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 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 the presence of Safety information regarding potential minor or moderate injury to Patients or Users, or damage to the device.
 WARNING	Indicates the 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
IFU	Instructions For Use
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	Display Port is a digital display interface used to connect the Monitor Display to the CCU
ICG	Indo-cyanine Green
AC	Alternating Current
AMVI	Advanced Microvascular Imaging
BF	Body Floating
NIR	Near-Infrared
FWHM	Full Width at Half Maximum

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Chapter 1 - Introduction

Figure 1.1: Irillic L.nm Laparoscopic Imaging System

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 Head.

The Camera Head 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
- Multi-axis Colour Adjustment to personalise tissue differentiation
- Enhance the contrast of fine features and edges
- True 4K colour vision with ICG Fluorescence Imaging
- Multiple feed views for fluorescence imaging
- Quantitative assessment for fluorescence imaging
- NIR/ICG-based fluorescence imaging for real-time tissue perfusion assessment

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Chapter 2 - Prerequisites

To ensure the Irillic L.nm system delivers consistent results, it is important to have the following attributes/facilities:

Environment

- Air Conditioning is recommended for the room/site where the system will be used. System must always be maintained within the specified temperature and humidity range as below:

    a) Storage condition - Temperature range of 10 ^{O}C - 40 ^{O}C and the humidity range of 20% - 70% (non-condensing)
    b) Operating condition - Temperature range of 10 ^{O}C - 30 ^{O}C and the humidity range of 20% to 70% (non-condensing)

- The device is only to be used in professional healthcare environments like Hospitals, Medical Centres, Clinics, Operating Theatres, etc.

Power for uninterrupted operation of the system

- Ensure the availability of two 240V AC UPS-connected 3-pin power sockets. A clean, surge-protected power source (240V AC, 50Hz) is essential for maintaining system stability. The system has a power rating of 1000VA; therefore, it is recommended to use a UPS with a minimum capacity of 1KVA or higher.

- 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 updates will require internet connectivity using the ethernet port on the Camera Control Unit.

Authorised Personnel

- Only trained users are authorised 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) Preparing the Irillic L.nm System for use during surgical procedures, including sterilising the rigid laparoscope and the light guide, cleaning the Camera Head and the cable.

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

  c) Operate the Irillic L.nm System with familiarity of its commonly used functions and user interface.

  d) After usage, safely shut down and power off the Irillic L.nm System. Disconnect all components properly and store the device securely.

Irillic (or Irillic-authorised partners) will provide training on operating the Irillic L.nm system.

Storage and handling

- The Irillic L.nm System should not be exposed to chemicals and liquids at any time; users are required to follow the instructions listed in Chapter 10 - Reprocessing Instructions for cleaning purposes.
- When the system is in storage, ensure the Camera Head cable is carefully coiled. If possible, store the Camera Head separately in a secure area in accordance with the hospital's storage protocols.
- When the system is placed into storage after use, it is advisable to utilise the provided cable management hooks to neatly secure and organise power cable to prevent damage.
- Ensure that the system is stored in an area where there is no direct sunlight and is within the acceptable temperature (10^{O}C - 40^{O}C) and humidity range (20% - 70% 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, process, and display anatomical image information on the monitor mounted to the trolley for surgical visualisation.

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

If any unavoidable EMI/EMC disruption takes place during device operation, it might result in flickering or interruption of the live video feed or the touchscreen displays. In such events, users are recommended to Power OFF and then Restart the device. If the problem persists, please contact Irillic for further action. Refer to Chapter 9 - Maintenance for information regarding testing processes and frequencies to ensure the Basic Safety parameters of the device are being met.

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Chapter 3 - Intended Use

The Irillic L.nm Fluorescence 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 images from the Irillic L.nm System only.

Indications of use

Irillic L.nm Fluorescence Imaging System is indicated for the illumination and visualisation 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 hysteroscopy, 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 are imposed by the device, except those associated with injectable Indocyanine Green (ICG), which is contraindicated in patients with known ICG or iodine hypersensitivity.

Contraindications

There are no known contraindications associated with the use of the Irillic L.nm Fluorescence Imaging System itself. Contraindications related to administered agents, including Indocyanine Green (ICG), must be observed in accordance with their respective labelling.

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

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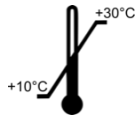
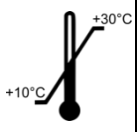
Chapter 4 - Safety Information and Precautions

⚠ **CAUTION**	
	1. Personnel operating the Irillic L.nm Fluorescence Imaging System should be familiar with the correct procedures for operating the system.
	2. Information obtained through the use of the system should be used in combination with other clinically relevant information when planning interventions.
	3. Before using the system, verify that the mobile cartwheels are in a locked position.
	4. When moving the mobile cart, use only the handles provided.
	5. The system can be used only within the specified operating temperature range (10 °C - 30 °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 imaging or illumination functionality.
	7. In the event of any damage to any optical components including the Fusion Light Unit or White Light Unit, Light Guide, Rigid Laparoscope, 4K-White or 4K-ICG Camera Head, contact Irillic immediately for maintenance and performance verification before using the system.
	8. Repairs and service activities shall be performed only by Irillic-authorised personnel. Irillic will not have responsibility of product liability or warranty for devices repaired or serviced by third-party service organisations.
	9. Avoid operating the system in areas with strong electrical or magnetic fields or close to high-frequency devices. Doing so may cause reduced performance or even system malfunction.
	10. To minimize interference from high-frequency electrosurgical units (ESUs), avoid using the same power outlet for both devices and maintain as much distance as possible between the equipment and the ESU.
	11. If the monitor image appears blurred, it may indicate that the tip of the laparoscope has become contaminated with blood, mucus, or tissue fragments. The laparoscope should be withdrawn carefully from the patient so the tip can be cleaned, allowing proper illumination and ensuring safe examination conditions

WARNING	
General	1. To avoid risk of electric shock, this equipment shall only be connected to a supply main with protective earth.
	2. Do not attempt any modification of the system unless authorised. Unauthorised 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.
	4. Do not attempt to repair or open the system; servicing is to be done by authorised personnel only.
	5. To avoid biocompatibility issues, the Camera Head is recommended to be used only in conjunction with surgical gloves.

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 that 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-White Camera Head and 4K-ICG Camera Head	1. The Camera Head (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 authorised personnel only
	3. The Camera Head may reach temperatures up to 48 °C during long use, especially when it is not being held continuously. No special precautions are required for its handling.
	4. To ensure optimal performance, it is recommended that only Irillic-provided rigid laparoscope and light guide accessories be

	used. Using alternate accessories may lead to deterioration in essential performance.
	5. Always clean the Camera Head before use as per the instruction given in Chapter 10 - Cleaning Instructions
	6. Ensure adequate care is taken when handling the Camera Head. Always store the Camera Head in the provided slot on the Trolley after use to prevent accidental damage.
	7. Always treat the Camera Head with care. The Camera Head contains sensitive parts that are precisely aligned and may suffer damage if dropped or mistreated.
	8. After use, it is advisable to secure the Camera Head with the provided dust cap before placing the system into storage to protect it from dust and debris.
	9. Camera Probe connector includes a mechanical orientation feature (locating pin and corresponding locating hole) to ensure correct alignment. Do not force insertion of the camera probe. Misaligned or forced connection may damage the camera connector. Always align the probe correctly before insertion.
	10. If the Camera Head is dropped or subjected to mechanical impact, discontinue use and inform Irillic or authorised service personnel for inspection and evaluation before further use.
	11. The camera head is non-autoclavable and must not be exposed to steam sterilization or autoclave cycles. Clean and disinfect only using approved wipe-down methods specified by the Irillic.

⚠ WARNING	
ICG (Indo Cyanine Green)	1. ICG vials are for single use only. Any prepared solution remaining after each procedure must be discarded. Do not store or reuse leftover solution. 
	2. ICG spills on gloves (when injecting ICG or cleaning injection site) can lead to erroneous results; if this occurs, replace gloves immediately.
	3. Please refer to the information provided by ICG supplier for all details such as Directions of Use, Description, Comp 4. osition, Indications, contra-indications, interaction with other drugs, recommended time period of usage, warnings & precautions, toxicity & side-effects, disposal and storage considerations.

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 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 an un-locked position and the Camera Head 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 an 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.
	6. To minimise the risk of vibrational damage, the device is equipped with medical-grade caster wheels. Do not move the device over excessively rough surfaces or obstacles exceeding 5 cm in height.
	7. Always place the power cable onto the trolley's rear cable hooks before moving the cart. Failure to do so may strain or damage the power cable.

WARNING	
Camera Control Unit	1. When connecting the Camera Head to the Camera Control Unit, verify that the connecting cable is fastened securely by pressing the connector until it clicks in place.
	2. Always turn off power before connecting or disconnecting cable(s) to the Camera Control Unit.
	3. Verify Laser Light Source is on in ICG Imaging Mode before clinical use.
	4. When switching to ICG Imaging Mode, verify ICG Imaging Mode initialisation is complete before clinical use.
	5. Ensure the interconnect cable lock on the Camera Control Unit is fully engaged to prevent loosening or unintentional disconnection during operation.
	6. Ensure that any External SSD is connected only to the designated USB storage ports and not the Interconnect port USB (female) on 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 White Light Unit by pushing the long connector end firmly into the Light Guide Port on the White Light Unit 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 White Light Unit leading to loss of illumination during surgical procedures
	5. Do not remove the connection between the Rigid Laparoscope and the Light Guide while the White Light Unit is in operation. Always switch Off the Light Source or place the White Light Unit in Standby mode before disconnecting the Light Guide from the Rigid Laparoscope .
	6. Always ensure to push the Slide Lock to the open position before inserting or removing the Light Guide from the Light Port of the White Light Unit.
	7. Do not attempt to repair or open the White Light Unit; servicing is to be carried out only by authorised Irillic personnel only.
	8. The White Light Unit Light Port, Light Guide connectors, and Rigid Laparoscope tip may all be heated to temperatures above 40^{O}C during operation due to the significant amount of Light Energy emitted. Always ensure to take sufficient care when handling these parts during operation.
	9. 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.
	10. Ensure the interconnect cable lock on the White Light Unit is fully engaged to prevent loosening or unintentional disconnection during operation.
	11. Ensure the interconnect cable lock on the White Light Unit is fully engaged prevent loosening or unintentional disconnection during operation.

WARNING	
Fusion Light Unit	1. The device emits high-intensity White Light radiation. Always avoid any direct eye exposure. 
	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 Fusion Light Unit by pushing the long connector end firmly into the Light Guide Port on the Fusion Light Unit 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 Fusion Light Unit leading to loss of illumination during surgical procedures
	7. Do not remove the connection between the Rigid Laparoscope and the Light Guide while the Fusion Light Unit is in operation. Always switch Off the Light Source or place the Fusion Light Unit in Standby mode 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 Fusion Light Unit.
	9. Do not attempt to repair or open the Fusion Light Unit; servicing is to be carried out only by authorised Irillic personnel only.
	10. The Fusion Light Unit Light Port, Light Guide connectors, and Rigid Laparoscope tip may all be heated to temperatures above $40^{O}C$ during operation due to the 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.
	12. Ensure the interconnect cable lock on the Fusion Light Unit is fully engaged prevent loosening or unintentional disconnection during operation.

WARNING	
Rigid Laparoscope & Light Guide	1. Always sterilise the Rigid Laparoscope and Light Guide before use either using an Autoclave or other means of approved high-temperature sterilisation methods to avoid risk of infection to the patient or loss of sterility to the operator. (Refer to the respective User Manual for a complete description of the approved sterilisation, cleaning, & disinfection methods)
	2. The Rigid Laparoscope is intended to come into invasive contact with the Patient and care is to be taken to ensure safety. Refer to the included User Manual for the Rigid Laparoscope for more safety-related information.
	3. The Rigid Laparoscope is BF-rated applied part that come in contact with the patient body. 
	4. While storing the Light Guide after use, cover the two ends with the plastic end caps provided, and ensure to not roll or bend the Light Guide tightly as this may damage the optical fibres inside and reduce the performance.
	5. 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 the performance of the device.
	6. 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	
Connections	1. Connecting the trolley to a power supply other than a surge-protected 240 V AC, 50 Hz source may result in equipment damage, malfunction, or unsafe operation.
	2. Ensure the monitor is properly connected to the CCU before powering on the system. In the event that the monitor is improperly connected, the CCU shall emit five audible beeps to alert the user of a monitor connection failure.
	3. Ensure all other connection are secure. Refer to Chapter 6 - Setup and Connections.
	4. Ensure the interconnect cable is securely connected to the Light Unit and the CCU, and that the interconnect lock knobs are tightened to prevent loose or sudden disconnections.
	5. 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 the performance of the device.
	6. 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.
	7. Keep the ESU cables positioned as far away from the system as possible. If they are too close, the ESU's high-frequency output can interfere with the system's performance.

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Chapter 5 - System Overview

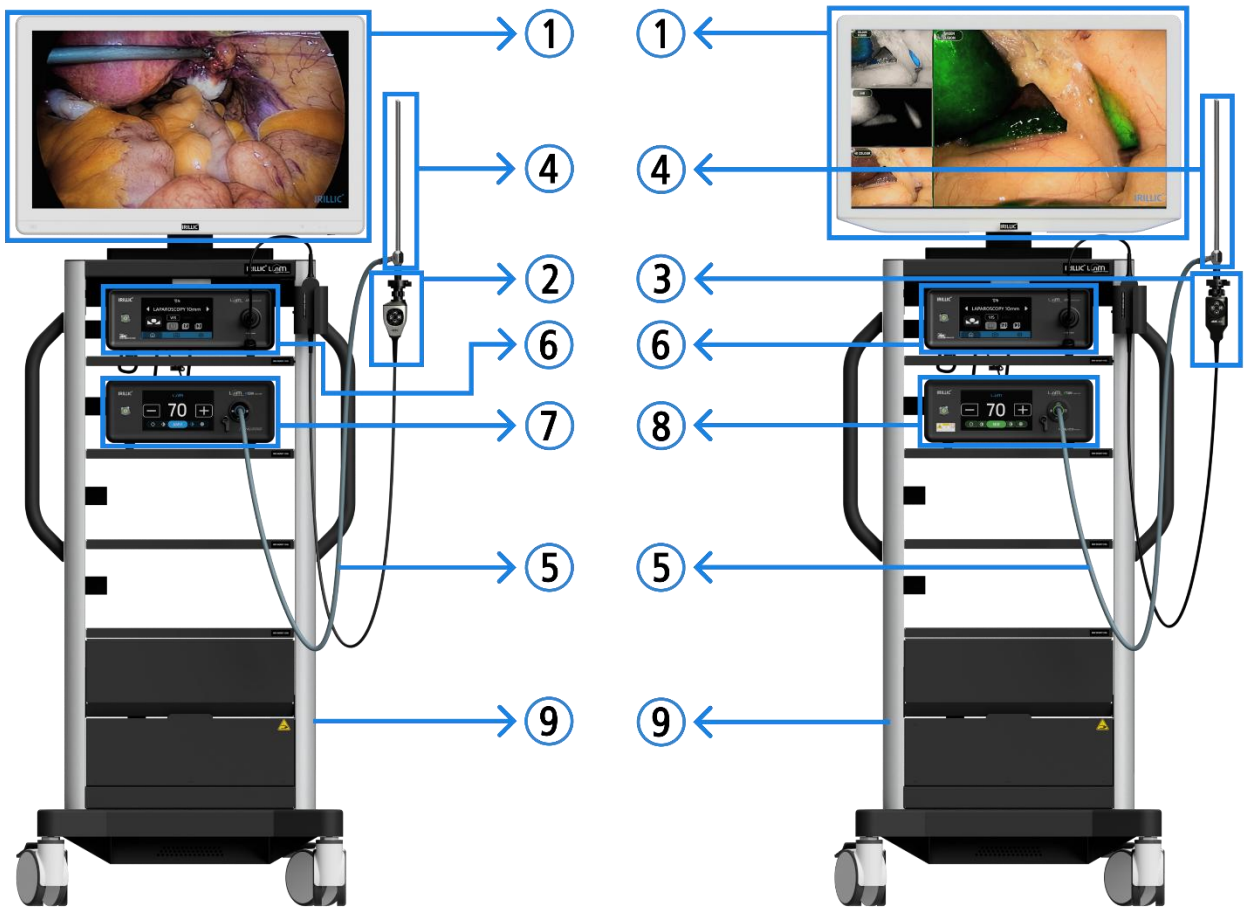


Fig 5.1: Irillic L.nm system comes in two variants - the 4K-White Light system (left) and the 4K-ICG system (right)

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

2. The 4K-White Camera Head 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.

3. The 4K-ICG Camera Head 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.

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

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

6. The Camera Control Unit (CCU) is used to connect to the Camera Head 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.

7. The White Light Unit 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 White Light Unit.

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

9. The Trolley is a mobile cart and consists of 2 trays which contain the CCU & Light Unit, 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 in operation, ensure that the wheels are secured in the brake-locked position and that the monitor arm adjustment knob is tightened to the required position to prevent unintended monitor movement.

Camera Control Unit (CCU)

The Camera Control Unit is the main processing center of the Irillic L.nm 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. **Touch Display** – Where the majority of the User Interaction takes place, allowing for selection of Imaging Profiles, Imaging Modes, Recording, Zoom, etc.
4. **Camera Head Port** for connecting the Camera Head, with a locating hole to ensure correct alignment during insertion.

Power Button:

- When the system is in power off condition, pressing it once will power on the system.
- When the system is in operating condition, pressing it once initiates a 10-second shutdown sequence and displays a confirmation prompt on the monitor. Press the power button again within 10 seconds to cancel; otherwise, the system will automatically power off. When the system is in operating condition, 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 the system is not yet switched on, the Power indicator will remain off.
- Once the system is powered ON, the power button indicator turns green.

CCU Home screen Overview

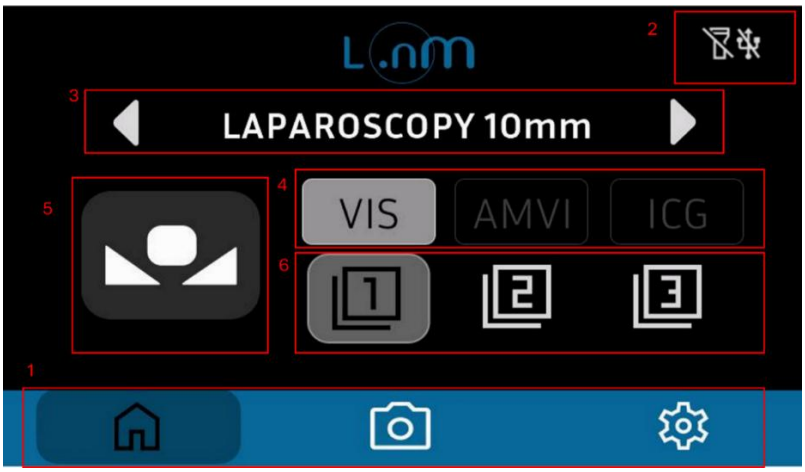
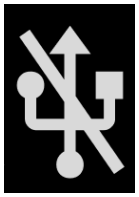


Fig 5.3: CCU Home Page - 4K ICG Configuration
(Note – in the 4K White Light Variant the ICG Imaging Mode will remain disabled)

1. **Navigation bar:** The Bar at the bottom of the Touch Display allows users to switch between different pages. The pages are **Home, Camera** and **Settings**. Detailed descriptions of every separate page are provided below.
2. **Notification bar:** The section of Icons on the top centre of the Touch Display provides users with quick notification of the status of different processes and any warnings or error states as described in the below sections of this chapter.

- **Light Unit Disconnected Warning -** This symbol indicates the Light Unit is not connected to the CCU. If the White Light Unit and 4K White Camera Head is connected to the CCU., the icon shall disappear and the AMVI Imaging Mode will be available in the Imaging Mode Widget. If the Fusion Light Unit and 4K ICG Camera Head is connected to the CCU, the icon shall disappear and the AMVI and ICG Imaging Mode will be available in the Imaging Mode Widget.



- **USB Storage Device Not Connected Notification -** This symbol indicates that no valid storage device is not connected to the CCU. Recording and Snapshot features shall remain disabled. Upon initiation of device refresh, the system shall check if a valid storage device is connected to the CCU. If a valid storage device is detected, the notification icon shall disappear. Refer to section Recording in Chapter 7 for more information on storage devices supported by the Irillic L.nm System.

Camera Control Unit - Rear Panel

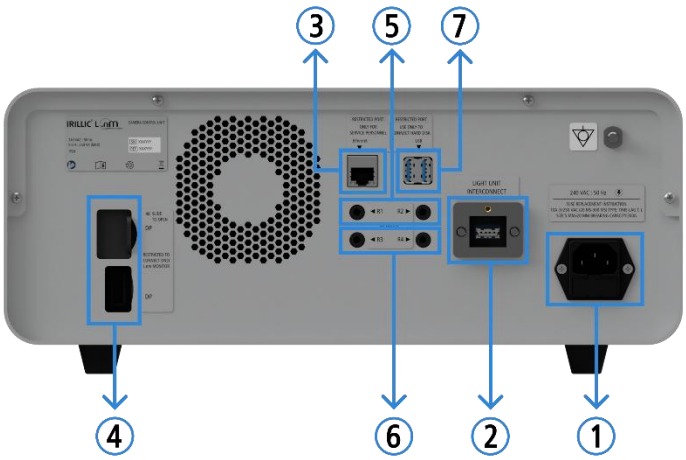


Fig 5.4: Camera Control Unit Rear Panel

1. **240V 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, with interconnect cable lock mount.
3. **RJ-45 Ethernet Port** for network connection via LAN
4. **2 Display Ports** for connection to Display Monitor.
5. **R1** and **R2** sockets for Paddle Control
6. **R3** and **R4** socket for Recorder control
7. **Restricted USB ports** for connecting hard disk and keyboard when necessary

- **USB & Ethernet Ports provided are only for use for Data Transfer activities by authorised personnel.**
- **Do NOT use the USB & Ethernet Ports for any other function, unless authorised 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 and marked with the symbol seen here. These connection points can be used to connect to a potential equalisation conductor. The resulting medical electrical system shall follow all applicable IEC 60601-1 requirements.

