Branchpoint Technologies

AURA™ Monitor Pack

INSTRUCTIONS FOR USE

TK101-A

Revised 2018-09-13

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1. SYSTEM DESCRIPTION

This AURA™ Monitor Pack (TK101-A) contains one AURA™ Monitor (TX101-A), two rechargeable batteries (TB101-A), one battery charger (TC101-A), one power supply, and one antenna (TA101-A).

This pack is intended to be used with AURA™ Sensor Tray and AURA™ Data Receiver Pack, which are part of the AURA™ ICP Monitoring System (Figure 1 and Table 1).

The AURA™ Monitor is a non-sterile, non-implantable hand-held device powered by rechargeable lithium ion batteries (included in this pack). The device has an OLED display screen and is controlled by buttons on its control panel. The AURA™ Monitor receives intra-cranial pressure (ICP) data via RF telemetry from a coupled AURA™ Sensor and relays the ICP waveform to a paired AURA™ Data Receiver. The AURA™ Data Receiver makes it possible for the data obtained by the AURA™ Monitor to be displayed onto bedside patient monitor.

The AURA™ Antenna is placed above the AURA™ Sensor to provide power and receive data. It is held in place by the sterile Antenna Holster provided in the AURA™ Sensor Tray (SP101).

Table 1: Components of the AURA™ ICP Monitoring System.

Component	Model #
AURA™ Sensor	**SP101**
AURA™ Monitor	**TX101**
AURA™ Antenna	**TA101**
AURA™ Data Receiver	**DG101**
AURA™ Battery	**TB101**
AURA™ Battery Charger	**TC101**

Figure 1: AURA™ ICP Monitoring System.

2. INDICATIONS FOR USE

The Branchpoint AURA™ ICP Monitoring System is intended for use by a qualified neurosurgeon in the direct monitoring of intracranial pressure in intraparenchymal applications.

3. CONTRAINDICATIONS

This device is not intended for any use other than that indicated. This device is not designed, sold, or intended for use as a therapeutic device.

4. RELATED INFORMATION

Before using the AURA™ Monitor, read and follow all instructions, warnings, and precautions provided in the AURA™ Monitor Pack manual and in the manuals for the other system components. Manuals for the other system components are listed below.

- AURA™ Sensor Tray Instructions for Use
- AURA™ Data Receiver Pack Instructions for Use

These manuals are also made available on the Internet and can be found at www.auramonitor.com.

5. WARNINGS

There are no user-serviceable components inside this device. Refer servicing to authorized personnel only. Unauthorized servicing, modification, or internal access may be hazardous or damage the product.

Use only the Branchpoint Technologies supplied AURA™ Data Receiver and software application with the AURA™ Monitor.

No modifications of this equipment are allowed unless approved by Branchpoint Technologies. Additions or modifications may interfere with system performance.

The AURA™ Monitor is MR Unsafe – keep away from magnetic resonance imaging (MRI) equipment.

Do not subject the AURA™ Monitor to temperatures outside of the 0°C to 50°C (32°F to 122°F) storage range. Exposure to high temperatures may cause the AURA™ Monitor to overheat and may reduce its performance and service life.

The AURA™ Monitor Pack components are only for use in non-condensing humidity conditions.

Do not discard the AURA™ Monitor in a fire or incinerate.

Do not immerse the AURA™ Monitor in liquid of any kind. AURA™ Monitor will be permanently damaged if it is submerged in liquid. Continued usage after submersion may result in further damage. If the AURA™ Monitor gets wet, turn the device off, disconnect all cables, remove the battery, wipe the wet surfaces dry, and contact Branchpoint Technologies customer service. Do NOT attempt to dry the AURA™ Monitor in an oven, microwave, or dryer.

Only power the AURA™ Monitor with the provided lithium-ion batteries. Using other sources of power may be hazardous or cause damage to the AURA™ Monitor. Only recharge the lithium-ion batteries with the provided charger and power supply (REF# WSA515MD). Using other sources of power may be hazardous or cause damage to the batteries.

The AURA™ Battery Charger should be positioned to allow immediate disconnection from the supply mains. Connection and disconnection can be established by plugging and unplugging the power supply from mains.

Always keep the spare battery charging while the other is in use to ensure continuous availability of power. Change batteries as needed.

Never use a damaged battery or damaged AURA™ Monitor. Doing so could result in user injury.

To avoid risk of electric shock, do not disassemble the AURA™ Monitor, batteries, battery charger, power supply, or antenna.

Tampering with the AURA™ Battery could result in a hazard, such as fire, explosion or shock.

By design, the AURA™ Monitor and its antenna emit radio frequency in the 13.56 MHz and 2.4 GHz bands. This may interfere with nearby medical or office equipment. When using the AURA™ Monitor, closely monitor equipment in the vicinity to verify normal operation.

The presence of other equipment operating in the same frequency bands used by the AURA™ Monitor may interfere with communication. Interference can occur even if the other equipment complies with the International Special Committee on Radio Interference (CISPR) emission requirements. This RF interference can be reduced by increasing the distance between the interfering device and the AURA™ Monitor. If communication problems persist, refer to the Troubleshooting section of this manual.

The use of any accessories with the AURA™ Monitor other than those specified by Branchpoint Technologies in this manual may result in increased emissions or decreased immunity of the AURA™ Monitor and may cause decreased functionality or unintended operational behavior of the AURA™ Monitor.

The use of the AURA™ Monitor around strong sources of electromagnetism and electric fields should be avoided.

For disposal of the AURA™ Monitor Pack, follow applicable hospital procedures and local regulations or return the product to Branchpoint Technologies. Improper disposal of products may pose biohazards or environmental hazards.

