English

Caring For Life,

GIVING HOPE

A partnership with Liger Medical

For professional use. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

INDICATIONS FOR USE

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

USE ENVIRONMENT

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

USER QUALIFICATION

The handheld IRIS Thermocoagulator & Digital Colposcope (viewing the cervix) 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 explanation of clinical procedures.

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

DESCRIPTION

The Liger Medical IRIS Digital Colposcope and Thermocoagulator is a portable thermal coagulator with integral colposcope that provides assistance for clinician examination of the cervix as well as utilizes 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 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 accessories:

- Liger Medical HTU-110 Thermocoagulator 19mm Flat Probe
- Liger Medical HTU-110 Thermocoagulator 19mm Nipple Probe
- Liger Medical HTU-110 Thermocoagulator 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.

Figure 1: The IRIS (logo) Digital Colposcope and Thermocoagulator

HOW SUPPLIED

The following components are included with the Liger Medical IRIS:

- Liger Medical's IRIS Digital Colposcope and Thermocoagulator Device
- Four HTU-110 Probes: 19mm flat, 19mm nipple, or 16mm flat (preference specified at time of order)
- Two Removable Lithium Ion Battery Packs
- Instructions for Use
- Charging Base with A/C Adapter
- Hard Shell Carrying Case

Figure 2: The IRIS is battery operated and is designed to be portable

CONTRAINDICATIONS

The user should be familiar with the use of thermal coagulation instruments and take precautions accordingly.

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 burn, 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 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 condition:**
    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. **WiFi Connection Issues: If there are issues connecting to a WiFi network, ensure that you have the correct password and that you are entering it correctly. WiFi passwords are case sensitive. If problems still persist, restart the device, forget the WiFi connection, and try again. Ensure that other WiFi devices can connect to the WiFi successfully. Try connecting the device to another WiFi network. If problems still persist, user should contact customer service.**

22. **Patient Data Transmission Issues: If patient data transmission fails, please reboot the device and try again. Ensure that your WiFi connection to the Internet is functioning correctly. Ensure that no firewall or proxy settings on the WiFi network are limiting access to the internet.**
23. **Bluetooth Keyboard Pairing Issues: If there are issues pairing to a Bluetooth keyboard, check the batteries in the keyboard have sufficient charge. Ensure the keyboard is not connected to another device. Remove batteries from the keyboard and the device and restart them both. Ensure the keyboard works by connecting to another device such as a laptop or mobile phone.**
24. **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.**
25. **The Liger Medical IRIS device contains an 12V lithium-ion battery pack. Please observe the following practices:**

1. **Do not place the device on or near fires, heaters, other high temperature locations, or apply heat directly to the unit or battery pack.**
2. **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.**
3. **Do not subject the unit to strong impacts or shocks.**
4. **Do not expose the unit or battery to water or any other types of liquid, or allow the battery to get wet.**
5. **Do not leave the unit or battery in direct sunlight, and avoid storing 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.**

   Remove the battery if the device is not likely to be used for some time.

SERVICE AND MAINTENANCE

There are no serviceable parts. If any failure has developed, contact Liger Medical to purchase a replacement part or system. The IRIS includes a USB-C interface that is for maintenance use only.

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:

- Battery pre-charged. Full charge is recommended but not required.
- IRIS compatible 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 “Activating the Unit” 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 head, pulling the battery down and out of the handle.*

DIRECTIONS FOR USE

Read all instructions before use.

Figure 3: IRIS Battery

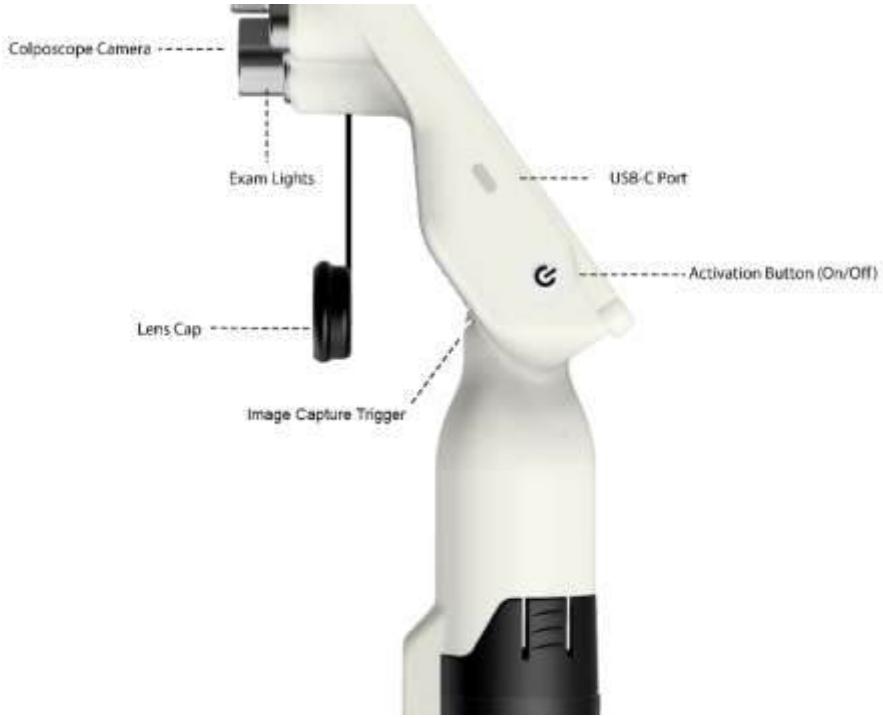


Figure 4: Activating the IRIS

Activation (ON/OFF) Button: Press once to turn unit on. The device will power on and the display will boot will show a boot logo. If the battery is low upon startup, the device will show low battery 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.

USER LOGIN

Figure 5: User Login

If you are a new user add yourself by tapping Add User.

USER LOGIN – ADD NEW USER

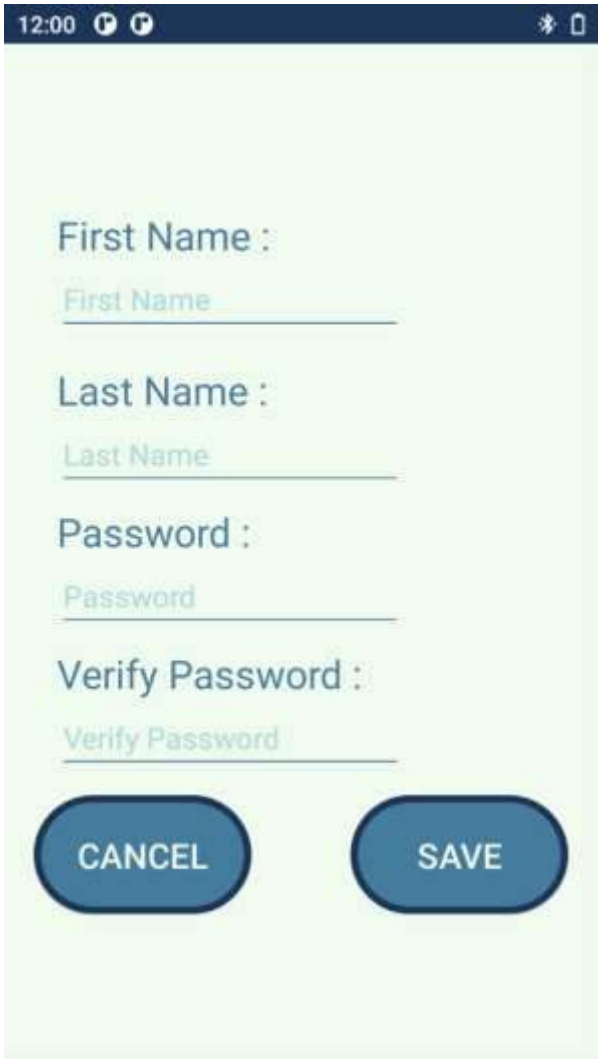


Figure 6: Add User

Enter your name and enter a password for your login. You will be required to use this login each time you use the device. Each user can only access their saved patient data and cannot access other user's data.

NAVIGATING THE INTERFACE AND CONNECTIONS

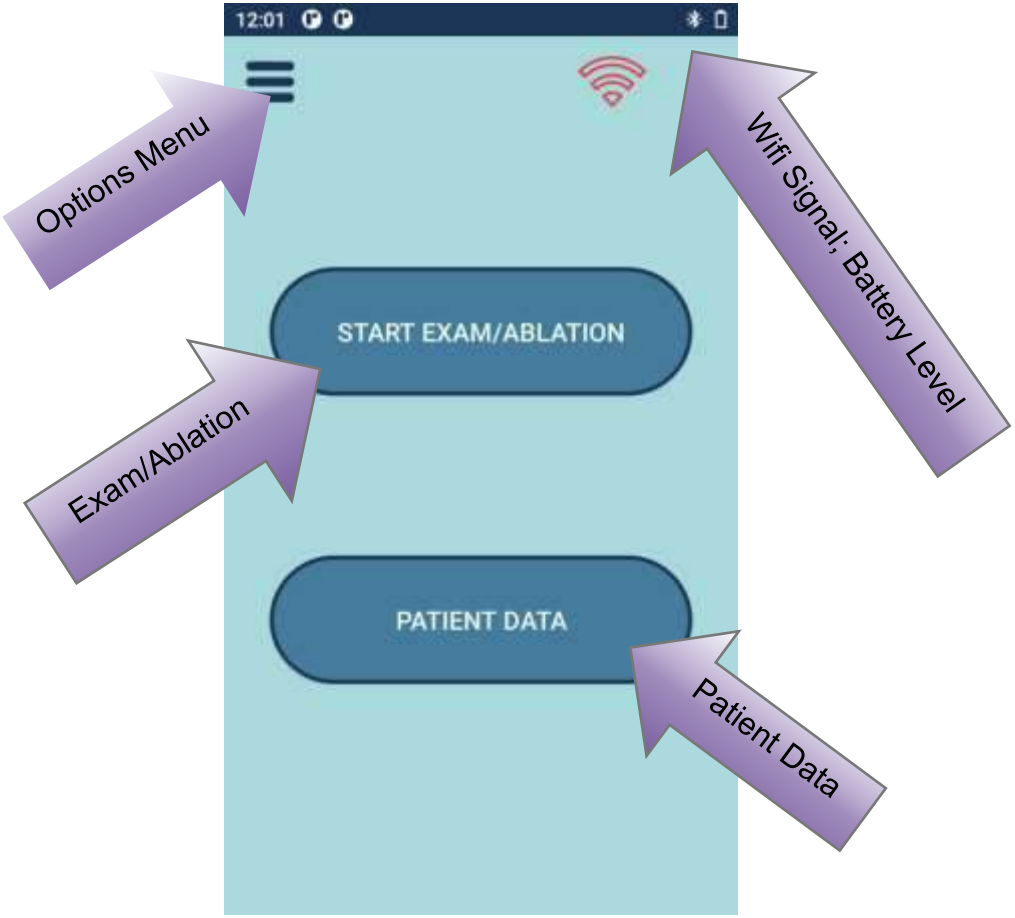


Figure 7: IRIS Main Screen

From the main screen, choose whether to start the exam/ablation or review a patient's previous exam. If you are a new user, add yourself and enter your new password. You will be required to use this password each time you use the device. Each user can only access their own saved patient data and cannot access other user's data.

