Instructions For Use

iris

thermocoagulator® &
digital colposcope

Thank you for purchasing an Iris device, by Liger Medical. Please read this guide carefully before using your device. The user guide can be found online at www.ligermedical.com.

Iris has been designed to maximize safety and minimize strain for users and patients. However, precautions must be taken to further reduce the risk of personal injury or damage to the device.

Refer to the Declaration of Conformity for a list of the compliance standards and guidelines for the Iris. Liger Medical operates a Quality Management System that has been certified for compliance with the requirements of ISO 13485:2016.

For further support, please contact us:

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Building G, Basement Suite G20
Lehi, UT 84043 USA
Email: support@LigerMedical.com
Tel.: +1 (801) 256-6576
Website: www.ligermedical.com

The following is the contact information for the European Authorized Representative used for this device:

EC REP

MedNet EC-REP GmbH
Borkstrasse 10, 48163 Münster, Germany
http://www.mednet-eurep.com

MD

Training materials for the Iris can be found at: www.ligermedical.com

Contents

INDICATIONS FOR USE

Intended to provide magnified visualization of the tissues of the vagina, cervix, and external genitalia to aid in selecting areas for biopsy and diagnosing abnormalities as needed for a colposcopy exam. And for the destruction of human tissue with high temperatures by tissue contact with an electrically heated probe.

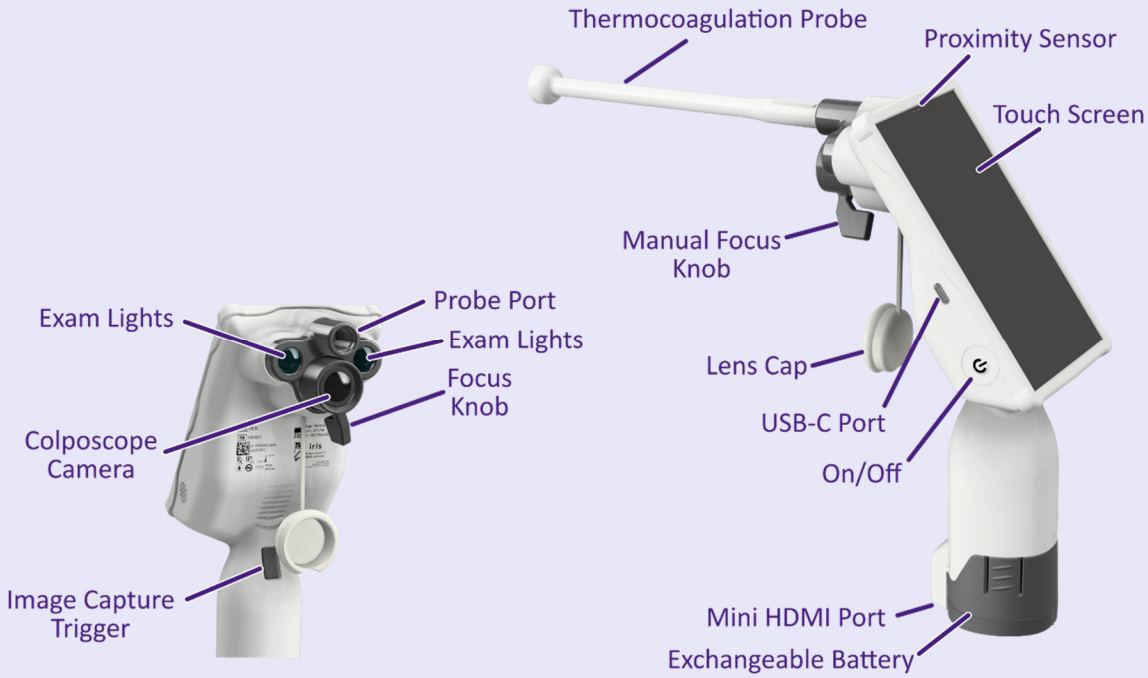
USE ENVIRONMENT

The IRIS is intended for use in hospitals, clinics, and doctor's offices.

USER QUALIFICATION

The handheld IRIS Thermocoagulator & Digital Colposcope must be used by a physician or by medical personnel under the supervision of a physician. The user must have received sufficient training in clinical procedures. Liger Medical does not discuss or provide explanations of clinical procedures.

CAUTION: Read all warnings and cautions provided in these instructions before using the Iris device.
Read all the instructions before using the iris device.



Iris Thermocoagulator and Digital Colposcope

DESCRIPTION

The Liger Medical IRIS Thermocoagulator & Digital Colposcope is a portable thermal coagulator with an integral colposcope that aids with clinical examination of the cervix as well as utilizing a heated probe to ablate human tissue. It is specifically designed for use in resource-limited settings. The colposcope and thermal ablation modes can be used separately from each other. The device is a handheld, portable, battery-operated, ablator with an LCD display and optical camera to assist diagnosis and treatment, in a safe, effective, easy to use package with sufficient battery life to sustain work for up to 4 hours. Thermal

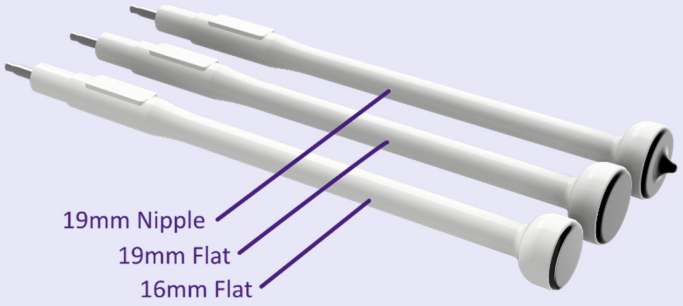
coagulation or tissue ablation has proven safe, effective, and takes less than one minute to administer, which can be used in hospital and non-hospital professional healthcare locations. The IRIS colposcope/thermal ablation device is not intended for introduction into the vaginal canal during colposcopic examination. The camera remains outside the vaginal cavity and functions comparably to a standard non-invasive colposcope in terms of providing magnified visual assistance to the clinician. There is no patient contact during the colposcopic examination. Contact between the clinician and the device is mitigated through good clinical practice of wearing protective gloves, limiting contact to intact skin protected by operating gloves. It is well established that not only are colposcopes inherently safe for the intended use of cervical inspection, but that they are effective both for improving visual acuity through magnification to aid the process of cervical intraepithelial neoplasia diagnosis, reducing false negative diagnoses, and have been demonstrated in combination with telemedicine and image capture to allow for remote diagnoses that are comparable to standard colposcopic examination, thus expanding the ability for appropriately trained nurses to perform colposcopic exams.

The thermal ablation probe, which is reusable and provided non-sterile, is designed to perform low-power destruction of human tissue with high temperatures by tissue contact with an electrically heated probe tip.

ACCESSORIES

The IRIS is compatible with the following Liger Medical HTU-110 Thermocoagulator probes:

- 19mm Flat Probe
- 19mm Nipple Probe
- 16mm Flat Probe



Heated Probe Tip

The probe tip contains a heating element which is heated to approximately 100°C (212°F) for the destruction of human tissue. The probe tip should only be applied to tissue, which is intended to be ablated, and care should be taken to avoid touching any other tissue with the heated probe tip.
The probe shaft is not intended to deliver heat. The probe shaft has a maximum temperature of 43°C (109°F). Contact with the probe shaft should be avoided during the procedure.

ITEMS INCLUDED

The following items are included with the Liger Medical IRIS device:

- Liger Medical's IRIS Thermocoagulator & Digital Colposcope Device.
- Four HTU-110 Probes: (2) 19mm flat, (1) 19mm nipple, and (1) 16mm flat.
- Instructions for Use (digital form on the device).
- Two Removable Lithium-Ion Battery Packs.
- Charging Base with A/C Adapter.
- Hard Shell Carrying Case.
- Screen Cleaning Cloth.
- Tripod Adaptor.

CONTRAINDICATIONS

Thermal ablation of the cervix is a procedure used to treat abnormal cervical tissue, often related to precancerous changes such as dysplasia. However, there are certain contraindications where this procedure should be avoided or carefully considered. Here are the main contraindications for performing thermal ablation on a woman's cervix:

1. **Pregnancy**: The procedure is not recommended during pregnancy as it may harm the fetus or cause complications during labor and delivery.
2. **Inadequate Access or Visualization**: If the cervix cannot be properly visualized or if there is difficulty accessing the area due to anatomical abnormalities (e.g., vaginal atresia, severe pelvic adhesions), the procedure may not be safely performed.
3. **Presence of Invasive Cervical Cancer**: Thermal ablation is typically used for precancerous lesions (CIN) and not for invasive cervical cancer. If there is evidence of invasive carcinoma, a different treatment approach is required.
4. **History of Radiation Therapy to the Pelvis**: Previous pelvic radiation therapy can lead to tissue changes that make thermal ablation less effective and increase the risk of complications, such as severe scarring or delayed healing.
5. **Inability to Follow Up**: Since thermal ablation requires proper post-procedure follow-up to monitor for recurrence or complications, women who cannot comply with follow-up care or those who have difficulty accessing healthcare should not undergo this procedure.
6. **Immunocompromised States**: Women with conditions that severely weaken the immune system (e.g., HIV/AIDS with low CD4 count, organ transplant recipients, or those on immunosuppressive therapy) may have an increased risk of complications such as infection or delayed healing.
7. **Active Menstrual Bleeding**: If the patient is experiencing heavy menstrual bleeding, it might not be ideal to perform thermal ablation until the bleeding is controlled.

These contraindications should always be evaluated by a healthcare provider to ensure the safety and appropriateness of the procedure for the individual.

COMPLICATIONS AND SIDE-EFFECTS

No known complications to the patient will occur during digital colposcopic examination. If acetic acid or iodine is applied during VIA or VILA, standard complications with their use may occur.
Cervical ablation is generally considered a safe procedure, but as with any medical treatment, there are potential complications and side effects. Here are some of the common and less common ones:

Common Complications and Side Effects:

1. **Post-procedure Discharge**: It's common to experience vaginal discharge after the procedure, which may last for a few weeks. This can be clear, bloody, or watery in nature. The discharge may be a sign of healing but should be monitored for any unusual changes.
2. **Cramping or Pain**: Mild to moderate pelvic cramping or pain may occur after the procedure, similar to menstrual cramps. This usually subsides within a few days.
3. **Spotting or Bleeding**: Spotting or light bleeding may occur for a few days to a couple of weeks after the procedure. This is generally normal but should be monitored. Heavy bleeding is uncommon but could indicate a complication.
4. **Infection**: As with any procedure that involves the cervix, there is a small risk of infection. Signs of infection may include fever, foul-smelling discharge, or increased pain. Early treatment with antibiotics can usually manage infections effectively.

5. **Delayed Healing or Scarring (Cervical Stenosis)**: The healing process after cervical ablation might involve scar tissue formation. If scarring is severe, it can lead to **cervical stenosis** (narrowing of the cervix), which may make future gynecological exams, treatments, or even childbirth difficult.
6. **Changes in Menstrual Cycle**: Some women report changes in their menstrual cycle following cervical ablation, including heavier or lighter periods. These changes are usually temporary, but in some cases, they may persist.

Less Common or Severe Complications:

1. **Severe Bleeding**: Though rare, excessive bleeding can occur after cervical ablation. If a woman experiences heavy bleeding that doesn't subside, it may require medical intervention, such as cauterization or surgery.
2. **Injury to Surrounding Organs**: The procedure can carry a small risk of injury to nearby structures, such as the vaginal wall. However, these complications are rare because the procedure is typically done under direct visualization and with caution.
3. **Chronic Pelvic Pain**: In some rare cases, women may experience chronic pelvic pain following cervical ablation, though this is not commonly reported.

Other Considerations:

- **Psychological Effects**: Some women may experience psychological effects such as anxiety or stress due to the uncertainty of post-procedure healing or worries about the risk of recurrence of abnormal cells. It's important to provide counseling and support during this period.

It's important for women undergoing cervical ablation to be aware of these potential complications, and any unusual symptoms should be reported to a healthcare provider. Follow-up visits are important to ensure that healing is progressing well and to catch any problems early.

RESIDUAL RISKS

There are no residual risks associated with this device.

