IRILLIC L.nm Laparoscopic Imaging

Irillic L.nm Laparoscopic Imaging System

Operator's Manual

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Irillic L.nm Operator's Manual
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FOR AUTHORIZED PERSONNEL ONLY

Please follow the safety precautions in Chapter 4 of this manual in order to avoid personal injury or damage to the system during use.

Copyright Information

Conventions Used

This section describes the conventions used in this manual.

 CAUTION	Indicates presence of Safety information regarding potential minor or moderate injury to Patients or Users, or damage to the device.
 WARNING	Indicates presence of Safety information regarding potential serious injury to Patients or Users, or damage to the device.

Table of Contents

TERMINOLOGY

Some of the terminologies used in this manual are listed below:

Term	Description
CCU	Camera Control Unit of the Irillic L.nm Laparoscopic Imaging System
WLU	White Light Unit of the Irillic L.nm Laparoscopic Imaging System
FLU	Fusion Light Unit of the Irillic L.nm Laparoscopic Imaging System
USB	Universal Serial Bus Ports are used to connect peripherals such as removable drive
UPS	Uninterruptible Power Supply that provides emergency power in the event of a utility power failure
HDMI	High-Definition Multimedia Interface Port is used to connect the Monitor Display to the CCU
DP	DisplayPort is a digital display interface used to connect the Monitor Display to the CCU

1

1. Introduction

Irillic L.nm Laparoscopic Imaging System captures and displays real-time colour images in 4K resolution obtained in-vivo during surgical procedures.

It consists of a Rigid Laparoscope that is introduced into the patient's body, connected by an optical coupler to a Camera Probe.

The Camera Probe is controlled via the Camera Control Unit, while the illumination is provided by a Light Unit and is transmitted to the Rigid Laparoscope via a Light Guide.

The system can be used for any endoscopic / laparoscopic surgical procedure for visualising the internal tissues and organs of the patient, with additional features:

- Record videos & still images
- Visualise subsurface vasculature with AMVI
- Control appearance of colours of individual tissue
- Enhance contrast of fine features and edges
- Control all aspects using programmable buttons

2

2. Prerequisites

In order for the Irillic L.nm system to yield consistent results, it is important to have the site (where system is used) ready with the following attributes/facilities:

Environment

- Air Conditioning is recommended for the room/site where the system will be used. System must always be operated within the specified operating and storage temperature range (10^{O}C – 30^{O}C) and the humidity range (25% - 75% non-condensing).
- The device is to only be used in professional healthcare environments only like Hospitals, Medical Centres, Clinics, Operating Theatres, etc.

Power

- 240V AC UPS-connected power 3-pin sockets (at least two sockets) to allow for uninterrupted use of the system. A clean (surge-protected) power source (240 V AC, 50 Hz) is critical for system stability. The system is rated for 1000VA; UPS with at least 1KVA (or higher) capacity is therefore recommended.
- If using Extension Boards for the power sockets, the Irillic L.nm system MUST be connected to an independent 2 x 3-pin socket power extension board to avoid interference from other equipment in the operating area. Avoid connecting this system and other equipment on the same power extension board.

Network connectivity

- For certain features, specifically remote troubleshooting and remote software update, will require internet connectivity using a Wi-Fi Adapter provided by Irillic Pvt Ltd.

Authorized users

Only trained users are authorized to operate the equipment for imaging requirements during minimally invasive surgical procedures. Such users of the system are required to be trained on or experienced with:

a) Readying the L.nm for use during surgical procedures, including sterilizing the rigid laparoscope accessory, cleaning the Camera Probe and the cable, and cleaning the fiber optic light guide accessory.

b) Setting up the L.nm to be ready for use by completing all connections required for operation, and powering on the device.

c) Operating Irillic L.nm system and awareness of the commonly used functions and user interface experience

d) After usage, powering off the device and safely dismantling the parts and placing the device in storage.

Irillic (or Irillic-authorized partners) will provide training on Operating the Irillic L.nm system.

Storage and handling

- The L.nm system should not be exposed to chemicals and liquids at any time; users are required to follow the instructions listed in the Chapter "Cleaning Instructions" for cleaning purposes.
- When the system is in a storage area, it is advisable to exercise caution in ensuring the Probe cable is properly coiled and/or storing the Probe separately in a safe area/safe box.
- Ensure that the system is stored in an area where there is no direct sun light, and is within the acceptable temperature (10^{O}C – 30^{O}C) and humidity range (25% - 75% non-condensing).
- Always contact Irillic if there is any requirement to move the equipment to another location by any means of ground transport.

Essential performance

The essential performance of the Irillic L.nm Laparoscopic Imaging System is to capture and display anatomical image information on the monitor display attached to the trolley.

In case of any disruption due to any Electro-Magnetic Interference, please refer to Chapter 4 – Safety Information & Precautions of this manual, and ensure all the warnings in the subsection entitled EMC are adhered to.

If any unavoidable EMI/EMC disruption of the operation of the operation of the device takes place, it might result in flickering or interruption of the live video feed, or the touchscreen displays. In such an event, users are recommended to Power OFF and then Restart the device. If the problem persists, please contact Irillic for further actions.

Refer to Chapter 9 – Maintenance for information regarding testing processes and frequencies to ensure Basic Safety parameters of the device are being met

3

3. Intended Use

The Irillic L.nm Laparoscopic Imaging System is intended for diagnosis, monitoring, and observation of anatomy and diseases

- through visualisation of the internal anatomical structure and infrared fluorescence information of the patient's body simultaneously,

or

- solely through visualisation of the internal anatomical structure,

in the areas of general surgery, gastroenterology, obstetrics, gynaecology and other surgical or interventional procedures as decided by the clinician.

It is not recommended to diagnose or make clinical decisions using only images from Irillic L.nm.

Indications of use

Irillic L.nm Laparoscopic Imaging System is indicated for the illumination and visualization of the internal anatomy of patients during minimally invasive procedures in general surgery, gastroenterology, obstetrics & gynaecology and other types of surgeries wherever an endoscope or laparoscope is indicated for use.

A few examples of the more common laparoscopic surgeries are: laparoscopic cholecystectomy, laparoscopic hernia repair, laparoscopically assisted hysterectomy, total laparoscopic hysterectomy, laparoscopic salpingectomy, etc.

Intended patient population

Patient Age	Adults and paediatric patients one month and older
Patient Gender	No gender restrictions
Patient Weight	No weight restrictions
Patient Health	No limitations on patient health except those that arise from the use of the injectable dye Indocyanine Green

Contraindications

There are no known contraindications associated with the use of the Irillic L.nm Laparoscopic Imaging System.

Indocyanine Green (ICG) has contraindications for use which are listed in the Information Booklet available with the packaging of the dye from the supplier, which are listed below:

- General Information: Radioactive iodine uptake studies should not be conducted for a minimum of 1 week following the use of indocyanine green.
- Iodine hypersensitivity: Indocyanine green contains sodium iodide and is contraindicated in patients with iodine hypersensitivity. Anaphylaxis or other allergic reactions may occur.
- Dialysis, renal failure, uremia: Indocyanine green should be used with caution in patients with renal failure or uremia, and those who are on dialysis. In 1 case report, anaphylactoid reactions with various manifestations occurred in 4 of 43 (9.3%) patients on hemodialysis who received indocyanine green for cardiac output studies. Specific reactions included dyspnea, palpitations, anxiety, nausea, edema, hypotension. Reasons for these adverse effects in this vulnerable patient population are unclear; however, patients that reacted to indocyanine green were found to have significantly higher eosinophil counts than those who did not react (937 +/- 271 vs. 378 +/- 67; $p < 0.025$).
- Neonates: The safety and effectiveness of indocyanine green have not been established in neonates.
- Pregnancy: Indocyanine green is classified as FDA pregnancy category C. No well controlled studies have assessed the effect of indocyanine green on the fetus or female reproduction capacity. A small study in 9 pregnant patients examined placental transfer of indocyanine green during labor. Maternal doses of indocyanine green ranging from 0.5—5 mg/kg were administered during stage 1 or 2 of labor. Blood samples were obtained from the mother and the fetal scalp at baseline, 2—4 minutes, and 6—8 minutes following dye injection. No indocyanine green was found in the fetal blood of all 9 infants or the umbilical vein blood of 4 infants, thus demonstrating no placental transfer.
- Breast-feeding: According to the manufacturer, it is not known if indocyanine green is excreted in human milk. Caution is advised when administering indocyanine green to a nursing woman. Consider the benefits of breast-feeding, the risk of potential infant drug exposure, and the risk of an untreated or inadequately treated condition. If a breast-feeding infant experiences an adverse effect related to a maternally ingested drug, healthcare providers are encouraged to report the adverse effect to the FDA.
- Avoid use of alcohol-based disinfectants on the patient at the region of interest prior to or during Imaging.

It is recommended to understand the contraindications for the use of ICG before it is administered to any patients.

4

4. Safety Information and Precautions

CAUTION	
General	1. Personnel operating the Irillic L.nm Laparoscopic Imaging System should be familiar with the correct procedures for operating and using the equipment.
	2. Information obtained through the use of the system should be used in combination with other clinically relevant information when planning alternative or added interventions.
	3. Before using the system, verify that the mobile cart wheels are in a locked position.
	4. When moving the mobile cart, use only the handles for grasping.
	5. The system can be used only within the specified operating temperature range (10^{O}C – 30^{O}C); failure to do so may lead to incorrect results and in extreme cases, damage to the system. 
	6. Usage of the system beyond its operating life may lead to loss of some imaging or illumination functionality.
	7. In the event of any damage to any optical components (FLU / WLU, Light Guide, Rigid Laparoscope, 4K / 4K ICG Camera Probe), contact Irillic immediately for maintenance and performance verification before using the system.
	8. Do not attempt to service or perform maintenance on any part of the device at any time, including while it is in use during surgery or on any patient. Any such changes can impact the proper functioning of the device. In such an event, contact Irillic for further action.

WARNING	
General	1. To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.
	2. Do not attempt any modification of the system unless authorized. Unauthorized changes to the system can lead to improper functioning and may lead to injury to the patient or operator
	3. Ensure the cleanliness of the system before use to avoid any likelihood of infection or contamination of the patient.

WARNING	
Electro-Magnetic Compatibility	1. The system is a Class I ME equipment and is to be used in professional healthcare environments.
	2. Other devices which emit high intensity Radio Frequencies can interfere with the operation of our system and should not be used within a distance of 30 cm (12 in).
	3. Usage of non-Irillic cables or accessories may adversely affect the electromagnetic compatibility performance of the system and should not be done.
	4. The environment of the system should adhere to the EMC compliance table in Appendix III of this document to avoid interference with the correct operation of our system.
	5. Avoid stacking this device with other ME equipment since it could result in improper operation. If unavoidable, ensure proper operation of both devices before use.

WARNING	
4K Camera Probe / Fusion Camera Probe	1. The Camera Probe (and the rest of the system) can be used only within the specified temperature range ($10^{O}C$ – $30^{O}C$); failure to do so may lead to incorrect results and in extreme cases, damage to the system. 
	2. Do not attempt to repair or open the system; servicing is to be done by authorized personnel only
	3. Camera Probe may reach temperatures up to $48^{O}C$ during long use, especially when it is not being held continuously. No special precaution is required for its handling.
	4. It is recommended to only use Irillic provided Rigid Laparoscope & Light Guide accessories to ensure optimal performance. Usage of alternate accessories may lead to deterioration in expected performance.
	5. Always turn off power before connecting/disconnecting the Camera Probe to/from the Control Unit.
	6. Always clean the Camera Probe before use as per the instruction given in Chapter 10 – Cleaning Instructions
	7. Ensure adequate care is taken when handling the Camera Probe. Always store the Camera Probe in the provided slot on the Trolley after use to prevent accidental damage.

WARNING	
Camera Control Unit	1. When connecting the Camera Probe to the Camera Control Unit, verify that the connecting cable is fastened securely by pressing the connector until it clicks in place.
	2. Do not attempt to repair or open the system; servicing is to be done by authorized personnel only
	3. Always turn off power before connecting/disconnecting cable(s) to the Camera Control Unit.

WARNING	
White Light Unit	1. The device emits high-intensity White Light radiation. Avoid any direct eye exposure at all times. 
	2. The device emits high-intensity White Light radiation. Avoid directly irradiating the skin for any period of time. 
	3. Ensure that the Light Guide accessory is firmly connected to the WLU by pushing the long connector end firmly into the Light Guide Port on the WLU until an audible click. The click means that the Light Guide is locked in position.
	4. Ensure care is taken to prevent sudden jerks or pulls on the Light Guide as it may be disconnected from the WLU leading to loss of illumination during surgical procedures
	5. Do not remove the connection between the Rigid Laparoscope and the Light Guide while the WLU is in operation. Always place the WLU in Standy, or reduce the setting to 0 before disconnecting the Light Guide from the Rigid Laparoscope.

WARNING	
Fusion Light Unit	1. The device emits high-intensity White Light radiation. Avoid any direct eye exposure at all times. 
	2. The device emits high-intensity White Light radiation. Avoid directly irradiating the skin at all times. 
	3. The device emits high-intensity Infrared Laser radiation. Avoid any direct eye exposure at all times. 
	4. The device emits high-intensity Infrared Laser radiation. Avoid directly irradiating the skin at all times. 
	5. Ensure that the Light Guide accessory is firmly connected to the FLU by pushing the long connector end firmly into the Light Guide Port on the FLU until an audible click. The click means that the Light Guide is locked in position.
	6. Ensure care is taken to prevent sudden jerks or pulls on the Light Guide as it may be disconnected from the FLU leading to loss of illumination during surgical procedures
	7. Do not remove the connection between the Rigid Laparoscope and the Light Guide while the FLU is in operation. Always switch Off the Light Source or place the FLU in Standy mdoe before disconnecting the Light Guide from the Rigid Laparoscope.

	8. Always ensure to push the Slide Lock to the open position before inserting or removing the Light Guide from the Light Port of the FLU.
	9. Do not attempt to repair or open the FLU; servicing is to be carried out only by authorized Irillic personnel only.
	10. The FLU Light Port, Light Guide connectors, Rigid Laparoscope tip may all be heated to temperatures above 40^{O}C during operation due to significant amount of Light Energy emitted. Always ensure to take sufficient care when handling these parts during operation.
	11. Avoid touching the Rigid Laparoscope tip or the Light Guide tip to the patient, and never place them on top of the patient, as doing so may result in burns to the patient or user.

WARNING	
Accessories (Laparoscope & Light Guide)	1. Always sterilize the Rigid Laparoscope and Light Guide before use either using an Autoclave or other means of approved high temperature sterilization methods to avoid risk of infection to the patient, or loss of sterility to the operator.
	2. The Rigid Laparoscope accessory is intended to come into invasive contact with the Patient and care is to be taken to ensure safety. Refer the included User Manual for the Rigid Laparoscope for more safety related information.
	3. The Light Guide accessory is rated as an Applied Part and may come into contact with the Patient. It is CF rated and may come into contact with the patient body or heart, but not during defibrillation. 
	4. Always sterilize the Light Guide & Rigid Laparoscope before use, either using an Autoclave or other means of high temperature sterilization. (Refer the respective User Manual for complete description of the approved sterilization, cleaning, & disinfection methods)
	5. While storing the Light Guide accessory after use, cover the two ends with plastic end caps provided, and ensure to not roll or bend the accessory tightly as this may damage the optical fibres inside and reduce the performance.
	6. Always take special care when handling the Rigid Laparoscope or Light Guide, as any physical damage may lead to degradation of Image Quality and can affect performance of the device.
	7. Avoid placing the Light Guide or Rigid Laparoscope close to the patient or operator when still Powered On but not in use to avoid any risk of burn injury due to heat supplied by the illumination.

WARNING	
Mobile Cart (Trolley)	1. Each shelf on the Trolley is rated for a maximum load of 10 Kg. Do not place any equipment or item on the Trolley that weighs more than 10 Kg.
	2. Before using the system, verify that the mobile cart wheels are in locked position.
	3. When moving the mobile cart, use only the handles for grasping.
	4. When moving the mobile cart, verify that the wheels are in un-locked position and the Probe is docked in its holder.
	5. The two Non-Isolated Power Supply Sockets on the Trolley can be used to connect approved medical devices. Such a connection creates and ME System which can lead to reduced levels of safety. Each socket can only support a load of 0.6 A at 240 V (~ 150 VAC). Ensure that no system that may draw a higher load should be connected at any time. Ensure that only approved medical grade devices are connected to these sockets to avoid unacceptable risks due to electromagnetic interference or current leakage.

