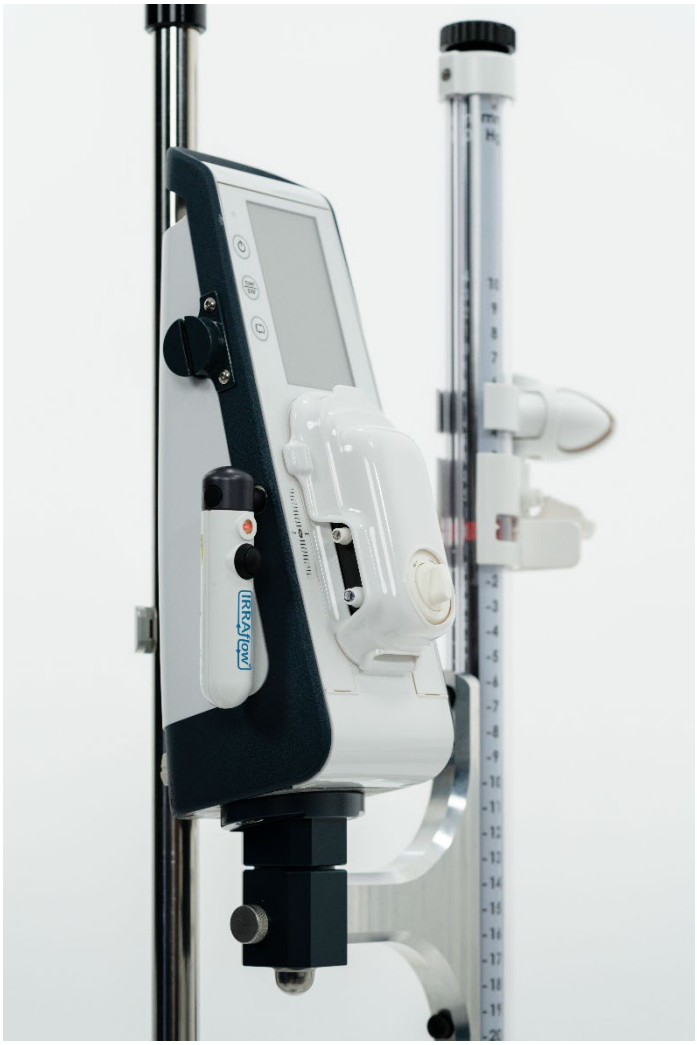
IRRA*flow*® Active Fluid Exchange System



Instructions For Use

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General Description

IRRA*flow* Active Fluid Exchange System (AFES) is an intracranial drainage system intended for use by professional medical hospital personnel, trained and experienced in neurosurgical medical care.

The intracranial pressure (ICP) is kept at a safe level by draining excessive intracranial fluid. The system incorporates an irrigation support mechanism, used to irrigate the system in a controlled, programmed manner. IRRA*flow* is the only system that provides intelligent, automated and gravity driven drainage and irrigation along with precise ICP monitoring in an integrated and easy to use device that is designed to assist in providing intelligent ICP monitoring with intuitive automated controls.

ICP monitoring is measured by pressure sensors in the IRRA*flow* Intelligent Digital Cassette.

The treatment begins by preparing the IRRA*flow* Active Fluid Exchange System. This involves installing the IRRA*flow* Tube Set (herein described as Tube Set or Cassette), onto the IRRA*flow* Control Unit (herein described as Control Unit), priming the tubing of the Cassette, calibrating pressure sensors as well as entering patient settings. In parallel, the IRRA*flow* Catheter (herein described as Catheter) is placed at the correct position in the skull, secured with sutures, and checked for function.

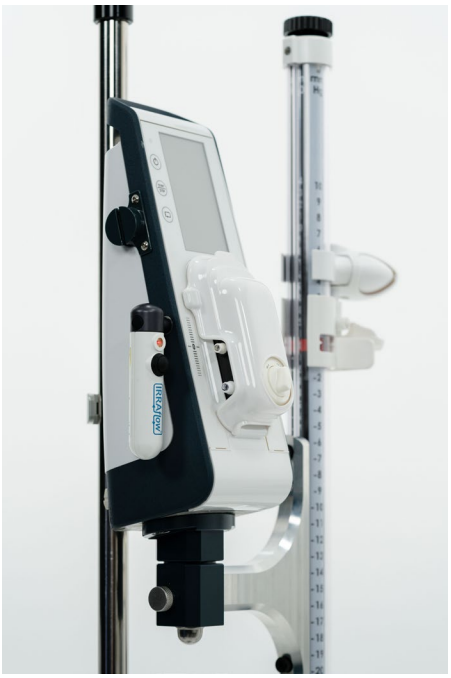


Figure 1 - IRRA*flow* Control Unit

The Cassette 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 the treatment, the measured ICP data is shown on the Control Unit display in the form of numbers. Twelve hours of ICP data is also collected and displayed in Treatment History. 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).

The user may choose to end the treatment at any time.

The equipment uses a three-priority level alarm system intrinsic to the Control Unit to provide different alarms when an error occurs. The three-priority level alarm system is based on the seriousness of the problem and to ensure the patient's safety.

Key Functions

Key features provided by the ICP Monitor include:

- ICP numeric value display
- Treatment state identification: Irrigate, Drain, Monitor
- Programmable fluid irrigation rates
- ICP-Monitored CSF drainage
- User programmable visual and audible ICP alarms that activate if the ICP value exceeds a user-specified limit
- Continuous operation on AC power
- Internal rechargeable battery for up to 60 minutes of continuous operation

Intended Use

The IRRA*flow* Active Fluid Exchange System is intended to be used for ICP monitoring and drainage of intracranial fluid. The System consists of the IRRA*flow* Active Fluid Exchange System and two disposable parts, the Cassette and the Catheter.

The IRRA*flow* Active Fluid Exchange 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.

The Control Unit may only be used with the Cassette, Catheter, and irrigation fluids specified by the manufacturer, IRRAS.

Intended Users

The IRRA*flow* is 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*.

Indications for Use

The use of the IRRA*flow* Active Fluid Exchange System 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* Active Fluid Exchange System is not suitable for lumbar drainage.

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

The Control Unit is contraindicated for use in a Magnetic Resonance (MR) environment. Refer to the IRRA*flow* Catheter IFU for MR environment use.

MRI Information

The Control Unit is MR Unsafe. Do not bring the Control Unit or accessory cables into the MR environment.

Training

The Instructions for Use serve as the primary training resource for Intended Users. Additional training resources offered by IRRAS may include:

- In-Person training by IRRAS personnel
- IRRAS Academy (A mobile application offered through Google Play and Apple App Store)

Contact IRRAS for more information.

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 the IRRA*flow* Cassette and IRRA*flow* Catheter may be used together with IRRA*flow* Control Unit. Using other components can injure patients.
- To reduce the risk of interference from outside sources, avoid using the IRRA*flow* Control Unit and IRRA*flow* Cassette near strong sources of electromagnetic radiation (e.g., diathermy equipment, MRI).
- Misalignment of the IRRA*flow* Cassette on the Control Unit may result in unimpeded flow of irrigation solution.
- The patient may not touch the Control Unit during treatment. The treatment may be disturbed if the patient mistakenly touches any part of the equipment.
- To reduce risk of electrical shock, the operator should take note not to touch the electrical connections for the cassette after the unit is turned on from Standby. Take special precaution not to touch the patient while attaching the cassette.
- 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 Control Unit is not permitted. Unauthorized modifications to the Control Unit 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).
- Electrical Shock Hazard:
    - Use only IRRAS approved power supplies listed in Recommended Accessories and Reordering Information section.
    - Use of another power supply may not provide electrical isolation from supply mains and protection against electrical hazards.
- Do not remove front or rear panels. Service of the IRRA*flow* System shall only be performed by IRRAS authorized service personnel. Contact Technical Support for service and repair.
- Stopping treatment too early may impact the patient's outcome.
- Setting the ICP alarm levels too high could result in a patient experiencing a higher-than-expected ICP. This could negatively impact the patient's clinical outcome.
- Setting the ICP alarm levels too low may result in over drainage.
- Failure to monitor drainage could result in too little or too much drainage.
- Too little drainage may increase the patient's ICP to an undesirable state.
- Too much drainage may result in over drainage.
- The IRRA*flow* Catheter is not suitable for lumbar introduction.
- The IRRA*flow* Cassette and IRRA*flow* Catheter is not to be reused, reprocessed or re-sterilized when open but unused.
- The use of IRRA*flow* Cassette is limited to ≤ 5 days.
- The use of IRRA*flow* Catheter is limited to ≤ 5 days.
- The device is provided with clamps and designed to protect the patient from over-irrigation. Always use device as intended and described within these instructions for use.

Precautions

- The Catheter must not be connected to the IRRA*flow* Control Unit while setting up the Control Unit for treatment. This could potentially harm the patient.
- User should use care when securing Control Unit to pole to avoid being pinched by securement device.
- IRRA*flow* Cassette and IRRA*flow* Catheter are sterile, single-use devices. Using the same component for multiple treatments can potentially harm the patient.
- Take care to follow sterile handling techniques with all IRRA*flow* consumables and always inspect packaging for breaches in sterility.
- The IRRA*flow* Catheter shall be unpacked and prepared in a sterile area and in a sterile manner.
- To avoid contamination, the IRRA*flow* Cassette and IRRA*flow* Catheter are to be handled with care when being attached. Special care should be taken with the Catheter, as well as the connections of the Cassette to the Catheter and the connection to the fluid drainage bag.
- Precautions must be taken when changing an empty drainage bag for a new bag to prevent patient infection.
- Precautions must be taken when disconnecting the IRRA*flow* Catheter from the IRRA*flow* Cassette 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.
- User should ensure the IRRA*flow* Cassette is mounted appropriately onto the IRRA*flow* Control Unit. Misalignment of the IRRA*flow* Cassette on the Control Unit may result in unimpeded flow of irrigation solution.
- When treating patients, the irrigation solution should be positioned above the catheter tip and match the prescribed ICP limit.
- 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 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* Control Unit, Cassette or Catheter 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. The Catheter may be occluded by ventricular collapse. Always monitor drainage progress by checking the drained volume in the drainage bag.
- Clamping the drainage tube may result in retention of fluid or undesirable patient conditions.
- Never pour liquids on any part of the IRRA*flow* Control Unit. If this occurs, dry off with a clean cloth.
- No tools need to be, nor should be used when handling the IRRA*flow* Control Unit. All attempts to open or modify the unit involve risks to the user and potentially to the patient.
- 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.
- Take USB precautions when using the USB contact.

Control Unit Layout: Front

Figure 2 - IRRA*flow* Touch Screen and Buttons Front

Item	Specification	Description
1	LED	• When lit: Indicates when the unit is connected to main power.
2	Standby	• Press for 1 second to turn device on. • Display is lit = Device powered on. • Press for 3 second to turn device off. ○ Note: Device may not be turned off during active treatment. Stop treatment first, then turn off system. • No light = Device powered off.
3	Treatment Start / Stop	• Press for approximately 1 second to start treatment. • Press for approximately 3 seconds to stop treatment.
4	Manual Bolus	• Press for approximately 1 second deliver a manual bolus of fluid.
5	Touch LCD	Allows user interaction with system by direct touch of system icons.

