



BRANCHPOINT
TECHNOLOGIES

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MADE IN USA

IFU PN I-0033 rev. A



BRANCHPOINT
TECHNOLOGIES

Branchpoint Technologies

AURA™ ICP Monitoring Kit

INSTRUCTIONS FOR USE

SP 101-A

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Revised 2017-05-24

STERILE	EO
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1. DESCRIPTION

This AURA™ ICP Monitoring Kit (SP101-A) contains one AURA™ Intracranial Pressure (ICP) Sensor, one drill bit with collar, one hex wrench, one scalp retractor, one disposable antenna holster (AH101), four patient registration card, and five patient labels (Figure 1). The AURA™ Sensor can be placed with standard surgical instruments.



Figure 1: AURA™ ICP Monitoring Kit.

The AURA™ ICP Monitoring Kit is provided sterile and is sterilized by ethylene oxidation. This kit is part of the AURA™ Intracranial Monitoring System (Figure 2) whose function is to determine safely, quickly, and accurately the level and change in ICP.



Figure 1: AURA™ Intracranial Monitoring System.

CAUTION: Federal Law (U.S.A.) restricts this device to be sold by or on the order of a physician.

2. INDICATIONS FOR USE

The Branchpoint AURA™ Intracranial Monitoring System is for use by qualified neurosurgeons in the direct monitoring of intracranial pressure in the parenchyma for neurological patients.

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™ ICP Monitoring Kit, read and follow all instructions, warnings, and precautions provided in the AURA™ ICP Monitoring Kit manual and in the manuals for the other system components. Manuals for the other system components are listed below.

- AURA™ Monitor Kit Instructions for Use
- AURA™ Data Receiver Instructions for Use

This manual is also made available on the Internet and can be found at www.auramonitor.com.

5. WARNINGS

Sterile techniques should be used at all times when handling components of the AURA™ ICP Monitoring Kit and inserting the AURA™ ICP Sensor.

Placement of the AURA™ ICP Sensor must be carried out by a qualified health care provider. The health care provider should take appropriate steps and procedures to avoid infections and complications.

If monitoring is continued for more than 29 days, placement of a new system under sterile conditions is recommended. The AURA™ ICP Sensor must be explanted from patient after usage or when implantation has reached 29 days. Usage beyond maximum specified duration may result in patient harm or system malfunction.

The AURA™ ICP Sensor and the items included in the AURA™ ICP Monitoring Kit are designed for SINGLE USE ONLY. DO NOT RESTERILIZE OR REUSE AURA™ ICP Sensor if it has previously been implanted in another patient. DO NOT REUSE any portions of the kit that have been partially or totally implanted in a patient. Disposal of parts must be in accordance with hospital policy. Improper disposal may pose biohazards or environmental hazards.

All Branchpoint Technologies AURA™ components are designed for use with the AURA™ ICP Monitoring System only. Usage of product outside of specified indications may result in patient or operator harm.

There are no user serviceable components within the AURA™ ICP Monitoring System. Any additions or modifications to this system, except those supplied or recommended by Branchpoint Technologies, are prohibited and may interfere with system performance or result in a hazard or hazardous condition.

Do not subject the AURA™ ICP Monitoring Kit components to temperatures outside of 0°C to 50°C (32°F to 122°F) storage range. Usage outside of specified conditions may result in patient harm, packaging damage or system malfunction. Allow the AURA™ ICP Sensor to reach room temperature before it is inserted and before "In-Package Check" is performed.

Do not insert the AURA™ ICP Sensor after the "Use by" date on the package label.

Do not modify, cut, kink, crush, stretch, drop, or otherwise damage any component of the AURA™ ICP Sensor. Impairment to the AURA™ ICP Sensor may result in device malfunction.

The AURA™ ICP Monitoring Kit is provided sterile in sealed packaging.

DO NOT USE if the packaging is wet, punctured, opened, or otherwise damaged. Usage of damaged products may result in a hazard or hazardous condition. Contact Branchpoint Technologies for instructions to return the AURA™ ICP Monitoring Kit.

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

Compatibility of AURA™ ICP Sensor with magnetic resonance imaging (MRI) has not been validated.

6. PRECAUTIONS

Patients should avoid devices or medical treatments that generate strong sources of electromagnetic interference (EMI). EMI may result in device malfunction or damage.

Patients should avoid medical treatments and diagnostic tests in which an electrical current is passed through the body, such as TENS, electrocautery, electrolysis/thermolysis, electromyography, or nerve conduction studies.

Patients should avoid sources of therapeutic ultrasound. Therapeutic ultrasound may damage the device, however, the damage may not be immediately detectable.

