (DSA) Display
         2.2.2.2 BIS Trend Data Display
         2.2.2.3 EEG Waveform Display
         2.2.2.4 ASYM Display
   2.3 Menu Items
      2.3.1 Bilateral Display Menu
      2.3.2 Additional Secondary Variables
      2.3.3 Chart Data
      2.3.4 BIS/EEG Display Mode
      2.3.5 EEG Channels
      2.3.6 Demo Case

3. Glossary, Specifications and Notes
   3.1 Glossary
   3.2 Specifications and Notes
      3.2.1 EEG Specifications
      3.2.2 BISx4
<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Figure 1</td>
<td>The BIS VISTA Bilateral Monitoring System</td>
<td>3</td>
</tr>
<tr>
<td>Figure 2</td>
<td>Sensor Check (Values not Shown)</td>
<td>4</td>
</tr>
<tr>
<td>Figure 3</td>
<td>Sensor Check with Values Shown</td>
<td>5</td>
</tr>
<tr>
<td>Figure 4</td>
<td>BIS Number Display/Bilateral Touch Key</td>
<td>6</td>
</tr>
<tr>
<td>Figure 5</td>
<td>Main Display (DSA) and Small Display (BIS Trend)</td>
<td>7</td>
</tr>
<tr>
<td>Figure 6</td>
<td>DSA Display</td>
<td>8</td>
</tr>
<tr>
<td>Figure 7</td>
<td>BIS Trend Display</td>
<td>9</td>
</tr>
<tr>
<td>Figure 8</td>
<td>Four-channel EEG with ASYM Display</td>
<td>10</td>
</tr>
<tr>
<td>Figure 9</td>
<td>Bilateral Display Menu</td>
<td>11</td>
</tr>
<tr>
<td>Figure 10</td>
<td>Secondary Variable Menu: Bilateral</td>
<td>13</td>
</tr>
<tr>
<td>Figure 11</td>
<td>Chart Data Screen</td>
<td>14</td>
</tr>
<tr>
<td>Figure 12</td>
<td>Demo Case</td>
<td>15</td>
</tr>
</tbody>
</table>
ABOUT THIS DOCUMENT

This document contains supplementary information for an Aspect Medical Systems BIS VISTA™ Monitoring System when it is used with the BISx™4, PIC-4 and BIS™ Bilateral Sensor. It is intended to be used in conjunction with the BIS VISTA Monitoring System Operating Manual.
Important Information about Using BIS Monitoring

The BIS EEG VISTA Monitor System is intended for use under the direct supervision of a licensed healthcare practitioner or by personnel trained in their proper use. The system, and all its associated parameters, 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 Index, one of the VISTA Monitor output parameters, may be used as an aid in monitoring the effects of certain anesthetic agents; and its usage with certain anesthetic agents may be associated with a reduction in primary anesthetic use and a reduction in emergence and recovery time.

Use of the BIS Index for monitoring to help guide anesthetic administration may be associated with the reduction of incidence of awareness with recall in adults during general anesthesia and sedation.

BIS is a complex monitoring technology intended for use as an adjunct to clinical judgment and training. Clinical judgment should always be used when interpreting the BIS in conjunction with other available clinical signs. Reliance on the BIS alone for intraoperative anesthetic management is not recommended. As with any monitored parameter, artifacts and poor signal quality may lead to inappropriate BIS values. Potential artifacts may be caused by poor skin contact (high impedance), muscle activity or rigidity, head and body motion, sustained eye movements, improper sensor placement and unusual or excessive electrical interference. BIS values should also be interpreted cautiously with certain anesthetic combinations, such as those relying primarily on either ketamine or nitrous oxide/narcotics to produce unconsciousness. Due to limited clinical experience in the following applications, BIS values should be interpreted cautiously in patients with known neurological disorders and those taking other psychoactive medications.

Important Note: The Density Spectral Array (DSA) and Asymmetry (ASYM) displays are indicated in this device only 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. All other parameters (the BIS Index and associated signal quality indicators) are indicated for all indications listed in the above box.

