Hummingbird®
ICP Monitoring

Instructions for Use

Hummingbird ICP Control Module

Picture for Reference Only

REF **HICP200**

P/N: 7000717 Rev C, Released Date: 2023-11-22;

Table of Contents

List of Symbols and Abbreviations

Symbol	Meaning
	Manufacturer
	Date of manufacture expressed as year-month-day (yyyy-mm-dd).
	Refer to the Instructions for Use (also available at www.irras.com/eifu)
	In the United States of America, federal law restricts this device to sale by or on the order of a physician, physical therapist, occupational therapist, or equivalent healthcare professional.
	Monitor Interconnect Cable Port
	Contents
	Model number
	Serial number
	Type BF applied part (per IEC 60601-1)
	Temperature limits
	Relative humidity limits
	Keep dry
	Keep out of direct sunlight
	Medical Device
	Class II equipment per IEC 60601-1
	Only use the Hummingbird ICP Control Module AC Power Supply with the Hummingbird ICP Control Module device:
	MR Unsafe
	General Warning

System Overview

Description

The **Hummingbird ICP Control Module (REF: HICP200)** is a ICP Control Module with an integrated Patient Cable Module and a Monitor Cable specific to the hospital's monitor. The Hummingbird ICP Control Module, when used with a Hummingbird H110 and H610 devices and a cable compatible with the hospital's monitor, comprises a system whose principle of operation is based on air-coupled pressure transduction.

The Hummingbird Patient Cable Module houses the pressure transducer and provides a high-reliability pneumatic connection to the Hummingbird H110 and H610 devices. The connector provides for audible and tactile feedback indicating a secure connection. The intracranial pressure (ICP)waveform is transduced in the Patient Cable Module and the analog signal is transmitted to the patient monitor, according to AAMI BP-22 standard protocol of 5μV/V/mmHg.

The Hummingbird ICP Control Module monitors the same ICP signal transmitted to the hospital monitor to control and implement system air priming cycle requirements and user interface audio/visual system status.

The Hummingbird ICP Control Module is reusable so long as the instructions contained herein are followed, while the Hummingbird H110 and H610 devices are single-use devices only. The Hummingbird ICP Control Module is compatible with the following patient monitors.

Table 1: Compatible Patient Monitors and Corresponding Monitor-Specific Cable Model Number

Patient monitor	Monitor Cable Model Number	Image
Spacelabs Scout 6-Pin	7000332	
HP / Philips 12-Pin Veridia	7000334	
GE / Marquette Tram 11-Pin	7000335	

The Hummingbird ICP Control Module only supports the following Hummingbird Devices:

Table 2: Compatible Hummingbird ICP Control Module Catheters

IRRAS Model (REF#)	Parenchymal ICP	Bolt Access	Ventricular Drainage	2-probe ports
H110	√	√		
H610	√	√	√	√

Note
Hummingbird Catheter Model #s H110 and H610 are MR Conditional at 1.5/3.0T.

The Hummingbird ICP Control Module with an integrated Patient Cable Module and a Monitor Cable is contraindicated for use in a Magnetic Resonance (MR) environment.

All Hummingbird devices measure ICP with a sensor that sits in the parenchyma. This design eliminates the need for a fluid-filled system to communicate pressure (and carry waves) to an external transducer.

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
- H110 and H610 Catheters are MR Conditional: 1.5T / 3.0T

Indications For Use

The Hummingbird ICP Control Module is designed for use with the Hummingbird H110 and H610 devices. Together, they comprise a system that is indicated for use in those conditions where continuous monitoring of ICP is required. As dictated by clinical judgment, direct measurement of ICP may be obtained from the subdural, parenchymal, or intraventricular locations.

Contraindications

The Hummingbird ICP Control Module with an integrated Patient Cable Module and a Monitor Cable is contraindicated for use in a Magnetic Resonance (MR) environment.

Intended User

The Hummingbird ICP Control Module is intended to be used by the following qualified medical and biomedical professionals:

- A qualified healthcare professional should perform the placement and handling of the catheters.
- Designated qualified hospital staff (e.g. neurosurgeon, nurse, intensivist, trauma physician, or physician's assistant) should operate the Hummingbird ICP Control Module.

MR Compatibility

The Hummingbird H110 and H610 has been found to be MR conditional at:

- 1.5 Tesla
- 3.0 Tesla

Please refer to the MR Conditional Information section in the H110 and H610 IFU.

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

The probes used with the H610 must not enter the MRI field

Shipping
Refer to HICP200 Technical Specifications for shipping conditions.

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 H610 Technical Specifications for storage conditions.

Components of the Hummingbird ICP Control Module

The following section provides information on the different components of the Hummingbird ICP Control Module

Front View

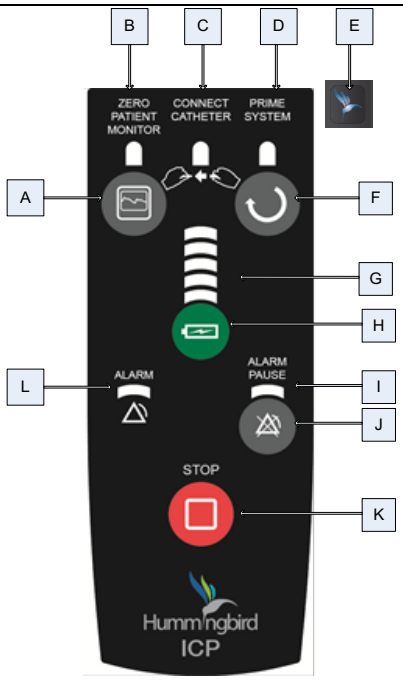
I HUMMINGBIRD ICP CONTROL MODULE

II PATIENT CABLE MODULE

III MONITOR CABLE

IV AC POWER SUPPLY CABLE

Figure 1 – Hummingbird ICP Control Module, Patient Cable Module, and Monitor Cable



