IRRA*flow*® CNS System, Control Unit and Tube Set

User Manual

7000219 Rev. G

ICP monitoring and intracranial fluid drainage

CE 0344

Release Date: 2022-06-14

Table of Contents

⚠ IMPORTANT

Read all instructions and warnings prior to use.
Users of the IRRA*flow* CNS System shall be trained medical personnel with training and experience in neurological/neurosurgical medical care.

IRRAS only accepts responsibility for the equipment's safety, usability and performance if:

- the equipment is used in accordance with its intended use, and
- maintenance and repairs are performed by individuals appointed by IRRAS, and
- the equipment is used in accordance with the product documentation.

1. Introduction

1.1. Definitions

IRRA*flow* CNS System	Intracranial fluid drainage system and ICP monitoring device
IRRA*flow* Control Unit	The controlling unit of the IRRA*flow* CNS System
IRRA*flow* Tube Set	Sterile disposable cassette and tubing set
IRRA*flow* Catheter	Sterile disposable catheter
ICP	Intracranial pressure
CSF	Cerebrospinal fluid

1.2. General Description

IRRA*flow* CNS System is an intracranial drainage system intended for use by professional medical hospital personnel, trained and experienced in neurosurgical medical care.

The 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 in order to minimize catheter occlusion. Additionally, a manual bolus can be given to facilitate keeping the catheter clear of occlusion or to clear the catheter of occlusion if one is present. This mechanism works by producing a bolus pulse using short periods of high flow (i.e. flow pulses).

ICP monitoring is done by pressure sensors in the IRRA*flow* Tube Set.

The treatment begins by preparing the IRRA*flow* CNS System, such as 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 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.

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 prior to beginning treatment.

During the treatment, the measured ICP data is shown on the Control Unit display in the form of numbers. The ICP data is also collected into a log file.

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).

After completion of the treatment, a log file containing events and the ICP trends can be extracted to a USB storage device.

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 based on the seriousness of the problem and to ensure the patient's safety.

1.3. Intended Use

The IRRA*flow* CNS System is intended to be used for Intracranial Pressure monitoring and drainage of intracranial fluid. The System consists of the IRRA*flow* Control Unit and two disposable parts, the IRRA*flow* Tube Set and the IRRA*flow* Catheter.

The IRRA*flow* CNS 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 Tube Set, Catheter and irrigation fluids specified by the manufacturer, IRRAS.

1.4. Indications for Use

The use of the IRRA*flow* CNS System is indicated when Intracranial Pressure (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.

1.5. Contraindications

The IRRA*flow* CNS System is not suitable for lumbar drainage.

Due to the severity of the underlying pathology, all the following contraindications for the IRRA*flow* CNS System are relative and should be considered by the medical professional if applicable;

- Known bleeding Diathesis
- Anticoagulation therapy
- Coagulation disorders
- Haemophilia
- A low thrombocyte count
- Treatment with Warfarin or Clopidogrel
- In the presence of infections in the surrounding catheter placement area which includes the skin, subcutaneous tissue, bone and the epidural space.

The use of the Control Unit is contradicted when 24-hour-a-day trained personnel to supervise monitoring and drainage is not available.

2. Safety Regulations

2.1. General Safety Regulations

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 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* Tube Set near strong sources of electromagnetic radiation (e.g. diathermy equipment, MRI).

There is a risk of the user getting pinched when moving the Control Unit up or down. Use care when performing these actions.

After use, the IRRA*flow* Tube Set, IRRA*flow* Catheter and used drainage bag are to be handled per the instructions found in Section 7.15.

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.

No other components than USB memory sticks may be inserted into the USB memory slot in the IRRA*flow* Control Unit. Erroneous use could potentially endanger the integrity of the Control Unit.

Treatments may not be conducted if the surrounding temperature or the atmospheric pressure exceeds any of the limits stated in the manual (see Section 13).

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.

No modification of this equipment is allowed and may interfere with performance and safety.

The IRRA*flow* Catheter is not suitable for lumbar introduction.

⚠ 24-hour-a-day availability of trained personnel to supervise monitoring and drainage is required.

⚠ The IRRA*flow* Tube Set and IRRA*flow* Catheter 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.

⚠ The use of IRRA*flow* Catheter is limited to ≤ 5 days.

2.2. Patient Safety

⚠ 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.

⚠ An unused and sterile IRRA*flow* Tube Set and IRRA*flow* Catheter shall be attached per the instructions in Section 7.2 prior to the treatment of each new patient. To ensure that these accessories are sterile, the user is required to check that the product packaging has not been damaged prior to use and that its expiration date has not been exceeded.

⚠ IRRA*flow* Tube Set and IRRA*flow* Catheter are single-use components. Using the same component for multiple treatments can potentially harm the patient.

⚠ The IRRA*flow* Catheter shall be unpacked and prepared in a sterile area.

⚠ Sterile gloves and mask must be worn when performing care around the area of the Catheter.

⚠ To avoid contamination, the IRRA*flow* Tube Set and IRRA*flow* Catheter are to be handled with care when being attached. Special care should be taken with the Catheter, and the connection of the Tube Set to the Catheter and the connection of the fluid drainage bag.

⚠ Precautions must be taken when changing an empty drainage bag for a new bag to prevent patient infections (Section 7.7).

⚠ Precautions must be taken when disconnecting the IRRA*flow* Catheter from the IRRA*flow* Tube Set to prevent patient infections (Section 7.9).

Only Irrigation fluids specified in this manual can be used when conducting treatments with the IRRA*flow* CNS System (Section 6.1). 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. 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.

To avoid strain between the IRRA*flow* Control Unit and IRRA*flow* Catheter, both the IRRA*flow* Control Unit IV pole and patient bed wheels are to be locked during the treatment. Care should be taken when moving the patient.

Always 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 Section 10.2. 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, IRRA*flow* Tube Set or IRRA*flow* 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, then this could result in injury to the patient and/or the user.

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.

2.3. Operational Safety

Never pour liquids on any part of the IRRA*flow* Control Unit. If this occurs, dry off with a clean cloth.

Always follow the preventive maintenance instructions for the IRRA*flow* Control Unit (Section 10.1).

⚠ No tools need to be, nor should be used when handling the IRRA*flow* CNS System. 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 (Section 6.2).

⚠ To avoid electric shock, this equipment must only be connected to a main with protective earth.

3. The Manual

This manual describes the use of the Control Unit, Tube Set and Catheter, referred to as the IRRA*flow* CNS System.

Users must read this manual and the Catheter User Manual carefully prior to using the IRRA*flow* CNS System for the first time, so that the functions and features are thoroughly understood.

Failure to follow the instructions in this manual may endanger the patient and/or the user!

