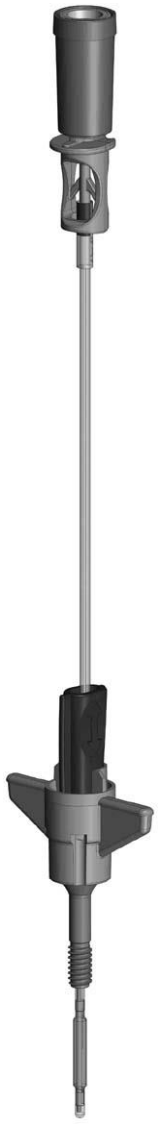
Hummingbird®

Solo ICP Monitoring

Instructions for Use



REF **H110**

DESCRIPTION:

Hummingbird Parenchymal Intracranial Pressure Monitoring Catheter Kit

KIT CONTENTS:

1 Bolted Parenchymal ICP Catheter Kit:
- **Parenchymal ICP Monitoring Catheter**
- **Bolt with Dilator**
- **Drill Bit with Collar and Hex Wrench**

1 Skull Thickness Caliper

1 Stab Incision Knife

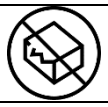
MR
1.5T / 3.0T

P/N: 7000608 Rev D Released Date: 2023-11-22;

Table of Contents

List of Symbols and Terminology

List of Symbols

Symbol	Meaning
	Manufacturer
	Refer to the Instructions for Use (also available at www.irras.com/eifu)
	Expiration Date expressed as year-month-day (yyyy-mm-dd).
	Non-Pyrogenic
	Do not reuse after opening
	Model number
	Lot Number
	Sterile unless package is open. Method of sterilization – ethylene oxide.
	Temperature limits
	Relative humidity limits
	Keep dry
	Keep out of direct sunlight
	Medical Device
	Do not use if package is damaged
	General Warning
	Federal (USA) law restricts this device to sale by or on the order of a physician.
	MR Unsafe
	MR Conditional (refer to MR Conditional Information section): • 1.5 Tesla • 3.0 Tesla

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Terminology

ICP	Intracranial Pressure
ICP Monitoring System	The system is comprised of the HICP200 and a Hummingbird Catheter (in the case of this IFU, the Hummingbird Parenchymal ICP Monitoring Catheter.)
HICP200	The HICP200 is comprised of the Control Module, Patient Cable Module, Monitor Cable and AC Power Supply.
ICP Lumen	The air lumen that connects the pressure-sensing air bladder to the pressure transducer located in the Patient Cable Module and provides communication between the parenchymal ICP monitoring site and the pressure transducer.

SYSTEM OVERVIEW

Description

The Hummingbird Solo ICP Monitoring device (H110), is an advanced bolted parenchymal ICP monitoring technology that is designed for accuracy and ease of use. The H110, when used with HICP200 comprises a system whose principle of operation is based on air-coupled pressure transduction. The H110 measures ICP with a pressure sensing air bladder located in the parenchyma. The HICP200 employs air rather than liquid to transduce pressure waves to the reusable pressure sensor housed in the Patient Cable Module, thus providing for ICP waveform display and calculation of mean ICP pressure. Refer to the HICP200 Quick Reference Guide and Instructions For Use (IFU) for operating instructions. The Patient Cable Module requires no leveling and can be zeroed in-situ. The H110 is packaged in a kit that kit consists of the following items:

- Parenchymal ICP Monitoring Catheter
- Drill Bit Assembly (consisting of Depth Limiting Collar and 4 mm diameter drill bit) and hex wrench
- Bolt with Dilator
- Skull Thickness Caliper
- Stab Incision Knife

NOTE: *The following required items are **not provided** by this kit and must be obtained separately in order to place the H110 and measure ICP:*

- *A cranial access kit that includes a hand drill*
- *HICP200 ICP Control Module* with the appropriate *Monitor Cable* for connection to the patient monitor

Clinical Benefit

The Hummingbird System delivers a unique approach to neuromonitoring by, offering:

- The most accurate parenchymal ICP monitor (*Note: Hummingbird ICP monitoring is the only product on the market that meets NS28 accuracy standards; see Technical Specifications*)
- Ability to be re-zeroed in situ
- Automatic recalibration
- ICP reading independent of patient position
- MR Conditional: 1.5T / 3.0T

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Indications

The H110 is designed for use with HICP200. Together, they comprise a system that is indicated for use in those conditions where continuous monitoring of ICP is required. The device should be utilized by a qualified healthcare professional in clinical conditions that warrant direct measurement of intracranial pressure is clinically important.