During normal or single fault conditions, the AURA™ Antenna may reach a maximum temperature of 43°C. There is a safety cutoff to prevent temperature from exceeding this value and mitigate the likelihood of detrimental clinical effects.

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the AURA™ ICP Monitoring System or AURA™ Battery Charger, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

6. PRECAUTIONS

Do not disassemble, alter, or modify any parts of the AURA™ Monitor or AURA™ Data Receiver.

The AURA™ Monitor Pack shall not be placed in oxygen rich environments. Use only the designated Branchpoint Technologies AURA™ Monitor and appropriate software application to communicate with the AURA™ Sensor and AURA™ Data Receiver.

The AURA™ Monitor is intended for use by or under the direction of healthcare professionals only.

The AURA™ Sensor and Antenna Holster are type BF applied parts. The AURA™ Monitor, AURA™ Antenna, batteries, battery charger, and AURA™ Data Receiver are accessible parts.

Mishandling (such as dropping or crushing) could damage the AURA™ Monitor.

If you suspect damage to the AURA™ Monitor, contact your Branchpoint Technologies representative or the customer service department for instructions and return packaging.

The AURA™ Monitor has been classified with an International Protection Marking of IP43. The AURA™ Monitor is therefore not waterproof or explosion-proof and cannot be sterilized. Do not use it in the presence of flammable gas mixtures containing anesthetics, oxygen, or nitrous oxide.

The AURA™ Monitor may be affected by electrostatic discharge (ESD). If ESD occurs and the AURA™ Monitor's functionality is affected, attempt to reset the AURA™ Monitor or contact Branchpoint Technologies for instructions.

AURA™ ICP Monitoring System has not been evaluated for pediatric use.

Avoid sources of ionizing radiation. If ionizing radiation must be used, avoid focusing near the AURA™ Sensor placement site. Ionizing radiation may damage the device, however, the damage may not be immediately detectable.

7. INSTRUCTIONS FOR USE

INSPECT THE PACKAGING

Visually inspect for mechanical and functional integrity of the packaging and its contents as well as the legibility and adherence of the AURA™ Monitor labels. If there is evidence of damage or tampering, do NOT use the product. Contact Customer Service, and Branchpoint Technologies will provide instructions for return.

Package contents include:

- AURA™ Monitor (1)
- AURA™ Antenna (1)
- Lithium Ion 11V rechargeable batteries (2)
- Battery Charger (1)
- Power Supply (1)

CONTROL PANEL

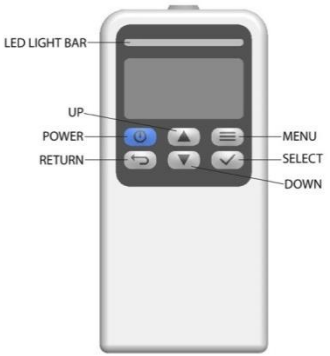


Figure 2: AURA™ Monitor Controls.

INSERTING AND CHANGING THE AURA™ BATTERY

To remove the battery:

- Press the release buttons on the sides of the battery pack (Figure 3).
- Slide the battery pack towards the bottom of the AURA™ Monitor (Figure 4).
- Lift up to remove the battery pack from the AURA™ Monitor (Figure 5).

Figure 3: Press locking buttons simultaneously to release battery.

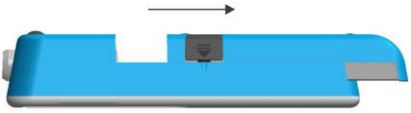


Figure 4: Slide battery to guide markers.

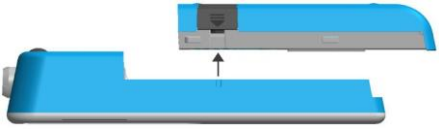


Figure 5: Lift and remove battery.

To insert the battery into the AURA™ Monitor:

- Line up guide markers on the sides of both the battery and AURA™ Monitor (Figure 6).
- Insert the battery into the AURA™ Monitor.
- Slide the battery forward into the AURA™ Monitor until the locking mechanism is activated (Figure 7).

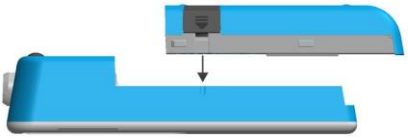


Figure 6: Line up and insert battery at guide markers.

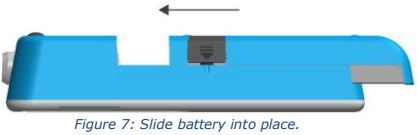


Figure 7: Slide battery into place.

CHARGING THE AURA™ BATTERY

Figure 8: Slide batteries into battery charger.

To charge a battery, gently slide it into the battery charger (Figure 8). The LEDs next to the batteries will illuminate according to Table 3 below.

Table 3: Battery charger LED indicator status and indication.

LED Indicator	Indication
LED Indicator does not illuminate	No battery is charging
LED Indicator is solid blue	The battery is charging
LED Indicator is solid green	The battery is fully recharged
LED indicator is blinking blue	An error with the battery has been detected

NOTE: *Battery Status LED indicator blinking blue indicates there is an error with the battery. Try to remove then re-insert the battery. If problem persists, replace the battery or contact Customer Service.*

Charge the spare battery when not in use to ensure ready availability of power for the AURA™ Monitor.

Each battery will typically provide at least 8 hours of battery life.

TURNING THE AURA™ MONITOR ON AND OFF

To turn on, press the power button.

To turn off, press and hold the power button for two seconds until the display screen is deactivated.

READING BATTERY LEVEL

The battery level icon located on the upper right corner of the screen indicates the remaining battery level (Figure 9). The icon will be empty and flashing when the battery level is critically low.

