IRRA*flow*® Tube Set Instructions For Use

IRRA*flow* Tube Set

User Manual

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Table of Contents

IRRA*flow* Control Unit System & Tube Set Overview

General Description

The IRRA*flow* Tube Set is Compatible with of the IRRA*flow* Active Fluid Exchange System.

Figure 1 - IRRA*flow* Tube Set installed on Control Unit

The IRRA*flow* Tube Set is a sterile, single-use medical device that includes: the Intelligent Digital Cassette, IV bag spike, irrigation tubing, and drainage tubing. The intelligent digital cassette docks to the IRRA*flow* Control Unit and facilitates the measurement of intracranial pressure (ICP), irrigation of physician specified fluids, and drainage of delivered fluids and intracranial fluids (such as blood and CSF).

ICP monitoring is performed by pressure sensors within the IRRA*flow* Tube Set. Patient intracranial pressure is measured using a fluid column model that is height-calibrated to the Control Unit's zero pressure location.

The treatment begins by preparing the IRRA*flo*w Active Fluid Exchange System. This involves installing the IRRA*flow* Tube Set (herein described as Tube Set), onto the IRRA*flow* Control Unit (herein described as Control Unit), priming the tubing of the Tube Set, calibrating pressure sensors and selecting treatment settings.

In parallel, the IRRA*flow* Catheter (herein described as Catheter) is inserted in the desired patient location appropriate to the etiology being treated, secured with sutures, and checked for function.

The Tube Set is then connected to the Catheter; the height of the Control Unit is adjusted to align with the patient's external auditory meatus, or top of the eyebrow, prior to beginning treatment.

During treatment, the measured ICP values are shown on the Control Unit display. Alarm levels for high and low ICP are visible on the Control Unit and can be adjusted in the settings.

The treatment may be paused, and the patient can be disconnected from the Control Unit for a short period of time if needed (e.g. for an MRI examination).

Key Functions

Key features provided by the Tube Set include:

- Accurate ICP measurement supplied to IRRA*flow* Active Fluid Exchange System.
- Means to calibrate ICP values to atmospheric pressure. Intuitive design has prominent calibration knob and diagrams to assure correct orientation.
- Fluid delivery and drainage through sterile tubing lines per IRRA*flow* Active Fluid Exchange System settings.
- Universal irrigation spike compatibility with standard IV fluid bags.
- Additional tube line closures (roller clamps) for secure fluid management.
- One way security valve between the irrigation spike and cassette. When the cassette is correctly mounted to the Control Unit, the pump closes the irrigation line. The security valve will prevent the free flow of irrigation fluid into the brain of the patient in the event that the cassette is removed while still connected to the patient, or if the pump's irrigation control malfunctions.

Intended Use

The IRRA*flow* Tube Set and Active Fluid Exchange System are intended to be used for ICP monitoring and drainage of intracranial fluid. The System consists of the IRRA*flow* Control Unit and three disposable parts: the IRRA*flow* Tube Set, the IRRA*flow* Catheter, and the IRRA*flow* Drainage Collection System.

IRRA*flow* Tube Set and System may only be used by medical professionals specifically trained in relevant clinical conditions. The user must monitor both the patient and the equipment throughout the entire treatment.

Intended Users

The IRRA*flow* system and Tube Set are designed for worldwide use in a clinical setting by qualified medical personnel, including the neurosurgeon, nurse, or healthcare professional, who can perform the operation of the IRRA*flow* system.

Indications for Use

The use of the IRRA*flow* Tube Set is indicated when ICP monitoring is required, and for externally draining intracranial fluid as a means of reducing ICP in patients where an external drainage and monitoring system is needed.

Contraindications

The IRRA*flow* Tube Set is not suitable for lumbar drainage.

The use of the Tube Set is contraindicated when trained personnel to supervise monitoring and drainage are not available.

The Tube Set is contraindicated for use in a Magnetic Resonance (MR) environment.

MRI Information

The Tube Set is MR incompatible. Do not bring the Tube Set into the MR environment.