Contraindications

Invasive ICP monitoring should not be performed where components of the monitoring system will come into direct contact with any infected tissue. The H110 is contraindicated:

- When the patient is receiving anticoagulants
- When the patient is known to have a bleeding diathesis
- If trained personnel are not available to continuously supervise ICP monitoring

Intended User

The H110 is intended to be used by trained and experienced medical and biomedical professionals:

- A qualified healthcare professional should perform the placement and handling of the ICP catheter.
- Qualified hospital staff (e.g. neurosurgeon, nurse, intensivist, trauma physician, or physician's assistant) should oversee ICP monitoring.

IRRAS USA, Inc. recommends that all physicians, nurses, and technicians who will be using, operating, and maintaining the H110, review the IFU prior to using the system. If there are additional questions after reading this IFU, contact In IRRAS USA, Inc.

Sterility

This product is provided sterile and is for SINGLE USE ONLY. DO NOT RESTERILIZE.

Kit contents are sterile and non-pyrogenic if package is undamaged and unopened. Do not re-sterilize. For single-use only—Do not reuse. If opened and unused, discard immediately.

The H110 has not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. These devices are intended to come into contact with the central nervous system and the ability does not currently exist to destroy possible contaminants such as Creutzfeldt-Jakob Disease agents. Reuse can also compromise device performance characteristics and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality.

MR Compatibility

The Hummingbird H10 has been found to be MR conditional at:

- 1.5 Tesla
- 3.0 Tesla

The HICP200 is MR Unsafe and must not enter the MRI field.

Shipping

Refer to H110 Technical Specifications for shipping conditions.

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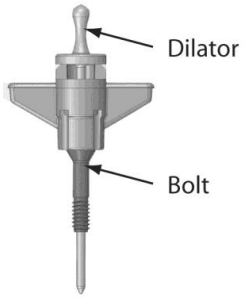
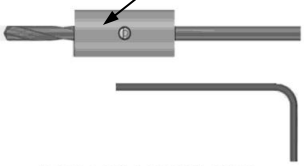
Storage

Store this product in a cool, dry location, away from direct sunlight. Do not remove the product from the packaging until it will be used. Refer to H110 Technical Specifications for storage condition.

Components of the H110



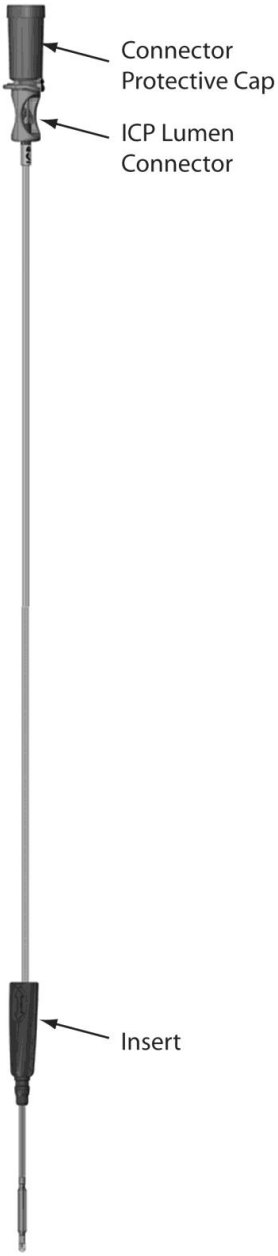
BOLT WITH DILATOR



DRILL BIT ASSEMBLY
WITH HEX WRENCH

STAB INCISION KNIFE

SKULL THICKNESS
CALIPER



CATHETER

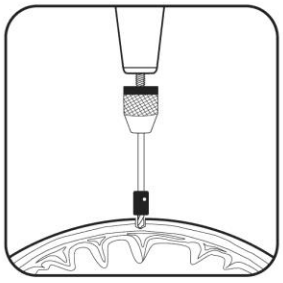
H110 Insertion Procedure

H110 Insertion Summary Figures

STEP 1

Make an incision in the scalp and expose the bone with a self-retaining type retractor, or similar device

STEP 2



Drill hole in skull using the drill bit provided within the H110 kit.

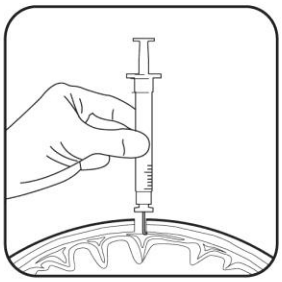
STEP 3

Irrigate the drill hole thoroughly to remove bone shards prior to catheer insertion.

STEP 4

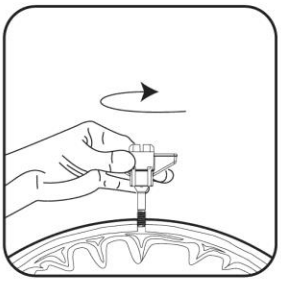
Carefully open the dura in a cruciate fashion using the stab knife provided in the H110 kit.