White Light Unit (WLU)

White Light Unit Front Panel

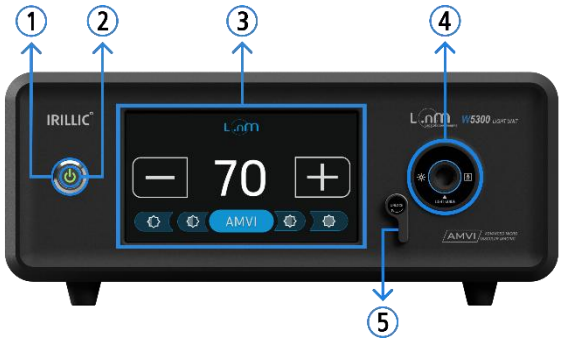


Fig 5.5: White Light Unit Front Panel

1. **Power Button** - To Power on the unit
2. **Power Indicator** - The power symbol in the button which lights up green when ON.
3. **Touch Display** - To change the light intensity.
4. **Light Guide Port** - To connect the light guide.
5. **Safety Lever** to be used to allow for safe connection and disconnection of the Light Guide.

Power Button:

- When the system is in power off condition, pressing it once will power on the system.
- When the system is in operating condition, pressing it once will power down the system.

Power Indicator

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

White Light Unit Rear Panel

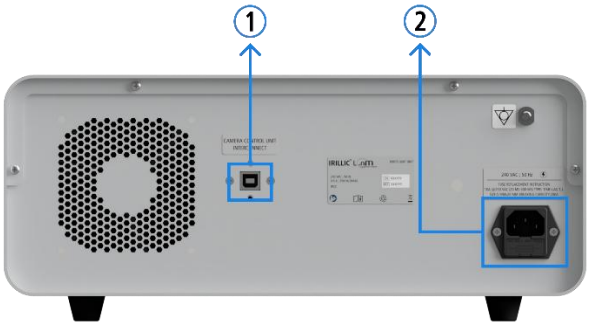


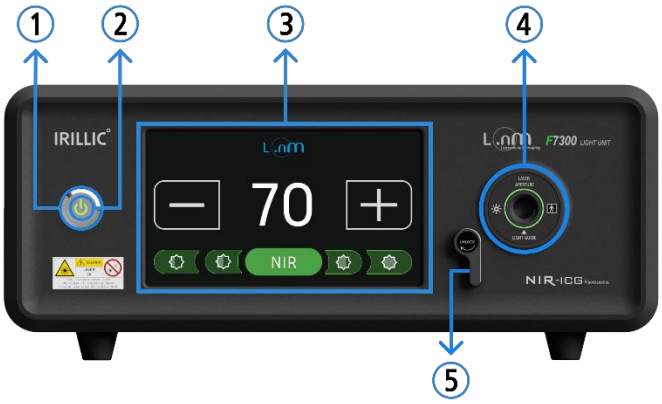
Fig 5.6: White light unit Rear Panel view

1. **Camera Control Unit Interconnect Port** for the communication between the White Light Unit and the Camera Control Unit, with interconnect cable lock mount.
2. **240V AC Power Receptacle** for connection to Input Power Supply. A fuse holder (with a second spare fuse) is located below the receptacle.

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

Fusion Light Unit (FLU)

Fusion Light Unit Front Panel



1. **Power Button**
2. **Power Button Indicator**
3. **Touch Display** for changing the White Light & 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 5.7: Fusion Light Unit Front Panel view

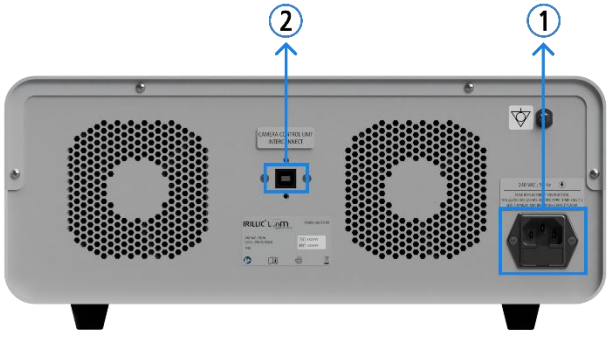
Power Button:

- When the system is currently powered off, pressing it once will power on the light unit.
- When the system is currently operating, pressing it once will power down the light unit.

Power Indicator

- When AC power is being supplied to the unit and the 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. **240V 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 White Light Unit and Camera Control Unit.

Fig 5.8: Fusion Light Unit Rear Panel view

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

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

4K-White Camera Head

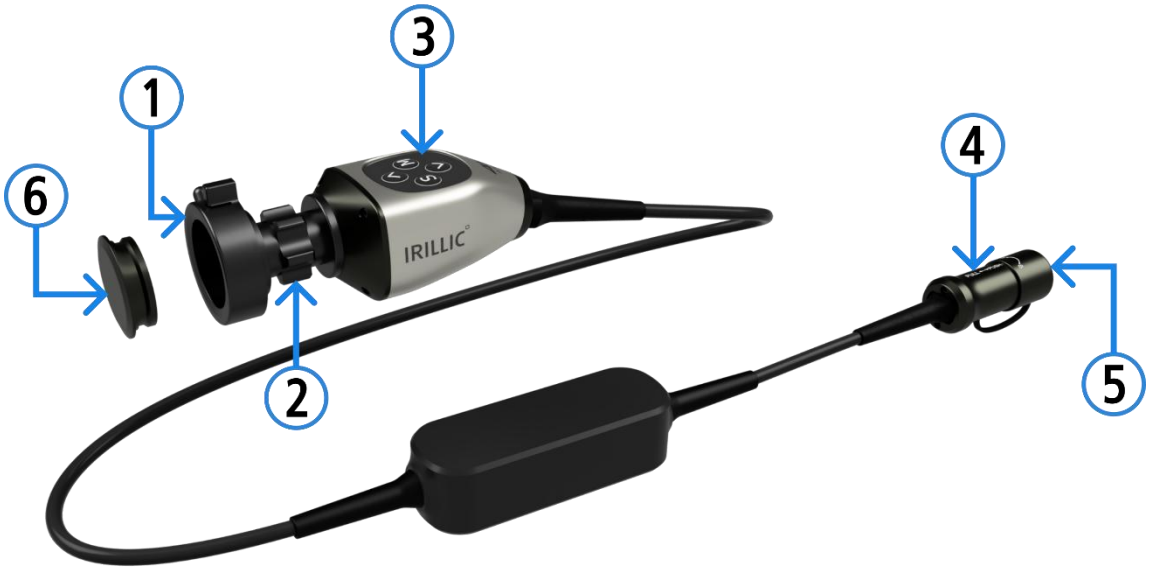


Fig 5.9: 4K-White Camera Head

1. **Camera Coupler –** To hold the scope in place
2. **Focus Ring –** To control the focus distance
3. **Camera Head button Panel –** To interact with the system
4. **Camera Head connector** – To interface with the Camera Control Unit via an integrated cable with an orientation pin to ensure correct alignment during connection.
5. **Camera Head Cap –** To close the connector when it is not in use
6. **Camera Dust Cap –** To protect the lens from dust, dirt and moisture when not in use.

4K-ICG Camera Head

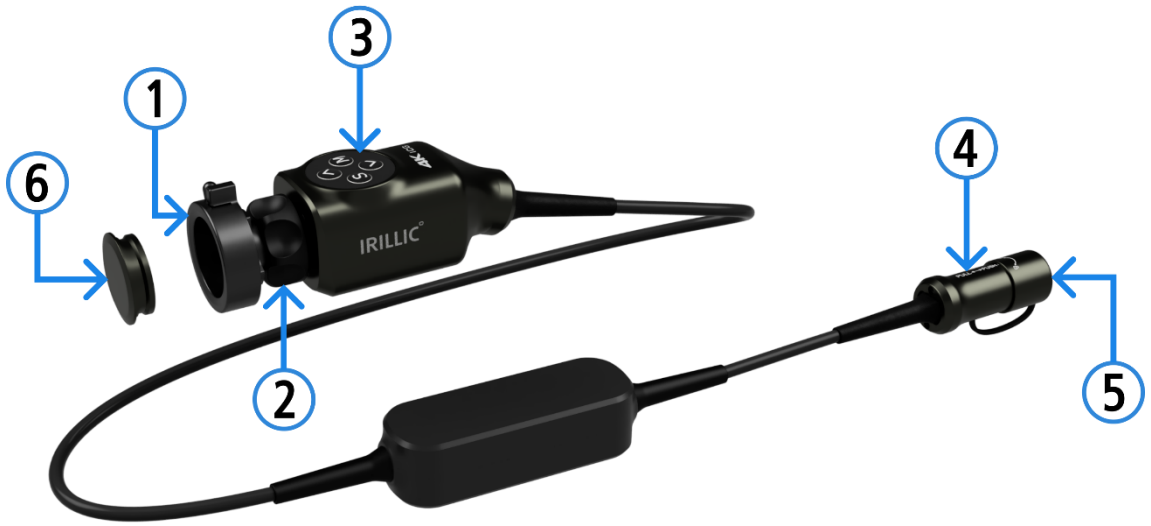


Fig 5.10 4K-NIR Camera Head

1. **Camera Coupler –** To hold the scope in place
2. **Focus Ring –** To control the focus distance
3. **Camera Head button Panel –** To interact with the system
4. **Camera Head connector –** To interface with the Camera Control Unit via an integrated cable with an orientation pin to ensure correct alignment during connection.
5. **Camera Head Cap –** To close the connector when it is not in use
6. **Camera Dust Cap –** To protect the lens from dust, dirt and moisture when not in use.

Camera Head Button Panel

Fig 5.11: Camera Head Button Panel

SET (S) button has two functions:

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

MODE (M) button has two functions:

- **Short Press:** Toggles between the VIS Imaging Mode and ICG Imaging Mode.
- **Long Press:** Opens the Menu in the Display Monitor.

UP (^) is used for moving up in the menu option. UP button also has a context specific purpose depending on the current Imaging Mode and Imaging View. Refer to the operating modes section for more information.

In the 4K White Light Variant, the UP button is mapped to the following functions:

- **Short Press:** Moves the selection upward when navigating the application menu. In **VIS** and **AMVI** modes, it adjusts the **Auto Exposure** setting.
- **Long Press:** Enables or disables **True EN+** for the selected imaging profile when in **VIS** and **AMVI** modes.

In the 4K ICG Variant, the UP button is mapped for the following functions:

- **Short Press:** Moves the selection upward when navigating the application menu. In **ICG - Multiview (Default Profile)** and **ICG - PIP (ICG Profile #2)** modes, it adjusts the **Auto Exposure** setting. In **ICG Profile #1** and **ICG Profile #3**, it sets the **Contour** level.

- **Long Press:** Cycles through the **ICG profile views** when in **ICG mode**. Otherwise, it enables **True EN+** in **VIS** and **AMVI** imaging profiles.

DOWN (v) is used for moving down in the menu option. DOWN button also has a context specific purpose depending on the current Imaging Mode and Imaging View. Refer to the operating modes section for more information.

In the 4K White Light Variant, the DOWN button is mapped for the following functions:

- **Short Press:** When navigating the application menu, the control moves the selection downward. In **VIS** and **AMVI** modes, it adjusts the **Zoom**.

In the 4K ICG Variant, the DOWN button is mapped for the following functions:

- **Short Press:** Moves the selection upward when navigating the application menu. Otherwise, it adjusts the **Sensitivity** control in all **ICG imaging profiles**.

4K Medical Grade Monitor

The Irillic L.nm system is available with two Medical Grade Display options:

32" Medical Grade Monitor

The Monitor along with the available ports in the back are shown in fig. 5.13a, 5.14a and 5.15a

Fig 5.12a: Monitor Front view

Fig 5.13a: Monitor Back view

Fig 5.14a: 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

32" Premium Medical Grade Monitor

The Premium Monitor along with the available ports in the back are shown in fig. 5.13b, 5.14b and 5.15b

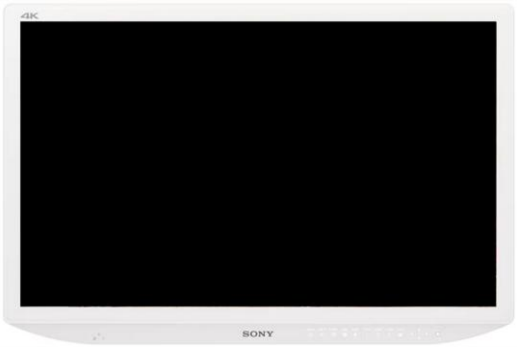


Fig 5.12b: Monitor Front

Fig 5.13b: Monitor Back

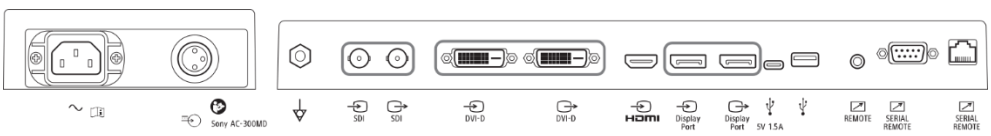


Fig 5.14b: Monitor connections in the back

- **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

Display Pan and Tilt Adjustment Option

The display can be tilted 15˚ up and down. It can also be panned 50˚ sideways as shown in fig. 5.16.

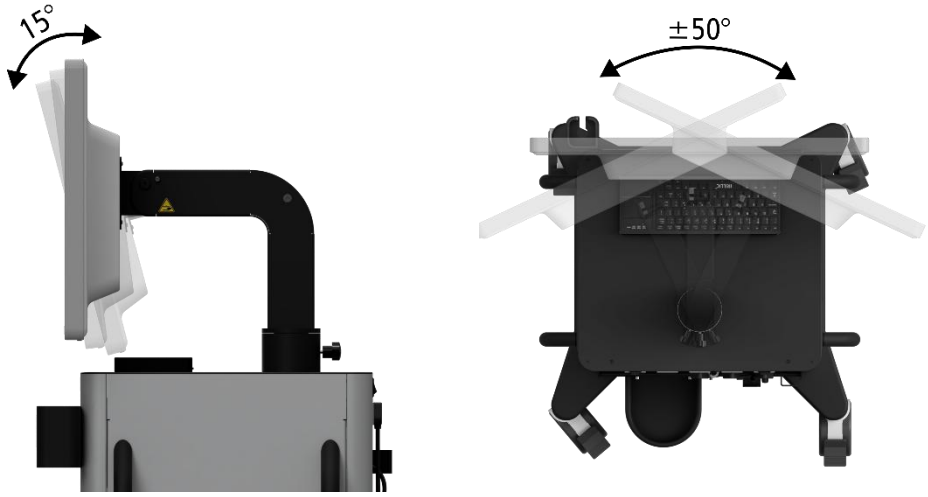
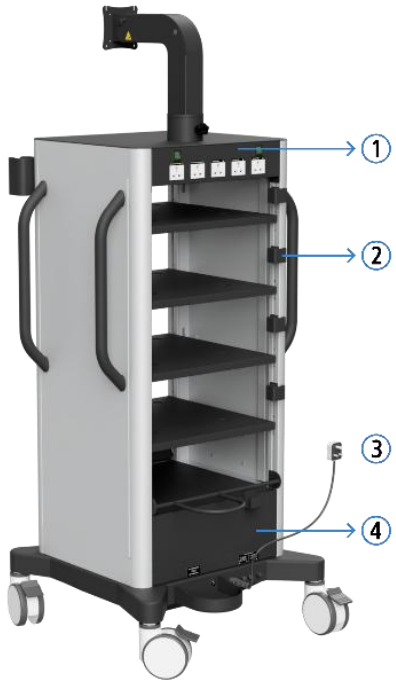


Fig 5.15: Display Tilt (left) and Pan (Right) Adjustment

Trolley

1. **Display Mount**
2. **Shelves** to keep the Light Unit and the Camera Control Unit, Electrosurgical Unit (Not supplied by Irillic) and Insufflator can also be kept in the rack.
3. **Handle** to move around the Trolley within the hospital
4. **Drawer** to keep drapes and accessories
5. **Trolley Wheels** with brake locks
6. **Camera Head Holder**

Fig 5.16: Trolley Front View



1. **5 Power sockets** (3 are isolated 2 are normal) to connect the Light Unit and the Camera 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 5.17: Trolley Rear View

Camera Head Holder

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

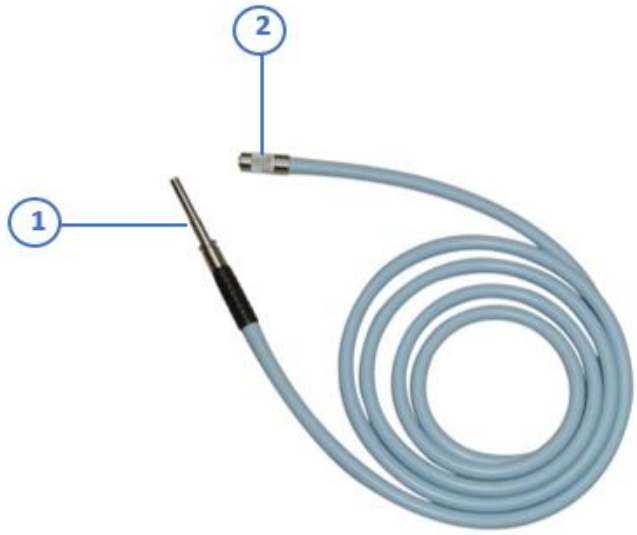
Option 1: Camera Head when stored without rigid laparoscope.

Option 2: Camera Head when stored along with the rigid laparoscope.

Fig 5.18: Usage of Camera Head Holder

- **Always ensure that the Camera Head is stored in the provided Camera Head Holder after each use of the device.**
- **Ensure that the Rigid Laparoscope is carefully inserted into the provided slot in the Camera Head Holder.**
- **Camera Head Holder can take a maximum load of 1 Kg. Only use the Holder for the Camera Head with or without Rigid Laparoscope.**
- **Secure and route the trolley power cable using the provided rear hooks to prevent strain or entanglement.**

Light Guide



1. The Light Unit Connector end goes into the White Light Unit or the Fusion Light Unit through the Light Guide port.
2. The Rigid Laparoscope end is connected to the Rigid Laparoscope for transmitting illumination from the Light Unit to the Laparoscope.

Fig 5.19: Light guide

Rigid Laparoscope

The Rigid Laparoscope attaches to the White Light Unit or Fusion Light Unit via the light guide and the Camera Head via the Camera Head Coupler (part of the Camera Head). Together this enables the illumination and visualisation of the internal anatomy of the patient.

Fig 5.20: 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 sterilise the Rigid Laparoscope & Light Guide before use either using an Autoclave or other means of approved sterilisation**
- **Always use Irillic accessories only 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**
- **Always ensure after attaching the Camera Head to the Rigid Laparoscope, pull back the coupler lock to engage the scope.**

Removable Storage Device

A 2 TB capacity removable Solid State Storage Device is provided along with the system to allow users to record video and image data as seen on the screen via the live real-time video feed.

Supported format is NTFS and FAT32 which is approved by Irillic.

- **Sudden loss of power can lead to partial loss of recorded data.**
- **Always use an Irillic provided removable Storage Device to ensure optimal performance during recording.**
- **Do NOT disconnect the Removable Storage Device when recording is in progress. This may result in partial or total loss of previously captured data.**
- **Ensure that the removable storage device is formatted and not corrupted which would otherwise lead to loss of data**
- **Always refresh and verify the Removable Storage Device status via the Recording Control Unit to ensure the SSD is properly mounted before use.**

List of Cables

1.	Trolley Power Cable (Qty: 1)
2.	Display Power Cable (Qty: 1)
3.	Camera Control Unit Power Cable (Qty: 1)
4.	White Light Unit or Fusion Light Unit Power Cable (Qty: 1)
5.	Display Port Cable (Qty: 1)
6.	Light Unit-CCU Interconnect Cable (Qty: 1)

Table 5.1: List of Cables

Keyboard

- A wired keyboard is provided for both in-person and remote troubleshooting when suggested by the service personnel.
- Connect the keyboard to one of the restricted USB ports on the CCU back panel whenever required during troubleshooting.
- Disconnect the keyboard and store it in the storage drawer after troubleshooting.