General Safety Warnings and Precautions

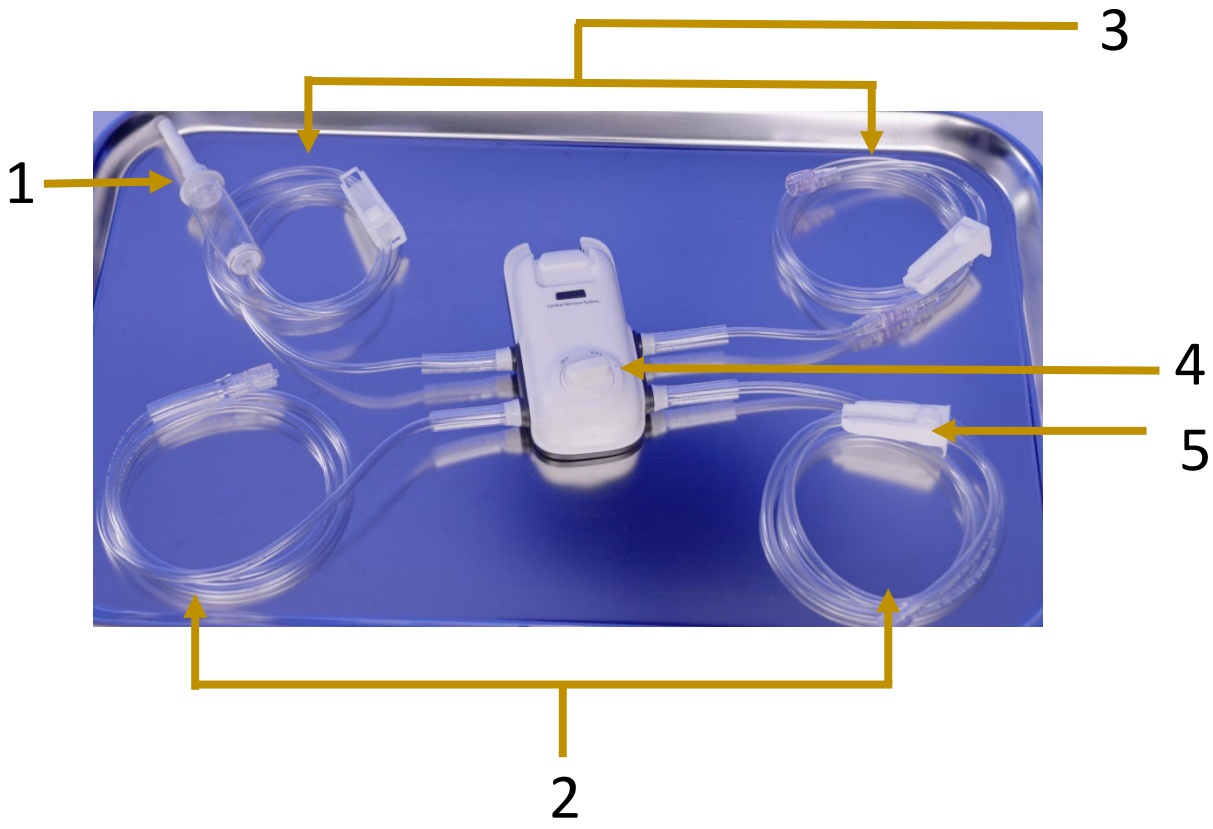
Warnings

- Only medical personnel with training and experience in neurosurgical medical care may perform treatments involving this Device. Use in any other way may potentially harm the patient and/or the user.
- Only IRRA*flow* Tube Set may be used together with IRRA*flow* Control Unit and IRRA*flow* Catheter. Using other components may injure patients.
- To reduce the risk of interference from outside sources, avoid using the IRRA*flow* Tube Set near strong sources of electromagnetic radiation (e.g. diathermy equipment, MRI).
- The patient may not touch the Tube Set during treatment. The treatment may be disturbed if the patient mistakenly touches any part of the equipment.
- Treatment may not be conducted if the surrounding temperature or the atmospheric pressure exceeds any of the limits stated in the manual.
- ICP measurements are not reliable during defibrillation and necessary precautions need to be made in such an event.
- The equipment is not intended for use in oxygen rich environments or in the presence of flammable anaesthetic mixtures or other flammable gases.
- Modification or disassembly of the Tube Set is not permitted. Unauthorized modifications to the Cassette can cause a malfunction resulting in serious patient injury, damage to internal circuitry or electric shock.
- Explosion Hazard: Do not use in the presence of flammable materials (e.g., anaesthetics, solvents, cleaning agents and endogenous gases).
- Stopping treatment too early may impact the patient's outcome.
- Failure to monitor drainage could result in too little or too much drainage.
- Under draining may increase the patient's ICP to an undesirable state.
- Over drainage may result in collapsing the ventricle, pulling the brain tissue away from the dura thus tearing cortical veins and leading to subdural haematoma .
- The IRRA*flow* Tube Set is not to be reused, reprocessed or re-sterilized when open but unused.
- The use of IRRA*flow* Tube Set is limited to ≤ 5 days.