STEP 5



Measure skull thickness using caliper provided in H110 kit.

STEP 6



Advance Bolt Assembly to level of inner table.

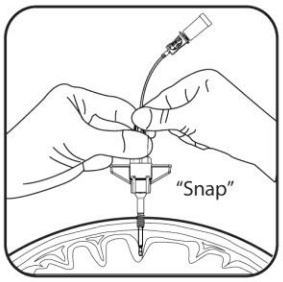
STEP 7

Advance dilator through the bolt to ensure the incision is large enough to accomodate the catheter.

STEP 8a

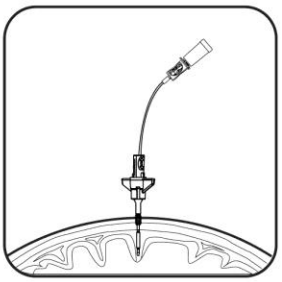
Hold the catheter by the blue insert. Align the insert's ribs to the bolt slots.

STEP 8b



Press down firmly on the insert until the catheter "Snaps" securely into the bolt.

STEP 9



Access complete, remove ICP Lumen Protective Cap and connect to HICP200.

H110 Insertion Procedure Instructions

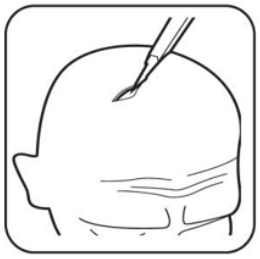
Procedure Preparation

- The following supplies are required:
  - H110 Solo ICP Monitoring device
  - A cranial access kit that includes a hand drill
  - HICP200 with the correct monitor cable for connection to the patient monitor
- Ensure the HICP200 has been properly prepared for the procedure. (For details see the Maintenance and Care section for the HICP200.)
- Connect the HICP200 to the patient monitor a minimum 15 minutes before beginning the procedure to allow the transducer to rise to an equilibrium temperature.
- Open the H110 kit using aseptic technique.

Step 1 – Estimate Skull Thickness and Prepare the Access Site

- Select the catheter insertion site for access to the parenchyma.
- Estimate skull thickness using CT scan(s).
- The operative site should be aseptically cleaned and draped.

  NOTE: *To minimize risk of surgical site infections, it is recommended to prepare the surgical area in accordance with evidenced-based guidelines*, such as Mangram et al. Guideline for Prevention of Surgical Site Infection, 1999. **Infection Control and Hospital Epidemiology**, 20(4), pp. 257-258 and Nichols RL. Preventing Surgical Site Infections: **A Surgeon's Perspective. Emerging Infectious Diseases**. 7(2), Mar-Apr 2001.
- Make an incision in the scalp and expose the bone with a self-retaining type retractor, or similar device.



Step 2 –Prepare the Drill Bit Assembly and Drill

- Adjust the Drill Bit Assembly by loosening the set screw on the Depth Limiting Collar with the provided hex wrench.
- Position the Depth Limiting Collar, exposing the tip of the drill just enough to completely drill through the skull's inner table according to the CT scan estimated skull thickness.

  ⚠ Ensure that the set screw is tight enough to prevent movement of the Depth Limiting Collar on the Drill Bit. However, do not over-torque the set screw.
- Drill a hole in skull using drill bit provided within the kit.

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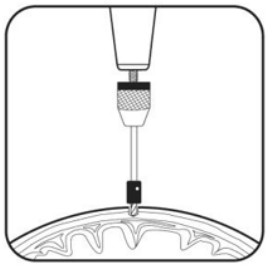


⚠ Do not change the angle of the drill while drilling, as this could cause the hole to become too wide or conical.

⚠ Care should be exercised to prevent excessive penetration and/or damage to the dura, cortex, and cortical vessels.

Step 3 – Irrigate the Twist Drill Hole

- Irrigate the drill hole with sterile saline, ensuring that it is cleared of any debris and/or bone shards.

⚠ Bone shards must be removed prior to catheter insertion. Failure to remove bone shards may damage the catheter's pressure-sensing bladder.

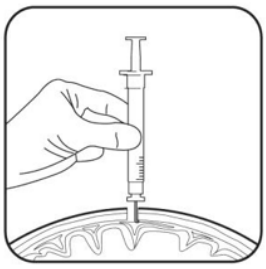
Step 4 – Incise the Dura

- Open the dura by making a cruciate incision, using the stab incision knife (provided in the Hummingbird Solo ICP Monitoring or equivalent). Recommended: use the Dilator provided within the kit, to ensure the incision is large enough to accommodate the catheter.