Note that a new exam cannot begin unless the user either saves the data to a patient or delete the data. If the device is shut off without saving data to a patient, when the same user logs back in they will be prompted to continue the exam session and either continue the exam, save the data to a patient, or delete the data.

OPTIONS MENU – User Not Logged In

Figure 8: Options Menu

If no user is logged in, the Options Menu has the following five items:

1) Quick Start Guide: Simplified overall user guide.
2) Instructions: Access the instructions for use for the IRIS.
3) About: The current software revision of the IRIS.
4) Settings: Provides a) System Settings (e.g., connect or change WiFi, Bluetooth, etc.); b) Updates: ability to update software via WiFi; c) Camera Settings: Photo sound and ablation (time, temp) settings.
5) Feedback: Submit any comments, recommendations, or problems to the manufacturer.

OPTIONS MENU – User Logged In

Figure 9: Options Menu - User Logged In

If a user is logged in, the Options Menu has the following two additional items:

1) User Profile: Allows user to change Ablation time and temp settings, Photo capture and sound settings, turn the Light Sensor capture feature on or off, and configure the function of the trigger during an exam.
2) Logout: Allows user to log out and return to the login page.

QUICK START GUIDE

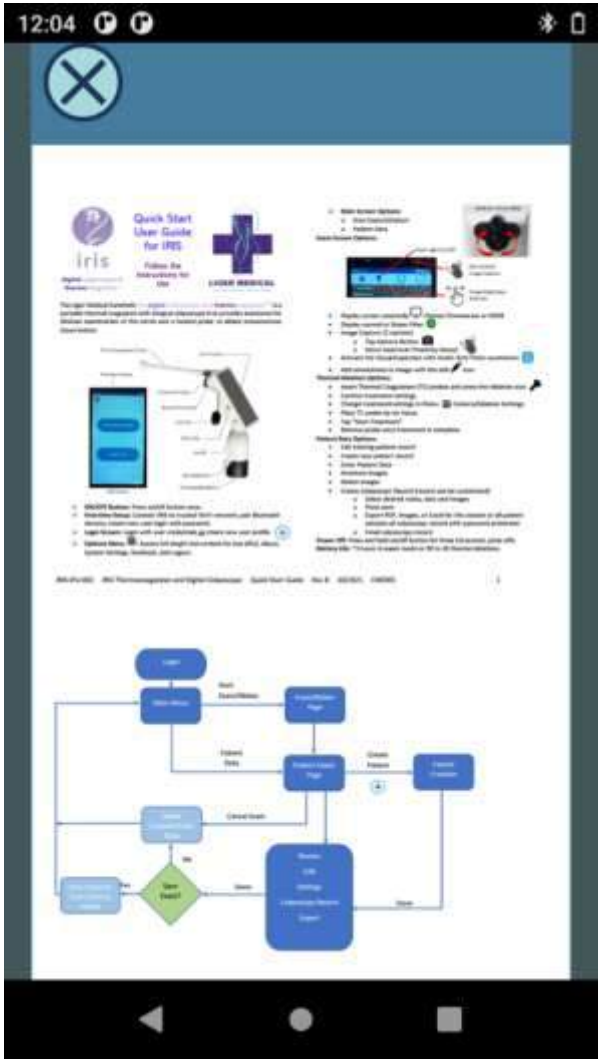


Figure 10: Quick Start Guide

Quick Start Guide: The quick start guide is provided in a digital format on the IRIS device.

INSTRUCTIONS FOR USE

Figure 11: Instructions for Use

Instructions for Use: The Instructions for Use is provided in a digital format on the IRIS device.

ABOUT

Figure 12: About

About: This screen shows the current software release version, including details about fixes and changes from the previous release version.

FEEDBACK

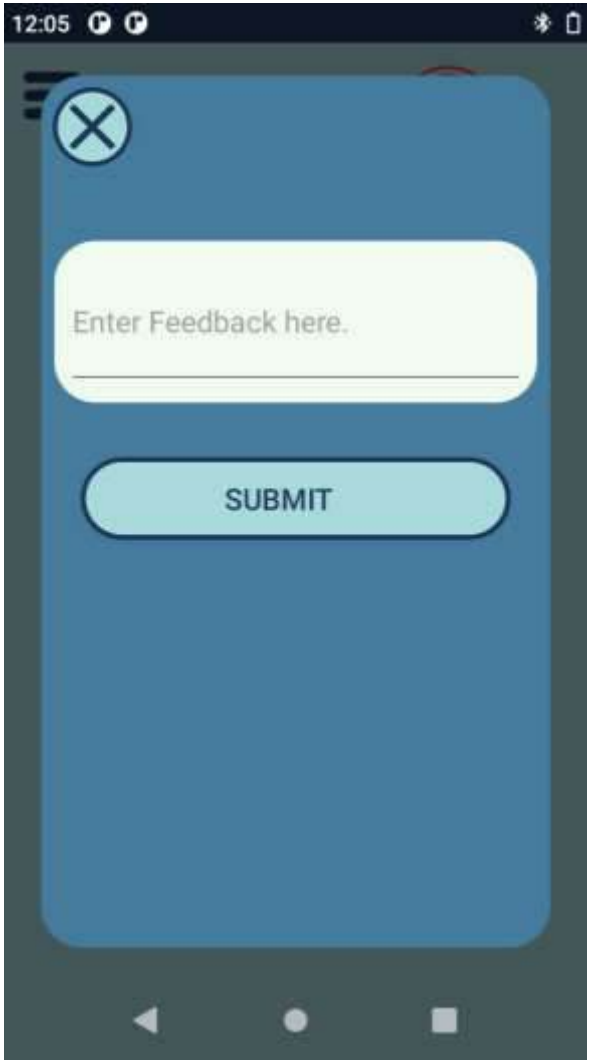


Figure 13: Feedback

Feedback: Enter and submit feedback regarding the IRIS. Feedback is sent directly to the manufacturer.

USER PROFILE

Figure 14: User Profile

User Profile: Adjust the camera/ablation settings or customize the colpo-record.

LOGOUT

Figure 15: Logged Out

Logout: Log user out.

EXAM/ABLATION

Figure 16: Exam/Ablation Screen

This screen previews the camera when an Exam or Ablation procedure is initiated.

1. Image brightness can be descreased or increased by sliding the indicator left or right.
2. Tap the camera icon to save a picture of the screen view. The “Picture Saved!” message will appear to confirm that the image has been saved.

EXAM/ABLATION CONTINUED

Figure 17: Exam/Ablation Screen

3. Alternately, briefly covering the light sensor above the display will save a picture of the screen view with an audible shutter sound. The light sensor does not need to be tapped; blocking light to the sensor with a “hand wave” is sufficient to save a picture.

GREEN FILTER

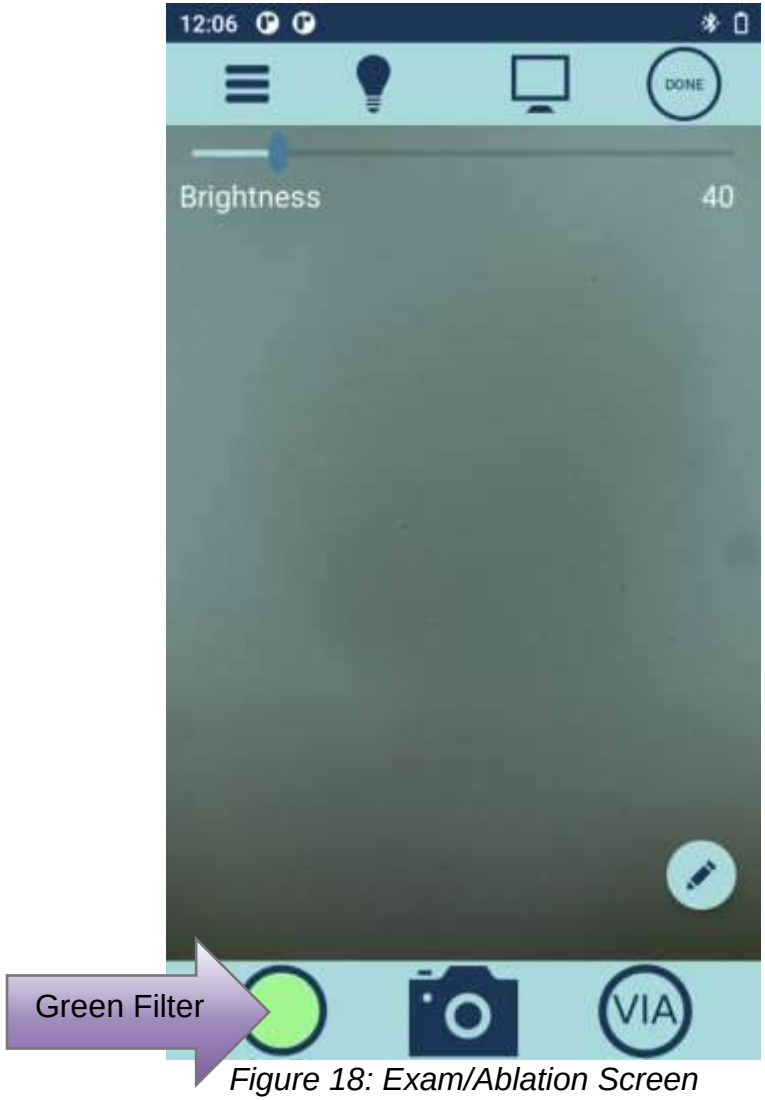


Figure 18: Exam/Ablation Screen

Toggle the Green Filter by tapping the Green Filter icon.