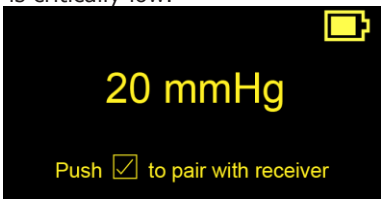


Figure 9: Battery level icon on the upper right corner of the AURA™ Monitor screen.

CONNECTING AND DISCONNECTING THE AURA™ ANTENNA

To connect the AURA™ Antenna to the AURA™ Monitor, align the arrows on the cable and connector (Figure 10) and until they click together (Figure 11). To disconnect the AURA™ Antenna, hold the cable by the plug and pull. Do not pull the cable. Pulling on the cable may damage it in a way that is not visibly detectable.

Figure 10: Align the arrow markings on the antenna cable and the AURA™ Monitor.

Figure 11: Plug antenna cable into AURA™ Monitor.

RUNNING IN-PACKAGE CHECK FOR AURA™ SENSOR

Before unpacking the AURA™ Sensor Tray box, the User can run in-package check for the pre-implantation status of the AURA™ Sensor.

To run in-package check:

- Plug the antenna cable into the AURA™ Monitor.
- Turn the AURA™ Monitor on and select the ⏏ button for in-package check.

The AURA™ Monitor will start searching for the AURA™ Sensor.

- Slowly move the AURA™ Antenna around the marked area on the AURA™ Sensor Tray box (Figure 12). The green light will illuminate on the antenna when the antenna is at the proper location. Hold the antenna at this location.

Figure 12: Positioning the AURA™ Antenna at the sticker on the AURA™ Sensor Tray box to run in-package check.

- If an AURA™ Sensor is found, the AURA™ Antenna will connect to the AURA™ Sensor and show its status.

- If no AURA™ Sensor is found, the AURA™ Monitor will display "No Sensor Found." Select the ⏏ button to re-run the in-package check and try to move the AURA™ Antenna around the marked area again as the AURA™ Sensor within the box may slightly shift during transportation. If failure persists, please contact Branchpoint Technologies for further instruction.
- Another option to run in-package check is to remove the sterile pouch from the AURA™ Sensor Tray box and position the AURA™ Antenna over the AURA™ Sensor visualized through the translucent side of the pouch.

CONNECTING TO AN AURA™ SENSOR

Ensure that an AURA™ Antenna is connected and turn the AURA™ Monitor on. The device will display the following screen as it seeks an AURA™ Sensor to connect to.

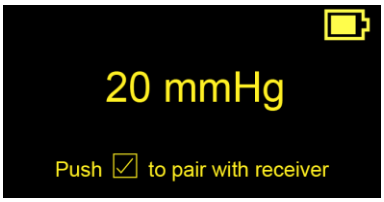
***CAUTION**: DO NOT run an in-package check after the sensor has been inserted. This will lead to an erroneous failure message for functional sensors.*

Place antenna directly over the AURA™ Sensor and into the Antenna Holster provided in the AURA™ Sensor Tray (Figure 13). The Antenna Holster will hold the AURA™ Antenna securely in place. The LED on the AURA™ Antenna will illuminate green upon successful connection to an AURA™ Sensor.

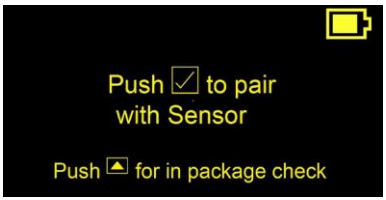
Figure 13: Antenna Holster being affixed onto scalp above AURA™ Sensor.

***CAUTION**: Please ensure that the AURA™ Antenna does not rest on or contact the patient's skin.*

Upon successful connection, the AURA™ Monitor will display the sensor's serial number then begin to stream ICP data.



If an AURA™ Sensor is not found within 20 seconds, the screen will display the following screens:



Press ☑ to command the antenna to search for a sensor connection again.

NOTE: *If ☑ is not pressed within 2 minutes, the AURA™ Monitor will turn off to save power.*

After successfully pairing with the AURA™ Sensor, The AURA™ Monitor is now ready to pair with the AURA™ Data Receiver. Press ☑ button to start paring with the Data Receiver or open the menu and select "Pair Receiver."

PAIRING WITH AN AURA™ DATA RECEIVER

After pressing ☑ to start pairing the AURA™ Monitor with the AURA™ Data Receiver, the screen will ask the user to plug the AURA™ Data Receiver into the patient monitor.

Ensure that the target AURA™ Data Receiver is connected to the patient monitor (Figure 14) and is calibrated (see AURA™ Data Receiver Pack Instructions for Use for directions).

Figure 14: AURA™ Data Receiver connecting into Patient Monitor IBP Port.

Press ☑ to continue pairing with a data receiver.

Select the serial number that matches the printed serial number on the label of the AURA™ Data Receiver being paired to (Figure 15).

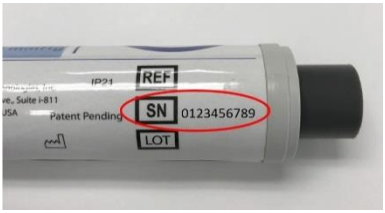
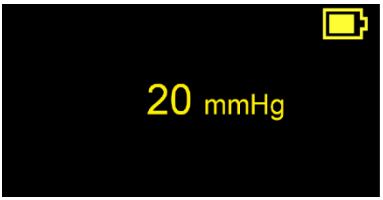


Figure 15: Example of printed serial number on the label of AURA™ Data Receiver.

Select "Connect."

The AURA™ Monitor will start pairing with the AURA™ Data Receiver.

After successfully paired with the AURA™ Data Receiver, the AURA™ Monitor will display the ICP.



