IRILLIC

.nm Fluorescence Imaging

Irillic .nm Fluorescence Imaging System

Operator's Manual

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FOR AUTHORIZED PERSONNEL ONLY

Please follow the safety precautions in Chapter 6 of this manual in order to avoid personal injury or damage to system during use.

Copyright Information

Conventions Used

This section describes the conventions used in this manual.

⚠ CAUTION and ⚠ WARNING	Indicates that the instructions for use contain important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
*	This symbol indicates a mandatory field in the User Interface. Example: Date Of Birth *
Bold Text	Buttons and fields are indicated in **Bold** text. Example: The user can update only **Full Name**, and **Study Notes** and click on **Save**.
Menu Item	Screen and section titles are indicated in grey highlights. Example: The **Study Management** screen lists all the existing patient details.

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TERMINOLOGY

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

Term	Description
IGU	This is the technical name for the Probe used in scanning. Any references to IGU imply Probe.
APU	This is the technical name for the Control unit that is used to control the Probe and associated processing. Any references to APU imply Control Unit.
ICG	Indo Cyanine Green contrast agent is a safe organic dye used on patients for various applications along with the 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 Monitor Display unit.

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1. Introduction

Irillic .nm Fluorescence Imaging System captures and displays in real-time NIR fluorescence images obtained in-vivo with Indocyanine Green contrast enhancement during surgery. The range of potential applications include:

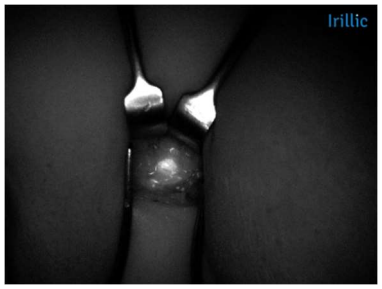
- Sentinel Lymph Node Biopsy
- Lymphatic mapping and
- Lymphatic micro surgery assistance
- Flap perfusion assessment
- Vascular Perfusion assessment
- Perfusion assessment in Wound Management

This new modality of fluorescence imaging opens up wide probable application areas where Irillic .nm Fluorescence Imaging System can be used, applying the principle of its operation in other applications such as Tumour Margin Assessment, Parathyroid Applications at the discretion of the physician.

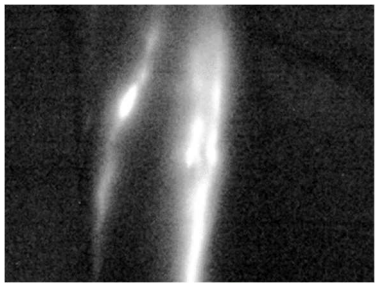
Features

- Setup & Use in < 3 minutes
- Real-time visualization
- Store & Playback videos and images
- Augmented Colour view
- Image and study export

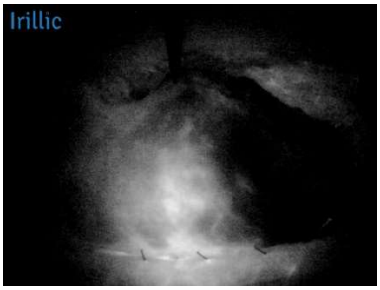
Fig 1.1: Irillic .nm system



Sentinel Lymph Node Mapping



Lymphatic Screening



Flap Perfusion Assessment

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2. Prerequisites

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

Environment

- Air Conditioning is recommended for the room/site where system will be used. System must always be operated within the specified operating temperature range ($15^{O}C$ – $40^{O}C$) and specified humidity range (20% - 70% non-condensing).

Power

- 230V AC UPS-connected power 3-pin sockets (at least two sockets) to allow for un-interrupted use of the system. A clean (surge-protected) power source (230V AC, 50Hz) is critical for system stability. The system is rated for 120VA; UPS with 1KVA (or higher) capacity is therefore recommended.

- If using Extension Boards for the power sockets, the Irillic .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.

Lighting

- While using Irillic .nm system, it is important to block any sunlight in the operating area. It is recommended to have easy-to-operate dark window blinds for all windows in the operating area.

- While using Irillic .nm system, overhead lights must be preferably switched OFF. It is recommended to have easy-to-operate ON/OFF mechanism for such overhead lights. If there is a high amount of background light in the images captured by the Probe, then the overhead lights must be switched OFF to get better fluorescence images.

- Further, ALL surgical lights must be switched OFF during system usage. It is recommended to have easy-to-operate ON/OFF mechanism for such surgical lights.

Network connectivity

- For certain features, remote troubleshooting and remote software update will require internet connectivity using Ethernet Port.

Authorized users

Only trained users are authorized to operate the equipment for scanning. Such users of the system are required to be trained on or experienced with:

a) Use of Fluorescence Imaging modality for specified application(s) and
b) Operating Irillic .nm system.

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

For reviewing recorded cases, system can be used by all customer authorized personnel after familiarizing themselves with the information in this operating manual.

Storage and handling

System should not be exposed to chemicals and liquids at any time; users are required to follow the instructions listed in the Chapter "Cleaning Instructions" for cleaning purposes.

When system is in a storage area, it is advisable to exercise caution in ensuring the Probe cable is properly coiled and/or storing the Probe separately in a safe area/safe box.

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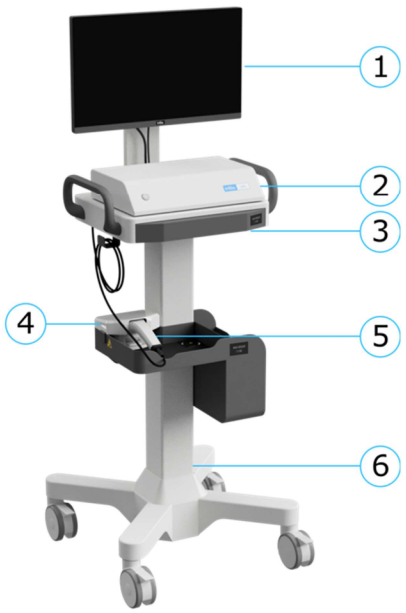
3. System Overview



1. Display Monitor
2. Control Unit (APU)
3. Keyboard (with touchpad)
4. Secure Probe Holder
5. Probe (IGU)
6. Trolley (Mobile Cart)

Fig 3.1: Irillic .nm system

- The Trolley is used to move the system within building premises. The front wheels of the trolley have brake locks that can be used to prevent inadvertent movements of the system either during operations or during storage.
- The Probe (also referred to as IGU) is the handheld part of the system to be used during scanning. The Probe is freely movable and is only constrained by the physical length of the cable from the Probe to the rest of the system.
- The Keyboard slides out from its storage position during operations. It has an integrated touch pad for both click and scroll functions.
- Control Unit (also referred to as APU) is used to control the Probe, the Display and the rest of the operations.
- Monitor is used to display all the system activities and status indications.

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

Control Unit (APU) Front Panel

1. Power button
2. Power indicator

Fig 3.2: Control Unit Front Panel

Fig 3.3: Power Indicator on Control Unit

Power Button:

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

Power Indicator

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

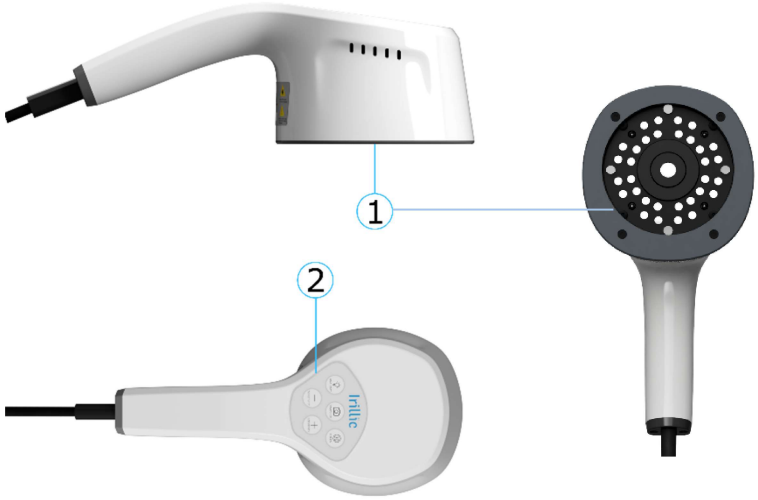
Control Unit (APU) Rear Panel

Fig 3.4: Control Unit Rear Panel

3. 230V AC Power Receptacle for connection to Power. A fuse holder (with a second spare fuse) is located below the receptacle.
4. IGU Port for connection to Probe (IGU)
5. RJ-45 Ethernet Port for network connection
6. Display Port / HDMI port for connection to Monitor

When connecting the Probe to the Control Unit's IGU Port, verify that the system is powered OFF. Connecting Probe when system is already powered ON may result in damage to the system.

Probe (IGU)



1. Scan window / Emission aperture
2. Probe button panel

Fig 3.5: Probe Side View, Top View, and Front View

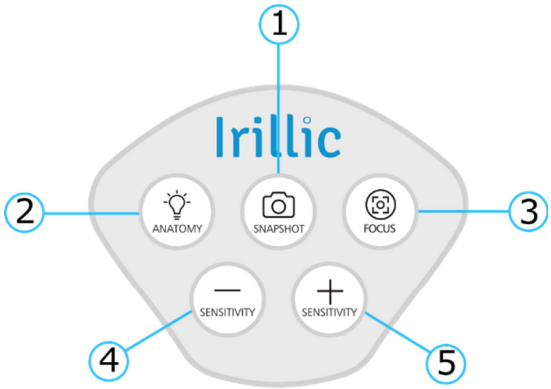


Fig 3.6: Probe button panel

1. In Scan mode, use SNAPSHOT button from the Probe to capture a still image. It can be used irrespective of whether Recording is in progress or not.

   In Gallery mode and Standby Mode use SNAPSHOT button to resume to Scan mode.

2. Anatomy Light (on the probe) is used to visualize the surrounding anatomy. Use this button to switch On/Off the Anatomy light as needed. By default, Anatomy light is always On.

3. The FOCUS button is used to toggle between pre-set working distance focus 10cm and 25cm.

4. "-" is used to decrease Sensitivity setting (Levels 5 to 1).

5. "+" is used to increase Sensitivity setting (Levels 1 to 5).

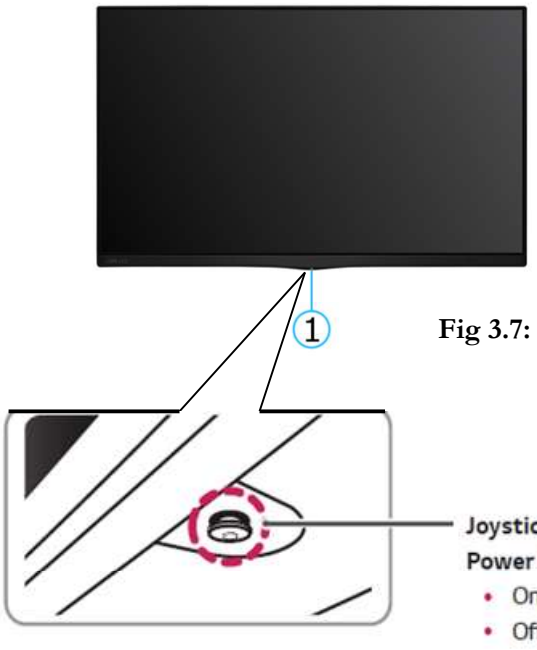
All of these controls are also available via the User Interface seen on the monitor.

Optical Characteristics of Fluorescence Illumination:

Nominal Spectral Irradiance:	2 mW/cm^2 @ 250mm Working Distance
Maximum Output:	5 mW/cm^2 @ 100mm Working Distance
Central Wavelength:	760nm
Full Width-Half Max:	48nm

Irillic .nm is classified as per IEC 62471:2006 as falling under "Risk Exempt Group" and is compliant to IEC 60601-2-57:2011.

Monitor



1. Monitor Power On/Off joystick button. When powered on, an LED indicator is also turned on.

Fig 3.7: Display Monitor and joystick button

	Power On. Press the joystick button once with your finger to switch on monitor.
	Power Off. Press and hold joystick button to switch off monitor.

Keyboard

Fig 3.8: Keyboard with Touchpad

1. Touchpad Point & Move; Point and slide one finger anywhere on the touchpad to move the screen pointer.
2. Left Mouse Click
3. Right Mouse Click

- **In the unlikely event that certain gloves make it impossible to use the touchpad, use the keyboard shortcuts and probe buttons**

Trolley

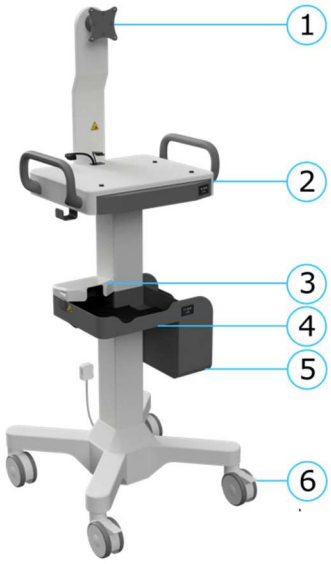


Fig 3.9: Trolley Front View

1. Monitor Mount
2. Keyboard and Control Unit mount
3. Secure Probe Holder
4. Tray holder for items such as ICG and Drape
5. Tray holder for Probe
6. Trolley Wheels with brake

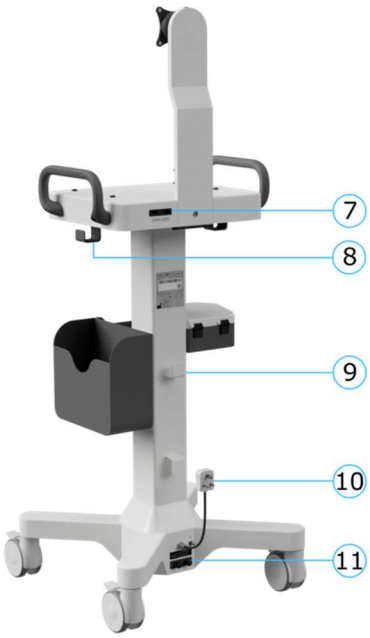
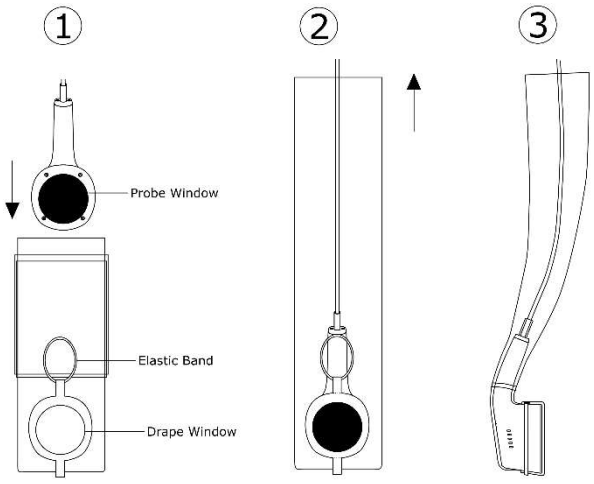


Fig 3.10: Trolley Rear View

7. USB Data Ports for connecting removable storage drives (used during Export).
8. Cable hook used to wrap excess cable lengths of the Probe cable
9. Cable hooks used to wrap excess cable lengths of the Power cord
10. Non-detachable Power Plug for connecting to 230V AC mains power socket (coming from a UPS)
11. Main System Fuse

Consumables (Sterile Drape):

The probe must be used at all times with a Sterile Drape that is specially designed for this purpose. Follow the procedure given below to wrap the probe with the supplied sterile drape:



1. Open the drape from its sterile packing. Holding the Probe handle, gently guide the Probe into the drape opening.
2. Holding the Probe cable let it gently glide into the drape until the Drape window and the Probe window are aligned on top of each other.
3. Use the attached elastic band to secure the drape and prevent it from shifting.