Precautions

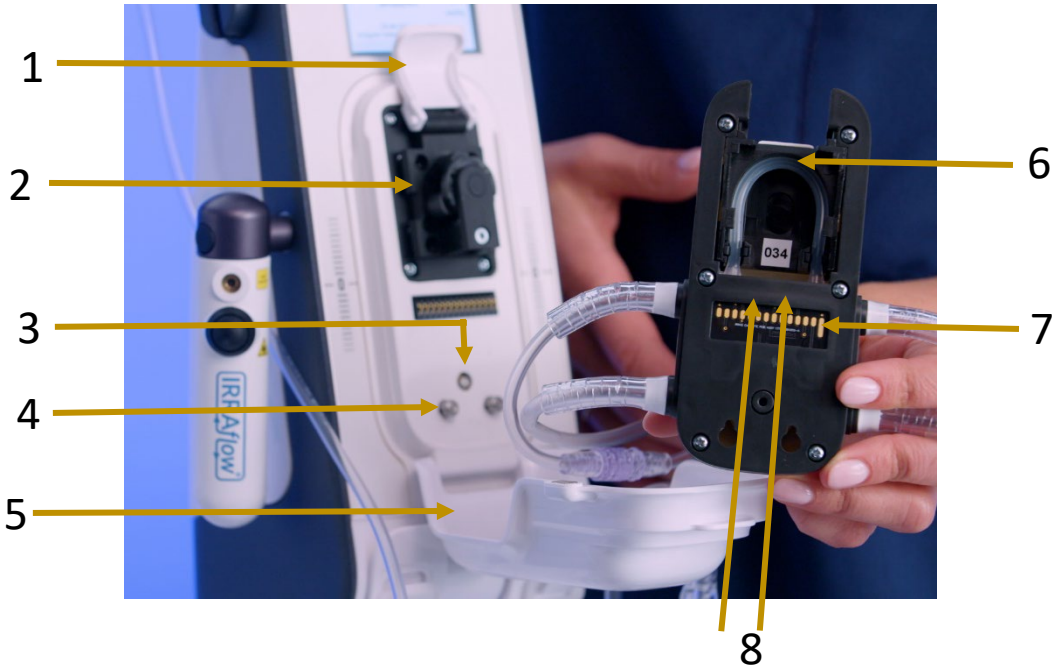
- User should use care when securing Control Unit to pole to avoid tubes being pinched by securement device.
- IRRA*flow* Tube Set and IRRA*flow* Catheter are sterile, single-use components. Using the same component for multiple treatments can potentially harm the patient.
- To avoid contamination, the IRRA*flow* Tube Set is to be handled with care when being attached. Special care should be taken with the connections of the Tube Set to the Catheter and the connection to the fluid drainage bag.
- Use sterile techniques when changing an empty drainage bag for a new bag to prevent patient infection.
- Use sterile techniques when disconnecting the IRRA*flow* Catheter from the IRRA*flow* Tube Set to prevent patient infection.
- Only irrigation fluids specified in this manual can be used when conducting treatments with the IRRA*flow* Active Fluid Exchange System. A completely new and sterile irrigation bag must be used for each new treatment.
- In order to have correct ICP measurements, and thus properly set pressure alarm levels, the 0 point of the control unit must always be aligned with the Catheter's tip position intracranially, which corresponds to the patient's external auditory meatus or top of the eyebrow. Care should be taken when moving the patient in the vertical axis in order to readjust the height of the control unit before restarting treatment.
- IV pole and patient bed wheels are to be locked during the treatment. Care should be taken when moving the patient.
- Set high and low ICP alarm limits before starting treatment according to the treating physician recommendation.
- Always follow the instructions for cleaning and disinfection found in this User Manual. If these instructions are not followed, the unit risks being damaged, and/or the patient and the user may be exposed to contaminated parts.
- If the IRRA*flow* Tube Set is used in a way that contradicts the intended use or by individuals who are not medical personnel with training and experience in neurological/ neurosurgical medical care, injury to the patient and/or the user could occur.
- Over-drainage of intracranial fluid may cause ventricular collapse and injury to the patient. Always monitor drainage progress by checking the drained volume in the drainage bag.
- Never pour liquids on any part of the IRRA*flow* Tube Set. If this occurs, dry off with a clean cloth.
- No tools need to be, nor should be used when handling the IRRA*flow* Tube Set.
- Only accessories delivered with the unit or provided by IRRAS or an IRRAS official distributor may be used. Using accessories from third parties may involve a safety risk and voids any warranty.

Tube Set Layout: Front/Contents



Item	Specification	Description
1	IV spike with drip chamber	• The spike with drip chamber is utilized to puncture the bag of irrigation fluid used throughout treatment before priming
2	Drainage Tubing	• The two bottom lines of tubing coming out of the Intelligent Digital Cassette that connects to the Drainage Bag to store and document patient output
3	Irrigation Tubing	• The two top lines of tubing coming out of the Intelligent Digital Cassette that connect to the irrigation fluid being delivered to the patient
4	Intelligent Digital Cassette	• Cassette that houses the transducers and is the interface between the Control Unit, Irrigation fluid, Drainage Bag, and Catheter.
5	Roller Clamps	• Clamps utilized along all lines of tubing to prevent fluid movement