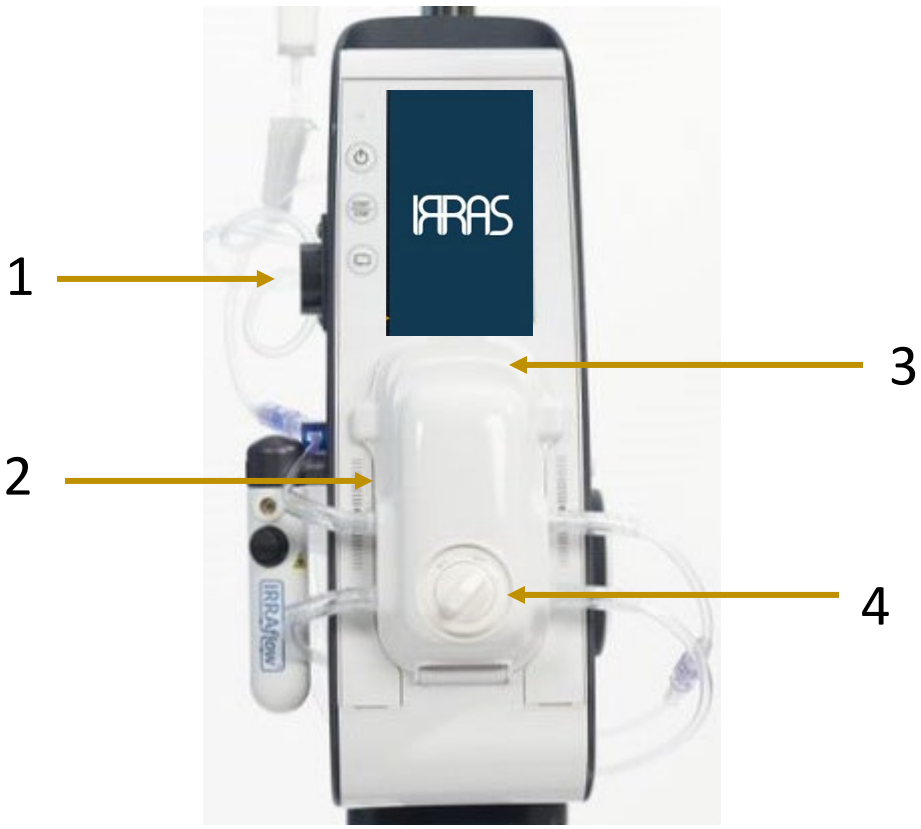


Figure 3 - IRRA*flow* Unit Front

Item	Specification	Description
1	Air Bubble Sensor	• Sensor that detects air bubbles in the irrigation tubing.
2	Cassette	• Cassette that houses the transducers and is the interface between the Control Unit, Irrigation Fluid, Drainage Bag and Catheter.
3	Cassette Cover	• Cover that protects the Cassette.
4	Cassette Knob	• Knob that is utilized to calibrate the transducers located in the Cassette.

Control Unit Layout: Back

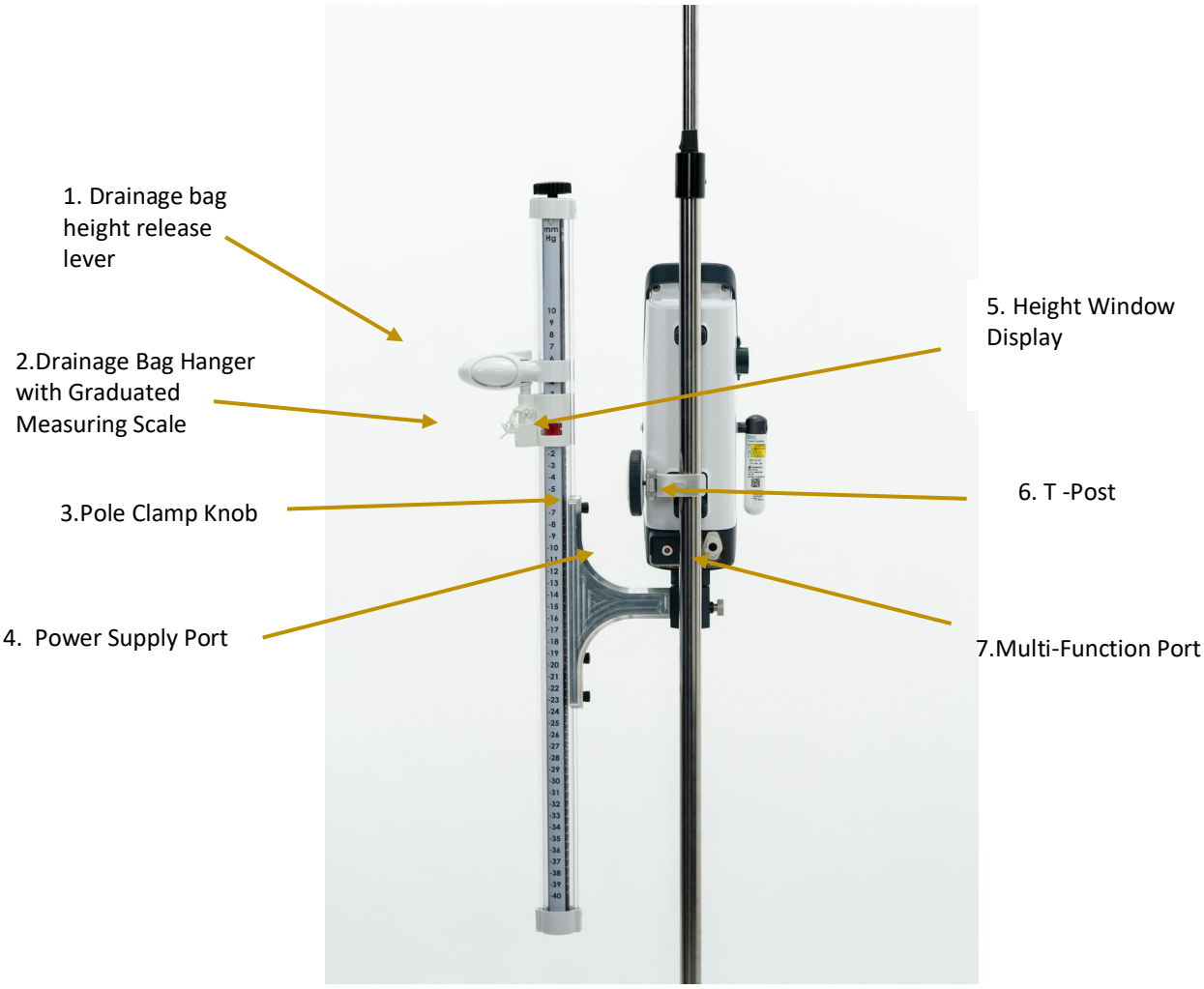


Figure 4 - IRRA*flow* Back

Item	Specification	Description
1	Drainage Bag Height Release Lever	• Mechanism to adjust and set the height of the drainage bag
2	Drainage Bag Hanger with Graduated Measuring Scale	• Mechanism to hold the drainage bag.
3	Pole Clamp Knob	• Device that is utilized to attach the Control Unit to an IV pole.
4	Power Supply Port	• Location to insert 18V power supply.
5	Height Window Display	• Location where the exact height of the drainage bag will be noted
6	T-Post	• Location available to hang the power supply for cord management.
7	Multi-Function Port	• Port is location to attach bedside monitoring cable for continuous ICP monitoring.

Treatment Information

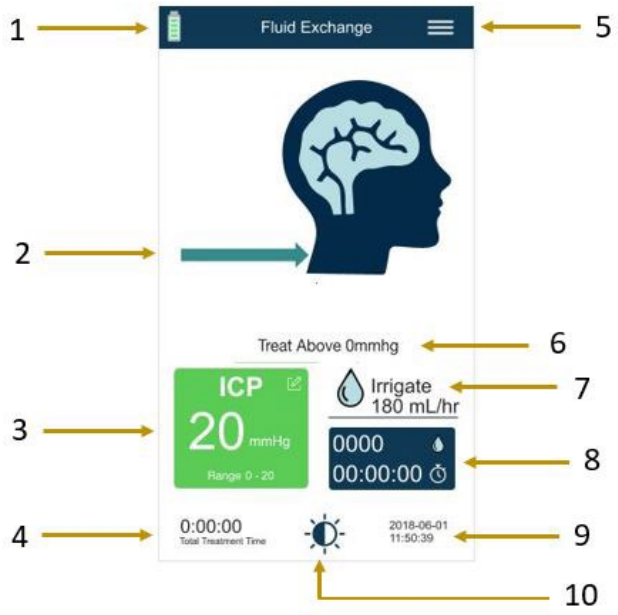


Figure 5 - IRRA*flow* Fluid Exchange Treatment Screen

Item	Specification	Description
1.	Battery indicator	• Displays battery charge status and when the Control Unit requires connection to mains.
2.	Patient fluid flow indicator	• Displays flow direction, blue arrows indicate irrigation, orange arrows indicate drainage, and purple arrows indicate monitoring.
3.	ICP	• Displays current ICP value. Updates once every cycle.
4.	Treatment time	• Indicates the duration of treatment.
5.	Menu	• Houses other functionalities that can be adjusted or utilized during the procedure such as: date, time, changing procedure settings or changing the procedure.
6.	Treat Above	• When Treat Above is triggered, the banner shows why the system is not treating. • Treat Above is user selected and allows treatment to occur only above the pressure setpoint.
7.	Current Mode	• Current procedure state that has been selected by the user. • Pressing on this area of the touchscreen will display the patient's treatment history.
8.	Irrigation Settings	• The Irrigation Rate is displayed above the line • The blue boxed feature is an irrigation timer: irrigation delivered during the displayed time. • Touching this area during treatment allows user to reset irrigation timer to zero irrigation & zero time.
9.	Date and Time	• Current date and time.
10.	Display Brightness	• Pressing the icon toggles between three display brightness settings.

ICP Measurement and Alarm Indicators

Icon	Meaning
	No treatment in progress
	Treatment in progress, no alerts or alarms

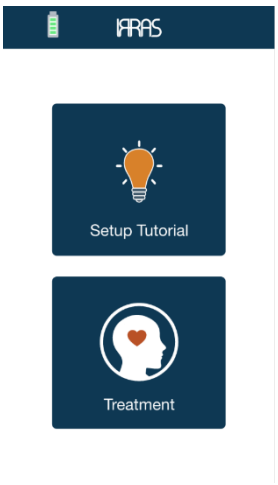
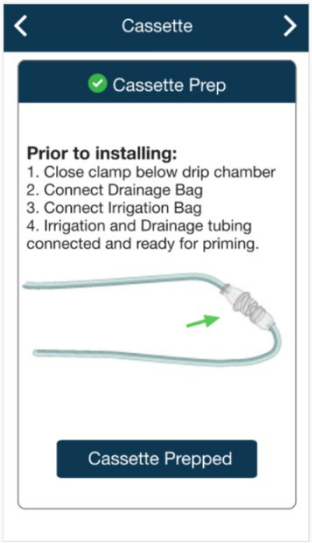
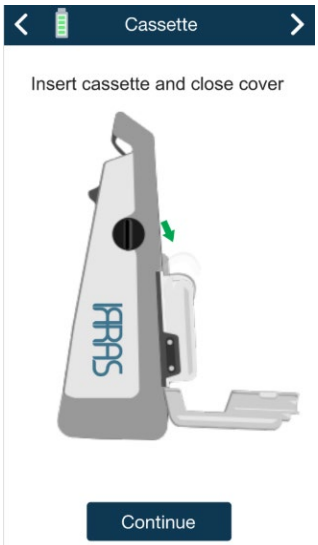
Icon	Meaning
	Low ICP alarm System delivers Low Priority alarm: • System enters 'Monitor Only' state and does not irrigate or drain • When ICP returns to acceptable range, Low ICP alarm resolves
	High ICP alarm System delivers High Priority alarm: • System enters a 'Drain Only' state and opens drain for 2 minutes • After 2 minutes, drain closes and High Priority alarm continues to sound