GREEN FILTER ACTIVE

Figure 19: Exam/Ablation with Green Filter Active

This is what the Exam/Ablation screen looks like with the Green Filter active.

VIA TIMER

Figure 20: Exam/Ablation Screen

Tap the VIA icon to activate the Visual Inspection with Acetic Acid timer.

VIA TIMER ACTIVE

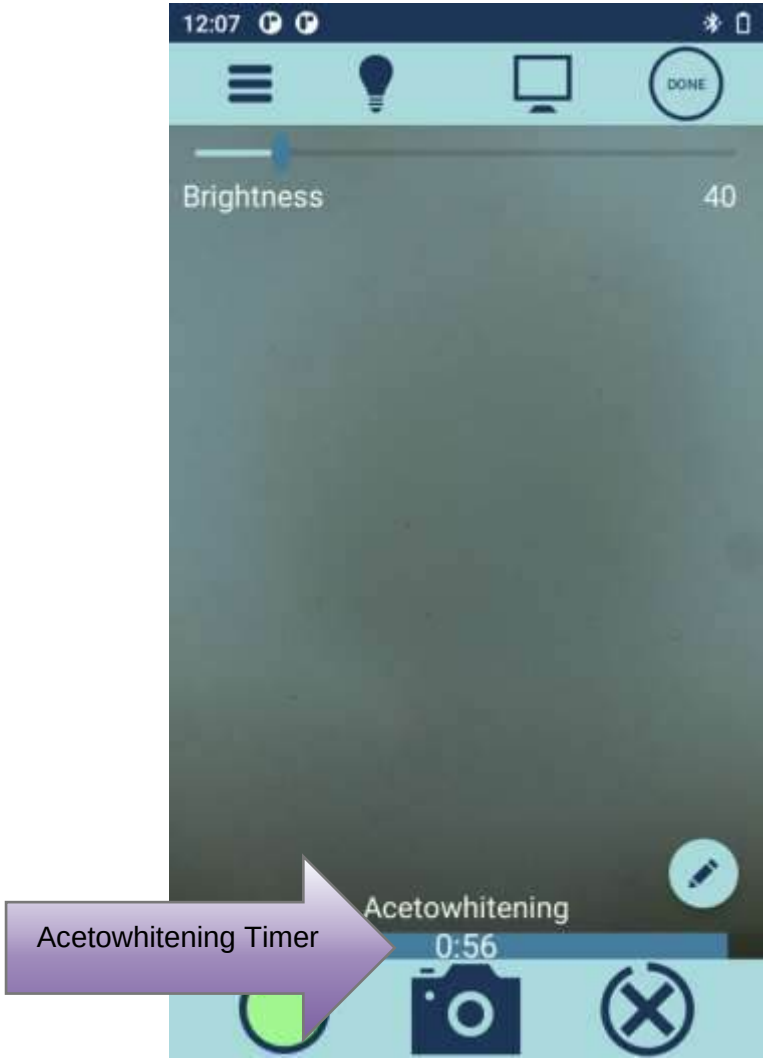


Figure 21: Save Picture

The Acetowhitening Timer will count down for 60 seconds, then counts up until stopped.

ADD ANNOTATIONS

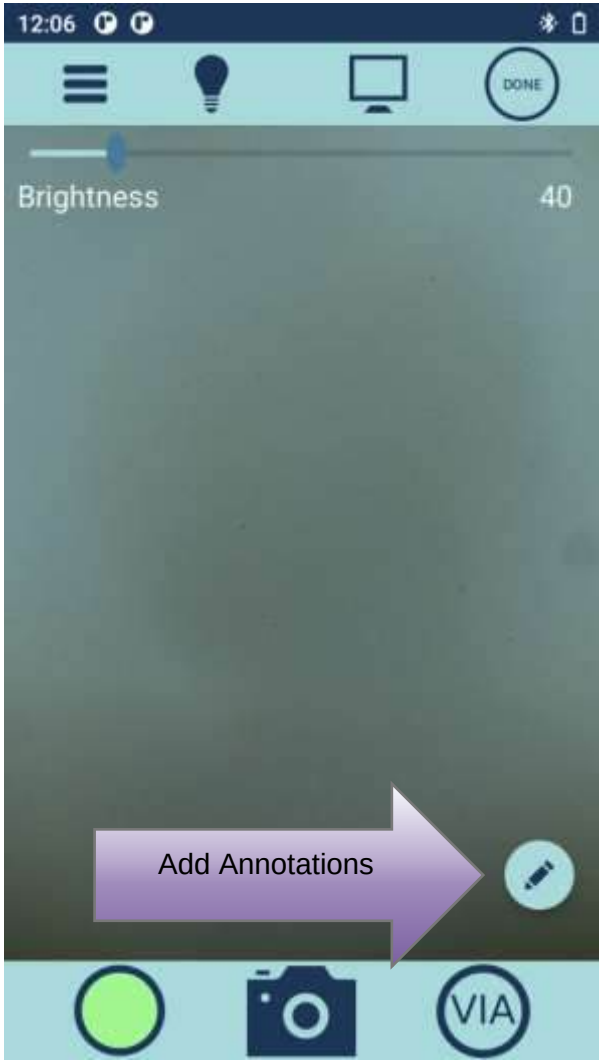


Figure 22: Add Annotations

To add annotations to an image, tap the Annotations icon to access the annotation options.

ANNOTATION OPTIONS

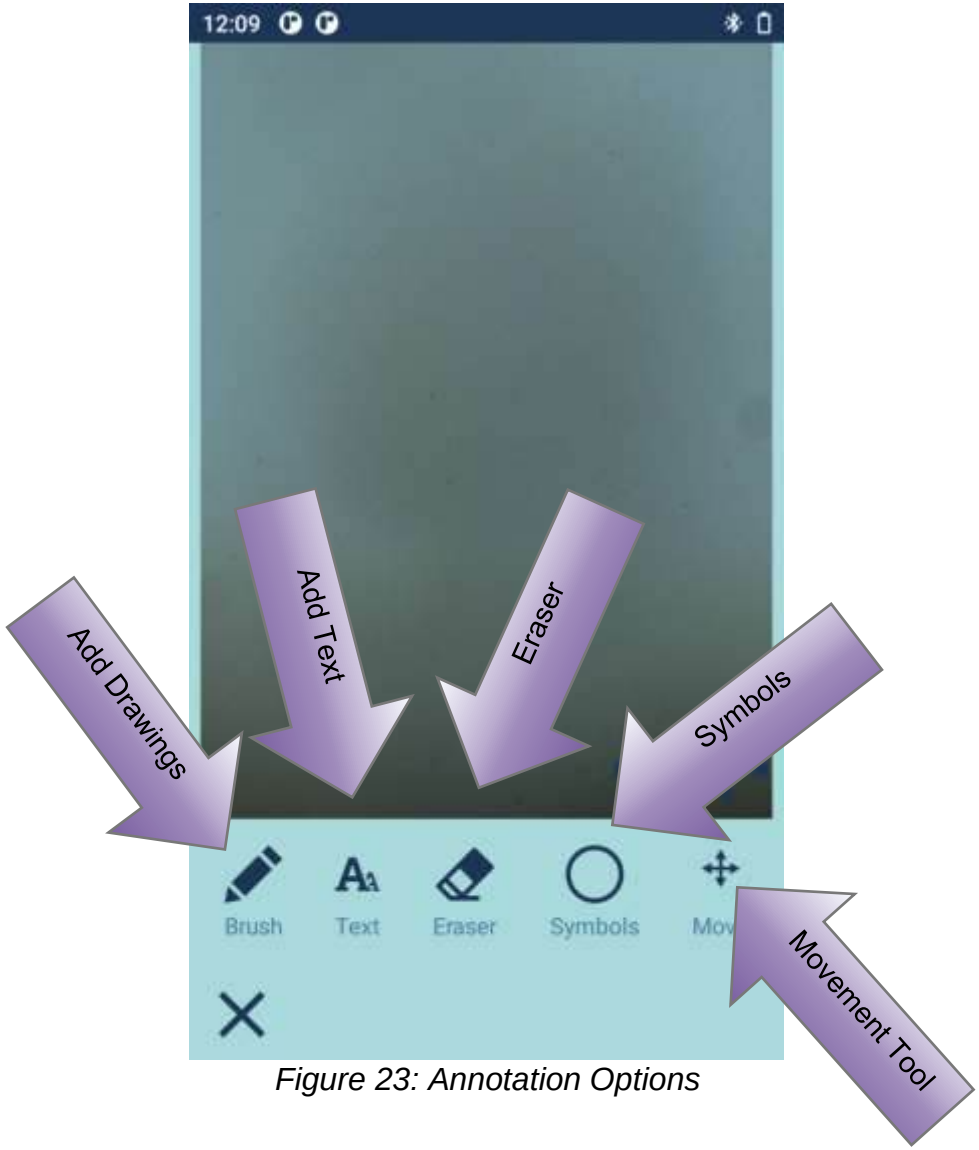


Figure 23: Annotation Options

Drawings, text, and symbols can be added to exam images. Drawings can also be erased using the eraser. The Movement tool can be used to move symbols which have been added to the image. Tap the corresponding icon to access each of these tools.