⚠ Failure to properly incise the dura could cause the catheter's pressure-sensing bladder tear during insertion of the H110 and performance to be compromised.

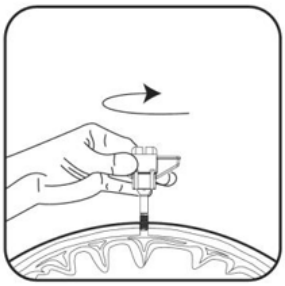
Step 5 – Measure Skull Thickness

Refer to the Skull Thickness Caliper Quick Guide section of this IFU to. Measure the skull thickness.



Step 6 - Fixation of Bolt

- Position the Bolt in the drill hole.
- To advance the Bolt, screw the Bolt clockwise in skull to the depth of the measured skull thickness.



⚠ If the bolt is loose, the insertion procedure must be repeated at a new site.

NOTE: *One full turn (360°) of the bolt advances the bolt 1mm into the skull.*

Step 7 – Ensure Incision is Large Enough for Catheter

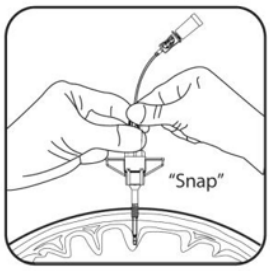
- Advance the dilator through the bolt to ensure the incision is large enough to accommodate the catheter.

Step 8a – Aligning the Catheter to the Bolt

- Holding the catheter by the blue insert, align the insert's ribs to the Bolt's slot (it can fit in one of two positions).

Step 8b - Insertion of the Catheter into the Bolt

- Press down on the insert firmly until the catheter snaps into the bolt.



Step 9 – Access Completed, Zeroing the ICP Monitoring System and Connecting the Catheter

- Ensure the patient monitor has been zeroed per the HICP200 IFU, remembering to disconnect the ICP lumen connector, if connected. The Patient Cable Module Protective Connector can be left in place, as it is vented. The objective is to ensure that the Patient Cable Module is open to atmosphere.

⚠ **Disconnect the ICP catheter from the Patient Cable Module prior to zeroing the patient monitor**, as failure to do so may result in inaccuracy. The Patient Cable Module must communicate with atmospheric pressure when zeroing the patient monitor.

- Connect the ICP lumen connector to the HICP200 Patient Cable Module. A secure connection can be confirmed by a tactile and audible indication.

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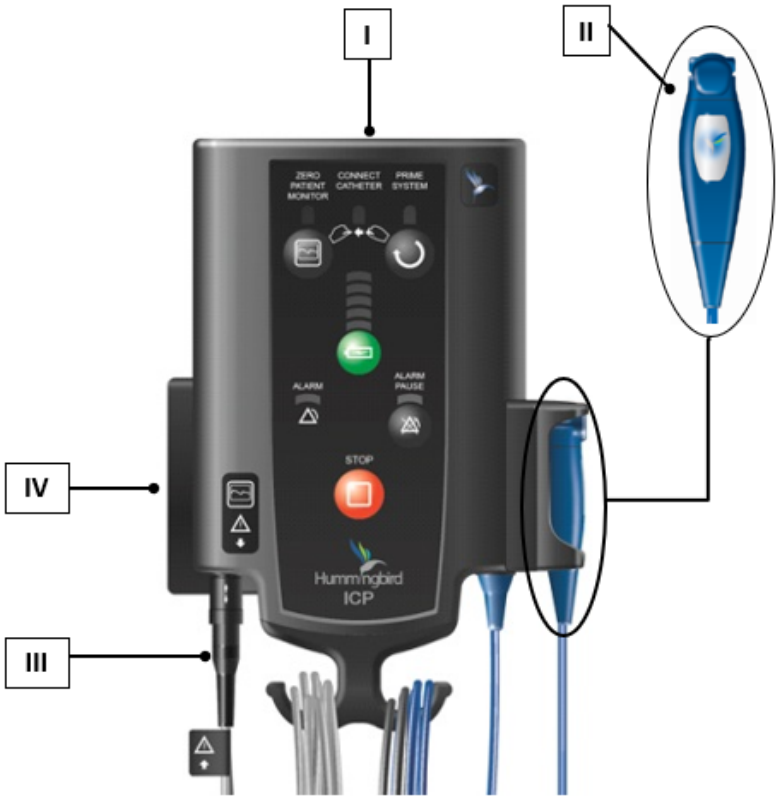
- Operate the HICP200 (figure below) per its instructions for use.