The following symbols are used in the manual:

Symbol	Meaning
	Failure to follow the instructions may endanger the patient and/or the user

4. Labels

4.1. Control Unit

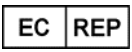
The Control Unit has been labelled with the following symbols:

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
	Name and address of manufacturer
	Date of manufacture
℞ Only	For Prescription Use Only
	Power ON/OFF symbol
	Catalog number
	Serial number: YYYY-XXXX YYYY: Year of manufacture; XXXX-: Four Digit Number
	Follow operating instructions
Input power: 100-240 V~, 50-60 Hz, 85 VA	Rated supply voltage and input power
	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
	Take ESD precautions when using the USB contact
	Unique Device Identifier (UDI) 2D Barcode, unique to each device
	MR-Unsafe – an item that is known to pose hazards in all MR environments
	YYYY-MM-DD Year-Month-Day of expiration
EC REP	European Authorized Representative

CE 0344	The Device Complies with Medical Device Directive 93/42/EEC

4.2. Tube Set

Tube Set has been labelled with the following symbols:

Symbol and Text	Meaning
	Do not reuse
	Name and address of manufacturer
	Date of manufacture
	Follow operating instructions
	Catalog number
	Batch code
	YYYY-MM-DD Year-Month-Day of expiration
	Sterile
	Do not use device if package is damaged
	For Prescription Use Only
	Store within given temperature range
	MR-Unsafe – an item that is known to pose hazards in all MR environments
	Unique Device Identifier (UDI) 2D Barcode, unique to each device
	European Authorized Representative
CE 0344	The Device Complies with Medical Device Directive 93/42/EEC

	Do not dispose device in unsorted trash. This unit should be disposed in accordance with the regulations for electronic waste followed by the hospital

4.3. Other Symbols

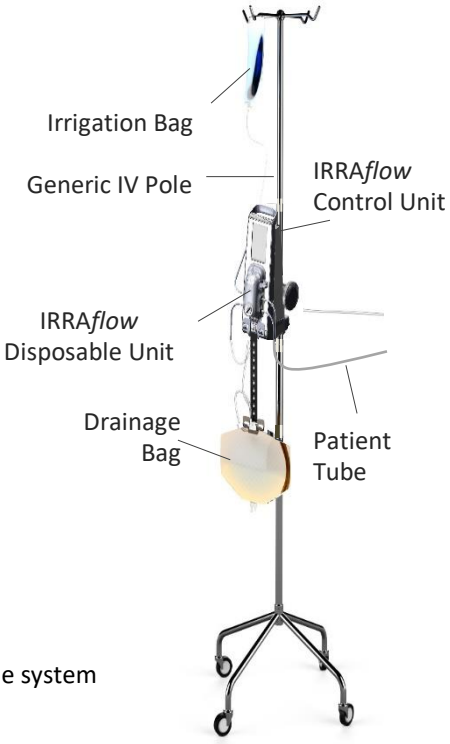
Other relevant symbols for the Control Unit and Tube Set

Symbol and text	Meaning
	The equipment is Class I electrical equipment
	Keep Dry
	Given humidity range

5. System Description

5.1. IRRA*flow* CNS System

The IRRA*flow* CNS System consists of a pole-mounted Control Unit (See inset figure) and two disposable accessories; the Tube Set and the Catheter. The Tube Set has a cassette that attaches to the Control Unit and aligns the tubing to the peristaltic pump and the pinch valve. The drainage bag, holding drained fluid, is attached to a graduated measuring band, defining the height of the bag.



The Control Unit is secured to the pole with a clamp for easy repositioning, to align its height in relation to the Catheter's tip position intracranially, which usually corresponds to the patient's external auditory meatus.
The tubing of the Tube Set and the Catheter can be connected and disconnected by standard Luer-Lock connections. Attached to the pole is also an irrigation bag, providing the system with irrigation fluid.

Settings can be changed on the user interface of the Control Unit. The pressure sensors can be calibrated at any time by using the calibration knob on the Tube Set cassette.

5.2. Function Description

The IRRA*flow* CNS System works as an ICP monitor and drainage system. If occlusion prevents drainage, the Catheter can be irrigated using the incorporated irrigation support.

ICP measurements are displayed on the Control Unit display in the form of numbers. The drainage rate of intracranial fluid is gravity driven and controlled by adjusting the height of the drainage bag.

The cassette part of the Tube Set is equipped with a calibration function for the pressure sensors, controlled by the user with a calibration knob.

The setting for fluid irrigation frequency is defined by the user using pre-set frequency settings. This frequency of irrigation is converted to a flow rate in ml/hour. The default flow rate ("Drain Above") mode is 0 ml/hour, meaning the Control Unit operates with drainage and ICP measurements only.

Irrigation of fluid (0.5 ml/ 1 sec or 1 ml/ 1 sec) can be provided in a single bolus operation or in cyclic mode, where the cyclic mode is a result of the flow rate setting.

The system has a Pre-set mode which is the same as 0 ml/ hour mode except that drainage only starts if the measured ICP value is above the high ICP alarm limit.

A single bolus injection is activated by pushing the bolus button on the user interface. This can be done in any treatment mode when the Control Unit is in a drainage phase. Multiple boluses can be provided if deemed necessary by the user/surgeon.

The system is equipped with an occlusion alarm mechanism. Occlusion is detected as a high ICP alarm.

5.3. User Controls

The panels on the Control Unit housing have the following components:

- Front panel with user interface
- LCD touchscreen display
- Tube Set attachment
- Control Unit height adjustment
- Drainage bag height adjustment

- Air Sensor
- Back panel

5.3.1. Front Panel with User Interface and Touchscreen

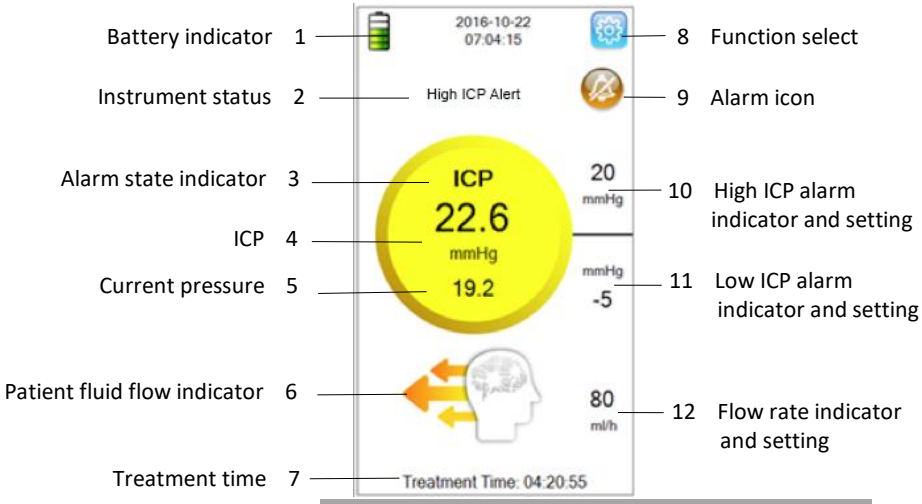
Function is described in the table and figure below.

ITEM	DESCRIPTION	FUNCTION
1	LED	Indicates connection to mains when illuminated
2	Power On	Button powers the Control Unit on or off
3	START/STOP	Button to initiate or terminate treatment
4	Bolus	Button to initiate bolus
5	LCD touch screen	Provides the user system controls and feedback

5.3.2. Display

Functions are described in the table and figure below.

ITEM	DESCRIPTION	FUNCTION
1	Battery indicator	Displays battery charge status and when the Control Unit requires connection to mains.
2	Instrument status	Displays text providing user prompts and warnings. Acts as a touch zone to clear most errors.
3	Alarm state indicator	Displays alarm state (red= excessive high alarm, yellow= high alarm, blue= low alert and grey= no current alarm).
4	ICP	Displays current ICP value. Updates once every cycle.
5	Current pressure	Displays the current pressure, similar to ICP but updated continuously.
6	Patient fluid flow indicator	Displays flow direction, blue arrows indicate irrigation, orange arrows indicate drainage, and green bars indicate no flow or measurement.
7	Treatment time	Indicates the duration of treatment.
8	Function select	Button to select functions within the touchscreen.
9	Alarm icon	Indicator and button to pause or clear the audible alarm.
10	High ICP alarm indicator and setting	Displays values for high ICP alarm level shown in millimeters of mercury. Selectable setting for user.
11	Low ICP alarm indicator and setting	Displays values for low ICP alarm level shown in millimeters of mercury. Selectable setting for user.
12	Flow rate indicator and setting	Displays the selected flow rate in milliliters per hour. Selectable setting for user.