ADD DRAWINGS

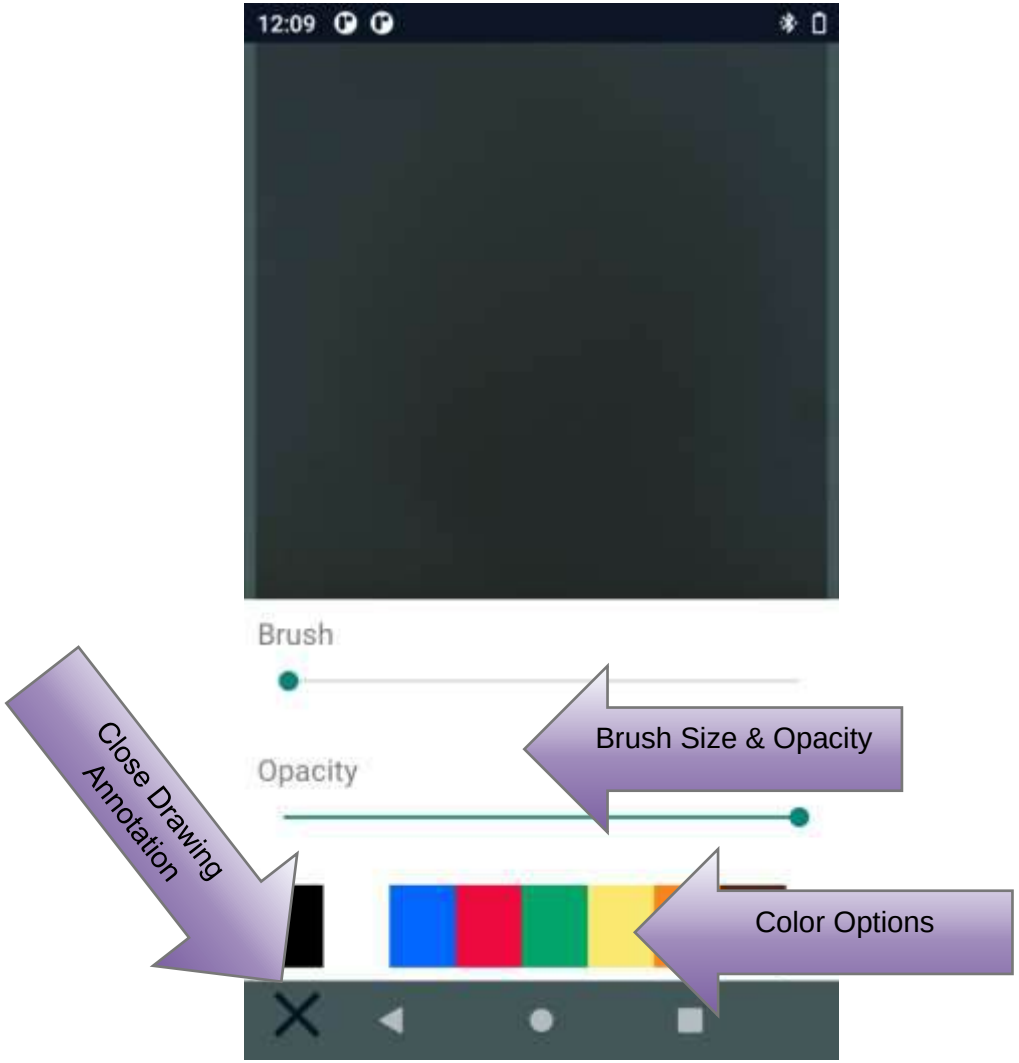


Figure 24: Annotation – Drawing

1. Change the size of the brush and the opacity of the drawing using the sliders.
2. Select the color of the drawing by tapping the desired color. The current selected color is on the left.
3. To close the drawing annotation options, click on the X.

ADD TEXT

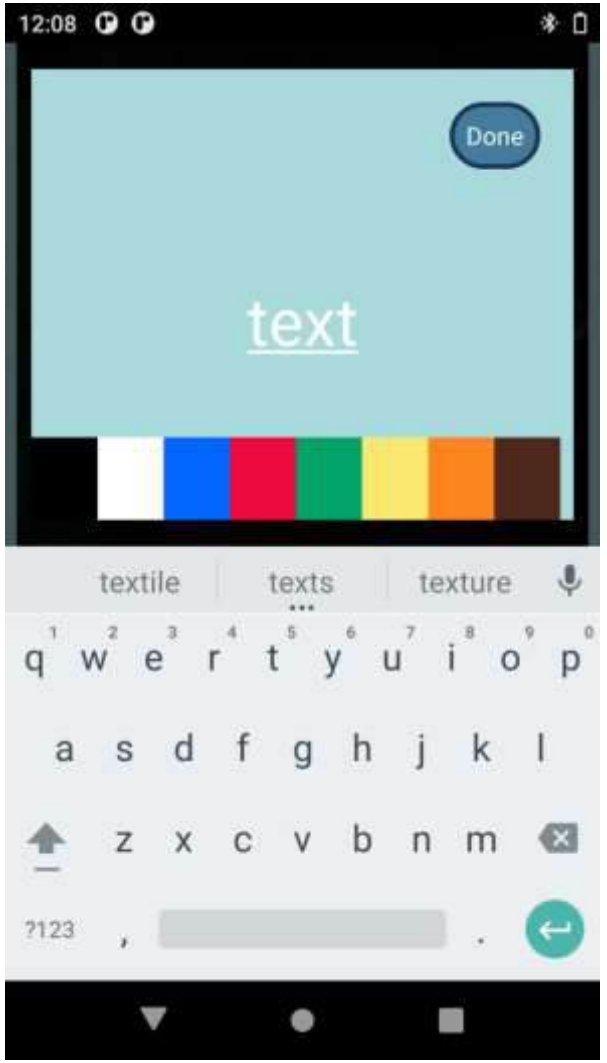


Figure 25: Annotation-Text

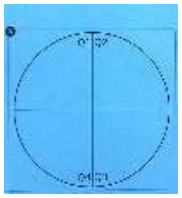
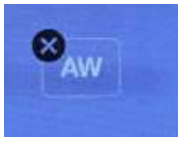
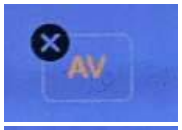
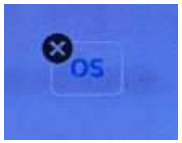
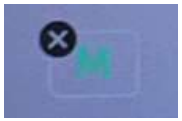
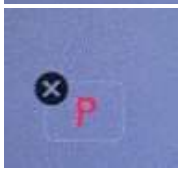
1. Select the color for the text from the color options.
2. Type desired text using the on-screen keyboard.

ADD SYMBOLS

Figure 26: Annotations – Symbols

Select the type of icon you want to add to the image by tapping the appropriate icon. Symbols can be resized by pinching the symbol larger or smaller. Symbols can be repositioned by tapping then holding and dragging the symbol.

SYMBOL DESCRIPTIONS

Item	Symbol	Meaning
SCJ		Site of squamous columnar junction
Quad		Adds a quadrant overlay ***NOTE: Add this symbol AFTER all other annotations are added***
Bx		Site of previous biopsy
AW		Site of acetowhitening
I		Site of negative iodine stain
AV		Site of abnormal blood vessels
Os		Site of cervical os
M		Site of blood vessel mosaic
P		Site of blood vessel punctuation

QUADRANT OVERLAY

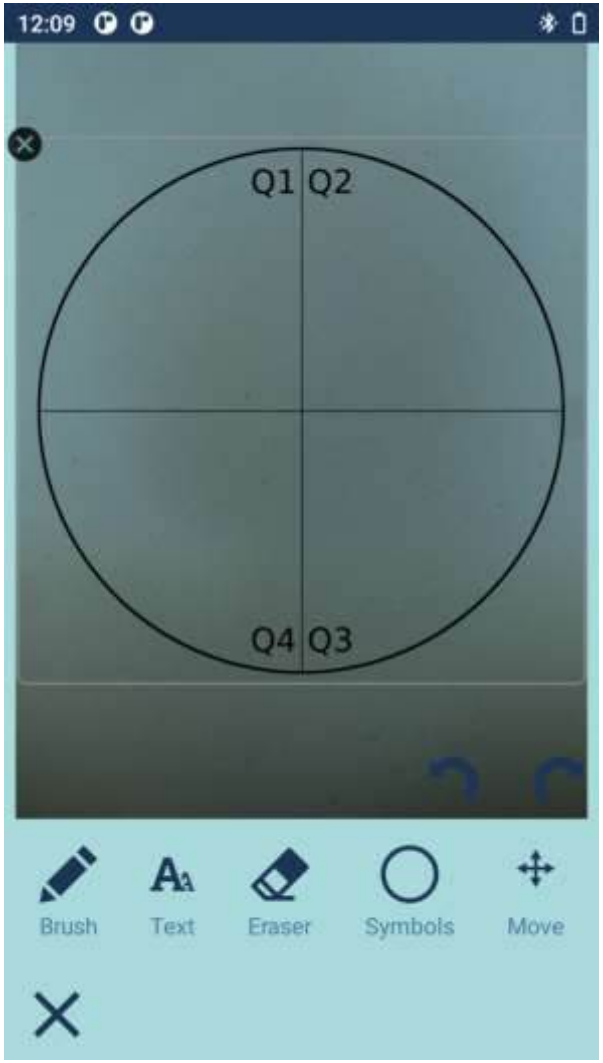


Figure 27: Quadrant Overlay

To discard an annotation, tap the X on the bottom left of the screen.

EXIT MESSAGE

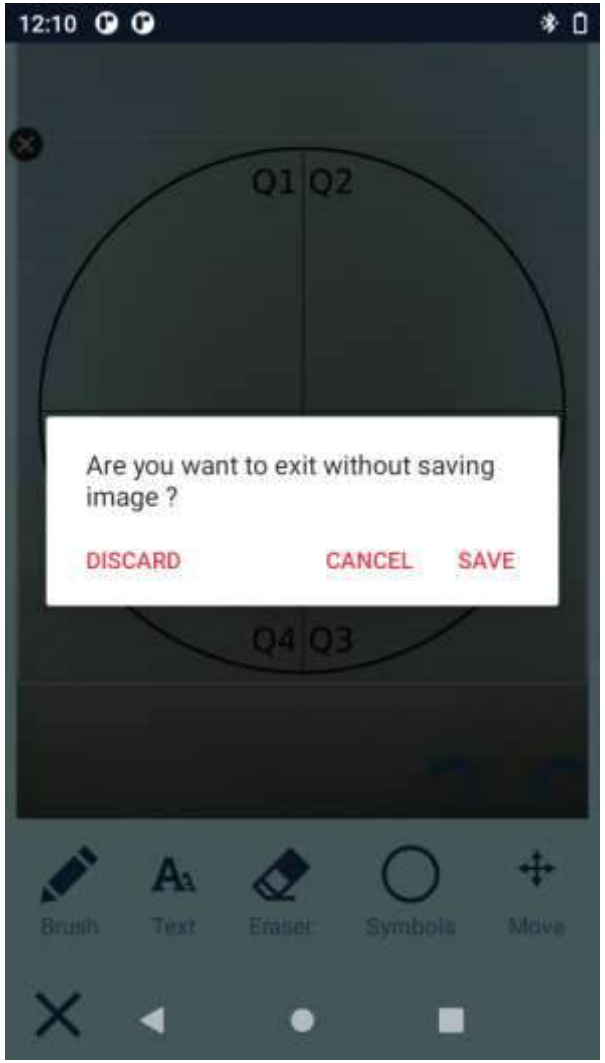


Figure 28: Cancel Annotation

Confirm whether you want to discard the image, cancel adding the annotation, or save the image with the annotation.