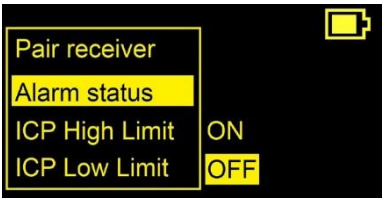
NOTE: *If the AURA™ Data Receiver is not calibrated, after selecting "Connect," the screen will display reminders to calibrate receiver.*

Calibrate receiver according to AURA™ Data Receiver Instructions For Use. After calibration for receiver is complete, the AURA™ Monitor will automatically display the ICP.

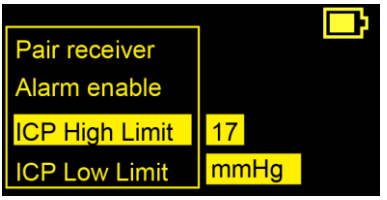
To unpair an AURA™ Data Receiver, press the Menu button and choose "Unpair Receiver" from the drop-down menu and then confirm unpairing. Unpairing will also occur when the AURA™ Monitor is turned off. Note that if an AURA™ Data Receiver is briefly turned off and on, connection to the prior AURA™ Monitor may be automatically re-established.

SETTING ICP ALARM LIMITS AND ALARM

To enable an alarm when the acquired ICP reaches the high or low limit set by the user, select the Menu button to get to the following screen. Select "Alarm Status" and then "Enable." To disable the alarm, select "Disable."



The User can set ICP alarm thresholds. To do so, select ICP High/Low Limit and use the Up and Down buttons to set the ICP threshold value. The LED light will flash when the alarm sounds for these thresholds as well.



NOTE: *The factory default ICP low alarm trigger value is 7 mmHg and the default ICP high alarm trigger value is 20 mmHg. If the User changes these trigger values, they will persist across power cycles. Trigger values do not reset to factory settings if the device is turned off and on.*

AUDIO TONES

The following table describes the audio output (including frequency, duration and tone) for different events.

Table 4: AURA™ Monitor Audio Output.

Event	Event Description	Audio
Startup	At power up.	880 Hz 250ms tone
Button Selection	Button (any except on/off) pressed.	880 Hz 50ms tone
Alarm (High Priority)	Enabled alarm condition detected. Audio pattern output repeatedly every 5 seconds until alarm cleared or user mutes the alarm.	**A A A – A A | A A A – A A** **A** = 440 Hz 100ms tone with 4 harmonics space indicates 50ms gap – indicates 250ms gap | indicates 2.5 second gap
Alarm (Medium Priority)	Enabled alarm condition detected. Audio pattern output repeatedly every 5 seconds until alarm cleared or user mutes the alarm.	**A A A** **A** = 440 Hz 150ms tone with 4 harmonics space indicates 150ms gap
Alarm (Low Priority)	Enabled alarm condition detected. Audio pattern output repeatedly every 20 seconds until alarm cleared or user mutes the alarm.	**C A** **C** = 523 Hz 200ms tone with 4 harmonics A = 440 Hz 200ms tone with 4 harmonics space indicates 200ms gap
Fault (Low Priority)	Fault condition detected. Audio pattern output repeatedly every 30 seconds until power off or user mutes the fault.	**C A** **C** = 523 Hz 200ms tone with 4 harmonics A = 440 Hz 200ms tone with 4 harmonics space indicates 200 ms gap
Sensor Pairing	The antenna pairs with the sensor.	**D A D** **D** = 587 Hz 100 ms tone **A** = 880 Hz 50 ms tone **D** = 1174 Hz 100 ms tone space indicates 50 ms gap
Sensor Unpairing	The Antenna unpairs from the Sensor.	**D A D** **D** = 1174 Hz 100 ms tone **A** = 880 Hz 50 ms tone **D** = 587 Hz 100 ms tone space indicates 50 ms gap
Data Receiver Pairing	The Monitor pairs with a receiver.	**D D** **D** = 587 Hz 100 ms tone **D** = 1174 Hz 100 ms tone space indicates 50 ms gap
Data Receiver Unpairing	The Monitor unpairs from a receiver.	**D D** **D** = 1174 Hz 100 ms tone **D** = 587 Hz 100 ms tone space indicates 50 ms gap

8. MAINTENANCE RECOMMENDATIONS

BATTERIES

If the AURA™ Monitor will not be used for some time, remove batteries from the device and place in charging dock to ensure that fully-charged batteries are readily available when needed.

CLEANING

Keep AURA™ Monitor Pack devices and accessories away from dust and dirt. Clean the external surfaces of the devices immediately after each use and prior to re-use.

Do not use harsh chemicals, cleaning solvents, or strong detergents to clean any of the devices. Do not spray or pour cleaning solutions directly onto any devices or submerge them.

Recommended cleaning procedure:

1. Turn off the device.
2. Use a clean, soft, lint-free cloth dampened with isopropanol, Cidex® or a non-staining chemical disinfectant to wipe the external surfaces of the devices.
3. Follow applicable hospital cleaning procedures and instructions on the cleaning agent.
4. If the device came in contact with blood or bodily fluids, perform intermediate disinfection per FDA and CDC guidelines.
5. Follow applicable instructions for the cleaning agent to remove excess cleaning solution or residue. Otherwise, wipe devices using a clean, dry, lint-free cloth.
6. Visually inspect the devices to ensure surfaces are free of residue and soil. Inspect for any signs of wear or damage to the devices such as discoloration and cracking. If damage is detected, discontinue use and contact the Manufacturer.

SERVICE

There are no user-accessible or user-serviceable parts or components in the AURA™ Monitor Pack. If any service, repair, or replacement of internal components is needed, the AURA™ Monitor Pack must be returned to Branchpoint Technologies. For instructions and return packaging, contact Branchpoint Technologies using the information on the back cover of this manual. When requesting service, please provide information concerning the nature of the failure and the manner in which the equipment was used when the failure occurred. The model number and serial number should also be provided.