A Zero Patient Monitor Button

B Zero Patient Monitor Indicator Light

C Connect Catheter Indicator Light

D Prime System Indicator Light

E Hummingbird, Run Mode Indicator Light

F Prime System Button

G Battery Status Lights/Error Codes

H Battery Status Button

I Pause Alarm Indicator Light

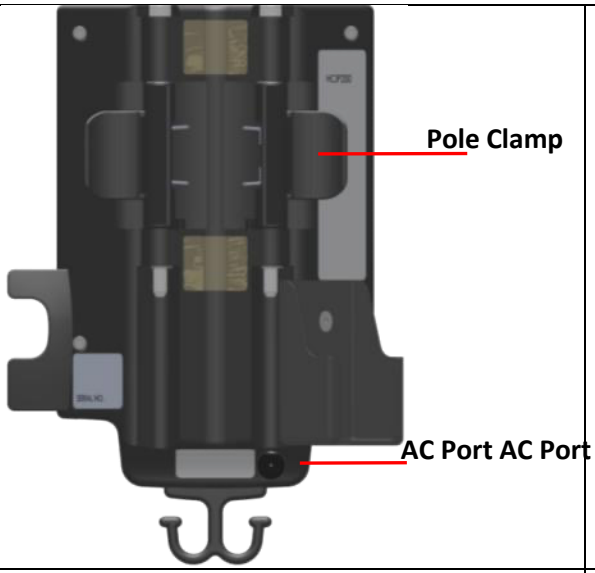
J Pause Alarm Button

K Stop Button

L Alarm Indicator Light

Figure 2 – Expanded view of Front Panel showing Indicator Lights and Control Buttons

Rear/Side/Top View

		
Rear View	Side View	Top View

Hummingbird ICP Control Module Setup

Setting Up The Control Module for the First Time

Step 1: Unpack the System (REF: HICP200)

Remove the contents from the Hummingbird ICP Control Module shipping box and verify the following items are included.

ICP Control Module
Qty. 1

Patient Cable Module
Qty. 1

Monitor Cable
Qty. 1

AC Power Supply
Qty. 1

After unpacking the contents, inspect the shipment for any signs of damage or loss. If any damages are discovered, notify the carrier, the supplier, and retain all shipping cartons for examination.

Step 2: Attach the AC Power Supply

a. Remove the AC Power Supply from the package and connect the AC Power Supply to the Hummingbird ICP Control Module.
   i. Insert the plug end of the AC Power Supply into a grounded AC wall outlet.
   ii. On the back of the Hummingbird ICP Control Module, attach the connector end of the AC Power Supply into the AC Port.

Step 3: Use AC Power to Charge the Battery to Full Capacity

a. ⚠ Keep the Hummingbird ICP Control Module on AC power for at least 10 hours. This will charge the battery to full capacity.

b. After 10 hours, depress battery status button on the main display to verify the display shows five green bars; this indicates the battery has full charge.

c. Use only the provided Hummingbird ICP Control Module AC Power Supply with the Hummingbird ICP Control Module. Plug the other end of the power cord into a hospital, 100-240 V, 50/60 Hz, wall outlet.

Step 4: Connect the Monitor Cable to the Hummingbird ICP Control Module

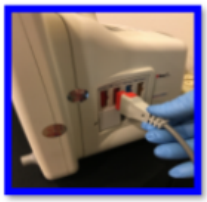
a. Confirm the Monitor Cable has clicked into the Hummingbird ICP Control Module cable port and is secure.

Setting Up Control Module for Clinical Use

The following section contains instructions for positioning the monitor, powering the monitor, and connecting catheters to the monitor.

Attach Control Module To Utility Pole

Plug AC Adaptor into grounded AC wall outlet



STEP 1: Insert monitor cable into Patient Monitor

STEP 2: Zero patient monitor using standard hospital protocol. (Note: Catheter must not be connected to HICP200.)

STEP 3: After zeroing the pressure transducer in the patient monitor, Press Zero Patient Monitor on HICP200

Place Hummingbird Catheter

STEP 4: Connect ICP Catheter Connector to Patient Cable Module

STEP 5: Press 'Prime System' on HICP200

Positioning the Hummingbird ICP Control Module

The Hummingbird ICP Control Module is intended to be securely clamped to an equipment pole or bed support next to the patient. The distance between the patient and the Hummingbird ICP Control Module (Fig. 3) is restricted by the length of the Patient Cable Module (6’ or 2m). The distance between the patient monitor and the Hummingbird ICP Control Module is restricted by the length of the Monitor Cable (10’ or 3m).

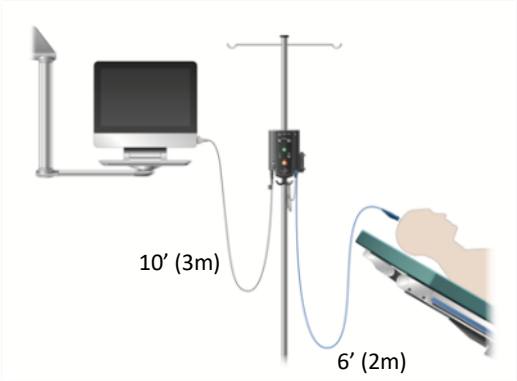


Fig. 3 Positioning the Hummingbird ICP Control Module Control

Attaching to Equipment Pole

The Hummingbird ICP Control Module includes a clamp to attach it to an equipment pole. To attach:

1. Position thumbs on the front panel of the ICP Control Module and the fingers on the spring-loaded tabs (Fig. 4) on the back panel of the Hummingbird ICP Control Module. Squeeze the tabs to open the equipment pole securement feature.
2. Gradually release the squeeze tabs on the pole clamp (Fig. 5) to secure the Hummingbird ICP Control Module to the equipment pole. Ensure that the Hummingbird ICP Control Module is securely attached to the equipment pole by pulling down slightly.