Residual risk

Irillic has carried out Risk Management during the design, manufacture, and testing of the Irillic L.nm Laparoscopic Imaging System as per EN ISO 14971:2019, and identified the following as residual risks after risk mitigation has been carried out via design control, protective measures and information provided to the user, where the Severity is classified as 'Minor' or above and the Probability is classified as 'Remote' or above:

- Distal tip of Laparoscope, or either ends of Light Guide become hot due to high intensity light supply leading to burn injury.
- Energy delivered to the eye for extended duration causing injury.
- Light Guide disconnected from the Rigid Laparoscope while Light Source is ON leading to uncontrolled output of high intensity light energy leading to eye or burn injury.
- Improper cleaning of the device leads to damage and failure of the equipment.
- Leakage of reflected Fluorescence Excitation Light into the Camera Probe leading to visualization of reflections and loss of fluorescence information.
- Improper light source maintenance leads to inability to visualize tissue or fluorescence.
- Unauthorized individual accesses underlying operating system leading to failure.
- Extended usage of the Camera Probe causes wear and tear in the interior cable connections leading to malfunction.
- Failure of brakes leads to unwanted motion of device causing harm to patient or operator.

If you encounter any such occurrence, please contact us and share details of the hazardous event at info@irillic.com

5

5. System Overview

1. Display Monitor
2. 4K Camera Probe
3. Fusion Camera Probe
4. Rigid Laparoscope
5. Light Guide
6. Camera Control Unit (CCU)
7. White Light Unit (WLU)
8. Fusion Light Unit (FLU)
9. Trolley (Mobile Cart)

Fig 5.1: Irillic L.nm system comes in two modalities - the 4K White Light system (left) and the 4K ICG system (right) with the added capability of fluorescence imaging

- A Medical Grade 4K Monitor is used to display the live feed during the procedure and also displays the modes and operations being performed.

- The 4K Camera Probe is the handheld part of the system and captures the live colour video feed of the internal anatomy of the patient via the Rigid Laparoscope it is connected to.

- The 4K Fusion Camera Probe is the handheld part of the system and captures the live colour and fluorescence video feed of the internal anatomy of the patient via the Rigid Laparoscope it is connected to.

- The Rigid Laparoscope is used to visualize the vessels and surface of the internal structure and anatomy of the organs and other parts of the human body relevant to the surgical procedure.

- The Light Guide is a bundle of fibre optic cables that connect that transmit light from the light unit to the Rigid Laparoscope to illuminate the anatomy of the patient.

- The Camera Control Unit (CCU) is used to connect to the Camera Probe and it controls the image chain of the system from the acquisition parameters of the Camera, to the display of the live feed on the Display Monitor.

- The White Light Unit (WLU) is used to generate the illumination necessary for the operation of the system and to control the intensity of the white light required by the user. The intensity of the light can be adjusted in the User Interface of the WLU.

- The Fusion Light Unit (FLU) is used to generate the illumination necessary for the operation of the system and to control the intensity of the white light required by the user. The intensity of the light can be adjusted in the User Interface of the WLU.

- The Trolley is a mobile cart and consists of 2 trays which contain the CCU & WLU/FLU, and an additional 2 trays for miscellaneous use. The wheels of the trolley have brake locks that can be used to prevent inadvertent movements of the system either during operations or during storage.

When the system is being operated, the wheels should be secured in Brake-Locked position.

Camera Control Unit (CCU)

The Camera Control Unit is the main processing center of the entire system. It contains the Central Processing Submodule, the Interfacing Subsystems, and the Communications Hub of the device.

The Front Panel of the CCU consists of a Touchscreen Display where the overall control of the Imaging parameters, recording subroutines, and overall system settings can be modified.

Camera Control Unit (CCU)- Front Panel

Fig 5.2: LF81 Camera Control Unit Front Panel

1. **Power button** – To Power on the unit
2. **Power indicator** – The Power symbol in the Button which lights up green when ON
3. **Touchscreen Display** – Where the majority of the User Interaction takes place, allowing for selection of Imaging Profiles, Imaging Modes, Recording, Zoom, etc.
4. **Camera Probe Port** for connecting the Camera Probe Connector

Power Button:

- When system is currently powered off, pressing it once boots up the system into the Kiosk mode.
- When system is currently operating, pressing it and holding it for a few seconds forces it into emergency power-down.

Power Indicator

- When AC power is being supplied to the unit and system is not yet switched on, the Power indicator will remain off.
- Once the system is powered ON, the indicator turns green.

Fig 5.3: Power Indicator on Camera Control Unit

Camera Control Unit - Rear Panel

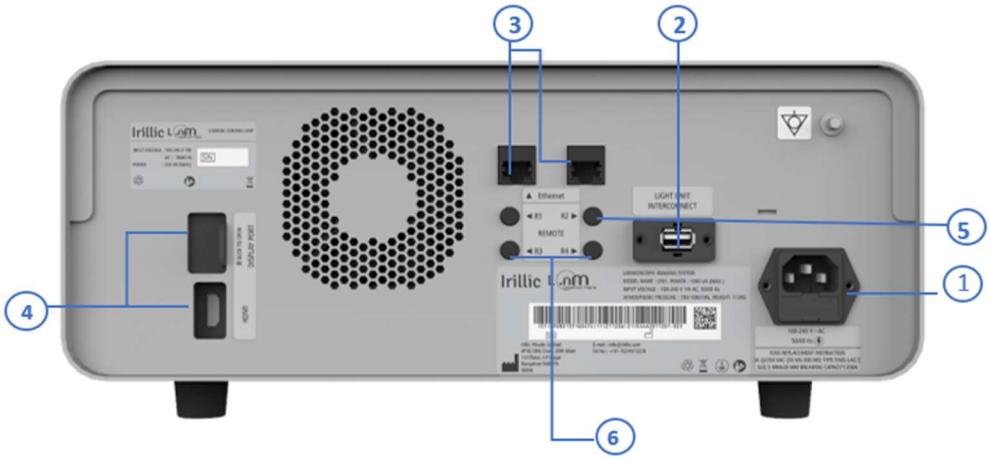


Fig 5.4: Camera Control Unit Rear Panel

1. **230V AC Power Receptacle** for connection to Input Power Supply. A fuse holder (with a second spare fuse) is located below the receptacle.
2. **Light Unit Interconnect Port** for communication between WLU and CCU.
3. **RJ-45 Ethernet Port** for network connection via LAN
4. **Display Port and HDMI port** for connection to Display Monitor. By default the Monitor mounted on the Trolley is connected via the HDMI port. The Display Port connection is therefore available for a secondary display.
5. **R1** and **R2** socket for Paddle control
6. **R3** and **R4** socket for Recorder control

- **USB & Ethernet Ports provided are only for use for Data Transfer activities by authorized personnel.**
- **Do NOT use the USB & Ethernet Ports for any other function, unless authorized to do so by Irillic Service Personnel.**

The **Camera Control Unit**, **White Light Unit**, **Fusion Light Unit**, and **Trolley** are all provided with an **Equipotential Point** on the respective rear panels of the CCU/WLU/FLU and at the rear of the Trolley Base, and marked with the symbol seen here.

These connection points can be used to connect to a potential equalization conductor. The resulting medical electrical system shall follow all applicable IEC 60601-1 requirements.

White Light Unit (WLU)

White Light Unit Front Panel

1. **Power Button**
2. **Power Button Indicator**
3. **Touch Display** for changing the light intensity
4. **Light Guide Port** for connecting the Light guide

Fig 5.5: White light unit Front Panel

Power Button:

- When system is currently powered off, pressing it once boots up the system into the Kiosk mode.
- When system is currently operating, pressing it and holding it for a few seconds forces it into emergency power-down.

Power Indicator

- When AC power is being supplied to the unit and system is not yet switched on, the Power indicator will remain off.
- Once the system is powered ON, the indicator turns green.

Fig 5.6: Power Indicator on LF81 White Light Unit

White Light Unit Rear Panel

1. **230V AC Power Receptacle** for connection to Input Power Supply. A fuse holder (with a second spare fuse) is located below the receptacle.
2. **Camera control Unit Interconnect Port** for the communication between WLU and Control Unit.

Fig 5.7: White light unit Rear Panel view

Fusion Light Unit (FLU)

Fusion Light Unit Front Panel

1. **Power Button**
2. **Power Button Indicator**
3. **Touch Display** for changing the White & NIR Light intensity
4. **Light Guide Port** for connecting the Light Guide.
5. **Safety Lever** to be used to allow for safe connection and disconnection of the Light Guide.

Fig 5.8: Fusion Light Unit Front Panel view

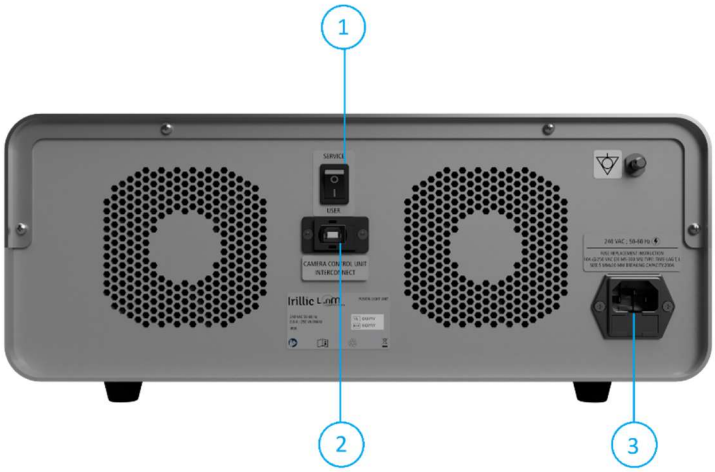
Power Button:

- When system is currently powered off, pressing it once boots up the system into the Kiosk mode.
- When system is currently operating, pressing it and holding it for a few seconds forces it into emergency power-down.

Power Indicator

- When AC power is being supplied to the unit and system is not yet switched on, the Power indicator will remain off.
- Once the system is powered ON, the indicator turns green.

Fusion Light Unit Rear Panel



1. **Service Mode Switch** to allow service personnel to update the FLU firmware
2. **Camera control Unit Interconnect Port** for the communication between WLU and Control Unit.
3. **230V AC Power Receptacle** for connection to Input Power Supply. A fuse holder (with a second spare fuse) is located below the receptacle.

Fig 5.9: Fusion Light Unit Rear Panel view

WLU / FLU Radiation Information

White Light Source Radiation

The White Light Unit and the Fusion Light Unit both have identical White Light Sources with the following optical output characteristics:

Parameter	Specification
Rated Maximum Luminosity	4545 lumens
Max Output Intensity	25 mW/cm^2 at 2cm WD from tip of Rigid Laparoscope
Angular Distribution	90° (60° FWHM)
Wavelength Range	450nm to 650nm
Colour Temperature	5700 K (neutral white)
Colour Rendering Index	70
Radiometric Flux	15.7 W
Classification	Risk Group 2 As per IEC 62471:2006 Photobiological Safety of Lamps
Safety Rating	Risk Group 2 As per IEC 60601-2-57:2023

- **High Intensity Optical Radiation**
- **Do NOT look at the source of light directly**
- **Avoid direct long exposure to skin to avoid burn injury.**

Near Infrared Light Source Radiation

The Fusion Light Unit incorporates a Near Infrared Laser Diode Light Source with the following optical output characteristics

Parameter	Specification
Rated Maximum Power	5 W (At Laser Diode Emission Point)
Max Output Intensity	25 mW/cm^2 at 2cm WD from tip of Rigid Laparoscope
Angular Distribution	90° (60° FWHM)
Wavelength	785 nm
Full Width at Half Maxima	3 nm
Operation Mode	Continuous
Classification	Class 3b As per IEC 60825-1:2014
Safety Rating	Risk Group 2 As per IEC 60601-2-22:2019

- **High Intensity Optical Radiation**
- **Do NOT look at the source of light directly**
- **Avoid direct long exposure to skin to avoid burn injury.**

4K Camera Probe

Fig 5.10: 4K Colour Camera Probe

1. **Camera Coupler** for holding the scope in place
2. **Focus Ring** for controlling the focus distance
3. **Camera Probe button Panel** for interacting with the system
4. **Camera Probe connector** for interfacing with the Control Unit via an integrated cable
5. **Probe Cap** for closing the connector when it is not in use.

4K Fusion Camera Probe

Fig 5.11: 4K ICG Camera Probe

1. **Camera Coupler** for holding the scope in place
2. **Focus Ring** for controlling the focus distance
3. **Camera Probe button Panel** for interacting with the system
4. **Camera Probe connector** for interfacing with the Control Unit via an integrated cable
5. **Probe Cap** for closing the connector when it is not in use.

Camera Probe Button Panel

Fig 5.12: Camera Probe Button

SET (S) button has three functionalities:

- Short Press: Takes a SNAPSHOT irrespective of whether Recording is in progress or not.
- Long Press: It starts RECORDING the procedure.
- If a recording is in Progress, A long press again would STOP the recording.

MODE (M) button has two functionalities

- **Short Press:** It is used for selecting a mode which is displayed on the monitor
- **Long Press:** It opens up the menu in the monitor.

UP (^) is used for moving up in the menu option. It is also used for ZOOM IN

DOWN (v) is used for moving down in the menu option. It is also used for ZOOM OUT

4K Medical Grade Monitor

4K 32" Medical grade monitor with ports in the back as shown in fig.

Fig 5.13: Monitor Front view

Fig 5.14: Monitor Back view

Fig 5.15: Monitor connections in the back

- **DC-In:** Power code of the monitor is plugged into the port
- **DP In**: Input from CCU for the monitor display
- **DP Out**: Open port available for display extension

Monitor Adjustment

The monitor can be tilted 15° front and back. It can also be tilted 50° sideways as sown in the fig

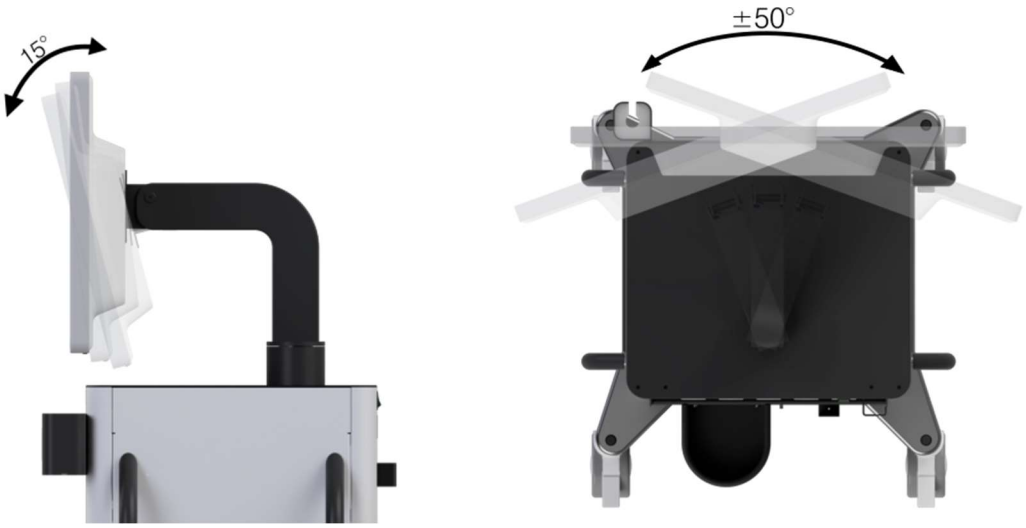


Fig 5.16: Monitor Orientations

Trolley

1. **Monitor Mount**
2. **Shelfs** to keep the WLU and Control unit. Cautery Unit can also be kept in the rack
3. **Camera Probe Holder**
4. **Drawer** to keep drapes and accessories
5. **Trolley Wheels** with brake locks
6. **Handle** to move around the Trolley within the hospital

Fig 5.17: Trolley Front View

1. **5 Power sockets** (3 are isolated 2 are normal) to connect the WLU and Control unit
2. **Cable hooks** used to wrap excess cable lengths of the Power cord
3. **Non-detachable Power Plug** for connecting to 230V AC mains power socket (coming from a UPS)
4. **Trolley Base** contains the **Main System Fuse.** It also contains the **Isolation Transformer** that isolates the system from the power supply and the corresponding **Transformer Fuse**

Fig 5.18: Trolley Rear View

Camera Probe Holder

The Camera Probe Holder is a custom storage slot provided on the Trolley to store the Camera Probe during and after use.