Fig 3.11: Wrapping Probe with a Sterile Drape

- **Do not put hands inside the drape to avoid contaminating the probe.**
- **Drape is sterilized by means of Ethylene Oxide (EO) Sterilization.**
- **Do not use if the packaging is damaged or if any contaminants are visible in the packaging.**
- **Sterile Drape is for single use only. Do not re-use.**
- **Do not re-sterilize.**

- **Avoid direct skin contact with the Sterile Drape to ensure no harm from any form of contamination.**
- **Physician or User shall wear medical grade compatible gloves during the usage of the device to prevent contamination and biological risks. The usage instrcutions of medical gloves shall be followed as per the glove's manufacturer's instructions.**

Essential Performance:

The essential performance of the Irillic .nm system is to capture and display fluorescence information on the monitor display attached to the trolley.

Excessive electro-magnetic disturbances above and beyond the limits described in the Annexure III – Electromagnetic Compatibility (EMC) Compliance may lead to loss in visualisation of fluorescence information on the monitor display.

In case of such disruption, please refer to Chapter 6 – Safety Information & Precautions of this manual, and ensure all the warnings in the subsection entitled EMC are adhered to.

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4. Installation and Connections

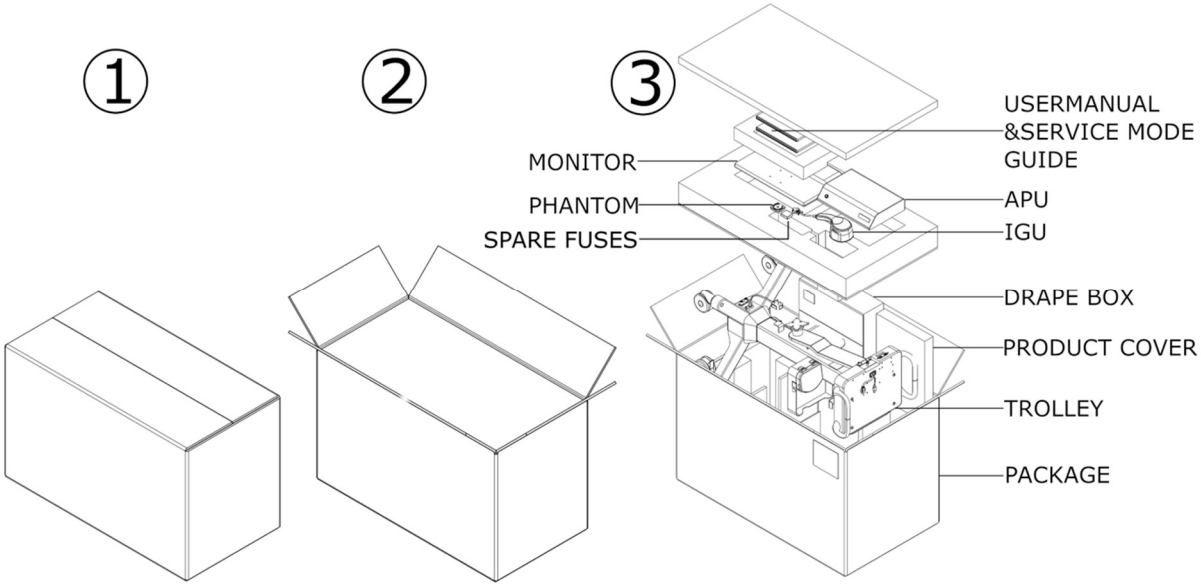
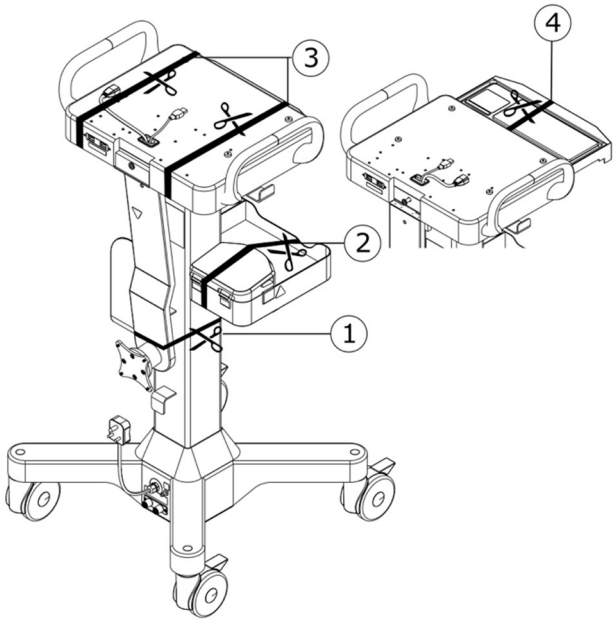


Fig 4.1: Removing system from Package

Remove all the items from the package carefully; set aside the package for future use (for example, in case of return for repair). Upon removal, the trolley unit must be placed upright with its wheels on firm flooring.



Remove all restraint cables or tapes before proceeding further with installation.

Fig 4.2: Removing restraint cables

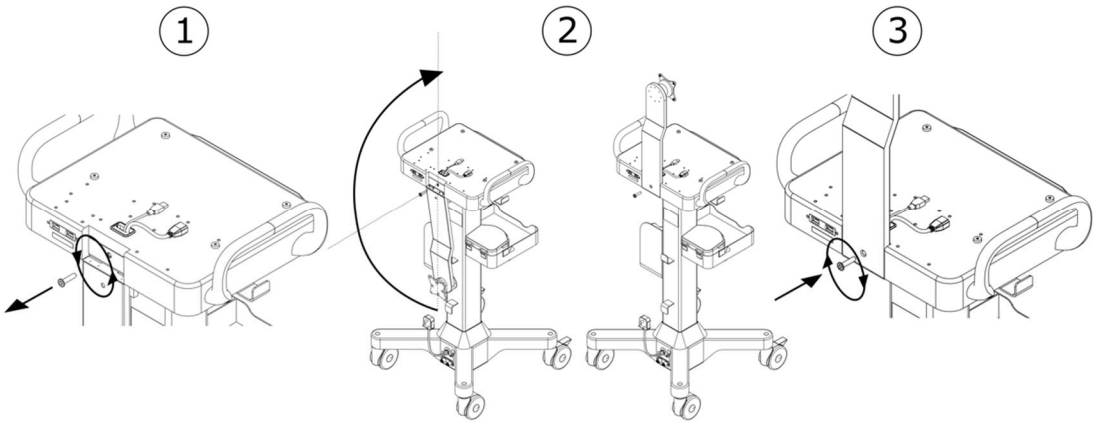


Fig 4.3: Assembling Trolley and Pillar

Remove screw to unlock the monitor-mount pillar from its storage-lock position. Position it as shown in the figure above and secure it in place with the screw that was removed earlier. Now the pillar is ready for mounting the display monitor.

Warning: Pinch hazard exists when the monitor-mount pillar is moved into the locking position.

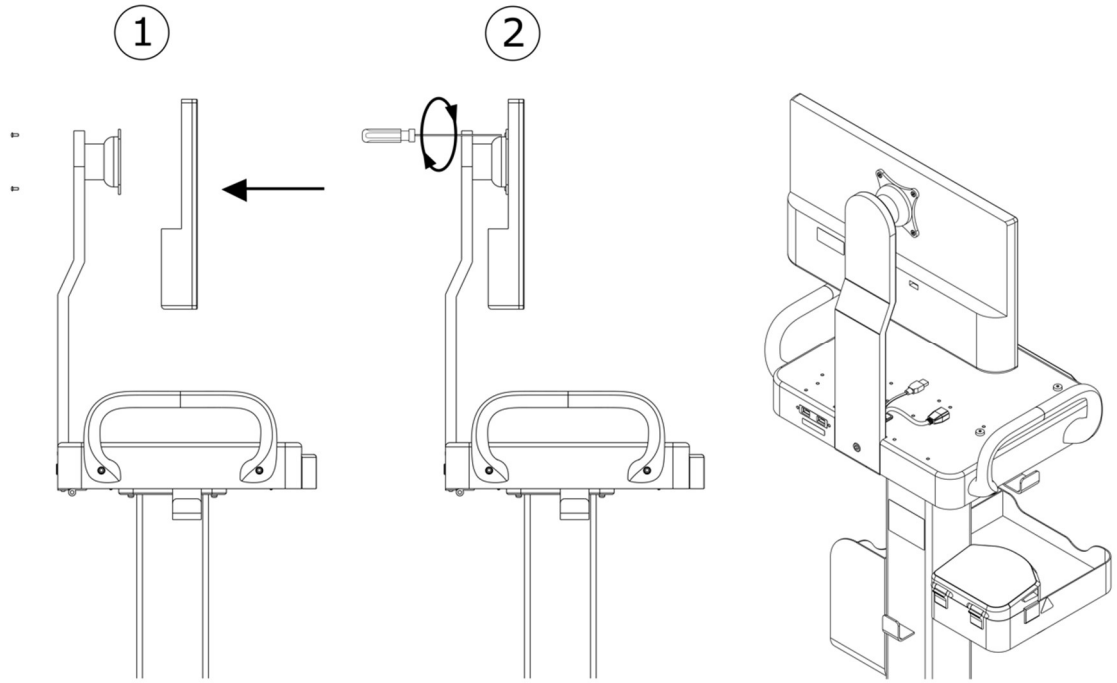


Fig 4.4: Assembling of the Monitor

Secure the display monitor on the mount as shown in the above figure. It is important to secure both the monitor-pillar and the monitor tightly to avoid injury to personnel. Now, the system is ready for mounting the Control Unit (APU).

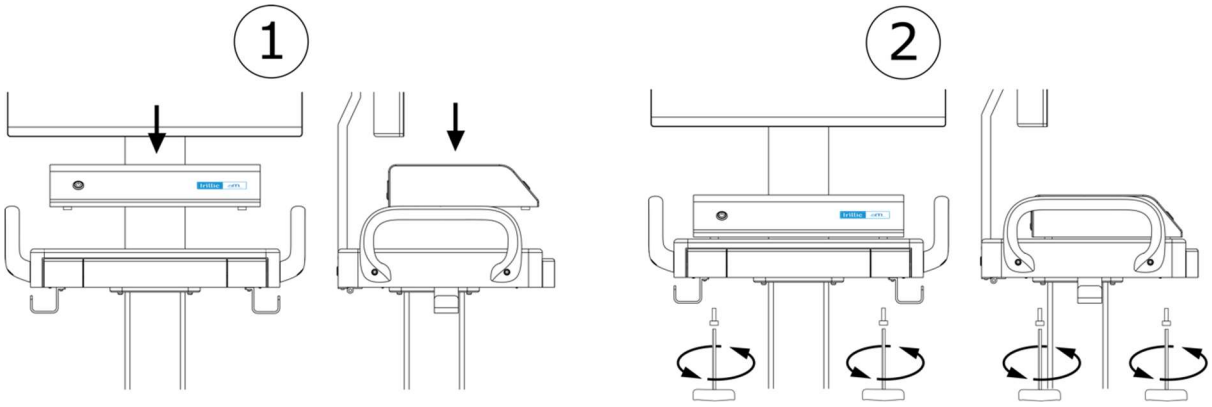


Fig 4.5: Assembling the rest of the system

Place the Control Unit on the flat trolley tray as shown in the figure above. Use the supplied screws to secure the Control Unit from beneath as shown in the above figure. Now the system is ready for wiring the various connections.

Connections during installation

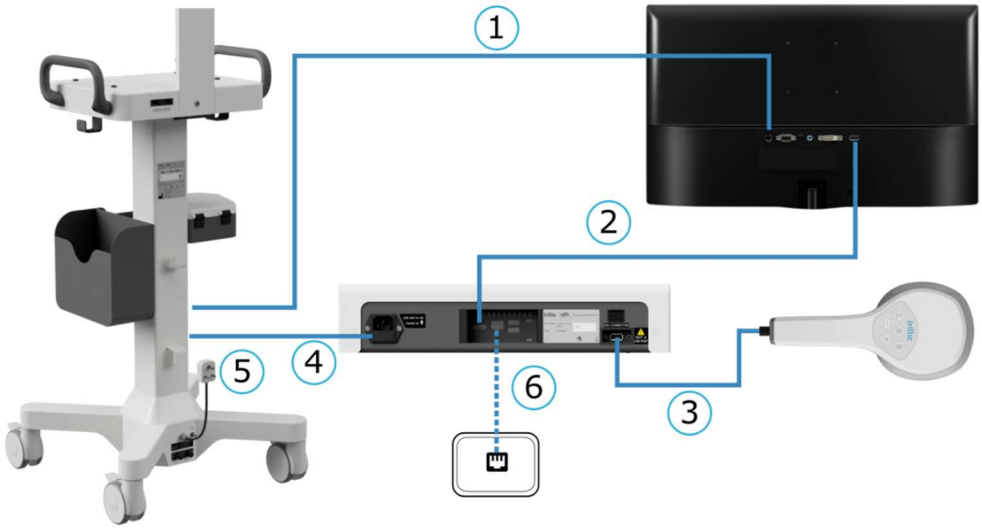


Fig 4.6: Connection diagram during installation

When installing the system for the first time, the wiring connections are depicted in the figure above. These are:

1. Connect monitor DC-power input port to the corresponding power adapter cable coming from the trolley.
2. Connect monitor HDMI port to the Display Port/HDMI port on the Control Unit.
3. Connect Probe to the IGU port on the Control Unit.
4. Connect Control Unit power to the APU power cable coming from the trolley.
5. Plug system into a 230V AC socket.
6. Optional, Ethernet Port for remote software update.??

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

Connections during normal usage

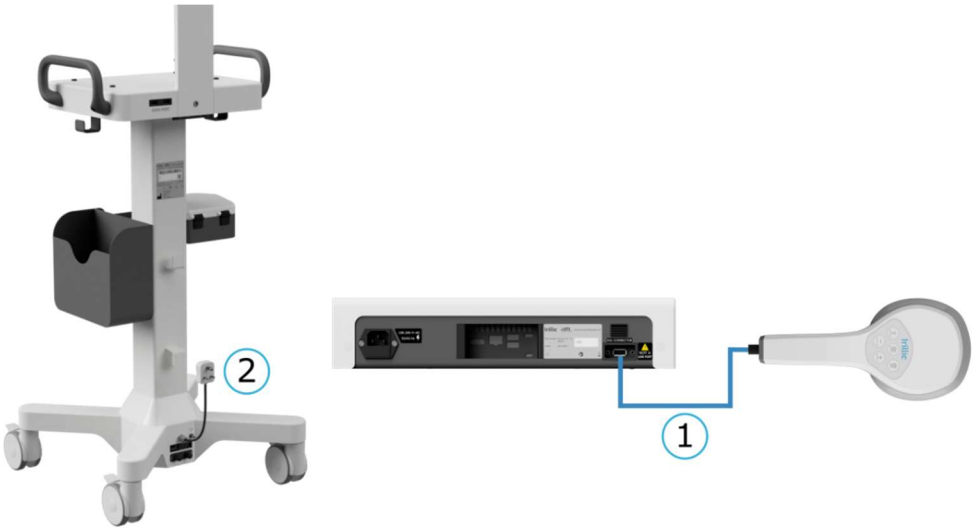


Fig 4.7: Connection diagram during normal use

Post installation, when bringing the system from storage area into operating environment, the wiring connections are depicted in the figure above. These are:

1. Connect Probe to the IGU port on the Control Unit.
2. Plug system into a 230V AC socket.

Use UPS powered 230V AC sockets to allow un-interrupted operation of the system.

When connecting the Probe to the Control Unit, verify that the system is powered OFF. Connecting Probe when system is already powered ON may result in damage to the system.

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

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5. Intended Use

Irillic .nm Fluorescence Imaging System is used adjunctively for the visualization and assessment of fluorescent images of blood flow, tissue perfusion, and lymphatic flow during surgical procedures and/or any non-surgical investigations of various anatomical structures of adults and pediatric patients one month of age and older.

The system is to be used under the direction of a physician.

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

Intended Patient Population:

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

Overweighut or obese patients with high BMI may present challenges in the visualization of fluorescence due to inability of the signal to penetrate to the required depths.

Patient Selection Criteria:

All patients where the use of the injectable dye Indocyanine Green is acceptable as deemed by the clinician are eligible to have the device used on them.

Patients who are undergoing surgical procedures or out-patient diagnostics where fluorescence imaging for purposes of navigation, visualization, or assessment is indicated as per the Intended Use of the device, can be selected to have the device used on them.