WARNINGS AND PRECAUTIONS

1. **No modification of this equipment is allowed.**
2. **Proper surgical procedures and techniques are the responsibility of the medical professional. Each practitioner must determine the appropriate use of this device for each patient based on medical training, experience, the type of procedure employed, and the benefits and risks associated with device use.**
3. **Always have spare probes available in order to replace the equipment in case of a malfunction or break.**
4. **Dispose of expired IRIS handle and probes according to national and local regulations and guidelines for electrical medical equipment.**
5. **Temperatures at the probe's distal tip may be hot enough to damage tissue.**
6. **Do not use excessive force or in a manner not consistent with normal instrumentation use.**
7. **Although the IRIS complies with EN IEC 60601-1-2:2015 (4th ed.) EN 55011 (2009) +A1 (2010) CISPR 11 EN 55011:2016 for electromagnetic phenomena (EMC) for the professional healthcare environment, the device may emit electromagnetic radiation that may affect the performance of other electrically powered equipment, or the performance of the device may be affected by electromagnetic radiation from other electrically powered equipment in the vicinity.**

8. **Other equipment could interfere with the IRIS, even if other equipment complies with CISPR emissions requirements.**
9. **NOTE: This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.**
10. **WARNING: 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 IRIS, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
11. **Only connect the IRIS to secured, trusted Wi-Fi networks.**
12. **The IRIS batteries should only be connected to the provided recharging base.**
13. **In some circumstances, potential exists for alternate site burns at points of skin contact (e.g., between the legs or on the external labia and inner vagina).**
14. **To avoid burning, always remove the probe from the handle when not using the thermal ablation function.**
15. **The IRIS device and accessories have not been tested for magnetic resonance imaging (MRI) safety. Avoid use of the device near MRI equipment.**
16. **The IRIS should only be transported in its protective carrying case to avoid overbalancing.**
17. **<u>FCC CAUTION:</u> Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment. This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:**
    a. **This device may not cause harmful interference; and**
    b. **This device must accept any interference received, including interference that may cause undesired operation.**
18. **This product complies with the US portable RF exposure limit set forth for an uncontrolled environment and is safe for intended operation as described in this manual. Further RF exposure reduction can be achieved if the product is kept as far as possible from the user body or is set to a lower output power if such function is available. This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter. This device is intended only for OEM integrators under the following conditions:**
    a. **The transmitter module may not be co-located with any other transmitter or antenna.**
    b. **If the condition above is met, further transmitter testing is not required. However, the OEM integrator is still responsible for testing their end-product for any additional compliance requirements required with this installed module.**
19. **Per AAMI TIR69:2017, the risk associated with this device is assessed as Category D NEGLIGIBLE for wireless QoS needed for safe and effective operation.**
20. **WPA2 wireless AP recommended.**
21. **Thermal/coagulative treatments of precancerous lesions during a colposcopic exam without histological confirmation of disease and disease extent could lead to under diagnosis of adenocarcinoma in situ (AIS), extent of dysplasia, cancer, or incur unnecessary potentially harmful treatment to the patient.**
22. **The Liger Medical IRIS device contains a 12V lithium-ion battery pack. Please observe the following practices:**

a. **Do not place the device on or near fires, heaters, other high temperature locations, or apply heat directly to the unit or battery pack.**
b. **Do not pierce the unit or battery pack with any sharp objects, strike the unit or battery pack with a hammer, tools, or heavy objects, step on the unit or battery pack, or otherwise damage the unit or battery pack.**
c. **Do not subject the unit to strong impacts or shocks.**
d. **Do not expose the unit or battery to water or any other types of liquid or allow the battery to get wet.**
e. **Do not leave the unit or battery in direct sunlight and avoid storing it in vehicles in extreme hot weather. Doing so may cause the battery to generate heat, rupture, or ignite. Using the battery in this manner may result in a loss of performance and short battery life.**

SERVICE AND MAINTENANCE

The Iris has no serviceable parts. If any failure has developed, contact Liger Medical for service.
The IRIS handle, charging base, and power supply are reusable and should be routinely cleaned with a clean damp cloth or with an anti-microbial wipe.
WARNING: Do not submerge the IRIS handle, battery charger, or battery in fluid of any type. It may short the electronics and cause an electrical shock to the user.

REQUIRED EQUIPMENT

Before using the IRIS, the following equipment should be accessible:

- A pre-charged battery. A full charge is recommended but not required.
- IRIS thermocoagulation probes (Sterilized or High-Level Disinfected).

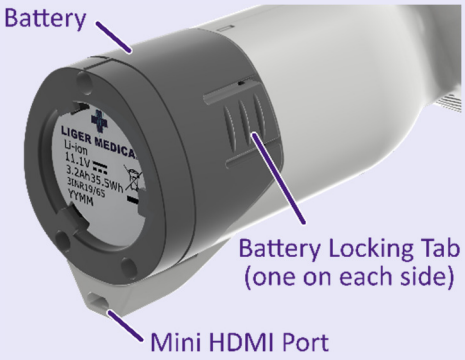
HANDLING AND PREPARATION

Inspection Before Each Use
Before each use, perform the following:
General Inspection

- Inspect for visible damage to the IRIS handle, battery, and probes and all connections.
- Make sure that no parts are missing or loose.
- Make sure that connecting elements between instruments function properly.
- Verify that the IRIS and accessories are in good working order by following the “Turning ON/OFF the Device” steps outlined in the following section.
- If the battery is not already installed, insert a charged battery into the handle of the unit. The battery can only be inserted in a single orientation. Push the battery into place until the locking tabs snap; these tabs lock the battery into the handle.

WARNING: Examine all accessories and connections to the IRIS before use. Ensure that the accessories function as intended. Improper connection may result in accessory malfunction.

NOTE: *The battery is removed by compressing the two locking tabs on the sides near the battery base releasing the lock and, while firmly holding the unit handle, pulling the battery down and out of the handle.*



PATIENT PREPARATION

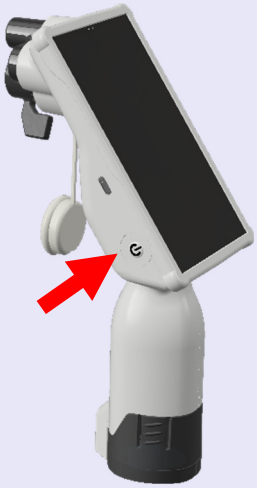
The patient should be prepared according to clinic protocol for the appropriate type of procedure.

TURNING ON/OFF THE DEVICE

Turning ON the Device

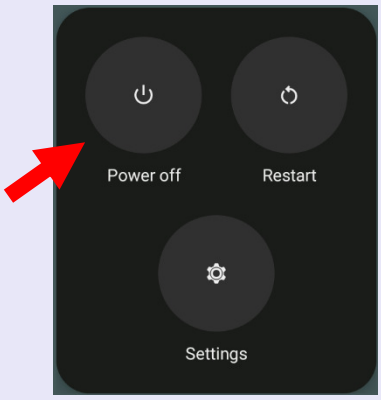
Press the ON/OFF button once to turn on the device. The device will power on and a boot logo will show on the display. If the battery is low upon startup, the device will show a low battery message on the display, then shut down.

After activation, the IRIS can be used for digital colposcopy, thermal ablation, or both. See individual sections below describing the functionality of each mode.



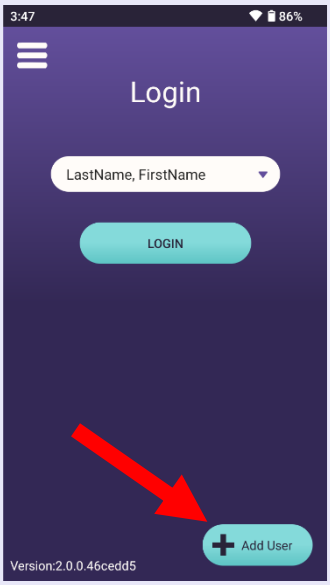
Turning OFF the Device

At any point, the iris device can be shut down by pressing and holding the ON/OFF button for approximately three (3) seconds. The power menu will display. Tap the Power Off button on the display to shut down the iris device.



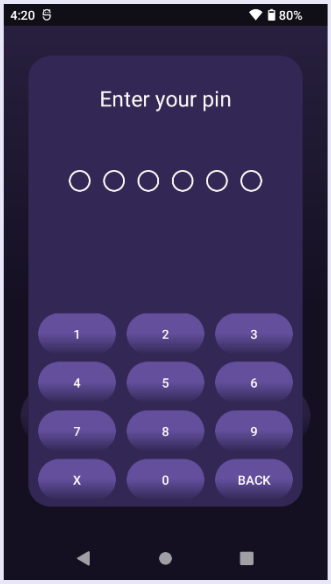
ADD NEW USER

1. To create a new user, tap the “Add User” button.
2. Select the account type for the user.
   a. DEFAULT
   b. IRIS CLOUD
   c. PAVE



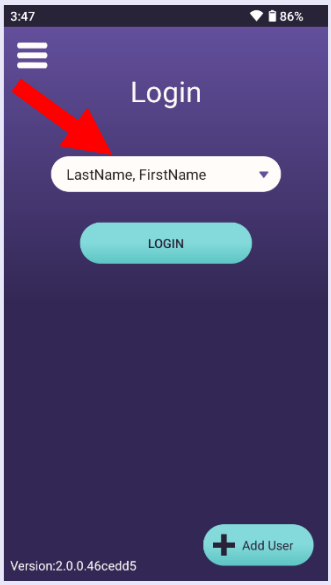
3. Enter the user’s first and last name.
   a. For “IRIS CLOUD” users, only your cloud credentials (username and password) will be required.
   b. For “PAVE” users, select the applicable PAVE study.
4. Tap the “SAVE” button.
5. Enter a 6-digit PIN for the user. Re-enter the PIN for confirmation.

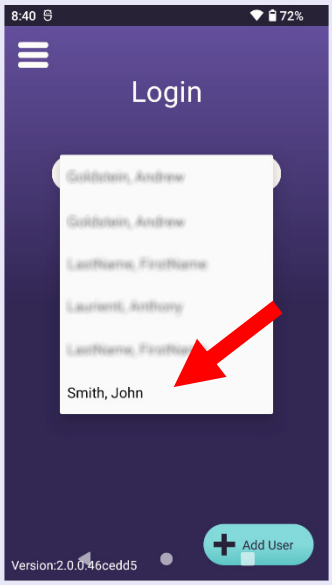
You will be required to use this login and PIN each time you use the device. Multiple users can be added to the device. Each user can only access their saved patient data and cannot access other user’s data.



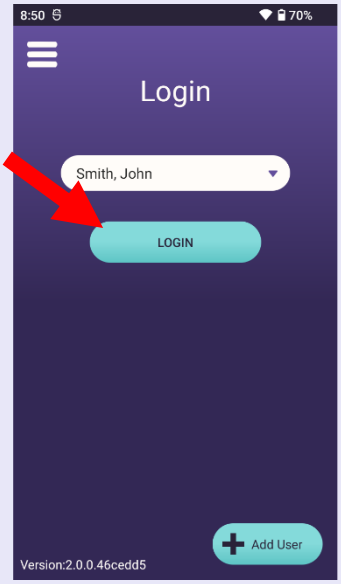
USER LOGIN

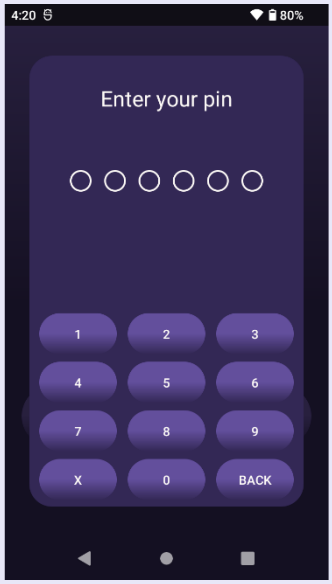
1. For existing users, tap on the username field to pull down a list of all users registered on the device and tap on the desired username.



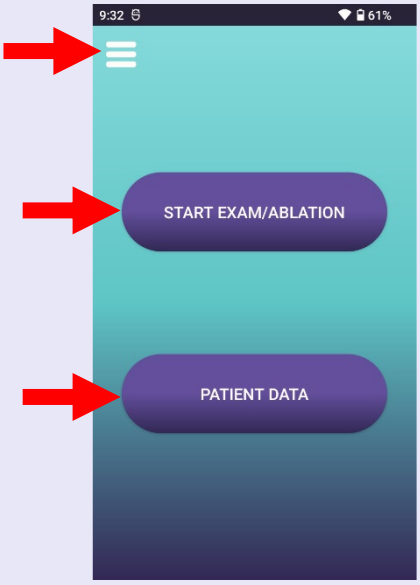


2. Tap the “LOGIN” button then enter the user’s PIN.



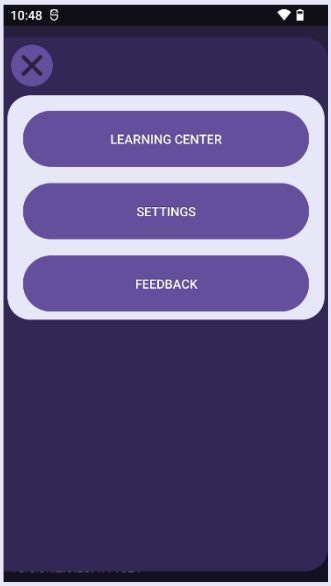


3. Once logged into the device, the home screen will appear. From the home screen, you can perform the following:
   a. Enter the Options Menu.
   b. Start an exam or ablation.
   c. Enter the patient data menu.

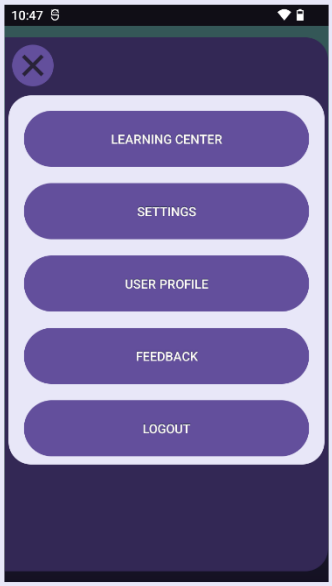


OPTIONS MENU

The Options Menu may be accessed before or after a user is logged in. However, when a user is logged in, two additional options are available, “USER PROFILE” and “LOGOUT”.