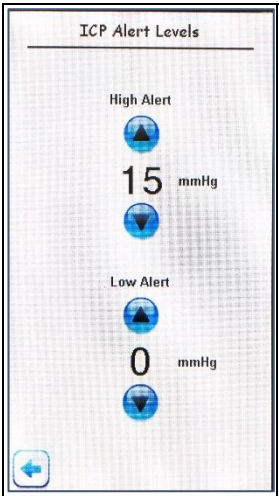


5.3.3. Display Screens

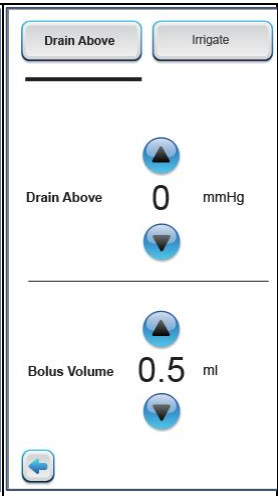
The display shows a broad range of IRRA*flow* CNS System prompts, settings, user information and controls during treatment. A short summary of the different parts of the display is given in the table and figures below (At any given time, only relevant segments of the display will be visible).

DESCRIPTION	FUNCTION
Select Language	Selects language, default is English
Setup Screen	Main setup
Reset Treatment Time	Resets treatment time
Date and Time	Adjusts date and time settings
Priming	Facilitates automated priming
Drain Above	Drainage settings
Irrigation Settings	Adjusts irrigation setting and bolus
ICP Alarm Levels	Adjusts high and low ICP alarm levels
Data Transfer	Facilitates data transfer operations
Main Low ICP Alarm	Blue indicator and short alarm
Main High ICP Alarm	Yellow indicator and medium duration alarm
Main Excessive High ICP Alarm	Red indicator and long or continuous duration alarm
Main Irrigation	Irrigation indicated by blue arrow facing anterior
Main Drainage	Drainage indicated by arrows facing posterior
Treatment Time	Duration of treatment, irrigation and drainage halted

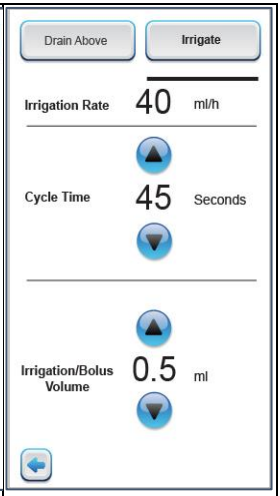
Examples of Display Screens:



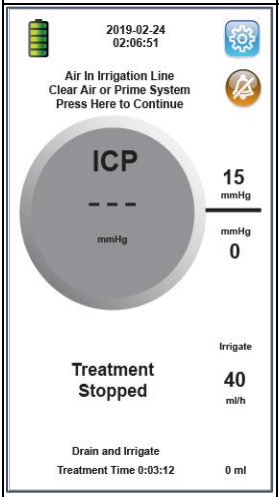
ICP ALERT LEVEL



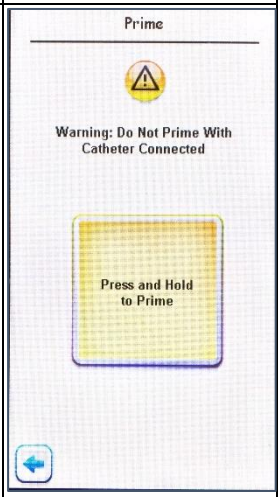
DRAIN ABOVE



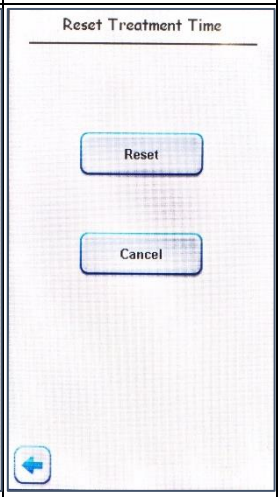
IRRIGATE



AIR IN IRRIGATION LINE



PRIME

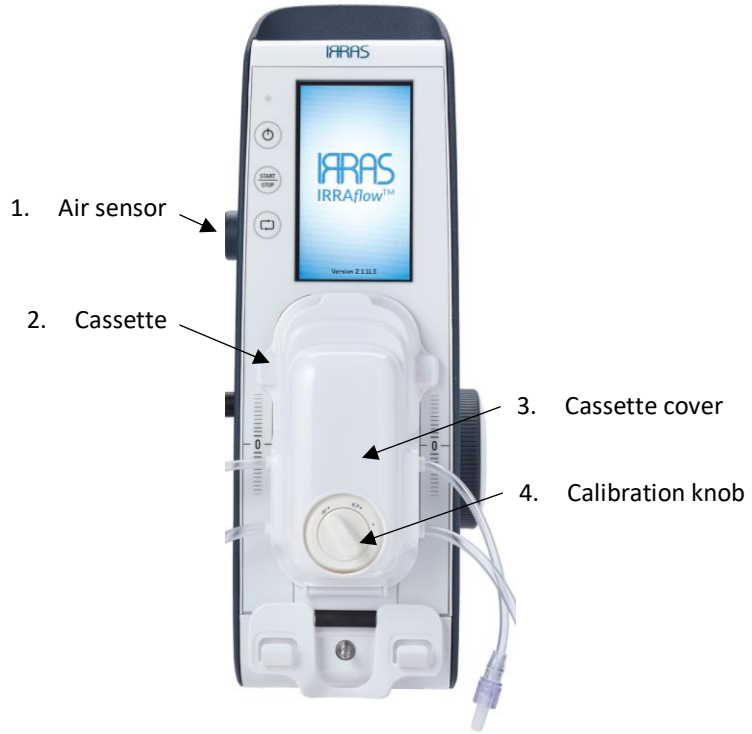


RESET TREATMENT TIME

5.4. Tube Set Attachment

The table and figure below describe the Tube Set attachment to the Control Unit before treatment.

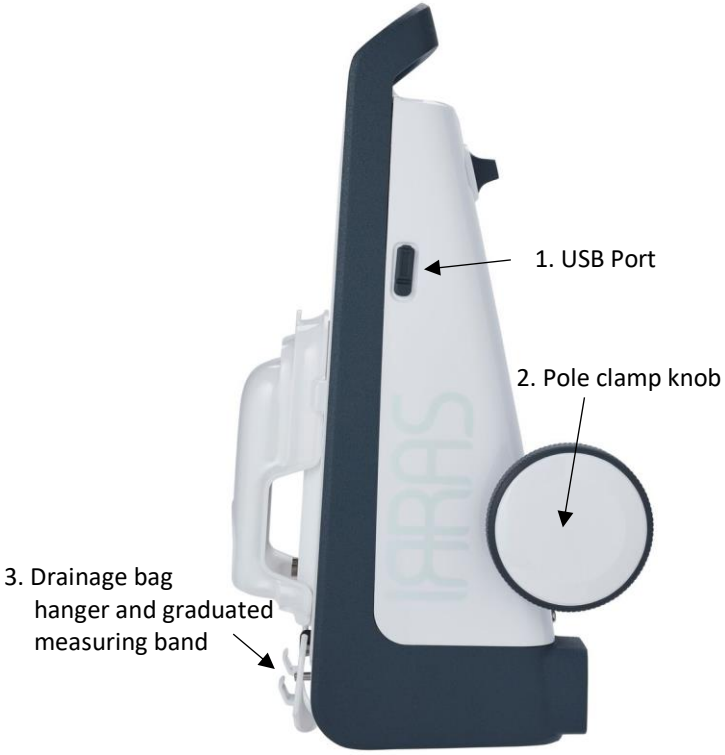
ITEM	DESCRIPTION	FUNCTION
1	Air sensor	A bubble detection sensor used to identify when the irrigation bag is depleted.
2	Cassette	A main component of the of IRRA*flow* Tube Set. The cassette connects the administration tubing to the Control Unit, housing pressure sensors, pinch valve, and peristaltic pump interface.
3	Cassette cover	Used to enclose the cassette.
4	Calibration knob	Used to calibrate the pressure sensors.