Fig 5.21: Wired Keyboard

6

Chapter 6 - Setup and Connections

Connections During Installation

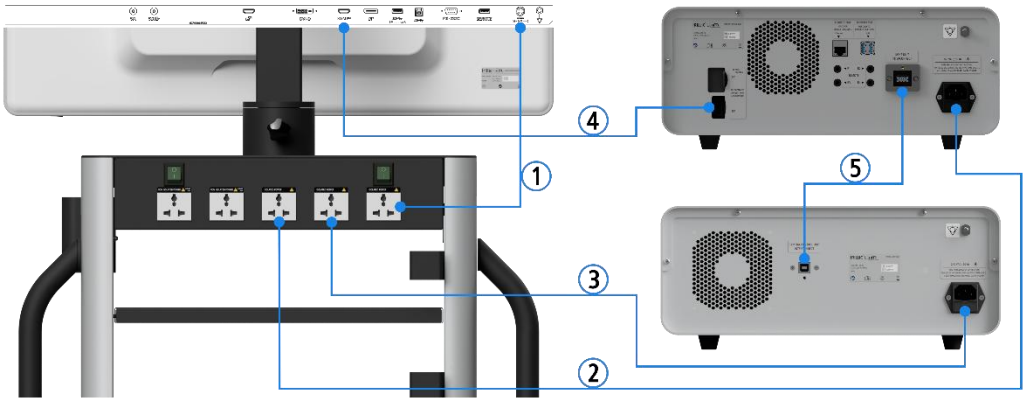


Fig 6.1a: Main system connections – with 32" Medical Grade Monitor

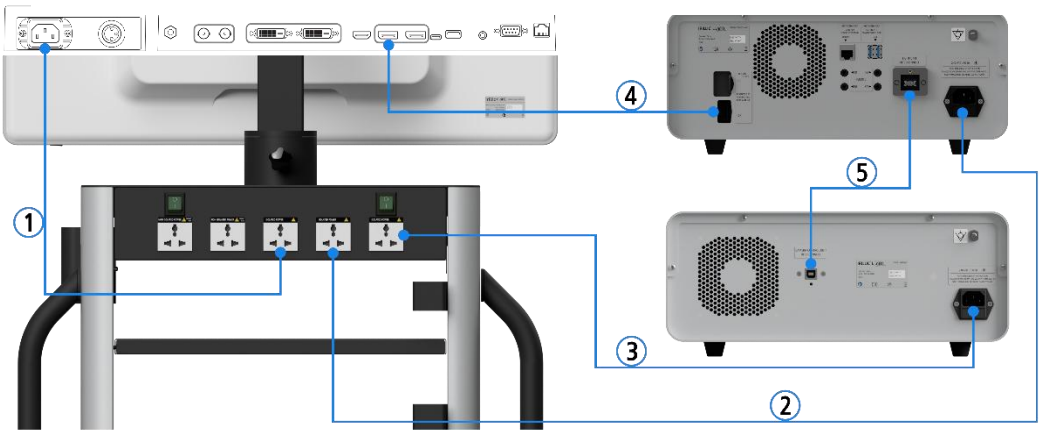


Fig 6.1b: Main system connections – with 32" Premium Medical Grade Monitor

1. Connect the monitor power supply to the Isolated Power socket in the Trolley
2. Connect the White Light Unit or Fusion Light Unit 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 Display Port cable from CCU to Monitor

5. Connect the Interconnect cable from CCU to White Light Unit or Fusion Light Unit and fasten it securely using the interconnect locks at both ends.

- **Unpacking and installation should only be carried out by authorised 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.**

Once these connections are established, they should remain intact and should only be disconnected by Irillic service personnel or authorised support staff during maintenance activities.

Connections during normal usage

1. Connect the Camera Head to the CCU by removing the Connector Cap, align the locating pin with the locating hole, and insert the Camera Head connector into the CCU socket following the PUSH-PULL indication until fully seated.

Fig 6.2: Camera Head to CCU Connection

2. Connect the Light Guide to the White Light Unit or Fusion Light Unit by rotating the Unlock Lever and inserting the Light Guide connector (light source end) into the Light Port until an audible click is heard. Gently tug the Light Guide to confirm it is securely locked.

3. If the Light Guide is improperly connected or slightly disconnected, the White Light Unit output drops to 0, and for the Fusion Light Unit, both visible and IR light outputs drop to 0.

Fig 6.3: Light Guide to Light Unit Connection

4. The Rigid Laparoscope is connected to the Camera Head, and the coupler lock is pulled back to engage and secure the scope.

Fig 6.4: Rigid Laparoscope to Camera Head attachment

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

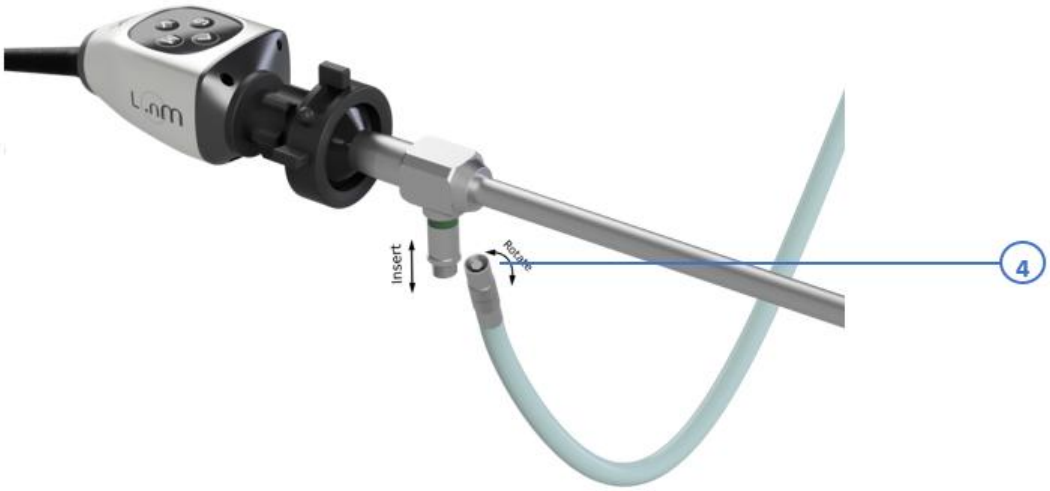


Fig 6.5: Light Guide to Rigid Laparoscope connection

- **Always go to Standby mode or Power OFF the light source before connecting or disconnecting the Light Guide from the Rigid Laparoscope.**
- **The Camera Port is not a standard USB Port. Do not connect a USB device to this port.**

- **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 which may cause mild burn injury or adversely affect vision if exposed to eye**

- **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 a substantial risk of Burn Injury or Fire Hazard due to the excessive heat generated by the high-intensity illumination.**

6. Connect the Trolley Power Supply Plug to a nearby UPS-Backed AC Power Inlet only.

Fig 6.6: Connecting Trolley Power Supply Plug to an AC Power Inlet

Use UPS powered 230V AC sockets to allow un-interrupted operation of the system and avoid potential data loss.

7. Connect the Removable 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

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 System for use

1. Move the system using the Trolley Handles to the Operating Theatre (OT). Ensure that any wires or raised partitions on the floor are navigated with care and precision.
2. Ensure all sterile components (Camera Head, Rigid Laparoscope, Light Guide) are properly sterilised or covered before handling or connecting to the system.
3. Position the system next to the OT table such that the system will be on the opposite side of the surgeons performing the surgery.
4. Adjust the Display orientation for both pan and tilt to ensure the surgeons have a clear, unobstructed view.
5. Below is a demonstrative depiction of a possible configuration of the placement of the device.

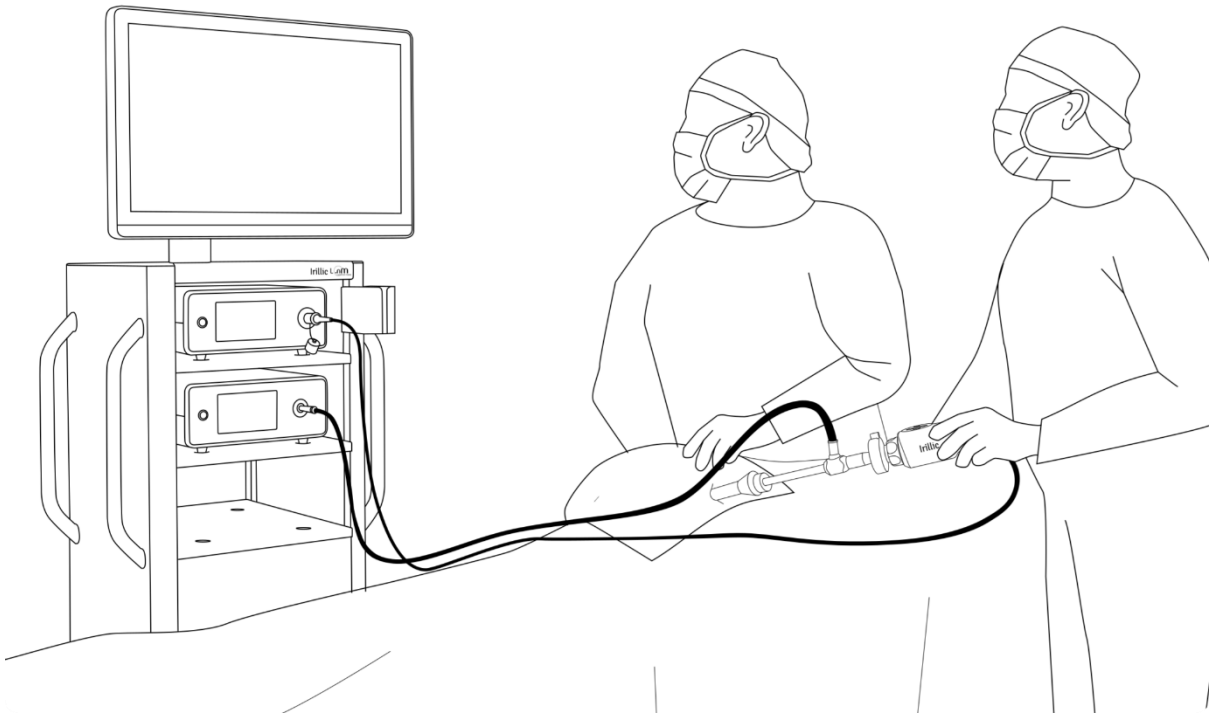


Fig 6.8: An example of system placement in the operating theatre during surgery

6. 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

Chapter 7 - Operating the Irillic L.nm system

System Interface and Workflow Overview

This section provides an overview and details of the workflow, system interface and features of the Irillic L.nm Fluorescence Imaging System. It is divided into sections covering different Touch Display Interface on the CCU / White Light Unit / Fusion Light Unit and the Application User Interface on the Main Display. The operating workflow of the Irillic L.nm System follows:

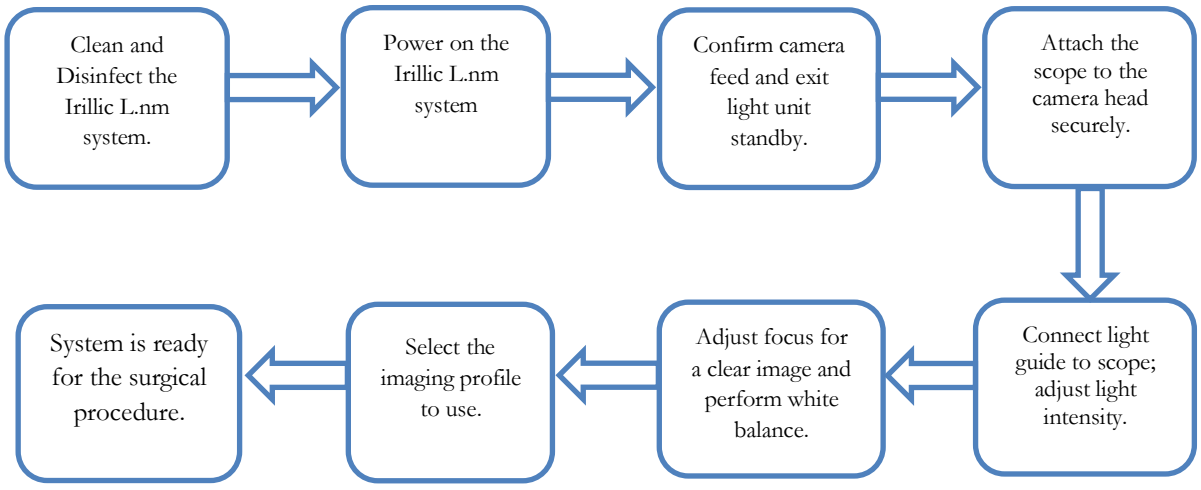


Fig 7.1: System Operating Workflow

Powering on the System

Pre-Power On Check:

Before powering on the system, ensure the following:

1. The system is properly installed as per the instructions in the Chapter 6 - Setup and Connections
2. All necessary connections (power cables, data interfaces, peripherals) are securely attached.

3. The operating environment meets the recommended conditions (temperature, humidity, ventilation).
4. There are no visible signs of damage to the power cable or unit.

Powering-On the Irillic L.nm System:

Follow the instructions below to power on the Irillic L.nm System:

1. Power on the Display Monitor.
2. Power on the CCU and the Light Unit using the Power Button.
3. If the Camera Head is disconnected, you shall see "Camera Head Disconnected" message on the main display. Connect the Camera Head ensuring the pin dots are aligned. The camera feed shall appear on the main display.
4. Ensure the Light Unit if off standby.
5. Proceed to the White Balance Operation

White Balancing Operation

White balancing ensures that the Irillic L.nm System accurately reproduces colours under different lighting conditions by adjusting the image sensor settings. Proper white balance calibration helps eliminate colour casts and ensures consistency across images.

Ensure White Balance Operation is performed before each procedure.

Before initiating the White Balance Operation, ensure the conditions below are met:

1. Ensure the camera feed is on and stable for optimal performance.
2. Position a neutral reference surface in the field of view. This could be white cotton surgical gauze.
3. Minimise external light interference by ensuring no unwanted reflections or colour contamination from surrounding objects.
4. Ensure the image is not flushed during the white balancing procedure. This may lead to incorrect white balance setting. Refer to the table below for a comparison between an ideal and non-ideal white balance target setup.

White Balance Reference Surface View	Remarks
	Image is well-exposed and ideal for White Balance.

✗		Image has colour pollution and will result in poor White Balance.
✗		Image is over-exposed and will result in poor White Balance.
✗		Image is under-exposed and will result in poor White Balance.

Table 7.1: White Balance Operation on Surface View

Operating White Balance from CCU:

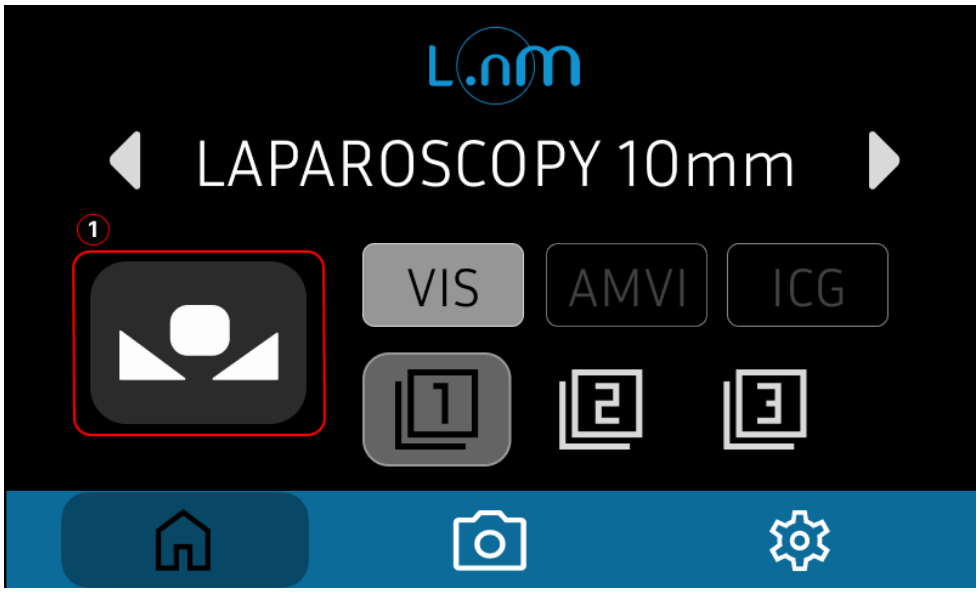


Fig 7.2a: White Balance Operation using the CCU Touch Display

1. Press the White Balance Button (shown as button 1) to initiate the White Balance Operation.
2. Hold the Camera Head steady and wait till the "White Balance Completed" message appears on the Main Display.
3. The White Balance operation is now complete.

Operating White Balance from the Application Menu:

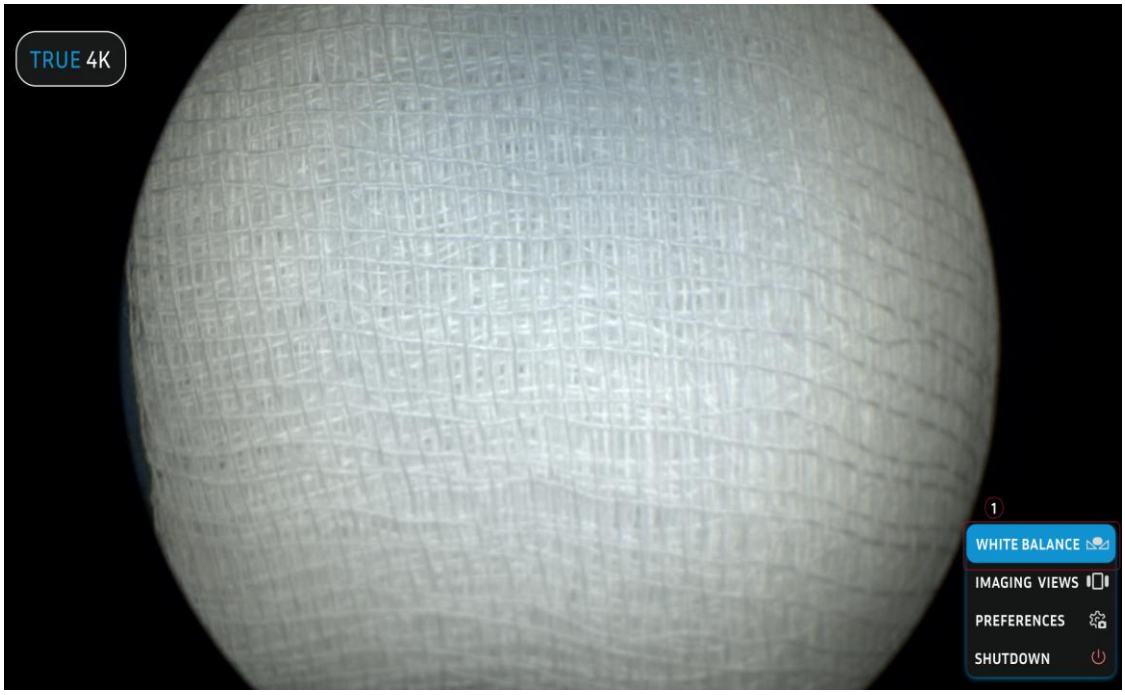


Fig 7.2b: White Balance Operation using the Application on Main Display

1. Long Press M on the camera head to open the application menu.
2. Press the White Balance Button (shown as button 1) to initiate the White Balance Operation.
3. Hold the Camera Head steady and wait till the "White Balance Completed" message appears on the Main Display.
4. The White Balance operation is now complete

Using Scope Modes

The Irillic L.nm System supports three scopes modes - Laparoscopy 10mm, Laparoscopy 5mm and Arthroscopy 4mm.

The Irillic L.nm System supports 10 mm, 5 mm, and Arthroscopy modes. In each mode, the Auto Exposure Control is specifically fine-tuned to match the corresponding rigid scope supported by the system, including the 10 mm and 5 mm Rigid Laparoscopes and the 4 mm Rigid Arthroscope. Use the arrow buttons to toggle through the 3 modes.