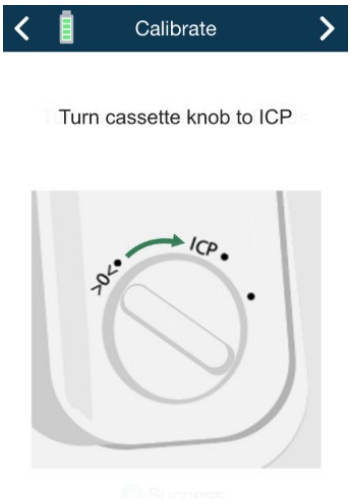
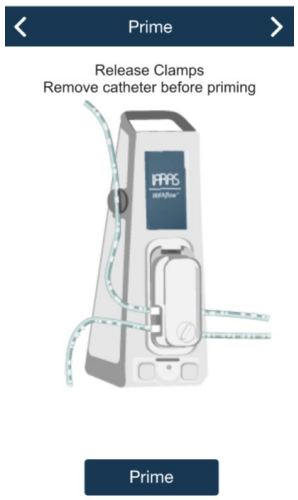
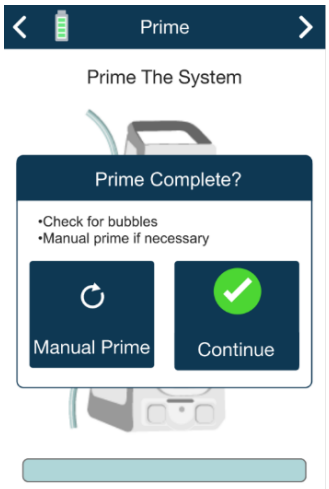
Mode Icons

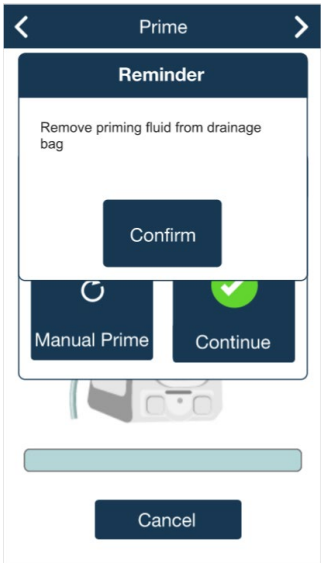
Icon	Meaning
	Treatment not started, or Treatment Paused
	Irrigate

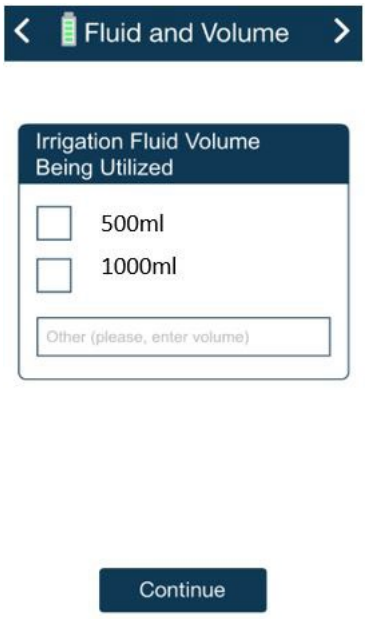
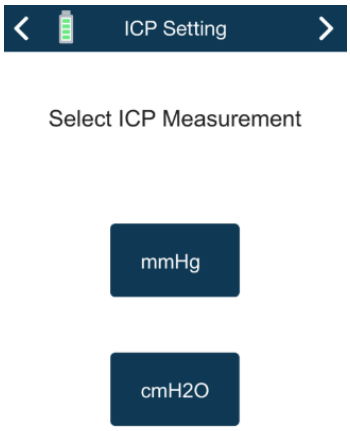
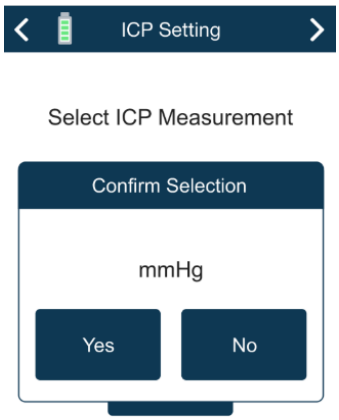
Icon	Meaning
	Drain
	Measure

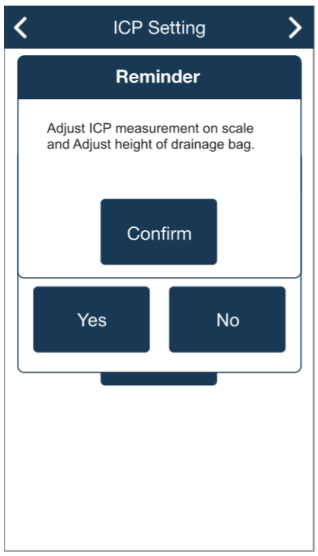
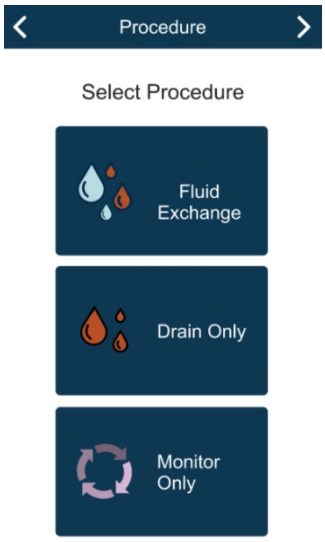
User Interface Screens

#	Screen Image	Screen Name	Details
UI-01		Setup Option Screen	Provides the following options • Tutorial to instruct user on system setup. • Advance to treatment homescreen
UI-02		Cassette Preparation Screen	• Provides instructions to clinician to ensure the Cassette is prepped prior to prepping the system for clinical use. • User must press the Cassette Prepped button to proceed.
UI-03		Cassette Insertion Animation Screen	• Animation demonstrating how to insert the Cassette. • User must insert the cassette and close the cassette lever. **Caution:** If excessive resistance is felt, open the Cassette lever, re-insert the Cassette, and try again. • Press the continue button to proceed.

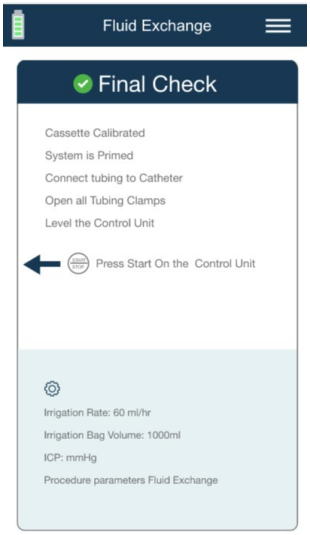
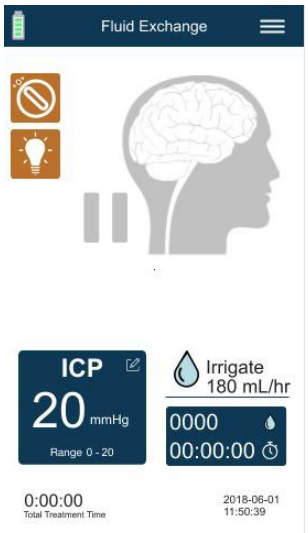
#	Screen Image	Screen Name	Details
UI-04		Calibration Screen	• Animation demonstrating how to calibrate the transducers in the cassette. • Once the Cassette is properly calibrated the user will automatically be directed to the next screen.
UI-05		Prime System Screen	• Animation that illustrates the system is priming the tubing for clinical use. • User must press the Prime button to have the system self-prime. User may not advance past this screen until self-priming is completed. • Prior to priming, ensure all roller clamps are open. • Once priming is complete, the user will be directed to the next screen.
UI-06		Prime System Completion Screen	• User is instructed to confirm priming has occurred. • If priming has occurred, used should press Continue. • If further priming is necessary, user should press and hold Manual Prime until they are satisfied. After they are satisfied, the user must press Continue. • User is instructed to ensure there is no continuous flow of fluid after priming has been completed.

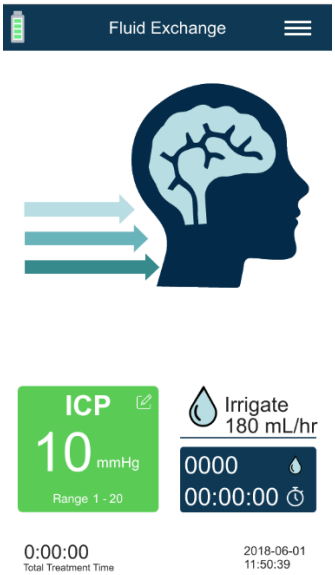
#	Screen Image	Screen Name	Details
UI-35		Prime System Reminder Screen	• User is instructed to remove the priming fluid from the drainage bag and the completion of priming. • Once action is completed, user must press Confirm
UI-07		Bubble Sensor Screen	• Animation instructing the user to place the irrigation tubing into the air bubble sensor. • Once tubing is in the air bubble sensor, the user must press Continue.

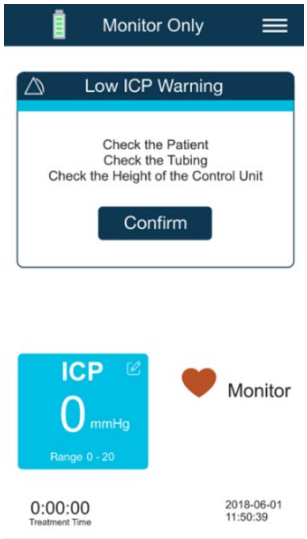
#	Screen Image	Screen Name	Details
UI-08		Fluid Volume Screen	• Screen instructing the user to inform the Control Unit what volume of the irrigation fluid bag is being utilized. • After telling the system what volume is being utilized, the user must press Continue. Note: System alerts user for fluid change when 70% of fluid volume has been irrigated with a low priority alert and a high priority alert when 90% has been used.
UI-09		ICP Measurement Units Screen	• The user is instructed to tell the Control Unit what unit of measurement will be utilized to measure ICP.
UI-10		ICP Measurement Units Confirmation Screen	• After selecting which unit of ICP measurement is being utilized, the user will be instructed to Confirm their selection. • User must press Yes to Continue. • If user presses No, they will be returned to the previous screen.

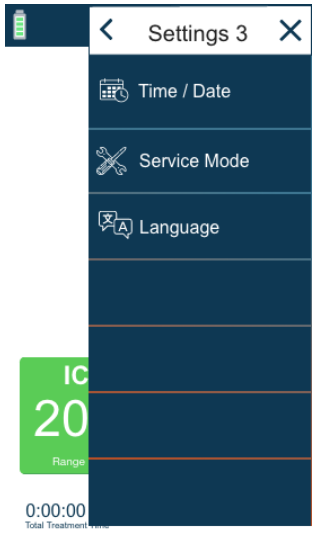
#	Screen Image	Screen Name	Details
UI-36		ICP Setting Reminder Screen	• The user is instructed to adjust the ICP measurements on the scale and adjust the height of the drainage bag. • Once action is completed, user must press Confirm
UI-11		Procedure Selection Screen	• User must select what procedure they want the Control Unit to perform. There are 3 options: 1. Fluid Exchange 2. Drain Only 3. Monitor Only
UI-12, UI-13 and **UI-14** have user-adjustable ICP limits, which trigger the audible system alarms for ICP. Alarm setting shall be set at the physician's direction.			