Options Menu –
No User Logged In



Options Menu –
User Logged In

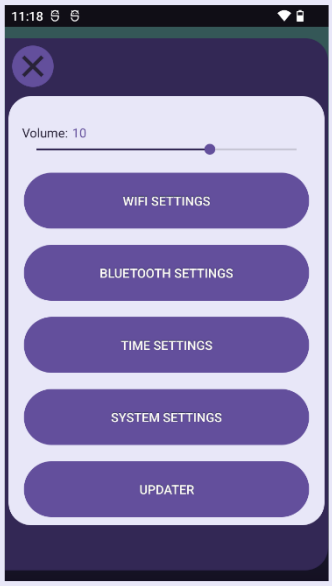
Options Menu – LEARNING CENTER

The LEARNING CENTER button pulls up options to view a digital version of training material or resources on the iris device screen. These resources include a “quick start guide” and the “instructions for use” manual.

Options Menu – SETTINGS

The SETTINGS button pulls up several options for controlling the Iris device. The settings that are available on this menu are:

- Volume – controls the volume of the audible feedback from the Iris device.
- WIFI SETTINGS – allows the Iris device to be connected to a local Wi-Fi network.
- BLUETOOTH SETTINGS – allows Bluetooth compatible devices such as a mouse, keyboard, clicker button or foot pedal to be connected to the Iris device via Bluetooth.
- TIME SETTINGS – allows the control of the date, time and time zone on the Iris device.
- SYSTEM SETTINGS – enters the system settings of the Android operating system of the Iris device.
- UPDATER – allows the iris device to check for and apply software updates.

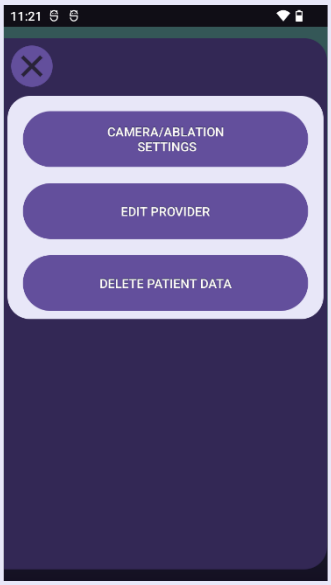


Options Menu – USER PROFILE

The USER PROFILE button is only available if a user is logged into the Iris device. The USER PROFILE button provides access to settings that are applied only to the user that is logged into the Iris device. The available options are:

- CAMERA/ABLATION SETTINGS
- EDIT PROVIDER
- DELETE PATIENT DATA

Each of these settings will be addressed in the appropriate sections in this manual.



Options Menu – FEEDBACK

The FEEDBACK button opens a form where the user may submit any comments, recommendations, questions, or problems directly to the manufacturer.

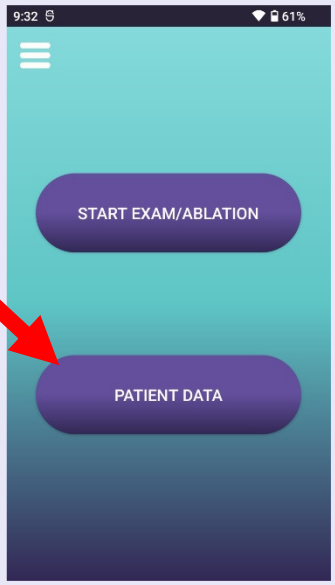
Options Menu – LOGOUT

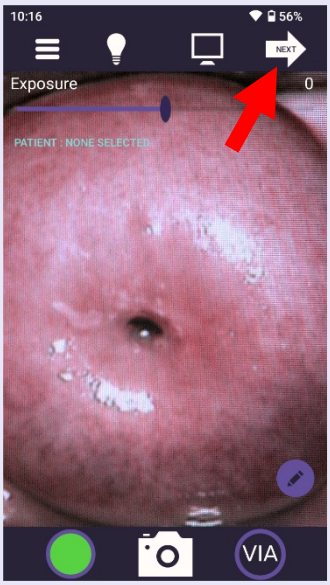
The LOGOUT button is only available if a user is logged into the Iris device. This button logs the current user off the Iris device.

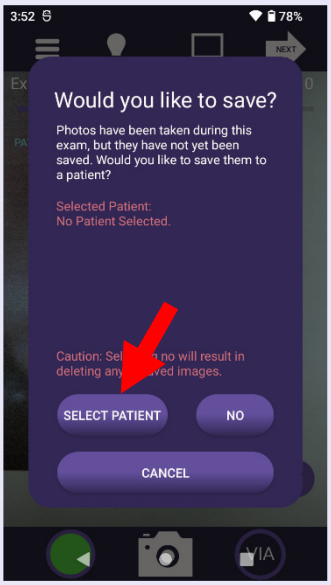
PATIENT DATA

Patient data can be entered after an exam, or by tapping “PATIENT DATA” icon from the home page. The data that can be entered includes personal information and pertinent medical history.

- To enter patient data from the home page, tap on the “PATIENT DATA” button.
- To enter patient data after an exam, tap the “NEXT” button on the exam screen, then tap “SELECT PATIENT”.

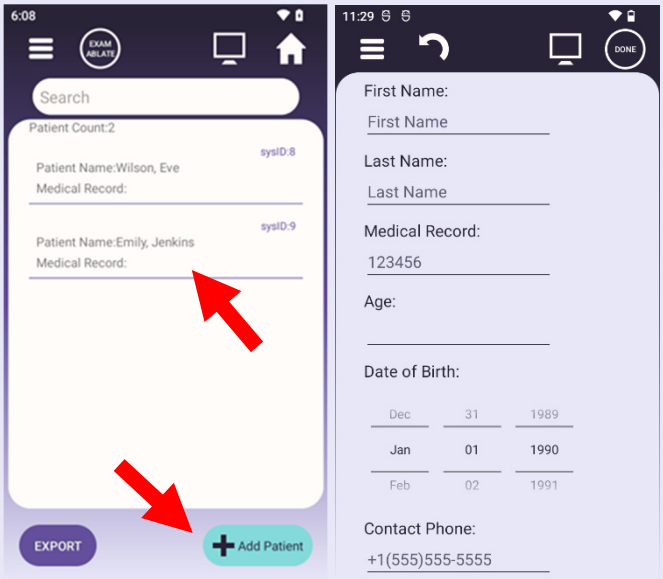






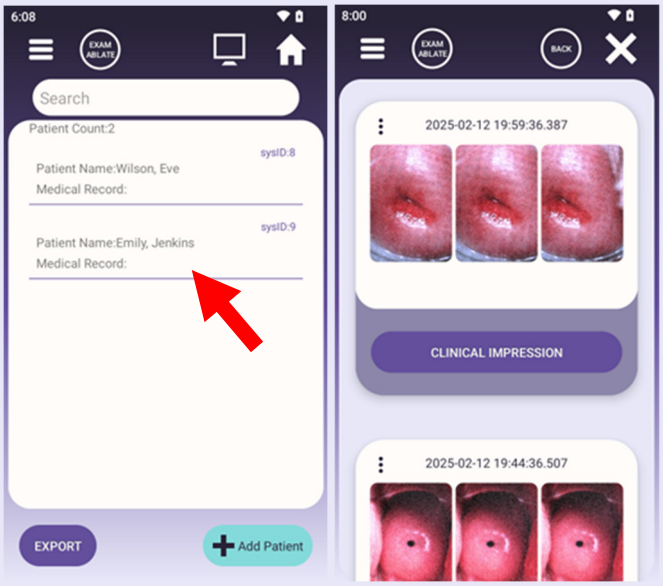
Patient Data – ADD/EDIT PATIENT

1. To add a new patient, tap the "ADD PATIENT" icon. To edit an existing patient, tap and hold on the patient's name from the list, then select "EDIT PATIENT".
2. Enter or edit the patient's data by tapping the appropriate field and using the on-screen keyboard.
3. Tap the "DONE" icon when completed.



Patient Data – Patient Review

1. The Patient Review page can be reached by selecting a patient from the Patient Selection page.
2. All exams saved for this patient will be displayed.
   a. Images may be viewed by tapping on the image thumbnail image.
   b. Clinical Impressions may be reviewed or edited by tapping on the "Clinical Impression" icon.



EXAMS

To perform a colposcopic exam, tap on the "START EXAM/ABLATION" button from the main menu. When an exam is initiated, the exam lights turn on and the screen shows a live image. Several icons appear near the top and bottom of the display.


Options Menu.


Exam Light Status/toggle on-off.


External Screen Mirroring.

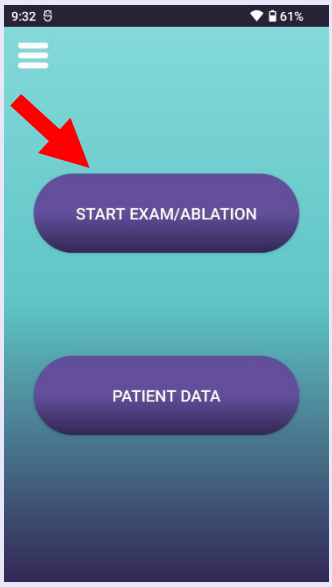

Home Screen.

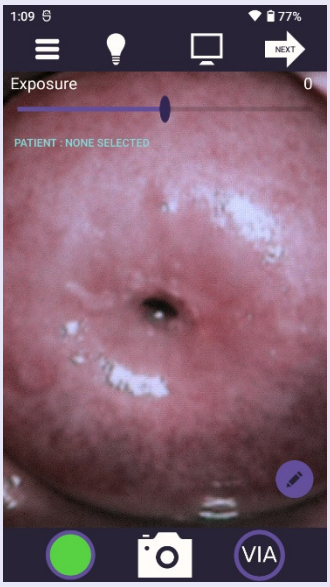
Next Screen.


Green Image Filter toggle.


Capture Image.

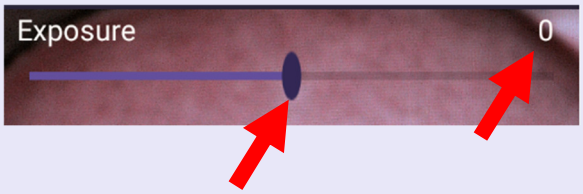
VIA Timer.





While performing a colposcopic exam, the image exposure level can be decreased or increased by moving the slider button to the left or right.

- The slider is located near the top of the screen.
- The exposure level value is displayed above and to the right of the slider button. The default exposure level is '0'.



Exam Mode –EXAM LIGHTS

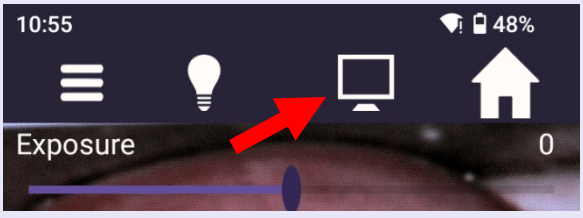
When an exam is initiated, the exam lights turn on. The lights may be toggled on or off by tapping the Exam Light Status icon. The icon will indicate when the exam lights are on or off.


Exam Lights ON


Exam Lights OFF

Exam Mode – EXTERNAL SCREEN MIRRORING

Using a micro-HDMI cable and an external screen monitor, you can extend your Iris display onto a larger screen. See section, "**CONNECTION TO EXTERNAL DISPLAY**" for instructions.



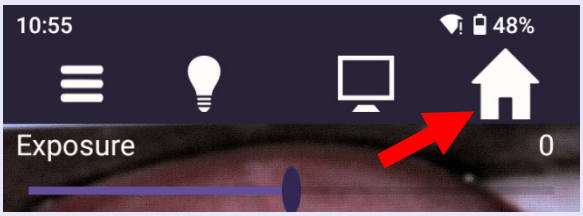
Exam Mode – HOME SCREEN/NEXT SCREEN

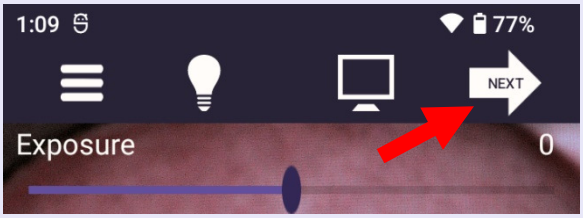
During an exam, if no images have been taken, the home screen icon is shown in the upper right corner of the screen.

- If the home screen icon is tapped, the exam mode will be ended, and the home screen will be displayed.

If images have been taken during an exam, the home screen icon will be replaced with the "NEXT screen" icon.

- If the next screen icon is tapped, the user will be given options to save the images to a patient profile. See SAVING/DELETING IMAGES section for further instructions.