.

It can be used to hold the Camera Probe when the equipment is being stored after use in a disconnected state, as seen here.

It can also be used to store the Camera Probe temporarily during use when it is connected to the Rigid Laparoscope along with the Light Guide as shown here.

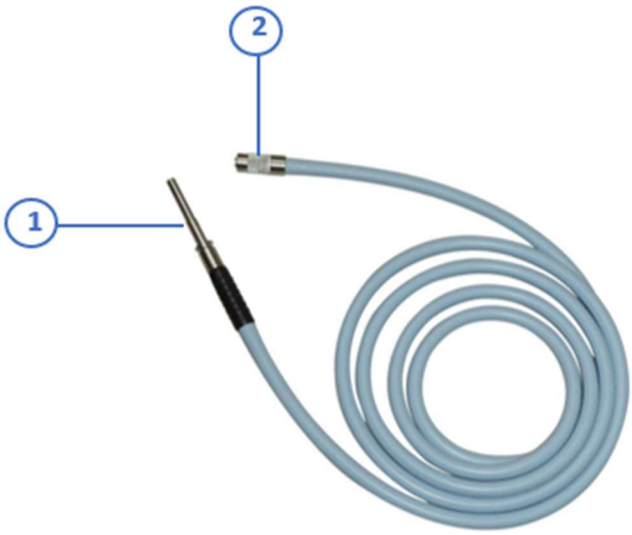
Fig 5.19: Usage of Camera Probe Holder

- **Always ensure that the Camera Probe is stowed in the provided Camera Probe Holder after each use of the device.**
- **Ensure that the Rigid Laparoscope is carefully inserted into the provided slot in the Camera Probe Holder.**
- **Camera Probe Holder can take a maximum load of 1 Kg. Only use the Holder for the Camera Probe and/or Rigid Laparoscope.**

Accessories

The L.nm Laparoscopic Imaging System contains three accessories necessary for its use:

Light Guide



1. The Light Unit Connector end goes into the WLU/FLU in the Light Guide socket.
2. The Rigid Scope end is connected to the Rigid Laparoscope for transmitting illumination from the Light Unit to the Laparoscope.

Fig 5.20: Accessory - Light guide

Rigid Laparoscope

Rigid Laparoscope is used for a minimally invasive procedure. It is a hollow tube which consist of optics. The Rigid Laparoscope attaches to the Camera Probe and allows for imaging of the internal anatomy of the patient & to also to the Light Unit (WLU/FLU) via the Light Guide which allows for illumination of the target tissue.

Fig 5.21: Rigid Laparoscope

- **Always ensure that the 4K ICG Compatible Rigid Laparoscope is used when connecting to the 4K ICG compatible Fusion Camera Head and the Fusion Light Unit.**
- **Always sterilize the Rigid Laparoscope & Light Guide before use either using an Autoclave or other means of approved sterilization**
- **Always use Irillic accessories to ensure that the performance of the system is as expected**
- **Use of non-Irillic accessories like the Rigid Laparoscope or the Light Guide and have a large impact on the performance of the system**
- **Use of non-Irillic accessories can lead to decrease in quality of the image and the illumination**
- **Always check for Image Quality prior to use, and in case of any damage to the optical parts**

Removable Storage Device

A 2 TB capacity removable Solid State Storage Device is provided along with the system in order to allow users to record video and image data as seen on the screen via the live real-time video feed. The data will be stored in automatically created folders and filed and marked by the timestamp when each image or video is recorded.

- **Sudden loss of power can lead to partial loss of recorded data.**
- **Always use only Irillic provided Removable Storage Device to ensure optimal performance during recording.**
- **Do NOT disconnect the Removable Storage Device when recording is in progress, doing so will result in partial or total loss of previously captured data.**

List of Cables & Accessories

Cables

1.	Trolley Power Cable
2.	Monitor Power Cable
3.	Camera Control Unit Power Cable
4.	White / Fusion Light Unit Power Cable
5.	HDMI 2.0 Cable
6.	USB 2.0 Interconnect Cable
7.	Camera Probe Cable
8.	Removable Storage Device USB Cable

Accessories

1.	Fiber Optic Light Guide
2.	Rigid Laparoscope
3.	Removable Storage Device
4.	Product Cover

6

6. Setup and Connections

Connections during installation

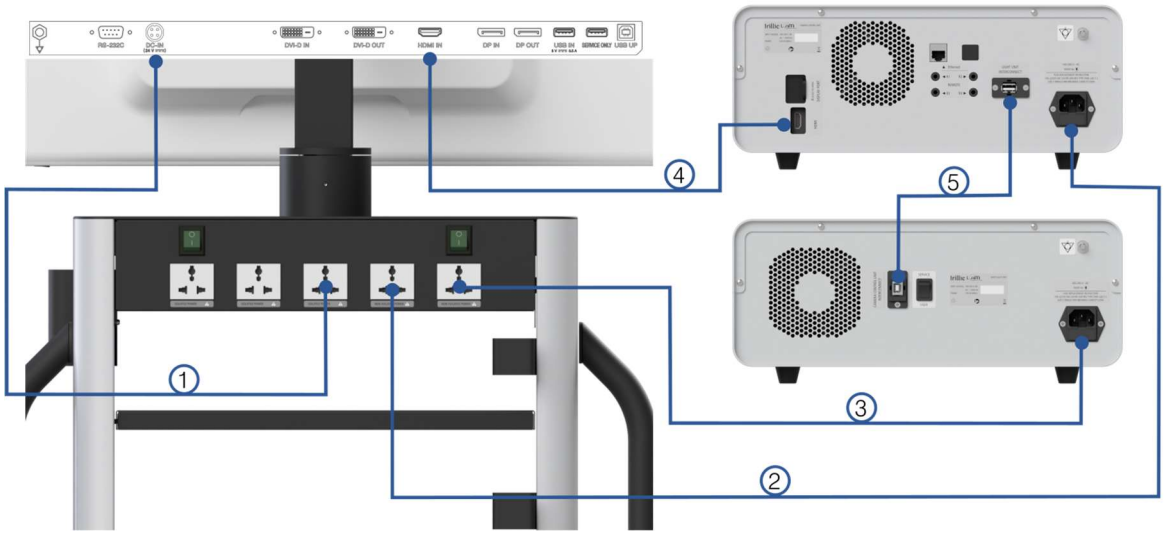


Fig 6.1: Main system connections

1. Connect the monitor power supply to the Isolated Power socket in the Trolley
2. Connect the WLU/FLU power supply to the Isolated Power socket in the Trolley
3. Connect the CCU power supply to the Isolated Power socket in the Trolley
4. Connect the HDMI cable from CCU to Monitor
5. Connect the Interconnect cable from CCU to WLU/FLU

- **Unpacking and installation should only be carried out by authorized Irillic personnel.**
- **Complete and detailed information on installation procedure can be found in the Service Manual.**
- **If any further information is required, please contact Irillic directly as per the information at the back of this document.**

These connections, once complete, need not be removed at any time, unless by Irillic service personnel or authorized support staff during maintenance activities.

Connections during normal usage

1. Connect the Camera Probe to the CCU by removing the Connector Cap and inserting the Connector into the provided socket as per the diagram below

Fig 6.2: Camera Probe to CCU Connection

2. Connect the Light Guide to the WLU or FLU by rotating the Unlock Lever and at the same time inserting the Light Unit End of the Light Guide into the provided slot until an audible click sound is heard. Then test the connection by lightly tugging on the Light Guide to ensure that it does not disconnect from the Light Unit too easily.

Fig 6.3: Light Guide to Light Unit Connection

(Note – The Unlock Lever may not be present in a White Light Unit)

3. Rigid Laparoscope is inserted into the camera probe and rotated to lock it securely.

Fig 6.4: Rigid Laparoscope to Camera Probe attachment

4. Insert the light guide to the scope and rotate it to secure it firmly with the scope

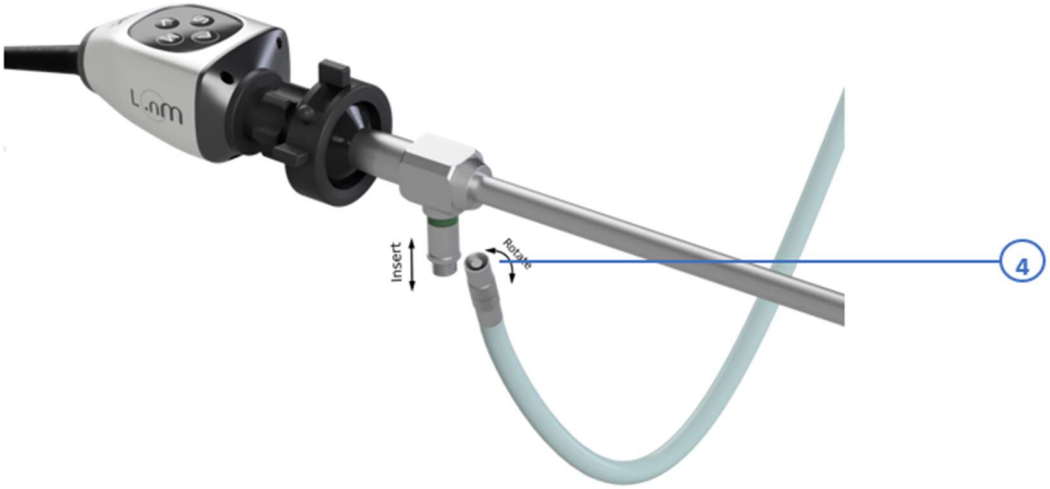
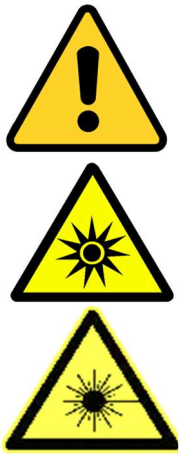


Fig 6.5: Light Guide to Rigid Laparoscope connection



- **Always Power OFF the light source before connecting or disconnecting the Light Guide from the Rigid Laparoscope**
- **Failure to Power OFF the light source before connecting or disconnecting the Light Guide from the Rigid Laparoscope may lead to uncontrolled release of high intensity Infrared or White Light Radiation, and may cause mild burn injury or adversely affect vision when exposed.**
- **If Light Guide is disconnected from the Rigid Laparoscope when the light source is still Powered ON and then placed near any sensitive tissue or flammable substance there is substantial risk of Burn Injury or Fire Hazard due to the excessive heat generated by the high intensity illumination**

5. Connect Trolley Power Supply Plug to nearby AC Socket via UPS only.

Fig 6.6: Connecting Trolley Power Supply Plug to wall AC socket

6. Connect the Removeable Storage Device for storing Images and Videos captured during the operation of the device at the provided USB slot on the Rear Panel of the Camera Control Unit.

Fig 6.7: Removable Storage Device to the Camera Control Unit connection

- **Use UPS powered 230V AC sockets to allow un-interrupted operation of the system.**
- **When connecting the Probe to the Control Unit, verify that the system is powered OFF. Connecting Probe when system is already powered ON may result in damage to the system.**

Preparing the Irillic L.nm for use

1. Move the system using the Trolley Handles to the Operating Theatre where the surgery is to take place while taking care to move slowly and smoothly and ensuring that any wires or raised partitions on the floor are navigated with care and precision.
2. Place the device next to the OT Bed where the patient will be placed on the opposite side to the expected positions of the surgeons performing the surgery.
3. Ensure that the Monitor positioning is adjusted along both the horizontal and vertical axes so that the surgeons will have a clear and unobstructed view and does not cause any excess strain to them when viewing the monitor.
4. Ensure that no other equipment is placed in front or too close to either side of the device to allow for ease of access and operation, and any connections and disconnections required during and after the surgery. .
5. Below is a demonstrative depiction of a possible configuration of the placement of the device.

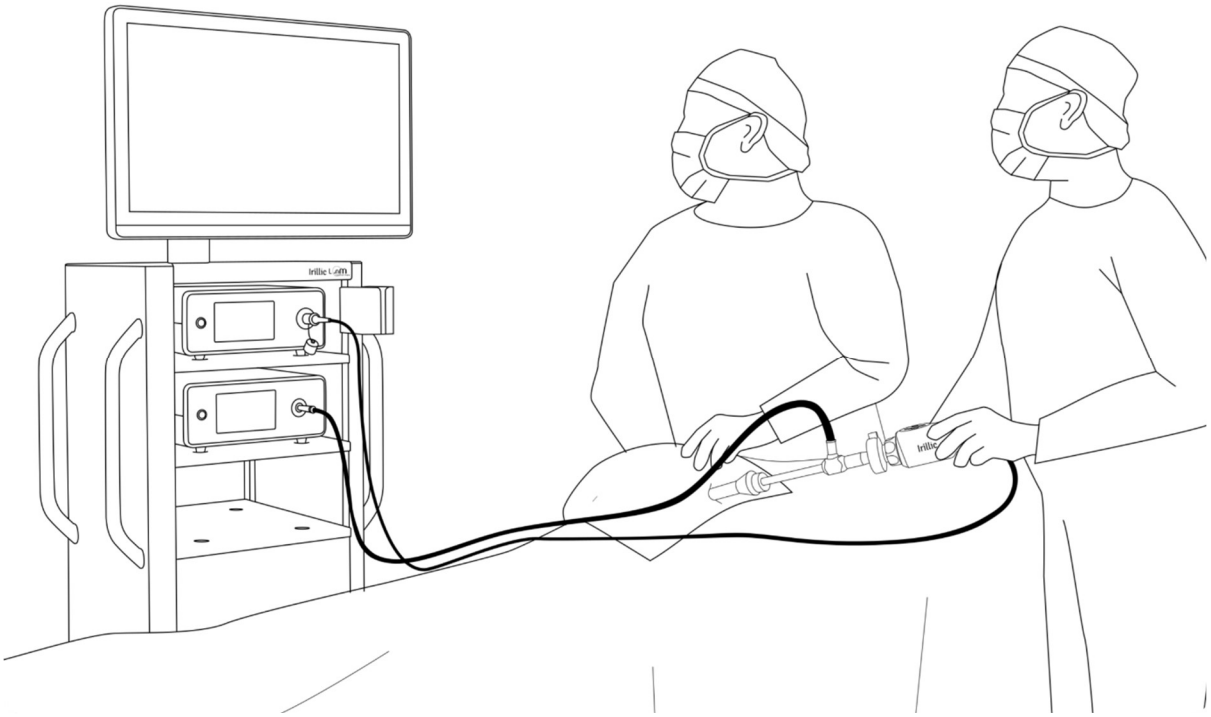


Fig 6.8: An example of system placement in the operating theatre during surgery

The system is now ready to be powered on and used. For information on powering on and operating the system refer to the "Operating the Irillic L.nm system" section.

7

7. Operating the Irillic L.nm system

Overview of User Interface

This section provides a completed overview of the different interfaces and features of the Irillic L.nm Laparoscopic Imaging System. It is divided into subsections where overviews of the different touchscreens on the CCU / WLU / FLU and also explanations of the Display Menu accessed via the Camera Probe buttons.

CCU Startup screen

Startup screen is displayed until the runtime application interfaces with the camera probe during the program runtime. Once a signal is received from the camera probe, the menu will be displayed.