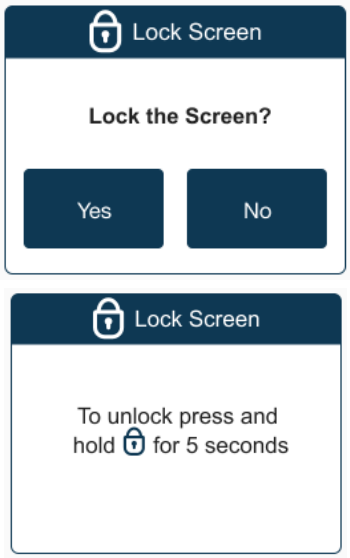
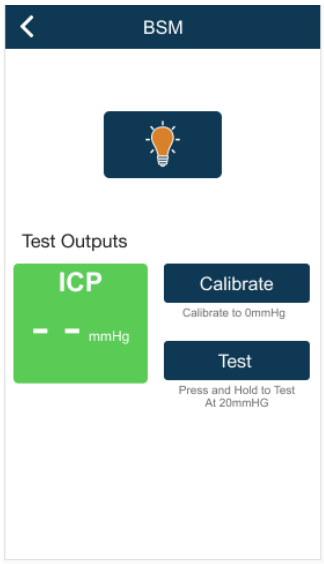
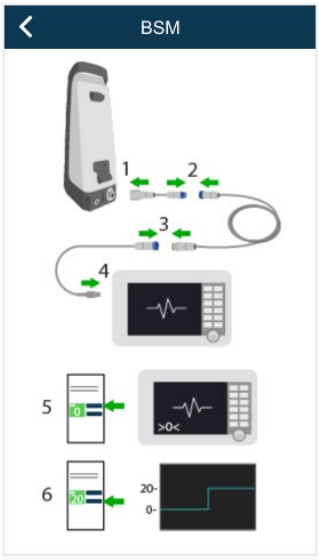
#	Screen Image	Screen Name	Details
UI-12		Fluid Exchange Settings Screen	High ICP Value • Values can be set from 11 to 99 mmHg • Values can be set from 14 to 134 cmH2O • Tapping the bell **disables** high ICP alarm. System will not alarm for high ICP values. Irrigation • Values can be set from 3mL/hr to 180mL/hr Treat Above • Values can be set from -99 to 99 mmHg • Values can be set from -134 to 134 cmH2O • Tapping the button will disable Treat Above and the system will always perform treatment as permitted by High and Low ICP setpoints and Irrigation rates. Low ICP • Values can be set from -99 to 10 mmHg • Values can be set from -134 to 13 cmH2O • Tapping the bell **disables** low ICP alarm. System will not alarm for low ICP values Information button ⓘ • Displays general representation of the treatment cycle
UI-13		Drain Only Settings Screen	High ICP Alert Value • Values can be set from 11 to 99 mmHg • Values can be set from 13 to 134 cmH2O Treat Above • Values can be set from -99 to 99 mmHg • Values can be set from -134 to 134 cmH2O Low ICP • Values can be set from -99 to 10 mmHg • Values can be set from -134 to 13 cmH2O

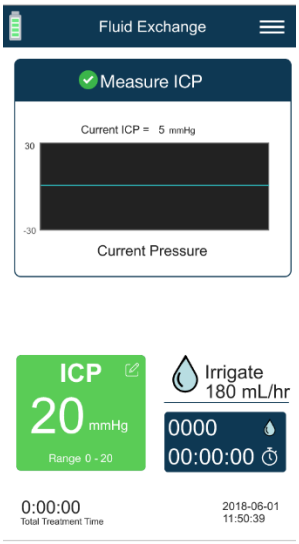
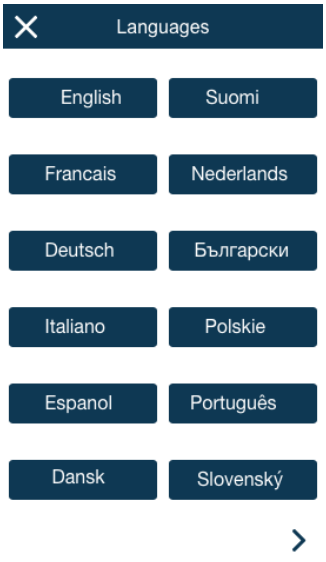
#	Screen Image	Screen Name	Details
UI-14		Monitor Only Settings Screen	High ICP Alert Value • Values can be set from 11 to 99 mmHg • Values can be set from 13 to 134 cmH2O Low ICP • Values can be set from -99 to 10 mmHg • Values can be set from -134 to 13 cmH2O **Note: In 'Monitor Only' mode, ICP alarm behavior is unchanged. High ICP triggers a two minute open drain state to alleviate high ICP conditions.**
UI-15		Setup Final Check Screen	• Provides instructions and settings verification to clinician. • Tapping anywhere on the screen or pressing Start Button will clear the information.
UI-16		Treatment screen	• Prior to the initiation of treatment, the head icon will be grey. • Two vertical bars will indicate treatment is currently not being performed, or that treatment is paused. • The top orange icon indicates calibration of cassette is required. • The bottom orange icon indicates the Set Up Tutorial should the user need to go back and review the necessary steps

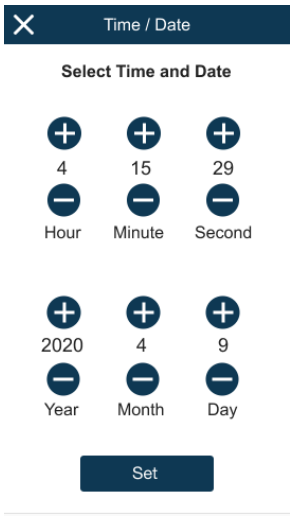
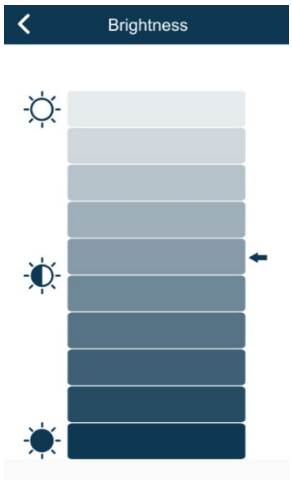
#	Screen Image	Screen Name	Details
UI-17		Monitor Treatment Cycle Screen	• Head icon is purple. • Circular arrows are purple. • ICP measurement taking place.
UI-18		Irrigation Treatment Cycle Screen	• Head icon is light blue. • Arrows are light blue and pointed towards the head. • Fluid is being delivered to the patient. • Bottom right corner displays the irrigation timer with the amount of irrigation that has been delivered as well as the running treatment time since the last reset.
UI-19		Drainage Treatment Cycle Screen	• Head icon is light orange. • Arrows are light orange and pointed away from the head. • Fluid is being drained from the patient.

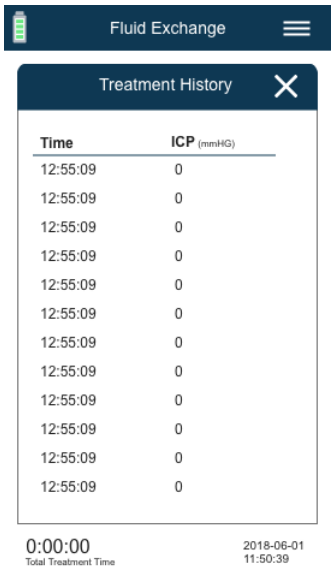
#	Screen Image	Screen Name	Details
Warning Screens			
UI-20		High ICP Warning Screen	• Provides instructions to the user. • ICP box is red. • Provides ICP measurement value. • Treatment is paused.
UI-21		Low ICP Warning Screen	• Provides instructions to the user. • ICP box is light blue. • Provides ICP measurement value.

#	Screen Image	Screen Name	Details
Miscellaneous Screens			
UI-22		Settings Menu Screen 1	• Procedure – allows user to adjust existing parameters or select new procedure. • ICP Value – Allows the user to set ICP units to mmHg or cmH2O. • Irrigation Solution – allows the user to reset fluid volume to 500ml, 1000ml, or custom size. • Measure ICP – Provides a wave graph of ICP measurements. • More – continues to Settings 2 screen.
UI-23		Settings Menu Screen 2	• Prime System – allows the user to prime the tube set. • Reset Treatment Time – allows the user to reset the current treatment time. • Bolus – allows the user to set the manual bolus value to 0.5ml or 1ml. • Brightness – allows user to select display brightness • Treatment History – displays patient's treatment history
UI-24		Settings Menu Screen 3	• Time/Date – allows the user to set the time and date. • Service Mode – For IRRAS use only. • Language – allows the user to change languages

#	Screen Image	Screen Name	Details
UI-25		Lock Screen	• From the Settings Menu, Lock Screen is a feature that disables general access to the IRRA*flow* display. • Lock Screen is deactivated by holding the lock symbol for 5 seconds. • In the event of an alarm, Lock Screen is automatically deactivated to allow for immediate user interaction.
UI-26		BSM Calibration	• For assistance with the BSM Setup, click on the lightbulb. • The Test Output ICP box shows live ICP data. • Press Calibrate to send a simulated zero signal to the bedside monitor system for 10 seconds. • Press Test to send a simulated 20mmHg signal to the bedside monitor system. IRRA*flow* Bedside Monitoring offers an averaged ICP value. The ICP signal is not appropriate for ICP waveform analysis, only ICP monitoring.
UI-27		BSM Setup	• Graphic displays the order to set up the bedside monitoring. • Three cables are required to connect IRRA*flow* Control Unit to Bedside Monitoring System. (Steps 1 to 4) Contact IRRAS for the patient monitoring brand-specific cables for your facility. • Step 5: Send simulated zero signal from Control Unit and apply calibration zero to Bedside Monitor. • Step 6: Send simulated 20mmHg signal from Control Unit and verify Bedside Monitor value increases to 20mmHg.

#	Screen Image	Screen Name	Details
UI-28		ICP Wavelength Display Screen	• Displays a wave form for the ICP measurement. • This takes approximately a minute during which other function controls are restricted. • Occurs every 60 minutes during treatment. • If system is in an alarm state at the top of the hour, the Measure ICP function waits 5 minutes after the alarm is cleared and then begins the 60 seconds of ICP measurement.
UI-29		Enter Fluid Volume Screen	• Number keys are touch activated. • System tracks irrigated fluid volume. • At 70% consumption, user is notified to check fluid levels with a low priority alert and with a high priority alert at 90%. • To avoid laborious re-prime of system, change irrigation bags when notified. • **If fluid bag is changed, user must enter new bag volume to reset system counter**.
UI-30		Select Language	• User can select what language they would like to utilize.

#	Screen Image	Screen Name	Details
UI-32		Set Date & Time Screen	• Allows the user to set the time and date. • + and - keys are touch activated.
UI-33		Display Brightness	• User may select desired display brightness by tapping scale. • The standard system brightness is restored during an alarm event. • The standard system brightness is restored after system restarts.

#	Screen Image	Screen Name	Details
UI-34		Patient Treatment History	• During treatment, at the top of every hour, the system pauses treatment to measure ICP accurately. • The ICP value for the hour is logged in the Patient History Screen. • Twelve (12) hours of data can be displayed. • The displayed data is overwritten as treatment goes beyond 12 hours. • A '–' in the Treatment History log indicates an invalid ICP measurement was taken. • User can access the Patient Treatment History by tapping the lower right button on the main screen. 

Initial Setup

Unpack IRRA*flow* System

WARNING: Only IRRA*flow* Cassette and IRRA*flow* Catheter may be used together with IRRA*flow* Control Unit. Using other devices can injure patients.

WARNING: Modification or disassembly of the Control Unit is not permitted. Unauthorized modifications to the Control Unit can cause a malfunction resulting in serious patient injury, damage to internal circuitry or electric shock.