The BIS education site, www.biseducation.com, offers relevant information and published articles on the clinical use of BIS. In addition, there is a “Monitoring Consciousness Using the Bispectral Index during Anesthesia” Clinician’s Pocket Guide available on the website and through your local Aspect Representative.

For more information, please contact Aspect Medical Systems at (800) 442-2051. If you require additional information on the use of BIS, please contact Aspect Medical Systems Clinical Support at 800-442-8655 or 617-559-7655 if calling from outside of the USA.
I The BIS Bilateral System

1.1 Overview
The BIS Bilateral System was designed to allow the user to record and display four channels of EEG; two from each side of the brain. The system consists of the BIS VISTA Monitor, the BISx4, the PIC-4 and a BIS Bilateral Sensor. This document describes the additional features and options available when the BIS Bilateral System is in use.

The system acquires four channels of EEG data, calculates BIS numbers and other variables for the left and right sides of the brain, and reports them to the monitor for display. The user selects which side of the brain is shown most prominently on the screen. (See Section 2.3.1 “Bilateral Display Menu.”) The designation ‘L’ (left) or ‘R’ (right) denotes which side of the brain is displayed. In addition, data from the left side of the brain display in yellow, while data from the right side display in blue. BIS is calculated the same way as for Aspect’s two-channel sensors (e.g. Quatro), using two EEG channels from the left side of the head for BIS L and two EEG channels from the right side for BIS R.

![Figure 1 - The BIS VISTA Bilateral Monitoring System](image)

1.2 Required Equipment and Supplies
To monitor four channels of EEG, the following items are required:
- BIS VISTA Monitor
- BISx4
- PIC-4 (Patient Interface Cable)
- BIS Bilateral Sensor
2 Using the BIS Bilateral System

System setup is the same as setup for two-channel monitoring, except that a BISx4, PIC-4 and BIS Bilateral Sensor are used. To begin:

1. Verify that all power and other cables are connected properly.
   • The BISx4’s long cable to the BISx port on the monitor.
   • The PIC-4 to the BISx4.
2. Press the button in the right corner of the monitor to turn the monitor and BISx4 on.
3. Prepare sensor site and place BIS Bilateral Sensor on the patient in accordance with manufacturer’s instructions.
4. Using the attachment clip, secure the BISx to a convenient location near the patient’s head.
5. Insert the BIS sensor tab into the PIC connector until fully engaged.

Note: The connector on the PIC is designed to work only with the BISx, and the PIC-4 connector is designed to work only with the BISx4. Do not mix components.

2.1 Sensor Check

The Sensor Check procedure for the BIS Bilateral Sensor is the same as for the BIS sensor. (See Section 3.2 of the BIS VISTA Operating Manual.) If the sensor does not immediately pass the test, or if the user has manually initiated the test, the Sensor Check Graphic Screen displays. This screen shows the sensor with each electrode labeled. Bilateral sensors have electrodes labeled: RT, RE, C, G, LE and LT.

![Sensor Check](image)

**Figure 2 - Sensor Check (Values not Shown)**

Colors indicate the status of each electrode:

- **Hollow circle** – No status is available. The electrode label will appear after a few seconds.
- **Green circle with Checkmark** – The electrode impedance is within the acceptable range. When all circles are green, monitoring can begin.
• **Red blinking circle** with ‘X’ – The electrode impedance is not within the acceptable range. Press the edges of the sensor to ensure adhesion and then press each circle for 5 seconds to ensure proper contact. Check all connections. If the problem persists, remove sensor, clean skin thoroughly, and reapply sensor or apply new sensor in accordance with instructions on the sensor packaging.

• **Gray circle** with question mark - The electrode impedance cannot be determined due to electrical interference (noise) from another source. Monitoring will not commence until the source of the noise has been removed and all electrodes have passed the sensor check.

If the user has requested the Sensor Check and all electrodes pass the test, the circles return to their original display color (blue) and the label, “PASS” displays at the bottom of the screen.

If user action is required, messages in the message region of the screen issue instructions.

For more detailed impedance information, press the **[Show Values]** touch key.