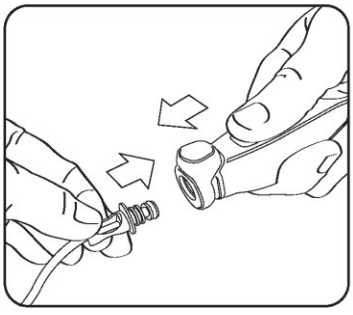
I – HUMMINGBIRD ICP

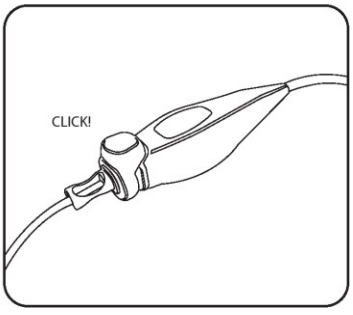
II – PATIENT CABLE MODULE

III – MONITOR CABLE

IV – AC POWER SUPPLY CABLE

CONNECTION / INSERTION





The HICP200 Control Module, Monitor Cable, Patient Cable Module and AC Adaptor are MR-unsafe and must not enter the MRI field.

Maintenance of the H110 and Bolt Insertion Site

⚠ In general, there is a risk of infection due to use of intracranial catheters. It is recommended that the H110 not be left in place for more than 5 days.

ICP Lumen Connector Maintenance

Before cleaning the surface of the ICP Lumen Connector, note the following:

- Use particular care when cleaning around the connectors. Be sure to wipe any excess fluid that accumulates in these areas.
- Always protect the HICP200 Plug when the catheter is disconnected from the HICP200 Patient Cable Module.

Caution: The ICP Lumen Connector must be kept dry. Always protect the catheter connector when the catheter and HICP200 Patient Cable Module are disconnected

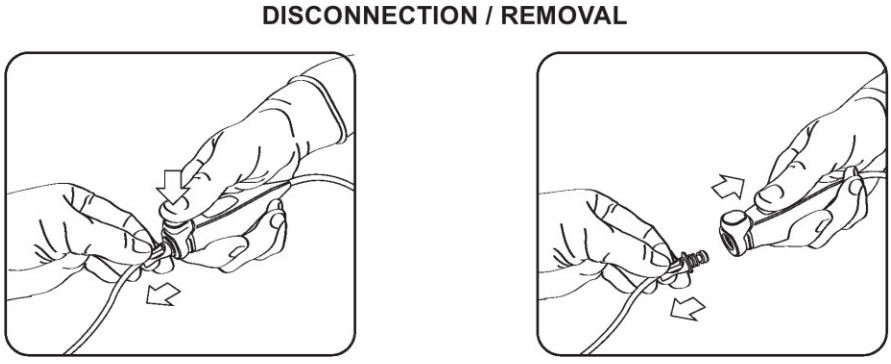
Maintain the Bolt insertion site during ICP monitoring according to standard hospital protocol. Avoid pulling on any of the lines or cables attached to the Bolt or Catheter. Avoid striking the Bolt.

H110 Removal Procedure

H110 Removal Procedure Instructions

Step 1 – Disconnect the Patient Cable Module

- Disconnect the catheter from the Patient Cable Module.
- Before insertion of any components in the Patient Cable Module, inspect the connection port. Use an IPA-moistened (dampened) swab to ensure that any debris has been carefully removed.



Step 2 – Removal of the Catheter from the Bolt

- Holding the bolt in one hand and the catheter in the other hand by its blue insert, pull the catheter straight from the bolt.
- Remove and dispose of the catheter and all accessories in the H110 Catheter Kit per hospital protocol.

Step 3– Removal of the Bolt

- Turn the bolt counter-clockwise to remove it from the skull.

Step 4 – Close surgical site

- Close cranial access site per standard hospital procedure.

Step 5 – Cleaning and care of the HICP200 and its components.

- Reference the HICP200 IFU (a summary is provided below).

MAINTENANCE AND CARE OF THE HICP200

It is recommended that the Control Module and its components be cleaned as soon as is reasonably practical after use. Reference HICP200 IFU for maintenance and cleaning procedures.

Inspect the HICP200 and the cables for wear or damage (e.g., frayed power cord, pinched cable, or cracked enclosure). Do NOT use the HICP200 if there is any sign of wear or damage.

⚠ Do not autoclave, use automated cleaning methods, or immerse the Control Module in liquid as damage may occur. If the Control Module is exposed to liquids, remove the AC Power Supply, dry the unit thoroughly, and send to biomed staff for evaluation before reapplying power.

Recommended Manual Cleaning Method

Using either 70% IPA with a lint free wipe or a Diversey Oxivir-Tb Wipes®, thoroughly wipe all surfaces at least three (3) times and then inspect the surfaces for visible residues. If residues remain, use a new Diversey Oxivir-Tb Wipes® or lint free wipe soaked with 70% IPA and continue wiping the surfaces until they are visibly free of residues.