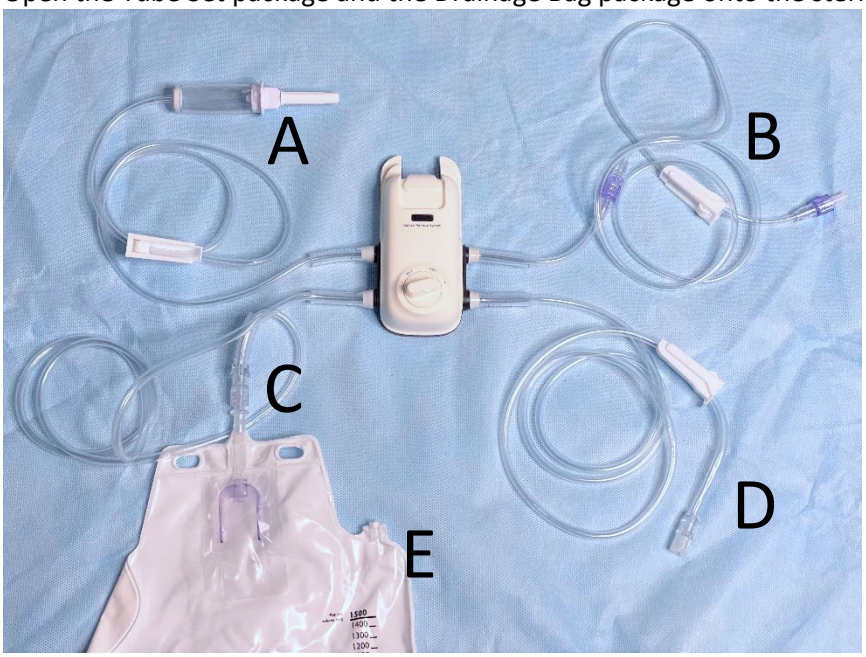
Tube Set Layout: Back



Item	Specification	Description
1	Locking Lever	• Secures and locks the cassette into place on the Control Unit
2	Peristaltic Pump	• Roller pump used to control fluid movement within the Tube Set
3	Pinch Valve	• Safety Mechanism that interacts with the drainage tubing to stop fluid from draining from the patient
4	Pins	• Ensures the cassette is aligned properly • Locks cassette into place by aligning with pin holes
5	Cassette Cover	• Covers and protects the Intelligent Digital Cassette
6	Seated Irrigation Tubing	• The segment of irrigation tubing that must be firmly seated in the cassette to interact with the rolling pump
7	Computer Board	• Allows for control and communication of all electronic components to deliver therapy
8	Transducers	• Two pressure transducers housed on the irrigation line of the cassette • During calibration, the transducers are opened to the atmospheric pressure in the room and ensure accurate ICP measurements

Sterile Preparation of Tube Set

1. Inspect the Tube Set Packaging for damage.
2. Check the expiration date on the packing label.
3. Create a sterile field.
4. Open the Tube Set package and the Drainage Bag package onto the sterile field.



5. Connect the irrigation line (B) to the drainage line (D) - this allows you to completely prime the system. These lines will remain on the sterile field as they connect the catheter prior to starting treatment.
6. Ensure roller clamps are open.
7. Disconnect the legacy drainage bag (E)
8. Connect this drainage line (C) to the buretrol drainage collection bag (see right)
9. Ensure all the roller clamps are open along all tubing. This step is crucial for priming of the system later on in the Set Up for Clinical Use. The Tube Set is now ready to be inserted into the Control Unit

Setup for IRRA*flow* Treatment

Reference IRRA*flow* Control Unit IFU for greater detail on system function. (Document 7000675)

Attach the Cassette to the IRRAflow Control Unit

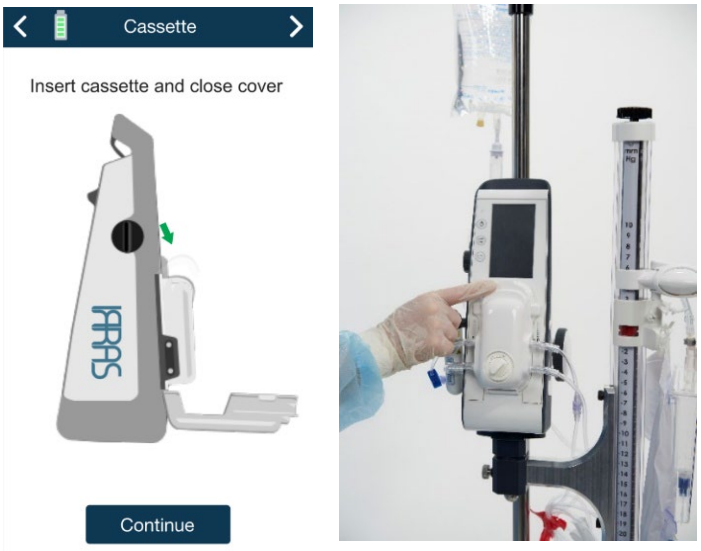
To start the process of Attaching the Cassette onto the Control Unit, power on Control Unit and allow system to go through self-checks.

1. Open the cassette door.
2. The Control Unit will now prompt you to Attach the Cassette, close the Cassette Lever, and then close the Cassette door.