Note that the pole clamp supports equipment poles between 0.8 and 1.5 inches (20 and 38mm) in diameter.

Fig. 4 Spring loaded pole clamp

Fig. 5 Clamp attached to equipment pole

Hummingbird ICP System Setup

The Hummingbird ICP Control Module Monitor Cable is designed to connect directly to the patient monitor with Invasive Blood Pressure (IBP) measurement capability.

Turn the patient monitor on.

To operate:

THINK I.C.P.

Step 1: Insert and Zero

a. Insert the Monitor Cable into the patient monitor's IBP receptacle. A connection from the Hummingbird ICP Control Module to the patient monitor's IBP receptacle will power-up the Hummingbird ICP Control Module.

b. Check functionality of the LEDs, the audible chimes, and the audible beeps. During power-up of the Hummingbird ICP Control Module, confirm that all Hummingbird ICP Control Module lights flash and audible indicators make a sound to ensure the alarm indicators are functioning properly.

Note:	
Connecting the Monitor Cable to the patient monitor's (IBP) receptacle will power-up the Hummingbird ICP Control Module.	

Note:	Indicator:
During power-up of the Hummingbird ICP Control Modul, confirm that all lights flash and audible indicators make a sound. **Confirm that a flat pressure signal appears on the patient monitor.**	

Note:
For ease of use, power-up the Hummingbird ICP Control Module and the patient monitor before beginning the procedure to allow the transducer within the Patient Cable Module to rise to an equilibrium temperature. During setup, if repeating the LED and audible chime / beep functional check is desired, disconnect and reconnect the Monitor Cable from the patient monitor. This action will result in the functional check being repeated and the system going to 'Zero Wait Mode'. If you do not see the expected results on the Hummingbird ICP Control Module or the patient monitor, check all connections. If you still do not see the expected results, do NOT use the Hummingbird ICP Control Module. Contact IRRAS USA, Inc. for assistance.

c. Zero patient monitor. Use the standard hospital protocol to "Zero" the patient monitor.

⚠ **Remove the catheter or HICP200 Plug (whichever is attached) on the Hummingbird ICP Control Module Patient Cable Module prior to zeroing patient monitor.** The Patient Cable Module must communicate with atmospheric pressure when zeroing the patient monitor. Failure to remove the catheter and/or HICP200 Plug from the Patient Cable Module prior to re-zeroing may result in inaccuracy.

d. Press 'Zero Monitor' button on the ICP Control Module.

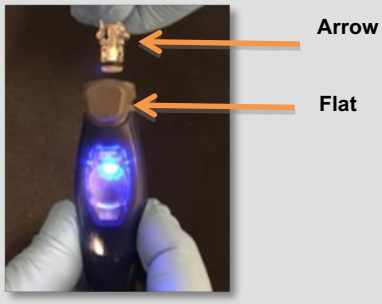
Note:	Indicator:
The Zero patient monitor indicator light on the main panel of the ICP Control Module will go from flashing blue to a solid blue.	

THINK I.C.P.

Step 2: Connect

a. Connect the Hummingbird ICP Control Module Catheter connector to the Patient Cable Module. Push firmly, listening for an audible click.

Note:
Prior to connecting the ICP Catheter to the Patient Cable Module, the Hummingbird ICP Control Module Catheter will have been placed. Please refer to the appropriate Hummingbird H110 and H610 IFU for the catheter placement procedure.

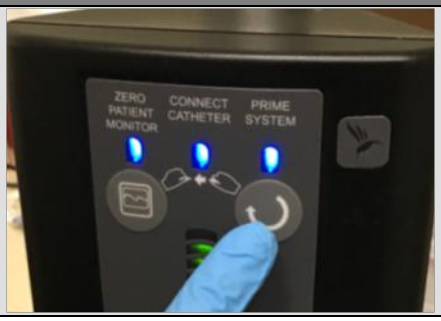
Note:	Indicator:
The arrow marking on the ICP Catheter Connector should align with the flat (keyway) on the Patient Cable Module. Firmly make the connection of the catheter to the Patient Cable Module and ensure that during the connection, there is an audible and tactile indication of a secure connection.	

Note:	Indicator:
The Connect Catheter, Prime System and Patient Cable Module lights will continue to flash after the ICP Catheter Connector and Patient Cable Module have been connected.	

THINK I.C.P.

Step 3: Prime

a. Press the “Prime System” button on the ICP Control Module to prime the catheter.

Note:	Indicator:
Pressing the Prime System button will automatically prime the ICP system with the requisite volume of air to measure ICP.	

Note:
In order to ensure that the proper volume of air is provided to the catheter’s pressure sensing membrane, software is used to control the sequencing of events. Priming the catheter begins with a diagnostic state to ensure that each component is operating correctly. All event commands are routed through the System Safety Integrated Circuit prior to implementation. This provides real-time verification of proper sequencing. During the priming sequence, the ICP waveform on the patient monitor will be a flat line reading approximately 0 mmHg. Do not zero the patient monitor during the priming sequence. Once priming is completed, the Hummingbird icon will change from a blinking blue to a solid blue light to indicate the ICP Control Module is in the Run / Operational state. Confirm that all 4 indicator lights across the top turn to solid blue during Run/Operational state (Zero patient monitor, Connect Catheter, Prime System, and Hummingbird-Run Mode Icon light)

Note:	Indicator:
The Connect Catheter, Prime System, and Hummingbird-Run Mode indicator lights on the main panel of the ICP Control Module will go from a flashing blue to a solid blue once the priming sequence is complete. The Hummingbird Run Mode icon light indicates the ICP Control Module is in the Run/Operational state.	

Run Mode

Set appropriate intracranial pressure alarm limits on the bedside patient monitor.