SAVING ANNOTATED IMAGE

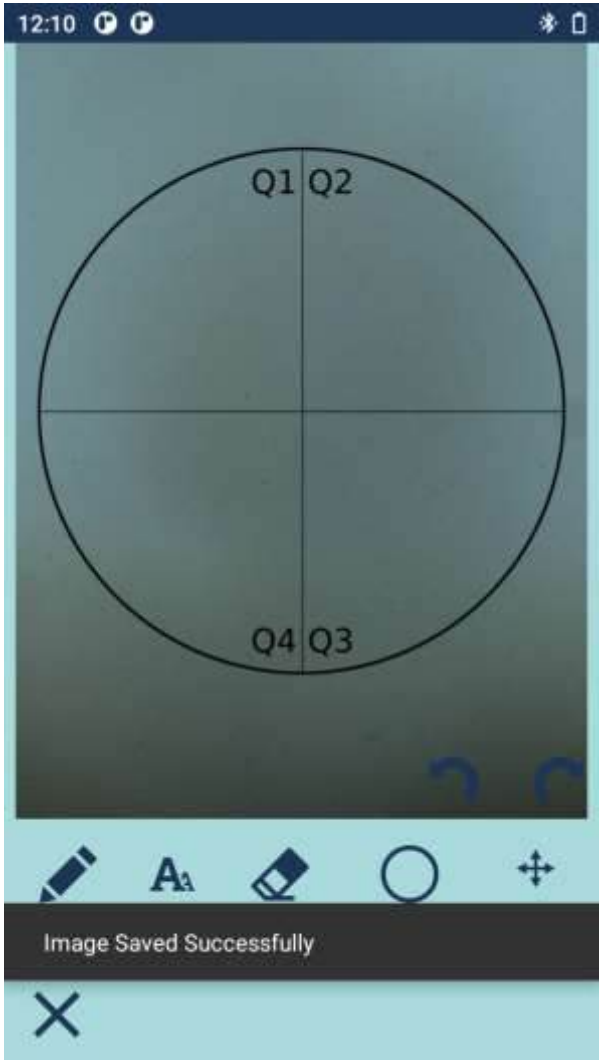


Figure 29: Saving Image Confirmation

Saving the annotated image will display a confirmation while the image is saved to the IRIS.

START ABLATION

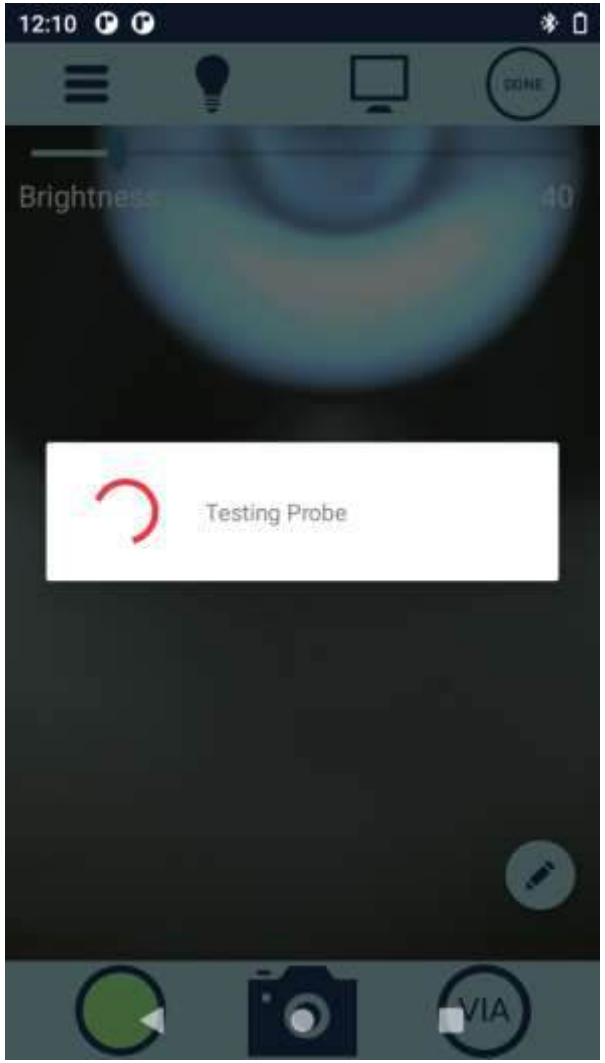


Figure 30: Ablation Mode

To activate ablation mode, insert a probe. The VIA icon will change to the ablation icon and the IRIS will perform a test to verify that the probe is functional.

ABLATION – PROBE ERROR

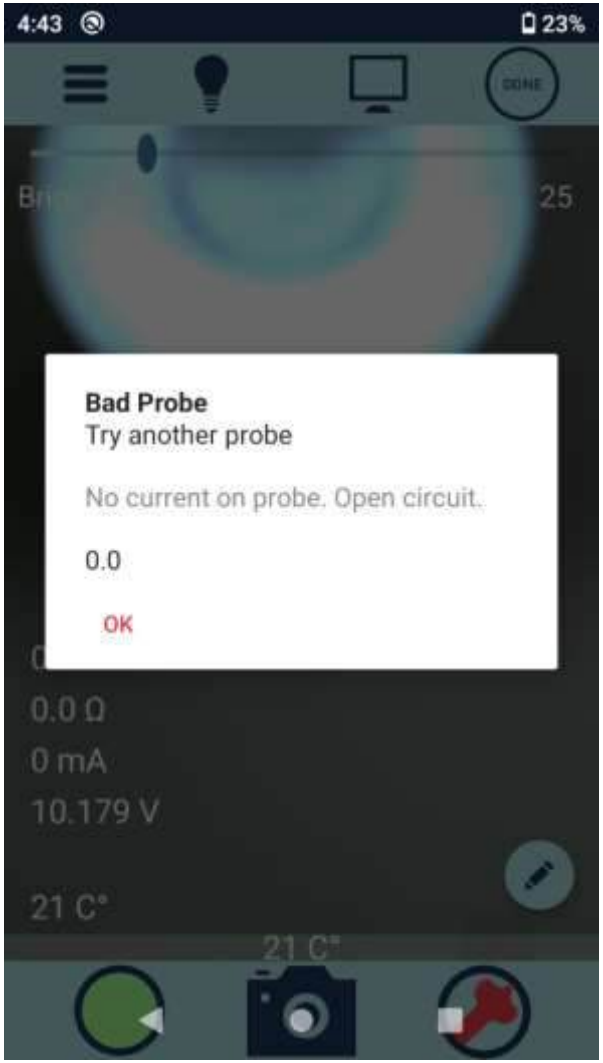


Figure 31: Ablation - Probe Error

If the probe is not functional, the IRIS will display this error message. Try another probe. The probe that triggered the Bad Probe error message should be removed from use.

ABLATION - TREATMENT

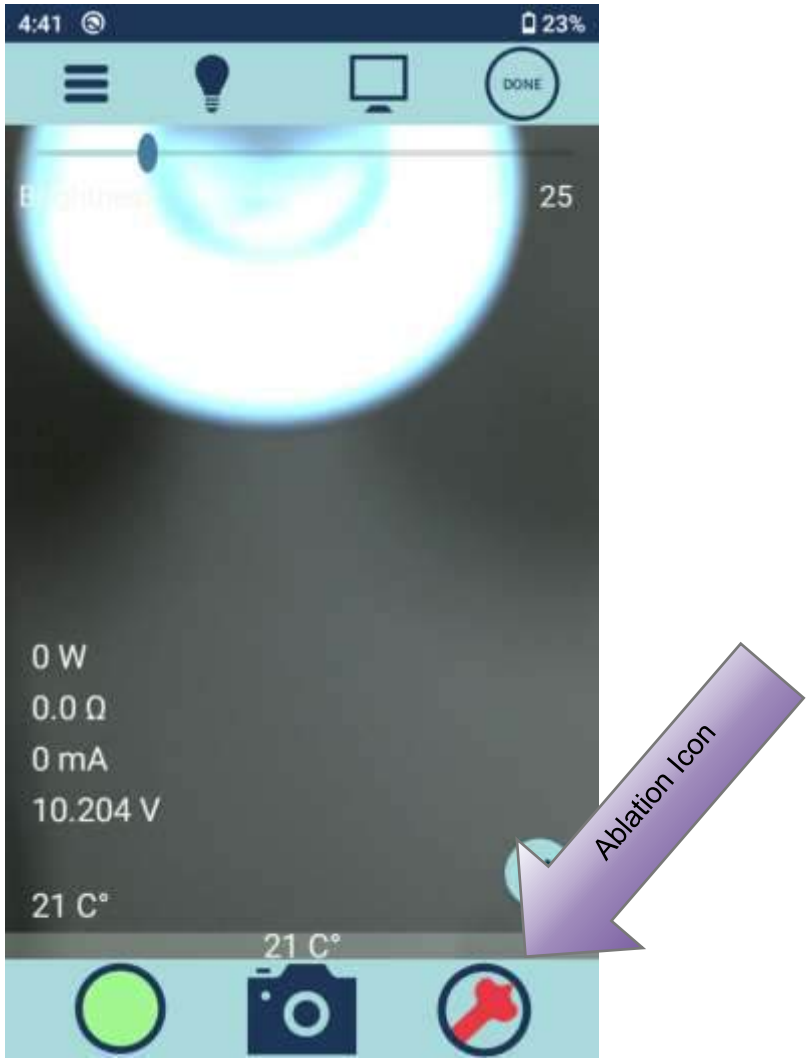


Figure 32: Ablation Ready

Insert the desired treatment probe (19mm flat, 19mm nipple, or 16mm flat) connector into the mating connector at the front of the unit. Ensure that the probe is tightly inserted. If the probe is not securely connected, inserted improperly, missing, or is broken, the IRIS will indicate that the probe needs to be replaced.