3. To attach the cassette, first insert the bottom and then the top of the cassette. Ensure the cassette is pushed down and firmly seated.

4. Once you have attached the Cassette, close the cassette lever. This will lock the cassette into place.
    - NOTE: The Cassette lever should easily go down and lock the Cassette into place. If excessive resistance is felt, open the Cassette lever, re-insert the Cassette, and try again.

5. Close the Cassette door as illustrated on the Control Unit touchscreen.



Connect Tube Set to Irrigation Fluid

- Using sterile technique, remove Drip Chamber spike cap to pierce port of desired irrigation fluid bag.
- As appropriate, during priming sequence, verify irrigation bag connection is free of leaks and drip chamber fills with fluid.

  Caution: Only irrigation fluids specified in this manual can be used when conducting treatments with the IRRA*flow* Active Fluid Exchange System. A completely new and sterile irrigation bag must be used for each new treatment.

Irrigation Bag and Irrigation Fluids

The IRRA*flow* Active Fluid Exchange System is intended to deliver physician directed fluids. Currently, IRRAS has tested use of standardized, sterile physiological, isotonic, IV solution in 500- or 1000-mL bags (such as a 0.9% solution NaCl and Ringer's).

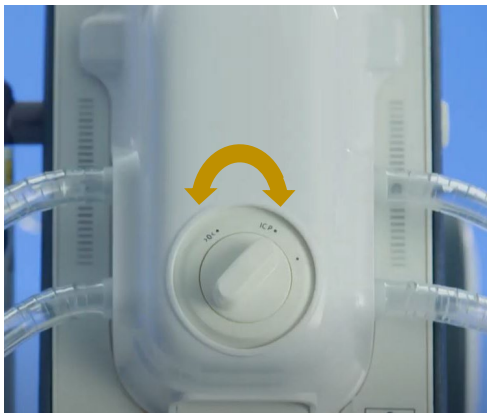
Administration of antibiotics and antithrombotic agents has been reported in literature.

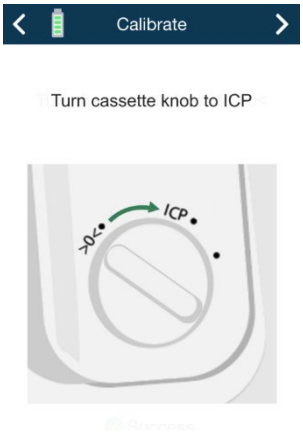
The temperature of the irrigation fluid is at the discretion of the physician.

Calibrate Tube Set:

The Tube Set must be calibrated. Calibrating ensures the transducers are reading the accurate ICP and considers the atmospheric pressure in the room. To calibrate the Tube Set:

1. Turn the cassette knob to the zero position, delineated by the zero icon, and wait for the Control Unit to calibrate.
2. When calibration is complete, the screen will confirm Calibration success. Once you see this message, turn the cassette knob back to the starting position, labeled ICP.





Note: You will be prompted to do this every 24 hours.

Caution: Using calibration as a form of troubleshooting is not recommended. Bench testing has demonstrated that rapid recalibrations increase the likelihood of a leak in the cassette.

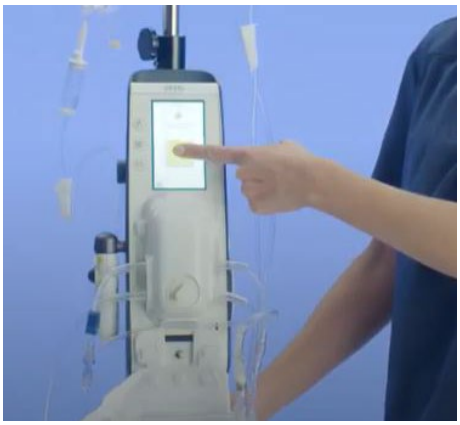
Inserting Irrigation Tubing into the Bubble Sensor

Prior to starting the procedure, the irrigation tubing must be inserted into the bubble sensor on the Control Unit. To insert the irrigation tubing into the Bubble Sensor:

1. Mount the upper tube on the left side of the Cassette in the air sensor slot on the left panel of the Control Unit (when seen from the front).
2. Make sure that the tubing in the air sensor slot is mounted all the way into the slot to ensure contact between tube and air sensor.

Priming

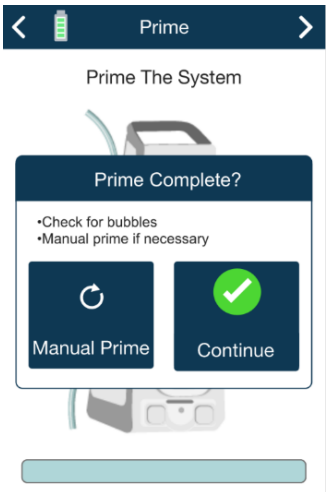
Priming is done to create a fluid filled system so that when you connect the tubing to the Catheter, there is minimal need to open the system during operation.