Fig 7.3: Scope Mode Selection on the Touch Display Interface

Imaging Modes and Imaging Views

The Irillic L.nm System supports three imaging modes - VIS (Visible Spectrum Imaging), AMVI (Advanced Microvascular Imaging) and ICG (ICG-based Fluorescence Imaging). Each Imaging Modes supports 4 independent Imaging Views which enable different clinical workflows and user preferences. The details follow:

a. VIS Imaging Mode

This is the default Imaging Mode for the Irillic L.nm System. The VIS Imaging Mode enables the user

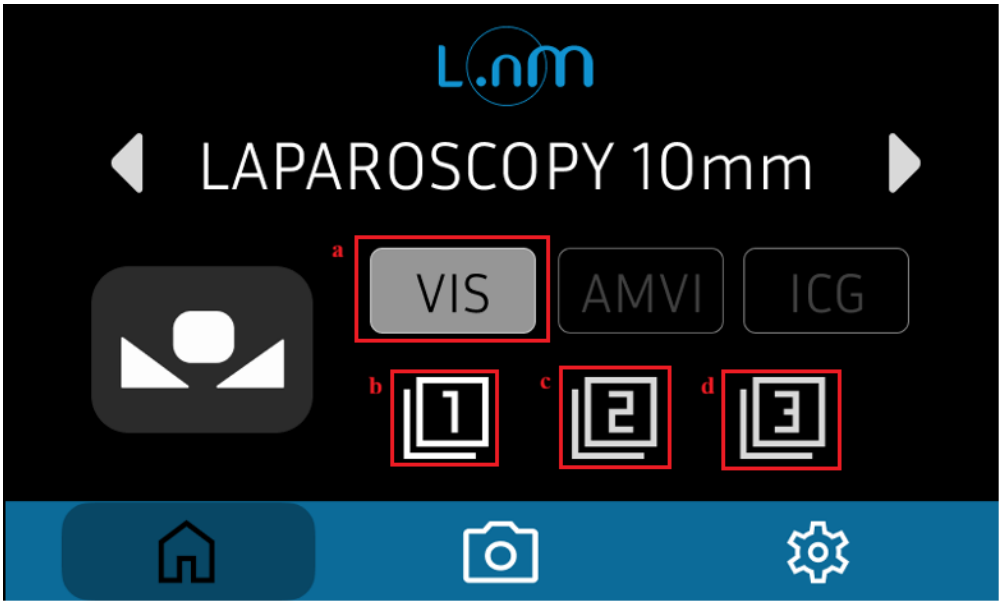


Fig 7.4: Default Imaging View in VIS Imaging Mode

to visualise the internal anatomy of the patient using the white light illumination from the White Light Unit. Since this is the default Imaging Mode, the system will power on directly to the VIS Imaging Mod

a. VIS Default - In this Imaging View, the 24-Axis Colour Adjustment (Refer Chapter 7: 24-axis Colour Adjustment) and Auto Exposure are enabled as a part of the factory settings.

b. VIS #1 - In this Imaging View, the 24-Axis Colour Adjustment (Refer Chapter 7: 24-axis Colour Adjustment) and Auto Exposure are disabled as a part of the factory settings.

c. VIS #2 - In this Imaging View, the 24-Axis Colour Adjustment (Refer Chapter 7: 24-axis Colour Adjustment) and Auto Exposure are disabled as a part of the factory settings.

d. VIS #3 - In this Imaging View, the 24-Axis Colour Adjustment (Refer Chapter 7: 24-axis Colour Adjustment), Auto Exposure and True EN^{+} are enabled as a part of the factory settings.

b. *Advanced Microvascular Imaging (AMVI) Mode*

The Advanced Micro-Vascular Imaging Mode or AMVI is an additional Imaging Mode in the Irillic L.nm System. In the AMVI Imaging Mode, the Light Unit changes the Illumination mode to AMVI and illuminates the surgical field with a custom wavelength of light. With additional processing from the CCU, the AMVI mode enhances visualisation of subsurface micro-vasculature structures.

The AMVI Imaging Mode can be activated by pressing the AMVI mode in the Camera Control Unit Touch Display. If the AMVI mode is not available, please verify the Light Unit-CCU Interconnect Cable is connected as per the instructions in Chapter 6 and the Ligh Unit powered on (not in standby)

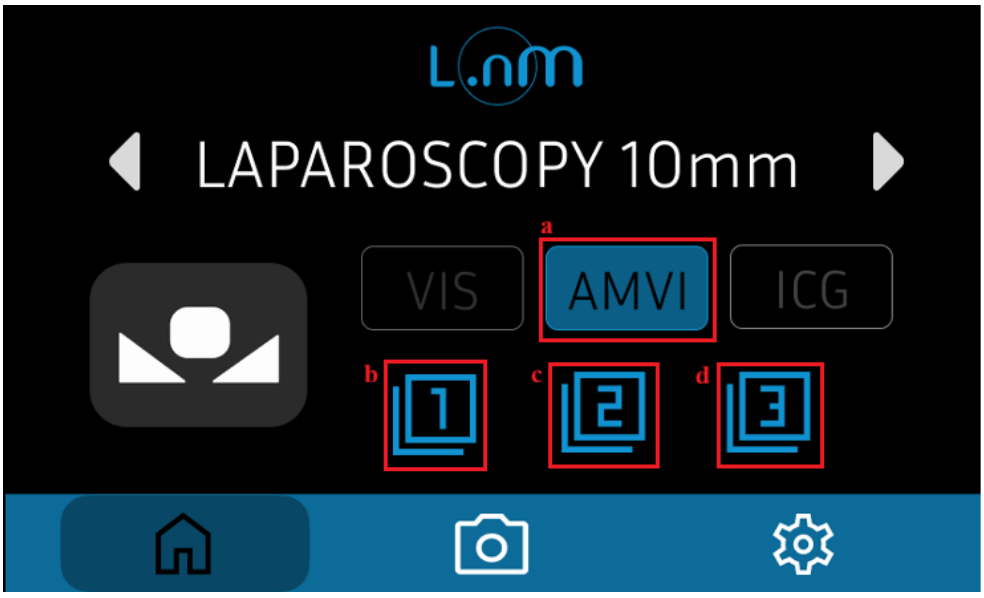


Fig 7.5: Default Imaging View in AMVI Imaging Mode

a. AMVI Default - In this Imaging View Auto Exposure is enabled and 24-Axis Colour Adjustment (Refer Chapter 7: 24-axis Colour Adjustment) is disabled as a part of the factory settings.

b. AMVI #1 - In this Imaging View Auto Exposure is enabled and 24-Axis Colour Adjustment (Refer Chapter 7: 24-axis Colour Adjustment) is disabled as a part of the factory settings.

c. AMVI #2 - In this Imaging View, the 24-Axis Colour Adjustment (Refer Chapter 7: 24-axis Colour Adjustment) and Auto Exposure are enabled as a part of the factory settings.

d. AMVI #3 - In this Imaging View, the 24-Axis Colour Adjustment (Refer Chapter 7: 24-axis Colour Adjustment), Auto Exposure and True EN^{+} are enabled as a part of the factory settings.

c. ICG Imaging Mode

The Indo-cyanine Green Imaging Mode or ICG Imaging Mode enables visualisation of blood flow and lymphatics through the use of the Indo-cyanine Green Dye.

If the ICG mode is not available, please verify the Fusion Light Unit-CCU Interconnect Cable is connected as per the instructions in Chapter 6 and the Fusion Light Unit powered on (not in standby)

If laser output is not detected, the application will display a warning when the NIR light source is off.

Fig 7.6: Default Imaging View when NIR light source is OFF

In the ICG Imaging Mode, the light unit shall switch to the NIR Illumination Mode. There are 4 independent Imaging Views which enable different clinical workflows and user preferences. The details are as follows:

i) ICG - Default Imaging View (Multi-View Imaging)

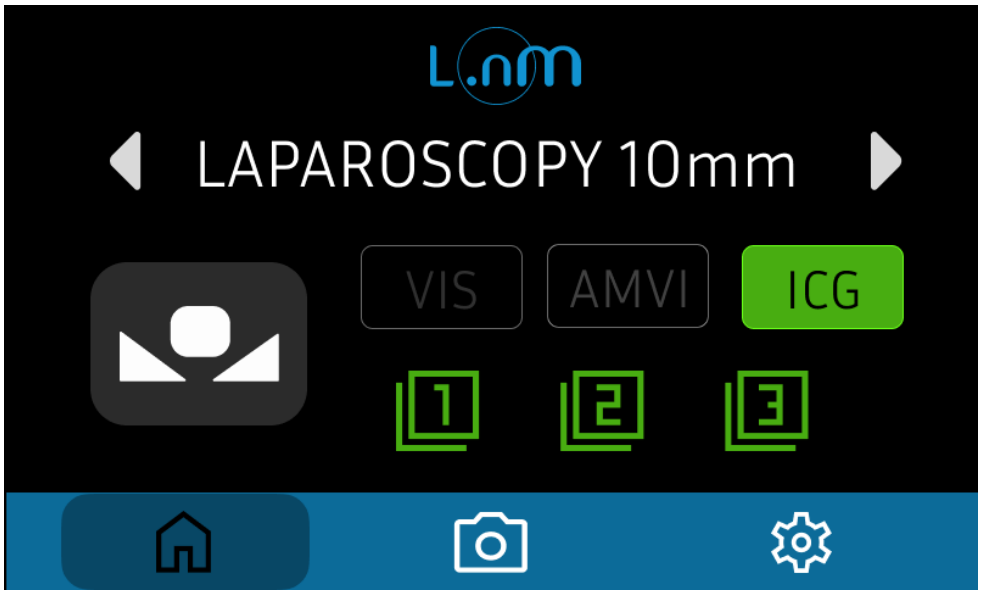


Fig 7.7: Default Imaging View in ICG Imaging Mode

The ICG Default Imaging View can be set by ICG Button on the Camera Control Unit Touch Display. The system will then enable the ICG Imaging Mode with the following acquisition parameters.

In the ICG - Default Imaging View, the Irillic L.nm System enables Multi-View Imaging. This includes a combination of 4 independent Visualisation Feeds combined into one Imaging View. The details regarding each visualisation feed are as follows:

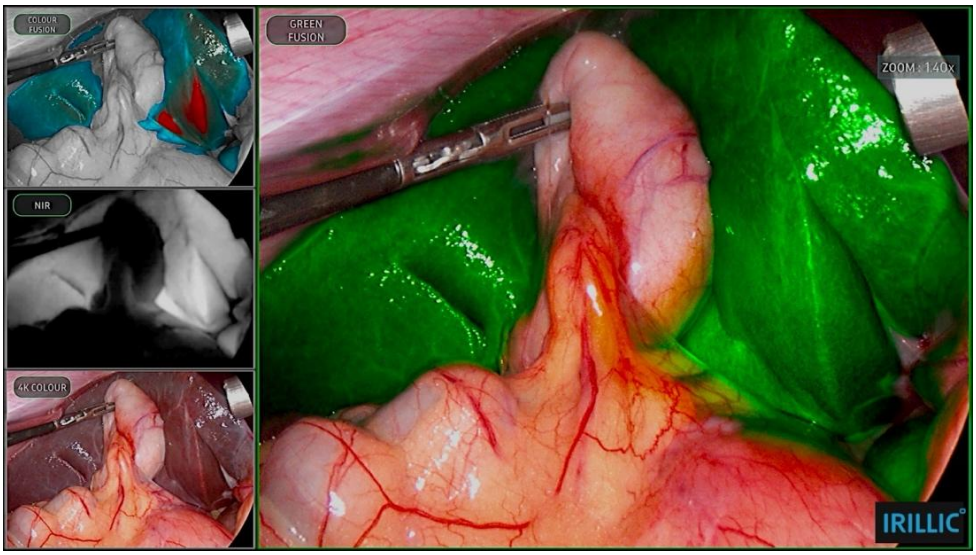


Fig 7.8: Multi-View in ICG Imaging Mode

1. **Green Fusion Visualisation:** In this visualisation, the fluorescence data is overlayed on the anatomy data as green overlay over the anatomy data which is displayed in 4K Colour.

2. **Colour Fusion Visualisation:** In this visualisation, the fluorescence data is overlayed on the anatomy data as Blue-Red gradient overlay where blue represents low fluorescence intensity and red represents high fluorescence intensity. The anatomy data is displayed in mono colour.
3. **NIR Visualisation:** In this visualisation, the raw fluorescence data is displayed.
4. **4K Colour Visualisation:** In this visualisation, the raw anatomy data is displayed.

ii) ICG - Imaging View #1 (Green Fusion IntelliQuant Imaging)

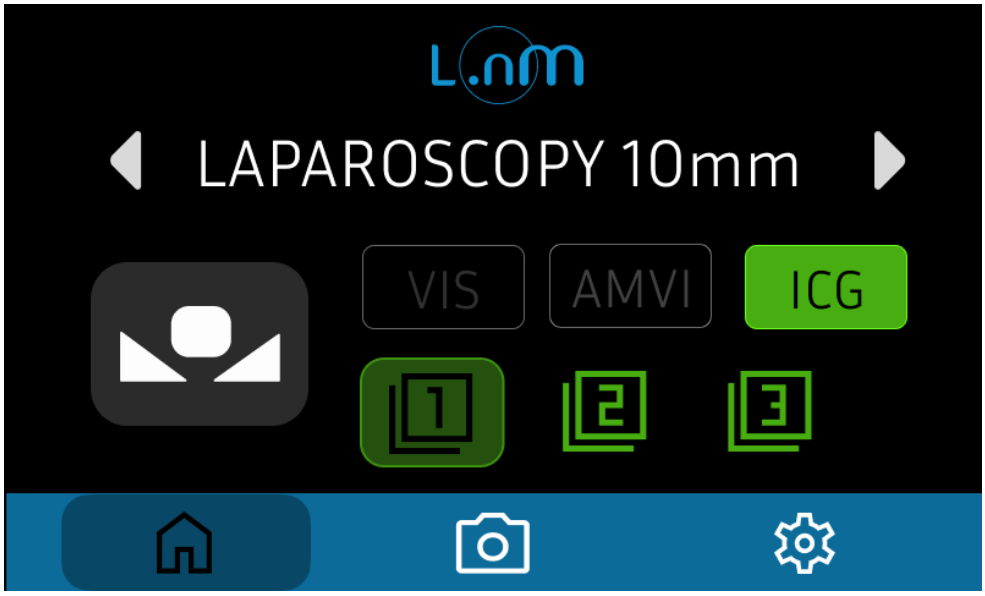


Fig 7.9: Imaging View #1 in ICG Imaging Mode

The ICG - Imaging View #1, can be set by pressing Imaging View 1 button under the ICG Imaging Mode. The following are the default acquisition settings under Imaging View #1

Fig 7.10: Green Fusion IntelliQuant View in ICG Imaging Mode

In the ICG Imaging View#1, the Irillic L.nm System enables Green Fusion IntelliQuant Imaging. The includes 2 Visualisation Feeds. Additionally, this imaging includes the IntelliQuant feature. The details follow:

1. **Green Fusion Visualisation:** In this visualisation, the fluorescence data is overlayed on the anatomy data as green overlay over the anatomy data which is displayed in 4K Colour.
2. **NIR Visualisation:** In this visualisation, the raw fluorescence data is displayed.
3. **IntelliQuant Visualisation:** In this visualisation, the user is able perform real-time spatial quantification analysis of the intensity of fluorescence data captured by the Irillic L.nm System. There are 2 features in this visualisation:

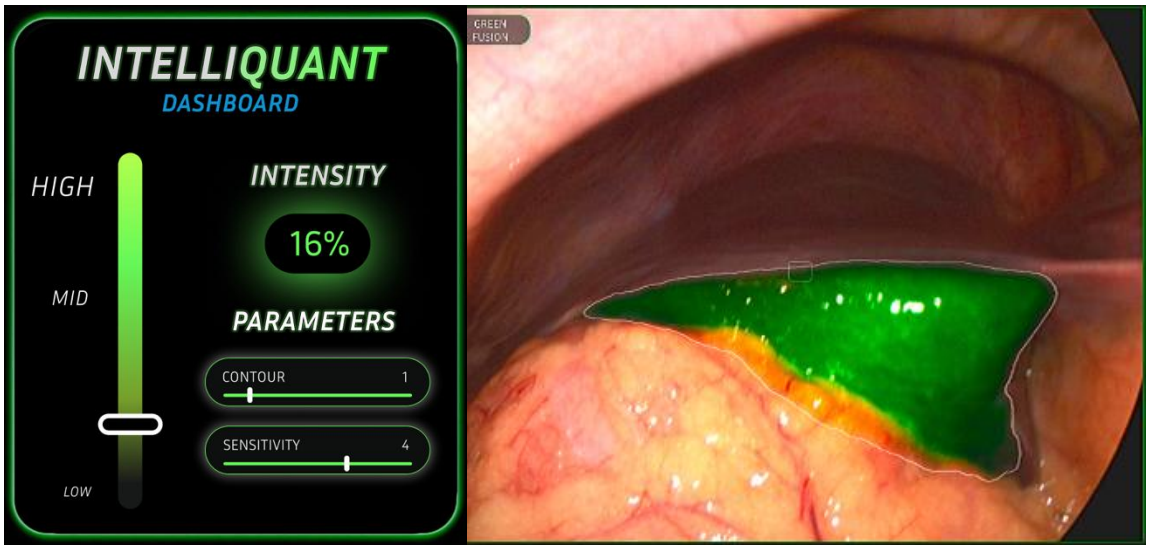


Fig 7.11: Live Intensity Reading in Green Fusion (IntelliQuant)

a. **Live Intensity Reading Scale:** This reading displays the overall NIR intensity recorded by the Irillic L.nm System on a vertical scale from Low to High
b. **Live Intensity Reading Value:** This reading shows the NIR intensity recorded by the Irillic L.nm System as a number from 0-100%.
c. **Contour Setting:** On a scale from 1 - 5, the Contour setting configures IntelliQuant to draws a visual contour on the Green Fusion Visualisation to demarcate parts of anatomy that show more fluorescence intensity than a cut-off threshold from those that show less fluorescence intensity. The mapping of the contour setting to the Fluorescence cut-off Threshold is as follows:

Contour Setting	Fluorescence Cut-off Threshold
1	20%
2	40%
3	60%
4	80%
5	100%

Table 7.12: Contour Settings for Green Fusion IntelliQuant View

d. **Sensitivity Setting:** On a scale from 1- 5, the Sensitivity setting configures the gain of the NIR data acquisition to increase from 0 dB to 40 dB. This increases the sensitivity of the Irillic L.nm System to fluorescence data.

iii) ICG - Imaging View #2 (Picture-in-Picture Imaging)

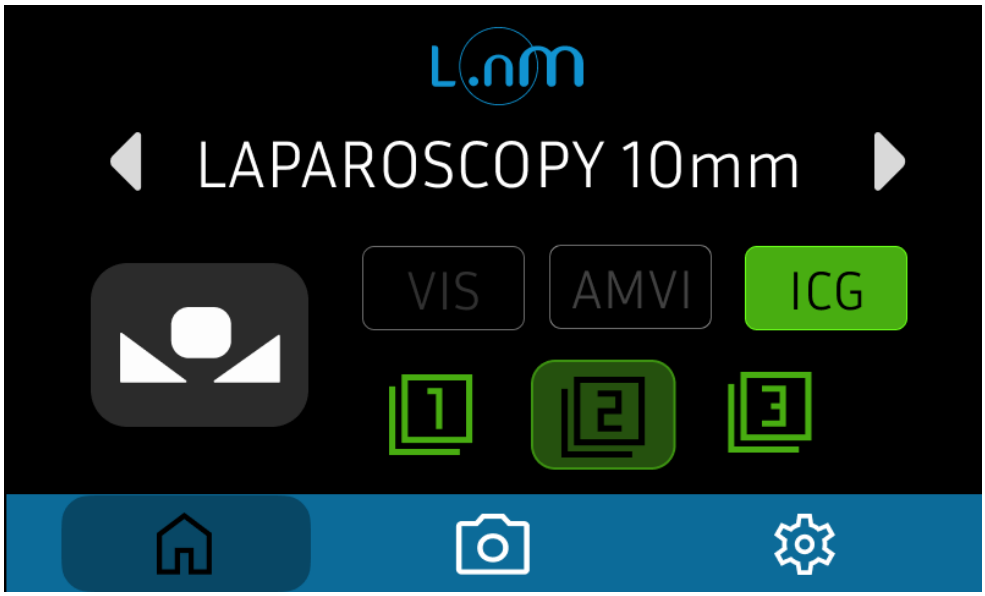


Fig 7.12 : Imaging View #2 in ICG Imaging Mode

The ICG - Imaging View #2, can be set by pressing Imaging View 2 button under the ICG Imaging Mode. The following are the default acquisition settings under Imaging View #2

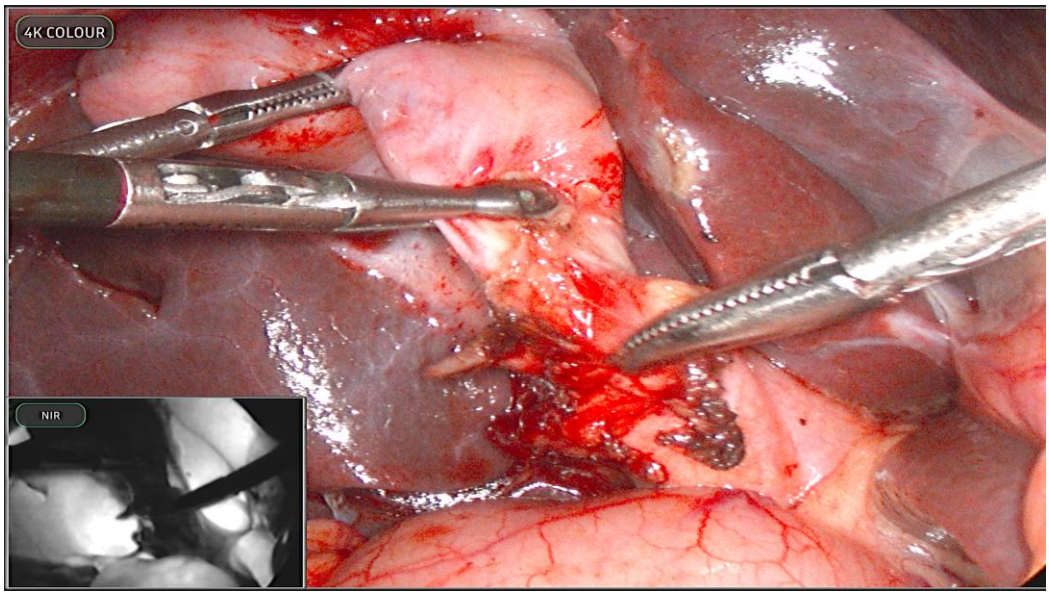


Fig 7.13: Picture in Picture View in ICG Imaging Mode (NIR Visualisation)

In ICG Imaging View #2, the Irillic L.nm System enables the Picture-In-Picture Imaging. The includes 2 Visualisation Feeds. The details follow:

1. **4K Colour Visualisation:** In this visualisation, the raw anatomy data is displayed.
2. **NIR Visualisation:** In this visualisation, the raw fluorescence data is displayed.

iv) ICG - Imaging View #3 (Colour Fusion IntelliQuant Imaging)

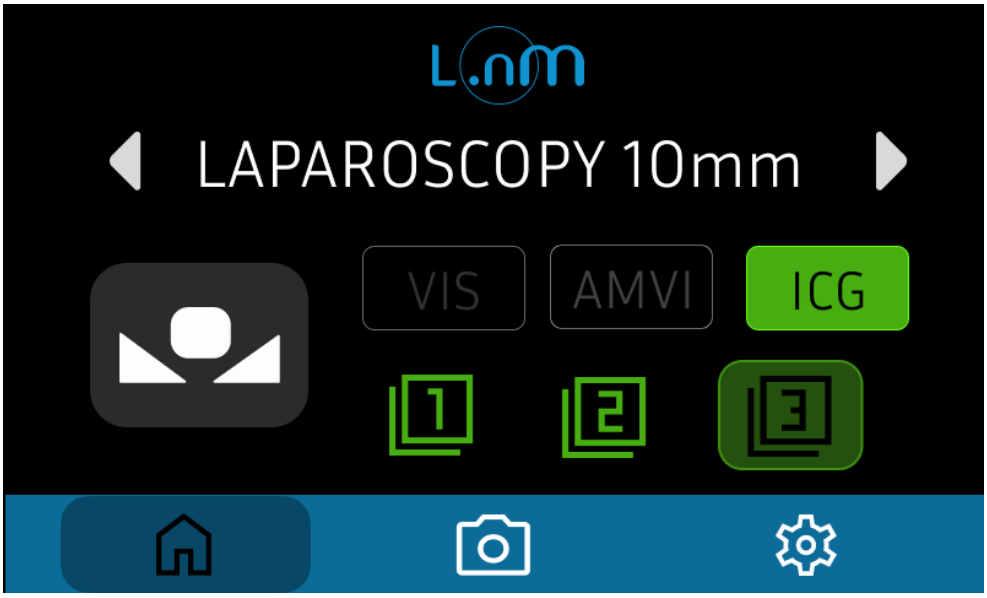


Fig 7.14: Imaging View #3 in ICG Imaging Mode

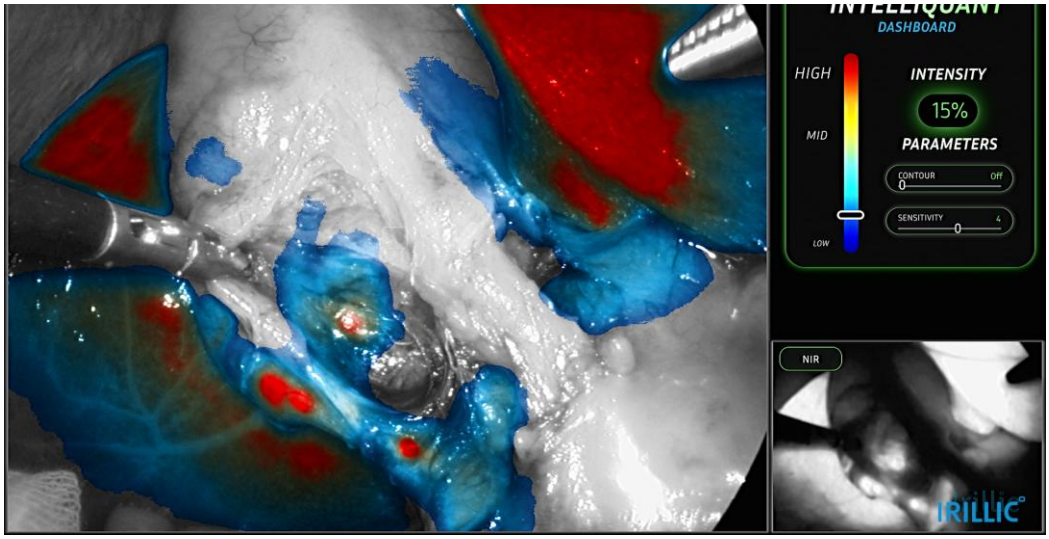


Fig 7.15: Colour Fusion IntelliQuant View in ICG Imaging Mode

In the ICG Imaging View#3, the Irillic L.nm System enables Colour Fusion IntelliQuant Imaging. The includes 2 Visualisation Feeds. Additionally, this imaging includes the IntelliQuant feature. The details follow:

1. **Colour Fusion Visualisation:** In this visualisation, the fluorescence data is overlayed on the anatomy data as Blue-Red gradient overlay where blue represents low fluorescence intensity and red represents high fluorescence intensity. The anatomy data is displayed in mono colour.
2. **NIR Visualisation:** In this visualisation, the raw fluorescence data is displayed.
3. **IntelliQuant Visualisation:** In this visualisation, the user is able perform real-time spatial quantification analysis of the intensity of fluorescence data captured by the Irillic L.nm System. There are 2 features in this visualisation:

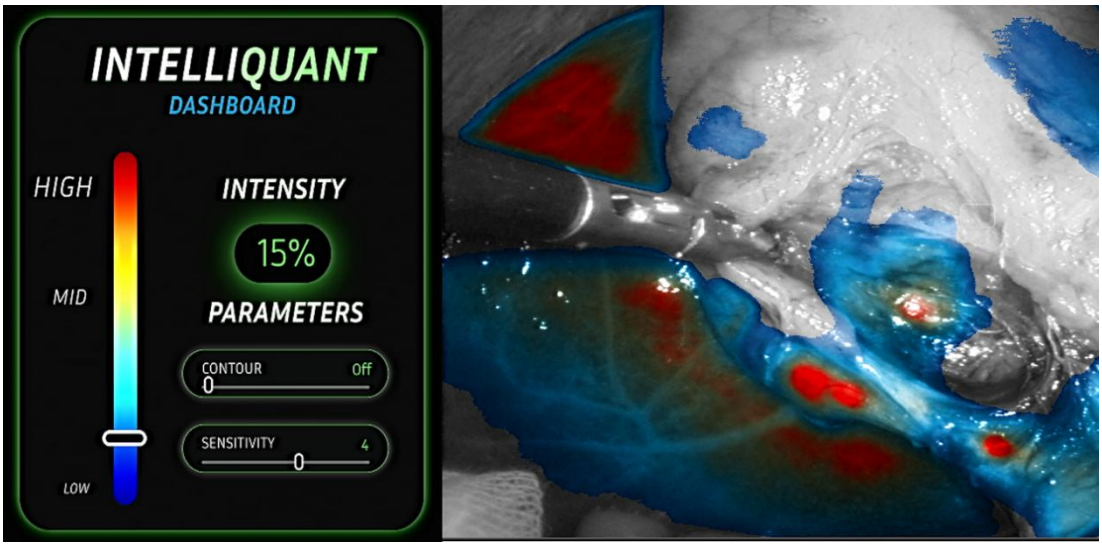


Fig 7.16: Live Intensity Reading in Colour Fusion (IntelliQuant)

a. **Live Intensity Reading Scale:** This reading displays the overall NIR intensity recorded by the Irillic L.nm System on a vertical scale from Low to High
b. **Live Intensity Reading Value:** This reading shows the NIR intensity recorded by the Irillic L.nm System as a number from 0-100%.
c. **Contour Setting:** On a scale from 1 - 5, the Contour setting configures IntelliQuant to draws a visual contour on the Colour Fusion Visualisation to demarcate parts of anatomy that show more fluorescence intensity than a cut-off threshold from those that show less fluorescence intensity. This can be controlled from the camera head. The mapping of the contour setting to the Fluorescence cut-off Threshold is as follows:

Contour Setting	Fluorescence Cut-off Threshold
1	20%
2	40%
3	60%
4	80%
5	100%

Table 7.15: Contour Settings Colour Fusion IntelliQuant View

d. **Sensitivity Setting:** On a scale from 1- 5, the Sensitivity setting configures the gain of the NIR data acquisition to increase from 0 dB to 40 dB. This increases the sensitivity of the Irillic L.nm System to fluorescence data.

View Customisation

The user can customise the acquisition parameters through the Application Menu (see Chapter 7 - Application Menu). Any changes made are automatically saved to the selected VIS - Imaging View profile (e.g., Imaging View #1). To restore the original factory settings, go to Preferences >> Reset View.

CCU Recording and Zoom Overview

The Irillic 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 either by the Camera head or the CCU Touch Interface.

a. Pre-Requisites:

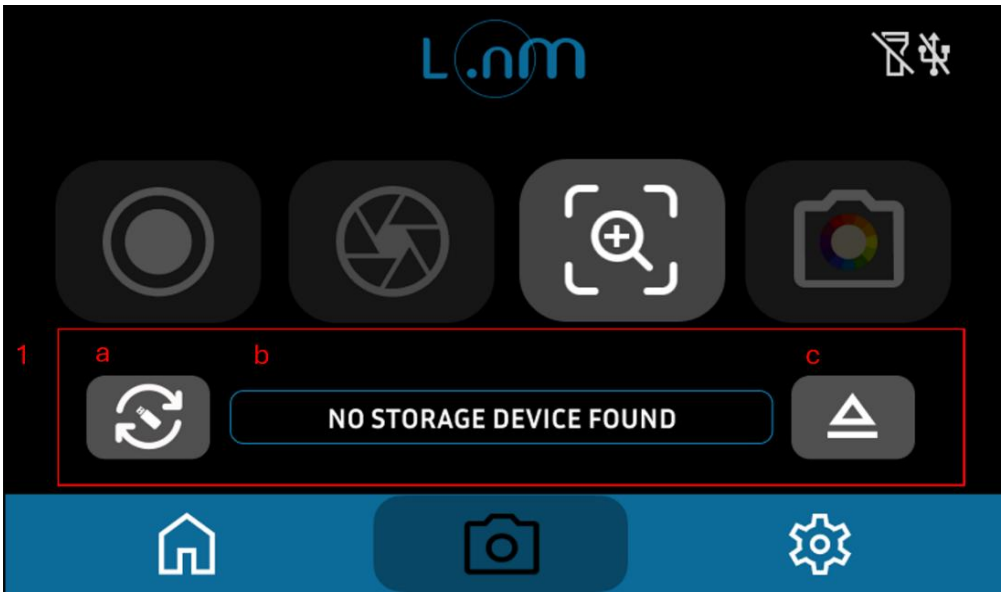


Fig 7.17: CCU-Camera Page (When USB Storage Device is Not Connected)

To enable the in-built recording, the user must ensure that a compatible storage device is available and mounted to the system. A 2 TB storage device is supplied along with the Irillic L.nm System for this purpose. Additionally, the system supports NTFS, FAT-32, and exFAT file systems.

1. **External Storage Device Menu**
    a. **Refresh Button:** To mount the device, the user must first connect the storage device to the CCU via the USB on the Back. 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.

b. **Validation Status Information:** Verify the mounting status in the status bar. Upon successful mounting and validation, recording and snapshot options become available in the Camera Settings menu. The status bar also shows connected drive details and displays "Please refresh drives" if no drive is detected.

c. **Eject Button:** The eject button shall safely eject the mounted storage device.

b. Recording Control

Fig 7.18: CCU-Camera Page (When USB Storage Device is Connected)

2. **Camera feed menu**: there are 4 buttons in this menu
   a. **Record ON/OFF Button:** Once a storage device has been mounted, the user may start recording by either Long Pressing the S Button on the Camera Head or press the record button on the CCU touch display. If there is no compatible storage device mounted, the button will be disabled. Once the recording has started, the REC ON is displayed at the bottom left of the feed. The recorded outputs are categorised according to date and stored within the mass storage device. To stop the recording, the user can either Long Press the S Button on the Camera Head or press the record button once again on the CCU touch display.
   b. **Snapshot Button:** The user may take a snapshot by either Short Pressing the S button on the Camera Head or by pressing the snapshot button on the CCU touch display. If there is no compatible storage device mounted, the button will be disabled.

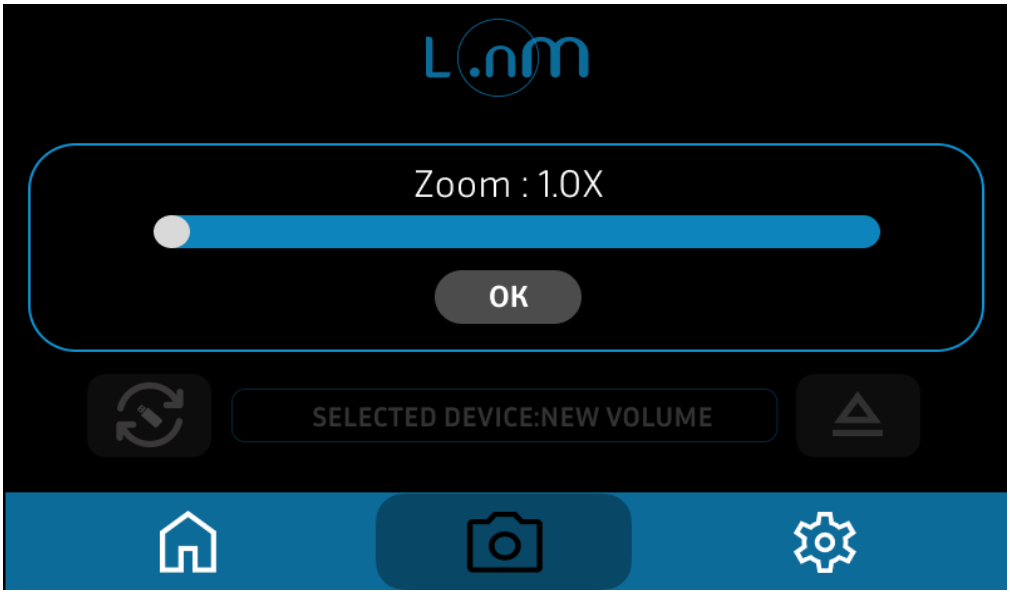


Fig 7.19: Zoom Adjust Parameter

c. **Zoom Adjust:** The zoom button enables adjustment of the Zoom Level of the camera feed on the Display. The Zoom Level can be adjusted from 1.0x to 2.5x.

3. **Recording Management**

The system provides real-time recording phase indicators and disk status alerts to ensure safe and reliable operation. Notifications are displayed on the monitor to confirm recording status as below:

a. Validation when USB is connected
Upon insertion, the system detects and validates the USB device. Recording remains disabled until validation is complete.

b. **Low Storage Space Alert**
Displays "Incompatible disk. Low capacity "or "Insufficient disk space left on USB drive" on the Runtime application when the connected drive has insufficient space.

c. **Disk Almost Full**
Displays "Disk almost full. Please insert new drive." which indicates critically low remaining capacity during recording.

d. Critical Storage Warning
Displays "Disk Full. Stopping Recording." If storage becomes insufficient during recording, recording is automatically stopped to prevent data loss. A warning is displayed.

e. Incompatible File System Alert
Displays "Incompatible disk. Incorrect filesystem." if the connected device is not formatted in NTFS, exFAT, or FAT32. Recording and snapshot functions remain disabled.

f. Low Disk Speed Warning

Displays "Incompatible disk. Low speed" on the runtime application if the device does not meet required write speed for recording.

g. **USB Connection Status Notification**
Confirms successful validation and mounting of the storage device and Indicates "Drive found: (Name of the Drive)" on the Runtime Application.

h. **Eject Warning**
Displays "Ejecting USB Device." On the Runtime Application if the storage device is ejected.

If a critical storage or disk performance condition occurs, recording functionality may be restricted to prevent data loss.

Unscheduled power outage during recording may impact previously recorded content and cause data loss. Ensure system is connected to UPS power supply only to prevent potential data loss.

CCU Settings Overview

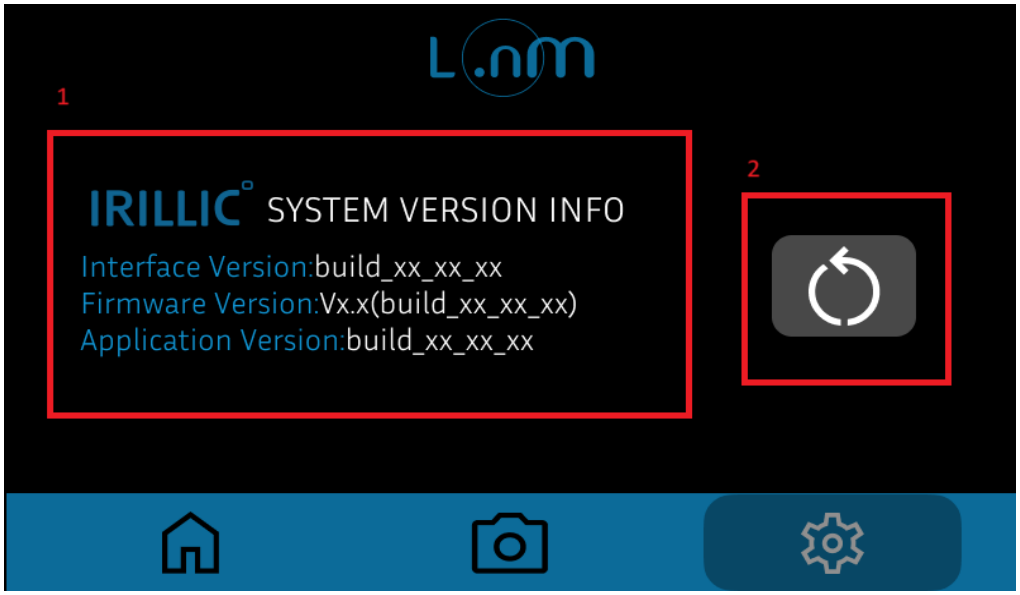


Fig 7.20: CCU-Settings Page

The settings menu displays information about the current firmware on the Camera Control Unit.

1. **Device Information**: Provides information to the authorised service personnel regarding the Application Version, Interface Version and Firmware Version.

2. **Reboot**: Allows the user to restart the camera control unit. When the Reboot button is pressed, the system prompts the user to confirm the action. If Yes is selected, the system proceeds with the reboot process. If Cancel is selected, the system returns to the Settings screen without performing a reboot.

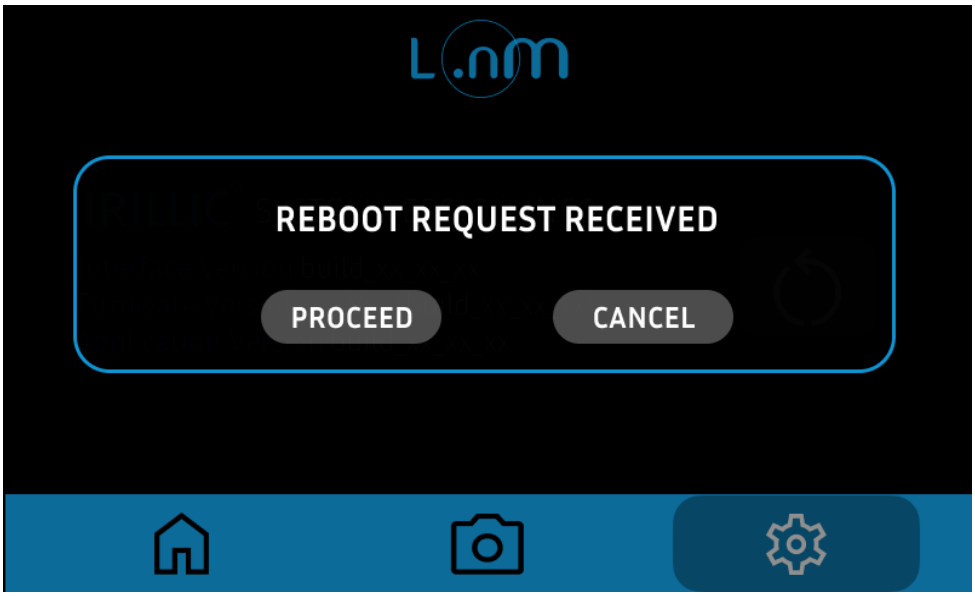


Fig 7.21: Reboot Request when prompted from the Touch Display

Unauthorised attempts to modify the software on the device may lead to system failure.

Additional Imaging Features Common to All Imaging Modes

True EN+

True EN+ is a real-time image enhancement feature of the system that improves anatomical sharpness during laparoscopic procedures. It increases overall image clarity and enhances the definition of tissue planes, small vessels, and fine microvascular structures. The feature also improves depth perception across the surgical field.

To activate True EN+, long press the "Up" button in the Camera Head.
When activated, the feed will display a 'triangle" in the top right corner of the screen. This feature is available in all imaging modes.