Recommended Disinfection Agents

The HICP200 has been tested and shown to withstand exposure to 70% IPA and Diversey Oxivir-Tb Wipes®. If used follow standard hospital procedures and manufacturer's instructions for use.

TROUBLESHOOTING THE SYSTEM

Complete the following steps until the problem is resolved:

Check the ICP Lumen Connector

The HICP200 Patient Cable Module and ICP Lumen Connector must be kept dry. Fluid that enters the connector may cause a dampened or flat pressure waveform and/or an inaccurately high-pressure reading. Visually inspect the filter within the ICP Lumen Connector and replace as required.

Re-zero the HICP200

When in Prime Mode, Priming Mode, Run Mode, or Fault Mode, press the "STOP" button to go to Zero Wait Mode and clear any error code. Press the "STOP" button and disconnect the ICP Lumen Connector from the Patient Cable Module. Perform the standard protocol for zeroing the patient monitor.

⚠ **Disconnect the ICP catheter from the Patient Cable Module prior to zeroing the patient monitor**, as failure to do so may result in pressure offset and inaccuracy. The Patient Cable Module must communicate with atmospheric pressure when zeroing the patient monitor.

Confirm that the HICP200 is powered on by checking the indicator lights.
If the HICP200 has no light indication, ensure the Monitor Cable is properly connected to the patient monitor and the monitor is turned on. If the HICP200 is plugged into the patient monitor and has no light indication, (a) plug the AC Power Supply Cable into a compatible outlet, (b) plug the HICP200 into a separate patient monitor module or (c) replace the HICP200 Monitor Cable.

If there is a large change in ICP pressure and waveform, press “PRIME SYSTEM” button on the HICP200.

If the previous trouble shooting steps did not result in a change in status, replace the HICP200.

If none of the above steps remedy the problem, consideration should be given to replace the catheter.

For additional information on troubleshooting, cleaning, and use questions regarding the HICP200, please consult the HICP200 IFU.

Contacting Technical Support

If any component of the ICP Monitoring System fails to perform as specified, and the cause cannot be determined, contact IRRAS USA, Inc. for technical support:

IRRAS USA, Inc
10965 Via Frontera,
San Diego, CA 92127
Tel: 1(800) 213-4604
US.customerservice@irras.com

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H110 TECHNICAL SPECIFICATIONS

Item	Specification
Principle Technology	Pressure Sensor Type: Solid State strain gauge pressure transducer
Operating Atmospheric Pressure (Absolute)	600 to 800 mmHg
Operation Limits	• Temperature = 15 °C to 39 °C • Humidity = 15% to 95% relative humidity, non-condensing
Shipping/Storage Limits	• Temperature = 5 °C to 40 °C • Humidity = Relative humidity ranging from 5% to 95% non-condensing
Rated ICP Accuracy Range	0 to 100 mmHg
Rated Pressure Accuracy	±2 mmHg or 10% whichever is greater **NOTE:** ±2 mmHg from 0-20 mmHg and ±10% from 20 to 100 mmHg (per ANSI / AAMI NS28)
Time of Use (for Assured Accurate Performance)	To maintain accuracy, re-prime is required if the Hummingbird ICP is exposed to a 10 °C (or greater) or 25%RH (or greater) change.
Stability over Temperature Range of 20 to 39°C (68 to 102°F):	Stable if used within 10 °C and 25%RH of initial set-up. **NOTE:** Re-prime required if exposed to a 10 °C (or greater) or 25%RH (or greater) change.
Drift of the Zero Point Reading	The zero point drift does not exceed ±0.15 mmHg per 24 hour period. Re-zeroing the transducer can be performed in-situ and is recommended if the user operates the system outside of the manufacturer's recommendations (temperature or barometric pressure) or the user questions the pressure value displayed on the patient monitor.
Maximum Frequency Response *	11Hz
Slew Rate *	220 mmHg/sec (zero to peak), 180 mmHg/sec (peak to zero)
Time Constant for Full Scale Deflection of the System **	0.045 sec
Catheter Size	5.5 French (0.073")
Drill Hole	4 mm (0.156")
Pyrogenicity	This device has been evaluated for bacterial endotoxins and complies with bacterial endotoxin limits for neurological devices contacting cerebral spinal fluid of < 2.15 EU/device. The Kit is supplied sterile and non-pyrogenic as long as the outer tray in not opened or damaged.