Remove the contents from the shipping box and verify the following items are included:

- Control Unit
- Power Supply
- Power Cord
- USB drive / USB Dongle
- Laser Leveller

After unpacking the contents, inspect the items for any signs of damage. If any damages are discovered, notify the supplier. Retain all shipping contents and boxes for examination.

Prepare the Power Cord Adapter Plug

Remove the Power supply and cord from the package and if necessary, attach the region-specific adapter plug to the Power Adapter.

Plug the ICP Monitor into AC Power

WARNING: Use only IRRAS approved power supplies listed in Recommended Accessories and Reordering Information section.

WARNING: Use of another power supply may not provide electrical isolation from supply mains and protection against electrical hazards.

Connect the Power Adapter to the Control Unit by inserting the connector end into the Power Input. Insert the plug end of the Power Cord into a wall outlet and ensure the Battery Indicator light is green.

Charge the Battery to Full Capacity

Keep the Control Unit turned on and plugged in for at least 5 hours to charge the battery to full capacity.

Mount Control Unit on the IV Pole

Mount the unit on the IV Pole.

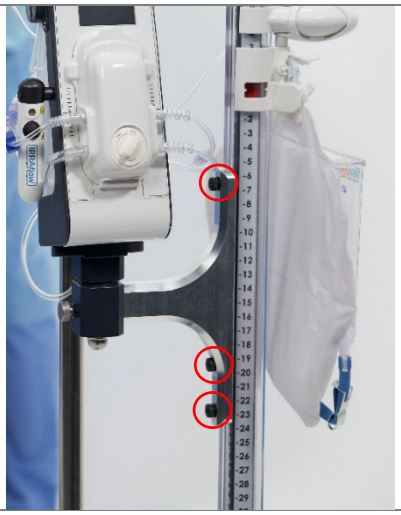
The Control Unit is intended to be securely clamped to an IV or equipment pole next to the patient.

Assembly of Control Unit

Attach the Drainage Collection Measuring Scale to the Control Unit

Once the Control Unit is mounted on the IV pole securely, remove the measuring scale from the foam placeholder in the box.

Attach the measuring scale to the Control Unit by aligning the 3 holes on the scale with the 3 push screws on the swing arm extending from the bottom of the Control Unit.



Secure the System in Place

Secure the measuring scale in place by rotating the push screws to the right once they are aligned with the correct hole.

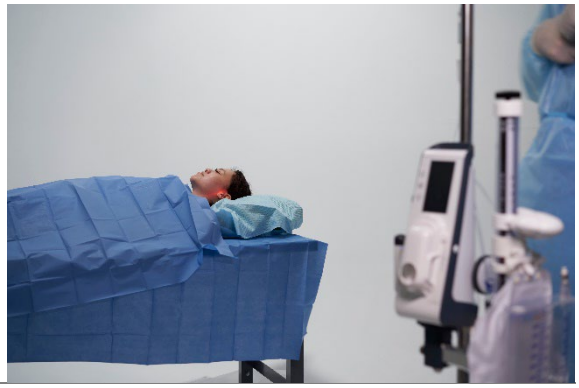
The Control Unit is now fully assembled and ready to be set up for Clinical Use.

Setup for Clinical Use

Level the Control Unit

Ensure the Control Unit is in a vertical position on an IV pole using the pole clamp knob and the attachment mechanism.

To level the Control Unit, adjust and verify that the zero line of Control Unit is at the same horizontal level with patient's external auditory meatus by utilizing the laser leveller installed on the side of the Control Unit.



Turn on the ICP Monitor

Press the Standby Button on the front of the Control Unit for at least 1 second (see Figure 2). Upon system start-up, observe system for alarms while system runs self-checks for operational performance and safety.

The screen will illuminate to indicate that the device is on. There will be two audible beeps.

After approximately 6 seconds, while performing internal self-checks, the Control Unit will display the "IRRAS" logo

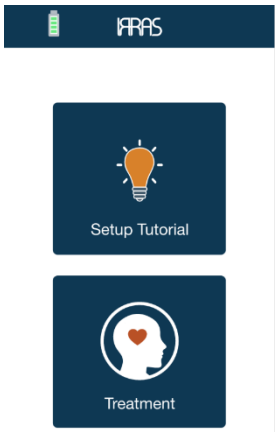
and then the "IRRA*flow*" logo.

Confirm that the battery is fully charged.

Set Up Unit for Treatment

Caution: The Catheter must not be connected to the IRRA*flow* Control Unit while setting up the Control Unit for treatment. This could potentially harm the patient.

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.



Once powered on the system will progress to the Setup Option Screen (see User Interface Screen UI-01).

The user can select form the following options:

- Setup Tutorial – This will walk the user through setting up the system.
- Treatment – This will allow the user to bypass the tutorial in setting up the system and progress to the treatment screen (see User Interface Screen UI-01).

Attach the Cassette

To start the process of Attaching the Intelligent Digital Cassette onto the Control Unit, open the cassette door.

- Hang the IV Bag of desired Irrigation Fluid, per Physician's orders, onto the IV pole. The irrigation solution should be positioned above the catheter tip that matches the prescribed ICP limit.
- Close clamp below drip chamber.
- Spike the irrigation bag with the IV spike on the irrigation tubing, filling the drip chamber 3/4 of the way.
- To attach the cassette, first insert the bottom and then the top of the cassette. Ensure the cassette is pushed down and firmly seated.
- Once you have attached the Cassette, close the cassette lever. This will lock the cassette into place.
  Caution: If excessive resistance is felt, open the Cassette lever, re-insert the Cassette, and try again.
- Close the Cassette door as illustrated on the Control Unit touchscreen.
- Ensure that there is no flow in the irrigation tubing prior to priming.
  Caution: If the Cassette is not appropriately attached, this may result in unimpeded flow of irrigation solution

Reference Tube Set IFU for further instruction.

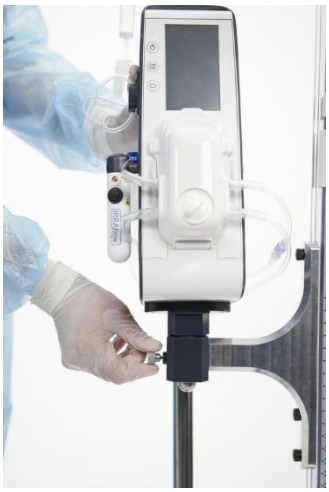
Set Up Drainage Collection System for Treatment

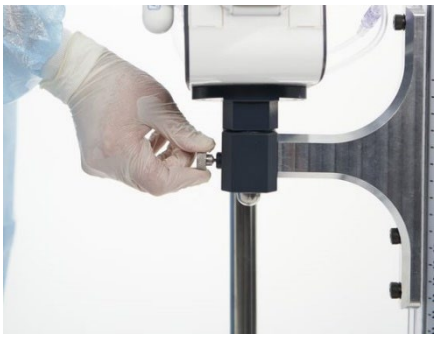
Part of setting up the Control Unit requires the proper set up of the Drainage Collection System.

Before treatment is started, the user must select the orientation of the Drainage Collection System, attach the drainage bag to the Drainage Collection System, and adjust the height of the drainage bag per physician orders.

Orientation

- Pull the pin located at the area of connection between the Drainage Collection System and the Control Unit outwards.
- This will release the lock and allow the Drainage Collection System to be moved from left to right.
- Set the Drainage Collection System to the desired side and release the pin.





Attach Drainage Collection Bag

- Attach the drainage bag onto the hanger and lock it into place by closing the locking lever.

Adjust Height

- Per Physician's orders, adjust the height of the drainage bag on the sliding scale by squeezing the drainage bag height release lever. Note that the exact height of the drainage bag height will be shown in the window display of the Drainage Collection System.

Adjust Units

- Scale may be read in either mmHg or cmH2O, per physician or facility preference.

Begin Treatment

WARNING: The patient may not touch the Control Unit during treatment. The treatment may be disturbed if the patient mistakenly touches any part of the equipment.

WARNING: Treatment may not be conducted if the surrounding temperature or the atmospheric pressure exceeds any of the limits stated in the manual.

Caution: IRRA*flow* Cassette and IRRA*flow* Catheter are single-use components. Using the same component for multiple treatments can potentially harm the patient.

Before starting treatment, ensure the following is accomplished:

- The cassette is installed in the Control Unit.
- Cassette is calibrated.
- Cassette is primed and all tubing clamps are open.
- Drainage bag is attached and height of drainage system is adjusted. (see Recommended Accessories)
- The irrigation tubing is in the air bubble sensor. (see User Interface Screen UI-07)
- Irrigation fluid volume is set. (see User Interface Screen UI-08)
- ICP unit of measure is set. (see User Interface Screen UI-09)
- Procedure is selected (Fluid Exchange, Drain only, Monitor only). (see User Interface Screen UI-11)
- High ICP value is set. (see User Interface Screen UI-12, 13, & 14). Alarm setting shall be set at the direction of the physician.
- Low ICP value is set. (see User Interface Screen UI-12, 13, & 14). Alarm setting shall be set at the direction of the physician.
- Observe system for alarms while system runs self-checks for operational performance and safety
- Final check is made. (see User Interface Screen UI-15)
- All clamps are opened along the Tube Set tubing and the Catheter tubing.
- There are no kinks in the Tube Set tubing and the Catheter tubing.

Once the unit has been set up and the patient prepared, initiate treatment by pressing the Start/Stop button once.

Instructions for Emptying the Contents of the Drainage Collection System

CAUTION: In order to prevent fluid contamination, do not empty or tip contents out of the Drainage Bag while the roller clamps are open or when the Cassette is not firmly seated in the Control Unit.

- Follow hospital procedures and practices for personal protective equipment.
- Hold bottom of drainage bag between forefinger and thumb.
- Lift and tilt meter to transfer contents from 400ml chamber to Drainage Collection System's drainage bag.
- Remove drain tube from holder.
- Open drainage spout and empty bag into collection vessel. Once drainage is completed, verify the drainage spout is closed.
- For continued use, after emptying the bag, close drainage spout and cleanse end of drain tube, per best medical practice, before replacing in holder following standard hospital procedure and practice.

Periodic Checks During Treatment

1	After starting treatment, for the first hour, the user should check the Control Unit every 15 minutes to ensure an ICP value is being displayed, the system is functioning as intended and (if irrigating), the drainage output is the same or greater than the irrigation volume.
2	During the second hour of treatment, the user should check the Control Unit every 30 minutes to ensure an ICP value is being displayed, the system is functioning as intended and (if irrigating), the drainage output is the same or greater than the irrigation volume.
3	During the third hour of treatment, the user should check the Control Unit every 30 minutes to ensure an ICP value is being displayed, the system is functioning as intended and (if irrigating), the drainage output is the same or greater than the irrigation volume.
4	During the fourth hour of treatment and on, the user is recommended to check the Control Unit at least every 60 minutes to ensure an ICP value is being displayed, the system is functioning as intended and (if irrigating), the drainage output is the same or greater than the irrigation volume.
5	Periodically check the drainage bag to ensure that it is not full, it is not kinked, and there is no blockage. Empty as required per provided instructions
6	If a treatment variable is changed, such as increasing or decreasing the irrigation rate and or adjusting the drainage bag height, the user should repeat periodic checks 1-5.

Transportation, Wiping, Storage and Troubleshooting

Transportation

When a patient undergoing treatment requires transportation, follow below workflows:
Note: Control Unit and Digital Cassette are MR UNSAFE

	If patient remains under treatment during transportation	**If patient is disconnected from treatment during transportation**
1	Unplug power cable and verify all tube lines and cables are not tangled.	Stop/Pause system treatment.
2	Patient may be transported with Control Unit mounted to IV pole.	Disengage Cassette. Gather Cassette, Irrigation bag lines, tube lines, and carefully place in a clean and dry location on patient transportation convoy.
3	Reconnect power cable upon return to care setting.	Upon return to care setting, reengage Tube Set with Control Unit and Air Bubble sensor, recalibrate Tube Set and restart treatment.