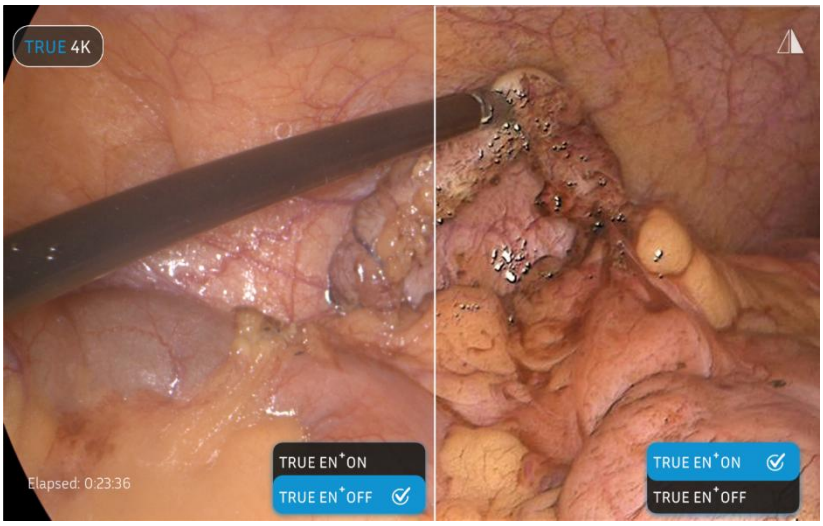


Fig 7.22: Side-by-side comparison of True EN+

24-Axis Colour Adjustment

A step-by-step guide to the 24 Axis - Colour Adjustment Tool on the Irillic L.nm System. This tool is always on in VIS default and VIS 3.

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 7.23: Menu selection of Quick Calibrate Mode

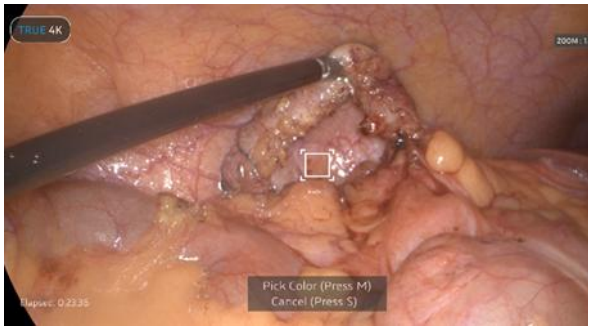


Fig 7.24: Pointer Box to select the tissue colour to calibrate

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

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.

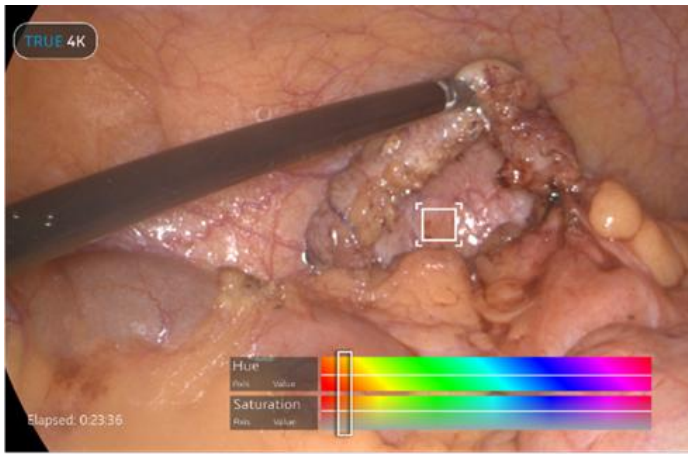


Fig 7.25: Selection of the colour channel for calibration

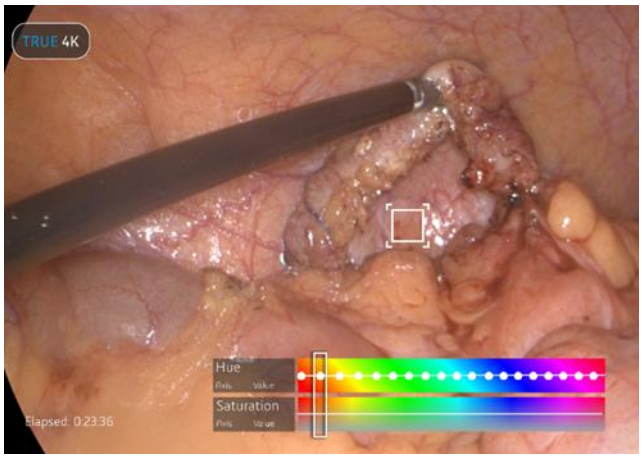


Fig 7.26: Selection of the Saturation of the chosen colour channel for calibration

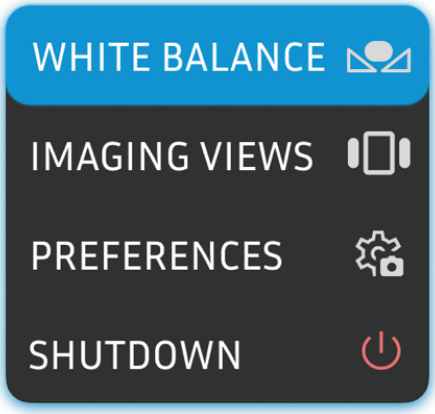
Step 4: Select either the Hue or Saturation of the chosen colour channel for calibration by using the Up and down buttons on the Camera Head

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

Using the Application User Interface on the Main Display

The user can access the application menu on the Display by long pressing "M" button on the Camera Head.

Main Menu



White Balance executes the White Balance operation upon selection.

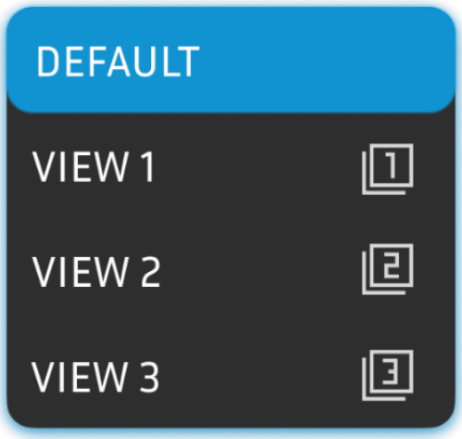
Imaging Views opens the Imaging View Selection Menu as seen below.

Preferences opens the System Settings Menu as seen below.

Shutdown initiates the shutdown sequence for the device.

Fig 7.27: Main Menu

User Profiles Menu



Default Selects the Default Imaging View under the current active Imaging Mode

View 1 Selects Imaging View#1 under the current active Imaging Mode

View 2 Selects Imaging View#2 under the current active Imaging Mode

View 3 Selects Imaging View#2 under the current active Imaging Mode

Fig 7.28: Imaging Views Menu

System Settings Menu

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

Camera opens the colour camera settings menu as seen below.

Fluoro opens the near-infrared camera settings menu as seen below. This option is disabled when the system is configured in the 4KWL configuration.

Reset Views pushes the View to the Default settings.

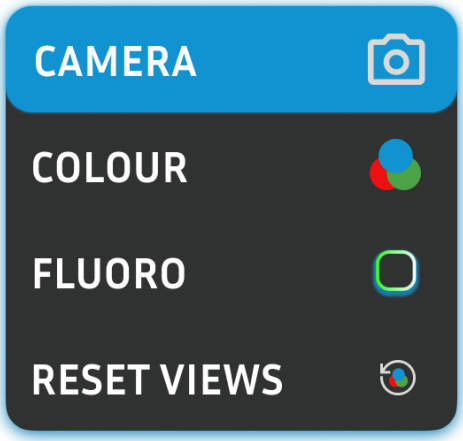


Fig 7.29: System Settings Menu, when ICG mode is enabled.

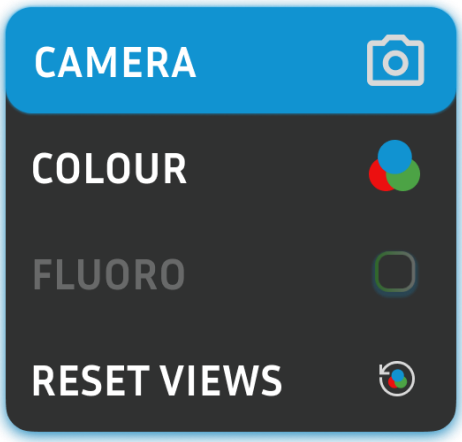


Fig 7.30: Camera Settings Menu, when ICG mode is disabled.

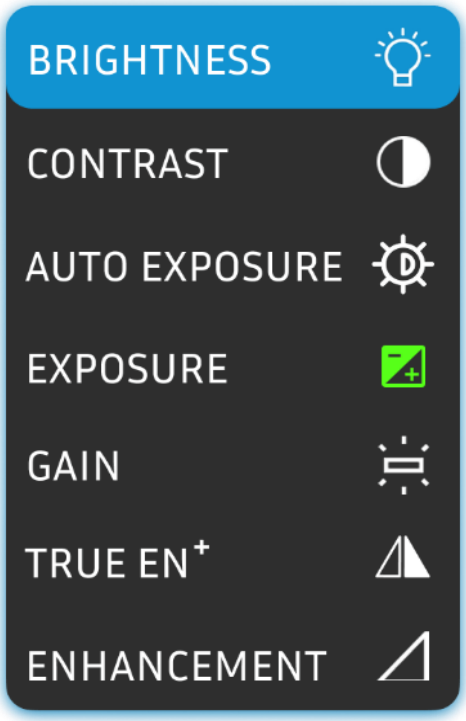


Fig 7.31: Camera Settings Menu

Camera Settings Menu

Brightness(0-100) Controls the overall brightness of the image shown on the Main Display.

Contrast(0-100) Controls the overall contrast of the image shown on the Main Display.

Auto Exposure (ON/OFF) Enables or disables the Auto Exposure function of the system. When enabled, the system will target a specific image brightness under varying illumination of the tissue.

Exposure(0-100) Available only when Auto Exposure is OFF. Controls the image exposure time of the visible image acquisition.

Gain(0-100) Available only when Auto Exposure is OFF. Controls the image gain dB of the visible image acquisition.

Enhancement (0-10) Controls the overall sharpness and noise of the image shown on the Main Display.

Colour Settings Menu

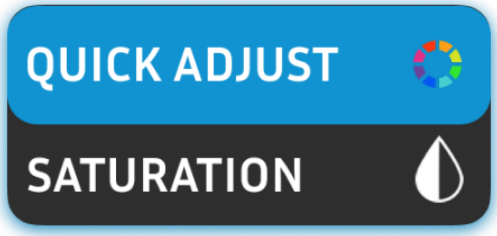


Fig 7.32: Colour Settings Menu

Quick Adjust opens the advanced colour calibration mode which allows users to independently tune specific axes of the colour gamut as described below. Only Accessible in the View 2 and View 3 of VIS and AMVI Mode.

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

Fluorescence Settings Menu

Fig 7.33: Fluorescence Settings Menu

Sensitivity opens a 6 step fluorescence sensitivity menu. This allows the user to adjust the sensitivity of the L.nm System NIR image data.

Black Level sets the offset for the video signal, this offset determines the darkest colour on the display.

Incorrect modification in the Settings Menu can affect Visualization of the Surgical Field. Incorrect modification in the Settings Menu can affect Visualisation of the Surgical Field. Press Reset Views in the

Monitor Settings Operating workflow

The high-level Settings Menu Operating Workflow on the Main Display is as follows:

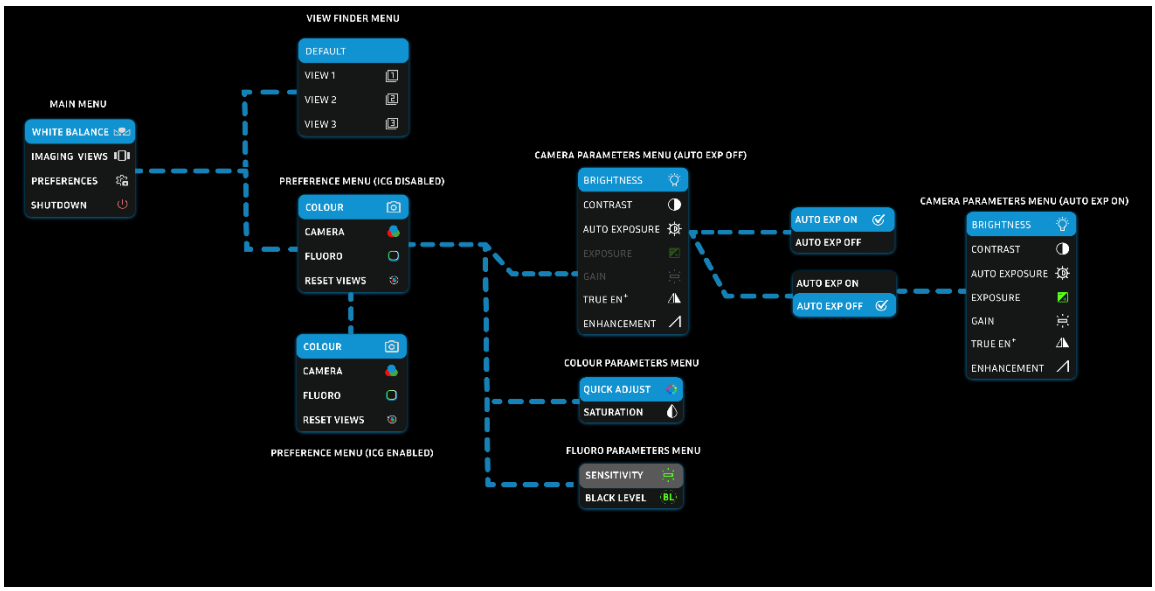


Fig 7.34: Settings Menu Operating Workflow

If an incompatible monitor is connected to the Irillic L.nm System, the application will notify the user of incorrect display settings. The user will be prompted to restart the system and configure the monitor according to the display specifications provided by Irillic.

Fig 7.35: Warning for Incompatible Display Resolution

Using the Light Unit

Touch Display Interface
(Applicable for WLU and FLU)

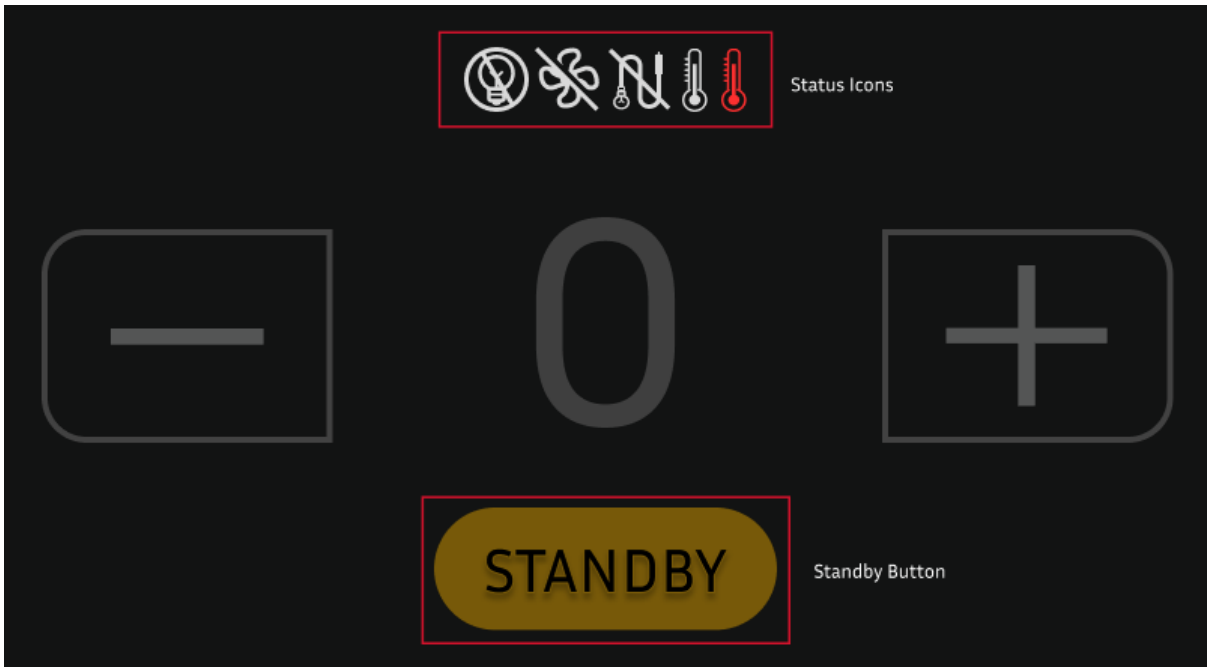


Fig 7.35: WLU Main Screen

The Light Unit provides illumination for the Irillic L.nm System. The home screen of the Light Unit is as follows:

Status Icons

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 authorised 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 due to overheating. Please contact Irillic to schedule a visit by authorised 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 (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.

High Temperature Warning (NIR Light Source) [Applicable for Fusion Light Unit only] - 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.

Standby Button

This is the central button of the menu which can be used to quickly toggle between the illuminated state and the standby state. Upon toggling back to the illumination mode, the light unit switches to VIS illumination mode with the last set light intensity. Additional information regarding the available illumination modes follows.

Light Unit Illumination Modes

The Light Unit supports three illumination modes - VIS (Illumination for Visible Spectrum), AMVI (Illumination for Advanced Microvascular Imaging) and NIR (Illumination for ICG-based Fluorescence Imaging). The details follow.

a. VIS Illumination Mode (Applicable to both WLU and FLU)

The VIS illumination mode provides white light illumination in the visible spectrum.

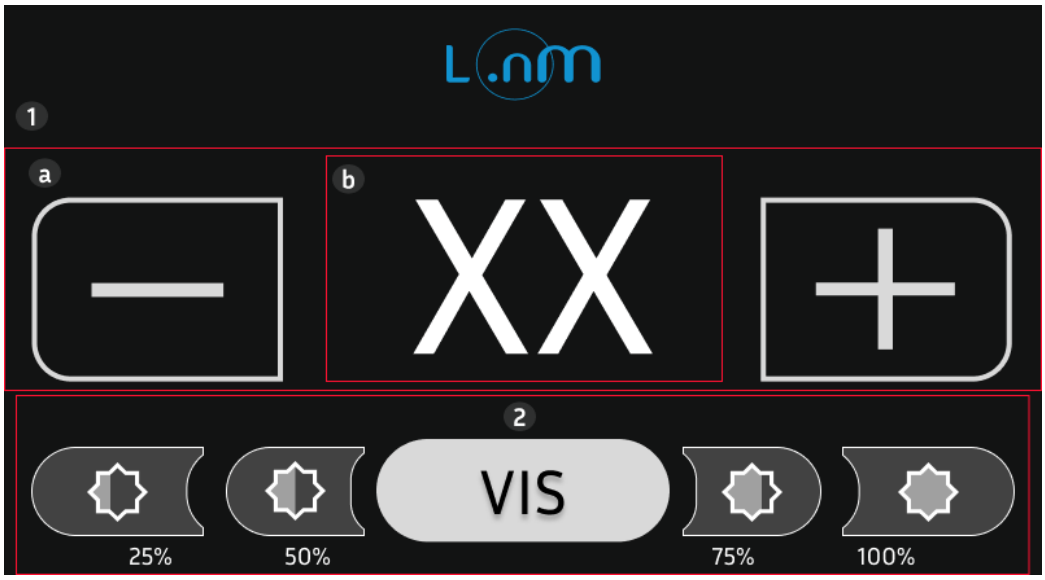


Fig 7.36: Light Unit – VIS Illumination Mode

1. **Light Intensity Control**:
   a) **Control Buttons:** The intensity controller menu contains two buttons for increasing and decreasing the light controller output. Each of these buttons increases or decreases the active intensity of the output by a factor of 5%.
   b) **Intensity Value Display:** This widget displays the intensity of the light output. The limits for this value are from 0 to 100. All relevant assets for the same are loaded.
2. **Quick Settings Buttons:** This menu contains a total of 4 buttons that can be used to control the light intensity to preset values of 25%, 50%, 75% and 100%
3. **VIS Button:** Pressing the VIS Button shall set the Light Unit into Standby Mode.

b. AMVI Illumination Mode (Applicable to both WLU and FLU)

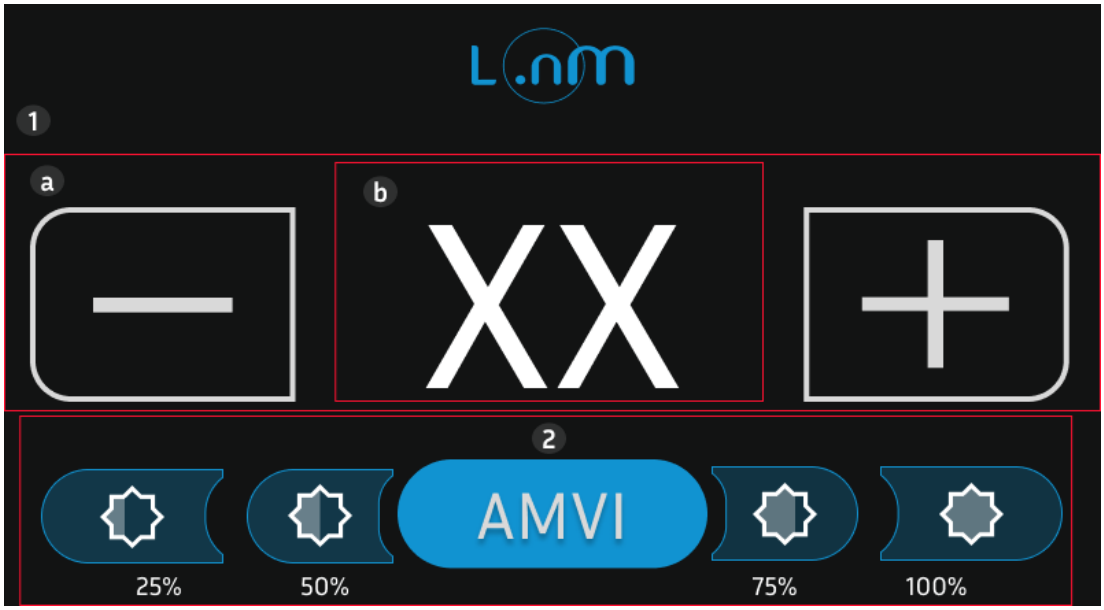


Fig 7.37: Light Unit – AMVI Illumination Mode

1. **Light Intensity Control**:
   a) **Control Buttons:** The intensity controller menu contains two buttons for increasing and decreasing the light controller output. Each of these buttons increases or decreases the active intensity of the output by a factor of 5%.
   b) **Intensity Value Display:** This widget displays the intensity of the light output. The limits for this value are from 0 to 100. All relevant assets for the same are loaded.
2. **Quick Settings Buttons:** This menu contains a total of 4 buttons that can be used to control the light intensity to preset values of 25%, 50%, 75% and 100%
3. **AMVI Button:** Pressing the AMVI Button shall set the Light Unit into Standby Mode.