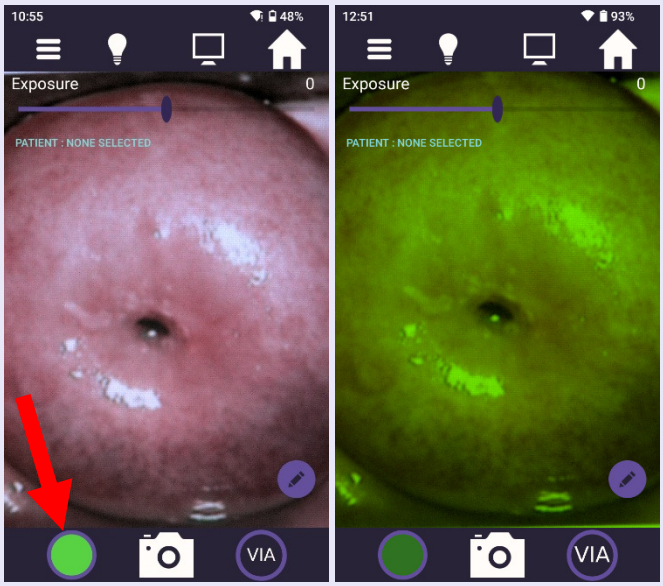




Exam Mode – GREEN IMAGE FILTER

The Iris device can apply a green filter to the live image stream. The green filter helps highlight blood vessels in the tissue.

- To turn on the green filter, tap the green button in the bottom, left corner of the screen.
- To turn off the green filter, tap the green button again.

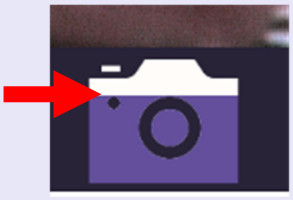


Exam Mode – IMAGE CAPTURE

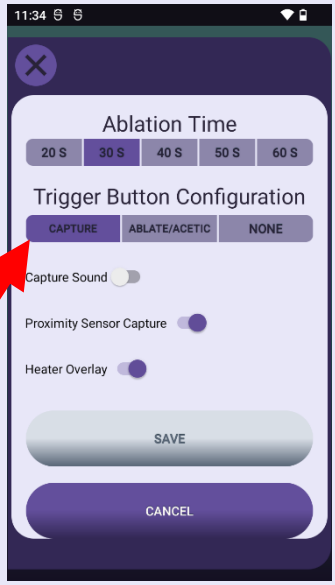
During an exam, image captures can be taken of what is currently on the display screen. The image may be captured by the image icon, using a proximity sensor, or using the image capture trigger on the device.

1. Image Icon:
   a. To capture an image using the capture image icon, simply tap the icon at the bottom, center of the screen.

2. Proximity Sensor:
    a. The proximity sensor is located at the top, center of the screen. To capture an image, move your hand or finger in front of the sensor.
    b. As you are holding your hand or finger in front of the proximity sensor, the capture image icon at the bottom center of the screen will “fill-up” and the image will be captured once the icon is “full” (approximately 1-2 seconds). It is not necessary to wave or move your hand.



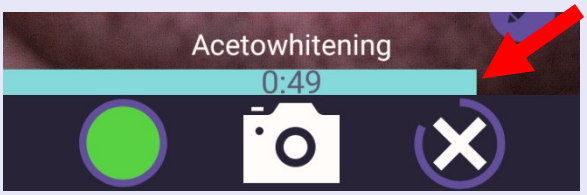
3. Image Capture Trigger:
    a. The image capture trigger is located on the front of the device near the top of the handle, just below the screen area. Press the trigger to capture the image.
    b. Note, the trigger settings must be enabled to capture images with it. To enable the trigger, go to the Options Menu → User Profile → Camera/Ablation Setting. Make sure the “CAPTURE” option is selected.

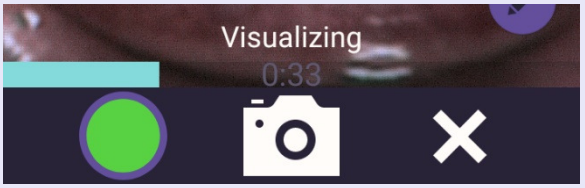


Exam Mode – VIA TIMER

When performing Visual Inspection with Acetic Acid (VIA), it is recommended to use the VIA Timer.

1. Immediately <u>after</u> application of acetic acid, tap the VIA Timer icon in the bottom, right corner of the screen.
    a. The VIA Timer icon will change to a circle around an “X” and a countdown timer of 1-minute will start with a progress bar.
    b. After the 1-minute timer is done, a count-up timer will begin for Visualization. The timer will continue until stopped by tapping on the “X” icon. Note, the timer can be stopped at any time, even during the countdown phase, by tapping the “X” icon.





It is advisable to take and capture images at the beginning and end of the visualization phase of the VIA process.

CAPTURING CLINICALLY USEFUL IMAGES

Clinically useful images are critical for image analysis, remote consultation, patient documentation, and quality assurance purposes. There are several factors to consider for ensuring high quality images.

Stability

The iris device should be in a stable position while capturing an image. The device can be stabilized by:

1. Using a stand: The iris device can be attached to a stand using the included adaptor plate. The height of the stand should be the same as the height of the examination table (standard medical table height is 80-110 cm/31.5-43.5 inch).
2. Proximity sensor feature: Images can be captured without touching the screen, through the proximity sensor feature. This enables the user to momentarily hold their hand in front of the proximity sensor above the visualization screen to capture an image.

Positioning

Distance: The device should be positioned at a distance of 17-40 cm / 7-15.7 inches from the patient's cervix. For best image results, position the device as close as possible to the cervix (within 20cm). Important: the iris device should never come into physical contact with the patient.
Angle: The entire face of the cervix should be captured in the image, without any obstruction by the speculum. The colposcope lens should be aimed directly at the patient's cervix and the cervix should fill a minimum of 80% of the frame.

Illumination

The cervix should be fully illuminated, while avoiding any glare. The iris device's LED lights reduce glare with a polarizer, however glare from the speculum reflection is still possible. If this is the case, reposition the colposcope and/or the speculum until there is less glare.

Focus

Move the focus knob all the way to the left. Bring the camera in close to the patient (around 20 cm from the cervix) and move the camera in and out until a sharp focus is achieved.

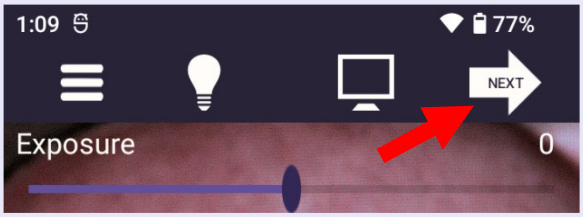
For determining whether or not a sharp focus has been achieved, find a crisp feature of the cervix, such as a vessel or a sharp shadow around the os.

After you have captured images, it is important to review the images to verify they are clinically useful.

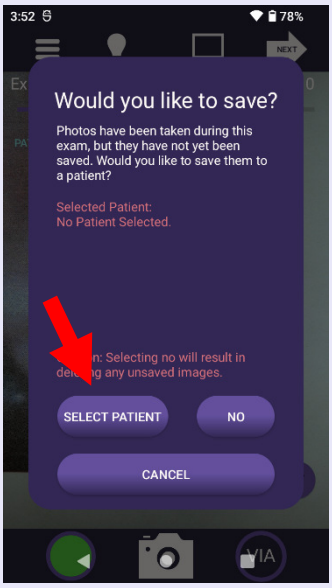
SAVING/DELETING IMAGES

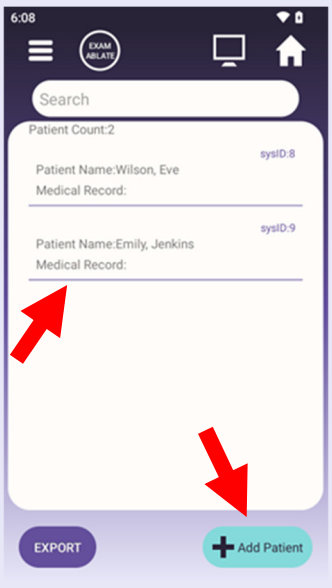
Saving Images

1. If images have been taken during an exam, the "NEXT" icon will appear at the top right corner of the display screen. To save the images taken, tap the "NEXT" icon.

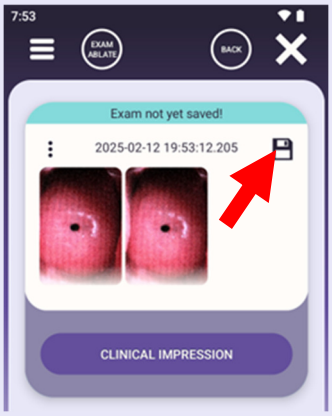


2. If no patient was selected at the start of the exam, a message will appear to select a patient. Tap the “SELECT PATIENT” icon to show a list of patients.
3. Select a patient by tapping on their name.
    a. If the exam is for a new patient not in the list, tap on the “Add Patient” icon at the bottom right of the screen.
4. After entering the new patient information or selecting a patient from the list, the patient will be selected for the exam.



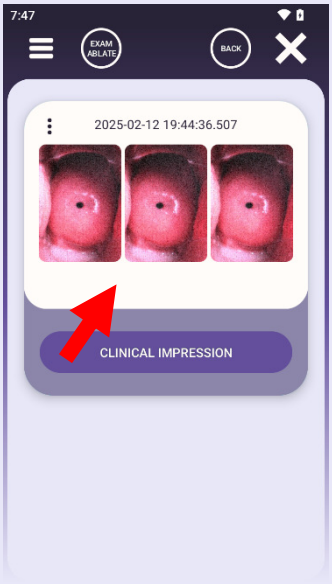


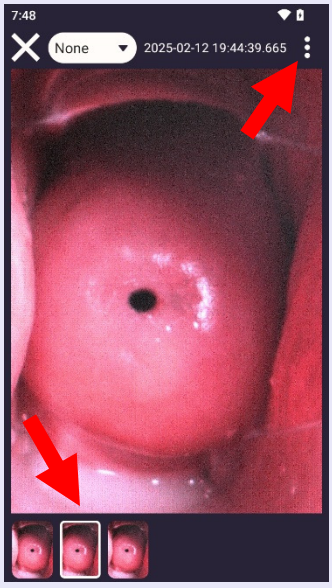
5. An exam preview will appear showing all the images from the exam. If all the images are acceptable, tap the save icon.
    a. Clinical impressions and other notes may be recorded and saved to this exam by tapping on the “CLINICAL IMPRESSION” button below the image(s).



Deleting Images

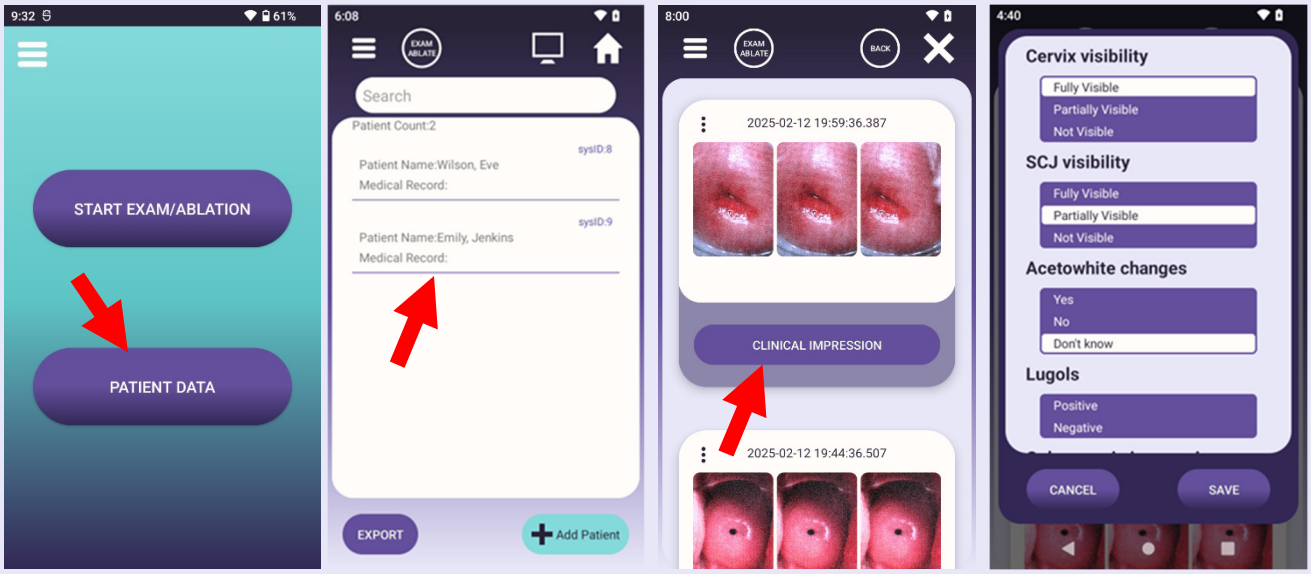
1. From the exam preview page, select the exam that has the photo you want to delete.
2. Tap on the preview window and then select the desired image at the bottom of the screen.
3. When the photo to be deleted is displayed, tap on the triple dot option in the upper right corner of the screen and select “Delete image”.
    a. Note: The photo will be permanently deleted and cannot be retrieved.