Patients with metal implants should not receive medical treatments and diagnostic tests using effects caused by electrical fields, such as diathermy.

Patients should avoid sources of ionizing radiation. Ionizing radiation may damage the device, however, the damage may not be immediately detectable.

By design, the AURA™ ICP Sensor emits radio frequency energy in the 2.4 GHz band and is powered by the AURA™ Antenna in the 13.56 MHz band. The presence of other equipment operating in the same frequency bands used by the AURA™ ICP Sensor may interfere with communication. This interference can be reduced by increasing the distance between the interfering device and the AURA™ ICP Sensor.

The AURA™ ICP Sensor shall not be placed in oxygen rich environments.

Cerebral Spinal Fluid leakage, hemorrhage, pain, infection and neurological damage are potential complications of this procedure. Testing of the blood clotting factor should be conducted on patients before insertion. Decisions regarding the possibility of hemorrhage at the site of placement are the sole responsibility of the practitioner.

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™ ICP Sensor labels. If there is evidence of damage or tampering, do NOT use the product and contact Customer Service. Branchpoint Technologies will provide instructions for return.

In-Package AURA™ ICP Sensor Check:

- Turn on the AURA™ Monitor.
- Select ↶ for in-package check and place AURA™ Antenna over AURA™ ICP Sensor.
 - Place the AURA™ Antenna over the marked portion of the box in proximity to the AURA™ ICP Sensor. Another option is to remove the translucent pouch from the sales container and position the Antenna over the AURA™ ICP sensor visualized through the translucent pouch.
- If In-Package Check is successful, AURA™ Monitor will display "Sensor OK." If In-Package Check fails, AURA™ Monitor will display "Sensor Check Failed." If this occurs, retry the In-Package Check. If the issue persists, use another AURA™ ICP Sensor and contact Branchpoint Technologies for further instruction.

INSERTING THE AURA™ ICP SENSOR

- Shave, prep and drape the patient's scalp.
- Make the necessary incision at Kocher's point or other desired location (Figure 2).
- Insert the provided self-retaining scalp retractor to expose skull (Figure 3).
- Place the drill bit with collar into the chuck.
- While holding the drill handle in place, turn the chuck clockwise to tighten the bit.

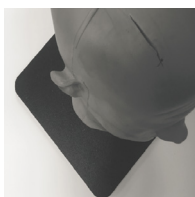


Figure 2

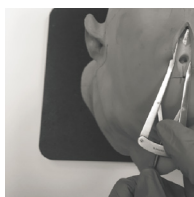


Figure 3

NOTE: To remove the drill bit from the collar, repeat this step, turning the chuck counterclockwise.

- Loosen the collar with the included hex wrench, and carefully slide the collar towards the tip of the bit until the desired skull depth is reached. It is important to note that the collar will not stop the drill. It is designed only to provide the surgeon with a marker for drilling depth.
- Tighten the collar in place with a hex wrench and begin drilling.

CAUTION: Proceed gently through the inner table with care to avoid injury to the dura or parenchyma.

- Check the patency of the burr hole prior to placing the AURA™ ICP Sensor.
- Fenestrate the dura prior to placing the AURA™ ICP Sensor.
- Place the tip of the AURA™ ICP Sensor in the parenchyma through the puncture in the dura (Figure 4) until the AURA™ ICP Sensor body is flush with the outer table of the skull (Figure 5).

CAUTION: To ensure accurate ICP measurement, position catheter tip orthogonal to the inner table of the skull.

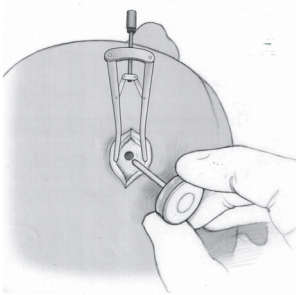


Figure 4

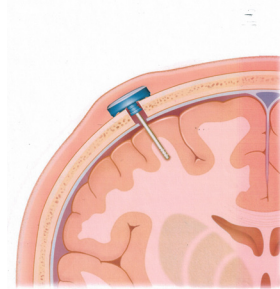


Figure 5

- Using the appropriate technique, close and dress the surgical site (Figure 6).

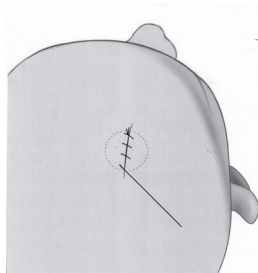


Figure 6

PAIRING THE AURA™ ICP SENSOR TO THE AURA™ MONITOR

- Turn the AURA™ Monitor "ON."
- Place AURA™ Monitor Antenna into Antenna Holster and affix the Antenna Holster to the scalp with provided adhesive backing on the Holster (Figure 7). Position the AURA™ Monitor Antenna overtop the AURA™ ICP Sensor insertion site to pair the AURA™ ICP Sensor with the AURA™ Monitor.