5.5. Height Adjustment, Bag Hanger and USB Port

The table below describes the parts used when adjusting the Control Unit height relative to the patient, the drainage bag height relative to the Control Unit and the port for transferring data from the Control Unit.

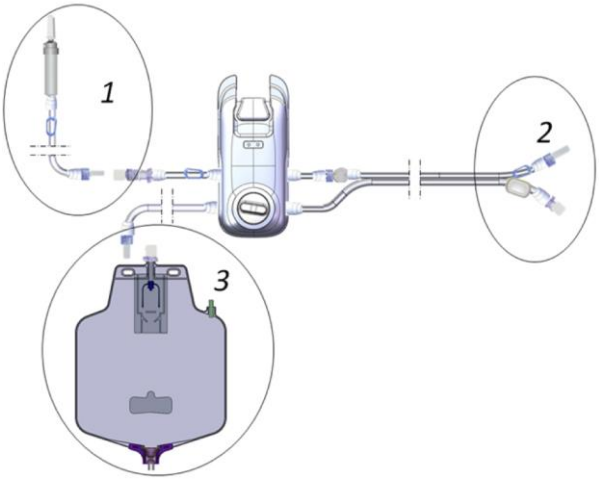
ITEM	DESCRIPTION	FUNCTION
1	USB Port	Data transfer to and from a USB memory stick.
2	Pole clamp knob	Hand knob used to tighten the pole clamp.
3	Drainage bag hanger and graduated measuring band	Mechanism to hold and set the height of the drainage bag.



5.6. Accessories

5.6.1. Tube Set Description

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



Tube Set contents:

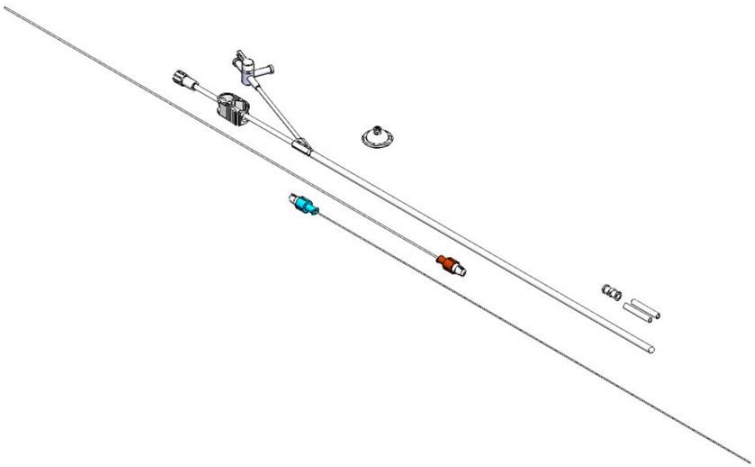
- The cassette that attaches to the front of the Control Unit housing (Section 7.2.6).
- Pressure sensors' calibration knob.
- Security valve between the irrigation spike and cassette. When the cassette is correctly mounted to the Control Unit, the pump closes the irrigation line. The security valve will prevent the free flow of irrigation fluid into the brain of the patient, if the cassette is removed while still connected to the patient, or if the pump's irrigation control malfunctions.
- A set of tubes channelling fluid to and from the patient.
- Drainage bag with a drain valve for emptying the bag.

5.6.2. Catheter Description

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

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.

6. Additional Equipment

6.1. Irrigation Bag and Irrigation Fluids

Only approved irrigation fluids are to be used for a treatment with the IRRA*flow* CNS System. Any, approved for hospital use, standardized, sterile physiological, isotonic, IV solution in 500- or 1000-mL bags (such as a 0.9% solution NaCl, Ringer's lactate etc.) is considered approved by IRRAS.

The irrigation bag must be sterile.

The temperature of the irrigation fluid is body temperature, or at the discretion of the physician.

6.2. USB Storage Device

A USB storage device can be used with the Control Unit to transfer measurement data from the unit to a separate computer for storage and importing into an excel spreadsheet report. When the USB storage device is connected after a treatment, all measurement data collected during the treatment is saved on the memory stick. The transfer log screen on the LCD display allows user to select the file or files designated for transfer to the USB storage device.

6.3. Laser Leveller

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.

7. Instructions for Use

7.1. Control Unit Initial Setup

The initial setup of the Control Unit shall be performed by authorized IRRAS personnel.

⚠ **Clean the IRRA*flow* Control Unit per the cleaning instructions provided in Section 10.2, prior to the first use.**

7.2. Preparations

7.2.1. Preparing the Control Unit

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

Adjust and verify that the zero line of the Control Unit is at the same horizontal level with patient's external auditory meatus.

Inspect the Control Unit cassette interface before use; no damage shall be visible on the pump, valve and connector.

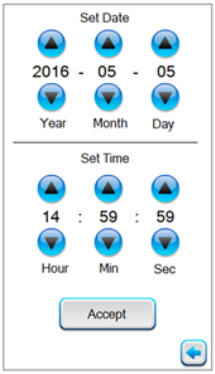
7.2.2. Start Up

Turn on the Control Unit by pressing the power button.

The display will ask you to set up the date and time. This can be done using the buttons on the touch screen.

7.2.3. Setting Time and Date

After pressing the power button, the Control Unit will display: "Touch here to set clock." The user can set the year, month, day, hour and minute by touching the arrows. Press Accept when finished setting up the date and time.



The time is displayed as a 24-hour clock.

7.2.4. Setting up the Control Unit for Treatment

To set up the Control Unit for treatment, the user must enter the following settings:

1. Set the appropriate upper and lower pressure alarms for the patient by using the buttons on the right side of the display.
2. Set the flow rate in the irrigation settings.
3. Adjust the Control Unit height to match the zero line at the patient's external auditory meatus. See Section 7.2.5 for instructions.

⚠ **Setting the upper alarm too high or lower alarm too low may put the patient at risk.**

7.2.5. Adjusting the Height of the Control Unit

The height of the Control Unit is adjusted in relation to the patient by using features of the Control Unit panel described in Section 5.5.

Adjust and verify that the zero line of Control Unit is at the same horizontal level as the patient's external auditory meatus.

⚠ The treatment shall always be paused when the patient is moved up or down. If this is not done, the Control Unit will fail to trigger alarms when necessary and may put patient at risk or trigger false alarms.

7.2.6. Attaching the Tube Set

Carry out the following to connect the IRRA*flow* Tube Set to the Control Unit front panel.

Additional accessories needed: Irrigation bag with approved irrigation fluid (Section 6.1).

NOTE: All handling of bags and sterilized components shall follow the hospital routines for such items.