CLINICAL IMPRESSION RECORD

1. Clinical impressions may be recorded for each patient's exam. To access the clinical impression page, go to the patient data page, select the desired patient's name then select the "CLINICAL IMPRESSION" button under the desired exam.
2. Select the desired record options. Swipe on the screen for additional options including an input box for notes.

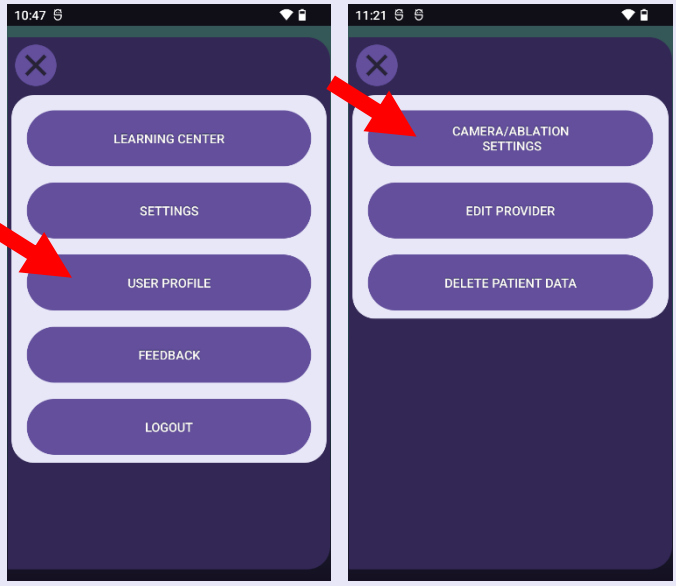


ABLATION SETTINGS

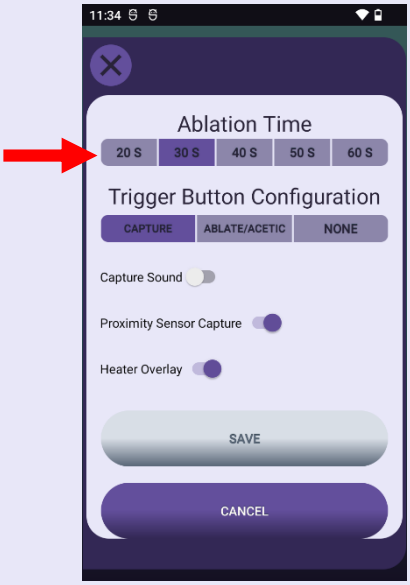
Time and Temperature Settings

The ablation time and temperature settings may be modified to fit the patient's needs or specific clinic protocol.

1. To change or verify the settings, tap on the menu icon from the home screen.
2. Tap on "USER PROFILE".
3. Tap on "CAMERA/ABLATION SETTINGS".

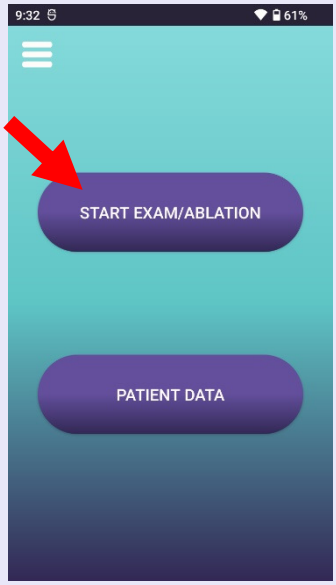


4. Tap the ablation time desired for the treatment. The selected setting will be highlighted in purple.
   a. Treatment times can be set from 20 to 60 seconds.
   b. The default time setting is 30 sec.
5. To save the ablation treatment settings, tap the Save icon. If no changes are needed to the ablation treatment settings, tap the Cancel icon.

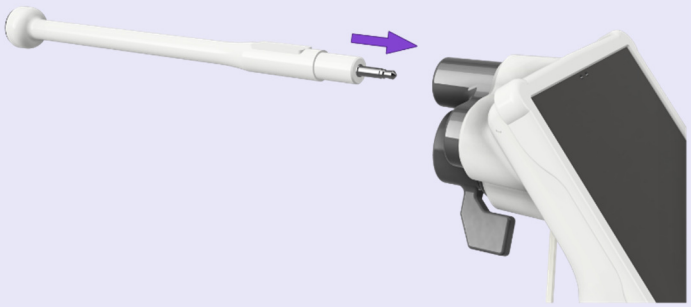


ABLATION MODE

1. To perform an ablation, tap on the “START EXAM/ABLATION” button from the main menu. When an “exam/ablation” is initiated, the exam lights turn on and the screen shows a live image.

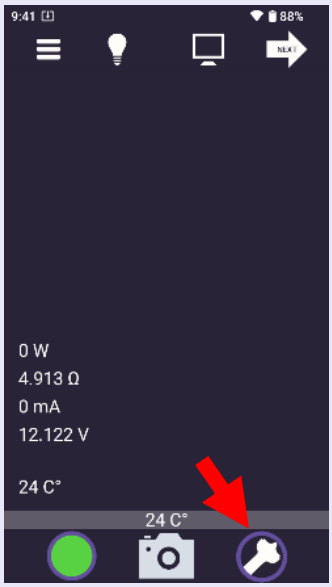


Insert Probe

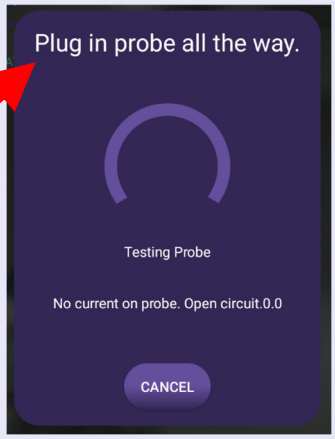


2. To activate ablation mode, insert the desired treatment probe into the mating connector at the front of the device to activate the ablation mode.
   a. Note the “VIA” icon 

in the bottom, right of the screen will change to the “ablation” probe tip icon  .



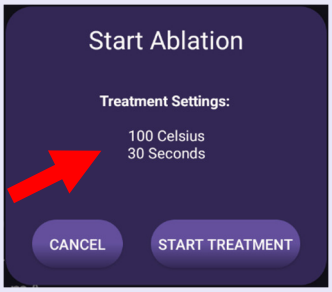
   b. Ensure that the probe is fully inserted. If the probe is not securely connected, inserted improperly, missing, or is broken, the IRIS will indicate that the probe needs to be fully inserted or replaced. If the probe tip icon will not appear when the probe is fully inserted, try a different probe.



Confirm Ablation Settings

3. After the probe is fully inserted, tap on the ablation icon  in the bottom, right corner of the screen.

4. The treatment settings will be displayed. Verify the settings are correct.



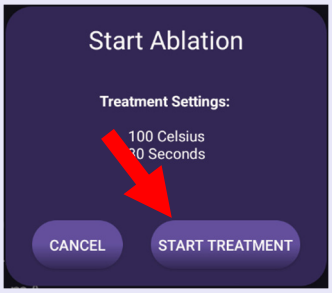
Place the Probe on the Tissue

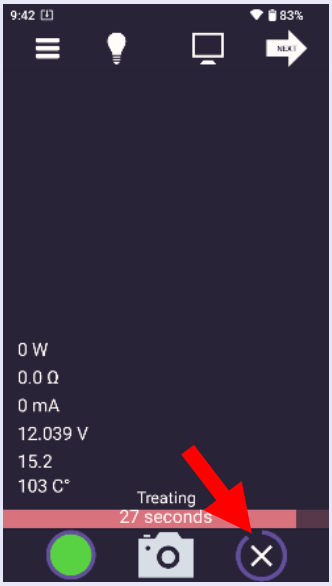
5. If treatment settings are correct, place the probe against the cervical tissue to be treated. The probe is not heated at this point. If the settings are incorrect, press “CANCEL” and change the settings as needed.

   NOTE: The probe is intended to be applied to tissue prior to being heated.

Start Treatment

6. When the probe has been placed against the tissue needing treatment, tap "START TREATMENT". The probe temperature and a heating progress bar are displayed. Once the probe reaches the set temperature, the time remaining for the treatment begins to count down. There will be an audible beep(s) at each quartile of the treatment.
   a. To cancel a treatment in progress, click on the cancel icon then confirm by tapping "YES".
   b. When the treatment cycle is complete, a cooldown progress bar displays the temperature and turns from red to gray once the probe reaches a safe level.
7. Once the cool down progress bar has reached below 50°C, remove the probe from the treatment area.





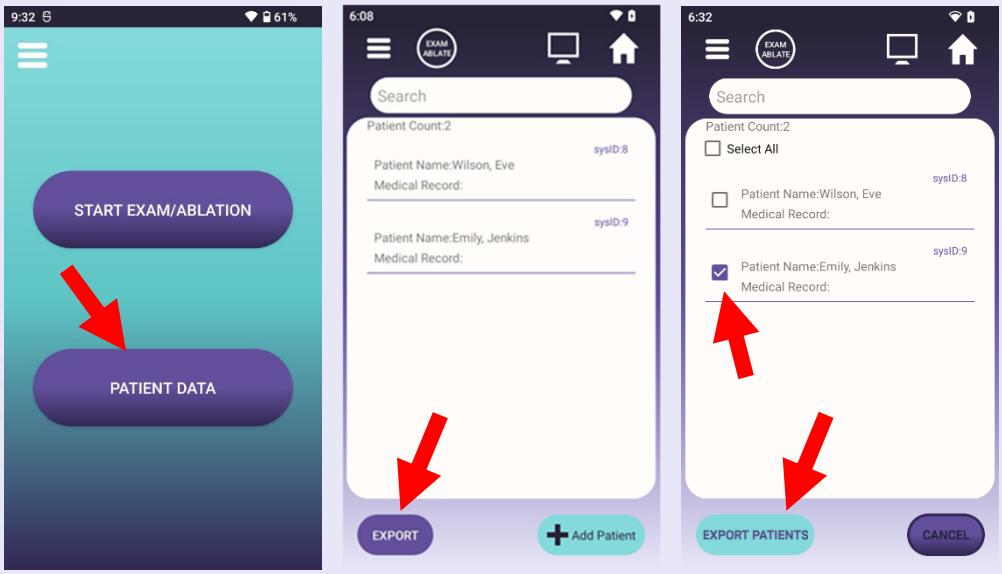
WARNING: Do not touch the active (heated) probe tip, as it may potentially cause burned tissue damage.

EXPORT DATA

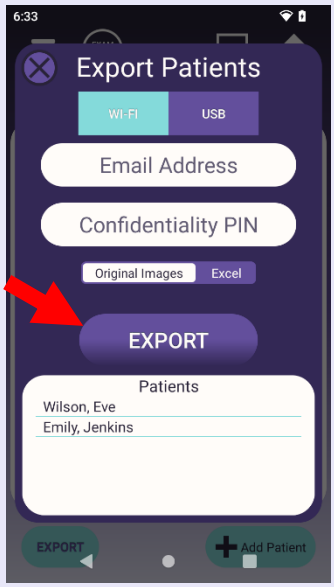
Patient exam records may be exported to an encrypted, PIN protected file. The export can be via e-mail (must be connected to WI-FI) or through the USB-C port on the iris device.

Exporting Data

1. From the home screen, tap the "PATIENT DATA" button. Then tap on the "EXPORT" button in the bottom, left corner of the screen.
2. Select the patients you would like to export.
3. Tap the "EXPORT PATIENTS" button.

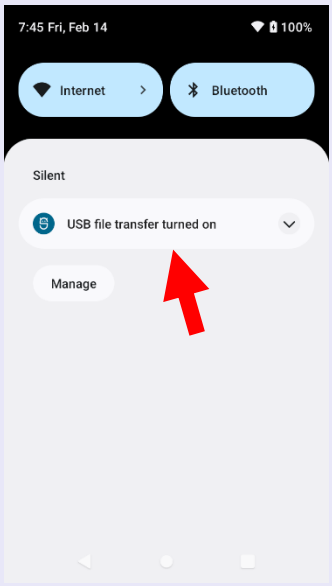


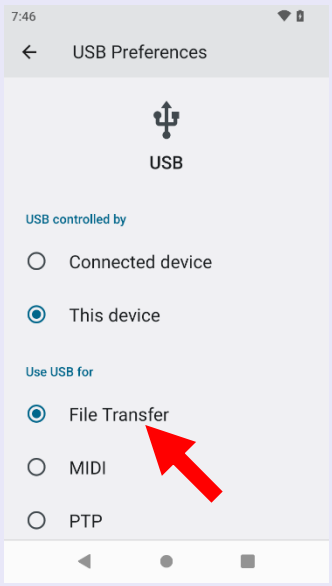
4. On the "Export Patients" screen:
   a. Select "WI-FI" or "USB".
   b. Enter a valid e-mail address (not required for USB export).
   c. Enter a Confidentiality PIN. PIN must be 4 digits or longer. This PIN will be required to un-zip the exported file.
5. Tap the "EXPORT" button.



