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CLEARPOINT NEURO

IRRA*flow* Laser Leveler

Instructions for Use

CE

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⚠ WARNING

Read all instructions and warnings prior to use.

1. Scope

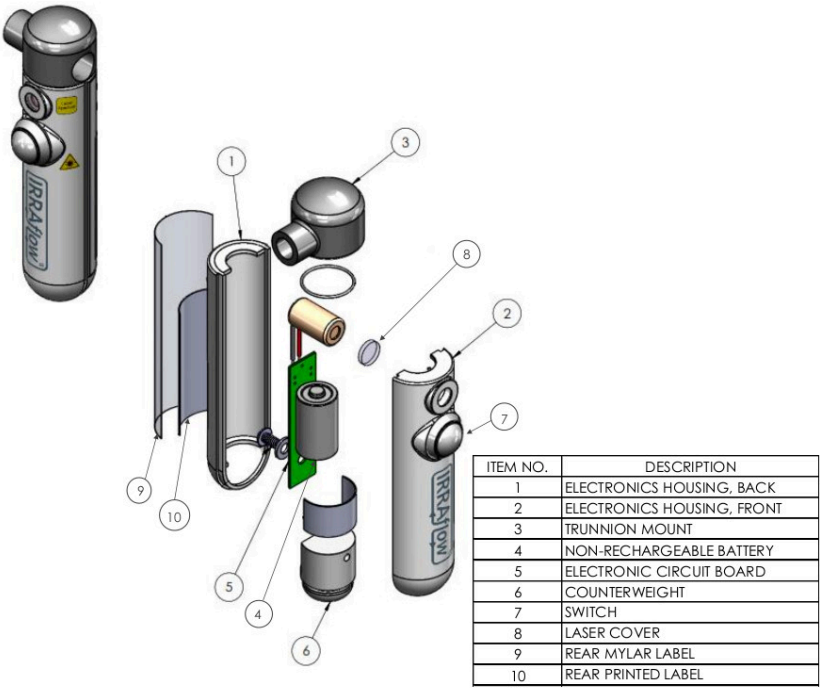
This manual describes the usage of the IRRA*flow* Laser Leveler (REF: ICLS 010). The Laser Leveler is intended to be used with the IRRA*flow* Active Fluid Exchange System.

Users must read this manual carefully prior to using the IRRA*flow* Laser Leveler for the first time so that the features are thoroughly understood.

⚠ **Warning: Failure to follow the instructions in this manual may endanger the patient and/or the operator**

2. Device Description

The IRRA*flow* Laser Leveler is a reusable accessory to the IRRA*flow* Active Fluid Exchange System and consists of a laser leveler as shown in **Figure 1**.



ITEM NO.	DESCRIPTION
1	ELECTRONICS HOUSING, BACK
2	ELECTRONICS HOUSING, FRONT
3	TRUNNION MOUNT
4	NON-RECHARGEABLE BATTERY
5	ELECTRONIC CIRCUIT BOARD
6	COUNTERWEIGHT
7	SWITCH
8	LASER COVER
9	REAR MYLAR LABEL
10	REAR PRINTED LABEL

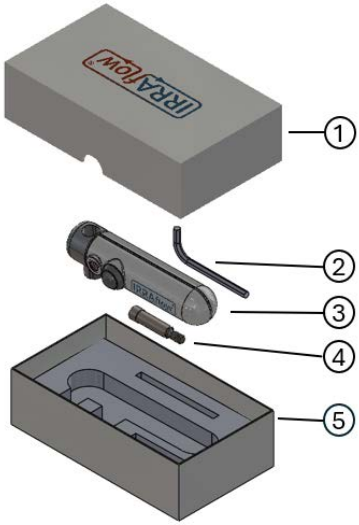
Figure 1. *IRRAflow Laser Leveler*

The laser leveler secures to the side of the control unit with the laser beam aligned to the control unit's zero point. When the control unit is attached to the vertical IV pole and the laser leveler button is pressed, the laser leveler generates a horizontal laser beam that extends the zero point of the control unit and assists the user in setting the height of the control unit to the auditory meatus (theoretical tip of the catheter in use). Note: after pressing the button to operate the laser, the laser will automatically shut off after approximately 20 seconds.

The laser leveler is packaged with accessories as shown in **Figure 2**. The package includes:

- Laser Leveler
- Shoulder screw
- Push on cap
- Allen wrench

The device does not include software. It is non-sterile, can be re-used multiple times based on battery life, and has no patient contact.