---

**Figure 3 - Sensor Check with Values Shown**

In this display, 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 (G) 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 (30 kilo ohms for the ground electrode). As long as the combined impedance of electrodes C and T and the combined impedance of electrodes C and E are less than 15 kilo ohms, and the ground electrode impedance is less than 30 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.

• **POOR CONTACT** - If the impedance check indicates that the electrode is not in contact with the patient, the label “POOR CONTACT” displays.
2.2  **Screen Displays**
The Bilateral Screen Display consists of three main areas; the BIS Number Display, the Main Display, and the Small Display. See Figure 5.

2.2.1  **BIS Number Display/Bilateral Touch Key**
During bilateral monitoring, the BIS Number, SQI, and EMG data displayed on the screen are from the hemisphere of the brain that was selected for display in the Bilateral Display Menu. (See Section 2.3.1 “Bilateral Display Menu.”) The letter L (Left) or R (Right) above the BIS number indicates which side is displayed.

![BIS Number Display/Bilateral Touch Key](image)

**Figure 4 - BIS Number Display/Bilateral Touch Key**
During bilateral monitoring, the BIS Number region of the screen functions as a touch key. Pressing this key allows the user to enter and exit the Bilateral Menu. See Section 2.3.1 “Bilateral Display Menu.”
2.2.2 Main Display and Small Display

The lower half of the screen is the Main Display area. Users may select whether to view DSA, EEG or BIS Trend data in this area. The upper right section of the screen is the “Small Display” area. Users may select whether to view BIS trend, EEG or ASYM (Asymmetry) data in this area. See Section 2.3.1 “Bilateral Display Menu” for instructions.

Figure 5 - Main Display (DSA) and Small Display (BIS Trend)
2.2.2.1 Density Spectral Array (DSA) Display

The Density Spectral Array (DSA), indicated only for “monitoring the state of the brain,” shows changes in the power spectrum distribution over a thirty minute time period. The DSA represents the power spectra ranging from 49-94 dB with respect to .0001 µV RMS. The color bar to the right of the time scale shows the range of colors used to indicate minimum and maximum power. The frequency scale is shown on the horizontal axis with a range from 0 – 30 Hz.

![Figure 6 - DSA Display](image)

A white Spectral Edge line is superimposed on the graph where 95% of the total power lies on one side of the line (toward the inside of the graph) and 5% lies on the other. The Spectral Edge Frequency value (SEF) displays above the graph.

The ASYM graph in the center of the screen shows the degree of asymmetry in EEG power between the left and right hemispheres. For more detail, refer to Section 2.2.2.4 “ASYM Display.”

DSA data may be sent to a removable drive in a PDF format for transfer to a personal computer. See Section 2.3.1 “Bilateral Display Menu.”
2.2.2.2 BIS Trend Data Display

The BIS Trend Display plots BIS values from the hemisphere of the brain that was selected in the Bilateral Display Menu. (See Section 2.3.1.) The letter L (Left) or R (Right) above the BIS number indicates which side is displayed. Note that the target range applies only to the side of the brain that was selected by the user.

To view BIS trend lines from both sides of the brain, the user may select BIS as a secondary variable. Data from the left side of the brain display in yellow. Data from the right side display in blue. Additional secondary variables are also available. See Section 2.3.2.
2.2.2.3 EEG Waveform Display

When EEG is selected as the Main Display, the screen shows up to 4 channels of EEG. Filtered EEG waveforms are displayed with a sweep rate of 25 millimeters per second and a scale of 25 microvolts per division (one channel display) or 50 microvolts per division (two or four channel display). The number of EEG channels displayed can be set in the menu system. Data from the left side of the brain display in yellow. Data from the right side display in blue.

When EEG is selected as the Small Display, one or two channels of EEG (from the temple electrode) are displayed. The one-channel display shows EEG from the side of the brain that was selected by the user in the Bilateral Display Menu. (See Figure 9.)