Note:
For continuous monitoring of intracranial pressure intra-hospital transport, check the battery status lights to confirm that the battery is fully charged before unplugging. If, in Run-Mode, the catheter is disconnected and then reconnected, the Hummingbird ICP Control Module will sense this event and require the user to re-prime the system. The Hummingbird ICP Control Module has BLUE indicator lights for the priming operation. A pulsating light indicates the Hummingbird ICP Control Module is being primed. Solid **BLUE** lights are displayed when the Hummingbird ICP Control Module is in Run Mode. The PRIME button can be pressed when in Run Mode to check the system and to ensure the device is working accurately.

Note:
After the initial prime sequence, the Hummingbird ICP Control Module will automatically perform a priming sequence three times within the first two hours: at 5 minutes, at 30 minutes and at 90 minutes and 60 minutes thereafter. This is designed to check the integrity of the Hummingbird ICP Control Module system. During the priming sequence, the ICP waveform on the patient monitor will be a flat line reading approximately 0 mmHg until priming is completed (note: this shall take less than 35 seconds). After this initial check, the Hummingbird ICP Control Module will typically re-prime automatically every hour.

Patient Transportation

Disconnecting the Patient Cable Module from the ICP Catheter Connector to transport the patient

1. Leave the ICP Control Module on Utility Pole and Monitor Cable attached to the IBP port on the patient monitor.
2. Disconnect the ICP Catheter Connector from the Patient Cable Module.
3. Place the ICP Connector Cap onto ICP Catheter Connector
4. Insert the HICP200 Plug into the Patient Cable Module
5. Place the Patient Cable Module into cable hook at base of ICP Control Module.

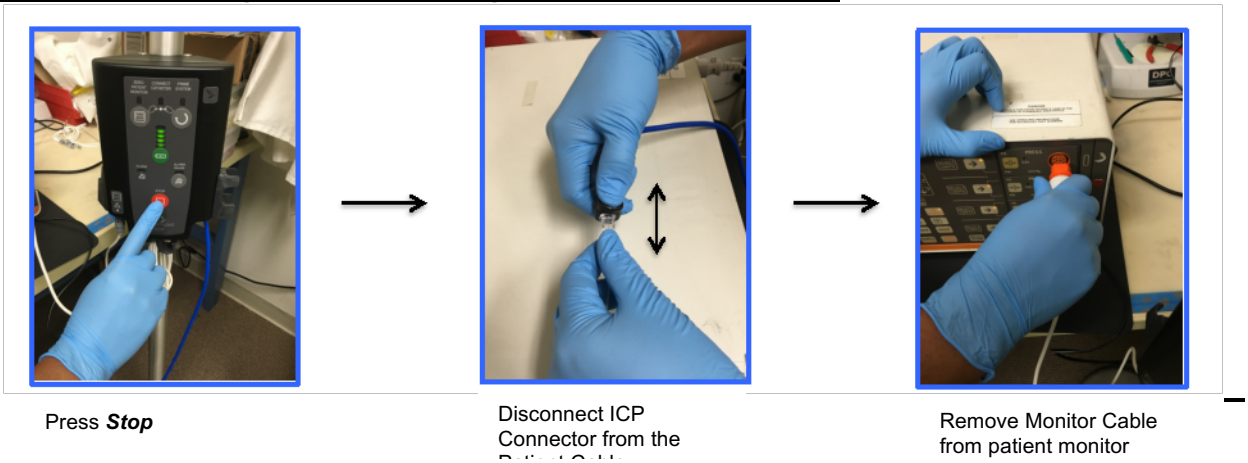
The Hummingbird ICP Control Module with Monitor Cable and Patient Cable Module is contraindicated for use in a Magnetic Resonance (MR) environment.

Note:
The Hummingbird ICP Control Module can remain on the equipment pole or be placed on the bed for transport.

Switching/Setting up a new patient monitor

⚠	Repeat the Hummingbird ICP Control Module Setup procedure, including the **I.C.P.** sequence, whenever changing the patient monitor.

Shutdown / Storage of the Hummingbird ICP Control Module



Press ***Stop***

Disconnect ICP Connector from the

Remove Monitor Cable from patient monitor

Disconnect the Monitor Cable from the patient monitor to turn off the Hummingbird ICP Control Module.

Note:
Disconnecting the Monitor Cable will place the Hummingbird ICP Control Module in standby state. **Ensure that the ICP Control Module is plugged into an AC outlet when stored.** Store the cables with the Hummingbird ICP Control Module. If the AC Power Supply is not plugged into the AC outlet, the battery charge will continue to deplete and the unit will alarm.

Battery Management

If the Hummingbird ICP Control Module is not used for a long duration of time, the battery will lose charge. Always make sure the battery is charged to full capacity prior to use. The Hummingbird ICP Control Module will charge the battery while the monitor is plugged into AC power.

⚠ Routinely check the performance of the battery prior to and during use. When the AC Power Supply is plugged into the outlet, the Battery Status Lights will be on and green. Each light that is on indicates 20% of battery life. When the unit is operating under battery power, the battery status lights will remain off until the Battery Status button is pressed or the battery is less than 40% charged.

The Hummingbird ICP Control Module displays the following symbols on the status bar to indicate battery charge levels when plugged into AC power outlet:

Symbol	Color	Available Charge
	Green	80 to 100%
	Green	60 to 80%
	Green	40 to 60%
	Green	20 to 40%
	Green	Less than 20%

The Hummingbird ICP Control Module displays the following symbols on the status bar to indicate battery charge levels when not plugged into AC power outlet:

Symbol	Color	Available Charge
	Green	80 to 100%
	Green	60 to 80%
	Green	40 to 60%
	Yellow	20 to 40%
	Yellow	Less than 20%

If the level of battery charge falls to 15 minutes or less, the monitor will display an error message on the status bar. If the level of battery charge falls to 5 minutes or less, the monitor will activate a technical alarm.

Storing the Hummingbird ICP Control Module

If the Hummingbird ICP Control Module will not be used for several months or longer, keep the monitor in a dry location that meets the following environmental conditions:

- Temperature: 15 °C to 30 °C
- Humidity: 20% to 80% RH, non-condensing

Also ensure the storage location is safe from any liquids that may drip inside the monitor and damage its internal components.