* Lowest maximum frequency/slew rate response measured at 10, 20, and 50 mmHg
** Approximate time constant measured at 10, 20, and 50 mmHg (increasing and decreasing pressures)

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MR Conditional Information

Non-clinical testing has demonstrated the IRRAS USA, Inc. bolt is MR-Conditional. It can be scanned safely under the following conditions:

- Static magnetic field of 3 Tesla or less
- Spatial gradient field of 1100 Gauss/cm (11 Tesla/m)
- Maximum whole body averaged specific absorption rate (SAR) of 2.1 W/kg for 15:00 minutes of scanning

MR Displacement Force and Torque

Entering the MR system using the recommended MR parameters is safe for the IRRAS USA, Inc. bolt in regard to magnetically induced displacement force and torque as long as the bolt is properly affixed to the skull. Non-clinical magnetic displacement force and torque testing have not been performed on the bolt.

MR RF Induced Heating

In non-clinical testing, the IRRAS USA, Inc. bolt produced a temperature rise of less than 0.2°C at a maximum SAR of 2.1 W/kg, as assessed by calorimeter for 15:00 minutes of MR scanning in a 1.5 Tesla Philips Intera (software release 10.6.2.0, 2006-03-10) MR scanner.

In non-clinical testing, the IRRAS USA, Inc. bolt produced a temperature rise of less than 0.3°C at a maximum SAR of 1.6 W/kg, as assessed by calorimeter for 15:00 minutes of MR scanning in a 3.0 Tesla Philips Intera (software: Numaris/4, syngo MR A30) MR scanner.

Image Artifact

MR Image quality may be compromised if the area of interest is in the same area or relatively close to the position of the IRRAS USA, Inc. bolt. Therefore, it may be necessary to optimize the MR imaging parameters for the presence of the device.

MR induced Nerve or Tissue Stimulation

No tests have been performed on possible nerve or other tissue stimulation due to strong gradient magnetic fields resulting in induced voltages. Due to the compact size of the bolt, it can be assumed that induced voltages would result in eddy currents and therefore would contribute to device heating rather than tissue or cell stimulation.

The HICP200 Control Module, Monitor Cable, Patient Cable Module and AC Adaptor must not enter the MRI field.

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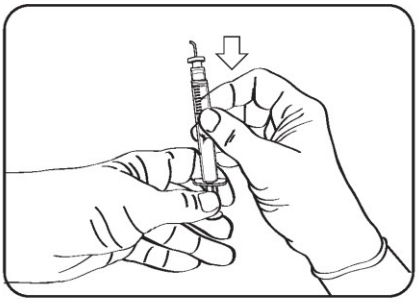
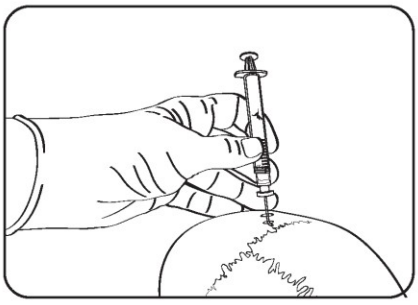
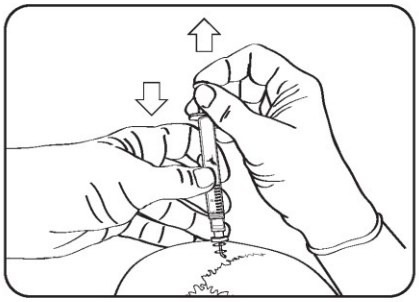
Skull Thickness Caliper Quick Guide



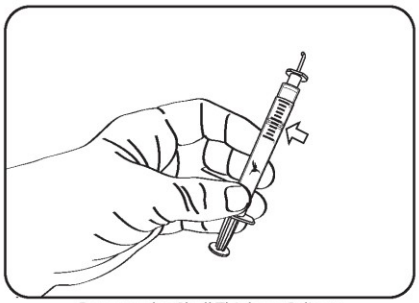
Expose the "L" shaped hook by
moving the syringe body downward.



Fit and secure the "L" shaped
hook under the shelf of the bone.



Holding the plunger, securely advance the
syringe body onto the suface of the outer table.



Remove the Skull Thickess Caliper.
The skull thickness is indicated by the plunger position.
Gradations are in 2mm increments from 0mm to 20mm.

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WARNINGS

Note: Failure to observe one or more of the following warnings could compromise patient safety or result in ICP measurement errors.

Probes must be removed prior to an MRI procedure.

Kit contents are sterile and non-pyrogenic if package is undamaged and unopened. Do not re-sterilize. For single-use only—Do not reuse. If opened and unused, discard immediately.

The H110 is contraindicated

- When the patient is receiving anticoagulants
- When the patient is known to have a bleeding diathesis
- If trained personnel are not available to continuously supervise ICP monitoring

The Hummingbird H110 is not recommended for skull thicknesses less than 4 mm.