ITEM NO	DESCRIPTION
1	PACKAGING, LID, LL
2	WRENCH, ALLEN 4MM
3	ASSEMBLY, LASER LEVELER
4	SCREW, SHOULDER
5	PACKAGING, BASE, LL

Figure 2. *IRRAflow Laser Leveler packaged with accessories*

Intended Use / Intended Purpose

The IRRAflow Active Fluid Exchange System is intended to be used for ICP monitoring and drainage of intracranial fluid. The System consists of the IRRAflow Active Fluid Exchange System and three disposable parts, the Cassette, Catheter and Drainage Collection System.

The IRRAflow 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 IRRAflow Laser Leveler is intended to be used with the IRRAflow Active Fluid Exchange System. The Laser Leveler is used to adjust the height of the IRRAflow Control Unit such that the zero point of the Control Unit is at the same elevation as the patient's auditory meatus (or ear canal) prior to beginning treatment.

Intended Users

Medical personnel with training and experience in neurological / neurosurgical medical care are the intended users of this device.

Intended Patient Population

The intended patient population for ICP monitoring and drainage of intracranial fluid include:

- Patients requiring an emergent, lifesaving procedure for management of hydrocephalus or intracranial hypertension.

- Patients experiencing neurosurgical conditions such as severe traumatic brain injuries (TBI), chronic subdural hematoma, hemorrhagic stroke, comatose, traumatic subarachnoid hemorrhage (SAH), diffuse axonal injury (DAI) and bifrontal contusions in non-comatose patients.
- Patients requiring monitoring following neurological procedures such as decompressive craniotomy or evacuation of a mass lesion.

3. Symbols

Symbol	Meaning
	Warning
	Consult Instructions for Use
	Manufacturer
EC REP	Authorized Representitive
	Date of Manufacture
IP22	Ingress Protection Level
	Do not dispose of device in trash
REF	Catalogue number
LOT	Batch Code

Symbol	Meaning
	Quantity
	Laser Warning/Rating Label
	Temperature limits
	Humidity limitation
	Laser symbol
	Laser aperture location
	Unique Device Identifier (UDI) 2D Barcode
	Do not use if the product sterilization barrier or its packaging is compromised
	Prescription Device
	Medical Device

4. General Warnings and Precautions

NOTE: This device complies with 21 CFR 1040.10 and 1040.11 except for conformance with IEC 60825-1 Ed.3., as described in Laser Notice No. 56, dated May 8, 2019.

NOTE: Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and appropriate Competent Authority of the Member State in which the incident occurred.

- Device is not MRI compatible.
- Do not attach other pieces (other than those specified) to the system.
- Do not touch parts that could result in excessive leakage currents and the patient at the same time.
- All specified cleaning and disinfection procedures must be performed.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- 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, result in improper operation and/or hazardous radiation exposure.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Laser Leveler, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- This is not a toy, keep away from children.
- Do not stare into laser. Do not point laser into someone's eyes.
- Device contains lithium metal (non-rechargeable) battery.
- Device is not rechargeable and should not be recharged.
- Do not open, crush, or heat device.
- No modification of the equipment is allowed.
- There are no serviceable parts. No part of this medical accessory is to be serviced or maintained while in use
- Corneal Exposure – Meets the Accessible Emissions Limits for Class 2 laser products. Never expose eyes to laser.
- Skin Exposure – The laser diode output is below the Acceptable Exposure

Limit (AEL) Class 3B and risk of burn when skin is exposed near the aperture to the active laser is unlikely. As with any laser, use appropriate precaution and avoid exposure near the aperature of the active laser diode.

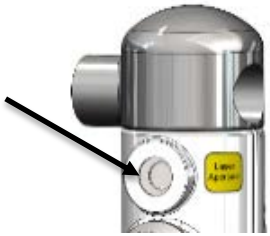


Figure 3. *Laser aperture shown.*

5. Environmental and Handling Conditions

Laser Leveler Operation Temperature range	+10°C to +40°C
Operation Air humidity	15 – 90%
Operation Ambient pressure	70 – 106 kPa
Storage and transport Temperature range	+2°C to +50 °C
Storage and transport Air humidity	15 – 90%
Storage and transport Ambient pressure	50 – 106 kPa
IP Rating	IP22
Power Source	3.6V Battery

⚠ Do not place the device near heating equipment nor expose to direct sunlight. Elevated temperatures can result in shortened battery life and degrade performance.

6. Installation Procedure

- This device is not intended to be used as an independent device. This device is intended and designed to be used with the IRRAflow Active Fluid Exchange System.
- The IRRA*flow* Laser Leveler device is provided with a mounting screw for use with the The IRRA*flow* Control Unit.
    - This device is not designed to be installed or used other than indicated.
- Clean and disinfect device per Section 9.
- Remove black cap from the head of the shoulder screw. Insert shoulder screw into the device as shown.