Fig 7.1: CCU startup page

CCU Home screen

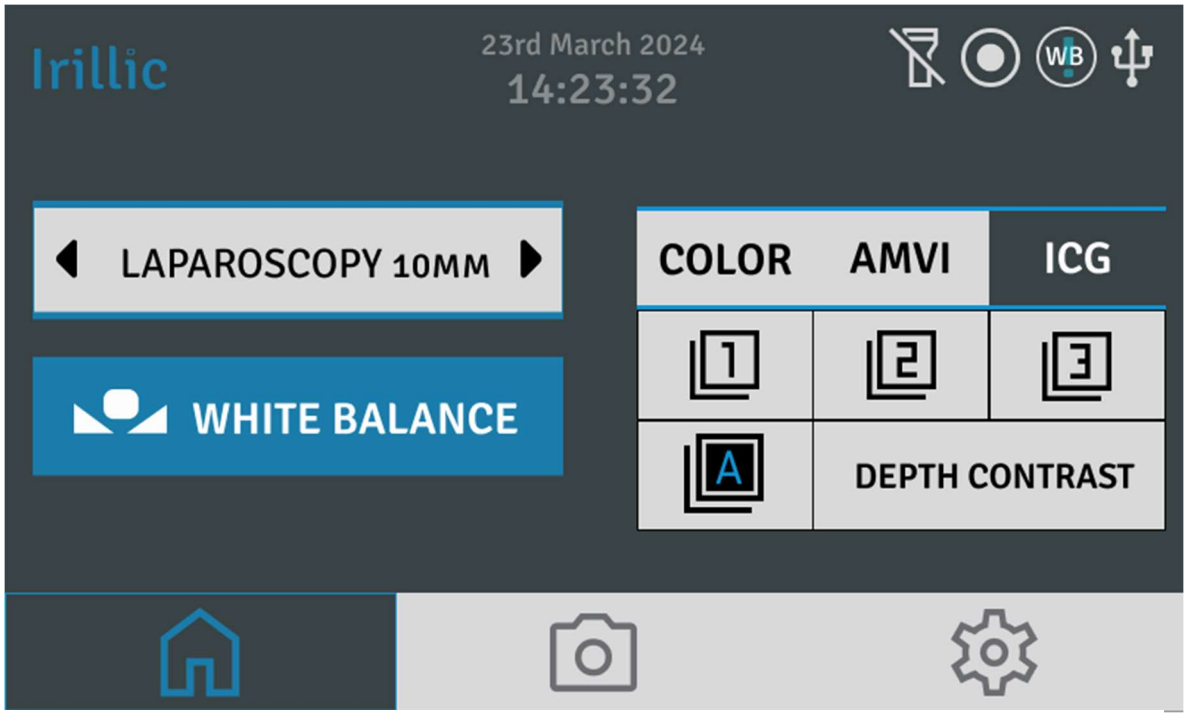


Fig 7.2: CCU Home Page – 4K ICG Configuration
(Note – in the 4K Colour Configuration the ICG Mode will be disabled)

The common elements across the camera control UI are the following:

- **Navigation bar:** The Bar at the bottom of the touch display screen allows users to shift between the different pages in the Camera Control Unit Touch Display Interface. The options are: **Home, Camera** and **Settings**. Detailed descriptions of every separate screen are provided below.

- **Notification bar:** The section of Icons on the top right of the Touch Display Interface provides users with a quick notification of the status of different processes and also any warnings or error states as described in below sections of this chapter.

- **Surgical Profile and Imaging Mode section:** The main middle section of the Touch Display Interface allows users to select the current surgical profile as required. The right-hand side of this section provides information as to the current Imaging Mode that is activated and also allows users to quickly change the User Profile and Imaging Modes that can also be accessed via the Display Menu controlled by the Camera Probe Buttons. The White Balane button also allows users to initiate the White Balance activity.

- **Date and time stamp:** this is displayed at the top of the screen and it displays the current date and time. time is displayed in 24h format, and date is displayed in DD/ Month / Year format.

CCU Camera screen

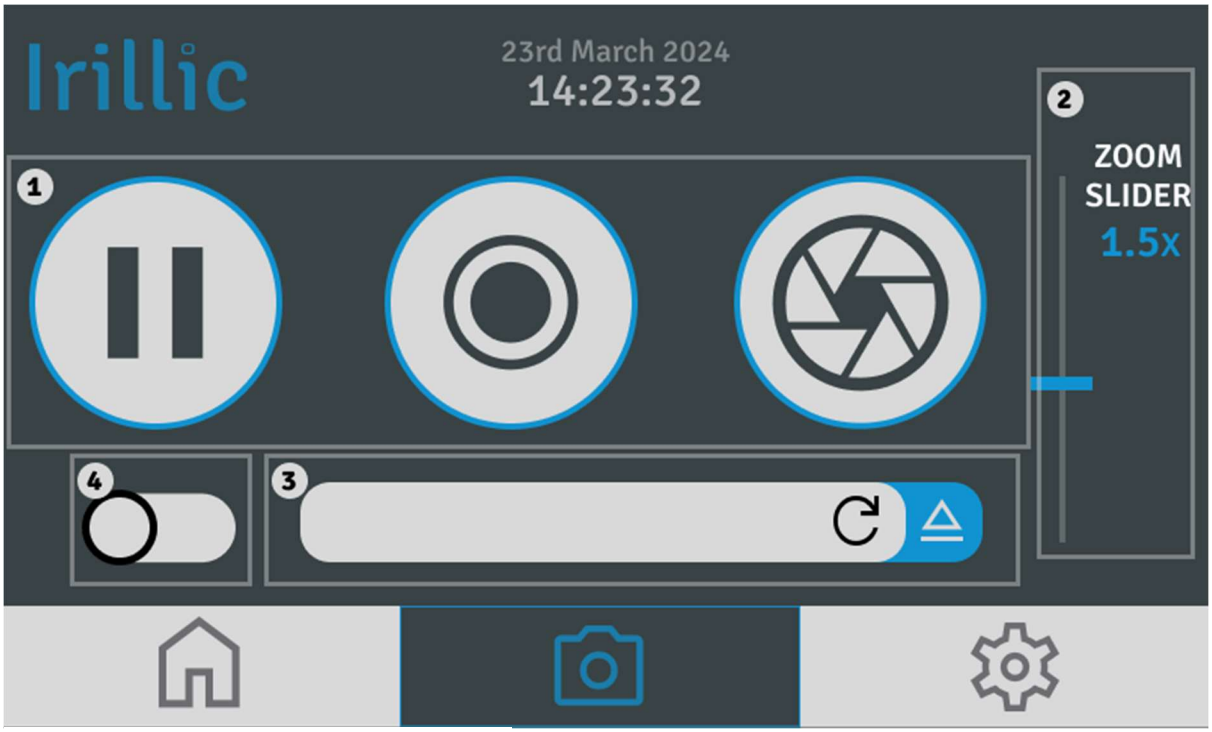


Fig 7.4: CCU Camera Page

The camera menu contains options for modifying and saving outputs from the system. The elements in the camera menu are described as follows.

1. **Camera feed menu**: there are 3 buttons in this menu
    a. **Pause or Freeze frame**: When the button is pressed, the camera feed is paused and the last frame displayed is maintained, and the button then changes to a Play or Unfreeze button. Pressing the button again revives the feed to continuous real-time display.
    b. **Recording toggle:** Pressing this button toggles on/off the recording status of the machine. if there is no suitable drive connected/mounted, the button will be disabled and inactive.
    c. **Snapshot button:** this executes the snapshot feature of the system. if there is no suitable drive connected/mounted to the system, the button will be disabled and inactive.
2. **Zoom slider:** Allows users to adjust the value of digital zoom of the camera feed. The default zoom level is set at 1.2x. The Zoom can also be adjusted using the < UP > and < DOWN > buttons of the Camera Probe.
3. **Status bar:** this status bar is a user facing functionality which will display progress updates and general messages to the text bar. in addition to the text bar, there are two other buttons in this status bar which are pertinent to smooth functioning
    - **Refresh button:** This button refreshes the list of currently connected usb devices. if there is a new mass storage device attached, it runs a couple of viability checks on the storage device, and correspondingly mounts the device if all checks are passed. do note that the recording and snapshot capability will remain disabled until a drive is connected.
    - **Eject drive:** This ejects the currently mounted media storage device

CCU Settings screen

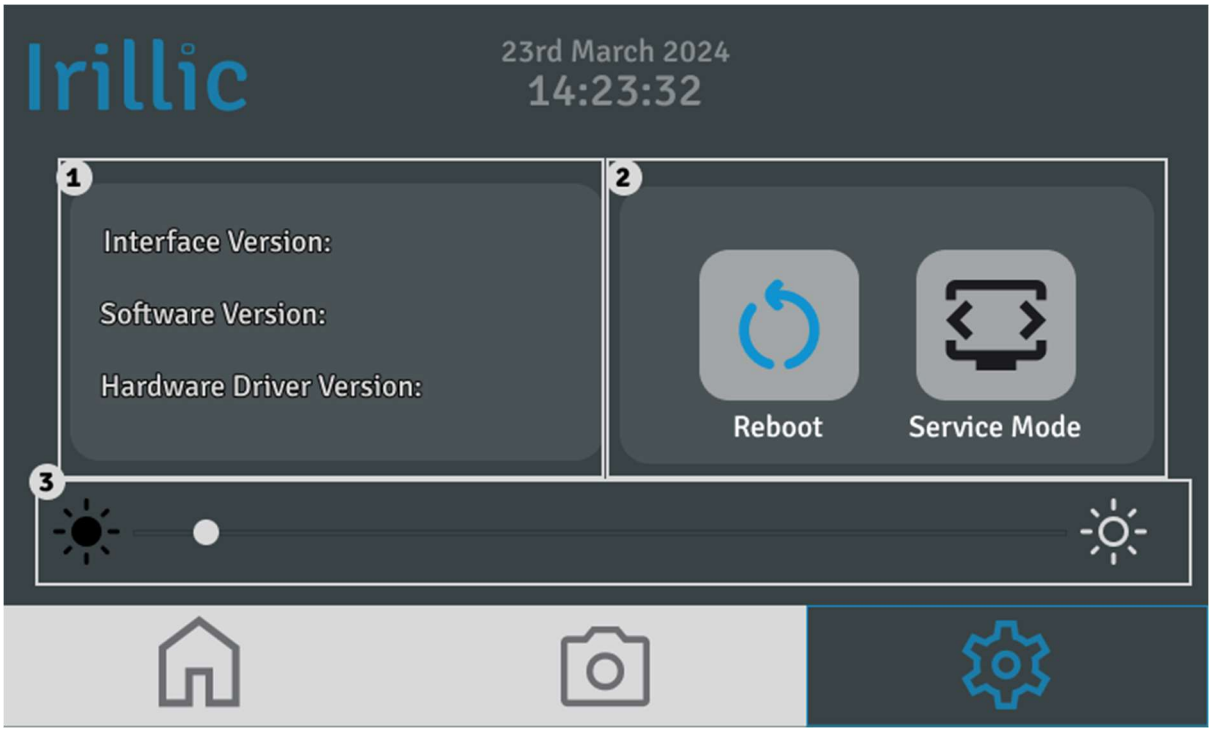


Fig 7.5: CCU Settings Page

The settings menu displays information about the current firmware of the Irillic system

1. **Device Information**: Provides information regarding the version of the peripherals, the application codebase, and the hardware drivers that make up the device. It is information required solely for service personnel.
2. **System Control Panel**: Allows users to perform safe and controlled Reboot of the device in case of any performance issues with the software, and also to activate Service Mode to allow service personnel to access the underlying operating system.
3. **Brightness Slider**: Allows users to change the brightness of the touch display.

- **Service Mode and access to the underlying operating system of the device is only for authorized service personnel or Irillic engineers only.**
- **Unauthorized attempts to modify the device may lead to equipment failure.**

WLU/FLU Startup screen

Fig 7.6: WLU/FLU Startup

This is the startup screen for the WLU or FLU. Once a touch is registered, the light unit interface appears

WLU Main screen

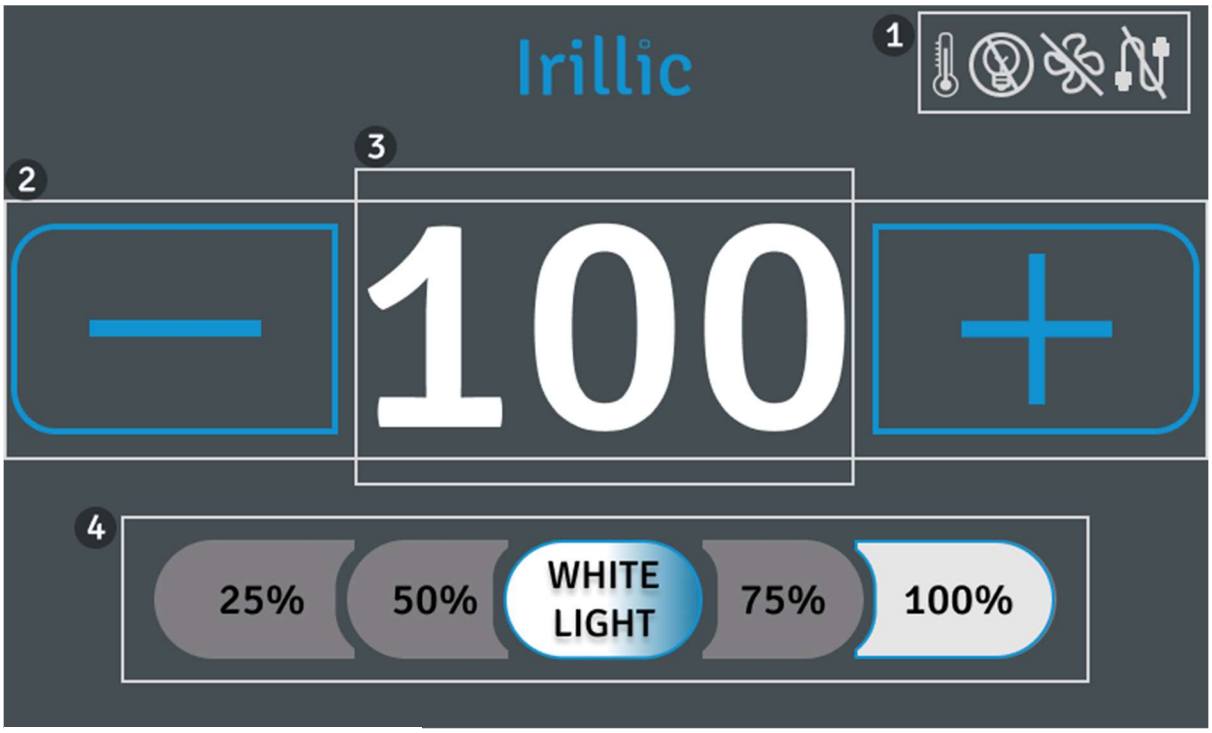


Fig 7.7: WLU Main Screen

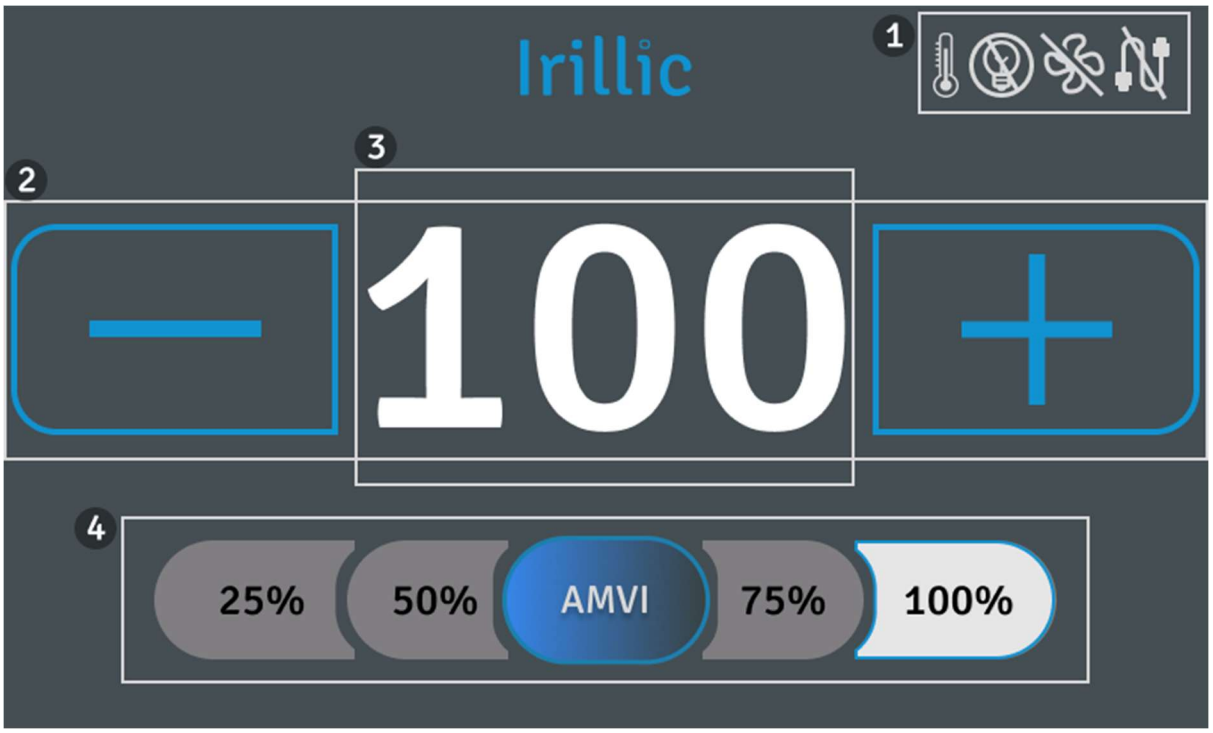


Fig 7.8: WLU Main Screen with AMVI Mode Enabled

1. **Notification bar:** It contains icons for displaying different error states in the light unit.
2. **Intensity Percentage:** This displays the intensity of the light in 5% increments
3. **< + > and < - > :** Increase and decrease the intensity of the light
4. **Intensity Bar:** It has a standard set of light intensities for quick settings change