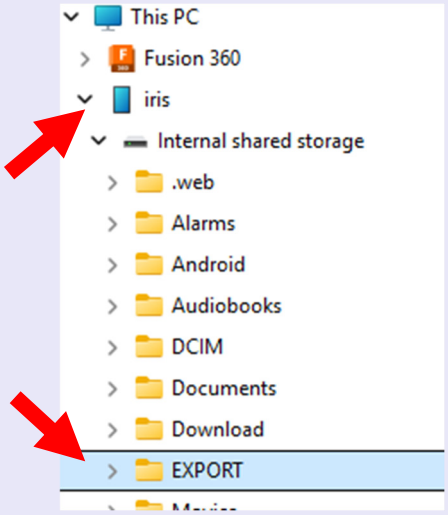
Retrieving Data

If the data was exported via the USB option, the following steps will be required to retrieve the exported data.





1. Connect the iris device to a computer using a USB cable between the USB-C port on the iris device and the USB-A or USB-C port on the computer.
2. Make sure the iris device is turned on. Swipe down from the top of the screen to access the Android System USB preferences menu.
3. Scroll down on the USB Preferences screen to the section titled, “Use USB for”, then select the “File Transfer” option.



4. On the computer’s file management app, find the iris device listed as a drive.
5. Expand the iris folder and find the “EXPORT” folder.
6. The exported, zipped file will be in this folder. Transfer the file to the desired location.

If the file was exported using the WI-FI option, the data file will be e-mailed to the address used.

Extracting Data

The exported data will be zipped into an encrypted file. To access the data in the file, it must be extracted. The PIN entered during the export will be requied to extract the data.

Older computer operating systems may not be able to extract the encrypted data. If needed, a file extraction utility like 7-ZIP can be used to extract the data. 7-ZIP is a free file utility and can be downloaded from www.7-zip.com.

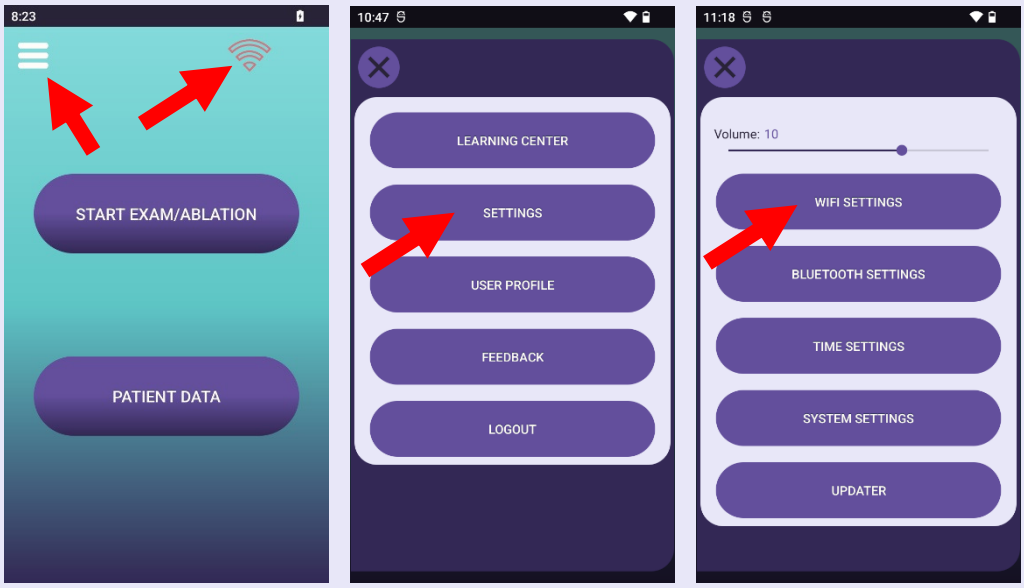
CONNECTING TO WI-FI

A WI-FI connection is required for the iris device to:

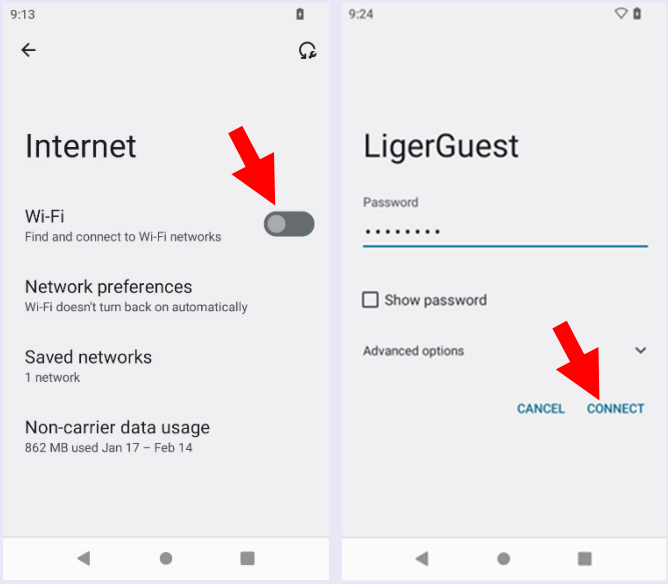
- Receive important software updates
- Export data via e-mail
- Upload data to the cloud

A red WI-FI icon on the home screen indicates that the iris device is not connected to WI-FI.

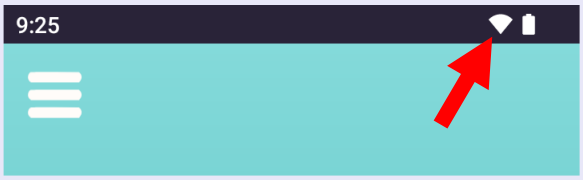
1. To connect to WI-FI, simply tap the red WI-FI icon. Or tap on the menu icon from the home screen.
2. Tap the “SETTINGS” button.



3. On the system Internet screen, tap the Wi-Fi switch to allow the device to start discovering available Wi-Fi networks.
4. Tap on your desired Wi-Fi network from the available list.
5. Enter the Wi-Fi network password and tap on “CONNECT”.



When connected to a WI-FI network, a WI-FI icon will appear at the top of the screen.

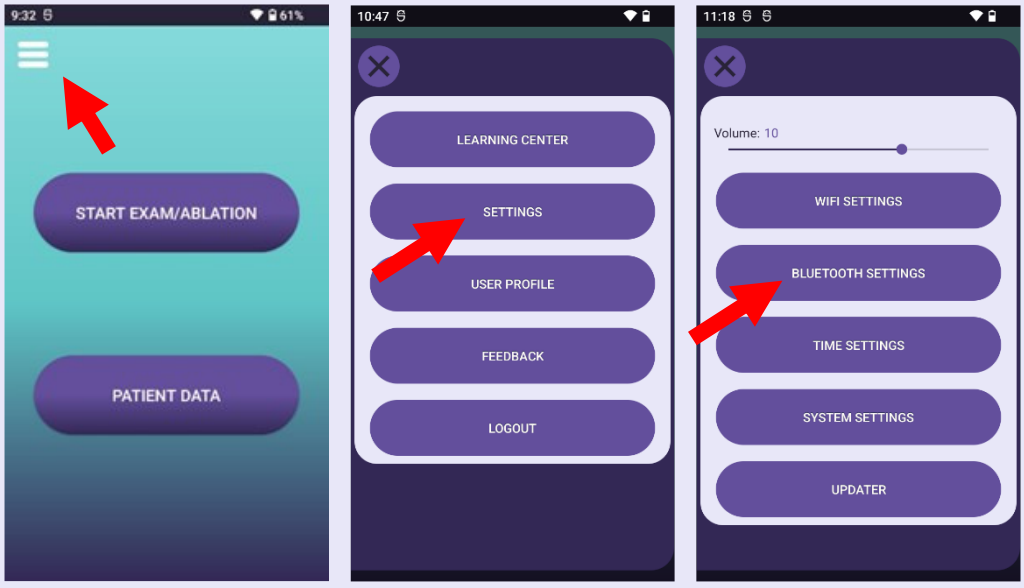


CONNECTING TO BLUETOOTH

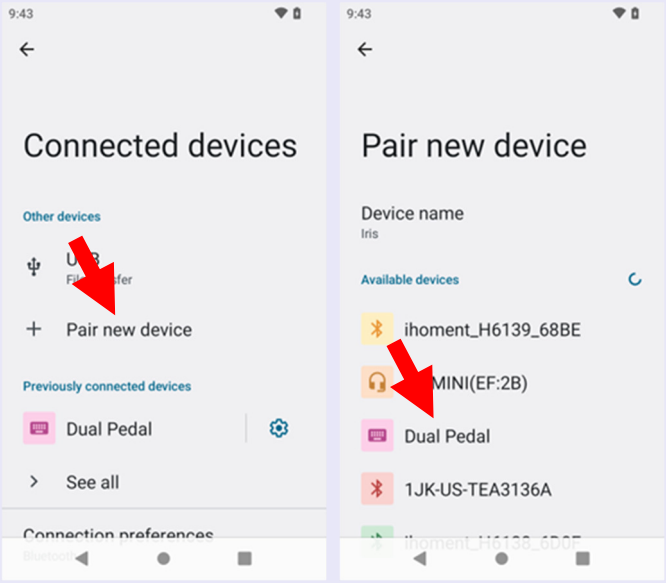
A Bluetooth connection will allow the iris device to connect to a:

- foot pedal
- clicker button
- external keyboard or mouse

1. To connect a Bluetooth device, tap the menu icon from the home page.
2. Tap the “SETTINGS” button.
3. Tap the “BLUETOOTH SETTINGS” button.



4. On the system “Connected devices” page, tap on “Pair new device”.
5. Make sure your Bluetooth device is on and select it from the list of available devices.
6. The paired device should be listed under “Connected devices”.
7. To return to the iris app, tap the back arrow at the top of the screen or the triangle icon at the bottom of the screen.

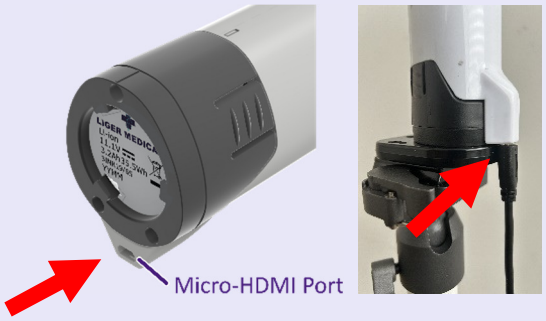


CONNECTING TO EXTERNAL DISPLAY

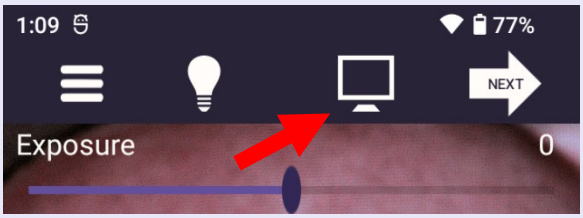
Required Equipment:

- Iris Device.
- External screen monitor with an available HDMI port.
- Micro-HDMI to HDMI cable (not included).

1. Connect the Micro HDMI cable.
   a. Insert the micro-HDMI plug into the micro-HDMI port on your Iris device. Note: the port is at the base of the device.
   b. Connect the other end of the cable (the standard HDMI plug toa an available HDMI Port on the external screen monitor.

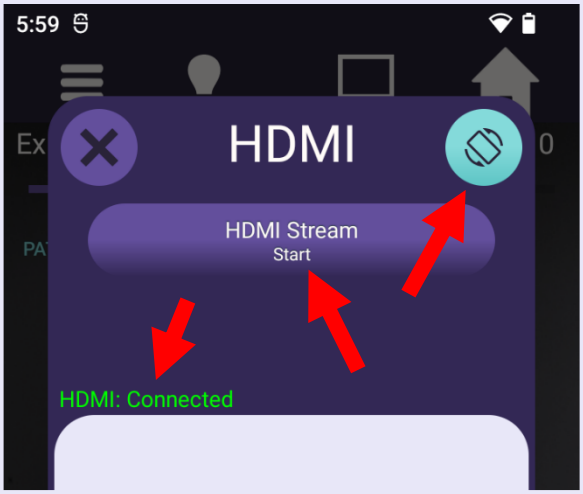


2. Turn on the external screen monitor.
3. Adjust the external screen monitor settings (if needed). Depending on your monitor, you may need to adjust display settings. Make any necessary adjustments to match your preferences.
4. To project the image to the monitor;
   c. Tap the monitor icon located at the top of the screen to access the external monitor options.
   d. An HDMI Display window will appear on the screen. If an external monitor is properly connected, the HDMI STREAM will show “HDMI: Connected”.
   e. Tap the “HDMI Stream Start” button.



f. If needed, the image on the external monitor may be rotated using the image rotation icon.

The device image stream should now be mirrored onto the external screen monitor. You can now use the monitor to view content from your Iris device.
When you're finished using the external monitor, simply unplug the cable from your Iris device.



CLEANING

The IRIS handle and probes are reusable and require specialized cleaning after each use. The probe must undergo cleaning and either high level disinfection or sterilization (per hospital or clinical requirements) prior to use. Follow the proper cleaning instructions for cleaning the device using the procedures that follow.