Using the Cable Hooks to Store the Monitor Cable and Patient Cable Module

The Hummingbird ICP Control Module also includes cables hooks at the base of the unit to store the cables during storage. The cables have a Velcro strap that can be adjusted to secure the cable loop into place.

Using the AC Power Supply Frame

The Hummingbird ICP Control Module comes with an AC Power Supply Frame that is designed to hold the AC Power Supply during transport or storage. Loop the cable and secure with the Velcro strap. Place the AC Power Supply into the frame.

About the Alarms

Physiological alarms are provided by the connected patient monitor and not the HICP200.

Technical alarms are alarms originating in the device due to faults, or scenarios that require user intervention.

The Hummingbird ICP Control Module activates one technical alarm for exceeding the out-of-range ICP alarm limits and several technical alarms for indicating equipment-related problems.

Fault Alarm Level	Fault LED	Alarm Speaker	User Response
Low – Various (See below)	Solid	On – Low priority alarm audio output	Press Stop button, system goes to Zero Wait Mode
Medium - System Fault	Blink Yellow at 0.8 Hz 50% Duty Cycle	On – Medium priority alarm output (3 beeps that repeat)	Press Stop button, system goes to Standby Mode
High – Pressure Output outside of accurate range	Blink Red at 2 Hz 50% Duty Cycle	On – High priority alarm output (10 beeps that repeat)	High priority visual alarm indicates the measured pressure is outside of the pressure accuracy limits of the device. *Note*: High priority visual alarm will be present until measured pressure is within the pressure accuracy range.

Low Priority Fault
Stuck Button Use Fault
Low Battery Voltage Fault
Failure to Vent Fault
Failure to Evacuate Fault
System Leak Fault
Patient Monitor Pulsed / AC Excitation Fault
Patient Monitor Excitation Range Fault

Alarm Battery Charge Level /Priority	Battery LED Indicator	Alarm Speaker Output
Battery ≤ 40% / Low Alarm	Solid yellow	Low priority alarm output. Note: Speaker is off if in fault mode or in a Pressure-out-of-range alarm.

Silencing Audio Alarms Temporarily

To silence an alarm temporarily, press the "Alarm Pause" button on the front panel of the Hummingbird ICP Control Module. This will silence the alarm for either 5 minutes or until the patient's mean ICP value falls within the specified limit. In this silenced state, the status bar indicator light will flashand the alarm indicator light is unaffected. If the patient's mean ICP value does not fall within the specified alarm limit, the alarm tone will resume.

Cleaning the System

Cleaning the System and Components

Before cleaning the surface of the Hummingbird ICP Control Module, note the following:

- Unplug the AC Power Supply from the outlet before cleaning.
- To reduce the risk of shock, follow all safety notices and never open the monitor case.
- The ICP Control Module is designed for surface cleaning only - do NOT immerse.
- Never spray cleaning agents or other fluids directly onto the ICP Control Module.
- Use particular care when cleaning around the connectors. Be sure to wipe any excess fluid that accumulates in these areas.

Cleaning Guidelines

Use the following guidelines when cleaning the Hummingbird ICP Control Module and each of its system components that are listed in the box below:

Note that each of these components should be cleaned immediately after contamination.

- ICP Control Module
- AC Power Supply
- Monitor Cable
- Patient Cable Module

Caution
Only use the cleaning agents listed in this section for cleaning and disinfecting the Hummingbird ICP Control Module and its components. Using solvents or cleaning agents not listed in the cleaning guidelines may damage the plastic exterior of the Hummingbird ICP Control Module.

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

Item	Guideline
Preparation for Cleaning	Ensure that all the connections between the cables, catheter, AC Power Supply, and monitor have been removed before cleaning the Hummingbird ICP Control Module.
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	Hummingbird ICP Control Module 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.
Inspection	After each reprocessing event, visually inspect the ICP Control Module and any of its system components for any wear and tear.
Containment and Transportation	It is recommended that the ICP Control Module and any of its system components be cleaned as soon as is reasonably practical after use.

Cleaning Patient Cable Module

1. Clean the outside of Patient Cable Module with 70% Isopropyl Alcohol (IPA) with a lint free wipe or a Diversey Oxivir-Tb Wipes®.
2. Moisten a swab with 70% IPA.
3. Insert the swab inside the Patient Cable Module connector.
4. Rotate the swab inside the connector.
5. Insert an HICP200 Plug into the Patient Cable Module

Note About Hummingbird Neuromonitoring Catheters

Hummingbird Neuromonitoring catheters are intended for single use only and cannot be resterilized. Hummingbird Neuromonitoring catheters have not been designed for multiple use and have not been tested for resterilizability in the hospital setting. Refer to the Hummingbird H110 and H610 IFU's for additional information.

Trouble Shooting the System

When in Prime Mode, Priming Mode, Run Mode, or Fault Mode, pressing the "STOP" button will allow the user to go to Zero Wait Mode and clear an error code. The patient monitor can be zeroed at any time by pressing the "STOP" button, disconnecting the catheter or HICP200 Plug (whichever is attached) from the Patient Cable Module and performing the standard protocol for zeroing the patient monitor.

⚠ **During trouble shooting**, remove the catheter or HICP200 Plug (whichever is attached) on the Hummingbird ICP Control Module Patient Cable Module prior to zeroing the patient monitor. Failure to remove the catheter and/or HICP200 Plug from the Patient Cable Module prior to re-zeroing may result in inaccuracy.

If the Hummingbird ICP Control Module has no light indication, ensure the Monitor Cable is properly connected to the patient monitor and the monitor is turned on. If the Hummingbird ICP Control Module is plugged into the patient monitor and has no light indication, (a) plug the AC Power Supply Cable in to a compatible outlet, (b) plug the Hummingbird ICP Control Module in a separate patient monitor module or (c) replace the Hummingbird ICP Control Module Monitor Cable.