MAINTENANCE CHECK

Perform a visual inspection and verify the following prior to each use:

- Mechanical and functional integrity of the AURA™ Monitor, cables, and accessories.
- Legibility and adherence of the AURA™ Monitor labels.

DISPOSAL

To dispose of, return, or exchange an AURA™ Monitor, contact Branchpoint Technologies using the information on the back cover of this manual or dispose in accordance with appropriate hospital policy. Do not dispose of the AURA™ Monitor in the trash or at electronics recycling facilities.

9. TROUBLESHOOTING

This section presents potential AURA™ Monitor operational issues and recommended solutions. Contact Branchpoint Technologies using the information on the back cover of this manual for additional assistance.

TROUBLE CONNECTING WITH THE AURA™ SENSOR OR POOR QUALITY OF SERVICE

- The AURA™ Monitor will display the messages: "Sensor Connection Lost," "Reposition Antenna, Check Connections," or "Sensor Error" to indicate an AURA™ Sensor connection issue.
- Reposition the AURA™ Antenna and check connections until a good connection is re-established between the AURA™ Sensor and AURA™ Monitor.

  NOTE: *If the AURA™ Monitor cannot connect to an AURA™ Sensor, try repositioning the AURA™ Antenna.*

TROUBLE CONNECTING WITH THE AURA™ DATA RECEIVER OR POOR QUALITY OF SERVICE

- The AURA™ Monitor will state "No Receivers Found" if it does not find any receivers ready for connection. In this case, verify that no other AURA™ Monitor is already connected to the target AURA™ Data Receiver.
- The AURA™ Monitor will display the words "Pairing Failed," "Receiver Error," or "Connect Receiver" to indicate failure to connect with a selected AURA™ Data Receiver. If the AURA™ Monitor fails to communicate with the AURA™ Data Receiver or determines there is a poor Quality of Service, it will automatically disconnect from the AURA™ Data Receiver.
- Verify there are no potential sources of interference in close proximity to the AURA™ Monitor or AURA™ Data Receiver.
- Check the connection of the AURA™ Data Receiver to the patient monitor.
- After verification, reset the AURA™ Monitor.

POINT MEASUREMENT MODE

In point measurement mode, the patient monitor displays ICP as a series of flat line values (10 to 30 seconds at each consecutive averaged value) instead of an ICP waveform. The point measurement mode allows the ICP monitoring system to operate in a low power state. When in this mode, try re-positioning the AURA™ Antenna for better alignment with the AURA™ Sensor. The system will automatically transition out of point measurement mode when the issue is resolved.

ALARMS

Table 5 lists all possible alarms that can be displayed to the User based on their significance, LED indicator status, and the audio alarm priority.

If a medium priority and a low priority alarm are active at the same time, the AURA™ Monitor will only sound the medium alarm.

If two or more medium alarms are active at the same time, the AURA™ Monitor will cycle through all of them and display the alarm text for each alarm as shown in Table 5.

Table 5: Alarms Condition, Display, LED status, and Audio Alarm output level.

Alarm Condition	Display	LED	Audio Alarm
Max. ICP Exceeded	Flashing "HI" text to left of ICP average	Y	Medium
Min. ICP Exceeded	Flashing "LO" text to left of ICP average	Y	Medium
In Package Check Failure	"Sensor Check Failure"	N	None
Monitor Over Temperature	"Monitor Cooling"	N	Medium
Battery Temperature High	Screen 1: "Battery Temp High" Screen 2: "Change Battery, Check Manual"	N	Medium
Low Battery	Screen 1: "Battery Low" Screen 2: "Change Battery"	N	Medium
Critically Low Battery	Screen 1: "Battery CRITICAL" Screen 2: "Change Battery"	N	Medium
Receiver Not Calibrated	Screen 1: "Receiver Not Calibrated" Screen 2: "Calibrate Receiver"	N	Low
Receiver Issue	Screen 1: "Receiver Error" Screen 2: "Connect Receiver"	N	Low

10. COMPLIANCE STATEMENTS

EMI/RFI

This equipment has been tested and found to comply with the applicable limits for medical devices, IEC 60601-1-2:2007.

Although this testing shows the device to provide reasonable protection against harmful interference in a typical medical installation, there is no guarantee that interference will not occur in a particular installation. If the device does cause harmful interference the user is encouraged to try and correct the interference by the following measures:

- Reorient or relocate the device
- Increase the separation between the devices
- Connect the equipment to an outlet on a different circuit
- Contact Branchpoint Technologies using the information on the back cover of this manual

> ***NOTE:*** *"Harmful interference" is defined by the FCC as follows: Any emission, radiation or induction that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs or repeatedly interrupts a radio communications service operating in accordance with FCC rules.*

ESSENTIAL PERFORMANCE

Essential performance is maintained as long as the AURA™ ICP Monitoring System can be brought back into a functional state to measure and display ICP to the user without requiring surgical intervention to remove or replace the sensor.

The performance limit for ICP measurement accuracy is ± 2 mmHg for ICP values of 0 to 20 mmHg, and ± 10% for ICP values above 20 mmHg during normal and single fault conditions.

FEDERAL COMMUNICATIONS COMMISSION (FCC) COMPLIANCE

AURA™ Monitor contains FCC ID T7V1740.