2.2.2.4 ASYM Display

Asymmetry (ASYM) is a processed variable indicating the percentage of EEG power present in left or right hemispheres with respect to total (left and right) EEG power. Asymmetry data is indicated only for “monitoring the state of the brain.” Asymmetry graphical data may be plotted as part of the DSA Display, or independently as the "Small Display". (See Figure 6 and Figure 8.) The ASYM scale begins at 20% at the center line and runs left or right to 100%. Asymmetry data less than 20% are not displayed on the graph, but are available in the Chart Data screen. The time scale appears on the left side of the graph. Fifteen minutes of data are shown at a time on the Small Display; thirty minutes of data are shown on the DSA Display.
2.3 Menu Items

2.3.1 Bilateral Display Menu

The “Bilateral” Menu selection appears only when a BISx4 is attached to the monitor and can only be accessed when a BIS Bilateral Sensor is attached to the BISx4 (via the PIC-4).

To access Bilateral (the Bilateral Display Menu):

1. Press [MENU].
2. Press [Next].

*Note:* The Bilateral Display Menu can also be accessed by pressing the BIS Number during four-channel bilateral monitoring.

---

**Bilateral**

**Figure 9 - Bilateral Display Menu**

When a BISx4 and the BIS Bilateral Sensor are attached to the monitor, this menu allows the user to determine how data is displayed.

**Main Display:** This refers to the area that normally displays the BIS trend information. The Main Display options are:

- BIS – BIS Trend Graph from the selected side of the brain (L or R)
- EEG – Up to four channels of EEG
- DSA – The Density Spectral Array for both sides of the brain

**Small Display:** This refers to the upper right portion of the screen, which normally displays EEG waveforms. The Small Display options are:

- BIS – BIS Trend Graph of the selected side. Note that this is not available when BIS Trend has been selected as the large display.
• EEG – One or two channels of EEG. The channels reported are from the temple electrodes. Note that this is not available when EEG has been selected as the large display.

• ASYM – The degree of asymmetry between the left and right hemispheres of the brain, over time. Note that this is not available when DSA has been selected as the large display.

**BIS L BIS R:** This key allows the user to select which side of the brain (L – Left, or R – Right) displays most prominently. Note that the Target Range, if set, applies only to the side of the brain that is selected here.

Although data shown may be from only one side of the brain, messages are reported for both sides of the brain. Messages are labeled with “L” when they are specific to the left side of the brain and with “R” when they are specific to the right side.

**DSA Print:** This option converts up to two hours of DSA data into a PDF format and sends it to a removable drive attached to the USB-A port on the rear of the monitor.

**Trend Review:** The Trend Review touch key is available in the Bilateral Display Menu. The Trend Review Screen allows the user to select the additional secondary variables listed in Section 2.3.2 “Additional Secondary Variables.” Trend Review is described in detail in the BIS VISTA Operating Manual.

**To change the Bilateral Display:**

1. Attach the BISx4 and a BIS Bilateral Sensor to the monitor (or start the Bilateral Demo Case).
2. Press [MENU] to access menu options.
3. Press [Next] to get to the next menu.
5. Press the Large Display touch key until the desired option (BIS, EEG, or DSA) displays in green.
6. Press the Small Display touch key until the desired option (BIS, EEG, or ASYM) displays in green.
7. Press the [BIS L BIS R] touch key until the brain hemisphere (L – Left or R – Right) to be displayed appears in green letters.
2.3.2 Additional Secondary Variables

When the BIS Bilateral Sensor and BISx4 are connected to the monitor, additional secondary variables can be selected from the Secondary Variable Menu. The selected variable is plotted on the BIS trend graph. The additional secondary variables are:

- **Bursts/Minute** – The number of bursts per minute
- **BIS** – When BIS is selected as the secondary variable, BIS values for both sides of the brain are plotted on the BIS trend graph. Data from the left side of the brain are shown in yellow, and data from the right side are shown in blue.
- **sBIS** (BIS Variability Index) – This number represents the standard deviation of the BIS variable over the last minute.
- **sEMG** (EMG Variability Index) – This number represents the standard deviation of the EMG value over the last minute.
2.3.3 Chart Data

The data reported on the Chart Data Screen are from the side of the brain that was selected to display in the Bilateral Display Menu. BIS data from the left side are displayed in yellow. BIS data from the right side are displayed in blue. Asymmetry data are also displayed, with the designation ‘L’ or ‘R’ to indicate the corresponding part of the brain. In the Figure above, ASYM of 0 indicates no asymmetry, and R2 denotes 2% asymmetry to the right side. Note that unlike the ASYM data graphed in DSA or ASYM "Small Display", ASYM in Chart Data represents the full 0 to 100% range of Asymmetry.