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

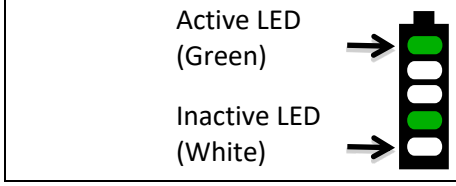
If the previous trouble shooting steps did not result in a change in status, replace the Hummingbird ICP Control Module.

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

Trouble Shooting Error Codes

The following table describes the error modes that can be checked. Pressing the STOP button will display the error code. Pressing the STOP button a second time will clear the error code.

KEY: troubleshooting error codes



Fault LED	Condition / Prompt
	**Priming Fault – gross system leak / catheter not connected to HICP200:** Check to make sure the catheter is connected. Visually check the catheter to make sure the catheter is connected to patient cable module. Re-prime once. If error occurs again, replace HICP200.
	**Battery Fault- charge very low:** Plug AC Power Supply to AC outlet and connect to HICP200.
	**Battery Fault – charge depleted:** Plug AC Power Supply to AC outlet and connect to HICP200.

Fault LED	Condition / Prompt
	**Priming Fault- prime zone not found:** Clear fault and re-prime the system. Monitor the condition.
	**Priming Fault – restricted flow, flow rate too low** Check the Cable to ensure that it is not kinked. Clear fault and re-prime the system. Monitor the condition.
	**Priming Fault - Source pressure too low during prime fill** Check the Cable to ensure that it is not kinked. Check the connector to ensure that it is properly seated in the catheter. Clear fault and re-prime the system.
	**Priming Fault - Source pressure too low during prime fill** Check the Cable to ensure that it is not kinked. Check the connector to ensure that it is properly seated in the catheter. Clear fault and re-prime the system.
	**Priming Fault – pneumatic source or cable kinked** Clear fault and re-prime the system. If fault does not clear, replace Hummingbird ICP Control Module.
	**Priming Fault – pneumatic source or cable kinked** Clear fault and re-prime the system. If fault does not clear, replace Hummingbird ICP Control Module.
	**Incompatible patient monitor:** Change patient monitors.
	**Incompatible patient monitor:** Change patient monitors.

Fault LED	Condition / Prompt
	**Stuck Button** Press each button and attempt to release button. Clear fault. If fault does not clear, replace Hummingbird ICP Control Module.

Note:
For Error Codes that involve a system leak or pneumatic line kink, disconnect the ICP Catheter Connector from the Patient Cable Module and follow THINK I.C.P: Zero patient monitor; Press Zero Patient Monitor button on ICP Control Module; Connect ICP Catheter Connector to Patient Cable Module; Press Prime System on ICP Control Module to prime catheter.

Note:
Any Error Codes that differ from those in the table, please contact IRRAS USA, Inc. Technical Support.

Contacting IRRAS USA, Inc. for Technical Support

About Technical Support

If the Hummingbird ICP Control Module fails to perform as specified, and the cause cannot be determined, do not use or attempt to repair it. Instead, contact IRRAS USA, Inc. for technical service:

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

There are no serviceable parts within the Hummingbird ICP Control Module Device.

Warning
⚠ To reduce the risk of electric shock, do not disassemble the Hummingbird ICP Control Module. Refer all servicing to qualified service personnel at IRRAS USA, Inc. No modification of the Hummingbird ICP Control Module is allowed.

Prior to each use

- If there is any visible debris, clean the Hummingbird ICP Control Module and its cables (See the CLEANING section of these instructions for use).

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

During Operation

- If it is determined that additional priming be completed, press the "PRIME Button". Confirm that all LEDs across the top turn **Blue** and are not blinking.

- The Hummingbird ICP Control Module is a precision air management system/pressure sensor and must be handled with care. Do not kink, puncture, or drop the Hummingbird ICP Control Module Patient Cable. A Hummingbird ICP Control Module patient cable that is kinked or damaged must not be used.

- Always inspect the Hummingbird ICP Control Module cables for damage prior to use.

- Always PRIME the Hummingbird ICP Control Module after reconnecting the catheter to the Hummingbird ICP Control Module.

- Use of excessive force on the components of the Hummingbird ICP Control Module may cause damage. All mechanical features of the Hummingbird ICP Control Module can be operated without the use of excessive force.

- The Patient Cable Module housing must be cleaned after each use to ensure saline or body fluid deposits have been removed.

- The Hummingbird ICP Control Module Patient Cable Module must be kept dry. Fluid that enters the connector may cause a dampened or flat pressure waveform and/or an inaccurately high-pressure reading.

Annually or after 6 months or longer in storage

While there are no known limits on shelf life, it is recommended that the following steps be followed. Contact a biomedical engineer or a similarly qualified person to conduct basic safety testing. The biomedical engineer should:

- Check leakage currents
- Check accuracy
- Set-up the Hummingbird ICP Control Module with a bedside monitor
- Apply a test pressure
- Confirm that the Hummingbird ICP Control Module provides the accuracy stated in the SPECIFICATIONS section of these instructions for use
- Plug in the Hummingbird ICP Control Module until the battery status shows that it is fully charged
- Set-up the Hummingbird ICP Control Module with a bedside monitor
- Confirm that the Hummingbird ICP Control Module runs for at least 1 hour

Replacement Parts

The following replacement parts are available:

- Monitor Cable (Monitor specific; contact IRRAS USA, Inc. for model number)

- Hummingbird ICP Control Module AC Power Supply (contact IRRAS USA, Inc. for specific model number).

To maintain the safe and accurate operation of the Hummingbird ICP Control Module, use only IRRAS USA, Inc. authorized replacement parts.