Fusion Light Unit Main Screen

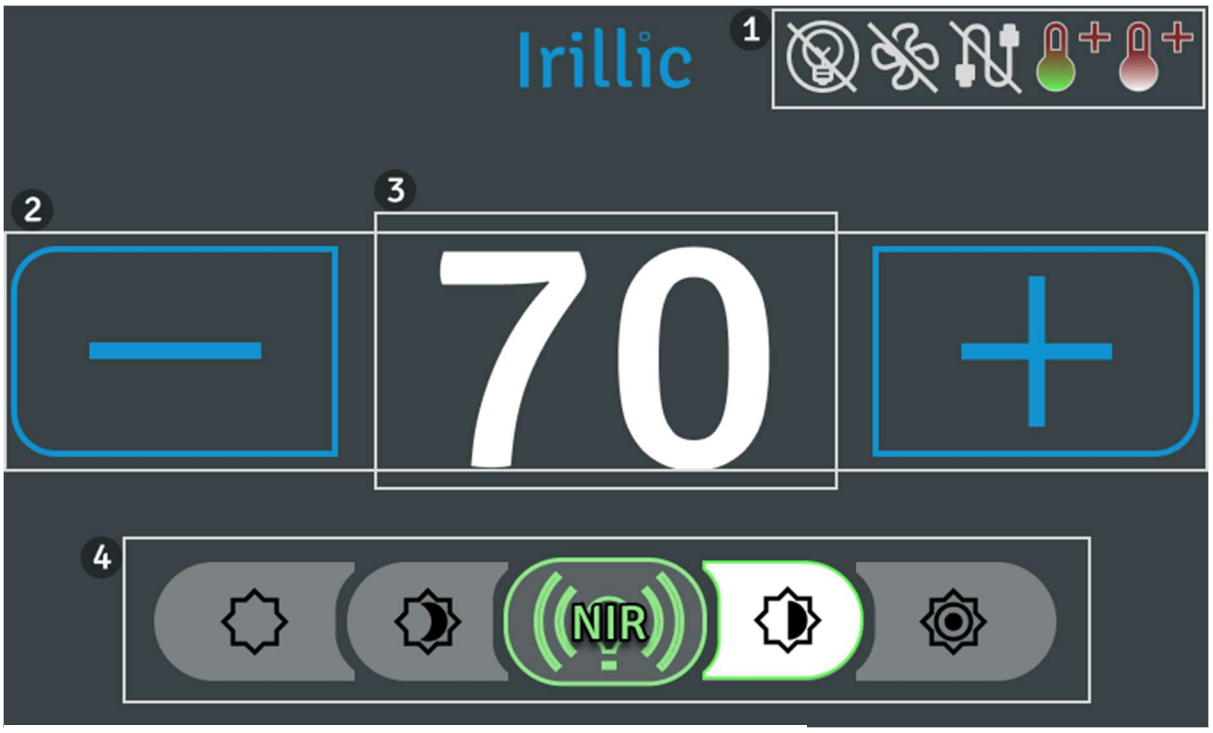


Fig 7.9: FLU Main Screen with NIR Laser Enabled

User Interface Warnings

CCU Touchscreen UI Warning & Notification Symbols

Interconnect Error – This symbol indicates that the WLU / FLU is not connected to the CCU via the Interconnect Cable. This Error State means that AMVI Mode cannot be enabled. The Interconnect Cable must be used to connect the WLU / FLU to the CCU as per the connections described in Chapter 6 of this manual.

Recording ON – This symbol indicates that the current live feed is being recorded onto the attached storage device. The saved video files will be named with the time stamp of the start of the recording. Videos will be captured in FHD resolution, while Images will be saved in the full 4K resolution that they are displayed in.

White Balance Incomplete – This symbol is displayed when the White Balance process has not yet been carried out. This can lead to an incorrect or inaccurate representation of the colour of the patient anatomy. Always make sure White Balance is performed by selecting the option from the Main Menu of the Camera Probe accessed via its' buttons.

USB Connection – This symbol appears when a USB connection to a Storage Device is successfully achieved and the system is ready to begin recording data in the form of Images and Videos to be saved on the connected storage media.

WLU/FLU Touchscreen UI Warning Symbols

Light Source Warning – This symbol indicates that due to some issue the Light Source is not operational at expected levels. This may be due to wear and tear or some other form of damage to the LEDs. Please contact Irillic to schedule a visit by an authorized Service personnel to rectify this issue.

Fan Error Warning – This symbol appears when the cooling fan within the Light Unit is not operational. This may be due to some internal failure of the fan or even due to some obstruction preventing its operation. This can lead to catastrophic failure of the Light Unit die to overheating. Please contact Irillic to schedule a visit by an authorized Service personnel to rectify this issue.

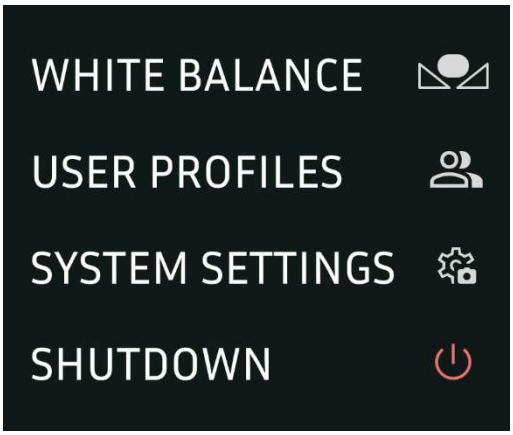
Light Guide Connection Warning – This symbol appears when the Light Guide is disconnected or dislodged from the Light Unit. This will also cause the light source to automatically power down to prevent any accidental emission of high intensity white light or infrared radiation. Please ensure the Light Guide is securely connected to the Light Unit by following the steps described in Chapter 6 of this manual.

High Temperature Warning (NIR Light Source) – This symbol appears when the temperature of the NIR light source reaches a critical level that requires the light source to be powered off to protect the system and the patient/user. The light source will power back on when its temperature reaches acceptable levels. If this condition is repeated or persists, contact Irillic to resolve the issue.

High Temperature Warning (White Light Source) - This symbol appears when the temperature of the White light source reaches a critical level that requires the light source to be powered off to protect the system and the patient/user. The light source will power back on when its temperature reaches acceptable levels. If this condition is repeated or persists, contact Irillic to resolve the issue

Camera Probe Menu System on Display Monitor

Main Menu



White Balance executes the White Balance operation upon selection.

User Profiles opens the Profile Selection Menu as seen below.

System Settings opens the System Settings Menu as seen below.

Shutdown initiates the shutdown sequence for the device.

User Profiles Menu

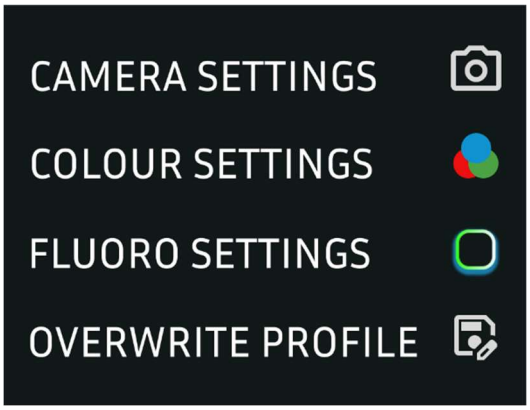
Auto Adjust is a system profile for setting the camera mode to automatically adjust the exposure and gain according to the lighting conditions.

Dissection profile produces an image with enhanced yellow hues for higher tonal contrast between tissues.

Resection profile produces an image with muted highlights for a smoother colour profile.

Bleeding profile reduces the saturation of the image feed to increase visibility in case of a lot of bleeding.

System Settings Menu



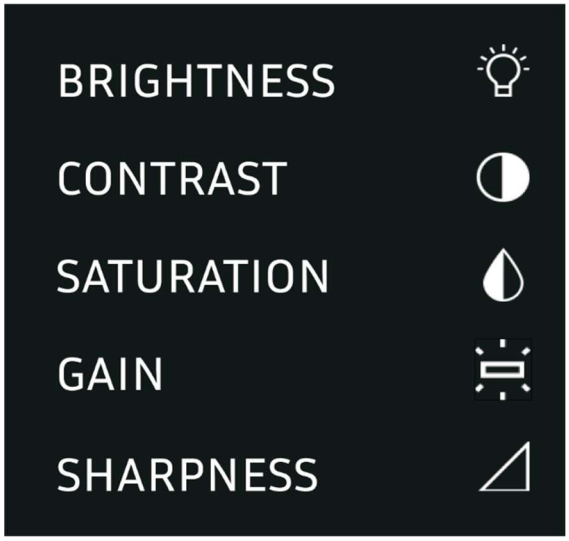
Camera Settings opens the colour camera settings menu as seen below.

Colour Settings opens the colour camera colour profile calibration menu as seen below.

Fluoro Settings opens the near infrared camera settings menu as seen below.

Overwrite Profile opens the menu to overwrite user profiles as seen below.

Camera Settings Menu



Brightness opens the Brightness Slider which allows users to modify the apparent brightness of the colour image.

Contrast opens the Contrast Slider which allows users to modify the apparent contrast of the colour image.

Saturation opens the Saturation Slider which allows users to adjust the overall colour saturation of the colour image.

Sharpness opens the Sharpness Slider allowing users to modify the sharpness setting of the colour image.

Colour Settings Menu

Quick Calibrate opens the advanced colour calibration mode which allows users to independently tune specific axes of the colour gamut as described below.

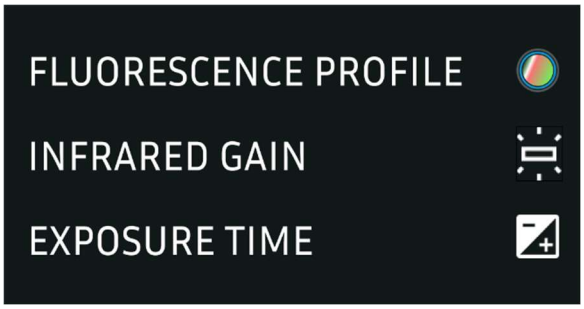
Red opens the Red Colour Slider to modify the colour images red tones.

Green opens the Green Colour Slider to modify the colour images red tones.

Blue opens the Blue Colour Slider to modify the colour images red tones.

Reset Colour returns all colour adjustments to the factory colour settings.

Fluorescence Settings Menu



Fluorescence Profile opens allows users to change the Fluorescence Fusion Overlay colourmap.

Infrared Gain opens the NIR Camera Gain Slider to adjust the fluorescence sensitivity.

Exposure Time opens the NIR Camera Exposure Slider to adjust exposure duration.

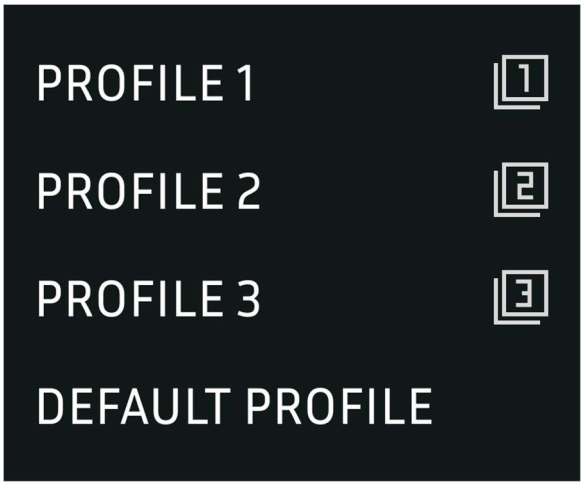
Fluorescence Profile Settings Menu

Green sets the Fluorescence Fusion Overlay colourmap to a Green colourmap and is the default setting.

Magma sets the Fluorescence Fusion Overlay colourmap to Magma.

Viridis sets the Fluorescence Fusion Overlay colourmap to Viridis.

Overwrite Profile Menu



Profile 1 overwrites the **Dissection** profile with the current system settings.

Profile 2 overwrites the **Resection** profile with the current system settings.

Profile 3 overwrites the **Bleeding** profile to with current system settings.

Default Profile overwrites the default runtime profile with the current system settings.

- **Overwritten profiles cannot be recovered. Always take care when overwriting existing profiles.**
- **In case of incorrect modification to default profiles, please contact Irillic to reset the User Profiles to factory settings.**

Typical Operating workflow

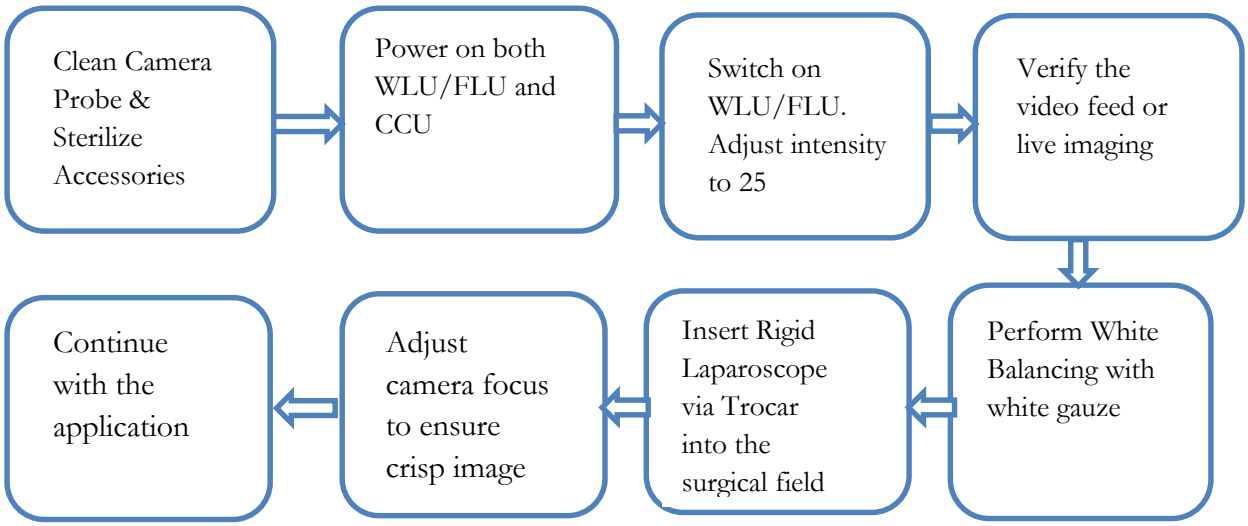


Fig 7.7: System Operating Workflow

Imaging Modes

4K Colour Mode

This is the default operational mode for the L.nm system. The raw camera feed is adjusted for the selected colour profile and displayed to the user in a low-latency manner. You may refer to the colour adjustment procedure to tune the colour to your own preference.