7.2.7. Tube Set Inspection, Setup, Calibration and Priming

Inspection

1. Inspect the Tube Set package for damage
2. Confirm that all clamps are open
3. Confirm that the tube in the cassette follows the black plastic evenly
4. Arrange to open Tube Set package carefully to maintain sterile condition as indicated in Figure 1. Strictly maintain sterile conditions when handling the irrigation spike and connectors.

Connecting the Tube Set to the Control Unit Front Panel

5. Attach the male Luer connector of the spike/drip chamber tube to the female Luer connector at the side of the cassette (position 1), see figure below. Unfold the tubes and drainage bag, no tangling or interference should remain between the separate ends of the Tube Set.
    - One end consists of a spike/drip chamber (position 1);
    - One end consists of two connectors (parallel tubes, position 2); and
    - One end consists of a drainage bag (position 3).

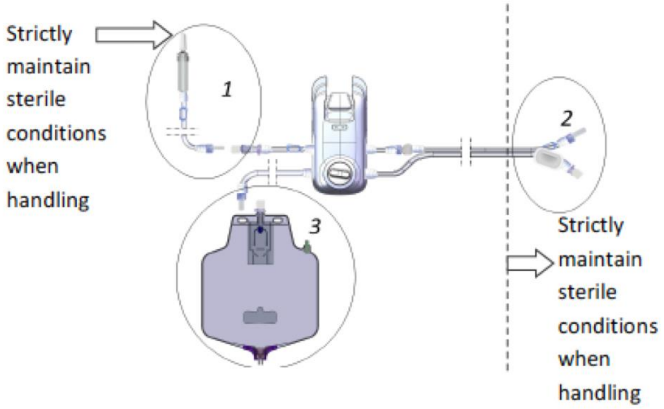
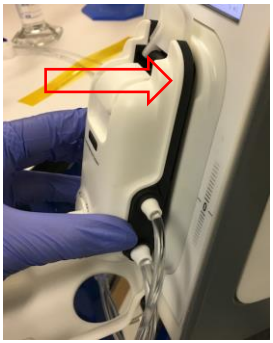
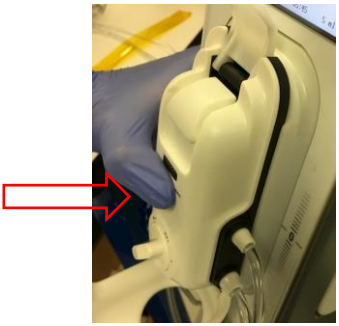


Figure 1: *The three ends of the Tube Set: (1) the irrigation bag spike; (2) two connectors; and (3) the drainage bag.*

6. Attach the Luer connections at position 2 together (male to female). Attach the provided extra length of tubing if needed.
7. Hang the irrigation bag onto the hook of the IV-pole. Permissible height of the irrigation bag is a maximum of 70 cm above the zero line of the Control Unit, and not any lower than the Control Unit.
8. Close the clamp just below the drip chamber (position 1) to prevent free flow and mount the spike into the irrigation bag.
9. Connect the drainage tube end to the drainage bag.
10. Mounting the Cassette onto the Control Unit:
    a. View the bottom serial number side of the cassette and confirm that the silicone tubing is oriented approximately normal to the inlet and outlet tubing. If not, adjust using a gloved forefinger.
    b. To install the cassette onto the Control Unit, open the cassette cover on the Control Unit, insert the upper end of the cassette onto the pump rollers and then fit lower end of the cassette onto the key-pins.



    c. Using your thumb, push the cassette flat against the front cover of the Control Unit. See below.



d. While holding the cassette flat against the front cover lever, press the cassette downward into the operating position. See below.

11. Press the cassette lever firmly downwards to lock the cassette into position. Raise the cassette lid to magnetically latch to the face of the Control Unit.

Calibration

The cassette part of the Tube Set is equipped with a calibration function, which is controlled by the calibration knob. Calibration needs to be performed when prompted by the Control Unit, the Control Unit will automatically prompt for calibration.

At delivery, the calibration knob is in the transport position which means that tubing inside is open to atmosphere. If the calibrated value is incorrect, the unit shall be removed from service and the fault should be reported to the distributor. Service may only be performed by authorized service personnel.

12. Calibrate the system by following the routine for calibration:

    a. Turn the calibration knob to Calibration-mode, passing first position which is operational mode. Once transport position is left, it cannot be returned.

    b. In Calibration-mode, the pressure sensors are connected to atmospheric pressure and the pressure signal is set to zero.

    c. With the calibration knob in Calibration-mode, wait until the ICP value is zero (0). The pressure sensors are now calibrated.

    d. Turn the calibration knob to Operational-ICP mode to make the Tube Set ready for treatment.

    e. IRRA*flow* CNS System will provide an alert to calibrate when needed.

13. The system automatically will prompt for calibration to be done once every 24-hours.

14. 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). 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. Also, make sure that the tube portion with printed text is not mounted into air sensor slot.

Priming

15. Hang the drainage bag onto the graduated measuring band on the Control Unit front. Adjust the height of the drainage bag, i.e. drainage force, by adjusting the graduated measuring band's length. The minimal height of the drainage bag is 15 cm.

    Check that all clamps are open, that the valve of the drainage bag is closed, that the Luer connections at position 2 are attached together (male to female).

    Press the Function Select tool on the display and open the Priming menu. Press the yellow "prime" field and hold until the tube is completely filled with irrigation fluid to the drainage bag. Return to the main display and touch "Press Here to Continue."

    When priming is complete and stopped, check that no irrigation flow occurs by inspecting the irrigation drip chamber for 5-10 seconds. Check that the Cassette and Tube Set are not leaking fluid. If leakage is found, replace the leaking part. Also, check that irrigation fluid has entered the drainage tubing all the way to the drainage bag.

    The Cassette and Tube Set are now mounted onto the Control Unit and the system is calibrated.

7.2.8. Inserting and Securing the Catheter

Before connecting the Tube Set and the Catheter, the patient settings need to be set (alarm levels and flow rate).

For procedures regarding the insertion and securing of the Catheter, thoroughly read the Catheter User Manual.

7.2.9. Catheter to Tube Set Connections

Connecting the Catheter to the Tube Set

1. Close the Tube Set lines by clamping the two roller-clamps.
2. Close the Catheter lines by clamping the pinch clamp and closing the stop-cock.
3. Mount the female connector of the Tube Set tubing to the male connector of the Catheter.

4. Mount the male connector of the Tube Set to the female connector of the Catheter.
5. Open the white clamps at the drainage side, then open all the blue clamps at the irrigation side.
6. The Catheter is now connected to the Tube Set. If the IRRA*flow* CNS System is not to be started immediately, close all clamps of the Catheter until treatment is about to start.

⚠ **Always maintain *strict* sterile conditions when handling the connection between the Catheter and Tube Set.**

7.3. User Check List

Prior to the start of treatment:

- Confirm that all clamps are open along the Tube Set and Catheter tubing
- Confirm that there are no kinks or blockage of the drainage tubing
- Check that the Control Unit has a correct vertical position at the patient's external auditory meatus

7.4. Start Treatment

Prior to start, the user must perform the User Check List above.

The Control Unit starts the cycle of irrigation and drainage as set by the user in Section 7.2.4.

The treatment is started by pressing the Start/Stop button once.

⚠ **If treatment is started without unclamping the drainage tubing, there is a risk of elevating ICP as the system may have been set up for irrigation during treatment.**

7.5. Checks During Treatment

Periodically check:

- Drainage to detect kinks or blockage in tubing and to inspect drainage rate
- Drainage bag, to see if it requires emptying or changing
- That the Control Unit has not changed vertical position

Failure to adjust the drainage rate correctly may result in serious injury to the patient.