Before priming, check to make sure all tubing clamps are open.

Follow the instructions provided by the IRRA*flow* Control Unit to facilitate priming.

1. Priming will occur after pressing the prime button and will take approximately 60 seconds.
2. When priming is complete, check the tubing for significant air bubbles.
3. If desired priming is achieved follow the prompts on the software to go to the next screen.



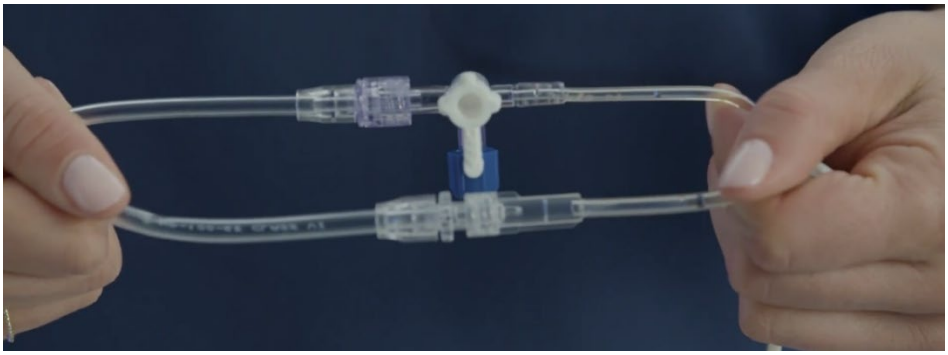
Note: If further priming is needed either press and hold the manual prime button and release once complete or press the auto-prime button.

Note: If there are no bubbles noted, clamp off the roller clamps on the irrigation and drainage tubing. This will make sure that when you connect the tubing to the Catheter, it does not lose its prime.

Attach Catheter

To attach the catheter, using sterile technique:

1. Verify tubing clamps are closed on the Tube Set.
2. Disconnect the Tube Set lines that were connected for priming.
3. Connectors are color-coded to prevent mismatch. Purple connectors are irrigation lines and transparent connectors are drainage lines.
4. Once the catheter is connected, check to make sure **all** roller clamps and stopcocks are open.



For further instructions to setup the IRRA*flow* system please refer to the IRRA*flow* Control Unit IFU.
https://irras.com/product/eifu/

For all product information and training resources, download our free educational app, IRRAS Academy from the app store.

Troubleshooting

Technical Support
+1-800-213-4604

Clinical Watchout	Action
Unable to Prime Intelligent Digital Cassette	• Ensure the tubing in the Intelligent Digital Cassette is fully engaged to the rollers on the peristaltic pump • Locking Lever is in place and not damaged • Remove the cassette from the Control Unit and re-insert
Treatment is on-going, but no flow is seen in the irrigation drip chamber.	• Check if treatment selected is Drain Only or Monitor Only. • Check to see if Treat Above is displayed on the screen. When the Treat Above is displayed on the screen, it means the patients' ICP has fallen below this set parameter. Irrigation and drainage will stop, monitoring only will occur. • Check if infusion bag is empty. • Check to see if the irrigation tubing has become dislodged from the air detector slot.
Treatment is on-going, but no flow is seen in the drainage bag.	• Check infusion rate settings and inspect infusion flow in infusion drip chamber. • If irrigation fluid is being administered, check to see that the drainage tube clamps are closed. They should be open during treatment. • Check to ensure no kink in tubing has occurred, check for alarms • Check to see if there is air in the drainage line, if so, re-priming the system may be necessary. • Check to ensure the drainage bag is not full. • Stop treatment and notify the neurosurgeon.
Treatment cannot be started	• Check alarm symbols on display – is cassette mounted correctly? Is irrigation tube mounted correctly into air detector slot?
Unexpected decrease or increase in drainage	• Check to ensure the Control Unit is level with the patient. • Check to ensure the drainage bag is in the correct position. • Check to ensure tubing or catheter is not kinked. • Adjust irrigation rate or drainage bag height to slow or increase drainage. • Ensure treatment settings are as ordered and reflect the desired clinical therapy to assist in minimizing over and under drainage.
Cassette removed during clinical use	• If intentional, make sure to adjust alarms or turn off the Control Unit and ensure desired amount of drainage is occurring. • If unintentional, re-attach the cassette.
If unable to remove cassette from the Control Unit at the end of Treatment	• If intentional, the Control Unit must be powered on to remove the cassette.