AURA™ Antenna contains FCC ID 2AJW602. This product complies with Part 18 of the FCC rules.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- This device may not cause harmful interference; and
- This device must accept any interference received, including interference that may cause undesired operation

> ***CAUTION****: Changes or modifications not expressly approved by Branchpoint Technologies could void the user's authority to operate the equipment.*

11. PRODUCT INFORMATION DISCLOSURE

Branchpoint Technologies has exercised reasonable care in the selection of materials and the manufacture of these products. Branchpoint Technologies excludes all warranties, whether expressed or implied, including but not limited to, any implied warranties of merchantability or fitness for a particular purpose. Branchpoint Technologies shall not be liable for any incidental or consequential loss, damage, or expense, directly or indirectly arising from use of these products. Branchpoint Technologies neither assumes nor authorizes any person to assume for it any other or additional liability or responsibility in connection with these products. Branchpoint Technologies intends that this device should be used only by physicians with educational and training background enabling the proper use of the device.

12. TECHNICAL SPECIFICATIONS

AURA™ ICP MONITORING SYSTEM

TECHNICAL AND PERFORMANCE SPECIFICATIONS

Frequency response The maximum frequency response of the AURA™ ICP Monitoring System, including the ICP readout display, at peak pressures of 10, 20, and 50 mmHg.	10 mmHg: 34 Hz 20 mmHg: 38 Hz 50 mmHg: 23 Hz AURA™ Monitor displays a 1 second moving average.
Slew rates The slew rates (the system's fastest output during a unit of time) from zero to peak and peak to zero for peak pressures of 10, 20, and 50 mmHg.	10 mmHg: 0.79 mmHg/ms 20 mmHg: 1.68 mmHg/ms 50 mmHg: 2.06 mmHg/ms
Time constants The time constants for full-scale deflection of the system, with both increasing and decreasing pressure.	With increasing pressure: 10 mmHg: 5.75 ms 20 mmHg: 5.62 ms 50 mmHg: 8.03 ms With decreasing pressure: 10 mmHg: 7.74 ms 20 mmHg: 8.99 ms 50 mmHg: 9.10 ms
Pressure range of the AURA™ ICP Monitoring System including display range.	-20 to 100 mmHg
Accuracy of ICP range.	-20 to 20 mmHg: ± 2 mmHg 20 to 100 mmHg: ± 10%
Length of time over which the device will maintain the specified accuracy.	29 Days
Pressure stability over temperature.	The stability of pressure measurement is not affected by sensor temperature between 25°C to 39°C.
The expected drift of the zero-point reading of the AURA™ Sensor.	First 24 hours: < 0 ± 2 mmHg per day 29 days: < 0.3 mmHg per day

AURA™ MONITOR SPECIFICATIONS

Physical dimension and weight	
Height	7.8 inches
Width	3.7 inches
Depth	1.8 inches
Weight (with battery inserted)	700 grams
Temperature limits	
Operating	15°C to 30°C
Storage	0°C to 50°C
Humidity limits	
Operating	20-85% R.H., non-condensing
Storage	20-85% R.H., non-condensing
Pressure limits	
Operating	795 mmHg to 700 mmHg
Storage	795 mmHg to 375 mmHg
RF data transmission (AURA™ Monitor and AURA™ Antenna)	
Frequency range	2.40 - 2.48 GHz
Output power	0dBm (0.001 watts)
Modulation	GFSK FHSS
Wireless power (AURA™ Antenna)	
Frequency range	13.553 - 13.567 MHz
Output power (variable)	Less than 4.5W
Transmission distance	
AURA™ Antenna to AURA™ Sensor	1.5 cm
AURA™ Monitor to AURA™ Data Receiver	7 meters
Software	
Version	BLE: SW-0008 rev. A MCU: SW-0006 rev. C

AURA™ ANTENNA SPECIFICATIONS

Physical dimension and weight	
Height	3.3 inches
Width	1.8 inches
Depth	0.8 inches
Weight	63 grams
AURA™ Antenna cable length	5 ft 0.2 inches
Transmission distance	
AURA™ Antenna to AURA™ Sensor	1.5 cm
AURA™ Monitor to AURA™ Data Receiver	7 meters
Wireless power	
Frequency range	13.553 - 13.567 MHz
Software	
Version	BLE: SW-0008 rev. A MCU: SW-0002 rev. D

AURA™ BATTERY SPECIFICATIONS

Battery	
Type	Li-ion, rechargeable
Capacity	5600 mAh
Charge duration	Operating: 8 hours (typical)
Voltage	11.1 V
Physical dimension and weight	
Height	5.2 inches
Width	3.4 inches
Depth	1.1 inches
Weight	400 grams
Temperature limits	
Operating	15°C to 30°C
Storage	0°C to 50°C
Humidity limits	
Operating	20-85% R.H., non-condensing
Storage	20-85% R.H., non-condensing
Pressure limits	
Operating	795 mmHg to 700 mmHg
Storage	795 mmHg to 375 mmHg

AURA™ BATTERY CHARGER SPECIFICATIONS

Charger AC power supply input requirements	
Voltage	100 - 240 VAC
Frequency	50-60 Hz
Charger Power Supply output	
Voltage	15 VDC
Power	30W
Charging output	
Voltage	12.6 VDC per charging bay
Current	895 mA per charging bay
Physical dimensions and weight	
Charger	
Height	5.8 inches
Width	5.8 inches
Depth	3.0 inches
Weight	375 grams
Charger Power Supply	
Height	3.3 inches
Width	2.8 inches
Depth	1.9 inches
Weight (with cable)	450 grams
Temperature limits	
Operating Storage	15°C to 30°C 0°C to 50°C
Humidity limits	
Operating Storage	20-85% R.H., non-condensing 20-85% R.H., non-condensing