Special attention to be given to the contraindications of the injectable dye Indocyanine Green prior to administering to any patients

Indications of Use:

Irillic .nm Fluorescence Imaging System is indicated for use during sentinel lymph node biopsy during breast cancer surgery for the purpose of visualization of lymphatic channels and lymphatic nodes using fluorescence generated by the subdermal injection of Indocyanine Green dye.

Irillic .nm Fluorescence Imaging System is also indicated for use during lymphedema screening procedures for the purpose of visualization of lymphatic vessels in order to assist the user in assessing the extent of lymphedema using fluorescence generated by the subdermal injection of Indocyanine Green dye.

Irillic .nm Fluorescence Imaging System is also indicated for use during flap reconstruction plastic surgery for the purpose of visualization and assessment of blood flow and tissue perfusion using fluorescence generated by the intravenous injection of Indocyanine Green dye.

Irillic .nm Fluorescence Imaging System is also indicated for use during thyroid and parathyroid surgeries for the purpose of visualization and assessment of the autofluorescence generated by the parathyroid gland without the use of Indocyanine Green dye.

Contraindications:

Irillic .nm Fluorescence Imaging System has no known contraindications.

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

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

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

6. Safety Information and Precautions

CAUTION	
General	1. Only authorised personnel who are familiar with the correct procedures for operating and using the equipment should operate the Irillic .nm system after completion of Application Training by Irillic.
	2. Information obtained through the use of the system should be used in combination with other clinically relevant information when planning alternative or added interventions.
	3. Before using the system, verify that the mobile cart wheels are in locked position.
	4. When moving the mobile cart, use only the handles for grasping.
	5. The system can be used only within the specified operating temperature range ($15^{O}C$ – $40^{O}C$); failure to do so may lead to incorrect results and in extreme cases, damage to the system. 
	6. Usage of system beyond it's operating life leading to loss of some fluorescence imaging functions.

WARNING	
Electro-Magnetic Compatiblity	1. The system is classified as a Class I ME Equipment as per IEC 60601-1:2012 and is to be used in professional healthcare environments.
	2. Other devices which emit 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. Stacking of other equipment on our system or placing other equipment too close to our system may interfere with the operation of our system and should be avoided.
	5. Environment in which system is used should adhere to the EMC compliance table as described in Annexure III to avoid interference with the correct operation of our system.

WARNING	
Probe (IGU)	1. The Probe (and the rest of the system) can be used only within the specified operating temperature range (15^{O}C – 40^{O}C); failure to do so may lead to incorrect results and in extreme cases, damage to the system. 
	2. The product emits Infra Red radiation. Avoid direct eye exposure. 
	3. The product emits Infra Red radiation. Avoid irradiating the skin for a long period of time. 
	4. The system is designed to be used with the probe positioned 10cm – 30cm from the patient; do not make direct contact with the patient.
	5. Do not attempt to repair or open the system; servicing is to be done by authorized personnel only
	6. Device is not sterile; use the Probe only with a sterile drape.
	7. Always turn off power before connecting/disconnecting Probe to/from the Control Unit.
	8. Avoid use of alcohol based solvents for cleaning; use ethanol- or isopropanol-dampened soft cloth or cotton pad for cleaning the IGU external surface.

CAUTION	
Control Unit (APU)	1. When connecting the Probe to the Control Unit, verify that the connecting cable is fastened with screws on the Control Unit end.
	2. Do not attempt to repair or open the system; servicing is to be done by authorized personnel only
	3. Always turn off power before connecting/disconnecting cable(s) to the Control Unit.

CAUTION	
Mobile Cart (Trolley)	1. Before using the system, verify that the mobile cart wheels are in locked position.
	2. When moving the mobile cart, use only the handles for grasping.
	3. When moving the mobile cart, verify that the wheels are in un-locked position and the Probe is docked in its holder.
	4. Do not attempt to repair or open the system; servicing is to be done by authorized personnel only.

WARNING	
ICG (Indo Cyanine Green)	1. ICG vial is a single-use kit; any prepared solution remaining after each procedure must be discarded. 
	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, Composition, Indications, contra-indications, interaction with other drugs, warnings & precautions, toxicity & side-effects and storage considerations.

WARNING	
Sterile Drape 	1. The Sterile Drape supplied with the system (or separately) is intended for single use only. DO NOT RE-STERILIZE OR REUSE. 
	2. In order to prevent contamination of the probe, the Probe MUST be wrapped in a Sterile Drape before using it on a subject.
	3. Avoid direct skin contact with the Sterile Drape after removing it from the packaging.
	4. Ensure compliance to all local, regional, and national regulation during disposal after use.

Residual Risk

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

- Leakage of fluorescence excitation light into the camera feed
- Liquid spilling or spraying onto the APU
- Liquid spilling or spraying onto the IGU
- Patient, operator, or user, tripping on the IGU cable
- Incorrect imaging setting leading to loss of visualization of fluorescence
- Incorrect anatomy illumination settings leading to misinterpretation by the user
- Drape optical window and probe optical window misaligned
- Incorrect deployment of the drape leading to reflections and subsequent misinterpretation by user
- Weld failure leading to a hazarduous event

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

7

7. Operating the Irillic .nm system

Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure

Overview of User Interface

Scan Acquisition mode

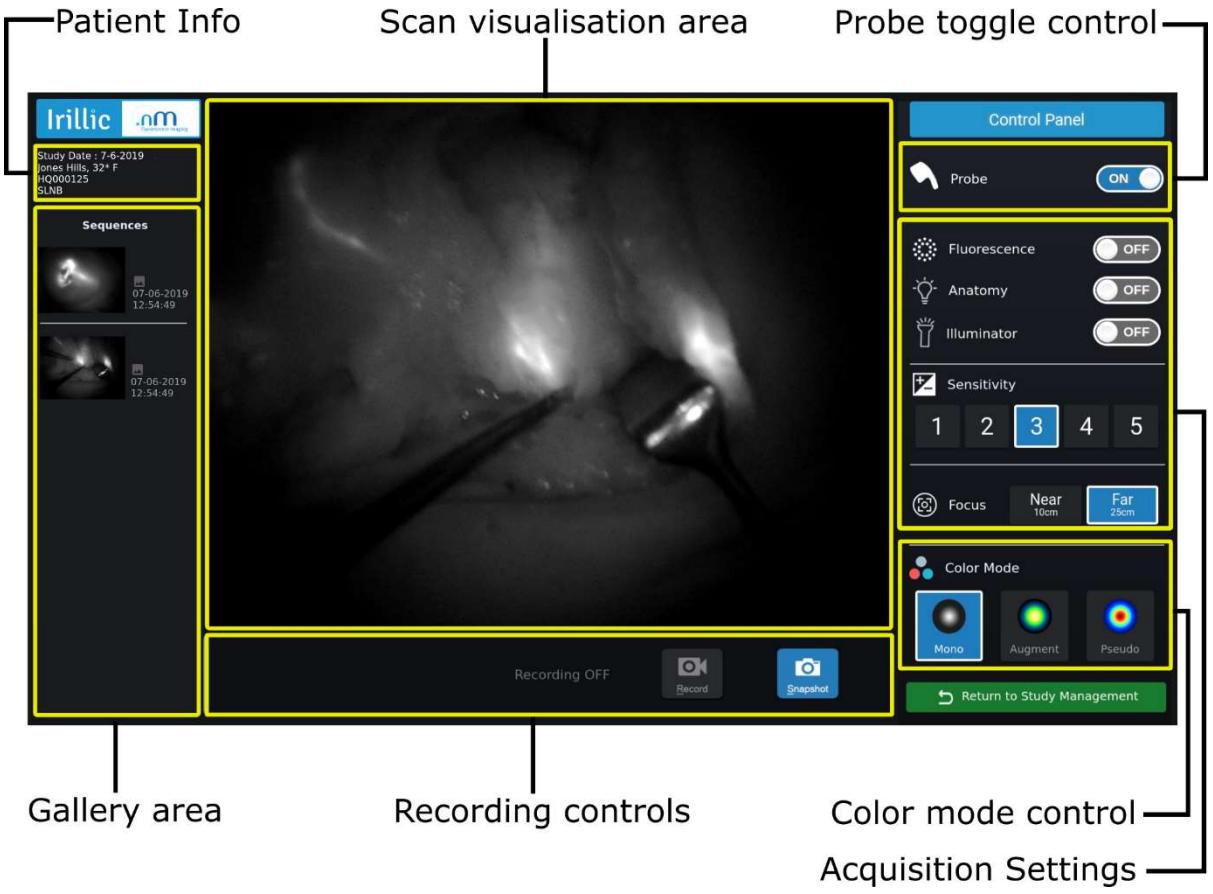


Fig 7.1: Scan Acquisition User Interface

Review Gallery mode

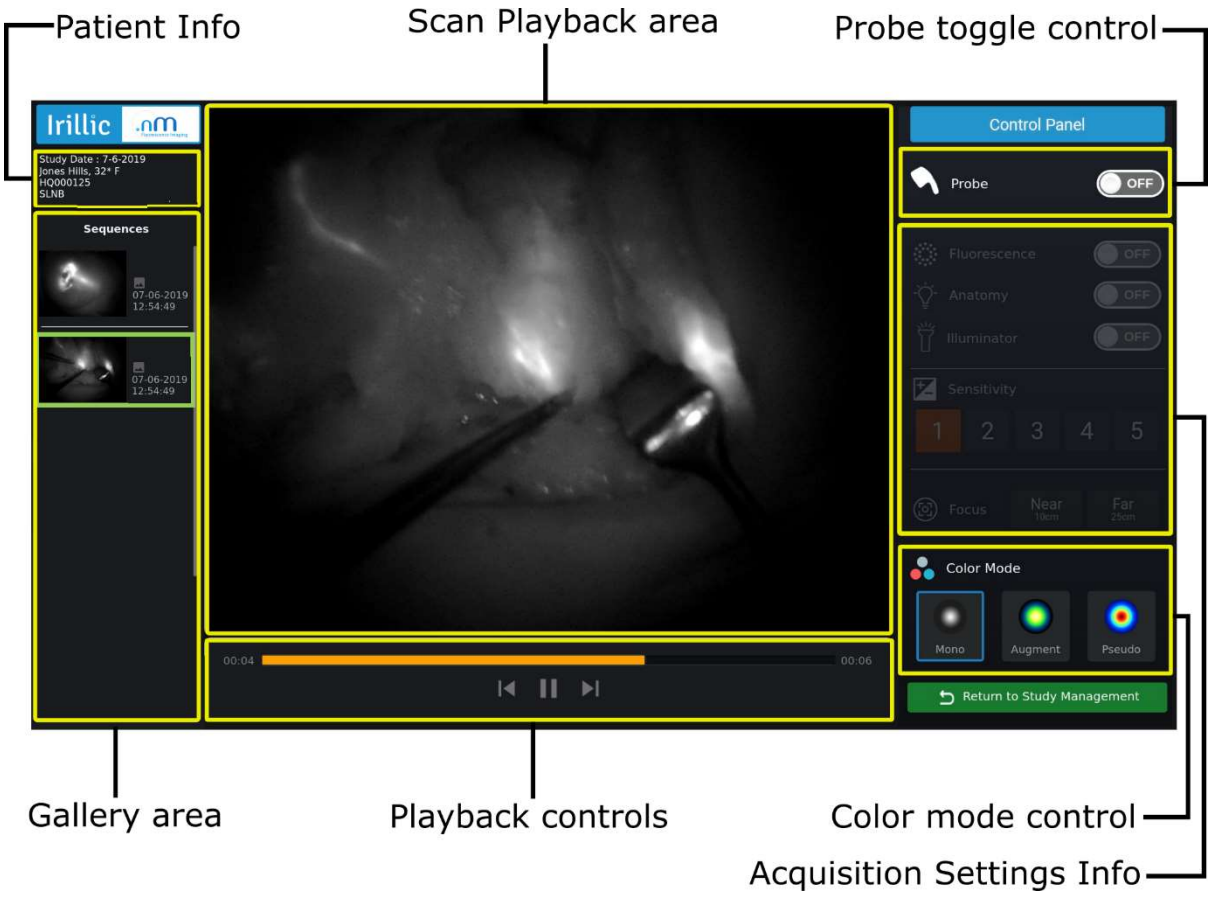


Fig 7.2: Review Gallery User Interface

Powering on the System

- Press the power button (power status indicator turns GREEN) to initiate system start-up
- Wait until the Study Management screen is displayed

Fig 7.3: Power ON indicators

Typical Operating workflow

Once the system boots up, the Study Management screen is displayed. Following are example steps to be performed during normal usage of the system.

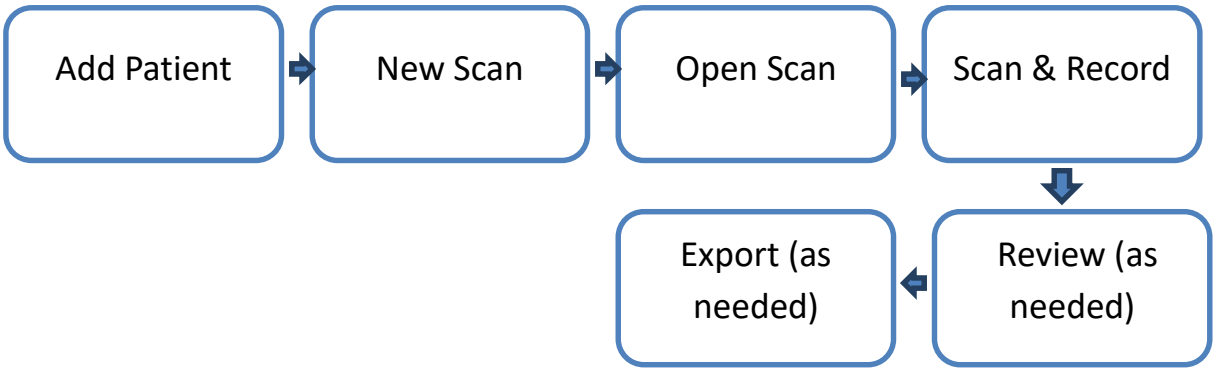


Fig 7.4: Typical operating workflow after powering on system

Study Management

1. Enter Patient Details in Study Management section using **Add Patient** and click **Save**.
2. The newly created study is shown selected in the Patient Details section. From the Scan Details section click **New Scan** to add information related to the visit.
3. Open Scan to start scanning.

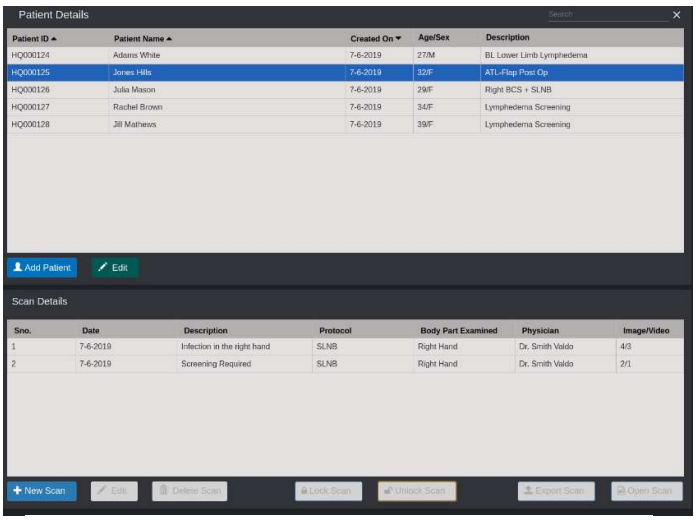


Fig 7.5: Study Management System

ICG injection

4. Inject ICG dye as per protocol

Scanning & Recording

5. Scanning can now be initiated any time by using the Probe
6. If needed adjust Acquisition Settings to obtain desired visualization
7. If needed adjust Focus (based on working distance) to obtain proper focus
8. Record scan videos or images using Record or Snapshot
9. Periodically (typically, every 5 minutes of non usage) system will temporarily switch to Standby mode; follow on-screen instructions to resume scanning again.