- Using the provided allen wrench, tighten the shoulder screw into the side of the IRRA*flow* Control Unit. The device should swing freely with no looseness along the shoulder screw. You should not be able to see screw thread.
- Replace the black cap over the head of the shoulder screw.

7. Instructions for Use

- The recommended workflow begins with verifying the patient is in a resting position, the patient's eyes are closed and shut via tape and the laser leveler is attached to the control unit. The treatment normally occurs at the bedside but anywhere with direct line of sight to the patient's head may work.
- Rotate the body of the device towards desired target location (away from eyes).
- Push button to activate laser. A red dot shall appear on or near the patient.

Note: Do not hold down the button.

- Adjust the body of the device as need.
- With the device hanging freely, adjust height of the IRRA*flow* Control Unit as necessary.
- Once the IRRAflow Control Unit is in the correct position, tighten the pole clamp feature to secure the Control Unit. Confirm the correct location via the laser leveler. Note: Do not hold onto the device during height positioning.

- Laser automatically turns off after approximately 20 seconds.

8. Disposal

Do not throw in trash. Recycle per your facility's electronic waste procedure and local regulations.

9. Cleaning and Disinfection

The Laser Leveler shall be cleaned and disinfected after each treatment.

If fluids spill onto the Laser Leveler during treatment, pause or stop treatment and wipe off the spillage immediately.

The recommended method for cleaning is to wipe the parts with a soft cloth dampened with soapy water until all foreign material has been removed.

The recommended method for surface disinfectant is to wipe the parts with a soft cloth dampened with the following intermediate level disinfectant agents or an intermediate level disinfectant wipe.

Only the following intermediate level disinfectant liquid may be used with a minimum dwell time of one minute exposure:

- 70% Isopropyl alcohol or 70% ethyl alcohol solution

⚠ No liquid may be allowed to be directly poured or sprayed onto the Laser Leveler during cleaning or disinfecting as this may damage the equipment.

⚠ 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 equipment.

⚠ Device is supplied non sterile. No components, parts or accessories to the IRRA*flow* Laser Leveler may be sterilized.

ClearPoint Neuro does not make any claims for or representation as to the performance characteristics of this product if it is used in conjunction with other accessories or other than intended. If there are doubts about how to install or clean the Laser Leveler, the effect of cleaning, the functions and/or safety of the unit, then the unit should be withdrawn from service and the distributor and/or manufacturer consulted.

10. Appendix

10.1 Laser Technical Specifications

ITEM	SPECIFICATION
Wavelength	630-680 nm
Beam Divergence (half-angle)	0.5 mRad
Pulse Pattern	Dot (5 mm)
Max Output	< 1 mW
Laser Product Classification	Class 2
Maximum Permissible Exposure, Eye [MPE (E)]*	6.36 J/m^2
Eye Maximum Permissible, Exposure [MPE (H)]*	25.5 W/m^2
Nominal Ocular Hazard Distance, Eye [NOHD]*	12m maximum
Assumed Exposure Duration	≤ 20 seconds

*The maximum anticipated exposure duration, intra-beam viewing for Continuous Wave Lasers is 0.25 seconds. This assumes unintentional viewing and is based on natural reactions times. Reference IEC 60825-1 Ed. 3, §C.2.4 for Class 2 Lasers.

10.2 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* Active Fluid Exchange System should assure that it is used in such an environment.		
Standard	**Description**	**IEC 60601-1-2 4th ed**
Cispr 11/EN55011	RF Emissions	Group 1, Class B
IEC61000-4-2	ESD	8 kV contact, 15 kV air
IEC61000-4-3	Radiated RF Immunity	80-2700MHz :3 V/m ordinary, 10V/m home healthcare, 80% AM, 1 kHz 385MHz :27 V/m, PM,18Hz 450MHz :28 V/m, FM+/-5kHz dev, 1 kHz sine 710, 745, 780MHz :9 V/m, PM, 217 Hz 810, 870, 930MHz :28 V/m, PM, 18Hz 1720, 1845, 1970MHz :28 V/m, PM, 217 Hz 2450MHz :28 V/m, PM, 217 Hz 5240, 5500, 5785MHz :9 V/m, PM, 217 Hz
IEC61000-4-8	Magnetic Immunity	30 A/m, 50 Hz

Table B-1 Electromagnetic compatibility

11. Contact

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Carlsbad, CA 92011
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E-Mail address: customerservice@clearpointneuro.com

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EC REP

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