Guidance and Manufacturer's Declaration - Emissions
The AURA™ Intracranial Monitor System and AURA™ System Battery Charger are intended for use in the electromagnetic environment specified below. The customer or user of the AURA™ Intracranial Monitor System and AURA System Battery Charger should ensure that they are used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF Emissions CISPR 11		
System	Group 2	The AURA™ Intracranial Monitor System uses Group 2 limits. The AURA™ Intracranial Monitor System must emit electromagnetic energy in order to perform its intended function. Nearby equipment may be affected.
Battery Charger	Group 1	The AURA™ System Battery Charger RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF Emissions CISPR 11	Class A	The AURA™ Intracranial Monitor System and AURA System Battery Charger are suitable for professional establishments only.
Harmonics IEC 61000-3-2	Class A	
Flicker IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Immunity
The AURA™ Intracranial Monitor System and AURA™ System Battery Charger are intended for use in the electromagnetic environment specified below. The customer or user of the AURA™ Intracranial Monitor System and AURA™ System Battery Charger should ensure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
ESD IEC 61000-4-2	±4kV Contact ±8kV Air	±4kV Contact ±8kV Air	Floors should be wood, concrete or ceramic tile. If floors are synthetic, the r/h should be at least 30%
EFT IEC 61000-4-4	±2kV Mains ±1kV I/O's	±2kV Mains ±1kV N/A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV Differential ±2kV Common	±1kV Differential ±2kV Common	Mains power quality should be that of a typical commercial or hospital environment.
Voltage Dips/ Dropout IEC 61000-4-11	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	>95% Dip for 0.5 Cycle >95% Dip for 1 Cycle 30% Dip for 25/30 Cycles >95% Dip for 250/300 Cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the AURA™ System Battery Charger requires continued operation during power mains interruptions, it is recommended that the AURA™ System Battery Charger be powered from an uninterruptible power supply or a battery.
Power Frequency 50/60Hz Magnetic Field IEC 61000-4-8	3 A/m	3A/m	Power frequency magnetic fields should be that of a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Immunity
The AURA™ Intracranial Monitor System and AURA™ System Battery Charger are intended for use in the electromagnetic environment specified below. The customer or user of the AURA™ Intracranial Monitor System and AURA™ System Battery Charger should ensure 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	3V 0.15MHz-80MHz 6V[1] in ISM between 0.15MHz and 80MHz[2] 80% AM at 1kHz	3V 0.15MHz-80MHz 6V[1] in ISM between 0.15MHz and 80MHz[2] 80% AM at 1kHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT
Radiated RF IEC 61000-4-3	3V/m 80MHz – 2.7GHZ 80% AM at 1kHz	3V/m 80MHz – 2.7GHZ 80% AM at 1kHz	PROFESSIONAL HEALTHCARE FACILITY ENVIRONMENT

[1] r.m.s. before modulation is applied.

[2]The ISM (industrial, scientific, and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz, 21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Guidance and Manufacturer's Declaration – Immunity
The AURA™ Intracranial Monitor System is intended for use in the electromagnetic environment specified below. The customer or user of the AURA™ Intracranial Monitor System should ensure that it is used in such an environment.

Test Frequency	Band[1]	Service[1]	Modulation[2]	Maximum Power	Distance	Immunity Test Level
MHz	MHz			W	Meters	(V/m)
385	380-390	TETRA 400	Pulse modulation[2] 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM[3] ± 5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation[2] 217 Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TEETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[2] 217 Hz	2	0.3	28
1720 1845 1970	1700-1900	GSM 1800; CDMA 900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation[2] 217 Hz	2	0.3	28
2450	2400-2750	WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation[2] 217 Hz	2	0.3	28
5240 5500 5785	5100 – 5800	WLAN 802.11a/n	Pulse modulation[2] 217 Hz	0.2	0.3	9

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[1] For some services, only the uplink frequencies are included.

[2] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[3] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

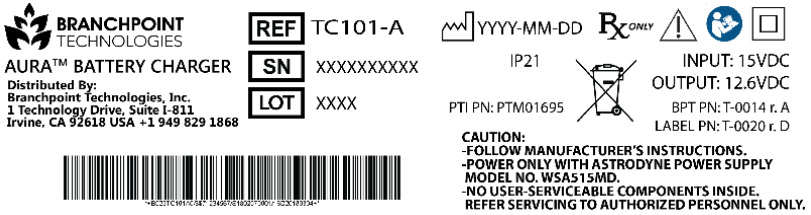
13. PACKAGING AND DEVICE SYMBOLS

The Following symbols may be used on the AURA™ Monitor, its accessories, and their packaging.

Symbol	Specification	Symbol	Specification
	Consult instructions for use		Manufacturer
	Temperature limitations		Date of Manufacture
	Atmospheric limitations		Sterilized using ethylene oxide
	Humidity limitations		Do not resterilize
	Serial Number		Non-ionizing electromagnetic radiation
	Reference/ Catalogue Number		Caution
	Lot Number		Do not use if package is damaged
	Use-by date		Do not reuse, single-use device
	Mark for Nationally Recognized testing for safety standards Conforms to AAMI STD ES60601-1 IEC STD 60601-1-6 IEC STD 60601-1-8		Non-sterile
	WEEE- Waste, Electrical, and Electronic Equipment (WEEE). Indicates separate collection for electrical and electronic equipment (i.e., do not throw this device in the trash).		Caution: Federal (USA) law restricts this device to sale by or on the order of a physician
	Federal Communications Commission (FCC)	IPXX	International Protection Rating
	Type BF Applied Part		Class II Electrical Appliance
	Non-Pyrogenic		Contains Lithium Ion Batteries
	MR Unsafe	NA	NA