Wiping and Storage

The Control Unit shall be cleaned after each treatment.

If fluids spill onto the Control Unit during treatment, pause or stop treatment and wipe off the spillage immediately. Keep the cassette lid closed during cleaning.

The recommended method for cleaning is to wipe the parts with a surface disinfectant using a disposable wipe, soft, damp cloth or sponge. Use one of the following to remove debris, stains or adhesives that stick to the surface:

- Combination wipes (Quaternary Ammonium / Isopropyl Alcohol)
- 70% Isopropyl alcohol
- 0.5% Bleach wipes

Caution: No liquid may be allowed to dispel from the cloth during cleaning, as this may damage the equipment. Never use any type of tools or brush when cleaning, as this may damage the unit.
No components, parts or accessories to the IRRA*flow* Control Unit may be sterilized.

For long term storage of the Control Unit, ensure that it is protected from dust and kept in a clean, dry environment with the following conditions:

- Humidity (RH) range: reference storage specified in the Technical Specifications, Environmental and Handling Conditions
- Temperature range: reference storage specified in the Technical Specifications, Environmental and Handling Conditions
- Annually, **Charge the Battery to Full Capacity by** Keeping the Control Unit plugged in for at least 5 hours

Troubleshooting

Technical Support
+1-800-213-4604

Clinical Watchout	Action
Treatment is on-going, but no flow is seen in the irrigation bag 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 irrigation bag is empty. • Check to see if the irrigation tubing has become dislodged from the air bubble sensor' slot.
Treatment is on-going, but no flow is seen in the drainage bag.	• Check infusion rate settings and inspect the irrigation drip chamber for fluid flow. • 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 cassette calibrated? Is irrigation tube mounted correctly into air bubble sensor's 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.

Alarm Information

There are three types of notifications the system employs to inform the user of physiological or technical conditions.

1. Physiological Alarms
   Alert the user that the patient's ICP has exceeded the set alarm limits.
   Physiological alarm sound can be paused temporarily for 2 minutes.

   CAUTION: Be aware that alarms may be user-disabled by selecting extreme limits.

2. System Alerts
   Notify user to take action under certain events, including:

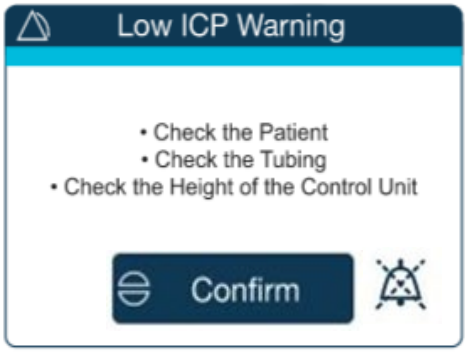
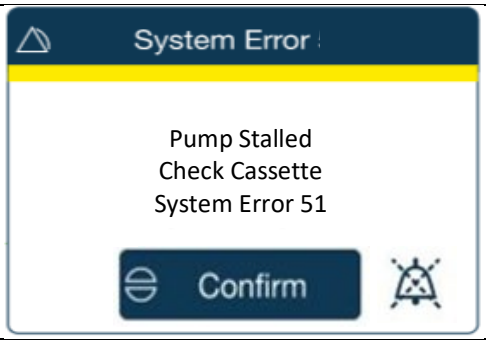
Alert	Why	Action
Change Irrigation Bag	System notifies user when 70% of fluid has been irrigated with a low priority alert and a high priority alert when 90% has been used.	Acknowledge alert and change bag as appropriate. Reset Irrigation Fluid amount in Menu for system to track irrigation for new bag.
Treat Above	When Treat Above is triggered, system does not drain or irrigate. System only measures ICP.	Treat Above notification is present on home screen until physiological condition changes or settings are adjusted.
Calibration Required	IRRAS Digital Cassette requires calibration every 24 hrs.	Turn IRRAS Digital Cassette knob to calibrate the system, following on-screen tutorial.
Change Cassette	IRRAS Digital Cassette and Catheter require replacement every 5 days.	Replace Digital Cassette and Catheter after notification. No further action with IRRAS Control Unit required.
System Paused	The IRRAS Digital Cassette is attached and the Control Unit has been paused for 10 minutes.	Acknowledge alert and resume treatment as appropriate.

3. System Technical Failure Alarms

   Notify user of system faults. Displays alarm troubleshooting, if any, and alarm error identification code. All error states are logged in the service menu.

Alarm Priority

The alarm priority is communicated with an audible signal and a visual alarm priority symbol on the system display. When several alarm conditions are present, alarm priority is determined by the condition with the highest priority

Alarm Priority	Audible Signal	Example Visual Symbol (Color and Symbols)
Low	2 beeps, repeating every 20 s	
Medium	3 beeps, repeating every 7.5 s	
High	10 beeps, repeating every 2.5 seconds	

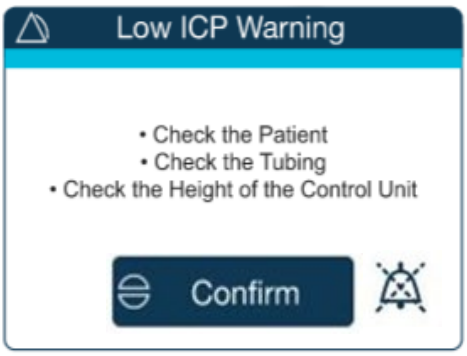
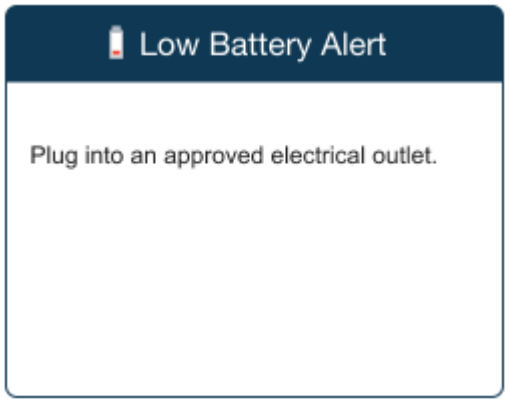
Alarm Technical Specifications

Item	Specification
Alarm Parameter	Intracranial Pressure (ICP)
High Alarm Settable Limits	+11 to 99mmHg
Low Alarm Settable Limits	-99 to 10mmHg
High/Low Alarm Step Resolution	1 mmHg
High Alarm Default Value	15 mmHg
Low Alarm Default Value	0 mmHg
Occlusion alarm pressure threshold	High ICP Alarm acts as the occlusion alarm (0-100 mmHg)
Means provided to protect the patient from air irrigation	Air Bubble Sensor Alarm
Operator Position	Alarm color and audible alarm pattern may be observed by Operators up to 3m away. User interacting with patient or device shall be able to observe alarm color, audible alarm pattern and symbology at a distance of 1m or less.

Item	Specification
Sound pressure level of alarms	45-65 dB Typical at 1 m from the control unit
	Sound level is same for all alarm conditions. Alarm priority differentiated by pulses and visual indicators.
Alarm Behavior after Power loss of less than 30 seconds	System is battery-powered. System will continue to function and maintain all alarm settings in the event of a power loss.
Alarm Behavior after Power Down event by user or by battery depletion	System shall restore default alarm limits
Elapsed time from alarm triggered to audible and visual alarm signal notification	Less than 10s
Alarm Pause	Pauses audible alarm for two (2) minutes. Display will retain color and visual indication of alarm.
Alarm Acknowledge	Dismisses alarm. If alarm condition is unresolved, system will alarm again when restarted or action reattempted.
Alarm System Log	The Treatment log, stored within the service menu and is available upon requests from an IRRAS representative and supplies the following Alarm information: 1. Date / Time of Alarm 2. Alarm Error Code Identification

Displays for Alerts, Warnings and System Errors
System messages are communicated in display boxes with color, blink rate and audible sound rate associated with alarm priority

Displays for Alerts, Warnings and System Errors			
#	**Screen Image**	**Screen Name**	**Details**
TS-01		High ICP Warning	• Examine and/or treat the patient for symptoms of high intracranial pressure. • Check the catheter and tubing to ensure there is no blockage of the fluid paths and the tubing is not kinked. • Ensure the system is set to the appropriate height in alignment with the patient. • Alarm bell icon may be pressed to silence alarm for 2 minutes. System remains in alarm state while silenced.

Displays for Alerts, Warnings and System Errors			
#	**Screen Image**	**Screen Name**	**Details**
TS-02		Low ICP Warning	• Examine and/or treat the patient for symptoms of low intracranial pressure or over drainage. • Check the catheter and tubing to ensure there is no leakage of the fluid paths. • Ensure the system is set to the appropriate height in alignment with the patient. • Alarm bell icon may be pressed to silence alarm.
TS-03		Bubble Detection Error	• An air bubble has been detected. • User should first check the tubing to ensure it has not dislodged from the air bubble sensor. • User should check to see if the irrigation bag needs replaced.
TS-04		Low Battery Alert	• Battery charge is depleting. • User will need to plug the Control Unit into an approved electrical outlet.

Alert Identification and Priority Table

Alert ID	Alert	Priority	System Message
1.	High ICP	High	Check the patient / Check the tubing / Check the height of Control Unit
2.	Low ICP	Low	Check the patient / Check the tubing / Check the height of Control Unit
3.	Air Bubble Detected	Low	Air in Irrigation line/ Clear Air or Prime System / Press Here to Continue
4.	Battery Low	Low	Low Battery, plug into approved electrical outlet
5.	Battery Depleted	High	Low Battery, plug into approved electrical outlet
6.	Calibrate Cassette	Low	Calibrate cassette / Please follow tutorial
7.	Irrigation Bag Warning	Low	Change the Irrigation Bag
8.	Irrigation Bag Warning	High	Change the Irrigation Bag
9.	Treatment Status	Low	Treatment is paused please resume if desired

Alarm Identification and Priority Table

Alarm ID	Error Code	Alarm	Priority	System Message
1.	4	RTCC bus error	High	Restart System / If problem persists, contact IRRAS for support
2.	6	Battery bus error	High	Restart System / If problem persists, contact IRRAS for support
3.	8	Battery bus message error	High	Restart System / If problem persists, contact IRRAS for support
4.	10	SPI Flash bus error	High	Restart System / If problem persists, contact IRRAS for support / System Error 10
5.	12	SPI SM bus error	High	Restart System / If problem persists, contact IRRAS for support / System Error 12
6.	13	SM data write verification failed	High	Restart System / If problem persists, contact IRRAS for support / System Error 13
7.	20	Programming error	High	Restart System / If problem persists, contact IRRAS for support / System Error 20
8.	21	Attempt to use null pointer	High	Restart System / If problem persists, contact IRRAS for support / System Error 21
9.	22	Too much time processing main loop	High	Restart System / If problem persists, contact IRRAS for support / System Error 22
10.	23	Program CRC doesn't match calculated	High	Restart System / If problem persists, contact IRRAS for support / System Error 23
11.	30	Pressure sensor over range	High	Restart System / If problem persists, contact IRRAS for support / System Error 30
12.	31	Pressure sensor difference	Medium	Pressure Error / Check Cassette / System Error 31
13.	32	Pressure sensor timeout	High	Restart System / If problem persists, contact IRRAS for support / System Error 32
14.	33	Valve open timeout	High	Restart System / If problem persists, contact IRRAS for support / System Error 33
15.	34	Pump run timeout	High	Restart System / If problem persists, contact IRRAS for support / System Error 34
16.	35	Bubble detected	High	Restart System / If problem persists, contact IRRAS for support / System Error 35
17.	36	Watchdog	High	Restart System / If problem persists, contact IRRAS for support / System Error 36
18.	40	Valve open when it should be closed	High	Restart System / If problem persists, contact IRRAS for support / System Error 40
19.	41	Valve closed when it should be open	High	Restart System / If problem persists, contact IRRAS for support / System Error 41
20.	51	Pump not running when it should be	Medium	Pump Stalled / Check Cassette / System Error 51
21.	124	Display didn't respond to a command	High	Restart System / If problem persists, contact IRRAS for support / System Error 124
22.	200	FPGA Done pin high while FPGA held reset	High	Restart System / If problem persists, contact IRRAS for support / System Error 200
23.	201	FPGA programming took longer than 2 seconds	High	Restart System / If problem persists, contact IRRAS for support / System Error 201
24.	202	FPGA INIT_B not asserted after programming	High	Restart System / If problem persists, contact IRRAS for support / System Error 202