Figure 7: AURA™ Antenna Holster being affixed onto scalp above AURA™ ICP Sensor.

- If no AURA™ Sensor is detected, reposition the AURA™ Monitor Antenna. If no AURA™ ICP Sensor is detected for 30 seconds, the AURA™ Monitor will sit idle and request the user to push the ☒ symbol to pair the AURA™ Monitor to the AURA™ ICP Sensor when the User is ready to reposition the AURA™ Monitor Antenna.

NOTE: See AURA™ Monitor Kit Instructions for Use for related information.

REMOVING AND DISPOSING THE ANTENNA HOLSTER

- Press down the scalp around the Antenna Holster.
- Gently lift up the edges of the adhesive from the patient's scalp.
- Carefully remove the Antenna Holster by peeling it away from the patient's scalp.
- Dispose the Antenna Holster in accordance with applicable hospital policy and regulations.

REMOVING AND DISPOSING THE AURA™ ICP SENSOR

- Prep and drape incision location in a sterile fashion.
- Open incision and carefully remove the AURA™ ICP sensor.
- Using an appropriate technique, close and dress the incision.

NOTE: Disposal of explanted devices is subject to applicable laws and regulations. Dispose in accordance with appropriate hospital policy.

8. MAINTENANCE RECOMMENDATIONS

SERVICE

There are no user-accessible or user-serviceable parts or components in the AURA™ ICP Sensor. If any service, repair, or replacement of internal components is needed, the AURA™ ICP Sensor 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

Prior to each use, you should perform a visual inspection and verify the following:

- Mechanical and functional integrity of all components in the AURA™ ICP Monitoring Kit.
- Legibility and adherence of the AURA™ ICP Sensor labels.
- Perform In-Package Check before unpackaging.

9. TROUBLESHOOTING

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

TROUBLE COMMUNICATING WITH THE AURA™ MONITOR

AURA™ Monitor will indicate inability to communicate with AURA™ ICP Sensor with the alarm message "No Sensor Found." Reposition AURA™ Antenna until good connection re-established between the AURA™ ICP Sensor and the AURA™ Monitor.

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 or Active Implantable Medical Device Directive 90/385/EEC.

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

Federal Communications Commission (FCC) Compliance

FCC ID: 2AJW6-BTAIS-01

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

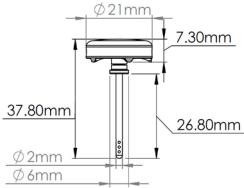
- This device may not cause harmful interference, and
- This device must accept any interference received, including interference that may cause undesired operation

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

11. PRODUCT INFORMATION DISCLOSURE

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12. TECHNICAL 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.	mmHg: 10: TBD 20: TBD 50: TBD
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: TBD 20: TBD 50: TBD
Full-Scale Deflection The time constants for full-scale deflection of the system, with both increasing and decreasing pressure.	TBD
Pressure Range of the AURA™ Intracranial Monitoring System.	X to Z mmHg
Accuracy of ICP range.	X to Y mmHg: ± (TBD) mmHg Y to Z mmHg: ± (TBD)mmHg
Length of time over which the device will maintain the specified accuracy.	29 Days
The size of the intracranial portion of the AURA™ ICP Monitoring System.	
The size of the skull hole needed for safe insertion of the intracranial portion of the AURA™ ICP Monitor.	≥ 6.3mm and ≤ 6.5 mm
The stability of the pressure measurements of the complete system, including any external transducers and strain gauges, over the temperature range of 20 to 39°C (68 to 102°F).	TBD
The expected drift of the zero-point reading of the AURA™ ICP Sensor.	First 24 hours (maximum): TBD ± TBD mmHg 29 days (average): TBDmmHg
The frequency with which the zero point should be corrected because of drift.	TBD
The expected daily drift inaccuracy of the system.	TBDmmHg per day
Software	
Version	TBD
Date of Revision	TBD
Wireless Specifications	
Quality of Service (QoS)	TBD
Transmission Frequency	TBD

Effective Power	2.4 GHz
Operating Range	0 dBm
Security	TBD

13. PACKAGING AND DEVICE SYMBOLS


The following symbols may be used on the AURA™ ICP Monitoring components.