c. NIR Illumination Mode (Applicable to FLU only)

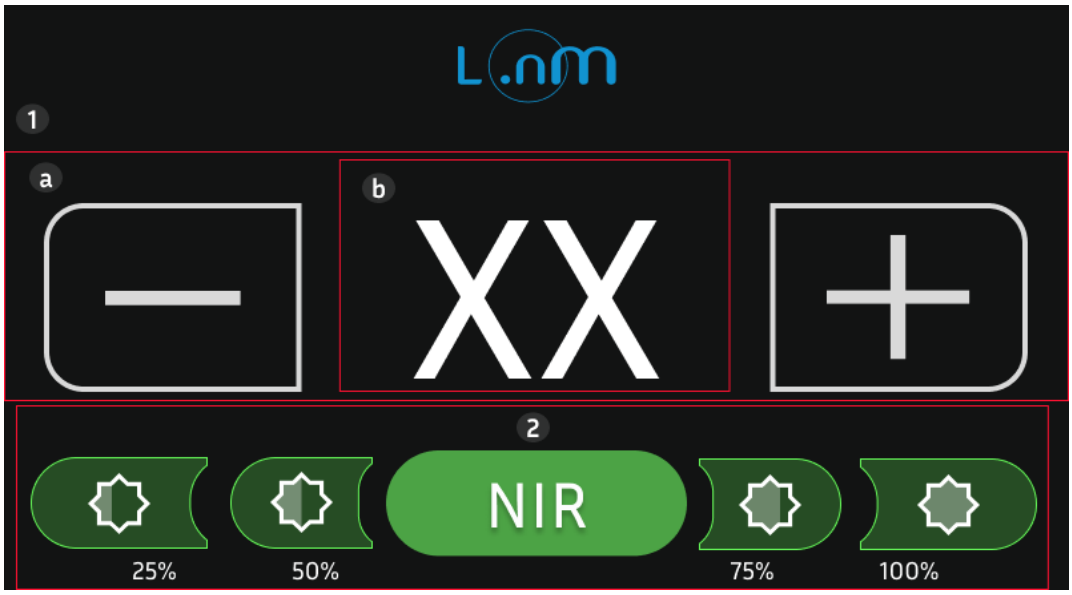


Fig 7.38: Light Unit - NIR Illumination Mode

1. **Light Intensity Control**:
    a. **Control Buttons:** The intensity controller menu contains two buttons for increasing and decreasing the light controller output. Each of these buttons increases or decreases the active intensity of the output by a factor of 5%.
    b. **Intensity Value Display:** This widget displays the intensity of the light output. The limits for this value are from 0 to 100. All relevant assets for the same are loaded.
2. **Quick Settings Buttons (Laser Intensity Control):** This menu contains a total of 4 buttons that can be used to control the laser intensity to preset values of 25%, 50%, 75% and 100%
3. **NIR Button:** Pressing the NIR Button shall set the Light Unit into Standby

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 Head

Press & Hold the Mode Button to open the Main Menu. Then toggle to the Shutdown Option.

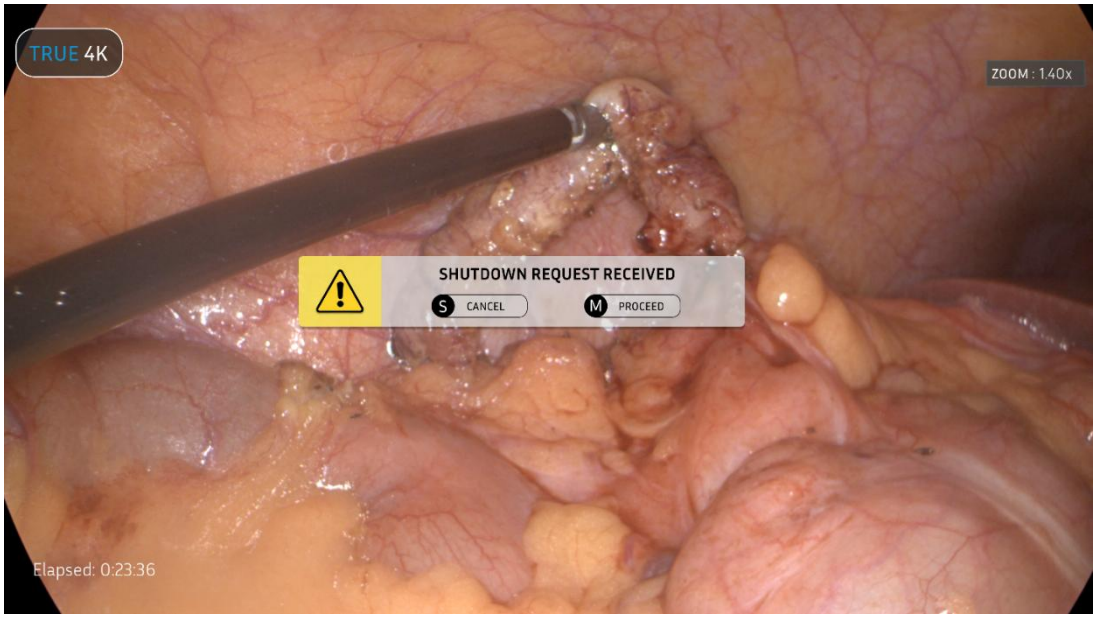


Fig 7.39: Shutdown Prompt (When requested from the Application Menu)

Additionally, when the Power button is pressed once, a shutdown request prompt is displayed. If no user response is provided, the CCU will automatically shut down after 10 seconds. If the Power button is pressed again during this interval, the shutdown request is cancelled and the system returns to normal operation.

This process ensures that all connected subsystems are properly powered down and that sensitive device data is protected. Once the monitor screen goes blank, the main power supply to the device may be switched off. The components may then be disconnected, cleaned according to approved procedures, and safely stored for subsequent use.

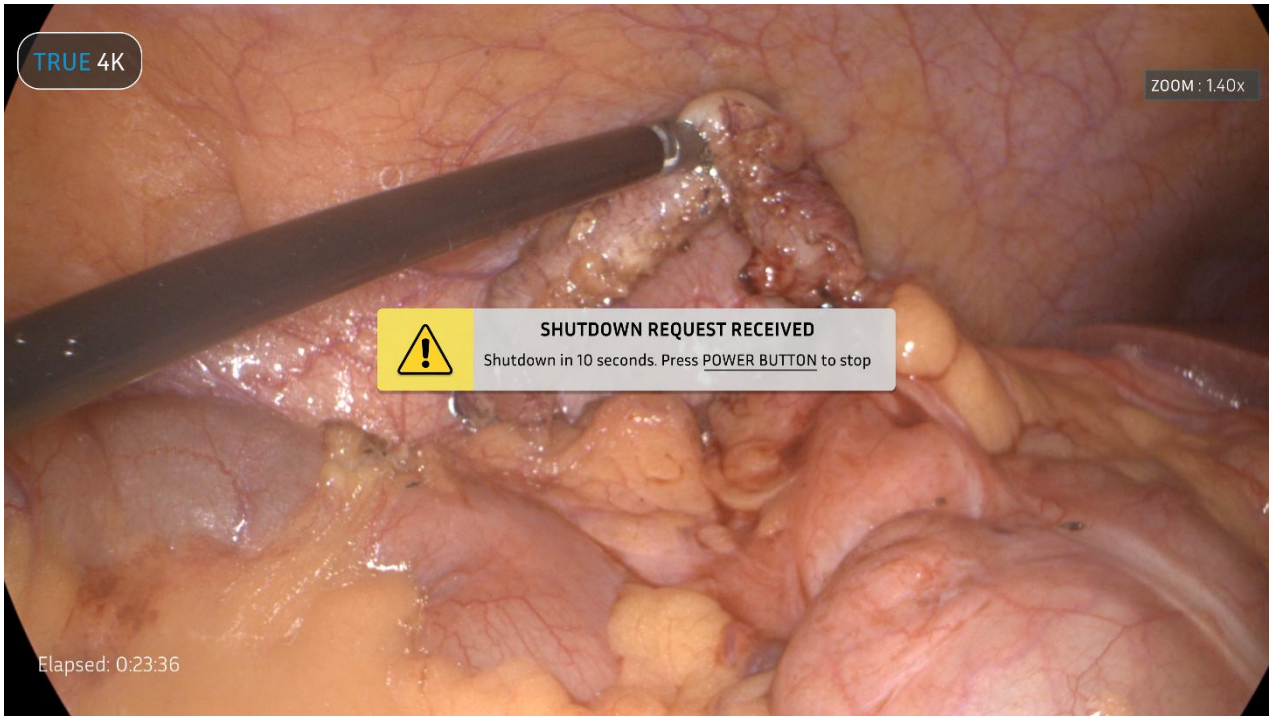


Fig 7.40: Shutdown Prompt (When the Power Button is pressed once)

- **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

Chapter 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 clean gauze or in warm distilled water. • Try changing the focus level using the Focussing Ring of the Camera Head based on the distance between the distal tip of the Rigid Laparoscope and the target tissue • Try setting the Enhancement Sensitivity in Preference Menu >> Camera Settings >> Preferences >> Enhancement >> Increase the Enhancement Sensitivity.
2.	Images appear grainy	• Try setting the Auto Exposure to On in Preference Menu >> Camera Settings >> Auto Exposure >> ON. • Try setting the True Vis+ to On in Preference Menu >> Camera Settings >> Preferences >> True EN^{+}>> ON • Try increasing the intensity of the white light illumination in the White Light Unit or Fusion Light Unit.
3.	Images appear excessively bright	• Try setting the Auto Exposure to On in Preference Menu >> Camera Settings >> Auto Exposure >> ON. Try changing the Target Auto Exposure Level by Short Pressing Up Arrow on the Camera Head. • Try decreasing the brightness parameter in Preference Menu>> Camera Settings >> Brightness
4.	Image appears too dark	• Try setting the Auto Exposure to On in Preference Menu >> Camera Settings >> Auto Exposure >> ON. • Try changing the Target Auto Exposure Level by Short Pressing Up Arrow on the Camera Head. • Try increasing the intensity of the white light illumination in the White Light Unit or Fusion Light Unit.
5.	Unable to differentiate between different types of tissues due to poor colour reproduction.	• Re-do the process of White Balance while focusing 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 Preference Menu >> Camera Settings >> Contrast

Sl. No.	Problem Scenario	Possible Solutions
		• Try to Reset View parameter in Preference Menu >> Reset View.
6.	Unable to switch to NIR Imaging Mode	• Try disconnecting and re-connecting the Light Unit Interconnect cable from the CCU to the FLU. • Verify the NIR Camera in Spin view software, this verification shall be done in Service mode • If not resolved Send the Camera head/FLU to the Irillic service centre.
7.	Power-on indicator is lit GREEN but there is no display on the monitor screen.	• Check if the monitor power cable is securely connected to the DC input port on the Monitor. • Check the connection of the video cable (DP Cable) from the Control Unit to Monitor. • After confirming the cable is connected, power off/on the display monitor once again. • Verify the selected ports (DP) in monitor setting with respected to connected cable • Verify the connected video cable is provided by irillic (Brand Shall be Honeywell)
8.	Fluorescence not visible/very faintly visible	• Verify ICG-dye has been injected as per clinical protocol. • Verify there is no warning related to NIR light source on the Main Display • Check if NIR-compatible Rigid Laparoscope is used. • Check the NIR laser intensity on the Light Unit. • Try increasing IR Sensitivity in System Settings >> Fluoro Settings >> Sensitivity
9.	External Storage Device is not getting detected	• Disconnect and Reconnect the Storage Device to another USB port and hit the Refresh Button. • Check the format of the Storage Device is NTFS. • Check that there is at least 5GB of free space is available on the Storage Device, if not Transfer the data to a customer's computer/Disk and free the space in disk
10.	Image Glitching due to cautery	• Verify that the head wire is not tangled with cautery wires • Ensure the cautery machine is not connected to the Trolley • Untangle cautery wires and use a separate power source
11.	Camera disconnected due to cauterisation interference	• In case the camera feed does not recover automatically, try disconnecting and reconnecting the Camera Head to the Camera Control Unit. • Place the system away from the device generating the interference. • In case the camera feed does not recover, restart the system.
12.	Buttons not working on the Camera Head	• Try disconnecting and reconnecting the Camera Head from the Camera Control Unit.
13.	Erroneous colour configuration parameters lead to poor visualisation	• Reset system colour configuration by going to Preferences Menu >> Reset View.

Sl. No.	Problem Scenario	Possible Solutions
14.	Freeze of touchscreen	• Turn off the system, wait for 30 sec and, turn it back on.
15.	No video picture when the camera head is plugged in	• Try checking if all devices in the system are plugged in and powered on. • Detach the Camera Head from the console and reconnect. • Verify the Camera in Pylon and Spin view software, this verification shall be done in Service mode.
16.	Dust Artifacts are visible on the Display.	• Follow Cleaning Instructions in Chapter 10 to clean the Rigid Laparoscope and the Camera Head. • Ensure the components are completely dry before using them to prevent any temporary fogging.
17.	Freeze / Non-responsive Main Display	• Reboot the system using the instructions in Chapter 7 => Settings Overview. • In case system does not reboot, Press and hold the power button for 5 seconds to force shutdown the CCU. Press the power button once again to power on the CCU.
18.	Mains Power Supply Issue	**A.** Check if mains power supply is turned on and the Light on the trolley switches is lit at on condition. **B.** Check if mains power supply voltage is 240 VAC using a digital multi-meter. If it's not resolved, then Change power supply.
19.	Electrical Failure of Trolley	Verify mains power supply functionality using Procedure **16.A** before proceeding further. Disconnect the CCU, Light Unit and monitor power supply. Turn on the mains power supply. **A.** Measure the AC voltage on trolley power supply box across Line and Neutral on the Trolley Non-Isolated power socket & Isolated Power socket using a digital multi meter. This should read 240 VAC. **B.** If point A has failed Remove the fuse from the rear of the Trolley and do a continuity check on the fuse. If the fuse has failed, then refer to Chapter 09 for fuse replacement.
20.	CCU/WLU/FLU Fuse Failure	Verify electrical functionality of the trolley using Procedure 16.B before proceeding further. Remove the fuse from the rear of the CCU/WLU/FLU and do a continuity check on the fuse. If the fuse has failed, then refer to Chapter 09 for fuse replacement.

Sl. No.	Problem Scenario	Possible Solutions
		A. Verify if CCU/WLU/FLU is powering on by clicking the power button in the front panel. If the green light does not show up on the power button, try switching off the mains power supply for 2 mins and try again. If there is still no response, then Send the CCU/WLU/FLU to the Irillic service center. B. If the CCU/WLU/FLU power button is powered on, the touch display UI should turn on. The software should be loaded within 120 seconds. If not, then Send the CCU/WLU/FLU to the Irillic service center.

Note: If this Troubleshooting section does not resolve the problem, please call Irillic for further assistance. Tel: +91-76249 73228, **Email:** service.irillic@motherson.com**.**

9

Chapter 9 - Maintenance

- **Only Irillic Authorised Personnel are allowed to perform maintenance on Irillic L.nm Laparoscopic Imaging System.**
- **Repairs and equipment modifications except fuse replacement should only be carried out by Irillic authorizsed personnel. Irillic disclaims any product liability or warranty responsibility for devices repaired by or obtained from third-party service providers.**

User initiated Maintenance

The user can do the following maintenance as needed:

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

Spare Fuses location - Trolley / CCU / WLU / FLU Fuses

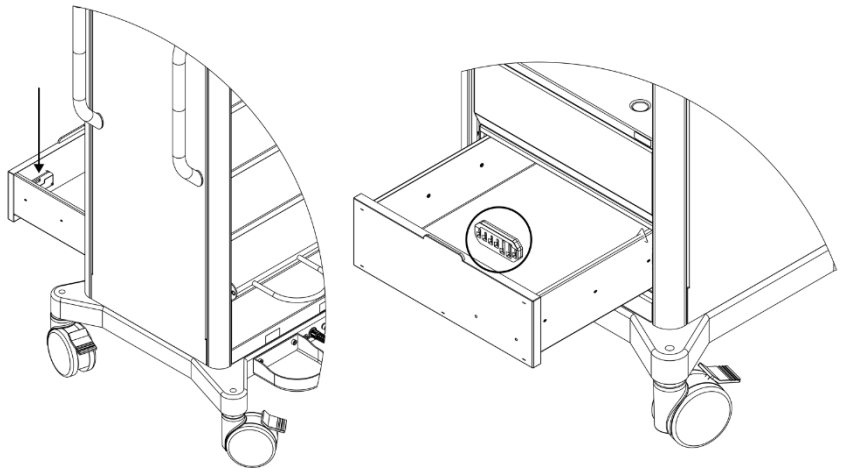


Fig 9.1 a: Location of Trolley/CCU/WLU/FLU spare Fuses

Spare fuses for Trolley, CCU, WLU/FLU are located inside the trolley drawer

1. Slide and open the trolley drawer
2. Lift the Spare fuses foam as shown in fig 9.1a
3. Refer the spare fuses info label on the spare fuses foam for fuse specifications

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 of the A/C Panel Input
3. Remove the existing fuse and dispose as per disposal instructions in Chapter 11.
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 a new spare fuse if needed
6. Push the rear cover of the A/C Panel Input back in place until you hear a click

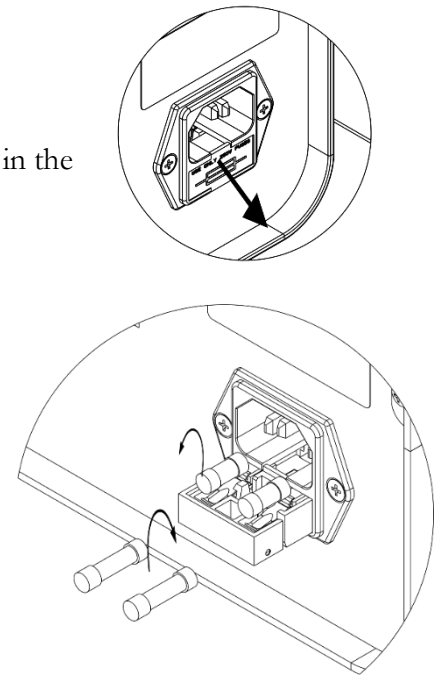


Fig 9.1 b: Replacing CCU/WLU/FLU Fuse

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 and / or Transformer Fuse

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

Steps to replace the fuse are given below:

1. The Main system Fuse is located at the bottom of the Trolley as shown in the image. (Marked as 1 and 2)
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.
6. Repeat the same process for the transformer fuse (Shown as 3)

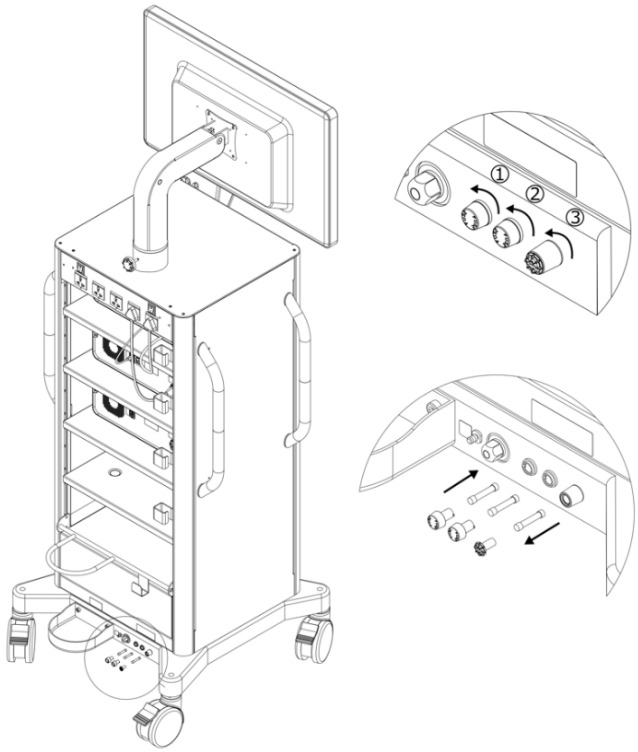


Fig 9.2: Replacing Main System and/or Transformer Fuse

Tilt and Swivel Friction Adjustment

While adjusting the monitor arm tilt movement, must hold the monitor to avoid any damage to the monitor.