A drainage flow that is too high may lead to over-drainage, which may cause intracranial bleeding.

7.6. Bolus

The user can irrigate the Catheter and irrigation part of tubing with a bolus injection of 0.5 ml or 1 ml by pressing the button with the circular arrow found to the middle left of the display, but only during the drainage phase of treatment.

When irrigating the system, drainage does not take place (i.e. the drainage valve is closed) and the irrigation pump runs for a short period of time. The user can recognize the bolus function operation by hearing pump action and observing fluid flow in the irrigation spike or drip chamber. The bolus function can be used according to the discretion of the treating neurosurgeon.

After a bolus irrigation, inspect ICP value and drainage progress in the drip chamber of the drainage bag.

7.7. Changing the Irrigation Bag

When changing the irrigation bag, use the following procedure:

1. Stop the treatment by pressing the Start/Stop button on the Control Unit
2. Clamp the irrigation tube
3. Arrange a sterile environment around the irrigation spike and work with sterile gloves
4. Hang a new, sterile irrigation bag on the IV pole
5. Remove the irrigation spike from the empty irrigation bag
6. Mount the irrigation spike to the new irrigation bag immediately
7. Unclamp the irrigation tube
8. Start treatment by pressing the Start/Stop button on the Control Unit
9. Inspect that fluid is flowing from the irrigation bag, unless a Drain Above or Irrigation rate of 0 ml/h is chosen

⚠ **Always maintain *strict* sterile conditions when handling the irrigation spike. If accidental contact with the spike occurs, replace with sterile spike.**

7.8. Emptying the Drainage Bag

When emptying the drainage bag, use the following procedure:

1. Stop the treatment by pressing the Start/Stop button on the Control Unit
2. Clamp the drainage tube
3. Open the drainage valve
4. Empty the drainage bag
5. Close the drainage valve
6. Unclamp the drainage tube
7. Start treatment by pressing the Start/Stop button on the Control Unit
8. Inspect that fluid is flowing into the drainage bag

7.9. Pause Treatment, Disconnecting the Catheter and Tube Set

To pause treatment or disconnect the Catheter and Tube Set, execute the following procedure:

1. Stop the treatment by pressing the Start/Stop button on the Control Unit. The system will give a visual indication that treatment is stopped.
2. Arrange a sterile environment around the connections and work with sterile gloves.
3. Clamp the two tubes near the Luer-lock connections on the Catheter.
4. Clamp the two tubes near the Luer-lock connections on the Tube Set.
5. Disconnect the Catheter from the Tube Set. Protect the Luer-lock connections from contamination while disconnected.
6. Unclamp both lumens of the Catheter, hold it lower than the patient's head and allow some fluid to exit, then irrigate 1 ml of physiological fluid into the irrigate lumen of the Catheter and then clamp the irrigation lumen. Then irrigate 1 ml of physiological fluid into the drainage lumen of the Catheter and clamp the drainage lumen. Then mount the two connectors of the Catheter tubing to each other, female to male.

7. Prime the system's tubing until the drainage line is clear of bloody or viscous fluid.
8. It is advisable to arrange a sterile compress, or similar around the connectors of each loop (Catheter and tubing).
9. The patient can now be transferred to other departments (MRI, etc.).

⚠ **To protect the patient from contamination, it is important that this procedure is followed and performed in a sterile environment, and that care is taken to protect the Luer-lock connections from any contamination.**

⚠ **Do not disconnect the cassette from Control Unit, unless the tube clamps are closed.**

⚠ **When treatment is stopped, no ICP measurements are made and the irrigation and drainage stop. This leads to a risk for high ICP which may lead to brain damage.**

7.10. Re-Connecting the Catheter and Tube Set after Pause

To connect the Tube Set with the Catheter after temporary treatment interruption, use the following procedure:

1. Make sure that this procedure is done in a sterile environment.
2. Make sure that all tubing of the Catheter and Tube Set are clamped before dismounting any Luer caps.
3. Dismount the Catheter female from the Catheter male connector. Dismount the Tube Set female connector from the Tube Set male connector.
4. Connect the irrigation side of the Catheter to the irrigation side of the Tube Set, blue clamp tubing. Then connect the drainage side of the Catheter to the drainage side of the Tube Set, white clamp tubing. The Catheter is now connected to the Tube Set.
5. Open the white clamps on the drainage side and then the blue clamps on the irrigation side and start treatment. If the IRRA*flow* CNS System is not to be started immediately, keep all clamps closed until treatment is about to start.

To protect the patient from contamination, it is important that this procedure is done in a sterile environment, and that care is taken to protect the Luer-lock connections from any contamination.

7.11. Setting Changes During Treatment

7.11.1. Changing Flow Rate Settings

Prior to the start of treatment, or at any time during the treatment, the user may change the flow rate settings by selecting the displayed flow rate on the LCD touch screen, and then by pressing the up/down button on the display.

The Drain Above mode makes no irrigations and only drains when the measured ICP is above the value set by the user.

A high flow setting could be used when draining a haemorrhagic fluid. A lower flow setting could be used for ICP monitoring and draining of clearer fluid.

Check periodically that the expected irrigation flow is present by viewing the irrigation drip chamber.

7.11.2. Upper and Lower ICP Alarm Controls

At any time during the treatment, the user can modify the upper and lower ICP alarm settings by pressing the respective buttons found to the right of the display.

The default upper ICP alarm level is 15 mmHg and the default lower ICP alarm level is 0 mmHg.

During a power loss, the modified upper and lower ICP alarm levels will be retained if the internal battery is not depleted. After the onset of a power loss, the battery will not be depleted until at least 30 minutes have passed.

ICP alarm levels are set according to the discretion of the responsible neurosurgeon. Incorrect ICP alarm levels could result in serious injury to the patient. The ICP alarms are a means of protecting the patient from any harmful over-irrigation or over-drainage due to a clinical change, equipment error, partial or total blockage in the IRRA*flow* Tube Set, or the IRRA*flow* Catheter.

7.12. Drainage Bag Height Adjustments

The distance of the drainage bag to the Control Unit can be adjusted by using part of the Control Unit panel described in Section 5.5.

By lowering the drainage bag, drainage flow is expected to increase. By elevating drainage bag, drainage flow is expected to decrease. Inspect the drainage flow in drainage bag drip chamber.

⚠ **Failure to adjust the drainage flow correctly may result in serious injury to the patient. Periodically monitor the drainage flow and progress.**

⚠ **A drainage flow that is too high may lead to an intracranial hemorrhage or Catheter occlusion.**

7.13. Stopping Treatment

Press the Start/Stop button on the Control Unit to stop treatment. The system will provide a visual indicator that treatment has stopped.

Go to Section 7.3 to perform necessary checks prior to restarting treatment.

⚠ **When treatment is stopped, no ICP measurements are made and irrigation and drainage are stopped.**

7.14. Moving the Control Unit

The Control Unit may be moved between different wards within the hospital during treatment. The Control Unit may operate with a battery, see Section 8 for battery operated treatment.

If the patient is considered stable enough, the Catheter may be clamped and disconnected for inter hospital transportation as described in Section 7.9.

7.15. Removal & Handling of Tube Set, Catheter & Irrigation Fluids

Stop the treatment by pressing Start/Stop button on the Control Unit.

To remove the Cassette from the Control Unit, make sure that the Control Unit is turned on; close the clamp on the tubing, open the Cassette lid and un-mount the Cassette from the Control Unit.