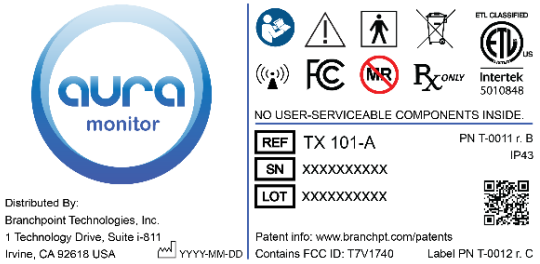
14. ASSOCIATED DEVICE LABELS

PN T-0020 AURA™ Battery Charger Label

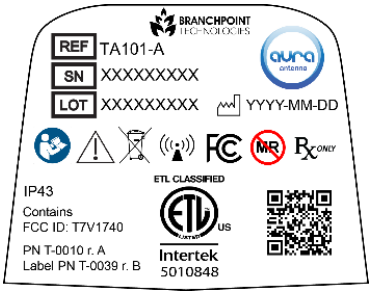


PN T-0032 AURA™ Battery Label

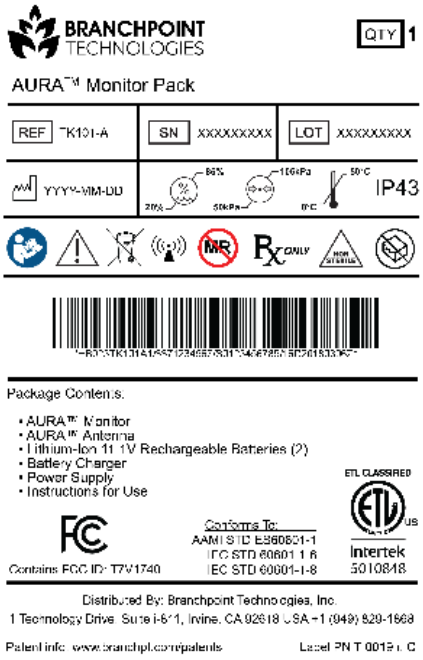
PN T-0012 AURA™ Monitor Label



PN T-0039 AURA™ Antenna Label



PN T-0019 AURA™ Monitor Pack Sales Container Label



PN T-0022 AURA™ Monitor Pack Shipping Container Label

15. END-USER SOFTWARE LICENSE AGREEMENT

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7. INDEMNIFICATION

The Software is not intended to replace the skill and judgment of a qualified medical practitioner and should only be used by people that have been appropriately trained in the functions, capabilities and limitations of the Software. You agree to hold harmless, indemnify and defend Branchpoint, its licensors, officers, directors and employees, from and against any losses, damages, fines and expenses (including attorneys' fees and costs) arising out of or relating to your use of the Software. THE ENTIRE RISK ARISING OUT OF YOUR USE OF THE SOFTWARE AND DOCUMENTATION REMAINS WITH YOU.

8. TERMINATION

This Agreement will automatically terminate at the end of the license period or if you fail to comply with any term hereof including failure to make any required payment when due. No notice shall be required from Branchpoint to effect such termination. You may also terminate this Agreement at any time by notifying Branchpoint in writing of termination. Without prejudice to any other rights, upon any termination of this Agreement, you shall immediately discontinue use of the Software and Documentation and shall within three (3) days return to Branchpoint, or certify destruction of, all full or partial copies of the Software, Documentation and related materials.

9. MISCELLANEOUS

This Agreement shall constitute the complete and exclusive agreement between the Parties, notwithstanding any variance with any other written instrument submitted by you, whether formally rejected by Branchpoint or not. Failure or delay on the part of Branchpoint to exercise any right, power, privilege, or remedy will not constitute a waiver of, or bar the later exercise of, that or any other right, power, privilege, or remedy of Branchpoint. The terms and conditions contained in this Agreement may not be modified except in a writing duly signed by you and an authorized representative of Branchpoint. This Agreement is personal to you, and may not be assigned, sublicensed or transferred without Branchpoint's express written consent. Any such attempted assignment, sublicense, or transfer will be null and void. Branchpoint may terminate this Agreement in the event of any such attempted assignment, sublicense, or transfer. If any provision of this Agreement is held to be unenforceable for any reason, such provision shall be reformed only to the extent necessary to make it enforceable, and such decision shall not affect the enforceability of such provision under other circumstances, or of the remaining provisions hereof under all circumstances. The parties specifically acknowledge and agree that this Agreement be drafted and fully enforceable as written in the English language. This Agreement shall be governed by the laws of the State of California, without regard to conflicts of law provisions. Any dispute between you and Branchpoint regarding this Agreement will be subject to the exclusive jurisdiction of the state and federal courts sitting in Orange County, California. Your remedies in this Agreement are exclusive. Any claim brought by you must be brought within one year of the date the cause of action has accrued or be forever waived. To the extent that you have breached or have indicated your intention to breach this Agreement in any manner which violates or may violate Branchpoint's or its licensors' intellectual property rights, or may cause continuing or irreparable harm to Branchpoint or its licensors (including, but not limited to, any breach that may impact Branchpoint's or its licensors' intellectual property rights, or a breach by reverse engineering), Branchpoint or its licensors may seek injunctive relief, or any other appropriate relief, in any court of competent jurisdiction. To that extent, Branchpoint's licensors shall be third party beneficiaries under this Agreement. This Agreement will not be governed by the United Nations Convention on Contracts for the International Sale of Goods, the application of which is hereby expressly excluded. No rule of strict construction shall apply against or in favor of either party in the construction and interpretation of this Agreement.

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The AURA™ Monitor Instructions For Use intends to provide all necessary information for proper operation of all AURA™ Monitor models.

Do not operate any component of the AURA™ ICP Monitoring System without completely reading and understanding these instructions.

CAUTION:
FEDERAL LAW (U.S.) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.

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See www.branchpt.com/patents for patent information.

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