Cleaning Procedure – Handle and Battery

1. Disassemble the IRIS device into three separate parts (handle, battery, probe).
2. Thoroughly wipe all surfaces of the IRIS handle and battery with a mild cleaning solution (i.e., 70% isopropyl alcohol) or disinfectant and damp cloth. The cleaning solution or disinfectant should not be applied directly to the IRIS device. Pour/spray the cleaning solution or disinfectant onto a cloth and ensure that the cloth is evenly damp prior to cleaning the IRIS.
3. Do not allow fluids to enter the IRIS device. Do not sterilize the IRIS handle or battery.
4. Special caution should be used not to scratch the camera lens or display.

Cleaning Procedure – Probes

The probes require specialized cleaning after each use to remove all visible soil. After cleaning prior to each use, additional sterilization or high-level disinfection (HLD) processing must be completed before each individual use of the probe. See "**Probe High-Level Disinfection/Sterilization**" section below for directions.

CAUTION: Only use a soft brush or cloth to manually remove impurities; never use abrasive materials as they may damage the probes. **Always place the silicone cap on the probe connector and do not immerse the probe connector in liquid.**

<u>Manual Cleaning of Probes*</u>

Equipment: Personal protective equipment, enzymatic detergent, brush/cloth, running water.

1. If possible, initiate instrument cleaning within 30 minutes following use.
2. Verify the probe tip is cooled to room temperature before cleaning
3. **Place silicone cap on probe connector**.

4. Rinse probe shaft using cool running water to remove gross soil. A soft bristled brush or cloth may be used to aid in the removal of soil. Run water over shaft, crevices, hard to reach areas until water runs clear.
5. Prepare an enzymatic detergent such as Enzol® per manufacturer's recommendations. Fully immerse the probe (except for connector covered by the protective cap) in the prepared detergent. Allow probe to soak for a minimum of one (1) minute.
6. Following the soak time, while still immersed, use a soft bristled brush or cloth to thoroughly clean the probe. Pay particular attention to hard-to-reach areas.
7. Remove the probe from the detergent solution and rinse with running water.
8. Visually inspect each probe for visible soil. If soil remains, repeat the cleaning procedure outlined above.
9. Perform the final probe rinse with clean water (i.e., Reverse Osmosis/De-ionized (RO/DI) water) that does not contribute to device staining or contamination.
10. If an alkaline-based detergent is used during the cleaning process, a neutralization solution may be used to remove alkaline-based residues and deposits. Follow the manufacturer's recommendations.

* Liger Medical validated the manual cleaning method using an independent accredited test laboratory and has the data on file. The validation was accomplished using Enzol® as the enzymatic detergent. Use of an automated cleaning system was not validated by Liger Medical and use of such a system is at the risk and discretion of the user.

Drying

Ensure the probes are free from residual moisture prior to sterilization or high-level disinfection. If moisture remains on the probe, dry using a clean lint-free cloth and/or filtered pressurized air.

WARNING: Failure to properly clean and dry the probes may lead to inadequate high-level disinfection or sterilization or a reduction in instrument life.

PROBE HIGH-LEVEL DISINFECTION/STERILIZATION

PROBE HIGH-LEVEL DISINFECTION (HLD)

Liger Medical has validated the following HLD methods (Glutaraldehyde, Boiling/Pasteurization, and Tristel DUO Foam) with an independent accredited test laboratory and has the data on file.

In global regions where the above-mentioned methods are not available/feasible there may be other HLDs available (e.g. Cidex OPA, Perasafe, etc.) in these cases follow the manufacturer's recommendations for processing. These HLD methods have not been validated by Liger Medical. Individuals or hospitals not using the recommended method are advised to validate an alternative method using appropriate laboratory techniques.

A 20-minute soak in a 0.5% Strong Chlorine Solution is not an HLD method. It is a Mid-Level Disinfection (MLD) method. The Center for Disease Control (US CDC) has instructions for preparing a 0.5% Strong Chlorine Solution. This MLD method has not been validated by Liger Medical for use on the probes.

WARNING: Failure to properly disinfect the probes per these instructions may lead to inadequate disinfection and/or reduction in instrument use-life.

HLD – Glutaraldehyde

Materials (not provided):

- Cidex®, in a basin deep enough for vertically immersing the distal end of the probe.
- Tongs
- Pure water (boiled or Reverse Osmosis/ De-ionized (RO/DI) water) at room temperature.
- Sterile cloths for drying and storage.

Disinfection Procedure:

1. Ensure minimum effective concentration (MEC) of the HLD following manufacture's guidelines.
2. **Place silicone cap firmly on probe connector.**
3. Vertically immerse the distal end of the heating tip of the probe into a basin of glutaraldehyde approximately 5 to 6 inches (12 to 13 cm) deep. Keep probes upright. Do not immerse the connector end in the solution.
4. Allow the probe to soak in Glutaraldehyde for 20 minutes.
5. Thoroughly rinse the probe(s) in pure water by agitating then allowing them to set for a minimum of 5 minutes.
6. Repeat the previous rinsing step (5) two more times for a total of 3 rinses using a fresh batch of pure water each time.
7. Dry with sterile lint-free cloth.
8. Store the probe in a sterile lint-free cloth until next use.

HLD – Boiling (Pasteurization)

Materials (not provided):

- Hot plate, gas burner, or other means of supplying heat to a container
- A water container that is over 6 inches (15 cm) in height and can withstand the heat of the boiling process.
- Tap water
- Sterile cloths for drying and storage.

Disinfection Procedure:

1. Fill container with water to 4.5" to 5" (11.5 cm to 13 cm) high
2. **Place silicone cap firmly on probe connector.**
3. Immerse ~4.5 inches (11.5 cm) of the device in room temperature tap water. Ensure that the distal heating tip is pointed downward, and the connector end is pointed upward. DO NOT immerse the connector end.
4. Begin to heat the tap water with the probe immersed until the water is boiling.
5. Once the water has reached boiling, allow the probe to remain in the boiling water for five (5) minutes.
6. Remove the probe from the water and allow the probe to air dry
7. Store the probe in a sterile lint-free cloth until next use.

HLD – Tristel Duo ULT Foam

Materials (not provided):

- Tristel Duo ULT Foam
- Tristel Duo Wipe

- Sterile cloths for drying and storage.

Disinfection Procedure:

1. **Place silicone cap firmly on probe connector.**
2. Prime the Tristel Duo ULT by depressing the pump 2-4 times
3. Dispense two pumps of the Tristel Duo ULT foam onto the Tristel Duo Wipe.
4. Allow the foam to dwell for 10 seconds on the wipe.
5. Apply the Tristel Duo ULT onto the distal 4.5 inches (11.5 cm) of the probe's tip end.
6. Use the wipe to spread the foam evenly on the distal end of the probe. Ensure that the foam is spread through the joint crevices of the probe.
   a. Apply new additional foam with new wipes as necessary so that the surfaces of the probe remain visibly wet for the entire two (2) minute contact time. Contact time is the amount of time that the probe surfaces appear visibly wet with the foam.
   b. Do NOT continuously wipe during the two (2) minute contact time.
7. Allow the probe to air dry.
8. Store the probe in a sterile lint-free cloth until next use.

PROBE STERILIZATION

1. Sterilize probes in sterilization trays/pouch and containers. Disposable sterilization packages may also be used.
2. **Place silicone cap on probe connector.**
3. Insert probe(s) into sterilization tray/pouch following sterilizer manufacturer guidelines for appropriate tray/pouch and packaging instructions.
4. Ensure that all surfaces will be exposed to the sterilizing agent. Ensure that probes do not contact each other if multiple probes are packaged together.
5. Control the water purity dedicated to steam production to prevent damage to the instruments.
6. Sterilization temperatures higher than 121°C (250°F) may damage the instruments.

To achieve a sterility assurance level of 10^{-6}, use of the following sterilization parameters is recommended:

Gravity Steam Sterilization Method*	Temperature	Time	Drying time**
Gravity Steam	121 °C (250 °F)	30 min	30 min

* Liger Medical validated this sterilization cycle using an independent accredited test laboratory and has the data on file. The validation was accomplished with probes individually double pouched and placed on edge in the sterilizer. Other sterilization cycles may be suitable; however, individuals or hospitals not using the recommended method are advised to validate an alternative method using appropriate laboratory techniques. Steam sterilization will significantly reduce the useful life of the probe.

** Liger Medical validated this dry time using probes individually double pouched, weighing approximately 17g (0.6 oz.). Longer dry times may be required for instrument trays exceeding this weight.

INSPECTION

Liger Medical recommends that the IRIS handle and probes be regularly inspected every month for visible damage. The following concerns should be addressed immediately:

- Signs of deterioration or obvious damage to the device.
- Signs of damage to any connector.
- Accumulation of lint or debris on or around the device.

In each case, discontinue using the device. If the device is damaged externally or has a damaged connector, contact Liger Medical. If the device has accumulated dust or debris, follow the cleaning procedure to remove the debris.

TROUBLESHOOTING

The Liger Medical IRIS has no user-adjustable controls or diagnostic tests. If the device fails to respond as expected, try the following steps before contacting Liger Medical:

1. If the IRIS will not turn on, please verify that the battery is fully charged. To prevent a low battery during a procedure, charge the battery before each day of procedures.
2. To determine whether the handle or probe are faulty, turn on the IRIS and enter the exam mode. Attach a probe to the IRIS handle. If the probe is faulty, the IRIS will display an error message indicating the fault.
3. If the IRIS app is not responding, restart the IRIS by turning it off and on.

DEVICE DISPOSAL

When the IRIS handle, probe, or battery are no longer functional or show signs of wear and damage, they should be disposed of in the same manner as electrical waste.

To order additional devices/accessories or replacement accessories go to www.ligermedical.com.

WARRANTY AND RETURN POLICY

Liger Medical warrants each product manufactured by it to be free from defects in material and workmanship under normal use and service for the period(s) set forth below.

Liger Medical's obligation under this warranty is limited to the repair or replacement, as its sole option, of any product, or part thereof, which has been returned to it or its Distributor within the applicable time period shown below, after delivery of the product to the original purchaser, and which examination discloses, to Liger Medical's satisfaction, that the product is indeed, defective.

This warranty does not apply to any product, or part thereof, which has been repaired or altered outside Liger Medical's factory in a way so as, in Liger Medical's judgment, to affect its stability or reliability, or which has been subjected to misuse, neglect, or accident.

The warranty period for Liger Medical products are as follows:

- IRIS Thermocoagulator & Digital Colposcope: Two (2) years from date of shipment.

- Thermocoagulation Probes: 240 Disinfection Cycles or Two (2) years from date of shipment, whichever comes first.

This warranty is in lieu of all other warranties, express or implied, including without limitation, the warranties of merchantability and fitness for a particular purpose, and of all other obligations or liabilities on the part of Liger Medical.

Liger Medical neither assumes nor authorizes any other person to assume for it any other liability in connection with the sale or use of any of Liger Medical's products.

Notwithstanding any other provision herein or in any other document or communication, Liger Medical's liability with respect to this agreement and products sold hereunder shall be limited to the aggregate purchase price for the goods sold by Liger Medical to the customer.

Liger Medical disclaims any liability hereunder or elsewhere in connection with the sale of this product, for indirect or consequential damages.

This warranty and the rights and obligations hereunder shall be construed under and governed by the laws of the State of Utah, United States of America (USA). The sole forum for resolving disputes arising under or relating in any way to this warranty is the 3rd District Court of Utah, USA.

Liger Medical, its dealers, and representatives reserve the right to make changes in equipment built and/or sold by them at any time without incurring any obligation to make the same or similar changes on equipment previously built and/or sold by them.

RECHARGING THE BATTERIES

The batteries supplied with the iris device may be recharged when needed. To recharge the batteries, perform the following:

1. Without a battery, plug the Wall Charger into a power source.
   a. Ensure the wall charger is plugged directly into a wall socket or a power strip that is turned on. The green light should turn on.

2. Connect the Adaptor to the Wall Charger.
   a. Firmly connect the adaptor to the wall charger.

3. Insert the Battery into the Adaptor.
    a. Verify the batteries are clean and dry.
    b. Make sure the battery is securely plugged into the adaptor. If the battery is low, the light should change to RED.
    c. Note: The charger can be plugged into an A/C power outlet of 100-240VAC, 50/60Hz, with the proper country adapter.

4. Once the battery is fully charged, the indicator light on the wall charger will change from red to green.
    a. A completely discharged battery should fully recharge in about two (2-4) hours.
    b. The battery will not be damaged by leaving the battery in the charging adapter after the battery is fully charged, making overnight charging convenient.

Note: If the wall charger is plugged into a power source (such as a power strip) that is turned off, the light indicator will still show green when the battery is connected, even though the battery is NOT fully charged.