Dispose of the Tube Set, the Catheter and the drainage bag with its remaining contents as contaminated biohazard waste in accordance with the hospital's standard routines.

⚠ **Do not disconnect the Cassette from the Control Unit, unless the clamps on the Tube Set are closed.**

7.16. Log

The Control Unit logs measurements and events which can be retrieved by inserting a USB memory stick into the USB port.

Contact customer service for details on extracting or using the log data.

The log is contained in non-volatile memory and is retained when the Control Unit is powered down as well as in the event of a power loss and eventual subsequent battery depletion. The time of the powering down is logged.

The logs will contain the following elements at a minimum:

- Real Time of event
- Type of event (e.g. normal log or error)
- Most recent pressure measurement at event
- Treatment phase at event
- Pump flow setting at event
- Pinch valve state at event

8. Battery

The Control Unit is equipped with a battery, rechargeable via mains power. When the Control Unit is connected to mains power, the battery is charging. The battery is designed for a minimum of 60 minutes of use. When the battery has a minimum of 30 minutes of use left, an alarm will sound and an indicator on the LCD display will indicate the Control Unit needs to be reconnected to the mains power.

When irrigation and drainage can no longer be performed due to low battery, the system will create a high intensity alarm for 5 minutes. When the battery is depleted, no irrigation or drainage is possible, and the system will go into a safe state.

Replacement of battery shall only be performed by personnel appointed by IRRAS.

To disconnect the unit from mains power, unplug the power cord from the back of the Control Unit.

9. Alarms, Alerts and Warnings

Problem	Possible Solution or Action
Treatment is on-going, but no flow is seen in the irrigation drip chamber.	Check if the Drain Above or Irrigation rate "0 ml/hr" is chosen. Check if the irrigation bag is empty.
Treatment is on-going, but no flow is seen in drainage drip chamber.	Check to see that the drainage tube clamps are closed, they should be open during treatment. Check to ensure there are no kinks or blockage in the tubing. Check the clamps throughout Tube Set. Check for alarms. Check the irrigation rate settings and inspect the irrigation flow in the irrigation drip chamber. Stop treatment and notify the neurosurgeon.
Treatment cannot be started.	Check alarm symbols on display (Alarm Information Section). Is the cassette mounted correctly? Is the irrigation tube mounted correctly into the air detector slot?

9.1. Alarm Information

Adjustable alarm limits are monitored periodically during treatment.

ICP Status	Alarm Priority	Displayed Message	Drainage Allowed	Irrigation Allowed	Additional Requirements
Low ICP Alarm	Low	Low ICP Alarm	No	No	➢ Alarm is triggered when ICP is less than Low ICP Alarm Limit ➢ Alarm is cleared when pressure exceeds Alarm Limit
High ICP Alarm	Medium	High ICP Alarm	Yes	Yes	➢ Alarm is triggered when ICP exceeds High ICP Alarm Limit ➢ Alarm is cleared when pressure drops below Alarm Limit

ICP Status	Alarm Priority	Displayed Message	Drainage Allowed	Irrigation Allowed	Additional Requirements
Excessive High ICP Alarm	High	High ICP Warning Touch Here to Continue Treatment	Yes	No	➢ Alarm is triggered when ICP exceeds High ICP Alarm Limit by more than 3 mmHg ➢ Drainage will start when this alarm is triggered and continue for two minutes. After two minutes, the valve will be closed. ➢ Unit will not return to programmed treatment until user acknowledges the alarm by touching the area indicated on the screen.

9.2. Alarm Limits

Low alarm range: -99 to 10, default 0 mmHg

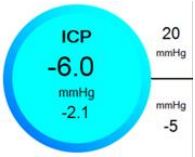
High alarm range: +11 to 99, default 15 mmHg

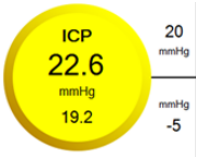
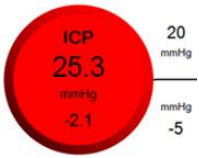
9.3. Clearing or Pausing Alarms

To clear pressure related alarms, press the alarm icon on the touch-screen. Note: This icon can pause the alarm for 30-seconds in all states other than pressure related alarms. While the alarm is silenced, the alarm icon blinks.

9.4. Alarm Priority

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

Alarm Priority	Audible Signal	Visual symbol
Low	2 Beeps repeating every 30 seconds	

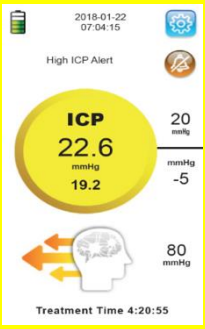
Medium	3 Beeps repeating every 7.5 seconds	
High	10 Beeps repeating every 2.5 seconds	

9.5. List of Warning Prompts

A combination of symbol and visual user prompts will be displayed on LCD.

WARNING or FAULT	PRIORITY	CORRECTION
Air sensor detects no tubing or an empty bag	High	Replace the tubing or irrigation fluid bag
Battery power low (<30 minutes)	Low	Reconnect to mains
Battery depleted	High	Reconnect to mains
Control Unit technical errors	Medium	Restart Control Unit or remount the cassette
Irrigation bag is empty	Low	Change the irrigation bag
Cassette door open	Low	Close the cassette door
Cassette mounting	Medium	Attach the cassette
Calibration required	Low	Perform calibration
Low ICP alarm. ICP below user set lower alarm level	Low	Notify qualified medical personnel
High ICP alarm. ICP above user set upper alarm level	Medium	Notify qualified medical personnel
Excessive high ICP alarm. ICP more than 3 mmHg above user set upper alarm level	High	Notify qualified medical personnel

9.6. Troubleshooting Alarms

Display	Potential Cause	Potential Resolutions
	1. Patient moving causing false ICP reading. 2. ICP is too high. 3. Catheter Occlusion. 4. Valve of tubing from catheter has been shutoff. Catheter or tubing from the catheter has become kinked. 5. Irrigation may be occurring which causes a momentary spike in the pressure reading. 6. Patient not being monitored appropriately.	• Assess Patient to ensure they are ok. • Remeasure Control Unit to zero. • Ensure catheter and lines going from catheter have not been kinked or damage has occurred that would cause flow to slow or discontinue. • Check the tubes and the catheter (kinking) and all clamps (open). • Wait a few cycles to see if system will adjust itself. • Call Physician.
	1. Patient moving causing false ICP reading. 2. ICP is too high. Catheter Occlusion. 3. Valve of tubing from catheter has been shutoff. 4. Catheter or tubing from the catheter has become kinked. 5. Irrigation may be occurring which causes a momentary spike in the pressure reading. 6. Patient not being monitored appropriately.	• Assess Patient to ensure they are ok. • Remeasure Control Unit to zero. • Ensure catheter and lines going from catheter have not been kinked or damage has occurred that would cause flow to slow or discontinue. • Provide bolus if you believe catheter is clogged. • Call Physician.
	1. Patient has moved causing false ICP reading. 2. Drainage bag has been placed too low causing excess drainage. 3. Patient not being monitored appropriately.	• Before taking any action, wait two cycles (you can silence the alarm), sometimes the system corrects itself. • Assess Patient to ensure they are ok. • Remeasure Control Unit to zero. • Ensure catheter and lines going from catheter have not been disconnected. • Lift up the drainage bag. • Call Physician.

10. Care and Maintenance

10.1. Preventative Maintenance

The user is not required to perform any preventive maintenance on the equipment. Service may only be performed by authorized IRRAS service personnel.