IRRAS USA, Inc. recommends that all physicians, nurses, and technicians who will be using, operating, and maintaining the H110, review the IFU prior to using the system. If there are additional questions after reading this IFU, contact IRRAS USA, Inc..

The H110 has not been designed to undergo or withstand any form of alteration, such as disassembly, cleaning or re-sterilization, after a single patient use. These devices are intended to come into contact with the central nervous system and the ability does not currently exist to destroy possible contaminants such as Creutzfeldt-Jakob Disease agents. Reuse can also compromise device performance and any usage beyond the design intent of this single-use device can result in unpredictable use hazards or loss of functionality.

The HICP200 Control Module, Monitor Cable, Patient Cable Module and AC Adaptor must not enter the MRI field.

Ensure that the set screw is tight enough to prevent movement of the Depth Limiting Collar on the Drill Bit. However, do not over-torque the set screw.

Do not change the angle of the drill while drilling, as this could cause the hole to become too wide or conical.

Care should be exercised to prevent excessive penetration and/or damage to the dura, cortex, and cortical vessels.

Bone shards must be removed prior to catheter insertion. Failure to remove bone shards may damage the catheter's pressure-sensing bladder.

Failure to properly incise the dura could cause the catheter's pressure-sensing bladder to tear during insertion of the H110.

If the bolt is too loose, the insertion procedure must be repeated at a new site.

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⚠ **Disconnect the ICP catheter from the Patient Cable Module prior to zeroing the patient monitor**, as failure to do so may result in inaccuracy. The Patient Cable Module must communicate with atmospheric pressure when zeroing the patient monitor.

⚠ In general, there is a risk of infection due to use of intracranial catheters. It is recommended that the H110 not be left in place for more than 5 days.

⚠ Do not autoclave, use automated cleaning methods, or immerse the Control Module in liquid as damage may occur. If the Control Module is exposed to liquids, remove the AC Power Supply, dry the unit thoroughly, and send to biomed staff for evaluation before reapplying power.

CAUTIONS

Note: *Caution statements are used to highlight information relating to special care that should be exercised to ensure the safe and effective use of the* ICP Monitoring System*.*

- **The ICP Lumen Connector must be kept dry.** In the event liquid enters the ICP Lumen Connector, a filter inside the connector will turn blue, indicating that the ICP Lumen Connector needs to be replaced. Ensure the ICP Protective Cap is installed on the ICP Lumen Connector when not connected to the HICP200.
- Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

IRRAS WARRANTY

WARRANTY

All devices bearing the IRRAS USA, Inc. brand are guaranteed to be free of functional defects in workmanship and materials when used normally for their intended surgical use. Any IRRAS USA, Inc. device proving to be defective will be replaced. Any type of misuse or abuse will render the warranty void. IRRAS USA, Inc. assumes no liability if the device is misused.

LIMITATIONS OF LIABILITY

IRRAS USA, Inc. has exercised reasonable care in the manufacture of this device. IRRAS USA, Inc. excludes all warranties, whether expressed or implied by operation of law or otherwise, including, but not limited to, any implied warranties of MERCHANTABILITY or FITNESS, since storage and handling of this device by the user, as well as other factors relating to the patient, the diagnosis, treatment, surgical therapy, and other matters beyond IRRAS USA, Inc. control directly affect this device and the results obtained from its use. IRRAS USA, Inc. will not be liable for INCIDENTAL or CONSEQUENTIAL LOSS, DAMAGE, or EXPENSE directly or indirectly arising from the use of this device. IRRAS USA, Inc. neither assumes, nor authorizes any other person to assume for it, any other or additional LIABILITY or RESPONSIBILITY in connection with this device.

IRRAS USA, Inc. makes no claim for or representations as to the performance characteristics of this product if it is used in conjunction with components of other manufacturers.

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Return Goods Policy

Products must be returned in unopened packages, with manufacturer's seals intact to be accepted for replacement or credit, unless returned due to a complaint or product defect.

Determination of a product defect will be made by IRRAS USA, Inc., which determination will be final. Products will not be accepted for replacement if they have been in the possession of the customer for more than 90 days.

General Information

Contact


Manufacturer

IRRAS USA, Inc.
10965 Via Frontera,
San Diego, CA 92127
Tel: 1-800-213-4604
info@irras.com

Ordering and Customer Service

All products can be ordered through your IRRAS USA, Inc. sales or Customer Service representative.

USA
Email: US.customerservice@irras.com
Tel: 1-800-946-0458

Global
Email: Global.customerservice@irras.com
Tel: +31-20-210-1098

CAUTION: Federal law restricts this device to sale by or on the order of a physician (licensed healthcare practitioner). Do not use if the package has been opened or damaged.

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