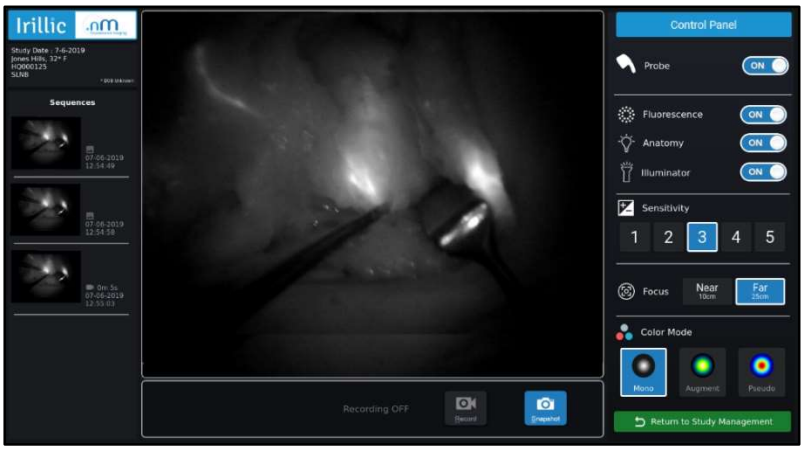


Fig 7.6: Scanning & Recording

10. Once the procedure is complete, user can return to Study Management using Return to Study Management

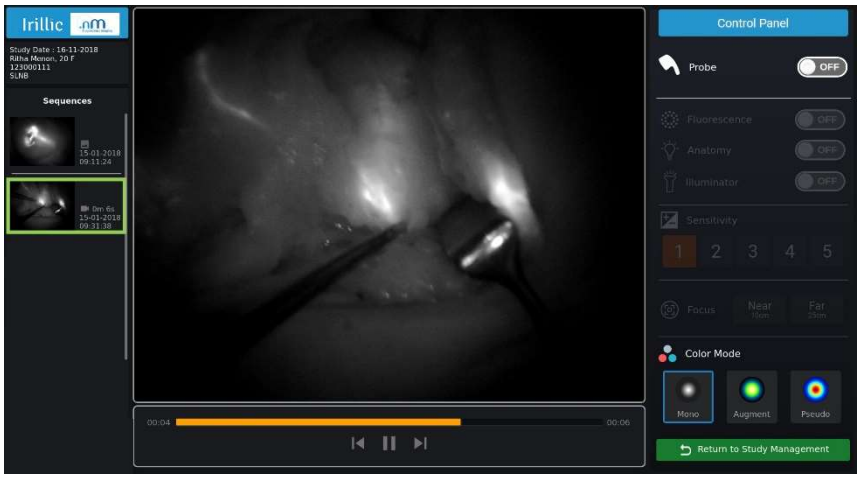


Fig 7.7: Reviewing Gallery

Reviewing

11. Review of the captured scan videos or images can be done anytime by clicking on the left Sequences panel (Review Gallery mode)
12. Users can switch between Scanning mode and Gallery mode as often as needed

Export to a removable Drive (Optional)

13. Review of the captured scans on a different computer can be done anytime by following this step; attach a removable drive to the available USB data port and Export the desired study.

Remove the attached drive after export is completed.

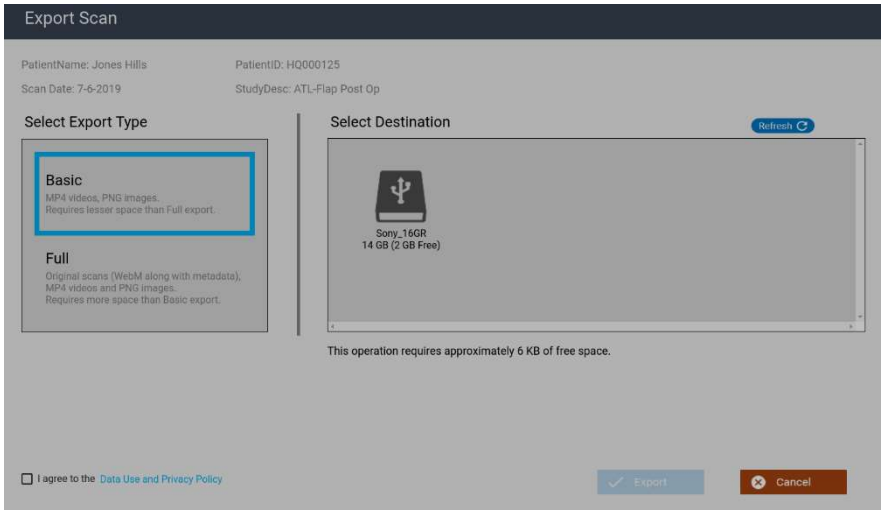


Fig 7.8: Exporting Scan Details

Shutdown

14. From the Study Management screen, click **Shutdown** to turn off the system.

Study Management System

In the Study Management screen, you can view all the existing patient records and perform the following actions:

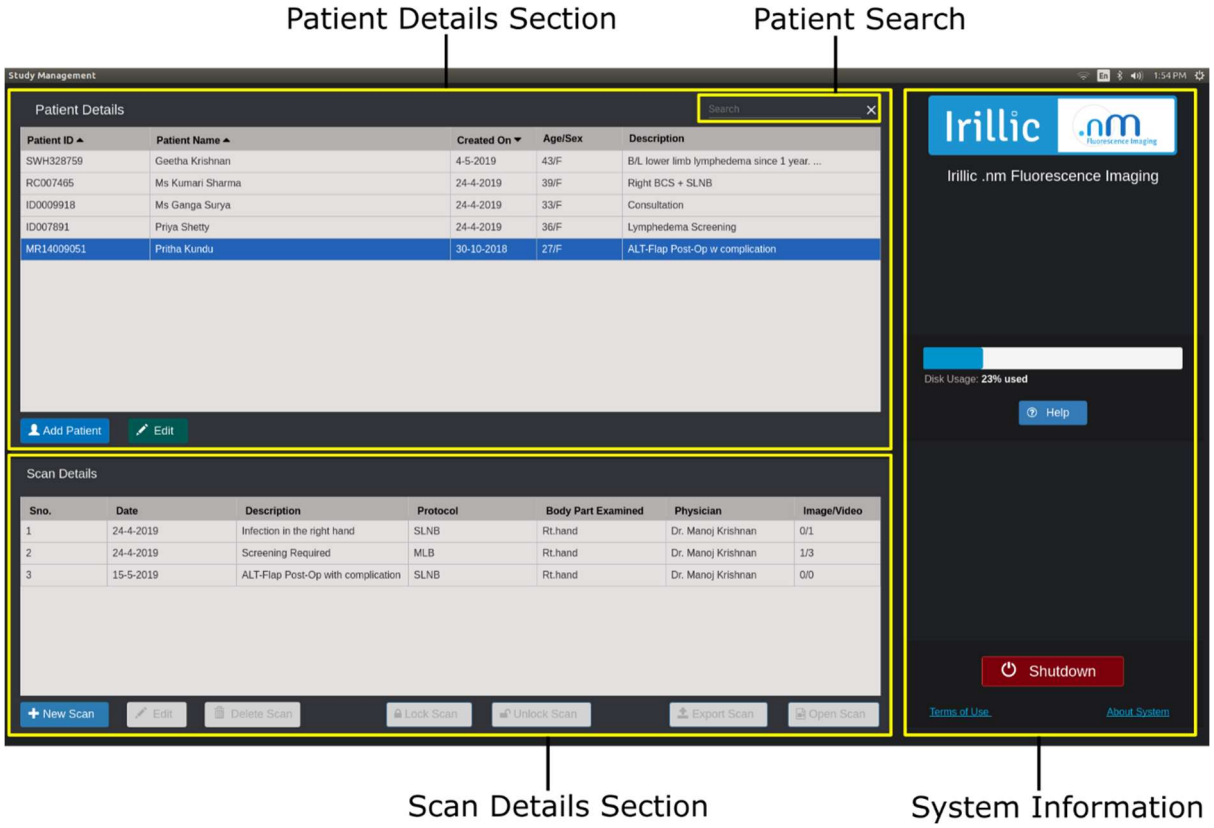


Fig 7.9: Study Management Screen

Patient Information:

- Add Patient details
- View Existing Patient Details
- Edit Patient details

Scanning and Review

- Add New Scan
- View existing Scans
- Edit Scan details
- Export Scan
- Delete Scan
- Lock / Unlock Scan

Add Patient Details

This feature is used when a patient is scanned for the first time.

To add a new study, click **Add Patient** in the Study Management screen.

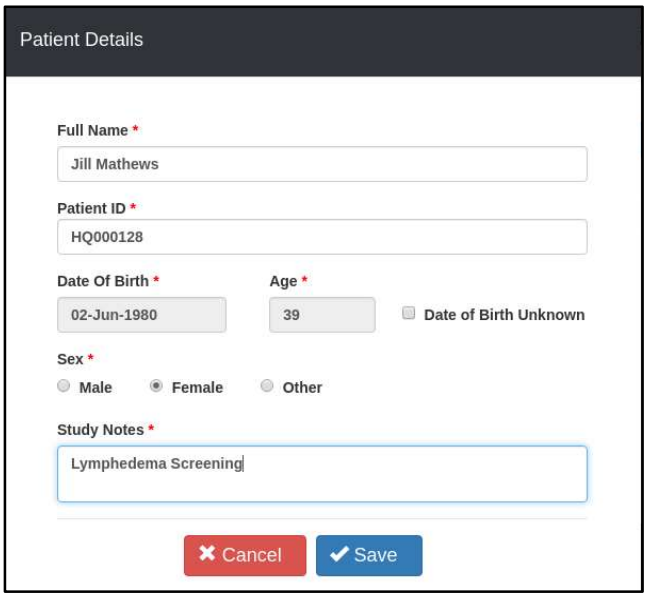


Fig 7.10: Add Patient Details

In the Patient Detail screen, enter Patient's **Full Name**, **Patient ID**, **Date of Birth** or **Age**, **Gender** and **Study Notes** of the procedure.

After the correct details have been entered, click S**ave** to initiate the study. Once saved users cannot edit **Patient ID** and **Date of Birth / Age**. The new study will be added to the study list and appears as the selected study in the list of studies.

The system is now ready for scanning & recording.

View Patient Details

The Study Management screen lists all the existing patient details. Users can search on Patient Name, Patient ID and Protocal to quickly shortlist the desired study.

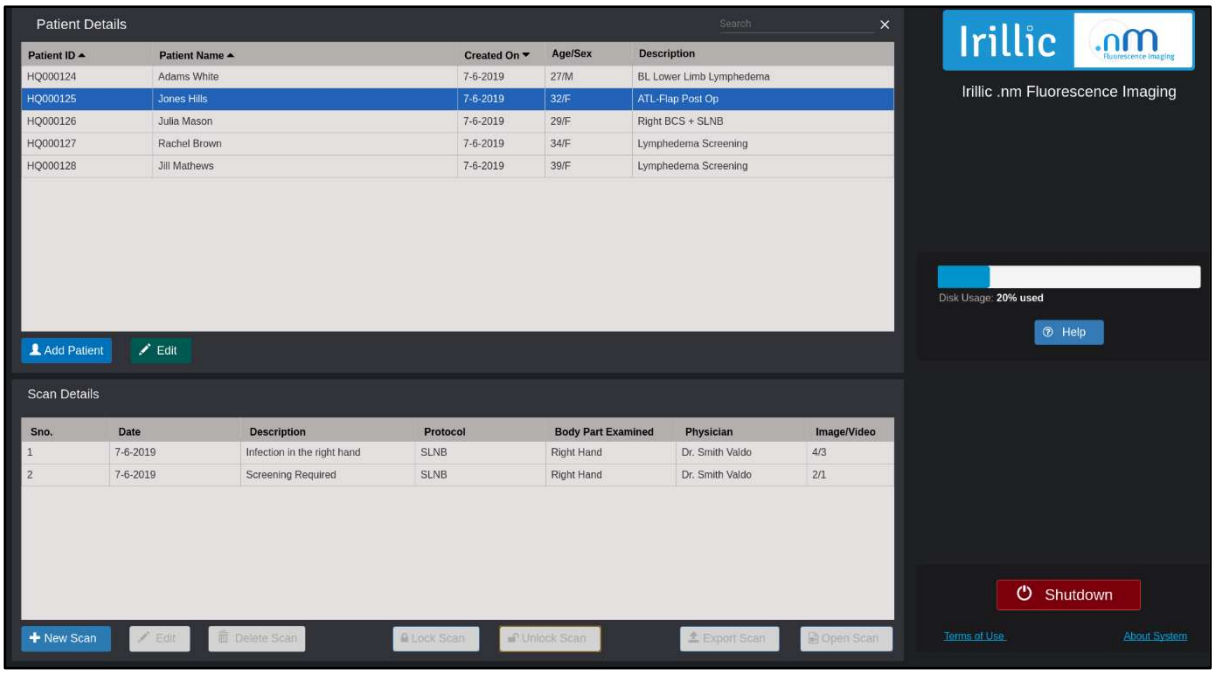


Fig 7.11: View all existing Patient Details

Edit Existing Patient Details

For existing patients, in addition to reviewing or adding new scans, it is also possible to edit a previously saved study.

Select desired study from the Patient Details section and click **Edit**.

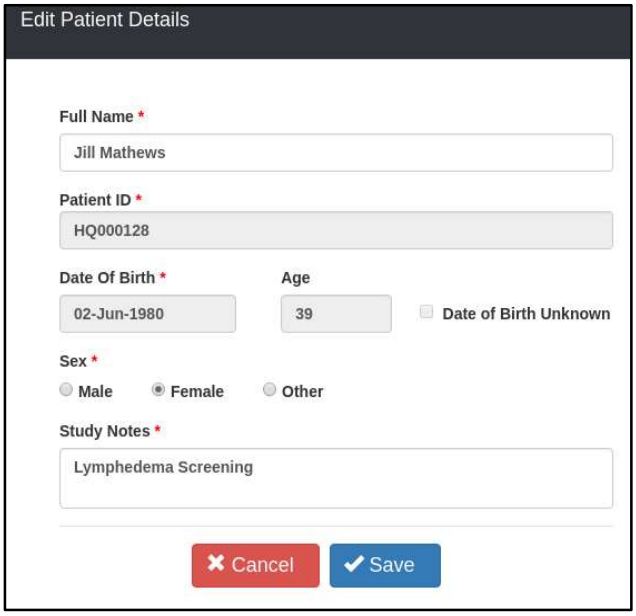


Fig 7.12: Edit Patient Details

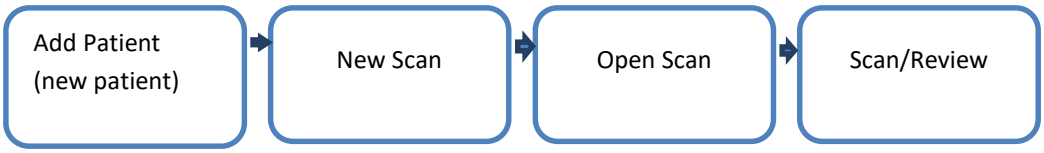
The user can update only **Full Name**, **Sex** and **Study Notes** and click on **Save**.

Only users authorized by the hospital should edit patient details. Exercise caution when making any changes to existing records; changes cannot be reverted once they are saved.

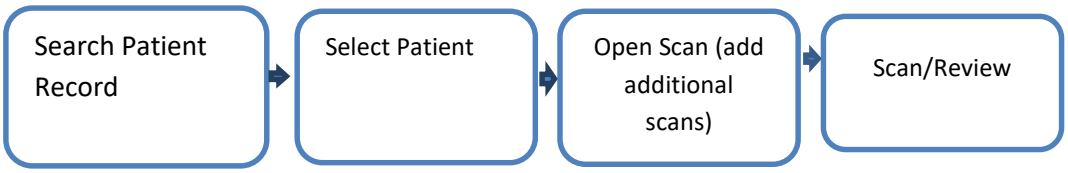
Scan workflow

The following are different scan scenarios:

For new patients scan record:



For existing patient within the same visit, add scan records:



For patient revisit, add new scan records:

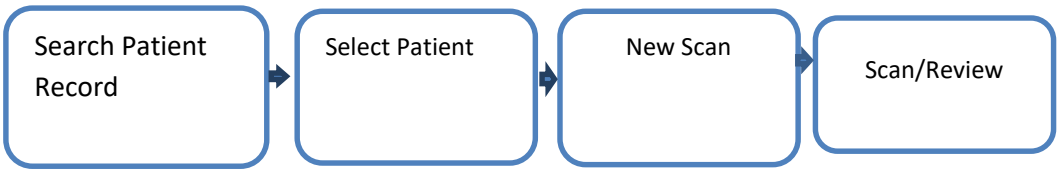


Fig 7.13: Patient Scan Scenarios

Add Scan Details

To add a new scan, select the desired patient record from the Study Management screen and click **New Scan** in the Scan Details section.