2.3.4 BIS/EEG Display Mode

The BIS/EEG Display Mode option is not available when a BIS Bilateral Sensor is attached via BISx4. Use the Bilateral Display Menu to change the display mode. See Section 2.3.1.

2.3.5 EEG Channels

When the BIS Bilateral Sensor is attached, the user may select one, two, or four channels of filtered EEG for display. The default number of channels when a Bilateral Sensor is attached is determined by the number of channels set and saved in Monitor Mode IV.
2.3.6 Demo Case

When Demo Case is selected from the Menu system, the user may choose “Dual Channel” or “Bilateral” for the Demonstration by pressing the appropriate touch key.
# 3 Glossary, Specifications and Notes

## 3.1 Glossary:

<table>
<thead>
<tr>
<th>Term</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ASYM</td>
<td>Asymmetry (ASYM) is a processed variable indicating the percentage of EEG power present in left or right hemispheres with respect to total (left and right) EEG power.</td>
</tr>
<tr>
<td>BIS Bilateral Sensor</td>
<td>A single patient use, disposable, pre-gelled 6-electrode array that is applied directly to the patient’s forehead and temple to record and display four channels of EEG; two from each side of the brain.</td>
</tr>
<tr>
<td>BISx4</td>
<td>The BISx4 is a unit similar to the BISx that is used during four-channel monitoring with the BIS Bilateral Sensor. It can be used in place of a BISx at any time as long as it is used with the PIC-4.</td>
</tr>
<tr>
<td>DSA (Density Spectral Array)</td>
<td>A graphic display of the power spectrum distribution over time, where the amplitudes of the power spectrum points are represented by varying colors. Blues represent the lowest powers; reds represent the highest powers.</td>
</tr>
<tr>
<td>PIC-4</td>
<td>The PIC-4 is a Patient Interface Cable that must be used when using the BISx4. It connects the BISx4 to the BIS sensor.</td>
</tr>
<tr>
<td>sBIS</td>
<td>sBIS is the BIS Variability Index, a number representing the standard deviation of the BIS variable over the last minute.</td>
</tr>
<tr>
<td>sEMG</td>
<td>sEMG is the EMG Variability Index, a number representing the standard deviation of the EMG value over the last minute.</td>
</tr>
<tr>
<td>SEF (Spectral Edge Frequency)</td>
<td>The frequency at which 95% of the total power lies below it and 5% lies above it.</td>
</tr>
</tbody>
</table>
3.2 Specifications and Notes:

3.2.1 EEG Specifications:

- EEG Scales:
  - One channel display: 25 μV/div (+/- 50 μV full scale)
  - Two or four channel display: 50 μV/div (+/- 50 μV per waveform)

3.2.2 BISx4:

The BISx4 (with attached PIC-4) may be substituted for the BISx at any time. The BISx4 and PIC-4 must be used when monitoring with the BIS Bilateral Sensor.

The connector on the PIC is designed to work only with the BISx, and the PIC-4 connector is designed to work only with the BISx4. Do not mix components.

- BISx and BISx4:
  - 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 (PIC-4)
Contact Information for:

Aspect Medical Systems, Inc.
One Upland Road
Norwood, MA  02062
U.S.A.

Main Business Phone:  (617) 559-7000
Main Business Fax:  (617) 559-7400
Customer Service:  (888) BIS-INDE(X)…press (6), or
(800) 442-7688 … press (6)
Technical Service:  (800) 442-2051
E-mail:   bis_info@aspectms.com

Web: www.aspectmedical.com
Service Information: www.aspectmedical.com/ASRS

Aspect Medical Systems International B.V.
Rijnzathe 7d2
3454 PV De Meern
The Netherlands

Main Business Phone:  +31.30.662.9140
Main Business Fax:  +31.30.662.9150
E-mail:   amsint@aspectms.com