Alarm ID	Error Code	Alarm	Priority	System Message
25.	203	Pressure sensor initialization failed	High	Restart System / If problem persists, contact IRRAS for support / System Error 203
26.	204	Air bubble sensor test pin didn't force a bubble detect event	High	Restart System / If problem persists, contact IRRAS for support / System Error 204
27.	205	Not able to read HWID.	High	Restart System / If problem persists, contact IRRAS for support / System Error 205
28.	206	MCU reset by watchdog timeout	Medium	Restart System / If problem persists, contact IRRAS for support / System Error 206
29.	207	1.2V supply outside 10% tolerance	High	Restart System / If problem persists, contact IRRAS for support / System Error 207
30.	208	5.0V supply outside 10% tolerance	High	Restart System / If problem persists, contact IRRAS for support / System Error 208
31.	209	12.0V supply outside 10% tolerance	High	Restart System / If problem persists, contact IRRAS for support / System Error 209
32.	210	18.0V supply outside 10% tolerance	High	Restart System / If problem persists, contact IRRAS for support / System Error 210
33.	212	Ambient temperature over 50C	Medium	System Overheating / If problem persists, contact IRRAS for support / System Error 212
34.	213	Safety Monitor version not valid for this firmware version	High	Restart System / If problem persists, contact IRRAS for support / System Error 213
35.	214	Audible alarm malfunction	High	Restart System / If problem persists, contact IRRAS for support / System Error 214
36.	215	Safety monitor ADC out of range after calibration	Medium	Calibration Error / System Error 215
37.	216	Control Processor ADC out of range after calibration	Medium	Calibration Error / System Error 216
38.	217	Sd card error	Medium	Restart System / If problem persists, contact IRRAS for support / System Error 217
39.	218	Hardware revision mismatch	High	Restart System / If problem persists, contact IRRAS for support / System Error 218
40.	300	Valve is not in the expected position	High	Restart System / If problem persists, contact IRRAS for support / System Error 300
41.	301	3.3V supply outside 10% tolerance	High	Restart System / If problem persists, contact IRRAS for support / System Error 301
42.	302	BSM Output Failed	Low	BSM Output Failed / Restart System / If problem persists, contact IRRAS for support / System Error 302

Technical Specifications, Environmental and Handling Conditions

Item	Specification
Description	Intracranial fluid drainage system & ICP monitoring device
Name	IRRA*flow* Control Unit
Catalog part number	ICCU 020
Dimensions	35 (H) x 14 (BW) x 19 (D) cm
Weight	3.5 kg
ICP range	-100 to +300 mmHg
ICP accuracy	Max ± 2 mmHg / 10% error in range 0-99 mmHg
ICP zero-point drift	less than 1 mmHg between calibrations
IRRA*flow* Displayed Pressure measurement refresh interval (mode-dependent)	Fluid Exchange: per cycle Drain Only: 180 sec Monitor Only: 9 sec BSM Setup Screen: 0.4 sec
ICP Frequency Response (@10, 20, and 50 mmHg)	The IRRA*flow* Control Unit provides an averaged ICP Only.
ICP Slew Rate (@10, 20, and 50 mmHg)	The IRRA*flow* Control Unit provides an averaged ICP Only.
ICP Time Constant (full scale: increasing and decreasing)	The IRRA*flow* Control Unit provides an averaged ICP Only.
Selectable Irrigation Flow Rates	3, 6, 10, 12, 20, 30, 60, 90, 120 and 180 mL/hour
Volume per bolus	0.5 or 1.0 ml
Maximum Bolus volume irrigated under single fault condition	1.4 ml
Maximum irrigation flow rate when a bolus is delivered	1 ml/s
Maximum flow, average over a full cycle	180 ml/hour (flow rate: 1 ml/s)

Item	Specification
Degree of enclosure protection	IP21
Vibration/Shock/Bump	Has met requirements to transport the system worldwide by air, road, ship, and train.
Drop/Free Fall	Has met requirements to transport the system worldwide by air, road, ship and train.
EMC/ESD	The IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette meet the requirements in accordance with IEC 60601-1-2 Electromagnetic compatibility.
Defibrillation Proof Type BF Applied Part	Cassette Irrigation Line and Catheter
Battery Voltage, Capacity	14 VDC, 3400 mAh
Operating time on battery at maximum irrigation rate with fully charged battery	Minimum of 60 minutes
Power supply	18VDC, 2.66A, 100 - 240 VAC, 50 – 60 Hz, 40 W
Power Cord Set Length	10 ft (~3 Meters)
Defibrillation recovery time	Maximum of 10 seconds
Operation: Temperature Range (IRRA*flow* Control Unit)	+15 to +30°C
Operation: Air Humidity (IRRA*flow* Control Unit)	30 – 90%
Operation: Ambient Pressure (IRRA*flow* Control Unit)	70 – 100 kPa (± 5%)
Storage and Transport: Temperature Range (IRRA*flow* Control Unit)	0 to +60 °C
Storage and Transport: Air Humidity (IRRA*flow* Control Unit)	15 – 90%
Storage and Transport: Ambient Pressure (IRRA*flow* Control Unit)	70 – 100 kPa (± 5%)
Service Life (IRRA*flow* Control Unit)	5 years

Item	Specification
Maximum irrigation test pressure	500 mmHg
Size of unintended bolus from occlusion:	Less than 1 ml

Item	Specification
IV Pole Recommendation	Minimum 1-inch (25.4mm) diameter stainless steel body, 48 inch long. 6-leg base, 20-inch diameter with 6 locking casters.

Symbols and Labels

The Control Unit has been labelled with the following symbols:

Symbol and Text	Meaning
	The parts applied to the patient are insulated from the mains according to defibrillation proof type body floating (BF) model described in IEC 60601-1
	For Prescription Use Only
	System Standby symbol
	Catalogue number
	Do not dispose device in unsorted trash. This unit should be disposed in accordance with the regulations for electronic waste followed by the hospital.
	Class II equipment symbol
	European Authorized Representative
	Store within given temperature range
	Follow operating instructions.
	Power cord
	The Device complies with Medical Device Regulations (EU) 2017/745

Symbol and Text	Meaning
	Name and address of manufacturer
	Serial number: YYYY-XXXX YYYY: Year of manufacture; XXXX-: Four Digit Number
	Follow operating instructions
Input power: 18 VDC 2.66 A	Rated supply voltage and input power
IP21	Degree of enclosure protection.
	Unique Device Identifier (UDI) 2D Barcode, unique to each device
	MR-Unsafe – an item that is known to pose hazards in all MR environments
	Date of manufacture
	USB Flash Drive
	Bedside monitor cable

Applicable Standards, Recommended Accessories and Reordering Information

Applicable Standards

The Control Unit is classified as:

- Class BF according to IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for safety.
- Defibrillation proof applied part according to IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for safety.
- Mobile device and tested as mobile device to IEC 60601-1 Medical Electrical Equipment – Part 1: General requirements for safety.

The Control Unit is type-approved in accordance with the following standards:

- IEC 60601-1: 2005+A1:2012 Medical Electrical Equipment – Part 1: General requirements for safety
- IEC 60601-1-2: 2014 Medical Electrical Equipment – Part 1: General requirements for safety – Section 2: Collateral standard: Electromagnetic compatibility – Requirements and tests
- EN 62304: 2006 Medical device software – Software life-cycle processes
- IEC 60601-1-6: 2010 Medical Electrical Equipment – Part 1: General requirements for safety – Section 6: Collateral standard: Usability
- IEC 60601-1-8: 2007+A1:2012Medical Electrical Equipment – Part 1: General requirements for safety – Section 8: Collateral standard: Tests and guidance for alarm systems in medical electrical equipment and medical electrical systems
- IEC 60825-1: 2014 3rd Edition – Safety of Laser Products – Part 1: Equipment classification and requirements

System Components

The IRRA*flow* Active Fluid Exchange System is comprised of 5 primary components:

Catalog Number	Name	Description
ICCU 020	Control Unit	Console, responsible for setting and controlling patient treatments. Includes replaceable DCS Measuring and Drainage Scale
ICLS010	Laser Leveller	Laser pointing tool used to assist with zeroing the patient ICP to the Control Unit
ICDS020/ICDS030	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.

Laser Leveller (ICLS010)

A laser leveller can be utilized with the Control Unit. The purpose of the laser leveller is to align the zero point on the Control Unit to the level in which the catheter is residing. This enables an accurate reading of ICP. Please see the Laser Leveler User Manual for the specific use details.

Tube Set (ICDS020/ICDS030)

Conducting a treatment with the Control Unit requires the use of a single-use, sterile Cassette attached to the front of the Control Unit housing (seen in figure).

Cassette contents:

- The cassette that attaches to the front of the Control Unit housing
- Pressure sensors' calibration knob
- Roller clamps along the tube lines. When the cassette is correctly mounted to the Control Unit, the pump closes the irrigation line. When engaged, the roller clamps will prevent the free flow of irrigation fluid into the brain of the patient, if the cassette is removed while still connected to the patient.
- A set of tubes channelling fluid to and from the patient

  Please see the Tube Set User Manual for the specific use details.

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 – replaceable component (P/N 7001008)
2. Mounting system that enables the DCS Measuring and Drainage Scale to be mounted to the Control Unit
3. Sterile Drainage bag that connects the Intelligent Digital Cassette and the DCS Measuring and Drainage Scale

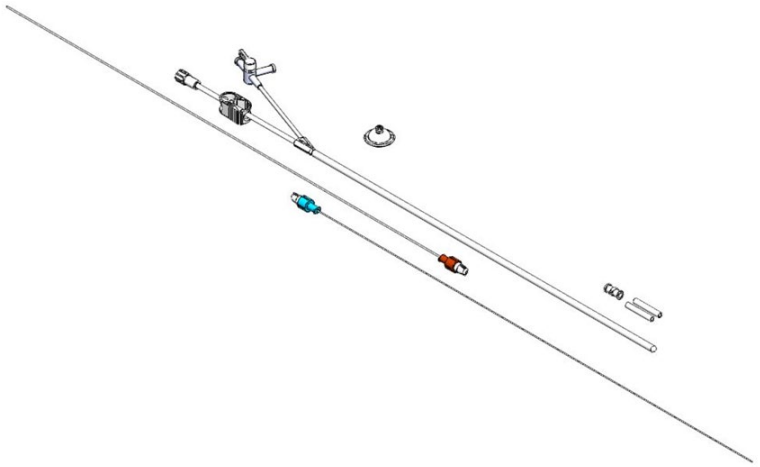
Together, these items use gravity to drain cerebrospinal fluid (CSF) from the patient's ventricles. It is a closed system that enables the critical care professional to efficiently and effectively drain intracranial fluid.