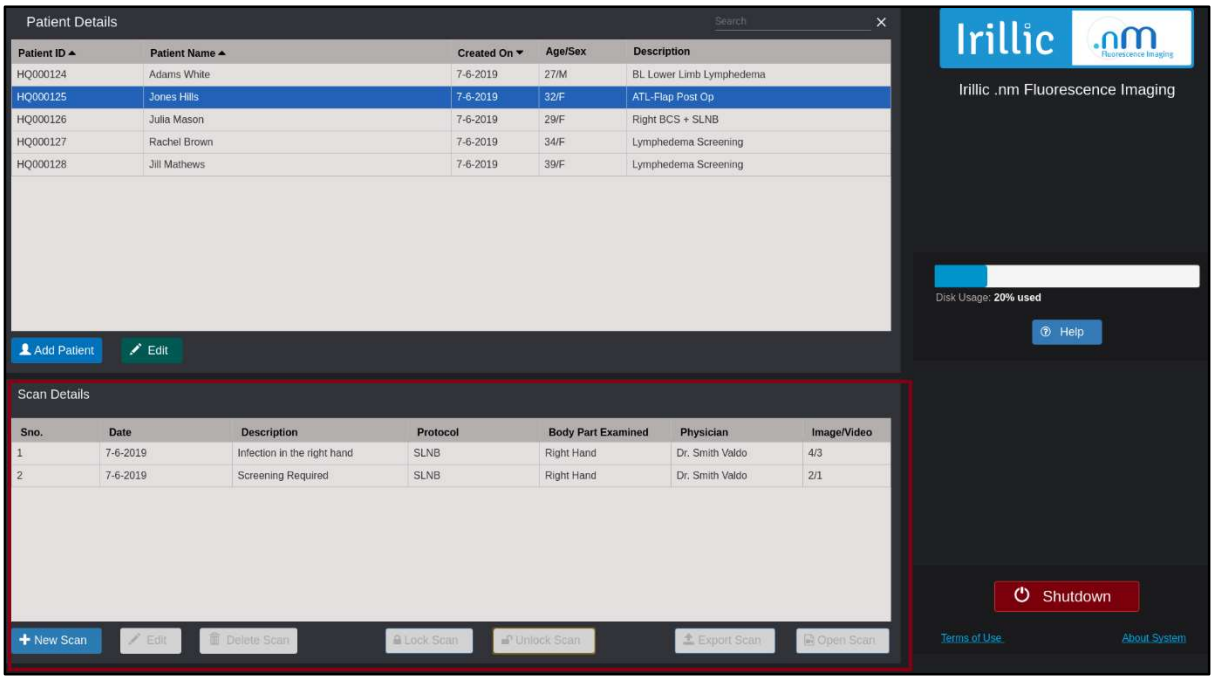


Fig 7.14: Add Scan Details

In the Scan Detail section, enter Protocol, Physician name, Body Part Examined and Create Notes.
After the details have been entered, click **Save** to complete the scan details.

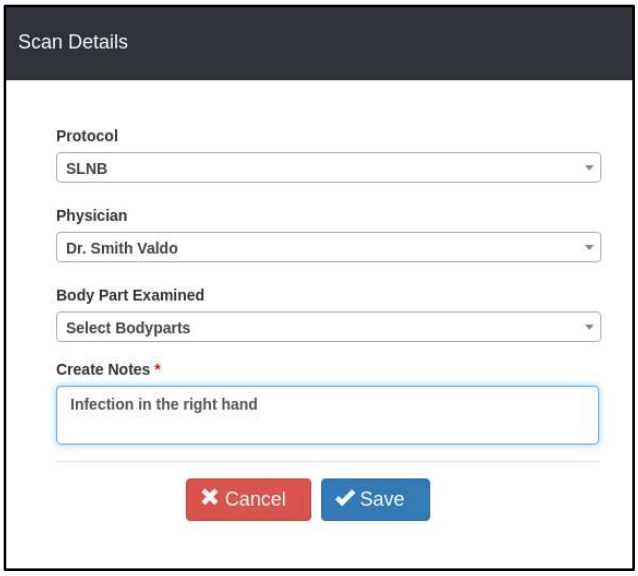


Fig 7.15: Save Scan Details

The new scan will be added to the patient record. One patient can have multiple scan records that can include images and videos.

Open Scan Details

The Study Management screen lists all the existing patient details. Select a desired patient record to view all scans pertaining to the select patient record.
From the Scan Details section select the desired scan record and click **Open Scan**.

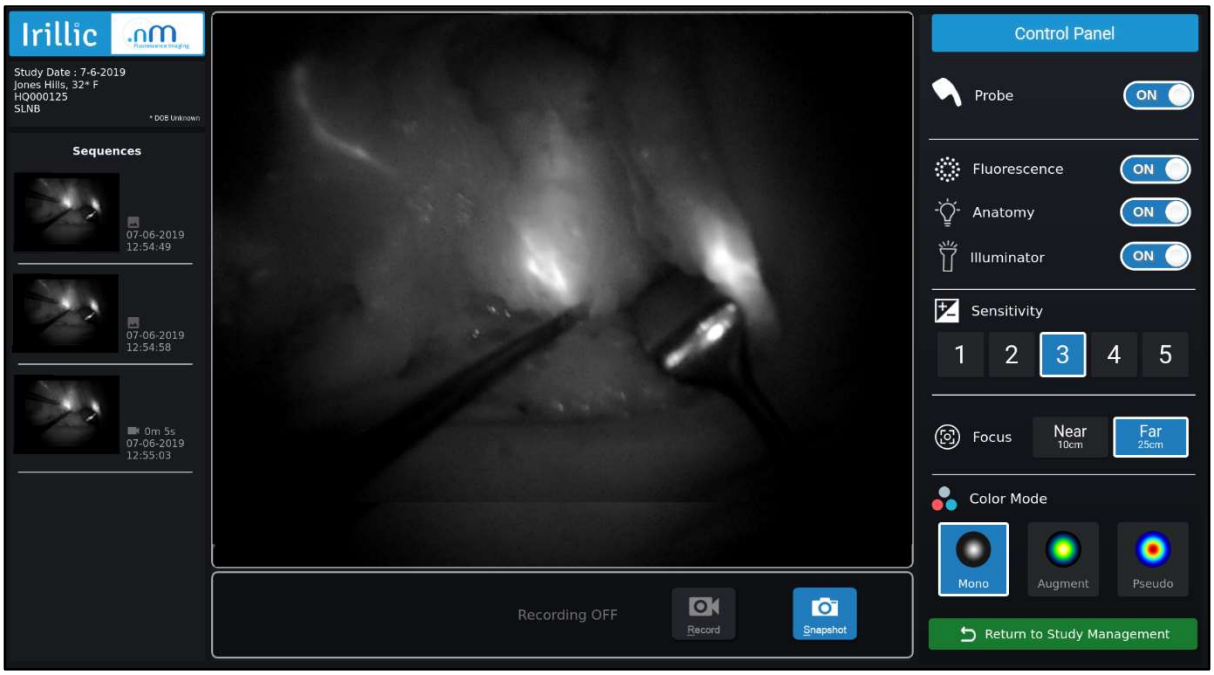


Fig 7.16: Open Scan Details

Edit Scan Details

For existing patient scans, in addition to reviewing or adding new scans, it is also possible to edit a previously saved scan.

Select desired scan from the Scan Details section and click **Edit**.

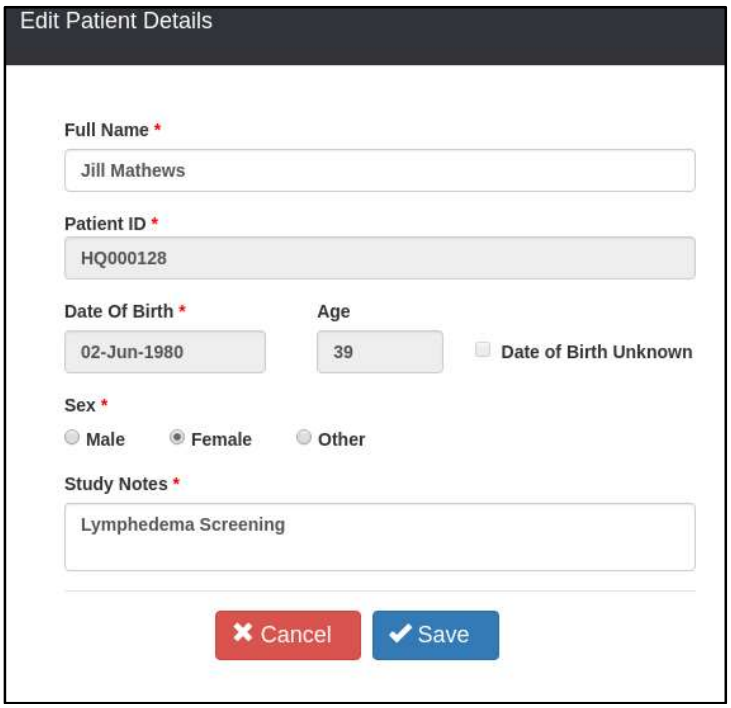


Fig 7.17: Edit Scan Details

The user can update the scan details and click **Save**. The changes made can be viewed in the Scan Details section.

Only users authorized by the hospital should edit patient details. Exercise caution when making any changes to existing records; changes cannot be reverted once they are saved.

Delete Scan Details

The Study Management screen lists all the existing patient details. Select a desired patient record to view all scans pertaining to the select patient record.

From the Scan Details section select the scan record and click **Delete Scan**.

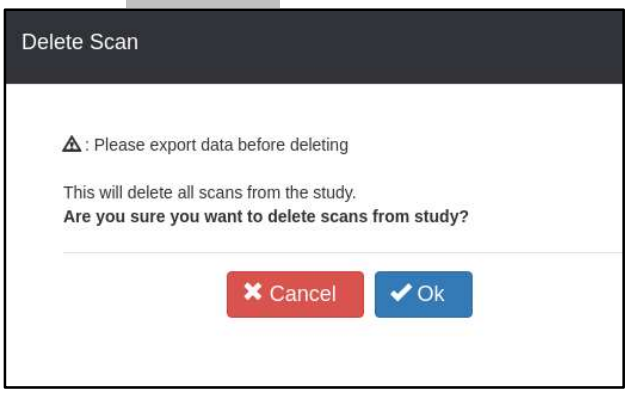


Fig 7.18: Delete Scan Details

A warning message is displayed, requesting users to export data before deleting the scan record.

Click on **OK** to confirm and proceed with deletion of the scan record.

Fig 7.19: Confirm Deletion of Scan

Click on **OK** to remove the scan record from the Scan Details section.

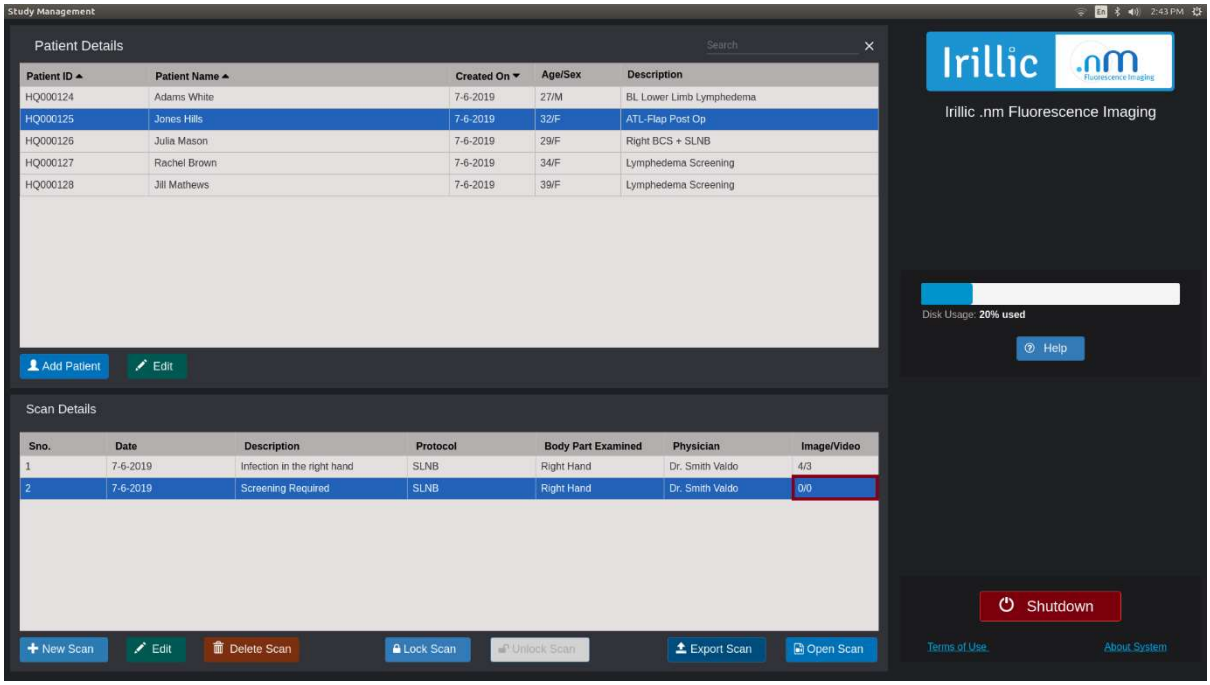


Fig 7.20: Confirm Deletion of Scan

This action will remove only the recorded images or videos; the patient record however is retained and is not deleted.

Only users authorized by the hospital can delete scan details. Use the Lock scan option to avoid any inadvertent deletion.

Lock and Unlock Scan

Lock scan option disables users to edit and delete scan records.

The Study Management screen lists all the existing patient details. Select a desired patient record to view all scans pertaining to the select patient record.

From the Scan Details section select the scan record and click **Lock Scan**.

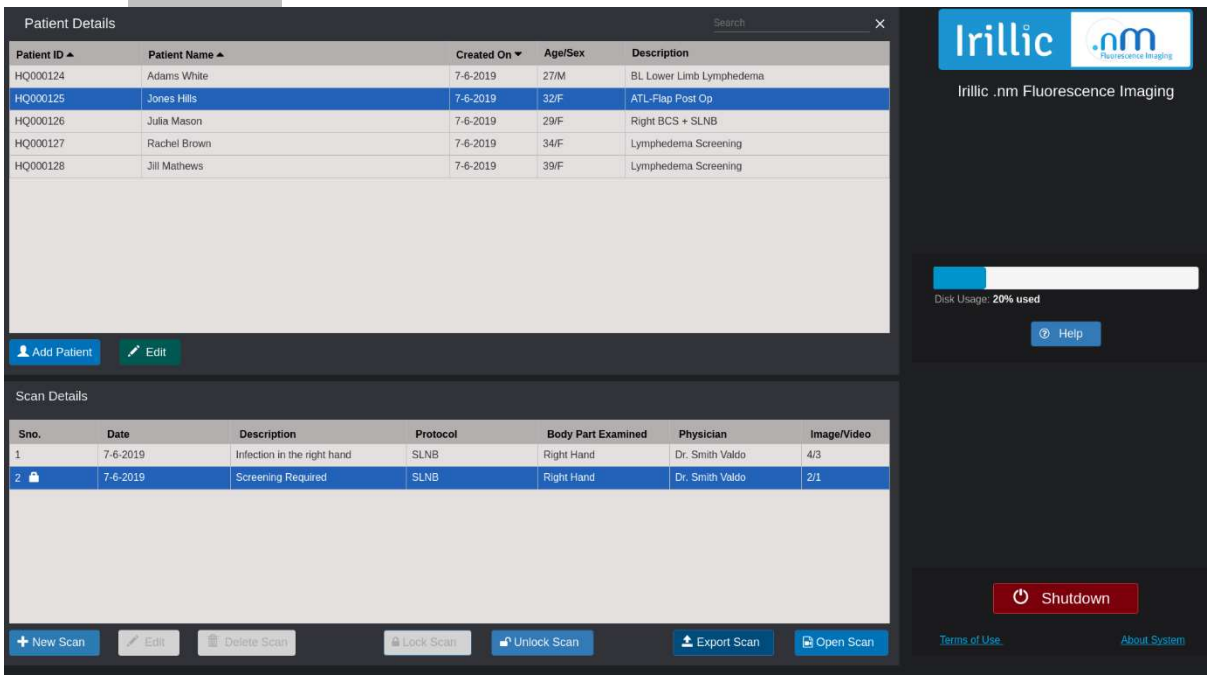


Fig 7.21: Lock Scan Details

From the Scan Details section select the Locked scan record and click **Unlock Scan** to enable edit and deletion of scan records.