Steps for Tilt Friction Adjustment:

- If the monitor does not tilt as expected, slightly tighten or loosen the Allen screw as shown in Fig 9.3: to adjust the monitor arm tilt movement

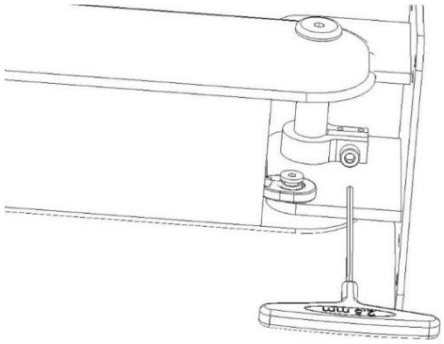


Fig 9.3a: Monitor arm bottom view

Steps for Swivel Friction Adjustment:

- Rotate the knob clockwise to increase the friction and anticlockwise to decrease the friction.
- The monitor arm should stay in place when the friction is increased and should not swivel when trolley is in motion.

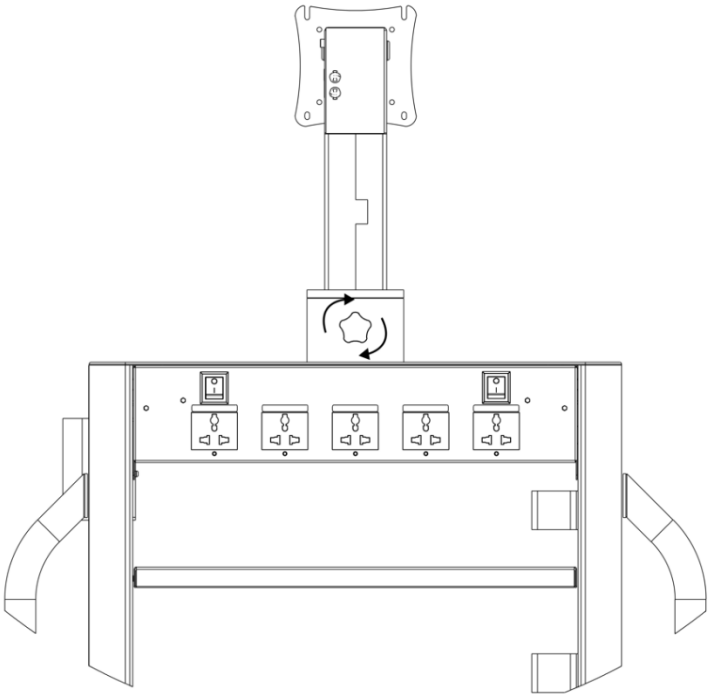


Fig 9.3b: Monitor arm Rear view

System Maintenance

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

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

Note: The maintenance schedule and terms are as per the maintenance contract agreed between the customer and Irillic. User personnel are required to perform certain activities as per the Preventive Maintenance Schedule shared at the time of installation.

10

Chapter 10 - Reprocessing Instructions

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

Cleaning the CCU / White Light Unit / Fusion Light Unit

Wipe the 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-White Camera Head / 4K-ICG Camera Head

Cleaning the Camera Head 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 Head 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 disinfectant solution[1] to the entire Camera Head
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 of drying, the Camera Head will be ready for use.
6. Camera head is non-autoclavable and must not be exposed to steam sterilization or autoclave cycles. Autoclaving can permanently damage the optics and internal electronics.
   Clean and disinfect only using approved wipe-down methods specified by the manufacturer.

- **Do NOT spray or splash the liquid; liquid entering the Camera Head 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.**

[1] Cleaning and disinfection of the Camera Head is validated using Sterillium® 2-Propanol, 1-Propanol Mecetronium Ethyl Sulphate Solution

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 sterilise the Light Guide before use, using Steam Sterilisation with an Autoclave before every procedure. Ensure that all precautions and processes described in the User Manual of the Light Guide are followed.
- Steam Sterilisation using an Autoclave can be performed for the Light Guide using demineralised feed water as per the following specifications:

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

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

- Always sterilise the Rigid Laparoscope before use, either using an Autoclave or other means of high-temperature sterilisation 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 are provided along with the device.
- Steam Sterilisation using an Autoclave can be performed for the Light Guide using demineralised 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 sterilisation 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 sterilisation process, failure to do so may lead to damage of the part and can affect the performance or lifetime of the Rigid Laparoscope.**

11

Chapter 11 - End of Life of the system

Service Life

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

Light Guide and Rigid Laparoscope are subject to user wear and tear and may require replacement before 5 years. For more information refer to the IFU of the Light Guide and Rigid Laparoscope.

Disposal

- This product contains electrical waste or electronic equipment. It must not be disposed of as unsorted municipal waste and must be collected separately per applicable national or institutional-related policies relating to obsolete electronic equipment.
- Dispose of the product packaging according to local regulations and hospital practices.

Appendix I - Technical Specifications

Imaging Sensor	CMOS Sensor
Imaging Modes	VIS Mode (4K Colour), AMVI Mode, ICG Mode [Multi-View Visualisation, Green Fusion IntelliQuant Visualisation, Picture-In-Picture Visualisation, Colour Fusion IntelliQuant Visualisation]
Additional Imaging Features	24 Axis - Colour Adjustment, True EN+
Video Output	Mode : 3840 x 2160 @ 60 Hz refresh rate Standard : 2 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
Input Voltage & Max Power Rating	240 V AC, 50 Hz, 1000VA(Max)
Fuse Ratings	Transformer: 250V, 5A (60 Minutes) Time-Lag, Breaking Capacity - 50A System: 250V, 10A (4Hr) Slow-Blow, Breaking Capacity - 10kA
Operating Condition	Temperature: +10 °C to +30 °C Relative Humidity: 20% to 70% (non-condensing) Atmospheric pressure: 700 - 1060 hPa
Storage condition	Temperature: +10 °C to +40 °C Relative Humidity: 20% to 70% (no condensing) Atmospheric pressure: 700 - 1060 hPa
Sterilization	Autoclave - Rigid Laparoscope & Light Guide Cleaning & Disinfection - Camera Head
Trolley - Dimensions, Net Weight	H 1950 x W 765 x D 745, 102 Kg
Camera Control Unit - Dimensions, Net Weight	H 160 x W 370 x D 374, 6.6 Kg
White Light Unit - Dimensions, Net Weight	H 160 x W 370 x D 374, 5.3 Kg
Fusion Light Unit - Dimensions, Net Weight	H 160 x W 370 x D 374, 7.5 Kg
4K White Camera Head - Dimensions, Net Weight	H 51.5 x W 62.5 x D 127 (without cable), 0.225 Kg
4K ICG Camera Head - Dimensions, Net Weight	H 53 x W 63 x D 135 (without cable), 0.250 Kg
System - Classification	Class I Medical-Electrical Equipment Rigid Laparoscope - Type BF Applied Part Ingress Protection, IP20
Contrast Agent for injection	ICG 25mg vial*
White Light Unit and Fusion Light Unit LED Specification	
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
Fusion Light Unit - Laser Specification	
Max Output Intensity	Below Class 3R Limit As per IEC 60825-1:2014
Wavelength	785 nm

* not provided with the system

Appendix II - Symbol Definitions

Packaging / Labeling

Main Product Label

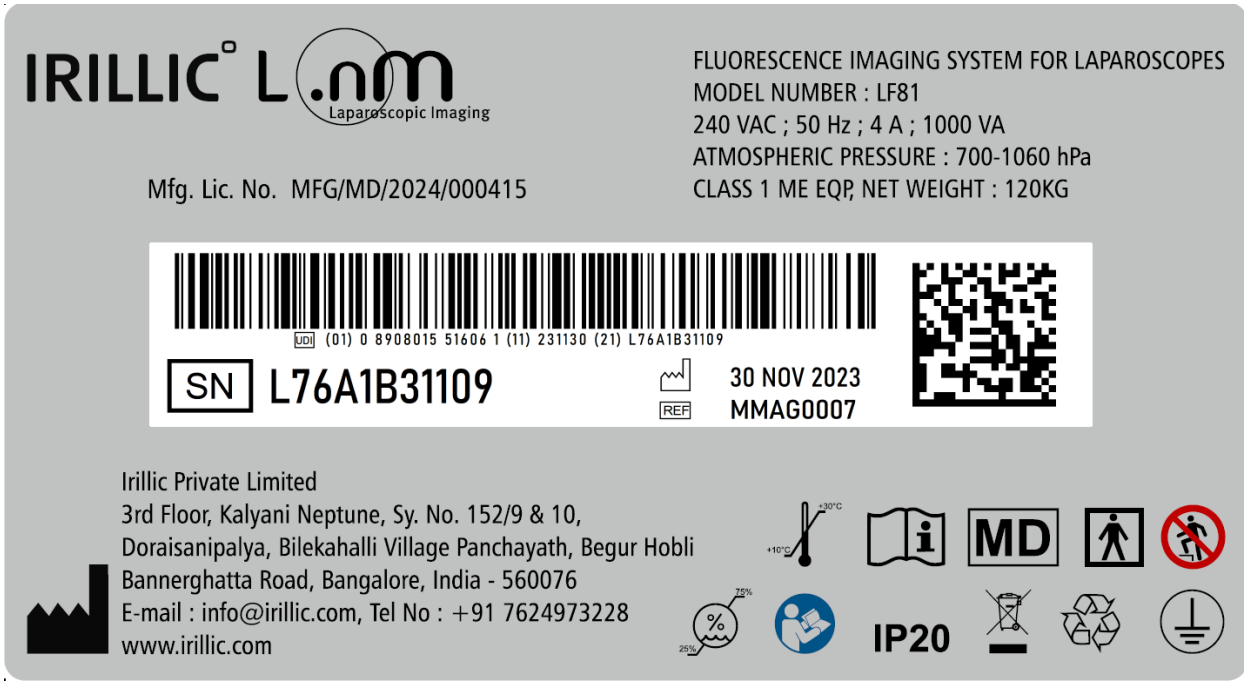


Fig 11.1: Main Product Label

Camera Control Unit Labels

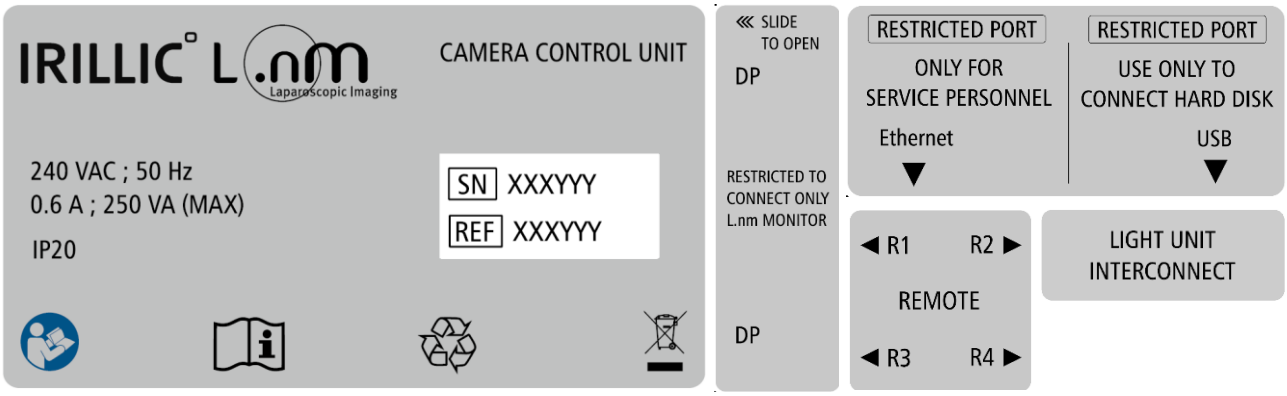


Fig 11.2: CCU Labels

White Light Unit Labels

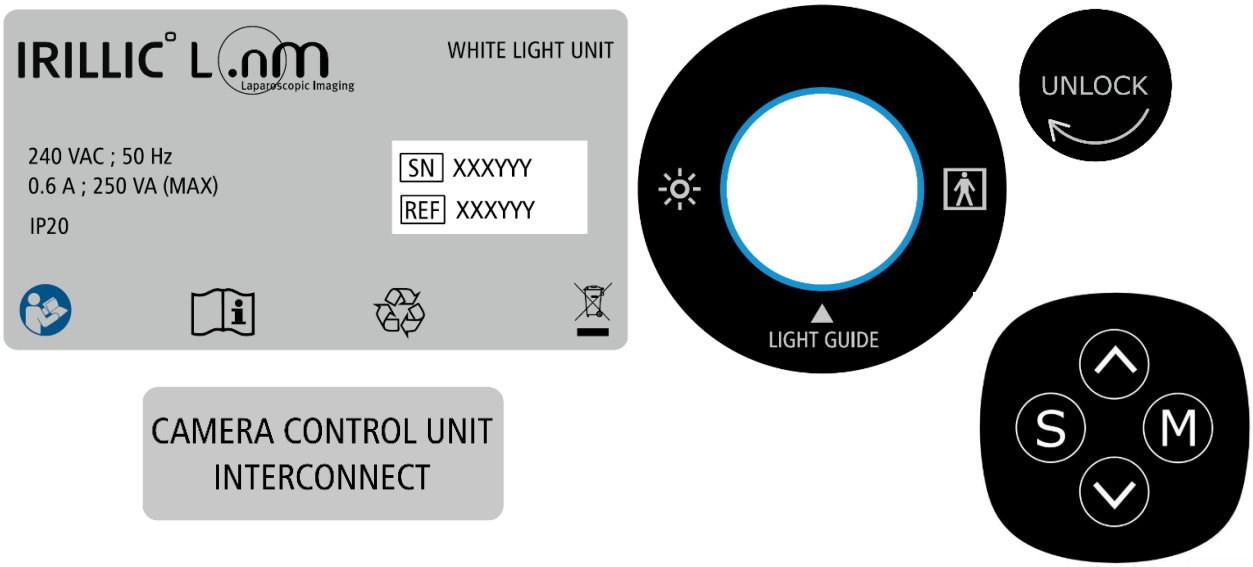


Fig 11.3: WLU Labels

Fusion Light Unit Labels

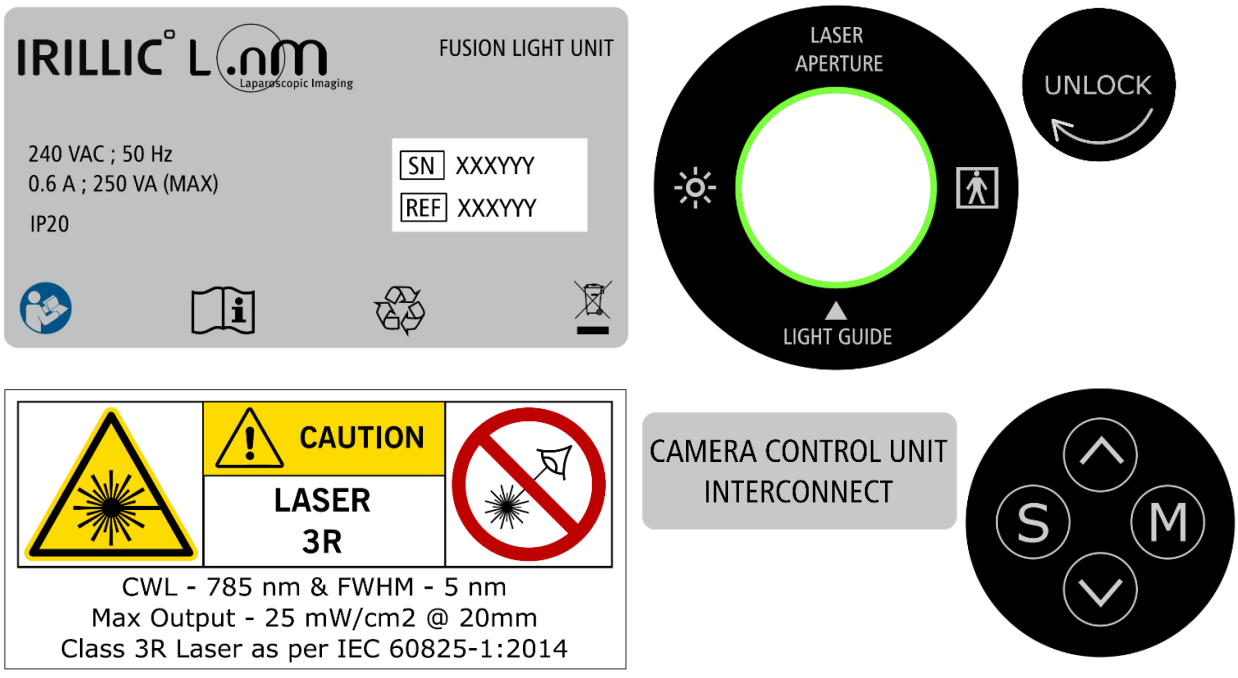


Fig 11.4: FLU Labels

Power Inlet Labels on CCU/WLU/FLU

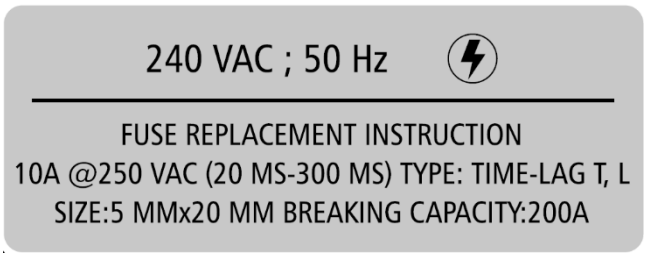


Fig 11.5: Power Inlet Labels

Trolley Labels

Fig 11.6: Trolley Labels

Monitor Labels

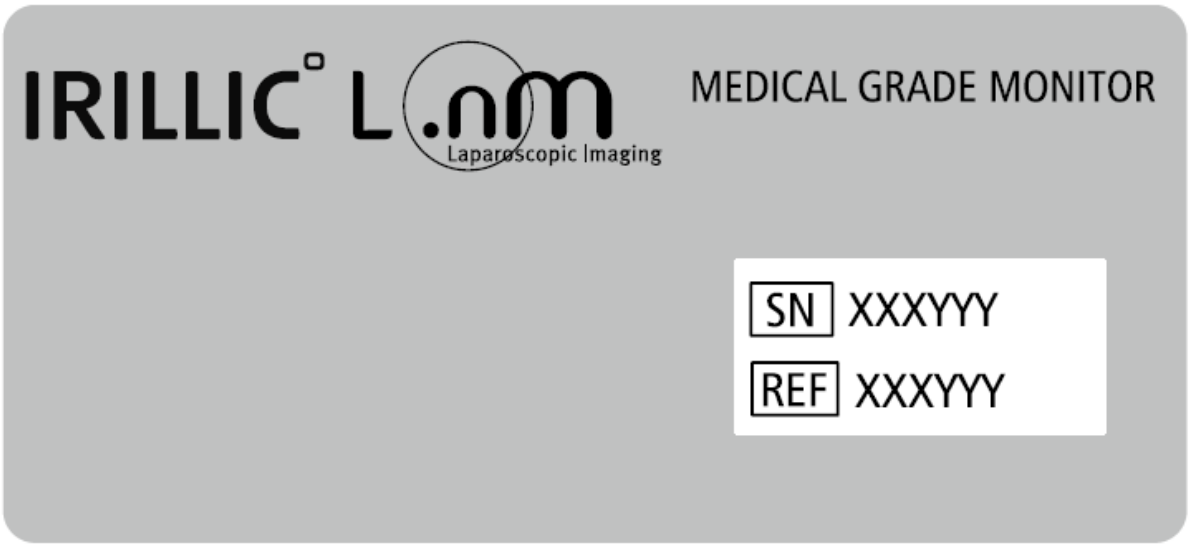
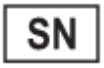
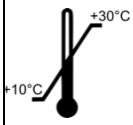
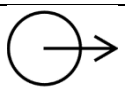
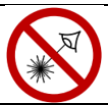
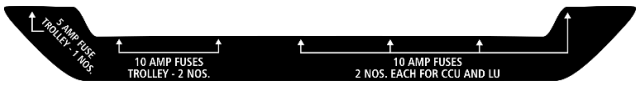


Fig 11.7: Monitor Label

Symbol Definitions

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

Symbol	Definition	Symbol	Definition
	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 the Operator's Manual before using the system		Non-Isolated power socket
	Isolated Power socket		Camera Head Holder Max Weight Label
	USB Socket		Warning: Visible White Light Radiation
	Conductor Earth (Ground)		Warning: Infrared Light Radiation
IP20	Ingress Protection Rating		Output Indication
MD	Medical Device		Do NOT look at the light source directly
	No Stepping On the Surface		Warning: Pinch Hazard

Symbol	Definition	Symbol	Definition
	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)
	Type BF applied part		High Voltage Indicator
	Reference Number		Illumination
	Shutter Unlock		Spare Fuses
		Spare Fuses Info Label	

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 per the EMC information provided in this document.
- Portable and mobile RF communications equipment can affect the behaviour 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 L.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 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 - Ordering Information

S No	Description	Part Number
1	4K White Light Laparoscopic Imaging System with 32" Medical Grade Monitor	MMAG0018
2	4K White Light Laparoscopic Imaging System with 32" Premium Medical Grade Monitor	MMAI0011
3	4K NIR / ICG Laparoscopic Imaging System with 32" Medical Grade Monitor	MMAI0010
4	4K NIR / ICG Laparoscopic Imaging System with 32" Premium Medical Grade Monitor	MMAI0012
5	Light Guide	BOXF0002
6	Rigid Laparoscope - 4K ICG 30 degree, 10 mm	BOFF0001
7	2 TB Storage Device	BXXG0001

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