Since this is the default operating mode, the system will boot directly to the 4K Colour feed. To switch back to the colour feed, you may press the <COLOR BUTTON ON HOME SCREEN> icon in the Camera Control Touch Interface, or alternatively press the M button (if you are currently in the Depth Contrast Mode)

4K Depth Contrast Imaging Mode

The depth contrast mode is a unique feature of the L.nm system where the contrast is enhanced using image processing to provide users with a perception of depth where sharp edges are present in the image. It allows for visualization of edges and vascularity with a higher contrast.

To activate the Depth Contrast mode, you may use the <DEPTH CONTRAST SLIDER> on the Camera Control Touch Interface, or alternatively press the M button to switch between the 4K Colour Mode. When activated, the feed will display a < DEPTH CONTRAST ICON > on the top left side of the screen.

The Depth Contrast Mode is a universal feature and can be activated across both the White Light Mode (4K Colour Mode) as well as the AMVI mode.

4K Advanced Micro Vascular Imaging Mode

The Advanced Micro-Vascular Imaging Mode or AMVI, is an additional feature to the L.nm system which makes use of a different imaging pipeline to display features pertaining to the micro-vascularity within the body. It is activated through the Camera Unit Touch Interface by pressing the < AMVI BUTTON >.

Upon pressing the AMVI button, the white light changes to a modified spectrum primarily composed of blue and green light and the colour correction profile are changed to that of the AMVI mode.

The AMVI Mode uses a special illumination and additional post capture image processing to enhance the visualization of subsurface microvasculature and can help surgeons make more informed diagnostic decisions and identify regions of interest.

NIR Fluorescence Imaging Mode

The NIR Fluorescence Imaging Mode is available only in the ICG Configuration of the L.nm.

This imaging mode displays only the ICG Near Infrared Fluorescence image captured by the 4K ICG Camera Probe in Black & White. The white parts of the image indicate high fluorescence intensity corresponding to higher concentrations of the bonded contrast agent, while the black parts of the image indicate low or no fluorescence intensity due to low concentration of the dye.

4K ICG Fusion Overlay Imaging Mode

The Fusion Overlay Imaging Mode is available only in the ICG Configuration of the L.nm.

The Fusion Overlay Mode is the primary Imaging Mode that is recommended for use since both colour as well as fluorescence information is displayed in this mode.

A Fusion Overlay Mode image is obtained by using the simultaneously captured images from the Colour & the Fluorescence sensors of the Camera Probe, and overlaying the fluorescence data on top the colour data. This overlay process is performed by applying a green colourmap (or predefined colourmap) to the Fluorescence data, and merging that image with the Colour data by a image processing process that ensures that no data from either of the source images is lost.

The Fusion Overlay Mode allows users to continue with their surgery without having to switch screens or require any interaction to view and interpret fluorescence information.

Note – the Field of View of the Fusion Overlay Mode may be smaller than the Field of View of the 4K Colour Imaging Mode due to the fact that the excess colour data that is outside the view of the Fluorescence data is discarded.

- **If any discrepancy or offset between the edges of the Fluorescence data and the edges of the Colour data is noticed, please contact Irillic to ensure alignment and calibration of the Fusion Overlay Mode is assessed and updated if required.**

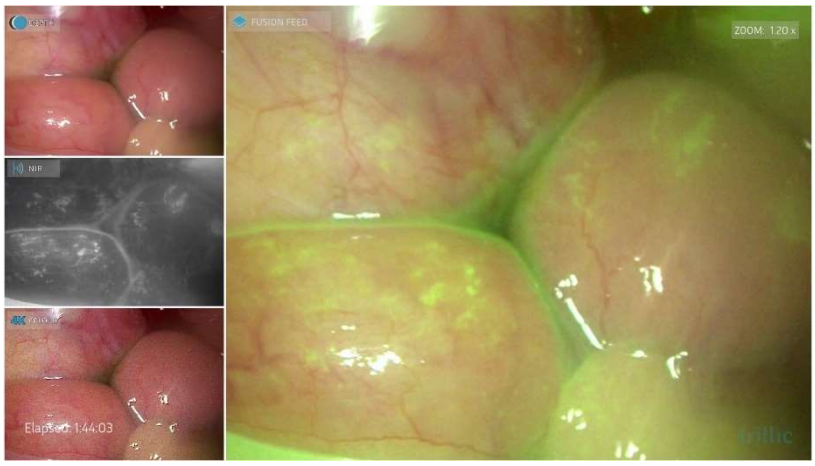
Multiview Imaging Mode

The Multiview Imaging Mode is available only in the ICG Configuration of the L.nm.

The Multiview Imaging Mode allows users to simultaneously view multiple Imaging Modes at the same time. This is the default Imaging Mode for the ICG Configuration of the L.nm. The primary Mode which is on the right of the screen can be toggled as the Imaging Mode by pressing the <MODE> button of the Camera Probe.

These modes are:

- 4K Colour Imaging Mode
- NIR Fluorescence Imaging Mode
- Depth Contrast Imaging Mode
- Fusion Overlay Imaging Mode



These modes are displayed in the configuration shown, and the mode being displayed in the larger section of the video feed can be cycled using the Camera Probe <UP> and <DOWN> buttons.


Colour Calibration

A step-by-step guide to the Advanced Colour Calibration module on the L.nm system

Step 1: Enter the User Settings menu by long pressing the M button on the probe, and navigate to the Quick Calibrate option in the User Settings Menu. Select the option by pressing the M button

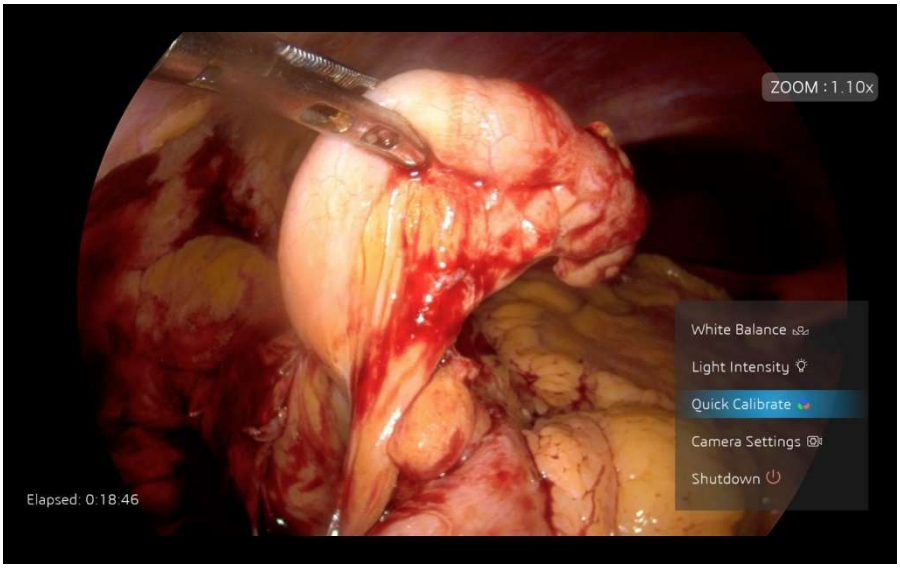


Fig 7.10: Menu selection of Quick Calibrate Mode

Step 2: Use the colour picker to point at the colour you wish to tune, and select it using the M button

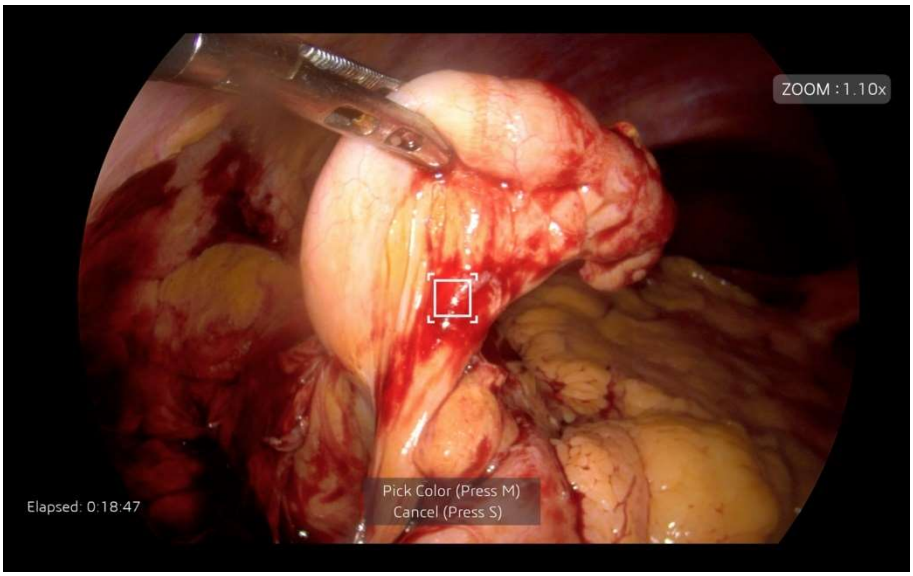


Fig 7.11: Pointer Box to select the tissue colour to calibrate

Step 3: Select the channel upon which you wish to make the changes. Select the Hue channel if you wish to modify the colour tone, and select the Saturation channel if you wish to change the degree of brightness/dullness associated with it.

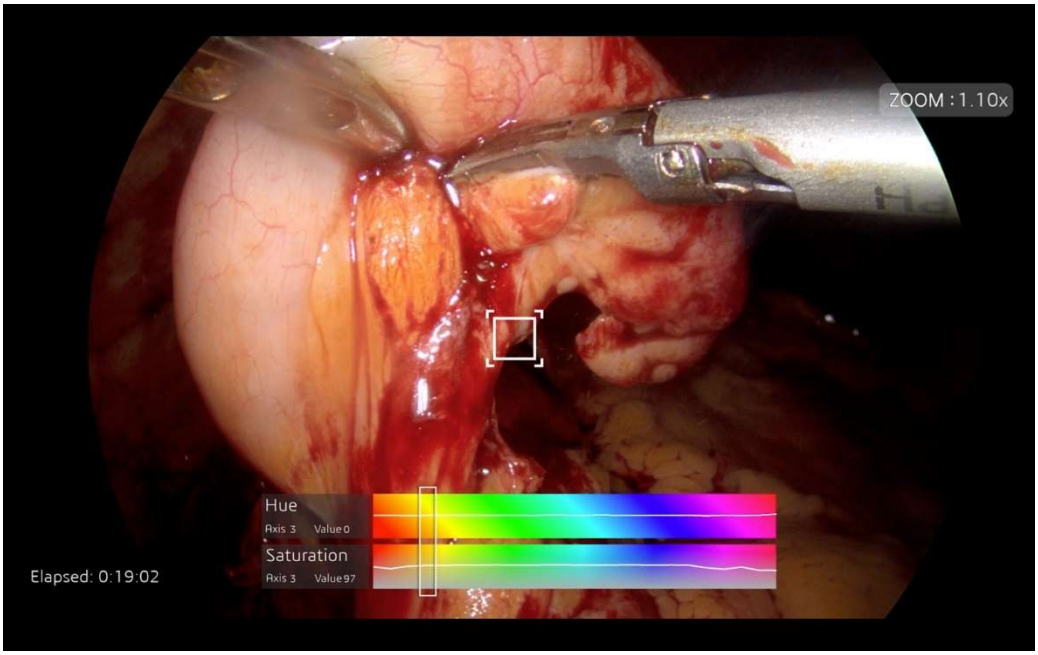


Fig 7.12: Selection of the colour channel for calibration

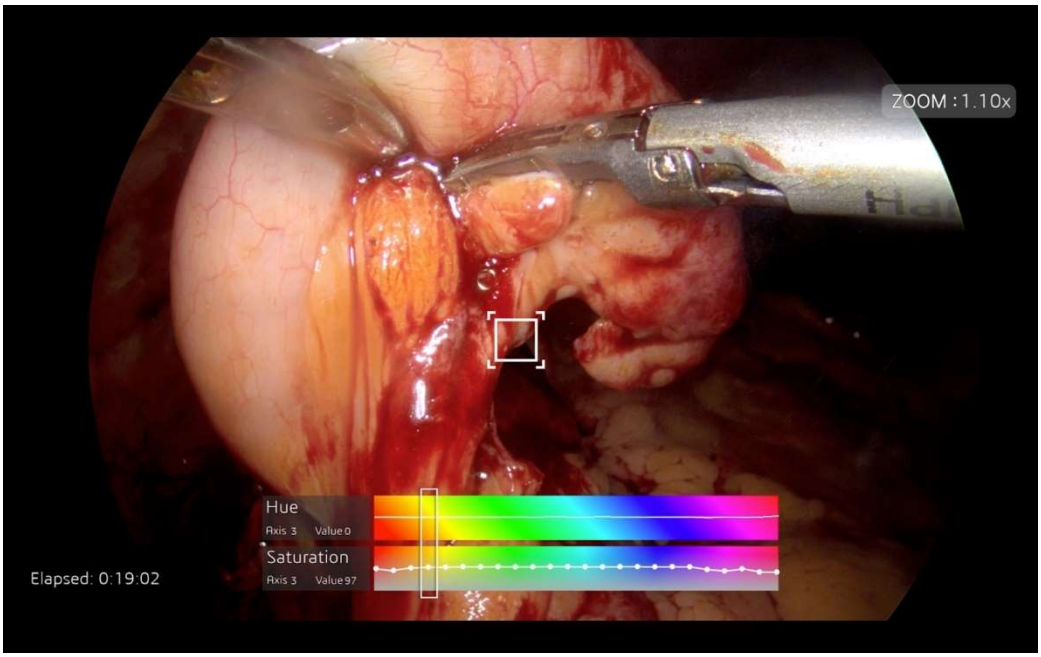


Fig 7.13: Selection of the Saturation of the chosen colour channel for calibration

Step 4: Select either the Hue or Saturation of the chosen colour channel for calibration by using the Up and down buttons on the camera probe

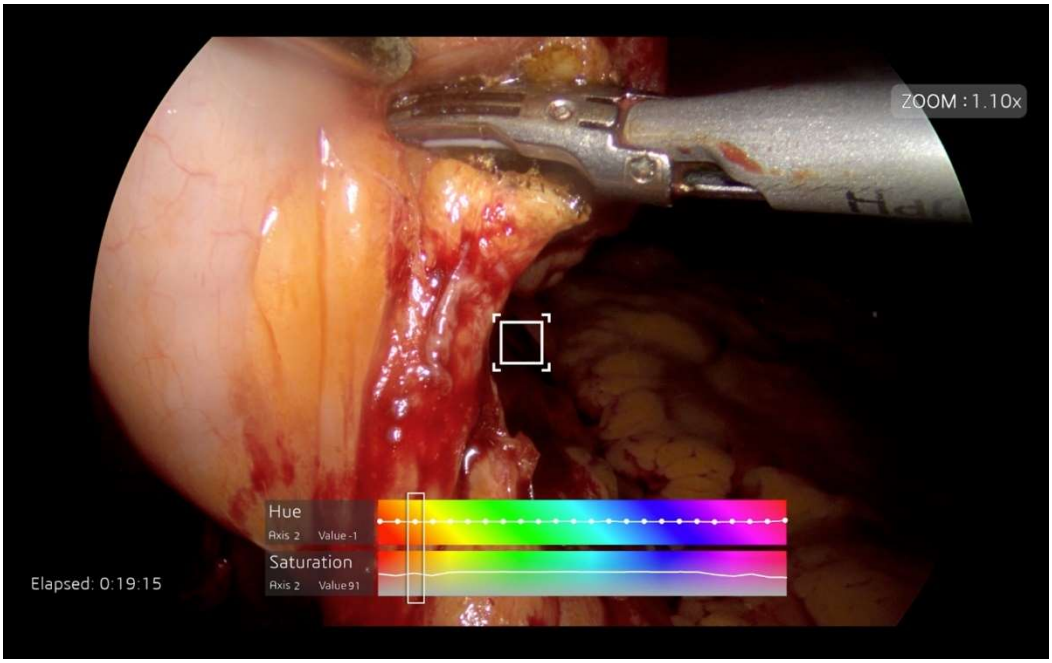


Fig 7.14: Selection of the Hue of the chosen colour channel for calibration

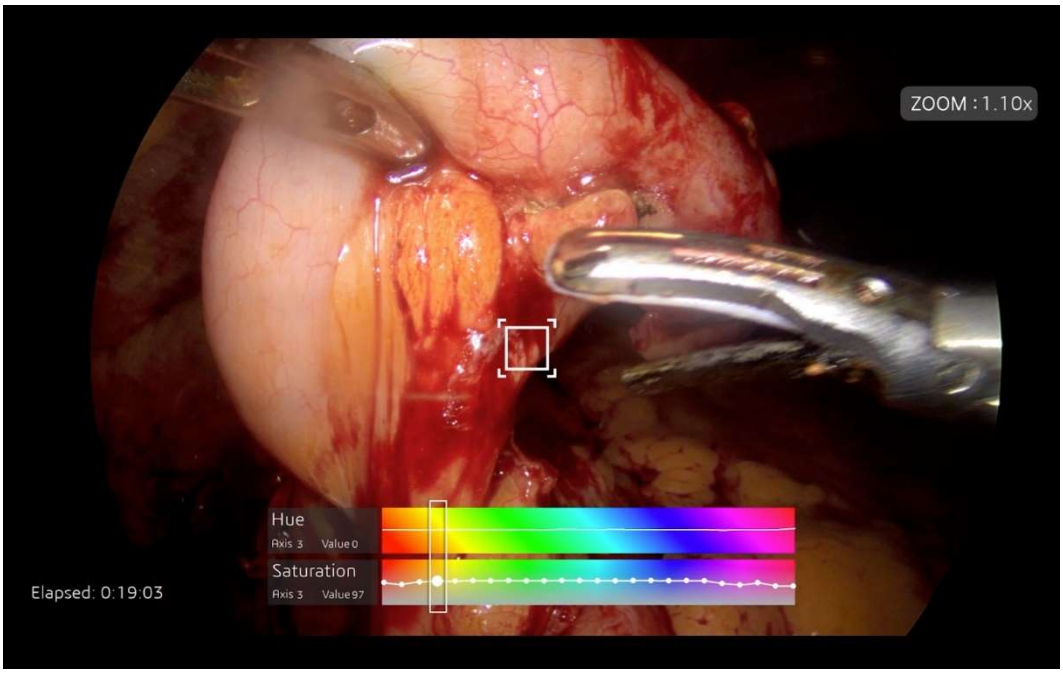


Fig 7.15: Adjustment of the Saturation of the chosen colour

Step 5: Use the up/down navigation buttons to increase/decrease the value across the selected axis.