Export Scan

Any existing scan can be exported to a removable drive (flash drive or external hard-disk). Before initiating export, plug in an external drive to the USB ports available on the back side of the trolley.

Currently, users can only export one study at a time. During export, all the saved images and videos in the study will be exported.

To begin export, from the Study Management screen go to the Patient Details sections and select a patient record, all existing Scans done on the patient are listed in the Scan details section. Select the Scan to be exported and click on **Export Scan**.

Choose Basic or Full

- Basic export transfer images as PNG, videos as MP4 files. This version is recommended for users to create reports and for sharing the details with authorized personnel. This option requires lesser disk space than Full export.
- Full version will export images as PNG, videos as MP4 and WEBM along with the corresponding metadata files. This version is recommended for backup. WEBM files are the original saved files without any compression. WEBM files require supported players for viewing (e.g. VLC player on Windows). This option requires more disk space than Basic export.

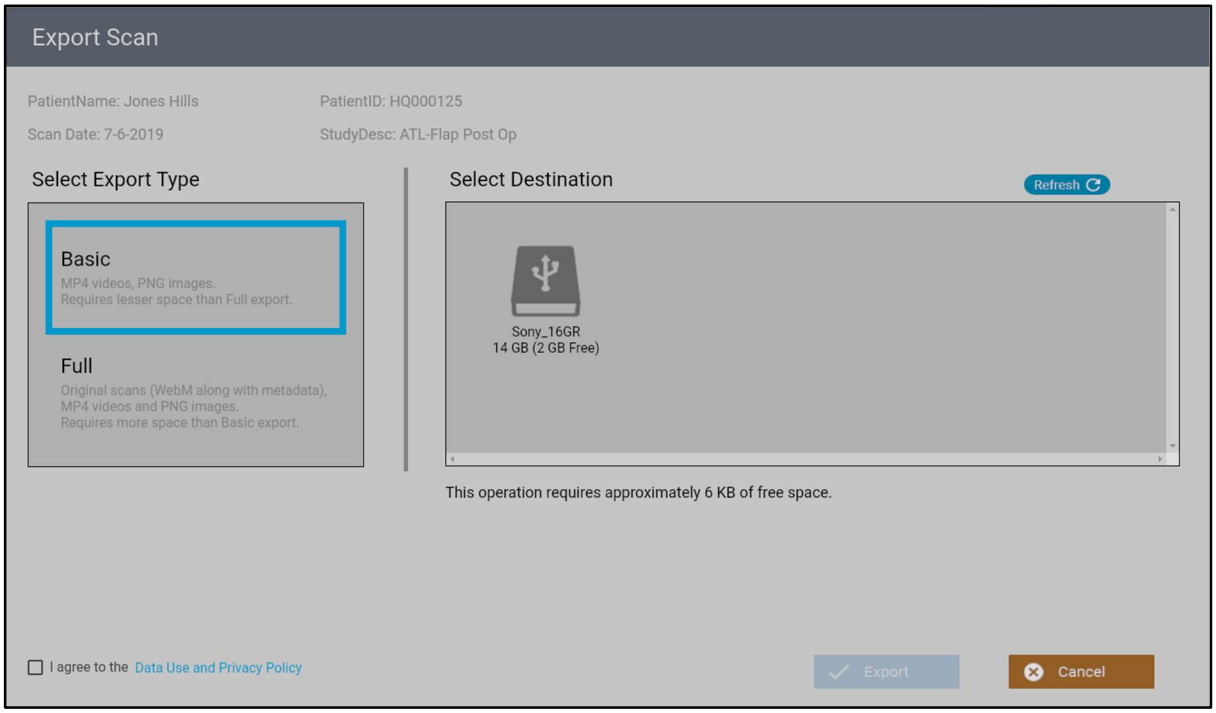


Fig 7.22: Export Basic (default)

- Next, select the destination drive. In case the selected disk does not have enough space, the system will display a warning message. The user should replace the external drive with one which has enough space.
- Read & accept "Privacy Policy" and click on **Export**.
- User can cancel the export anytime by clicking the **Cancel**.

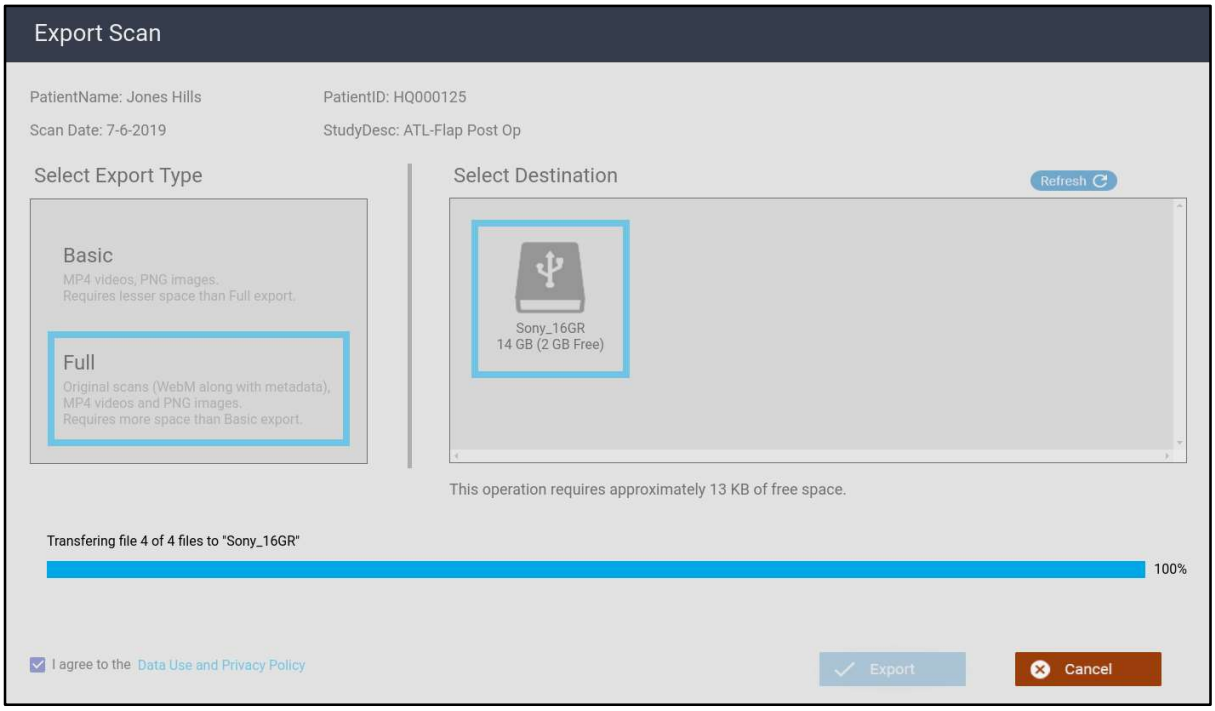


Fig 7.23: Export in progress

Do not remove the external drive or power off the system until the export is completed.

Use of USB OTG devices as an external drive is not supported.

System Modes

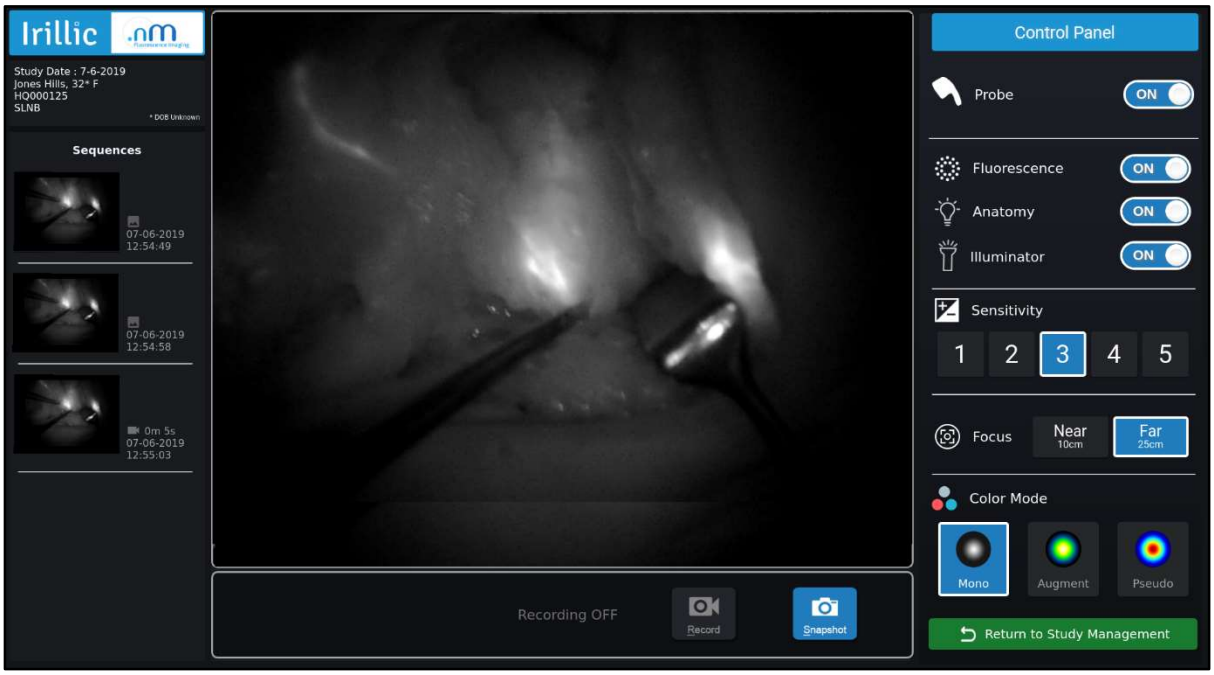


Fig 7.24: Scan Acquisition (for Scan and Record)

The Study Acquisition screen is used during Scanning, Recording and additionally, reviewing the stored recordings. The Probe can be in two modes: "ON" and "OFF". The mode can be seen on the "Probe" section. Probe is ready for scan acquisition and recording when Probe status is "ON".

The system operates in one of the following three modes:

- Scan Acquisition
- Standby
- Review Gallery

Scan Acquisition mode. In this mode, the user can view fluorescence images in real-time. This mode is enabled during the following scenarios:

- By clicking **Open Scan** from Study Management screen
- Resuming from Standby
- Use the toggle bar to manually switch ON mode

to

Fig 7.25: Probe Toggle (ON/OFF)

OFF/STANDBY mode. In this mode, system is temporarily in a standby state awaiting user input for resuming operations. Probe restores the last used settings when resuming from standby.

Fig 7.26: System (and

This mode is enabled during the following scenarios:

- No user input for five minutes in Scan Acquisition screen
- When in Scanning mode, use the toggle bar to manually switch to Standby mode

Review Gallery mode. In this mode, user can review the snapshot images and video recordings.

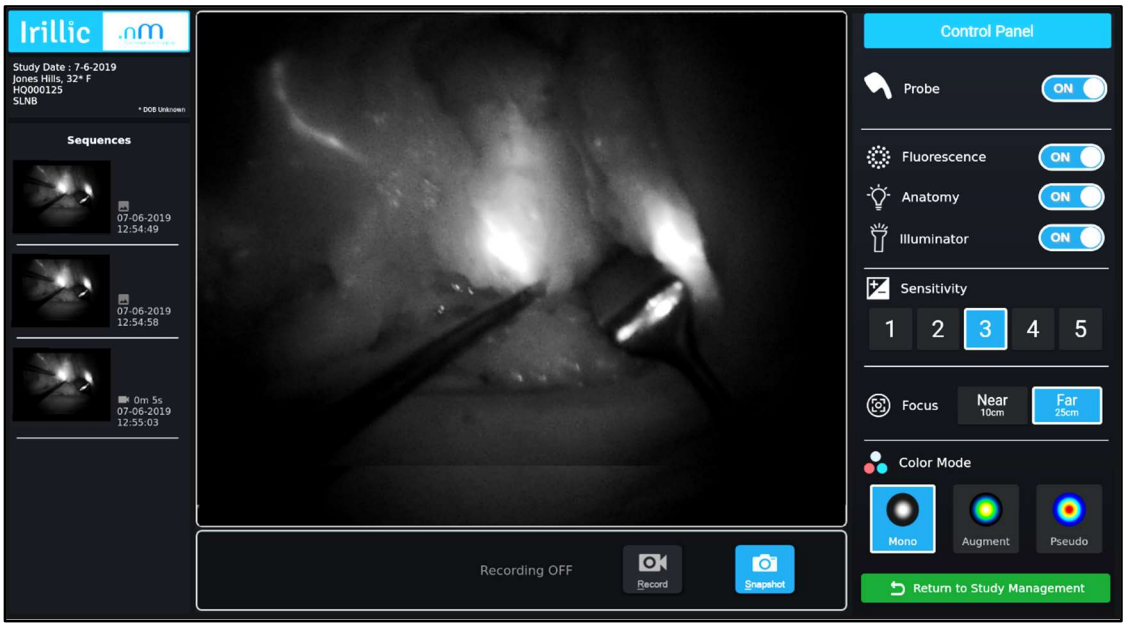


Fig 7.27: System in Review Gallery (Probe automatically in Standby)

This mode is enabled during the following scenarios:

- By clicking on an item in the gallery

Summary of system modes in Study acquisition view

Mode From	Mode To	User input(s) or Event(s)	Description
SCAN	STANDBY	User input: Using keyboard, toggle Probe to OFF *OR* Event: 5 minutes of non-usage of system *OR* 5 minutes of recording (with no key/button pressed during this time)	System switches from scan acquisition mode to STANDBY mode. A notification 1-min prior to switching to STANDBY is displayed; user can choose to extend scan mode for another 5 mins by pressing ENTER key.
SCAN	REVIEW	User input: Click on a Gallery item	System switches from scan acquisition mode to Review Gallery mode for Review of recorded scans (images, videos).
REVIEW	SCAN	User input: Using keyboard, toggle Probe to ON OR Press Snapshot on Probe	System switches from Gallery review mode to scan mode
STANDBY	SCAN	User input: Press Enter on keyboard or Snapshot on Probe	System switches from Standby mode to scan mode
STANDBY	REVIEW	User input: Click on a Gallery item	System switches from **Standby** mode to Review Gallery mode

Scanning

Acquisition Settings are important to visualize Fluorescence images correctly. The primary settings include:

- Fluorescence
- Anatomy
- Illuminator
- Sensitivity
- Focus
- Color Mode

Fluorescence turns on the excitation source required to capture the Fluorescence data from the target. By default, this is set to sensitivity level 3 and should suffice in most scenarios.

- If the fluorescence images appear excessively bright, try lowering sensitivity to 1-3. An example of where this might be needed is when the probe is held very close to a surgically opened anatomy area.

Anatomy turns on a special light source that allows users to see the background along with Fluorescence images. These lights allow users to see more of the surrounding area along with fluorescence images. By default, Anatomy Light is set to ON to allow for background visualization.

Illuminator turns on white light to provide basic illumination for a short time period around operating area for viewing in the absence of other lights (OT lights).

Sensitivity adjusts the optical sensitivity of the Probe. Higher Sensitivity settings allow for capture of weak fluorescence, but also allow higher noise. Lower Sensitivity settings allow for sharper images, but work best for relatively brighter fluorescence. By default, Sensitivity level is set to **3** and should suffice for many scenarios.