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.

Additional Equipment

Irrigation Bag and Irrigation Fluids

The IRRA*flow* Active Fluid Exchange System is also 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, Ringer's lactate etc.).

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

When irrigation is setup and the cassette is mounted to the Controller, verify there is no free-flow of irrigation fluid.

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

Additional Cables/Power Supply

The following part numbers may be (re)ordered to support system usage:

Function	Part Number	Description
External Power Supply	7001014	Power supply
Power Cord	7001127	US
Power Cord	7000913	EURO
Power Cord	7000917	UK
Power Cord	7000919	AUSTRALIA
Power Cord	7000924	BRAZIL
Power Cord	7000925	THAILAND
Bedside Monitoring	7001231	BSM Kit, - GE
Bedside Monitoring	7001232	BSM Kit, Draeger
Bedside Monitoring	7001233	BSM Kit, Philips
Bedside Monitoring	7001234	BSM Kit, Siemens 10 pin
Bedside Monitoring	7001235	BSM Kit, Spacelabs/Mindray 6 pin
Bedside Monitoring	7001237	BSM Kit, Marquette Series 7200 Tram Module
Bedside Monitoring	7001238	BSM Kit, Datascope 6 pin
Bedside Monitoring	7001266	BSM Kit, Airshields BP 441-1 IBP Plug – 10 pin
USB	7001096	USB Drive Dongle

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

Maintenance

The user is not required to perform any preventive maintenance on the equipment. While this device does not require periodic repair or calibration, general care, handling and maintenance will extend the life of the device. Such practices the user must observe include:

- The integrity of equipment, plastic covers, LCD and interconnecting cables is sound.
- External equipment markings remain legible.
- The equipment is free of dirt or debris likely to impair safety or performance (follow the instructions for wiping the device).
- The controls and display function in accordance with the Instruction Manual.
- The rechargeable battery is charged.
- After exposure to extreme temperatures allow the equipment to return to room temperature before use. Do not allow the Control Unit to stay in extreme temperatures for prolonged periods of time.
- Do not drop the device.
- The Control Unit operating efficiency is directly related to the physical condition of the unit. If any damage or abuse is observed the device must be returned to the nearest repair facility.
- The device has double insulation and does not require a safety connection to electrical earth (ground). Ground bond testing is not required as the system uses an approved Class II external Power Adapter (transformer).
- Annual Preventive Maintenance and Testing conducted by IRRAS is recommended to inspect for any possible wear that will degrade your IRRA*flow* Control Unit's essential performance or operation, including Electrical Safety Testing per 60601-1:2012
- Being proactive in your IRRA*flow* Control Unit Maintenance program ensures your equipment will run at optimal capability for longer, allowing you to get the most from your monitor, protecting your patients, users and your financial investment.
- Note that the Control Unit contains substances which can be harmful to humans, animals and their surroundings.

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

Product End of Life

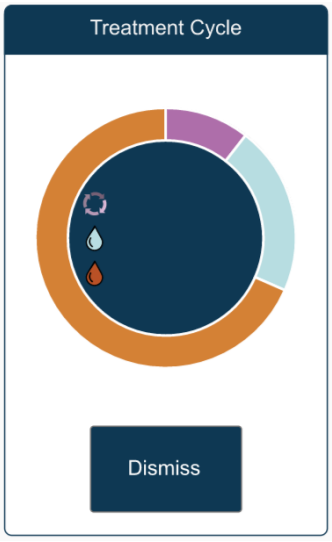
The monitor contains electrical components. Dispose of the equipment in accordance with local ordinances.

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: IRRIGATION RATE TABLE AND TREATMENT CYCLES

Irrigation Volume per hour (mL)	**3**	**6**	**10**	**12**	**20**	**30**	**60**	**90**	**120**	**180**
Irrigation volume per bolus (mL)	0.5	1	0.5	1	1	0.5	1	1	1	1
Number of Bolus's per hour	6	6	20	12	20	60	60	80	120	180
Time Dedicated to Drainage (seconds/hour)	3,540	3,540	3,400	3,480	3,400	3,00	3,000	2,800	2,400	1,800



A treatment cycle consists of:

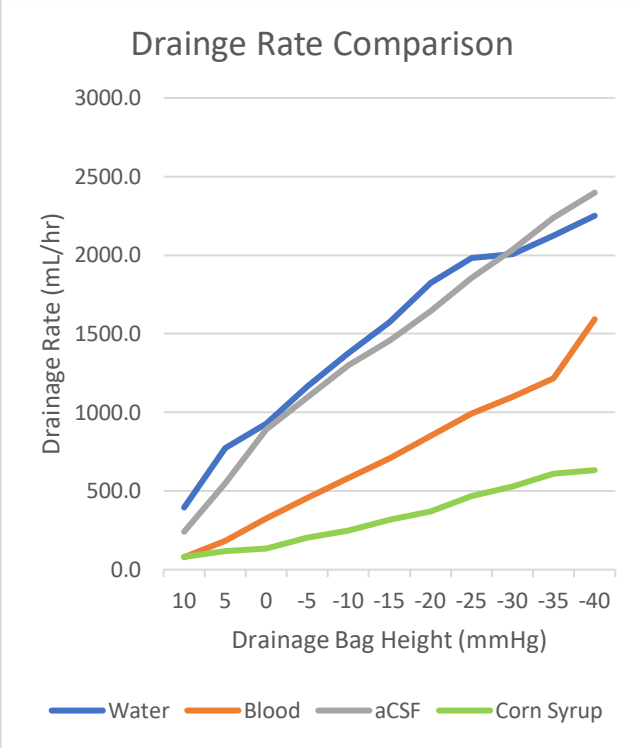
- 1 second to deliver the irrigation bolus
- 9 seconds to monitor ICP
- Rest of time is dedicated to drainage

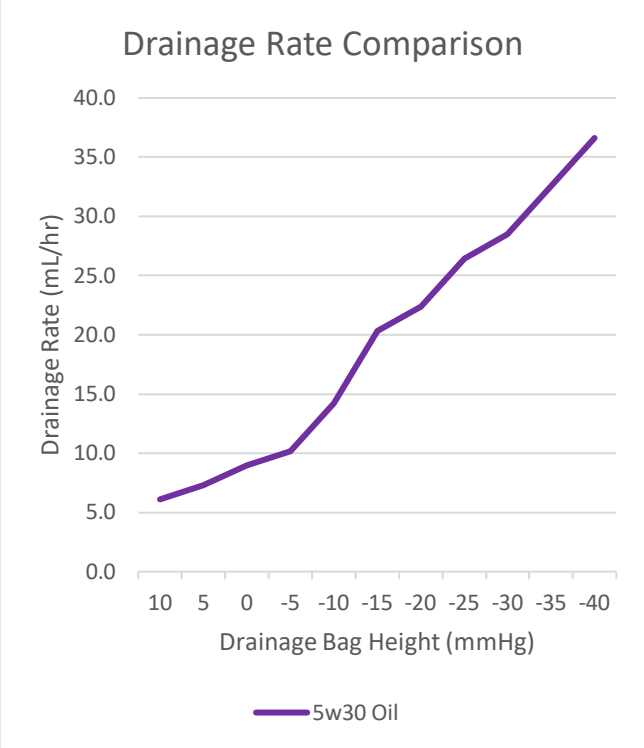
Drainage time will adjust based on the frequency in which the user irrigates. For example, the user chooses to deliver 3 mL's per hour. Therefore, the cycle time would be:

- Every 10 minutes a 0.5 cc of irrigation is delivered in 1 second
- After the irrigation bolus, 9 seconds are dedicated to monitor the patient
- 9 minutes and 50 seconds would be dedicated to drainage

APPENDIX B: DRAINAGE RATE INFORMATION

	WATER Density = 0.001 kg/mL	**BLOOD** Density = 0.00106 kg/mL	**aCSF** Density = 0.00106 kg/mL	**5w30 OIL** Density = 0.000859 kg/mL	**DILUTED CORN SYRUP** Density = 0.00116 kg/mL
Height (mmHg)	Flow Rate (mL/hr)				
10	395.0	79.1	241.2	6.1	81.4
5	772.4	184.6	548.7	7.3	117.5
0	926.2	326.4	891.3	9.0	132.6
-5	1163.9	455.0	1094.0	10.2	201.9
-10	1373.6	583.6	1300.2	14.2	250.1
-15	1576.3	708.9	1457.5	20.3	316.4
-20	1824.5	850.7	1642.7	22.4	370.6
-25	1981.7	992.5	1855.9	26.4	467.0
-30	2006.2	1098.0	2034.2	28.5	527.3
-35	2125.0	1216.7	2240.4	32.6	608.6
-40	2250.9	1592.6	2397.7	36.6	632.7





APPENDIX C: 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 D: TRANSPORTATION

Patient transportation

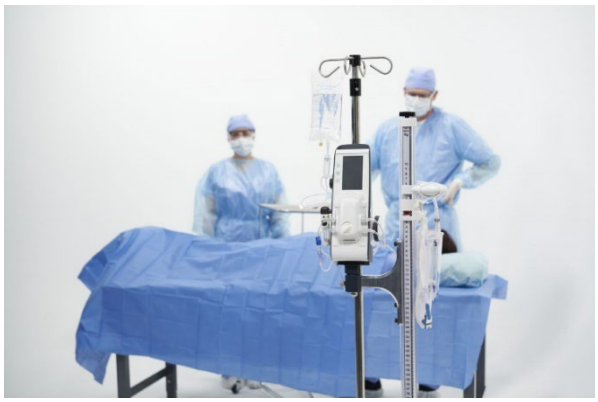
Daily imaging is a frequent occurrence in neurocritical patients and requires transportation of the Control Unit.

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 7001151)

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

APPENDIX E: ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility tests have been performed with a 2.5 m power cable.

CAUTION: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. Only use equipment indicated within this instructions for use.

Guidance and manufacturer's declaration – electromagnetic emissions		
The IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette is intended for use in the electromagnetic environment specified below. The customer or the user of the IRRA*flow* Active Fluid Exchange system should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette must emit electromagnetic energy in order to perform its internal function. Nearby electronic equipment may be affected.
RF emissions CISPR 11	Class A	The IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette is suitable for use in hospital environment, including operation theatres and intensive care units. It should be directly connected to the hospital low-voltage power supply network.

Table B-1 Electromagnetic compatibility

Immunity test	**IEC 60601 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV contact +/- 8 kV air	+/- 6 kV contact +/- 8 kV air
Electrical fast transient / Burst IEC 61000-4-4	+/- 2 kV for power supply lines	+/- 2 kV for power supply lines
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	+/- 1 kV differential mode +/- 2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT)) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT)) for 5 sec
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m

Table B-2 Electromagnetic immunity

Guidance and manufacturer's declaration – electromagnetic immunity

The IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette is intended for use in the electromagnetic environment specified below. The customer or the user of the IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette 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 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communication equipment should be used no closer to any part of the IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz to 800MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5GHz $d = 2.3\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m	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 80MHz and 800MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects and people.

[a] Field strength 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 IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette is used exceeds the applicable RF compliance level above, the IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette.
[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table B-3 Electromagnetic immunity

Recommended separation distances between portable and mobile RF communications equipment and the IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette

The IRRA*flow* system is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the IRRA*flow* Control Unit and IRRA*flow* Intelligent Digital Cassette as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHZ to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.78
1	1.2	1.2	2.3
10	3.8	3.8	7.8
100	12	12	23

For transmitters rated at 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.

Table B-4 Recommended separation distances