Recording

The L.nm system has a built-in low-latency recording functionality that makes it possible to record ongoing procedures in Full HD to an external drive of your choice. Recording functionalities can be triggered from either the Camera Probe head, or the CCU Touch Interface.

Pre-Requisites:

To enable the in-built recording, the user must ensure that an external mass storage device is available and mounted to the system. The provided 2TB HDD can be used, and is an ideal device for recording large format videos.

- To mount the device, the user must first connect the storage device to the CCU via the USB in the front. Upon validating the connection, the user then navigates to the Camera Settings Menu in the CCU Touch Interface and presses the refresh button in the menu.
- Verify the status of the mounting in the status bar. Upon successful mounting, the options for recording and snapshots are made available to the user in the Camera Settings Menu.

Recording Control

Once a storage device has been mounted, the user may start recording by either

- Long Pressing the M button on the camera probe
- Pressing the Record Button in Camera Settings Menu on the CCU Touch Interface.

Once the recording has started, the elapsed time is displayed at the bottom left of the feed. The recorded outputs are categorized according to date and stored within the mass storage device.

To stop the recording, the user can either

- Long Press the M button on the camera probe
- Press the Record Button in Camera Settings Menu on the Camera Unit Touch Interface.

Shutdown

Once the imaging part of the surgery is complete and the system is not being used any further, the device can be safely powered off using the Display Monitor Menu accessed from the Camera Probe Buttons:

Press & Hold the  <M> Mode Button to open the Main Menu. The bottom option is Shutdown.

This will ensure all connected subsystems are properly powered off and all sensitive device data is protected. Once the Monitor screen goes blank, the power supplied to the device can be switched off, and the components disconnected, cleaned as per the approved processes and safely stored in readiness for its next use.

- **Do NOT abruptly power OFF the device without ensuring that safe Shutdown is completed.**
- **Failure to properly shutdown the device repeatedly may lead to damage of internal components and impact proper functioning.**

8

8. Troubleshooting

Sl. No.	Problem Scenario	Possible Solutions
1.	Images appear hazy	• If there seems to be any tissue or bodily fluid covering the distal tip of the Rigid Laparoscope, try cleaning the laparoscope by removing it from the Trocar and wiping or washing the tip of the scope with a clean gauze or in warm distilled water. • Try changing the focus level using the Focussing Ring of the Camera Probe based on the distance between the distal tip of the Rigid Laparoscope and the target tissue
2.	Images appear grainy	• Try increasing the intensity of the white light illumination produced by the White Light Unit • Try decreasing the gain parameter in System Settings -> Camera Settings -> Gain
3.	Images appear excessively bright	• Try reducing the intensity of the white light illumination produced by the WLU/FLU • Try decreasing the brightness parameter in System Settings -> Camera Settings -> Brightness
4.	Unable to differentiate between different types of tissues due to poor colour reproduction.	• Re-do the process of White Balance of the camera while focussing on a clean white strip of gauze cloth • Try adjusting the appropriate colour axis using the Colour Calibration feature • Try increasing the contrast parameter in System Settings -> Camera Settings -> Contrast • Try selecting one of the Preset User Profiles to change the colour calibration feature set
5.	Power-on indicator is lit GREEN but there is no display on monitor screen.	• Check if monitor power cable is securely connected to the DC input port on the Monitor. • Check connection of video cable from Control Unit to Monitor • After confirming cable is connected, power off/on the display monitor once again.
6.	Fluorescence not visible/very faintly visible	• Check if 10mm scope is certified for NIR usage. • Check the NIR laser intensity on the Light Unit • Try increasing IR Gain in System Settings -> Fluoro Settings ->Infrared Gain

7.	External HDD not mounting	• Disconnect and reconnect the drive to another port and try refreshing USB devices • Try freeing up some space on the drive, or use an alternative external storage device
8.	Camera disconnected due to cauterization interference	• In case the feed does not recover automatically, try disconnecting and reconnecting the camera probe to the Camera Unit
9.	Buttons not working on the Camera Probe	• Try disconnecting and reconnecting the camera probe from the Camera Unit
10.	Erroneous colour configuration parameters lead to poor visualisation	• Reset system colour configuration by going to System Settings -> Colour Settings -> Reset Colour

- **If any device operation malfunction not in the above table occurs and persists after a system reset, please contact Irillic for further assistance.**

9

9. Maintenance

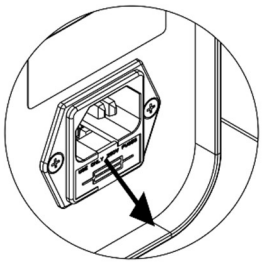
- **Only Irillic Authorised Personnel are allowed to perform maintenance on Irillic L.nm Laparoscopic Imaging System.**
- **Always consult Irillic before performing any modification to the device apart from those listed here below.**
- **Preventive maintenance to be followed as per the Preventive Maintenance Schedule document ELM001-G-0001 v 2.0 provided along with the device.**
- **Information on all manufacturer-initiated maintenance and servicing activities are available in the Service Manual.**

User initiated Maintenance

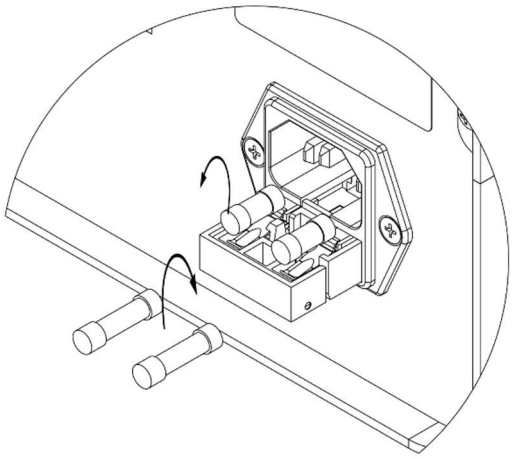
The user can do the following maintenance as needed:

1. Replacing CCU/WLU/FLU Fuse
2. Replacing Main System Fuse
3. Replacing Transformer Fuse

Replacing CCU / WLU / FLU Fuse



1. The Fuse is located behind the CCU/WLU/FLU in a slot in the A/C Panel Input as shown in the image
2. Open the rear cover the A/C Panel Input
3. Remove the existing fuse and keep it aside
4. Replace the blown fuse with a replacement (Contact Irillic for details on the fuse ratings, or refer to Appendix I)
5. Insert a new spare fuse in the spare fuse location (Optional); contact Irillic support for new spare fuse if needed
6. Push the rear cover of the A/C Panel Input back in place until you hear a click



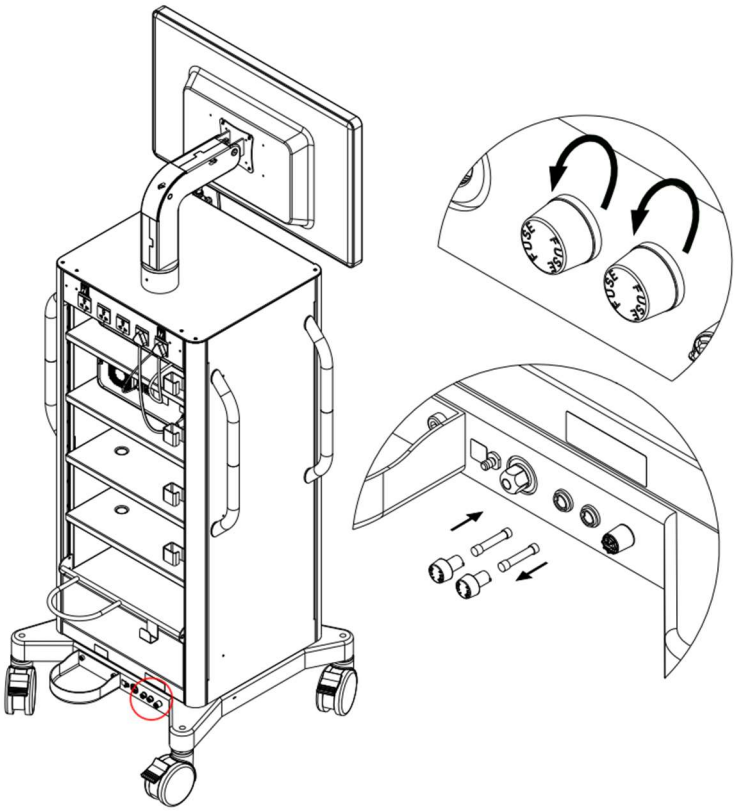
- **Take care to ensure that the correct fuse rating is used when replacing a blown fuse. Failure to do so may lead to improper functioning of the device or irreparable damage.**

Replacing Main System Fuse

If the system is not powering ON (Power indicator on CCU/WLU/FLU remains OFF and Power Indicator on Monitor remains OFF), the fuse on the Main System may need to be replaced.

Steps to replace the fuse are given below:

1. The Fuse is located at the bottom of the Trolley as shown in the image
2. Unscrew the two rear covers of the fuse
3. Remove the existing fuse and keep it aside
4. Replace the blown fuses with fresh ones (Contact Irillic for details on the fuse ratings, or refer to Appendix I)
5. Screw the rear cover of the fuse back in place until you hear a click



Replacing Transformer Fuse

The replacement of the Transformer fuse can be performed following the same steps as the System fuses found on the Trolley. The Transformer fuse is located in the same place at the base of the Trolley and is marked accordingly.

System Maintenance

Maintenance activities for the rest of the system will be done by Irillic or Irillic authorized personnel. These activities include but are not limited to:

- Hardware maintenance
- Mechanical part(s) maintenance
- Power Cord Replacement
- Detachable Part Replacement
- Software updates[1]

Note: The maintenance schedule and terms are as per maintenance contract agreed between customer and Irillic.

User personnel are required to perform regular system cleaning activities regularly – see the next chapter on "Cleaning Instructions" for more details.

[1]For some of the software updates, Irillic may choose to train user personnel for doing these activities.

10

10. Cleaning Instructions

It is strongly advisable for user personnel to clean the equipment regularly. Prior to each separate use during surgical procedures, the Light Guide, Rigid Laparoscope, and Camera Probe must necessarily be cleaned according to the instructions given below.

Cleaning the CCU / WLU / FLU

Wipe the Control Unit body with ethanol or isopropanol-dampened soft cloth or absorbent cotton pad.

- **Do NOT splash or spray the liquid; liquid entering the Camera Control Unit / White Light Unit / Fusion Light Unit may damage the system.**

Cleaning the 4K Camera Probe / 4K ICG Camera Probe

Cleaning the Camera Probe is an essential step in the preparation for a surgical procedure, as it ensures the part is free from any microbial contamination that could lead to infection or other complications.

1. The first step in the Camera Probe is to inspect it for any visible debris, such as blood or tissue.
2. After the visual inspection, remove any debris using a soft tissue.
3. Apply 6 ml of the provided disinfectant solution to the entire Camera Probe
4. Clean with a lint-free cloth for 2 minutes for effective cleaning while making sure to spread the disinfectant solution on every accessible surface.
5. After 2 minutes drying, the Camera Probe will be ready for use.

- **Do NOT spray or splash the liquid; liquid entering the probe may damage the system.**
- **Use of hard cloth may leave abrasions on the optical surfaces resulting in reduced visualization.**
- **Do not use alcohol-based cleaning agents or other organic solvents.**

Cleaning the Trolley

- Wipe the Trolley body with ethanol or isopropanol-dampened soft cloth or absorbent cotton pad. Do NOT spray or splash the liquid on the trolley

Cleaning the Light Guide

- Always sterilize the Light Guide before use either using Steam Sterilization with an Autoclave or Low-Temperature Plasma sterilisation with STERRAD 100S Long Cycle before every procedure.
- Ensure that all precautions and processes as described in the User Manual of the Light Guide provided along with the device.
- Steam Sterilization using an Autoclave can be performed for the Light Guide using demineralized feed water as per the following specifications:

Temperature	134 °C (273.2 °F)
Holding Time	5 minutes (effective sterilization time)

- **Risk of scalding or burn injury when loading or unloading the part in high temperature sterilization devices, wear suitable gloves.**
- **Light Guide may be shock sensitive when hot, avoid shaking or rough handling.**
- **Damage may result from sudden change in temperature, allow parts to cool to room temperature, do not use additional cooling measures.**
- **Always follow the recommended sterilization process, failure to do so may lead to damage of the part and can affect the performance or lifetime of the Light Guide.**

Cleaning the Rigid Laparoscopic

- Always sterilize Rigid Laparoscope before use either using an Autoclave or other means of high temperature sterilization before every procedure
- Wipe the Rigid laparoscope body with ethanol or isopropanol-dampened soft cloth or absorbent cotton pad otherwise and rinse with Iodine solution before use during surgery.
- Ensure that all precautions and processes as described in the User Manual of the Rigid Laparoscope provided along with the device
- Steam Sterilization using an Autoclave can be performed for the Light Guide using demineralized feed water as per the following specifications:

Wrapping	Double
Temperature	132 °C (270 °F)
Holding Time	4 minutes (18 minutes maximum)
Dry/Cool Time	45 minutes

- **Risk of scalding or burn injury when loading or unloading the part in high temperature sterilization devices, wear suitable gloves.**
- **Rigid Laparoscope may be shock sensitive when hot, avoid shaking or rough handling.**
- **Damage may result from sudden change in temperature, allow parts to cool to room temperature, do not use additional cooling measures.**
- **Always follow the recommended sterilization process, failure to do so may lead to damage of the part and can affect the performance or lifetime of the Rigid Laparoscope.**

Appendix I – Technical Specifications

Performance Specifications	
Imaging Sensor	CMOS Sensor
Optical Image / Video Resolution	3840 x 2160 pixels
Optical Modes	4K Colour Mode, 4K AMVI Mode, 4K Depth Contrast Mode, NIR Fluorescence Mode, 4K Fusion Overlay Mode, Colour Calibration Mode
Working Distance	2 Cm – 15 Cm (from Distal end of Rigid Laparoscope)
Recording Capability	Inbuilt FHD recording onto External Storage via USB
Display Resolution	3840 x 2160 pixels
Display Size	31.5 inch (80.01cm)
Operator Controls	Touchscreen Interface, Programmable Camera Probe Buttons
Interface Specifications	
Video Output	Mode : 3840 x 2160 @ 60 Hz refresh rate Standard : 1 x HDMI 2.0, 1 x DP
Data Interface	Usage : Data storage device, Future expansion Standard : 2 x USB 3.0 (also compatible with USB 2.0)
Network Interface	Usage : LAN connectivity Standard : 1 x Gigabit Ethernet
Electrical Specifications	
Electrical Class	Class I Medical-Electrical Equipment
Max Power Rating	1000 VA (Max)
Input Voltage & Current Consumption	240 V AC, 50 Hz
Fuse Ratings	Transformer: 250V, 5A (60 Minutes) Time-Lag, Breaking Capacity – 50A System: 250V, 10A (4Hr) Slow-Blow, Breaking Capacity – 10kA
Trolley Non-isolated Sockets Output	0.63 @ 240 V (~150 VAC)
Environment Specifications	
Operating / Storage Temperature	+10°C to +30°C
Operating / Storage Humidity	25% to 75% (no condensation)
Operating / Storage Atmospheric Pressure	700 – 1060 hPa
Operating / Storage Altitude	Maximum of 2000 metres above sea level
Sterilization	Autoclave – Rigid Laparoscope & Light Guide Cleaning & Disinfection – Camera Probe
Physical Specifications	
Trolley - Dimensions, Net Weight	H 1950 x W 765 x D 745, 102 Kg
Control Unit - Dimensions, Net Weight	H 160 x W 370 x D 374, 6.6 Kg
Light Unit - Dimensions, Net Weight	H 160 x W 370 x D 374, 5.3 Kg
Camera Probe - Dimensions, Net Weight	H 51.5 x W 62.5 x D 127 (without cable), 0.5 Kg

End of Life of the system

Essential performance of the system is assured for 5 years. After this period, it is recommended that you contact Irillic to plan further courses of action.