Technical Specifications

The following table lists the technical specifications for the Hummingbird ICP Control Module:

Hummingbird ICP Control Module Specifications and Operating Characteristics

Item	Specification
Dimensions	14 CM x 20 CM x 7 CM (Width x Height x Depth)
Weight	3.0 kg (6.7 lbs.)
AC Power Supply	Use only IRRAS-supplied AC Power Supply
Battery	Lithium ion battery: ➢ Charge time = Battery life will be fully charged within 10 hours ➢ Operation time = 24 Hours (battery fully charged)
Principle Technology	Pressure Sensor Type: ➢ Strain gauge pressure transducer
Out-of-Range ICP Alarm Limit	➢ < -10 or >110mmHg
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 Control Module 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.

Item	Specification
Drift of the Zero Point Reading	The zero point drift does not exceed ±.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 *	10Hz
Slew Rate *	200 mmHg/sec (zero to peak), 180 mmHg/sec (peak to zero)
Time Constant for Full Scale Deflection of the System *	0.04 sec (increasing and decreasing pressures)
Drainage Lumen Dead Space Volume	Refer to the specific Hummingbird H110 and H610 IFU's
Protection Against Electric Shock	Class II, type BF applied parts (Per IEC 60601-1)
Protection Against Harmful Liquid Ingress	IPX-2 (Tested as follows: Spillage of 1L in less than 5 seconds per 60601-1 clause 11.6, 15 minute drip at 15° tilt per 60529 clause 14.2)
Mode of Operation	Continuous
Fire Hazard	Not suitable for use in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide.
Applied Part Type	BF
Required Excitation Voltage From IBP Port	2.4-8.2 VDC

* Results reported at peak pressures of 10, 20, and 50 mmHg

Operation Modes

Item	Specification
Standby Mode	Initializes System
Zero Wait Mode	Entered by connecting Monitor Cable to patient monitor; prompts user to zero patient monitor
Prime Wait	System is ready to be primed
Priming Mode	System is being automatically primed
Run Mode	Allows measurement of ICP to display on patient monitor
Fault Mode	Provided to display and process faults that may occur while the Hummingbird ICP Control Module is in use

Classification and Standards

The IRRAS USA, Inc. Hummingbird ICP Control Module has been designed for continuous operation. The IRRAS USA, Inc. Hummingbird ICP Control Module meets the electrical

safety requirements of:

1. IEC 60601-1, EN 60601-1, AAMI-ANSI ES 60601-1
2. IEC/EN 60601-1-2

Manufacturer's Declaration Table

The information contained in this section (such as separation distances) is in general specifically written with regards to the IRRAS USA, Inc. Hummingbird ICP Control Module.

General Notes

In the event this device interferes with other devices or that other devices interfere with operation of this device, take the following steps:

- Move the devices farther away from each other.
- Move the cords from the devices as far apart as possible.
- If the cords from the devices must cross each other, try to have them cross at right angles (+). Running parallel (||) may increase interference.
- Plug the devices into different outlets. If possible, plug them into outlets on different circuits.

Medical equipment needs special precautions regarding EMC and must be installed and put into service according to the information provided in this IFU. Portable and mobile RF communications equipment (cell phones, wireless networks, etc.) can affect medical equipment. The following tables will help the user understand the EMC environment including how far away wireless devices should be kept to best ensure correct operation of the Hummingbird ICP Control Module.

During immunity testing, the Hummingbird ICP Control Module maintained its ability to monitor pressure within specification or issued an alarm to advise the user that the data was not reliable. Faults could be corrected by cycling the power.

Warning
⚠ Use of accessories and cables other than those specified by IRRAS USA, Inc. may result in increased emissions or decreased immunity of the Hummingbird ICP Control Module. Only use IRRAS USA, Inc. authorized accessories and cables.

Guidance and manufacturer's declaration – electromagnetic emissions

The Hummingbird ICP Control Module is intended for use in the electromagnetic environment specified below. The customer or the user of the Hummingbird ICP Control Module should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11 (150 kHz – 30 MHz)	Class A	The Hummingbird ICP Control Module uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions	Class A	

Guidance and manufacturer's declaration – electromagnetic emissions

The Hummingbird ICP Control Module is intended for use in the electromagnetic environment specified below. The customer or the user of the Hummingbird ICP Control Module should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
CISPR 11 (30 MHz – 1000 MHz)		
Harmonic emissions IEC 61000-3-2	Complies	The Hummingbird ICP Control Module is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

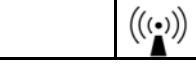
The Hummingbird ICP Control Module is intended for use in the electromagnetic environment specified below. The customer or the user of the Hummingbird ICP Control Module should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity

The Hummingbird ICP Control Module is intended for use in the electromagnetic environment specified below. The customer or the user of the Hummingbird ICP Control Module should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Duration (cycles) 0.5 (50 and 60Hz) Level 0% Duration (cycles) 1 (50 and 60Hz) Level 0% Duration (cycles) 25 (50 Hz) Level 70% Duration (cycles) 30 (60 Hz) Level 70% Duration (cycles) 250 (50 Hz) Level 0% Duration (cycles) 300 (60 Hz) Level 70%	Device shall meet manufacturer's performance criteria at minimum and maximum voltages listed on power supply	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Hummingbird ICP Control Module requires continued operation during power mains interruptions, it is recommended that the Hummingbird ICP Control Module be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the AC mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity

The Hummingbird ICP Control Module is intended for use in the electromagnetic environment specified below. The customer or the user of the Hummingbird ICP Control Module should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 V_{rms} 150 kHz to 30 MHz	3 V_{rms}	Portable and mobile RF communications equipment should be used no closer to any part of the Hummingbird ICP Control Module, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150 kHz to 30 MHz
Radiated RF IEC 61000-4-3	3 V/m 30 MHz to 1000 MHz	3 V/m	$d = 1.2\sqrt{P}$ 30 MHz to 300 MHz $d = 2.3\sqrt{P}$ 300 MHz to 1000 MHz where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1. At 30 MHz and 300 MHz, the higher frequency range applies.
NOTE 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Hummingbird ICP Control Module is used exceeds the applicable RF compliance level above, the Hummingbird ICP Control Module should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Hummingbird ICP Control Module.