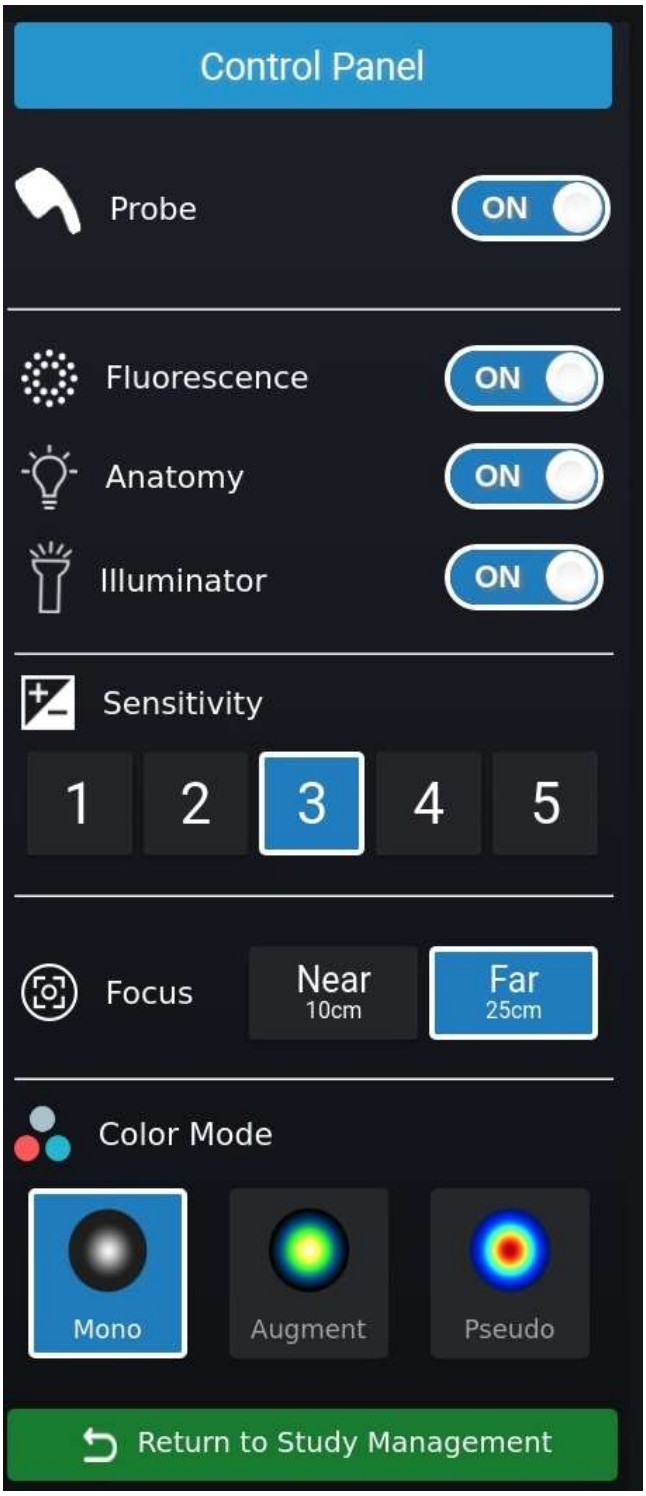


Fig 7.28: Control Panel

SENSITIVITY adjusts the optical sensitivity of the Probe. Higher Sensitivity settings allow for capture of weak fluorescence, but also allow higher noise. Lower Sensitivity settings allow for sharper images, but work best for relatively brighter fluorescence. By default, Sensitivity is set to 3 and should suffice for many scenarios.

- Users are encouraged to adjust Sensitivity to arrive at the most optimum fluorescence visualization from the Probe.
- If the images are too bright then try reducing Sensitivity and if images are too faint then try increasing Sensitivity.

See next page for example sensitivity settings

Example fluorescence images at different Sensitivity settings:

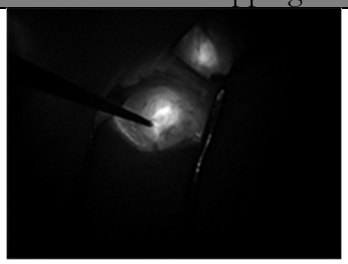
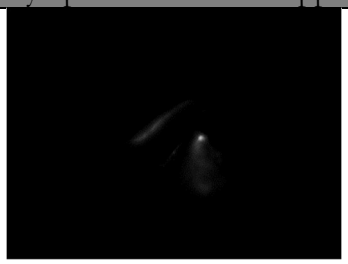
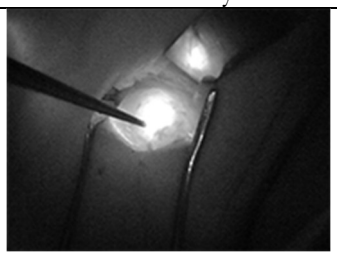
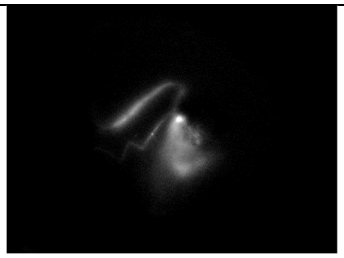
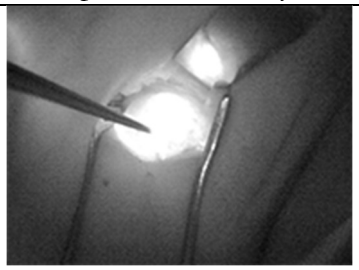
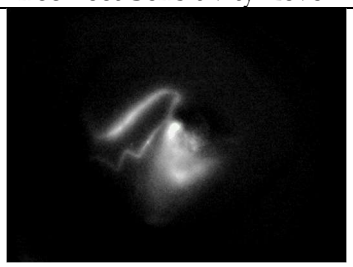
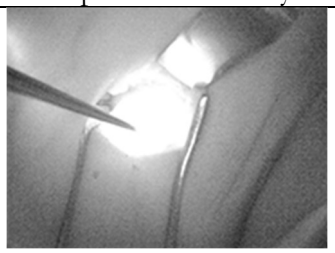
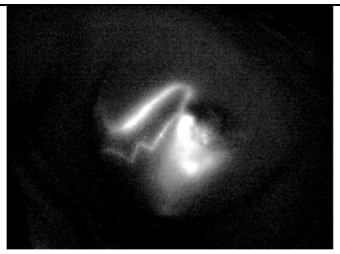
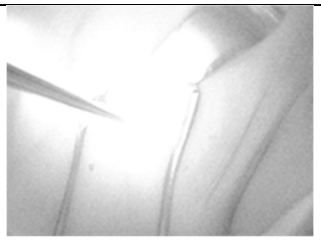
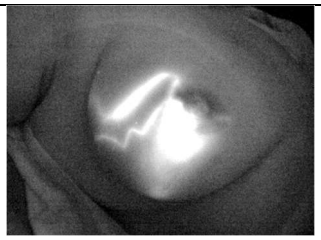
SENSITIVITY	Sentinel Node Mapping	Lymphatic Channel Mapping
1	 Best Contrast Correct Sensitivity Level	 Poor Contrast Incorrect Sensitivity Level
2	 Reasonable Contrast Sub-optimal Sensitivity Level	 Poor Contrast Incorrect Sensitivity Level
3	 Lower Contrast Sub-optimal Sensitivity Level	 Reasonable Contrast Sub-optimal Sensitivity Level
4	 Poor Contrast Incorrect Sensitivity Level	 Best Contrast Correct Sensitivity Level
5	 Poor Contrast Incorrect Sensitivity Level	 Reasonable Contrast Sub-optimal Sensitivity Level

Fig 7.29: Example Fluorescence Images at different Sensitivity settings

FOCUS adjusts the manual focus of the Probe. Users are required to use one of the 2 pre-sets (Near and Far) matching the working distance of the probe front face from the patient.

Working Distance	FOCUS
10 – 16Cms	Near
20 – 30Cms	Far

Color Mode allows users to select between Mono (grey-scale), Pseudo and Augment color mode. Color mode can be changed any time when system is in scan acquisition mode, when doing recording and also in Review Gallery mode. Changing of Color mode do not affect the original images captured from the Probe or even the recorded data. Recorded images are always saved in Monochromatic mode.

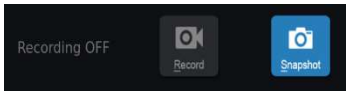
Color Modes	Description
Mono	Monochrome mode displays only a single **color**, typically uses grey-scale. The fluorescent image defines an outline of the color image, so that the color image is recognizable in a dark viewing area
Pseudo	Pseudo color allows better distinction between subtle differences in intensity thus making it easier to interpret an image.
Augment	This enables additional augmented-color visual modes for better contrast during scanning and playback.

Recording

When system is operating in scan acquisition mode and ICG contrast agent has been injected, users can visualize the fluorescence images in real-time. Probe can be moved freely during the visualization to see the regions of interest on the display monitor.

During this process, users can choose to record some of the visuals. These visuals include still images (PNG format) and videos (WEBM format).

- Videos can be recorded by clicking **Record**. Once recording is in progress, the icon changes to **Recording** as shown here.
- Click **Recording** to stop the video recording.



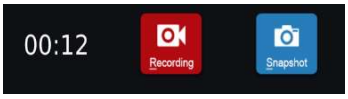


Fig 7.30: Record, Snapshot on Screen; Snapshot on Probe

Images can be recorded using one of the following methods:

- Click SNAPSHOT using Keyboard or
- Press SNAPSHOT button on the probe

Snapshot images can be captured both in normal acquisition mode or when Recording (video) is in progress.

The keyboard is equipped with a touchpad for both click and scroll actions. In the unlikely event that the touchpad cannot be operated due to usage of certain types of gloves, it is recommended to use keyboard shortcuts for recording – "R" for recording start/stop and "S" for snapshot when system is in Scan mode.

In order to maintain optimum system performance, default video recording length is limited to 5 minutes at a time before system switches to Standby. If longer duration recording is required in certain scenarios, users can press any key when the standby early warning (in 4 minutes) is displayed; this effectively restarts the 5 minute standby countdown.

In case of power loss during recording, the system may not retain the last 10 seconds of captured video data.

Review Gallery

When images or videos have been recorded during the scan acquisition, clicking any of these on the left Sequence panel switches system into Review gallery mode.

Images are marked with  and Videos are marked with 

Standard playback controls for video (e.g. play/pause, seek) are available.

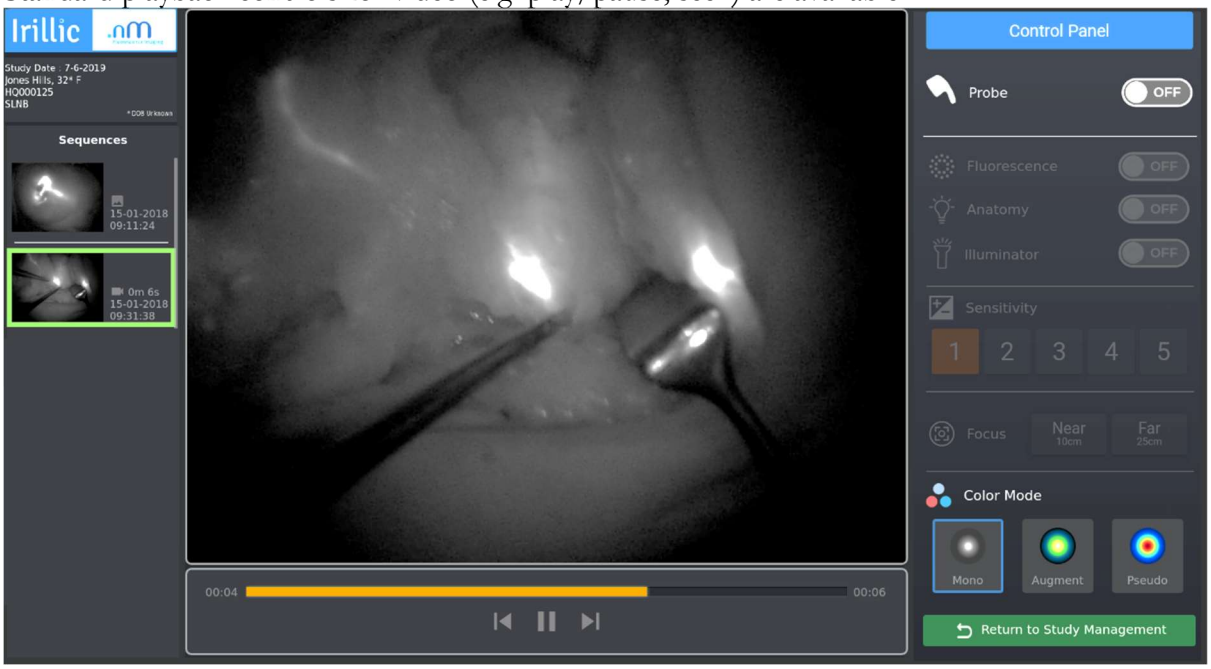


Fig 7.31: Playback of Recordings (in Gallery Review)

Since each recording can potentially have different acquisition settings, these settings for each recording are shown on right pane. These are for information purposes only and cannot be altered from the Review gallery mode. Color mode can however be used to view the monochrome recording in augmented color – this is for display purposes only and does not alter the underlying saved content in any way.

Playback controls for Pause/Play, Seek are available for videos. Using Left item or Right item controls in the playback panel allow users to view the previous or next items in the gallery.

The gallery panel is scroll-enabled to view the list of recorded images & videos. There are two ways to use scrolling in this view:

- Use Keyboard arrows (Up↑ or Down↓) OR
- Use the Scrollbar to the right of the gallery window to move through the gallery list

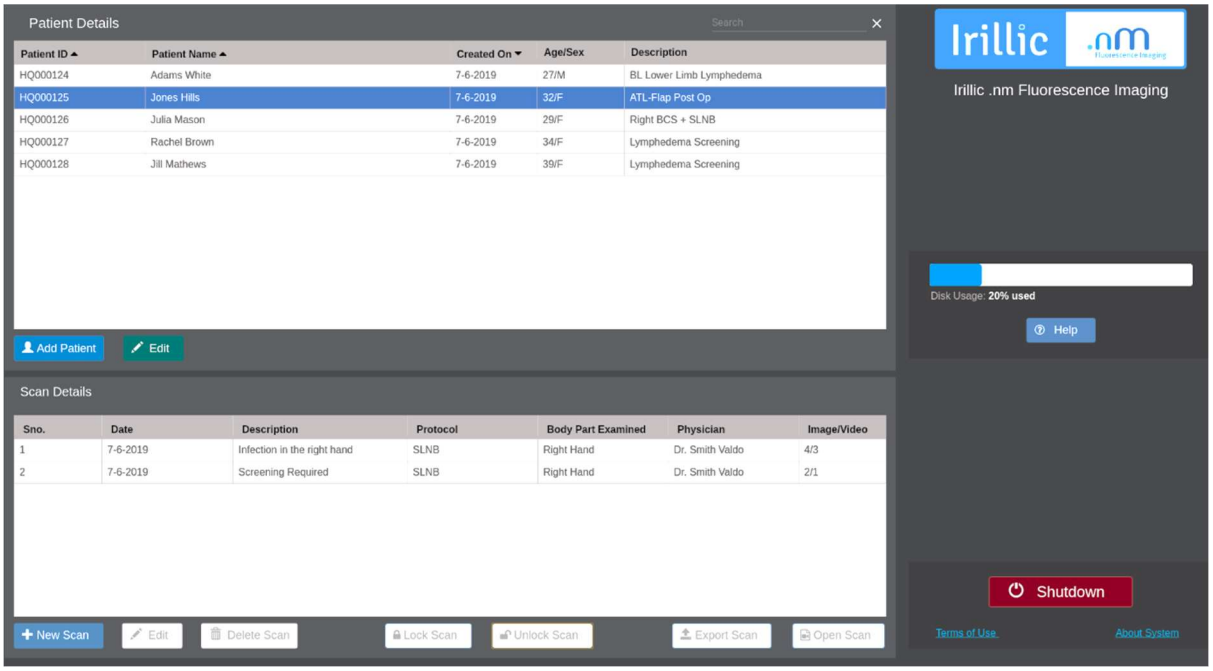
Analysis Mode

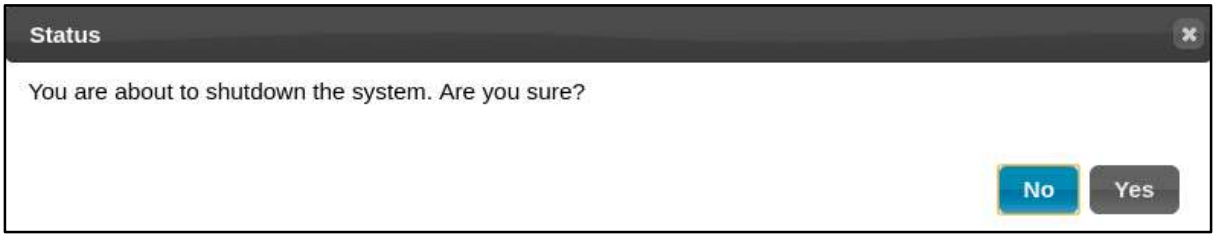
Refer Operator's Manual Addendum – Quantization for information on the operation of the Analysis functionality during Review Mode of any captured Snapshot.