10.2. Cleaning and Disinfection

The Tube Set is provided sterile for single use and may NOT be cleaned, disinfected, or re-sterilized.

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 soft cloth.

Only the following disinfectant liquids may be used:

1. Denatured ethanol
2. Isopropyl alcohol
3. Chloroxylenol 5%
4. Chlorhexidine

If there are doubts about how to clean the unit, the effect of cleaning, the functions and/or safety of the unit, then the unit should be withdrawn from service and the distributor consulted (Section 15).

⚠ **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.**

11. Transportation and Storage

During transportation, the Control Unit, Tube Set and Catheter are to be handled with care. The Control Unit is to be handled according to specifications in Section 13.1.

Never store the Control Unit in close proximity to heat sources or in places where the unit may become heated (e.g. in direct sunlight).

If the Control Unit is stored in an environment that differs from the operating environment, allow a minimum of 1 hour of acclimatization to the operating environment before starting the treatment.

12. Training and Assistance

Users shall be medical personnel with training and experience in neurosurgical medical care. For advice and assistance with the Control Unit and its accessories, please contact your local distributor.

Region:	**USA**
E-mail address:	US.customerservice@irras.com
Phone:	1-800-213-4604
Region:	**Global**
E-mail address:	global.customerservice@irras.com
Phone:	**3**1 20-210-1098
URL:	http://www.irras.com

13. Appendix A

13.1. Specifications

13.1.1. Classification of Medical Device

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
- For continuous operation

13.1.2. Safety Standards

The Control Unit and Tube Set are 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: 2015 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+A1:2017 Medical 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 60601-2-24: 2012 Medical electrical equipment – Part 2: Particular requirements for the safety of infusion pumps and controllers

13.1.3. Environmental and Handling Conditions

Control Unit Operation: Temperature range	+15 to +30°C
Tube Set Operation: Temperature range	+15 to +30°C
Operation: Air humidity	30 – 95 %

Operation: Ambient pressure	70 – 106 kPa
Storage and transport Temperature range	-25 to +60 °C (Control Unit) -25 to +50 °C (Tube Set)
Storage and transport air humidity	20 – 80 %
Storage and transport at ambient pressure	50 – 106 kPa
Vibration/Shock/Bump	It is possible to transport the system worldwide by air, road, ship, and train.
Drop/Free fall	It is possible to transport the system worldwide by air, road, ship and train.
EMC/ESD	The IRRA*flow* Control Unit and IRRA*flow* Tube Set meet the requirements in accordance with IEC 60601-1-2 Electromagnetic compatibility.
IRRA*flow* Control Unit service life	5 years
IRRA*flow* Tube Set maximum usage time	5 days

13.1.4. Technical Specifications

Description	Intracranial fluid drainage system & ICP monitoring device
Name	IRRA*flow* Control Unit
Catalogue part number	ICCU 020
Dimensions	35 (H) x 14 (BW) x 19 (D) cm
Weight	3.5 kg
ICP range*	-100 to 250 mmHg
ICP accuracy*	±2 mmHg or 10%, whichever is greater, in the range of 0-99 mmHg
ICP zero-point drift	< 1 mmHg between calibrations
Selectable rates	Irrigation Rates: 0.5 Bolus: 10, 15, 20, 30, 40, 45, 50 and 90 ml/hr 1.0 Bolus: 20, 30, 40, 60, 80, 90, 100 and 180 ml/hr

Volume per bolus	0.5 or 1.0 ml
Bolus volume accuracy	± 0.4 ml
Maximum irrigation *flow*, bolus	1 ml/s
Maximum flow, average over a full cycle	180 ml/hour (flow rate: 1 ml/s)
Maximum irrigation pressure	550 mmHg
Size of unintended bolus from occlusion	Less than 1 ml
Dead space from Catheter tip to pressure sensor	10 ml
Pressure measurement bandwidth (current pressure, not ICP)	1 Hz
Operating time on battery at maximum irrigation rate	Minimum of 30 minutes
Sound pressure level of alarms	60-70 dB(A) at 1 m from the control unit
Maximum volume that may be irrigated under single fault conditions	1.7 ml
Power supply	100 - 240 VAC, 50 – 60 Hz
Power consumption	Max 20 W
Defibrillation recovery time	10 seconds
Operating Mode	Continuous
Power cord set length	2.5-3.0 meter
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 Sensor
Defibrillation proof applied part	Cassette Irrigation Line and Catheter
Fuse	T1.0A/L250V

Note: Not made with natural rubber latex.

* Range and accuracy also applies to displayed values.

13.2. Accessories and Spare Parts

Please contact your local distributor to order the following accessories or spare parts.

- IRRA*flow* Tube Set, ICDS 020
- IRRA*flow* Laser Leveler, ICLS 010
- IRRA*flow* Drainage Collection System, DCS 010
- IRRA*flow* Catheter, ICGS 020
- IRRA*flow* CNS System User Manual
- IRRA*flow* Catheter User Manual

13.3. Support, Service and Scrapping

All maintenance and service of the Control Unit and its accessories is to be performed by IRRAS. There are no parts of the Control Unit, Tube Set or Catheter that can or may be repaired by the user. Any attempt to repair and/or modify the product constitutes a breach of the terms and conditions of the warranty and means that the function and safety of the unit can no longer be guaranteed.

Note that the Control Unit contains substances which can be harmful to humans, animals and their surroundings.

Region:	**USA**
E-mail address:	US.customerservice@irras.com
Phone:	1-800-213-4604
Region:	**Global**
E-mail address:	global.customerservice@irras.com
Phone:	**3**1 20-210-1098
URL:	http://www.irras.com

⚠ **The IRRA*flow* Control Unit, IRRA*flow* Tube Set and IRRA*flow* Catheter should be handled according to the hospital policy concerning the management of environmental and biological hazardous waste.**

14. Appendix B

14.1. Electromagnetic Compatibility

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

Guidance and manufacturer's declaration – electromagnetic emissions		
The IRRA*flow* Control Unit, and IRRA*flow* Tube Set is intended for use in the electromagnetic environment specified below. The customer or the user of the IRRA*flow* CNS 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* Tube Set 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* Tube Set 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* Tube Set is intended for use in the electromagnetic environment specified below. The customer or the user of the IRRA*flow* Control Unit and IRRA*flow* Tube Set 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_{rms}	Portable and mobile RF communication equipment should be used no closer to any part of the IRRA*flow* Control Unit and IRRA*flow* Tube Set, 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 $d = 2.3\sqrt{P}$ 800 MHz to 2.5GHz 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. 
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5 GHz	3 V/m	
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* Tube Set is used exceeds the applicable RF compliance level above, the IRRA*flow* Control Unit and IRRA*flow* Tube Set 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* Tube Set. [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* Tube Set

The IRRA*flow* CNS 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* Tube Set 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* Tube Set 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

15. Contact

Manufacturer:

Address: **USA**
IRRAS USA, Inc.
11975 El Camino Real, Suite 304
San Diego, CA 92130
USA
URL: http://www.irras.com
E-mail address: US.customerservice@irras.com
Phone: 1-800-946-0458

Re-Ordering Information:

Region: **USA**
E-mail address: US.customerservice@irras.com
Phone: 1-800-213-4604

Region: **Global**
E-mail address: global.customerservice@irras.com
Phone: **3**1 20-210-1098

URL: http://www.irras.com

EC Representative:

Emergo Europe
Prinsessegracht 20
2514 AP The Hague
The Netherlands