Technical Specifications, Environmental and Handling Conditions

Technical Specifications

Item	Specification
Dead space from Catheter tip to pressure sensor	10 ml
Storage and Transport: Temperature Range	0 to +50 °C
Storage and Transport: Air Humidity	15 – 90%
Storage and Transport: Ambient Pressure	70 – 100 kPa (± 5%)
Maximum Usage Time	5 days

Item	Specification
Defibrillation Proof Applied Part	Cassette Irrigation Line and Catheter
Operation: Temperature Range	+15 to +30°C
Operation: Air Humidity	30 – 90%
Operation: Ambient Pressure	70 – 100 kPa (± 5%)

Symbols and Labels

Symbol and Text	Meaning
	Do not reuse
	European Authorized Representative
	Catalog number
	YYYY-MM-DD Year-Month-Day of expiration
	Do not use device if package is damaged
	Store within given temperature range
	Unique Device Identifier (UDI) 2D Barcode, unique to each device

Symbol and Text	Meaning
	Name and address of manufacturer
	Follow operating instructions
	Batch code
	Sterile; sterilized by ethylene oxide exposure
	For Prescription Use Only
	MR-Unsafe – an item that is known to pose hazards in all MR environments
	The Device Complies with Medical Device Directive 93/42/EEC

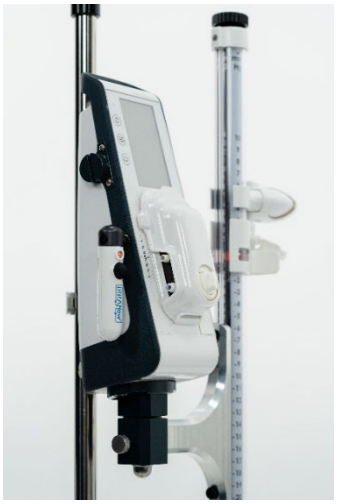
Recommended Accessories and Reordering Information

The IRRA*flow* Active Fluid Exchange System is comprised of 4 primary components:

Catalog Number	Name	Description
ICCU 020	Control Unit	Console, responsible for setting and controlling patient treatments
ICDS020	Tube Set	Sterile, single-use product, facilitates connection between Control Unit and i*n situ* catheter
ICGS020	Catheter	Sterile, single-use product for access and delivery of treatment to patient.
DCS010	Drainage Bag	Sterile, single-use product to connect to Tube Set and collects drained intracranial fluid.

IRRA*flow* Control Unit (ICCU 020)

IRRA*flow* combines drainage and pressure monitoring into one integrated fluid management system. This monitoring system automates pressure data collection, allows for custom alarms when pressure rises, and can actively manage ICP through its proprietary fluid exchange technology. The system has also been designed with an intuitive, touch screen interface that is designed to reduce the burden of care on Neuro ICU staff.



Dynamic fluid management takes place in a closed-circulatory system where pressure is continuously monitored and adjusted through cyclical fluid irrigation and drainage using a unique dual-lumen catheter design. As a result, the drainage rate can be actively guided and optimized for each patient.

Drainage Collection System (DCS 010 and DCS Measuring and Drainage Scale)

The drainage collection system is an external drainage system that is comprised of 3 components:

1. Measuring and Drainage Scale
2. Mounting system that enables the DCS Measuring and Drainage Scale to be mounted to the Control Unit
3. Drainage bag that connects the Tube Set and the DCS Measuring and Drainage Scale

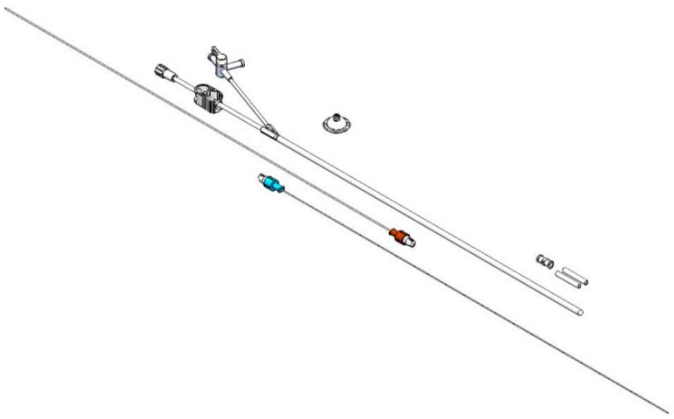
Together, these items use gravity to drain cerebrospinal fluid (CSF) from the patient's ventricles. It is a closed system that enables the critical care professional to efficiently and effectively drain intracranial fluid.

IRRA*flow* Catheter (ICGS020)

Conducting a treatment with the Control Unit requires a single-use, sterile IRRA*flow* Catheter for access and delivery of treatment to the patient.

The Catheter is delivered sterile and includes:

- 40 cm, 9F Catheter with stop cock, pinch clamp, double lumens and graduations every centimeter up to 15 cm from the Catheter tip.
- Catheter cover
- Anti-bacterial unit
- Forceps covers
- Female to female luer connector
- Rigid guidewire
- Flexible guidewire



Note: Catheter configuration and accessories may vary. Please see the Catheter User Manual for the specific Catheter in use for details.