Once a functional probe has been inserted, the temperature of the probe will display. To activate the ablation treatment cycle, tap the ablation icon. Or use the trigger button if it has been configured to control ablation.

ABLATION SETTINGS CONFIRMATION

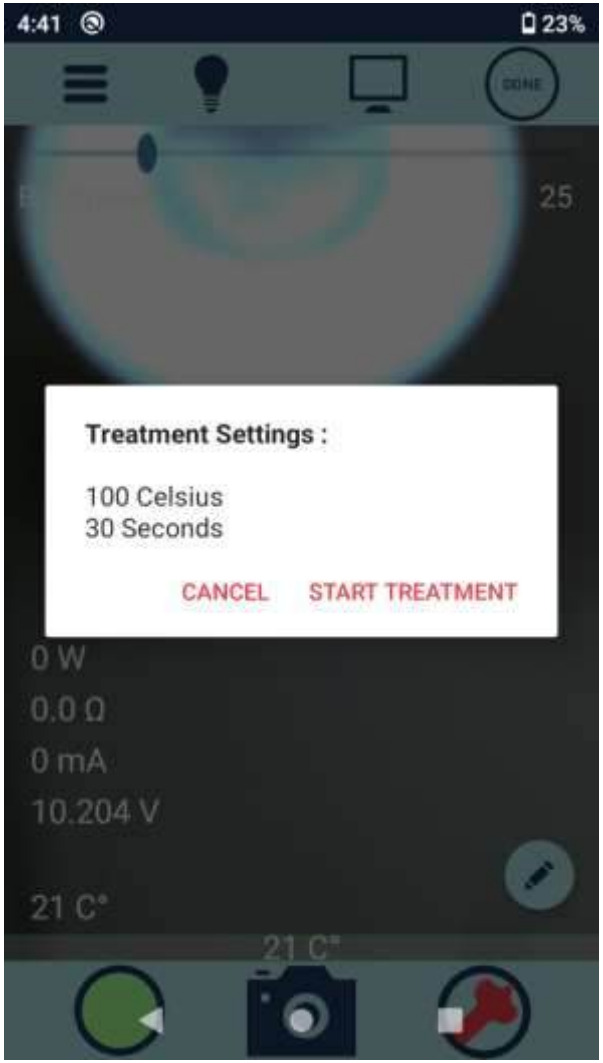


Figure 33: Treatment Settings

When the treatment cycle is activated, the IRIS will confirm that the treatment settings are correct. If the settings are correct, tap “Start Treatment” to begin the ablation treatment cycle. If the trigger has been configured to control ablation the trigger can be used instead of tapping “Start Treatment”.

CHANGE ABLATION SETTINGS

Figure 34: Exam/Ablate Menu

To change the ablation treatment settings, select the options icon at the top left. Tap User Profile and then Camera/Ablation Settings to change the treatment settings including temperature, duration. The trigger configuration can also be changed on the screen.

ABLATION SETTINGS OPTIONS

Figure 35: Ablation Treatment Options

1. Tap the ablation treatment time and temperature desired for the treatment. The selected time and temperature will highlight as red.
2. Treatment times and temperatures can be set from 20 – 60 sec and 100 – 120°C.
3. The default treatment cycle is 30 seconds at 100°C (212°F).
4. To save the ablation treatment settings, tap the Save icon. To cancel any changes to the ablation treatment settings, tap the Cancel icon.
5. When treatment settings are correct, place the probe against the tissue. The probe is not heated at this point.

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

ABLATION SETTINGS OPTIONS CONTINUED

6. When the probe has been placed against the tissue needing treatment, tap Start Treatment. The probe temperature is displayed and the time remaining for the treatment counts down.
7. To cancel a treatment in progress, click on the cancel icon.
8. When the treatment cycle completes, a cooldown progress bar shows progress until the probe tip temperature reaches a safe level.
9. Once the cool down cycle is complete. An audio cue will notify the user that the ablation is complete. Remove the probe from the treatment area. If a second treatment is needed, repeat the above steps before removing the probe.
10. The IRIS checks the functionality of each probe during heat-up mode. If the probe is unable to reach and maintain sufficient temperature, the unit will show an error message indicating what the problem is such as bad probe, low battery, etc. If this occurs, the probe or battery may be faulty and need replacing. The following actions should be taken:
    a. Replace the probe with a new one
    b. Replace the battery
    c. Re-activate the unit

If the IRIS gives an error message a second time and the battery is charged, the probe has exceeded its use life and is no longer functional.

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

NOTE: The IRIS is capable of performing ~4 hours of colposcopic examination or 30-60 procedures per battery charge. When the battery is low, an indicator error will be displayed. If the low battery error occurs during a procedure, the procedure in process should be completed first. Once completed, replace the battery.

NOTE: With continued use after the battery icon in the top right corner of the screen indicates the battery is low the unit will turn off to protect the battery from being overly discharged. Over-discharge of the battery could reduce the life of the battery. Recharge or replace the battery. In addition, to provide longer battery use time, after 10 minutes of no use IRIS will speak “about to shut down,” and the user needs to touch the screen if they do not want the unit to automatically shut off.

PATIENT DATA

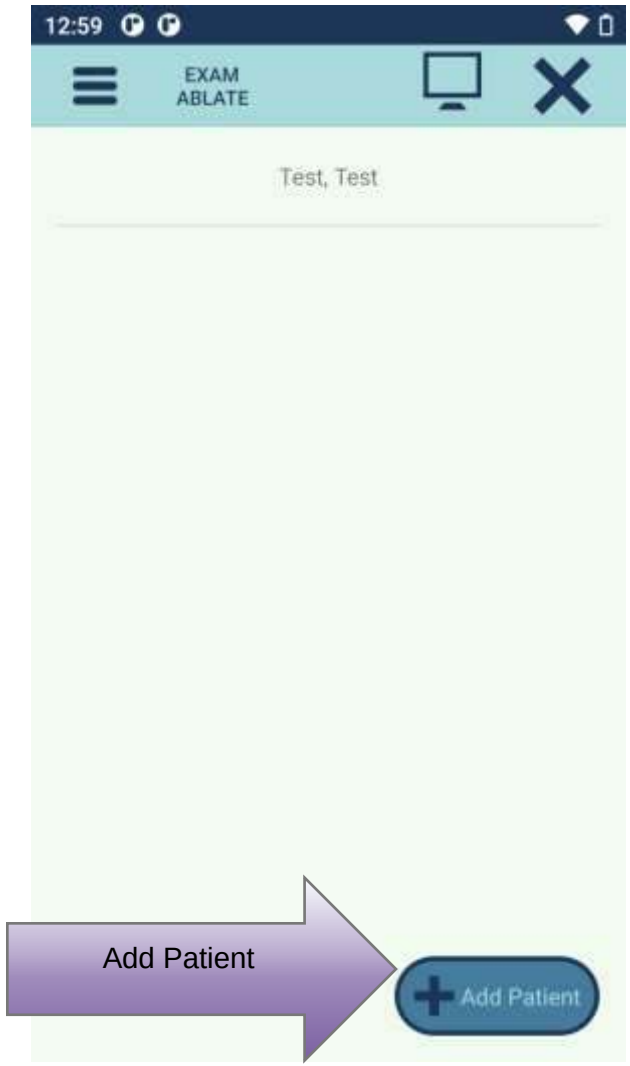


Figure 36: Patient Data

1. Patient data can be entered after an exam, after a treatment cycle, or by tapping Patient Information from the home page.
2. Select an existing patient from the list by tapping the patient's name.
3. Add new patient information by tapping the Add Patient icon.

PATIENT CREATION/EDIT

Figure 37: Patient Data

To enter patient data, tap the appropriate field: First Name, Last Name, Medical Record, Date of Birth, Phone Contact, Email Contact, Cytology/Histology, Colposcopy Findings, HPV, Serotypes Input, HIV, Biomarkers, Miscellaneous Notes. Use the on-screen keyboard to enter the information. For Date of Birth, swipe up or down in each column to select the month, day, and year. When patient information has been entered, tap the Done icon.

PATIENT REVIEW

Figure 38: Patient *Review*

The Patient Review page can be reached by selecting a patient from the Patient Selection page, or by creating a new patient. Any captured images will display below the patient information.

IMAGE REVIEW

Figure 39: *Image Review*

Image Review page. This page can be reached by tapping an image from the review page. Images can be tagged as “Normal”, “VIA”, or “VILA”.

IMAGE DELETE CONFIRMATION

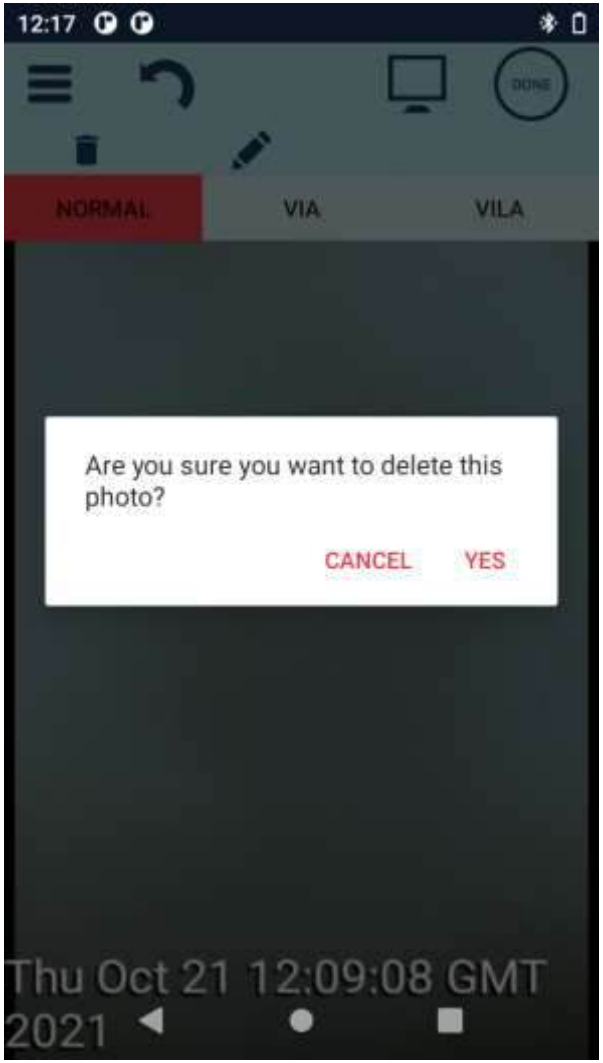


Figure 40: Delete Image From Patient Record

This dialog is shown when the user tries to delete an image. This can be done by tapping the garbage can icon in the image review page, or by long pressing the image in the exam review page. Confirm the deletion or cancel the deletion.