Shutdown the System

When finished with using the system, shutdown the system using any of the following methods:

- Click Shutdown in the Study Management screen and follow on-screen instructions for shutdown.





In the unlikely event that system appears unresponsive and shutdown cannot be used, press and hold the power button on the Control Unit panel for a few seconds to force power-off.

Fig 7.33: Shutdown button on study management screen

ge slot on the trolley and close the

Fig 7.32: Shutdown button on study management screen

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8. Troubleshooting

Sl. No.	Problem Scenario	Possible Solutions
1.	Images appear hazy	• Try changing the FOCUS settings based on the distance between the probe and the patient
2.	Images appear grainy	• Try decreasing SENSITIVITY settings (4 or lower)
3.	Images appear excessively bright	• If ambient light appears bright, try blocking sunlight by covering up the windows • Try switching off overhead and/or surgical lights • Try decreasing SENSITIVITY.
4.	Unable to differentiate between Background Anatomy and Fluorescence images.	• Switch Off ANATOMY LIGHT • Try decreasing SENSITIVITY
5.	Able to visualize fluorescence; but not able to see the surrounding anatomy.	• If ANATOMY light is off, turn in On. • Try increasing SENSITIVITY
6.	Unable to visualize fluorescence.	• Verify that ICG has been injected (no fluorescence will be visualized otherwise) • Verify that the Fluorescence Light is ON
7.	The main image window is filled with horizontal line or other unexplained artefacts.	• This can be caused due to high-frequency interference by other equipment (such as a Cauterizer). Try moving the Probe and Probe cable away from such equipment. • Toggle the Probe from On to Off and back to On • If the toggle doesn't work then try rebooting the system once again
8.	No Scan visualization seen on Display even though Probe Status shows ON	• Toggle the Probe from On to Off and back to On • If problem persists, Restart the system.
9.	Unable to differentiate between Background Anatomy and Fluorescence images.	• Switch Off ANATOMY LIGHT • Try decreasing SENSITIVITY
10.	System shows "Probe not detected" on	• Verify Probe is securely connected to

	the screen.	Control Unit • Toggle the Probe from Off to On
11.	Power-on indicator is lighted GREEN but there is no display on monitor screen.	• Power LED on the bottom side of the monitor should be ON at this time; if not, switch on the monitor first. • Check if monitor power cable is securely connected to the DC input port on the Monitor. • Check connection of video cable from Control Unit to Monitor • After confirming cable is connected, power off/on the display monitor once again.
12.	System shows "Probe not connected" on the screen.	• Shutdown system and re-connect Probe cable to the Control Unit • Power ON the system and verify if Probe is now connected (i.e. ON)
13.	UI screen appears to freeze, no effect of using Keyboard.	• Verify system is responding by using any of the Probe buttons. If system is responding, check keyboard as given below. • Check if Keyboard is active by pressing CAPS ON/OFF (**CAPS indicator on monitor screen** should be displayed). If indicator does not light up try the following: • The wireless keyboard has a ON/OFF button to conserve battery life when not in use for a long time. Bring the switch to OFF and then ON immediately • If problem persists, the "AA" batteries inside the Keyboard may need replacement; replace these and try again.
14.	Probe appears to be unusually hot on the surface.	• It is normal for Probe to become warm within 10 minutes of usage. In such situations, allow it to cool down by switching system to standby mode for at least 15 minutes. Alternatively, power OFF system for at least 15 minutes.

If none of the above actions leads to proper functioning of the device, contact Irillic at info@irillic.com for Service/Repair/or replacement of parts with Field Replacable Units (FRUs)

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9. Maintenance

User initiated Maintenance

The user can do the following maintenance as needed:

1. Replacing Control Unit (APU) Fuse
2. Replacing Main System Fuse

Replacing Control Unit (APU) Fuse

If the monitor is powering on by the control unit (APU) is not powering ON (Power indicator on Control Unit remains OFF), the fuse connected on the Control Unit subsystem may need to be replaced. A spare fuse is provided in the fuse holder below the Control Unit 230V power input.

Steps to replace the fuse are given below:

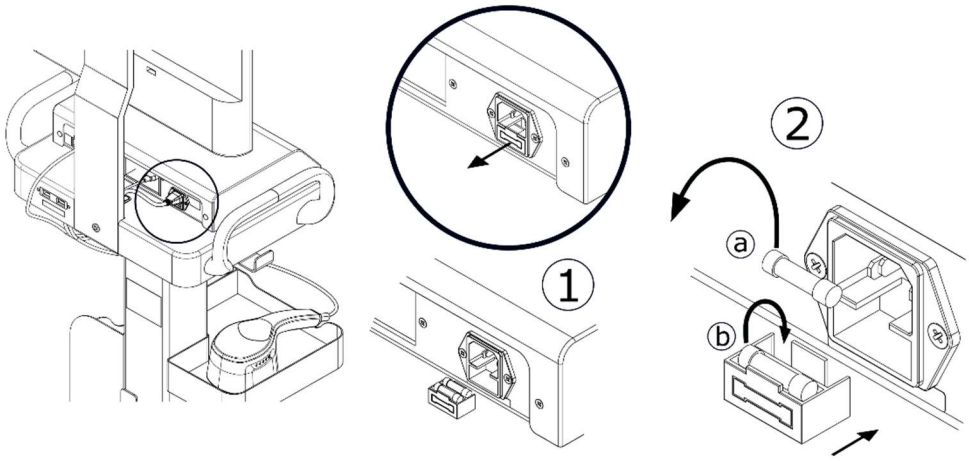

Fig 9.1: Control Unit (APU) Fuse removal and replacement

1. The Fuse is located behind the Control Unit as shown in the image above
2. Open the rear cover the A/C Panel Input (marked as "1")
3. Remove the existing fuse (marked as "a") and keep it aside
4. Remove the spare fuse (marked as "b") and place it the slot previously occupied by the blown fuse
5. Insert a new spare fuse in the spare fuse location (Optional); contact Irillic support for new spare fuse if needed
6. Push the rear cover of the A/C Panel Input back in place until you hear a click

Replacing Main System Fuse

If the system is not powering ON (Power indicator on Control Unit remains OFF and Power Indicator on Monitor remains OFF), the fuse on the Main System may need to be replaced. 2 spare fuses are provided along with every new system in the main packaging box.

Steps to replace the fuse are given below:

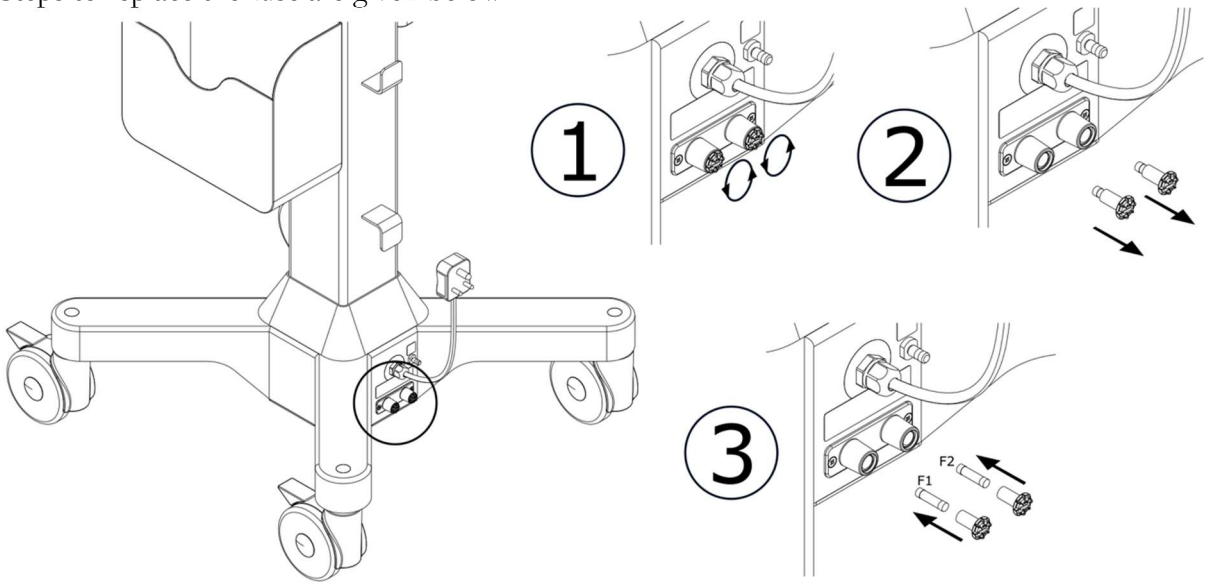

Fig 9.2: Main System Fuse removal and replacement

1. The Fuse is located at the bottom of the Trolley as shown in the image above
2. Unscrew the two rear covers of the fuse (marked as "1")
3. Remove the existing fuse (marked as "F1" and "F2") and keep it aside
4. Place the 2 new fuses in the slot previously occupied by the blown fuse
5. Contact Irillic support for new spare fuse if needed
6. Screw the rear cover of the fuse back in place until you hear a click

System Maintenance

Maintenance activities for the rest of the system will be done by Irillic or Irillic authorized personnel. These may include one or more of:

- Hardware maintenance
- Mechanical part(s) maintenance
- Optical maintenance
- Software updates[1]

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

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

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

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10. Cleaning Instructions

It is advisable for user personnel to clean the equipment regularly.

Cleaning the Control Unit

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

Do NOT splash or spray the liquid; liquid entering the Control Unit may damage the system.

Cleaning the Probe

Probe front face ONLY

- It is important to keep the Probe viewing window clean at all times to ensure optimal fluorescence visualization.
- Clean the Probe viewing window with a soft cloth such as a lens cleaning cloth.
- Since the front face is made of acrylic material, use of alcohol based solvent is not allowed. Use diluted ethanol or isopropanol-dampened soft cloth or absorbent cotton pad only when the dirt is tough or extreme.

Rest of the Probe

- For the rest of the Probe, wipe the body (excluding the front face) with ethanol or isopropanol-dampened soft cloth or absorbent cotton pad.

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

Cleaning the Trolley

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

Cleaning the Keyboard

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

Appendix I - Technical Specifications

Performance Specifications	
Optical Image/Video Resolution	640 x 480 pixels
Operational Modes	Monochrome (grayscale), Pseudocolour, and Augmented Colour
Fluorescence Excitation	CWL: 760nm FWHM: 48nm, Max Output: 5mW/cm^2 Classified under Risk Exempt Group as per EN IEC 60601-2-57:2011
Angular Field of View	90^0
Working Distance	10 Cms – 30 Cms (from Probe face)
Storage Drive for Image and Video Recording	SSD 250GB (Approx 200GB available to user)
Continuous Scanning or Recording duration	Upto 5 mins (Recommended)
Interface Specifications	
Video Output	Mode : 1920 x 1080 @50Hz Standard : HDMI No of Ports: 1
Data Interface	Usage : Data storage device, Future expansion Standard : USB 3.0 (also compatible with USB 2.0) No of Ports: 2
Network Interface	Usage : LAN connectivity Standard : Gigabit Ethernet No of Ports : 1
Environment Specifications	
Operating Temperature	+15°C to +40°C
Storage Temperature	+0°C to +40°C
Operating Humidity	20% to 70% (no condensation)
Storage Humidity	20% to 70% (no condensation)
Sterilization	Not sterilizable; probe should be covered with single use sterile drape in the operating environment.
Physical Specifications	
Trolley (with Display) Dimensions, Weight	650 mm (W) x 650 mm (D) x 1480 mm (H), ~30 Kg
Control Unit Dimensions, Weight	370 mm (W) x 253 mm (D) x 75 mm (H), ~4 Kg
Probe Dimensions Weight	112 mm (W) x 220 mm (D) x 81 mm (H) ~490gm (not including cables and accessories)
Consumables Specifications	
Sterile Drape (for Probe)	One-time use only (non-reusable). Refer to drape packaging for Sterilisation validity
Contrast agent for injection	ICG 25mg vial

End of Life of the system

Essential performance of the system is assured for 5 years. After this period, it is recommended that you contact Irillic to plan further course of action, failing which the following is to be adhered to:

- The .nm System components or whole device should be disposed of in compliance with local, regional, and national regulations, or returned to Irillic Pvt Ltd., for disposal.

- Single-use or consumable components or packing materials shall be disposed of in compliance with local, regional, and national regulations.

Annexure II - Symbol Definitions

Labelling Symbols

Product Label

SN	Serial Number		This product contains electrical waste or electronic equipment that is recyclable
REF	Reference Number	UDI	Unique Device Identifier
	Legal Manufacturer		Read Operator's Manual
	Date of Manufacturer		Read Operator's Manual Before Use
IP20	Ingress Protection	EC REP	Authorized representative in the European Community
	Protective Earth Ground	CE 0123	CE Mark & NB Code
	Contains electrical waste or electronic equipment. Must not be disposed of as unsorted municipal waste and must be collected separately	MD	Medical Device

Packaging Label

	Fragile, Handle With Care		Keep Dry
	Storage Humidity Limits		Storage Temperature Limits
	Store in Shade		This Side Up

Device Indicators & Warning Symbols

Device Labels & Symbols

IGU CONNECTOR	Probe (IGU) is connected here	DATA PORT	Trolley USB Data Port
	Warning: The Probe (IGU) port is not a standard usb port. Do not connect a USB device to this port		Warning: Do not use alcohol based disinfectant for cleaning the Probe window
	Warning: Pinch Hazard		Warning: Light Aperture LED Product classified under Risk Exempt Group as per IEC 60601-2-57:2011. Do not stare in to beam
	Equipotential Point		Power On

Image Grabber Unit (Probe) Buttons

	Anatomy Light Toggle
	Focus Toggle
	Capture Snapshot
	Increase Sensitivity
	Decrease Sensitivity

Annexure III- Electromagnetic Compatibility (EMC) Compliance

Guidance and manufacturer's declaration

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

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

The Irillic .nm Fluorescence 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 .nm Fluorescence Imaging System near other equipment.

Electromagnetic Emissions

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

Emissions test	Compliance	Electromagnetic Environment - guidance
RF emissions CISPR 11	Group 1	The Irillic .nm Fluorescence 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 .nm Fluorescence 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 .nm Fluorescence Imaging System is intended for use in the electromagnetic environment specified below. The customer or user of the Irillic .nm Fluorescence Imaging System should ensure that it is used in such an environment.

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 .nm Fluorescence Imaging System requires continued operation during power interruptions, it is recommended that the Irillic .nm Fluorescence 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
710 745 780	707-787	LTE Band 13, 17	Pulse Modulation 217 Hz	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse Modulation 18 Hz	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse Modulation 217 Hz	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse Modulation 217 Hz	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse Modulation 217 Hz	0.3	9

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 .nm Fluorescence Imaging System, including cables specified by the manufacturer, otherwise the device performance could degrade.

Irillic .nm Fluorescence 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.

Document Revision History		
Rev. No.	**Date**	**Changes**
1.0	18 JUL 2017	Initial Release
2.0	05 DEC 2019	Updated as per changes to design due to ECR-MKG-03
3.0	10 JAN 2023	Updated as per changes to design due to ECR-QAC-01
4.0	29 JUN 2023	Updated as per requirements from EN ISO 60601-2-57 & with new Irillic office address
5.0	21 JUN 2024	Updated as per CE MDR Application process requirements

For The Print Version of this document refer to the following file:

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MD5: TBD

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Model	OF81	Rev No	5.0	24 Sep 2024	Approved by	SK

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