Contact

Manufacturer:

Address: **USA**

IRRAS USA, Inc.
10965 Via Frontera,
San Diego, CA 92127
USA

URL: http://www.irras.com

E-mail address: US.customerservice@irras.com

Phone: 1-800-946-0458

Re-Ordering Information:

Region:	**USA**	**Region:**	**Global**
URL:	http://www.irras.com	**URL:**	http://www.irras.com
E-mail address:	us.customerservice@irras.com	**E-mail address:**	global.customerservice@irras.com
Phone:	+1-800-213-4604	**Phone:**	31 20-210-1098

EC Representative:

Emergo Europe

Westervoortsedijk 60,

6827 AT Arnhem

The Netherlands

Maintenance

The user is not required to perform any preventive maintenance on the equipment. The Tube Set is a single use only device.

PRODUCT INFORMATION DISCLOSURE

IRRAS CORPORATION (“IRRAS”) HAS EXERCISED REASONABLE CARE IN THE SELECTION OF MATERIALS AND THE MANUFACTURE OF THESE PRODUCTS. IRRAS WARRANTS THAT THESE PRODUCTS SHALL CONFORM TO THE PRODUCT LIMITED WARRANTY AS PROVIDED IN THE PRODUCT LABELING OR APPLICABLE PRODUCT CATALOG. THIS WARRANTY IS EXCLUSIVE AND INTEGRA DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO, ANY IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. IRRAS SHALL NOT BE LIABLE FOR ANY INCIDENTAL OR CONSEQUENTIAL LOSS, DAMAGE, OR EXPENSE, DIRECTLY OR INDIRECTLY ARISING FROM USE OF THESE PRODUCTS. IRRAS NEITHER ASSUMES NOR AUTHORIZES ANY PERSON TO ASSUME ANY OTHER OR ADDITIONAL LIABILITY OR RESPONSIBILITY IN CONNECTION WITH THESE PRODUCTS.

APPENDIX A: KEY WATCH OUTS

The user should be aware of the Key Clinical Variables while operating the IRRA*flow* System.

- ☐ **Drainage rate**
  - Ensure the total output volume is equal to or exceeding the irrigation volume.
  - Pay close attention to the output during the first few hours – check every 15 minutes.
  - Drainage rate is determined by bag height and irrigation rate.
    - Lower the bag height = more drainage
    - Lower irrigation rate = more time dedicated to drainage
- ☐ **Irrigation rate**
  - The higher the irrigation rate, the more drainage that will be needed.
  - The lower the irrigation rate, the less drainage that will be needed.
  - More irrigation is needed to facilitate active fluid exchange and dilution of cerebral fluids.
- ☐ **ICP**
  - A higher ICP measurement reflects the patient being less tolerant to changes in fluid volume.
  - A lower ICP measurement reflects the patient being more tolerant to changes in fluid volume.
- ☐ **Treat Above**
  - If the ICP is above the set value, then treatment will occur. If ICP is below the set value, then treatment will stop.
- ☐ **Cassette Calibration**
  - The Tube Set needs to be calibrated every 24 hours to ensure accuracy.
- ☐ **Cassette Replacement**
  - The Cassette should be replaced every 5 days. The system software reminds the user to replace the Tube Set at the 5-day interval.
- ☐ **Hourly Nursing Workflow**
  - Document hourly ICP's
  - Calculate hourly drainage
  - Ensure Control Unit is properly aligned to patient landmarks (tragus and lateral eyebrow).

APPENDIX B: TRANSPORTATION

Patient transportation

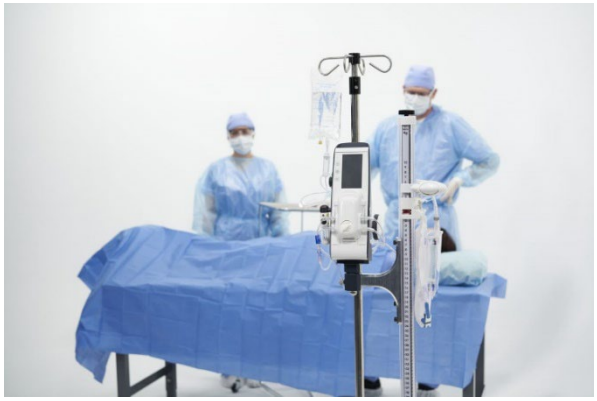
Daily imaging is a frequent occurrence in neurocritical patients and requires transportation of the Control Unit.

1. Pause treatment

2. Clamp off all tubing - Be cognizant of tubing catching onto an external obstruction.

3. Remove the Cassette from the Control Unit

4. Place the irrigation fluid, Cassette, and Drainage collection bag from the IRRA*flow* System in a secure location (e.g. the patient's lap) during transport.



5. When returning from transport, re-set up the Control Unit by referring to the Initial Set Up, Set Up for Clinical Use, and Set Up Unit for Treatment sections (from Control Unit IFU PN 7000675)

6. Prior to resuming treatment, ensure that all roller clamps and stopcocks are open.