[b] Over the frequency range 150 kHz to 30 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Hummingbird ICP Control Module

The Hummingbird ICP Control Module is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. Home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The customer or the user of the Hummingbird ICP Control Module can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Hummingbird ICP Control Module as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz	**80 MHz to 800 MHz**	**800 MHz to 2.5 GHz**
W	$d = 1.2\sqrt{P}$	$d = 1.2\sqrt{P}$	$d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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

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

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

Warnings

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

It is recommended that all physicians, nurses, and technicians who will be using, operating, and maintaining the Hummingbird ICP Control Module, review this Instructions For Use (IFU) prior to using the system. If there are additional questions after reading this IFU, contact IRRAS USA, Inc.

Use of the Hummingbird ICP Control Module is restricted to one patient at a time.

The Hummingbird ICP Control Module with Patient Cable Module and Monitor Cable is contraindicated for use in a Magnetic Resonance (MR) environment.

During setup, remove the catheter or HICP200 Plug (whichever is attached) on the Hummingbird ICP Control Module Patient Cable Module prior to zeroing the patient monitor. Failure to remove the catheter and/or HICP200 Plug from the Patient Cable Module prior to re-zeroing may result in inaccuracy.

Re-prime Hummingbird ICP Control Module if the device is exposed to a 10˚C (or greater) or 25%RH (or greater) change. Failure to re-prime may result in pressure readings higher or lower than the stated accuracy claims, such as in the case of transport from one location to another.

The Hummingbird ICP Control Module is a precision, high-quality medical device. Please observe the following recommendations:

When using the Hummingbird ICP Control Module, always handle with care. If damage is suspected, contact IRRAS USA, Inc.

Avoid locating the Hummingbird ICP Control Module adjacent to or stacking with other equipment. If you must stack or use adjacent equipment, observe the Hummingbird ICP Control Module's operation to verify it is working correctly. Other equipment may not have met the same stringent electromagnetic compatibility (EMC) standards as the Hummingbird ICP Control Module. Concerns include electromagnetism incompatibility, reduced ventilation, or the danger of equipment falling.

To prevent injury to the patient, user, or other persons, or damage to the Hummingbird ICP Control Module, always verify that it is clamped securely to the equipment pole.

Do not exceed the IV Pole manufacturer's guidelines on maximum weight and height. Ensure the Hummingbird ICP Control Module is mounted so that the IV Pole remains stable. If the pole is tipped 10 degrees (as might happen during transport on a ramp), be sure the pole does not tip over.

To reduce the risk of electric shock, do not disassemble the Hummingbird ICP Control Module. Refer all servicing to qualified service personnel at IRRAS USA, Inc.

To prevent damage to the precision equipment or personnel, only use the AC Power Supply provided by IRRAS USA, Inc. The AC Power Supply is identified and labeled to ensure proper identification. Reference the section Abbreviations and Symbols to correctly identify the AC Power Supply.

Danger - Possible explosion hazard if used in the presence of flammable anesthetics.

During initial setup, 10 hours charging on AC power is required to obtain full capacity. When relying on battery power, ensure adequate battery capacity for the intended duration.

Routinely check the performance and desired capacity of the battery prior to and during use.

Connect the monitor to an AC Power Supply immediately if the low battery alarm is activated.

To ensure safe operation:

Use of accessories and cables other than those specified by IRRAS USA, Inc. may result in increased emissions or decreased immunity of the Hummingbird ICP Control Module. Only use IRRAS USA, Inc. authorized accessories and cables.

Only use the Hummingbird ICP Control Module with the cables, catheter systems, and authorized accessories described in these instructions for use. Use of accessories and cables other than those specified by IRRAS USA, Inc. may result in increased emissions or decreased immunity of the Hummingbird ICP Control Module.

Never modify the Hummingbird ICP Control Module or its cables.

Only use IRRAS supplied accessories on the Hummingbird ICP Control Module. This applies in particular to catheters, catheter cables, battery, and AC Power Supply.

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

⚠ The Hummingbird ICP Control Module contains a Lithium Ion Battery. This battery is internal and is not user replaceable. If the battery needs replacement, refer servicing to qualified service personnel at IRRAS USA, Inc."

⚠ Repeat the Hummingbird ICP Control Module Setup procedure, including the **I.C.P.** sequence, whenever changing the patient monitor.

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* Hummingbird ICP Control Module*.*

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Use ECG and respiratory monitoring when using Hummingbird ICP Control Module for patients with downward transtentorial herniation.
- The Hummingbird ICP Control Module is intended to sense pressure and manage the air within the catheter's bladder when used with the Hummingbird ICP Control Module technology.
- The Hummingbird ICP Control Module is intended to be used in a hospital or similar environment. It may be used during intra-hospital transport.
- The IV Pole securement feature has been designed to secure the Hummingbird ICP Control Module to IV pole diameters in the range of 0.8" – 1.5" (20-38mm).
- The Hummingbird ICP Control Module is intended to be used by neurosurgeons, nurses, and other healthcare professionals who have experience with intracranial pressure monitoring.
- Fluid must not enter the Hummingbird ICP Control Module Patient Cable Module.
- To prevent liquid from dripping inside the ICP Control Module and damaging the internal components, do not mount the Hummingbird ICP Control Module underneath an I.V. bag or tube feed. If liquid does drip onto the Hummingbird ICP Control Module, dry the ICP Control Module immediately.
- Only use the cleaning agents listed for cleaning and disinfecting the Hummingbird ICP Control Module and its components. Using solvents or cleaning agents not listed in the cleaning guidelines may damage the plastic exterior of the Hummingbird ICP Control Module.
- 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.
- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

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.

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.

How Supplied

The Hummingbird ICP Control Module is supplied non-sterile.

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.