COLPOSCOPY RECORD CUSTOMIZATION

Figure 41: Colpo Record Customization

The colposcopy record customization page can be reached through the menu by tapping UserProfile > Colposcopy Customization.

PATIENT DATA NAME/MEDICAL RECORD DIALOGUE

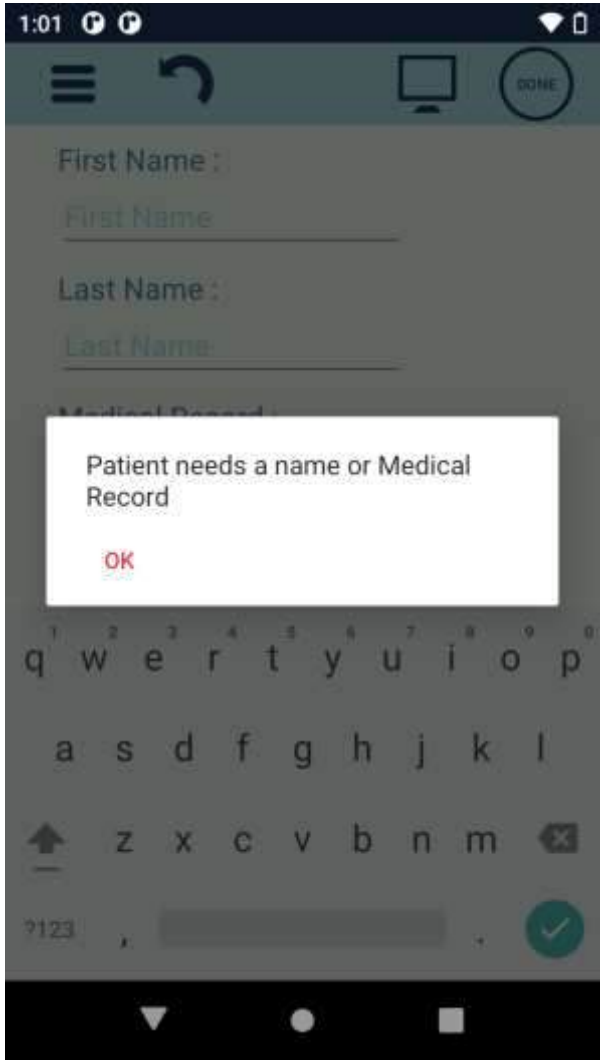


Figure 42: Patient Data Message If Name or Medical Record Not Entered

If the Patient Data is missing a name or Medical Record, an error prompt will display.

COLPOSCOPY RECORD PAGE

Figure 43: Colposcopy Record

Access the Colposcopy Record page by tapping the “Colposcopy Record” button for a specific Exam/Session. Select the adequacy of the colposcopy exam by tapping the appropriate text. Notes regarding adequacy can be added by tapping the input box under Adequacy Notes. Swipe up on the screen to add additional examination information including: cervix/SCJ visibility; transformation zone classification/size; use of acetowhitening; general assessment notes; colposcopy findings (normal, abnormal); Schiller test; colposcopic impressions; suspicious for invasion and notes; miscellaneous findings; Swede score; miscellaneous notes; provisional diagnosis; and management plan.

SAVE EXAM DIALOGUE

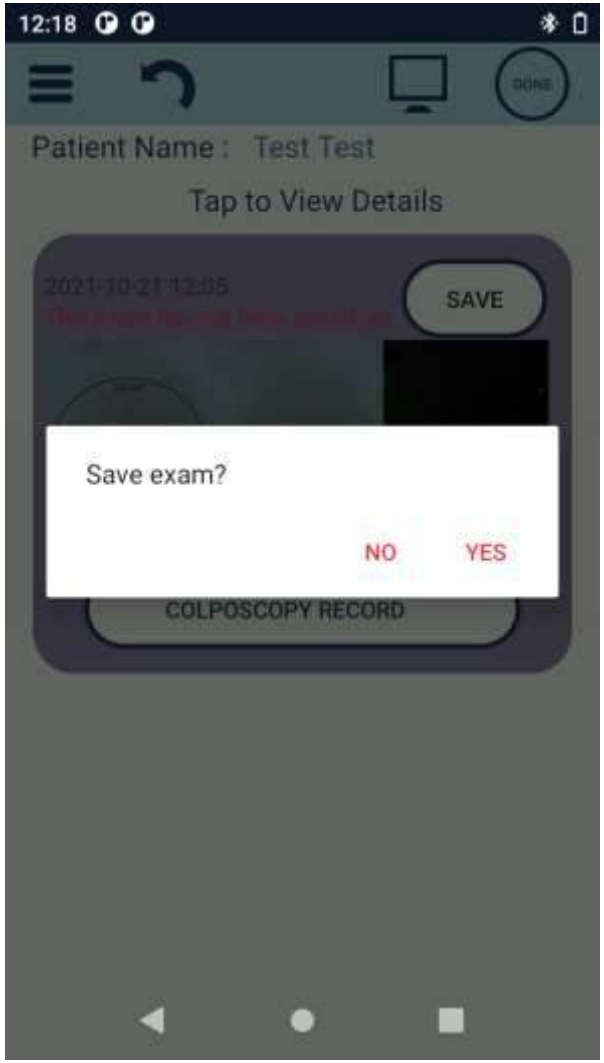


Figure 44: Save Exam

Tap Done to save the exam. Select No to discard the exam or Yes to save the exam.

CONFIRM DELETE PROMPT

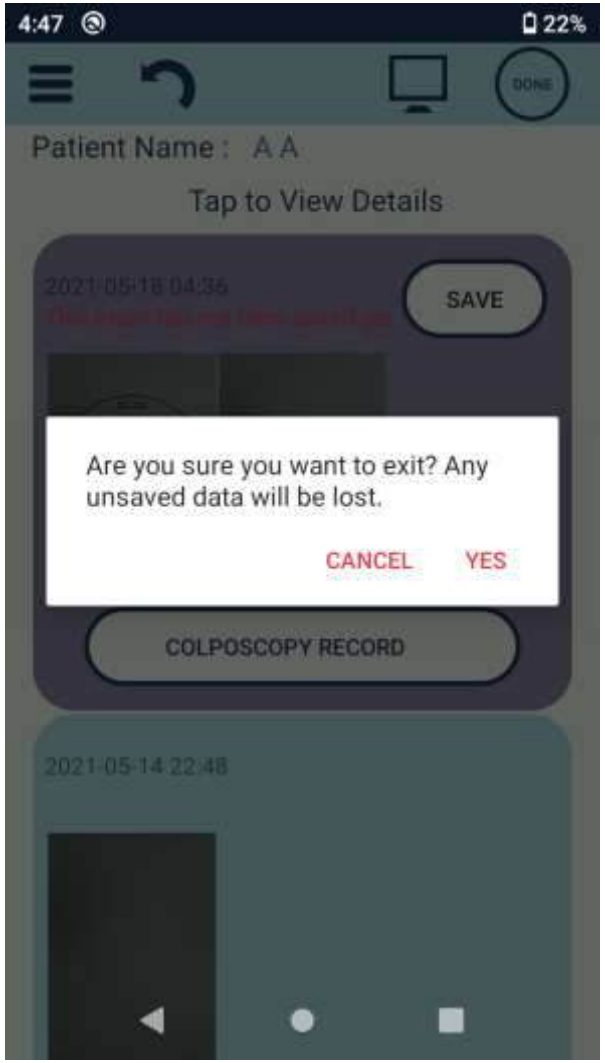


Figure 45: Unsaved Data May Be Lost Message

If you select No, the IRIS will confirm that you want to discard the exam data.

EXAM REVIEW

Figure 46: Exam Review – Saved Exam

After saving the exam you can review the exam. The session/exam background will change from purple to blue when saved.

EXPORT DATA

Figure 47: Export Session

Access Export Data by tapping the Export Session button on a saved exam. The user can export a single session or all sessions.

1. Tap Email Address to enter the email address you want to export the session to.
2. Tap the Confidentiality Pin to enter a PIN to restrict access of the exported session.
3. Select the desired file type for export.
4. Select whether to export only the current session or all sessions.
5. Tap Export to export the session.

MENU WITH EDIT PATIENT BUTTON

Figure 48: Menu with Edit Patient Button

To edit patient information, while viewing the patient record, tap the Menu icon then tap Edit Patient.

CONNECTIONS AND UPDATES

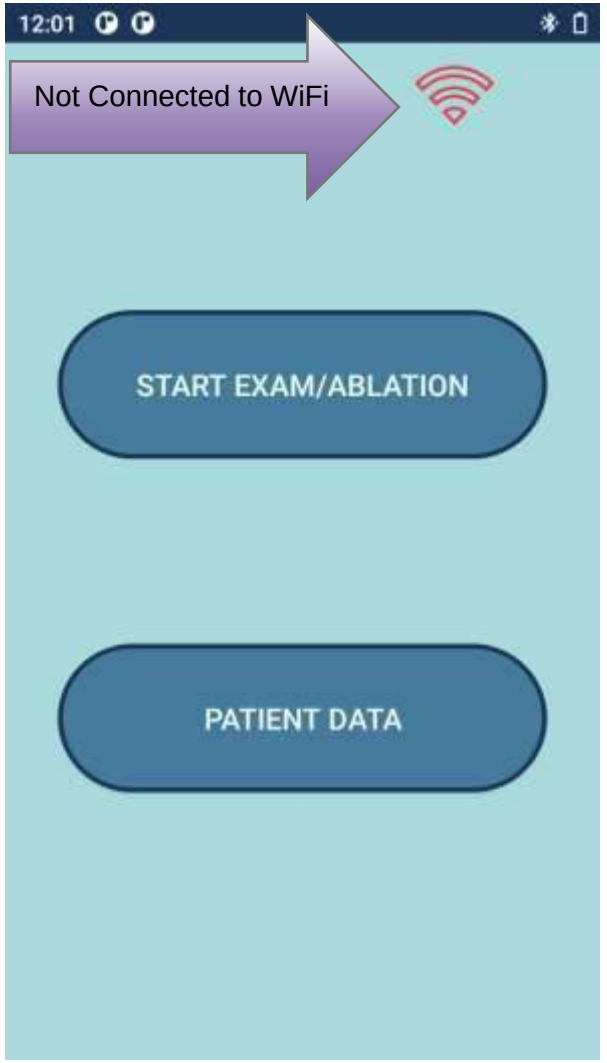


Figure 49: Connect to WiFi

A red WiFi icon indicates that the IRIS is not connected to WiFi.