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		CE mark of conformity with the identification of the notified body authorizing use of the mark
	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)		International Protection Rating

	Type BF Applied Part		Class II Electrical Appliance
	Non-Pyrogenic	NA	NA

14. ASSOCIATED DEVICE LABELS





PN I-0031 AURA™ ICP Monitoring Kit Sales Container Label






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


YYYY-MM-DD **QTY** 1

AURA™ Intracranial Pressure Monitoring Kit
For use with the AURA™ Monitor T-101.

REF SP101-A	SN XXXXXXXXXX	LOT XXXXXXXXXX
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 YYYY-MM-DD
  85%
  -119 kPa
  50°C








STERILE

UDI: (01)01234567890123(17)1234567890

Package Contents:

- AURA™ ICP Sensor
- Drill Bit with Collar
- Hex Wrench
- Scalp Retractor
- Antenna Holster
- Patient Registration Card
- Patient Labels (5)
- Instructions for Use

 FCC ID: XXXXXYY
Patent Pending

Before opening the package, run in-package check for pre-implantation status of AURA™ ICP Sensor. Follow steps in AURA™ Monitor Kit Instructions for Use to complete in-package check.

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PN: EMT AD-1413-001 r.C Irvine, CA 92618 USA +1 949 829 1868

PN I-0035 AURA™ ICP Monitoring Kit Patient Label

AURA™ ICP Sensor


 **BRANCHPOINT TECHNOLOGIES**

SN XXXXXXXXXX

LOT XXXXXXXXXX

PN: EMT AD-1415-001 r.B

PN I-0036 AURA™ ICP Monitoring Kit Patient Registration Card

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AURA™ ICP Sensor Patient Registration Card

Copy to: ☐ Patient ☐ Physician ☐ Hospital ☐ Manufacturer

Patient: _____ Tel: _____

Patient Address: _____

AURA™ Model: _____ Serial Number: _____

Hospital: _____ Implant Date: _____ Implant Location: _____

Surgeon: _____ Tel: _____

Branchpoint Technologies, Inc. 1 Technology Drive, Suite I-811, Irvine, CA 92618 Tel: +1 949 829 1868
www.branchpoint.com

PN: EMT CD-3173-001 r.C

PN I-0032 AURA™ ICP Monitoring Kit Sterile Packaging Label



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YYYY-MM-DD
QTY 1

AURA™ Intracranial Pressure Monitoring Kit
For use with AURA™ Monitor T-101.

REF SP101-A	SN XXXXXXXXXX	LOT XXXXXXXXXX
YYYY-MM-DD	85 % 20 %	119 kPa 50 kPa 50°C 0 °C



STERILEEO



UDI: (01)01234567890123(17)1234567890

- Package Contents:
- AURA™ ICP Sensor
 - Drill Bit with Collar
 - Hex Wrench
 - Scalp Retractor
 - Antenna Holster



FCC ID: XXXXXYY
Patent Pending

Inside contents intended for single use only.

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Irvine, CA 92618 USA+1 949 829 1868

PN: EMT AD-1412-001 c C

PN I-0037 AURA™ ICP Monitoring Kit Shipping Container Label

From:
Branchpoint Technologies
1 Technology Drive, Suite i-811
Irvine, CA 92618
USA

To:
Customer
Address 1
City, State Zip
Country

REF

SP101-A

PO #: XX-XXXX

QTY: 1 AURA™ Intracranial Pressure Monitoring Kit



GUIDID: (01)01234567890123(17)1234567890



Shipping Barcode: (01)01234567890123(17)1234567890

PN: EMT AD 1491-001 c A

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AGREEMENT OR THE USE OF OR INABILITY TO USE THE SOFTWARE OR DOCUMENTATION, EVEN IF BRANCHPOINT HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES.

BRANCHPOINT'S TOTAL LIABILITY FOR ANY DIRECT DAMAGES TO YOU, OR ANY THIRD PARTY CLAIMING THROUGH YOU, SHALL NOT EXCEED THE AMOUNT PAID FOR THE SOFTWARE OR FIVE DOLLARS (\$5.00), WHICHEVER IS HIGHER.

BECAUSE SOME JURISDICTIONS DO NOT ALLOW THE EXCLUSION OR LIMITATION OF LIABILITY FOR CONSEQUENTIAL OR INCIDENTAL DAMAGES, THE ABOVE LIMITATION(S) MAY NOT APPLY TO YOU. IN SUCH STATES AND JURISDICTIONS, BRANCHPOINT'S LIABILITY SHALL BE LIMITED TO THE GREATEST EXTENT PERMITTED BY LAW. THIS SECTION SHALL SURVIVE THE TERMINATION OF THE AGREEMENT.

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™ ICP Monitoring Kit Instructions For Use intends to provide all necessary information for proper operation of all AURA™ Sensor models.

Do not operate any component of the AURA™ Intracranial 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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