Do not attempt to dispose of the system without approval from Irillic, unless the method of disposal is in accordance with the local regulations governing disposal of electrical medical equipment.

Appendix II – Symbol Definitions

Packaging / Labeling

Main Product Label

Fig II.1: L.nm Product Label

Camera Control Unit Labels

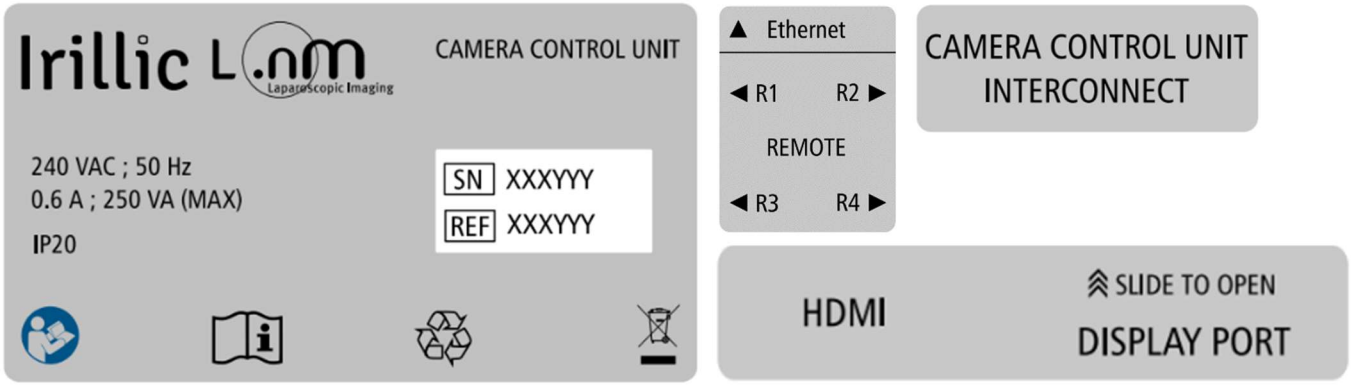


Fig II.2: CCU Labels

White Light Unit Labels

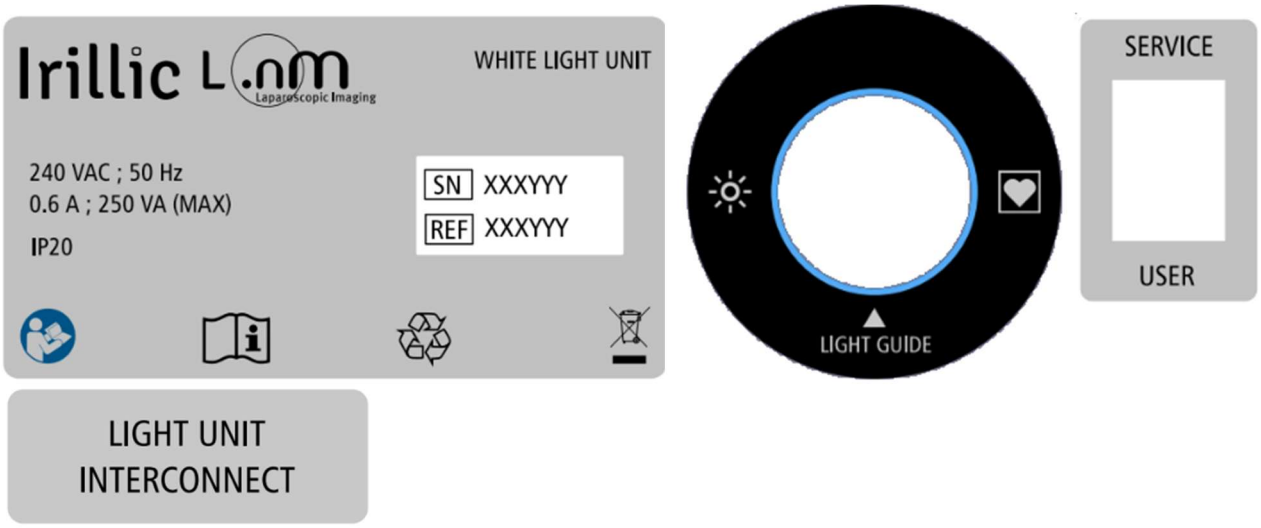
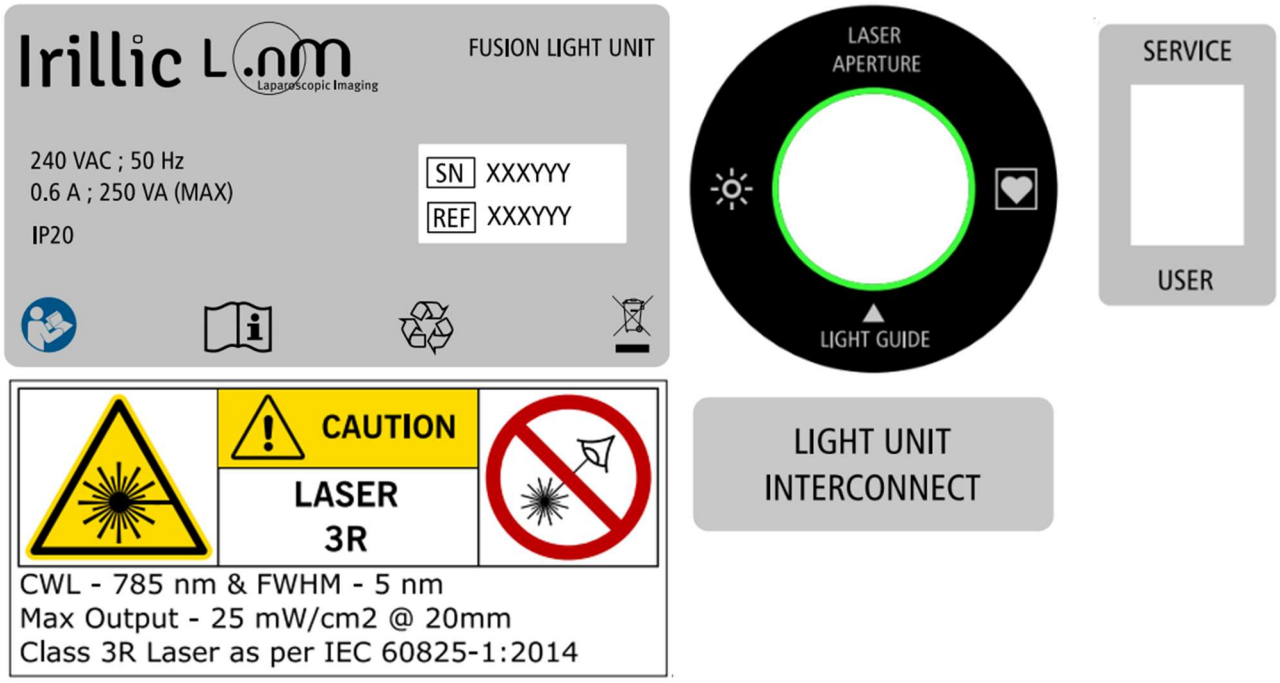
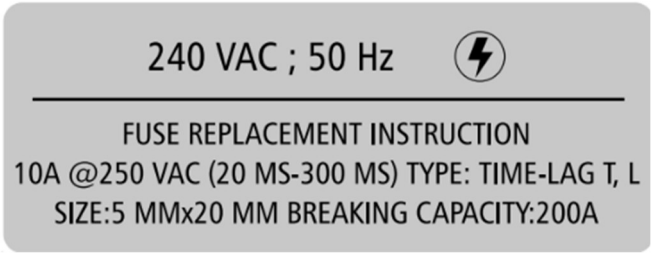


Fig II.3: WLU Labels

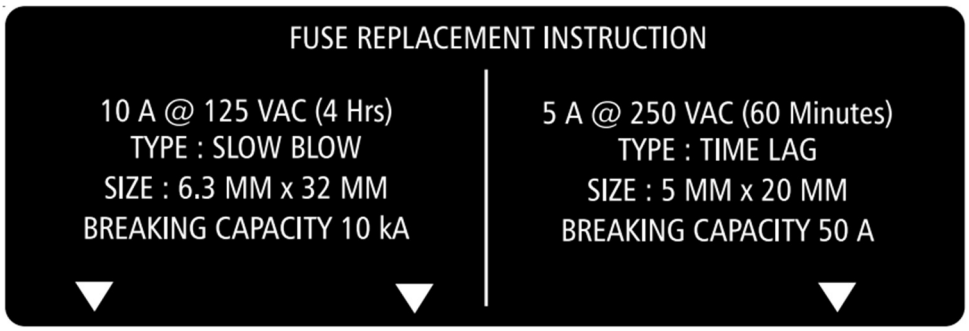
Fusion Light Unit Labels



Power Inlet Labels on CCU/WLU/FLU

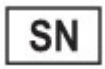


Trolley Labels



Symbol Definitions

Refer the below table for the details of the icons present in the various labels/parts of the device

	Serial Number		Indicates Fragile and handle with care
	Legal Manufacturer		Keep Dry
	Date of Manufacturer		Humidity Limits
	This product contains electrical waste or electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately.		Temperature Limits
	Protective Earth		Store in shade
	This product contains electrical waste or electronic equipment that is recyclable.		This side is up
	Read Operator's Manual		Equipotential Point.
	Read Operator's Manual before using the system		Non-Isolated power socket
	Isolated Power socket		Camera Probe Holder Max Weight Label
	USB Socket		Warning: Visible White Light Radiation
	Conductor Earth (Ground)		Warning: Infrared Light Radiation
	CF Type Applied Part		Output Indication
	Medical Device		Do NOT look at light source directly
	No Stepping On Surface		Ingress Protection Rating
	CCU / FLU / WLU Power Indicator in OFF State – Not In Use		CCU / FLU / WLU Power Indicator in ON State – Ready For Use (Green with Light)
	Warning: Pinch Hazard		

Appendix III – Electromagnetic Compatibility (EMC) Compliance

Guidance and manufacturer's declaration

Special precautions concerning electromagnetic compatibility (EMC) must be taken for all medical electrical equipment.

- All medical electrical equipment must be installed and put into service in accordance with the EMC information provided in this document.
- Portable and mobile RF communications equipment can affect the behavior of medical electrical equipment.

The Irillic L.nm Laparoscopic Imaging System and its accessories comply with all applicable and required standards for electromagnetic interference.

- It does not normally affect nearby equipment and devices.
- It is not normally affected by nearby equipment and devices.
- It is safe to operate it in the presence of high-frequency surgical equipment; however, it is good practice to avoid using the Irillic L.nm Laparoscopic Imaging System near other equipment.

Electromagnetic Emissions

The Irillic L.nm Laparoscopic Imaging System is intended for use in the electromagnetic environment specified below. The customer or user of the Irillic .nm Fluorescence Imaging System should ensure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR 11	Group 1	The Irillic L.nm Laparoscopic Imaging System uses RF energy only for its internal function; therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The Irillic L.nm Laparoscopic Imaging System is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC61000-3-2	Class A	
Voltage Fluctuations/ flicker emissions IEC61000-3-3	Complies	

Electromagnetic Immunity

The Irillic L.nm Laparoscopic Imaging System is intended for use in the electromagnetic environment specified below. The customer or user of the Irillic L.nm Laparoscopic Imaging System should ensure that it is used in such an environment.

Immunity Test	Test Level as per Standard	Compliance Level	Electromagnetic Environment - guidance
Electrostatic Discharge (ESD) IEC61000-4-2	± 8 kV contact ± 15 kV contact	± 8 kV contact ± 15 kV contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%

Electrical Fast Transients / Burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains Power Quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains Power Quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions, and voltage variations on power-supply input lines IEC 61000-4-11	>95% dip in 0.5 cycle >95% dip in 1 cycle 30% dip in 25 cycles >95% dip in 250 cycles	>95% dip in 0.5 cycle >95% dip in 1 cycle 30% dip in 25 cycles >95% dip in 250 cycles	AC power quality should be that of a typical commercial or hospital environment. If the intended use of the Irillic L.nm Laparoscopic Imaging System requires continued operation during power interruptions, it is recommended that the Irillic L.nm Laparoscopic Imaging System be powered from an uninterruptible power supply
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Tested Specifications for Immunity to RF Wireless Communications Equipment

Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Distance (m)**	**Immunity Test Level (V/m)**
385	380-390	TETRA 400	Pulse Modulation 18 Hz	0.3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation: 1 kHz sine	0.3	28
710	707-787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.3	9
745					
780					
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	0.3	28
870					
930					
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	0.3	28
1845					
1970					

2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.3	9
5500					
5785					
Note: 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 Irillic L.nm Laparoscopic Imaging System, including cables specified by the manufacturer, otherwise the device performance could degrade. Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.					
Irillic L.nm Laparoscopic Imaging System has been tested in accordance with IEC 60601-1-2 and is compliant with all the clauses of the standard and No Deviations were applied.					

Appendix IV – Accessory Ordering Information

S No	Description	Part Number
1	Light Guide	BOXF0002
2	Light Guide Connector – Light Unit End	BMXH0004
3	Light Guide Connector – Scope End	BMXH0005
4	Rigid Laparoscope – 4K 30deg 10mm	BOFF0001
5	Rigid Laparoscope – 4K 30deg 5mm	BOFH0001
6	Rigid Laparoscope – 4K ICG 30deg 10mm	BOFF0002
7	Rigid Laparoscope – 4K ICG 30deg 5mm	BOFH0002
8	2 TB Hard Disk Drive	BXXG0001

Document Revision History		
Rev. No.	**Date**	**Changes**
1.0	01 Jul 2023	Initial Release
2.0	04 Jan 2024	Updated as per changes to User Interface
3.0	12 Mar 2023	Major revision to include 4K ICG Variant description
4.0	27 May 2024	Updated as per changes required for regulatory compliance

CONTROLLED COPY

Irillic L.nm Operator's Manual					Prepared by	PSK
Product	Irillic L.nm	Doc No	ELM001-D-0005	Eff Date	Checked by	SK
Model	LF81	Rev No	4.0	27 May 2024	Approved by	SK

IRILLIC L.nm Laparoscopic Imaging

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Operator's Manual – Irillic L.nm LF81
Version 4.0