Internal Battery

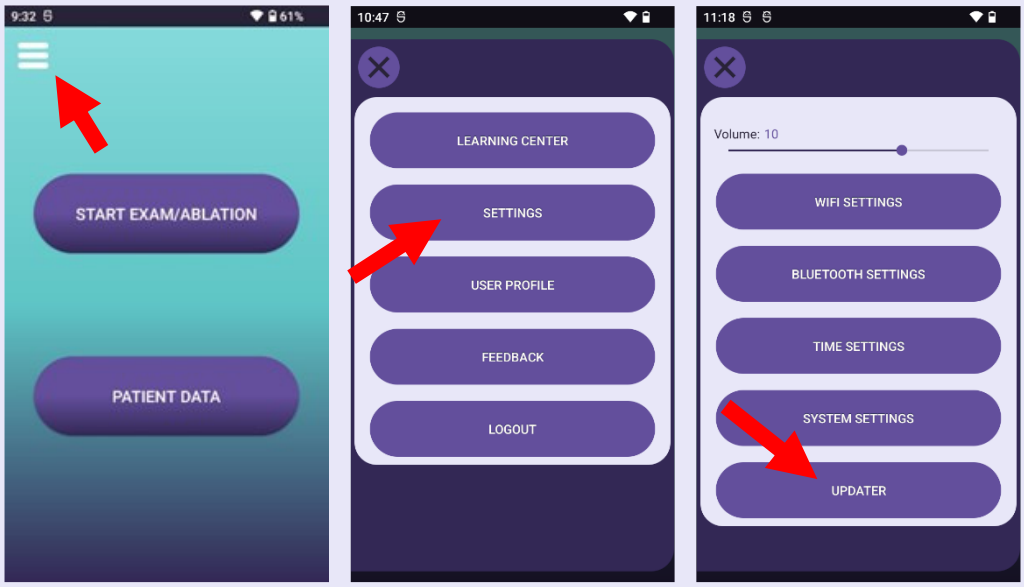
The iris device has an internal lithium-ion coin-cell battery (CR1225) that can only be changed by Liger Medical personnel that are trained to use the appropriate tools.

SOFTWARE UPDATES

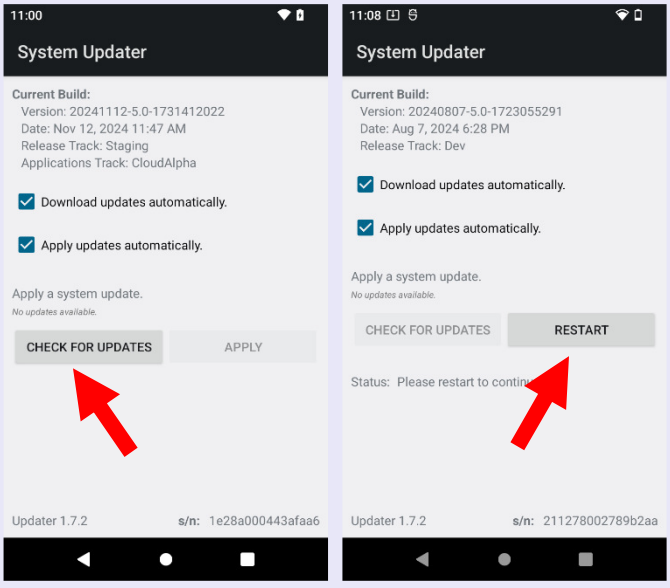
The iris device should be updated periodically for feature enhancements or to correct programing errors. Updates require a WI-FI connection and can be downloaded and applied automatically with little user interaction.

Manual Check for Updates

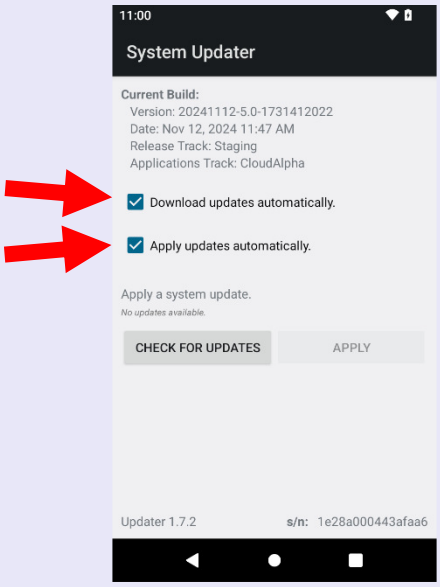
1. To manually check for software updates, tap the menu icon from the home page.
2. Tap the “SETTINGS” button.
3. Tap the “UPDATER” button.



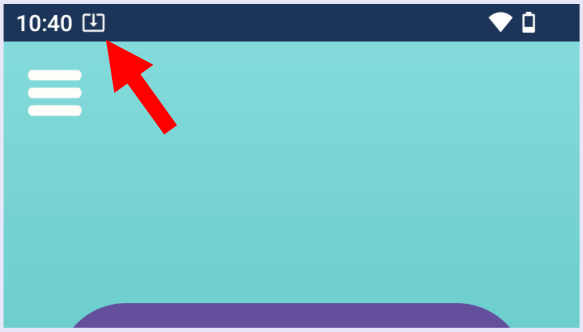
4. The “System Updater” will be launched. Tap on the “CHECK FOR UPDATES” button.
   a. If there are no updates currently available, the app will display “No updates available”.
5. If updates are available, the “APPLY” button will become active. Tap the “APPLY” button to install the update.
   a. It may be necessary to restart the device to fully install and apply the update. If needed, the “APPLY” button will change to “RESTART”. You may either tap the button to immediately start the reboot process, or you can wait and shut down the device in a normal manner at your convenience.



6. To allow the iris device to automatically check and install updates, make sure the check boxes are selected on the System Updater screen.



While the device is downloading an update, either automatically or manually, the display will show a download icon at the top of the screen.



TECHNICAL ASSISTANCE

For technical assistance, please call or email Liger Medical.

Phone: +1 (801) 256-6576
Email: support@ligermedical.com
Website: www.ligermedical.com

TECHNICAL SPECIFICATIONS

All specifications are nominal and subject to change without notice. A specification referred to as "typical" is within ±20% of a stated value at room temperature (25°C/77°F) and utilizing a sufficiently charged battery pack.

DEVICE PARAMETERS	
Power Parameters	
Power Supply:	12 VDC
	Rechargeable Lithium-Ion
Battery Pack:	3-cell 2.6AH Battery Pack
	BMS overcharge protection
Battery Charger:	12.6VDC, 1.8amp output
	Charge Time: 2-3 hours
Full-Charge Activation:	Until low-battery indicator illuminates
Power Output:	49 Watts
Treatment (Duty) Cycle:	~4 hours of examination time, 30-60 thermal ablation cycles
	~8 seconds of heat up; 20-60 seconds of therapy at 100-120°C; ~10 seconds of cool down
Digital Colposcope	
Working Distance:	17-40cm
Focus Mechanism:	Manual
Optical magnification:	3x
Digital Magnification:	9x
Field of View:	15.6°
Direction of View:	0°
F#:	>5
Average On-Axis Vertical Resolution:	15.75 line-pairs/mm
Average On-Axis Horizontal Resolution:	15.75 line-pairs/mm
Average Off-Axis Vertical Resolution:	11.56 line-pairs/mm
Average Off-Axis Horizontal Resolution:	10.33 line-pairs/mm
Image Resolution Pixels:	2016 X 2880 (5.8 megapixels)
Display	
Display area:	62.10(H) X 110.40(V) 5.0in Diagonal
Number of Pixels:	720 X 1280 (0.92 megapixels)
Display Colors:	16.7M colors
Dimensions and Weight	
Width:	3.2 inches (8cm)
Height:	9.5 inches (24cm)
Depth:	4.5 inches (11.5 cm)
Weight:	15.4 oz (435g)
Operating Conditions	
Ambient Temperature:	10°C to 40°
Relative Humidity:	0% to 80% non-condensing
Altitude:	2000m
Transport and Storage	

Ambient Temperature:	-18° to 60°C
Relative Humidity:	0% to 90% non-condensing
General Info	
Type B Applied Parts	
IP21 Rating	Solid particle protection: Level 2 (>12.5mm)
	Liquid ingress protection: Level 1 (dripping water)
Wireless Communications	
Wi-Fi IEEE 802.11	ac/a/b/g/n; transmits at 2.40 to 2.48 GHz at +16dBm Operating Range: 50m
IEEE 802.15.4 Bluetooth class II	Bluetooth 2.1_EDR/BLE 4.2; transmits at 2.40 to 2.48 GHz at +16dBm Operating Range: 20m

<table>
<tr><th colspan="4">ELECTROMAGNETIC COMPATIBILITY GUIDANCE</th></tr>
<tr><td colspan="4">Manufacturer’s Declaration – Electromagnetic Emissions</td></tr>
<tr><td colspan="4">The IRIS is intended for use in the electromagnetic environment specified below. The customer or the user of the IRIS should ensure that it is used in such an environment.</td></tr>
<tr><td>Emissions Test</td><td colspan="2">Compliance</td><td>EMC Environment Compliance</td></tr>
<tr><td>RF Emission
CISPR 11</td><td colspan="2">Group 1</td><td>The IRIS uses RF energy only for its internal function. Therefore, its RF emissions are very low and not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF Emission
CISPR 11</td><td colspan="2">Class A</td><td rowspan="7">The IRIS is suitable for use in professional healthcare environments.</td></tr>
<tr><td>Conducted RF Emissions</td><td colspan="2">Not Applicable</td></tr>
<tr><td>Radiated RF Emissions</td><td colspan="2">Complies</td></tr>
<tr><td>Harmonic Distortion
IEC 6100-3-2</td><td colspan="2">Not Applicable</td></tr>
<tr><td>Voltage Fluctuation and Flicker
IEC 61000-3-3</td><td colspan="2">Not Applicable</td></tr>
<tr><td colspan="4">Manufacturer’s Declaration – Electromagnetic Immunity</td></tr>
<tr><td colspan="4">The IRIS is intended for use in the electromagnetic environment specified below. The customer or user of the IRIS should ensure that it is used in such an environment.</td></tr>
<tr><td>Immunity Test</td><td>IEC 60601 Test Level</td><td>Compliance Level</td><td>Electromagnetic Environment – Guidance</td></tr>
<tr><td></td><td>±8 kV contact</td><td>Complies</td><td>Not Applicable</td></tr>
</table>

IEC 6100-4-2 – Electrostatic discharge (ESD)	±15 kV air	Complies	
IEC 61000-4-4 – Electrical fast transient/burst	2kV Mains 100kHz	Not Applicable	No external connections
	1kV Signal/Data 100kHz		
	2kV Control 100kHz		
	100kHz rep Rate		
IEC 61000-4-5 – Surge	Mains 1kV LL, 2kV LG	Not Applicable	No external connections
	DC 0.50.5kV LG		
IEC 61000-4-6 – Conducted Disturbances induced by RF fields	0.15-80MHz 3Vrms	Not Applicable	No external connections
	Frequencies of main interest at 6Vrms		
	Amplitude Modulation 1kHz sine 80%		
IEC 6100-4-11 – Voltage dips, short interruptions and voltage variations on power supply input lines	100% for 0.5 cycle at 0/40/90/135/180/225/270 & 315	Not Applicable	No external connections
	100% for 1 cycle		
	30% for 25/30 cycles		
	100% for 250/300		
IEC 61000-4-8 – Rated Power-Frequency Magnetic Field	30 A/m	Complies	See Warning 10 on Page 5 of this IFU
(50/60Hz) magnetic field			

Manufacturer's Declaration – Electromagnetic Immunity						
Enclosure Port Immunity to RF wireless communications equipment						
Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 499	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						

1720 1845 1970	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9

NOTE: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1m. The 1m test distance is permitted by IEC 61000-4-3.

a) For some services, only the uplink frequencies are included.

b) The carrier shall be modulated using a 50% duty cycle square wave signal.

c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be the worst case.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Radiated RF IEC 61000-4-3	3 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	Complies	Not Applicable

NOTE: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

[a]Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the IRIS is used exceeds the applicable RF compliance level alone, the IRIS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the IRIS.

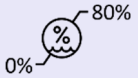
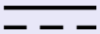
[b]Over the frequency range 160 kHz to 80 mHz, field strengths should be less than 3 V/m

Contains Transmitter Module FCC ID: TFB-1004
Contains Transmitter Module IC: 5969A-1004
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and receiver.*
- *Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.*
- *Consult the dealer or an experienced radio/TV technician for help.*

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

SYMBOL DEFINITIONS

Symbol	Standard	Description
	ISO 15223-1:2016	Device Name
	ISO 15223-1:2016	Serial Number
	ISO 15223-1:2021	Medical Device
	ISO 15223-1:2016	Manufacturer & Date of Manufacture
	ES 60601-1:2005+A1:2012	Attention! See Instructions for Use
	ES 60601-1:2005+A1:2012	Type B Applied Parts
	N/A	CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician
	ASTM F203	MRI Unsafe: Keep Away from Magnetic Resonance Imaging (MRI) Equipment
	ISO 15223-1:2016	Temperature Limits: -18°C to 60°C
	ISO 15223-1:2016	Humidity Limits: 0% to 90%
	ES 60601-1:2005+A1:2012	Solid Particle Protection Level 2 (>12.5mm); Liquid Ingress Protection Level 1 (dripping water)
	ES 60601-1:20-05+A1:2012	Rated Input Power: 12 Volts DC, 49 Watt Max
	ISO 15223-1:2016	Authorized Representative in the European Community

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