ANDROID SETTINGS APPLICATION

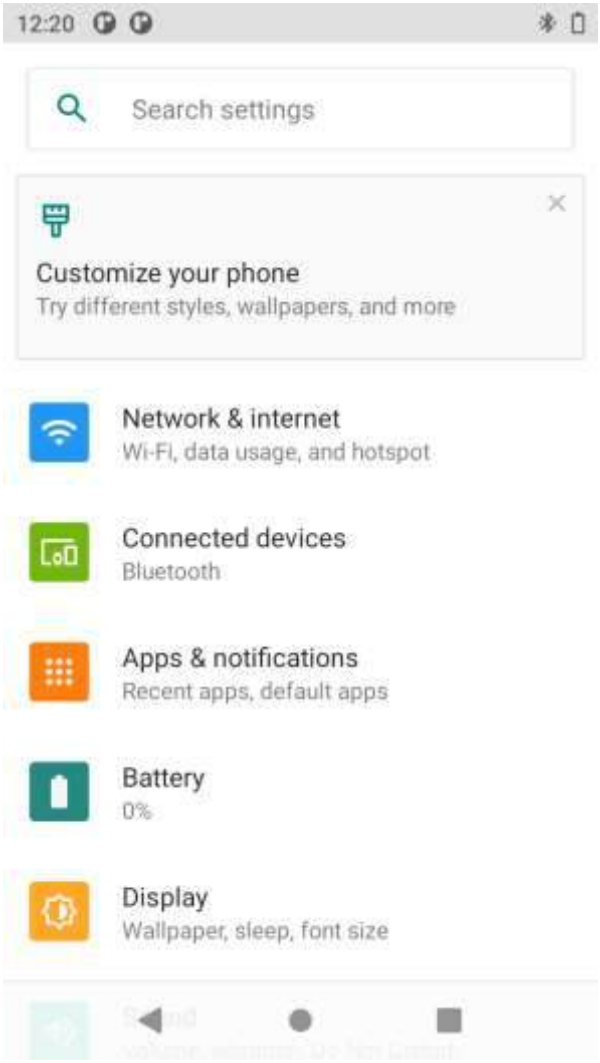


Figure 50: *Android Settings Application*

Connection settings can be reached by tapping Menu>Settings>System Settings.

CONNECT TO WIFI

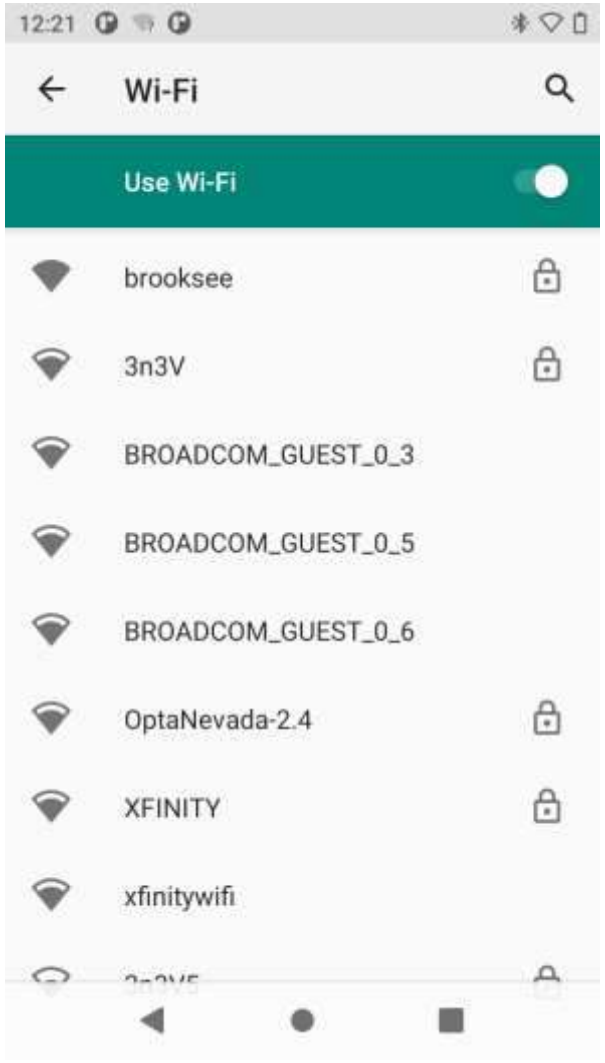


Figure 51: Network Selection

These settings can be reached by doing one of the following:

- Tap the red WiFi icon (only visible on Login page when not connected to WiFi).
- Menu>Settings>Wifi
- Menu>Settings>System Settings>Network & Internet

WIFI AUTHENTICATION PAGE

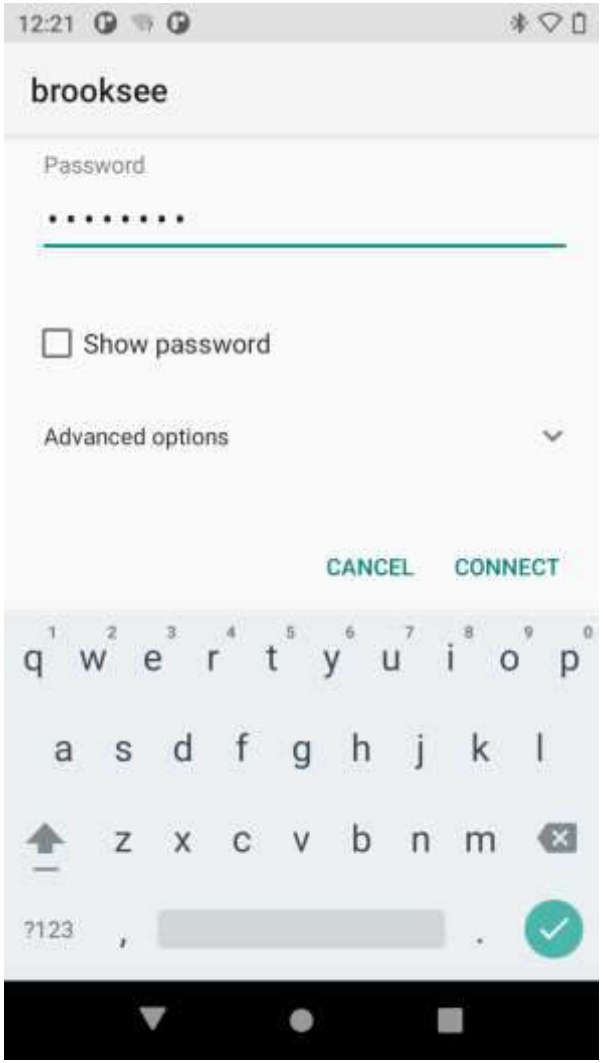


Figure 52: WiFi Authentication Page

Enter your network password and tap “Connect”.

CONNECTED TO WIFI

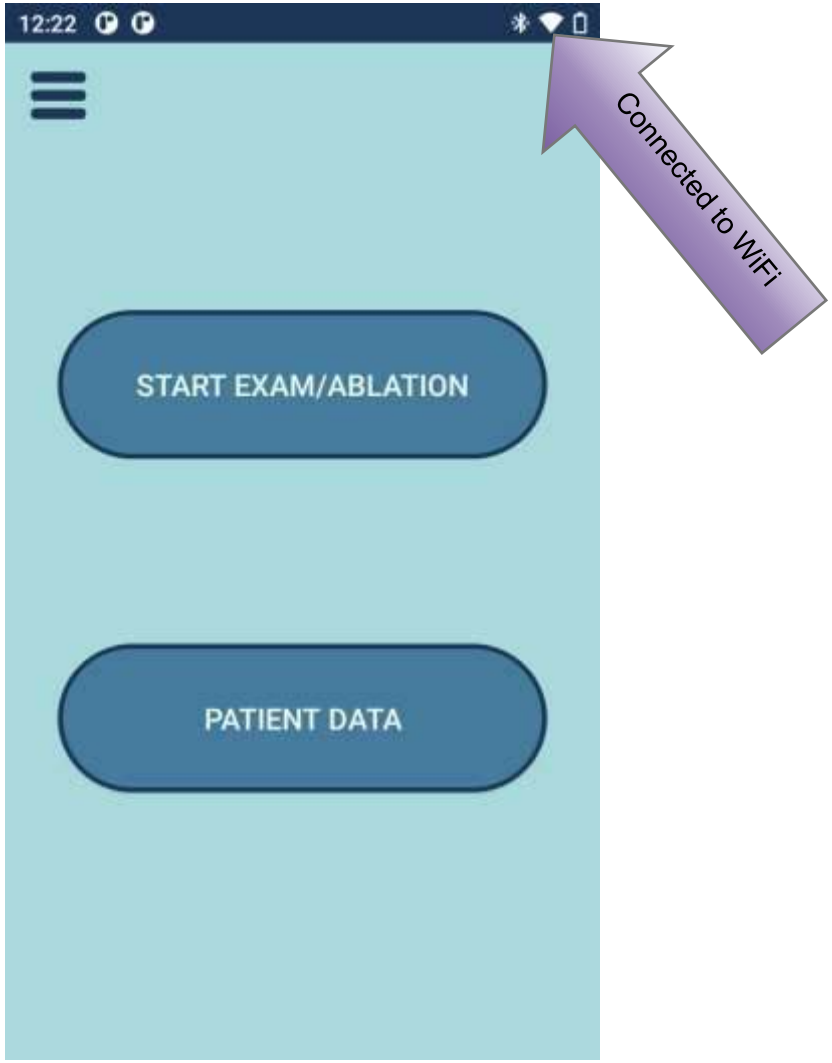


Figure 53: Wifi Connected

At the top of the screen a “connected” icon should appear.
NOTE: Wi-Fi is only supported on the 2.4GHz and 5Ghz ISM bands.

CONNECT TO BLUETOOTH

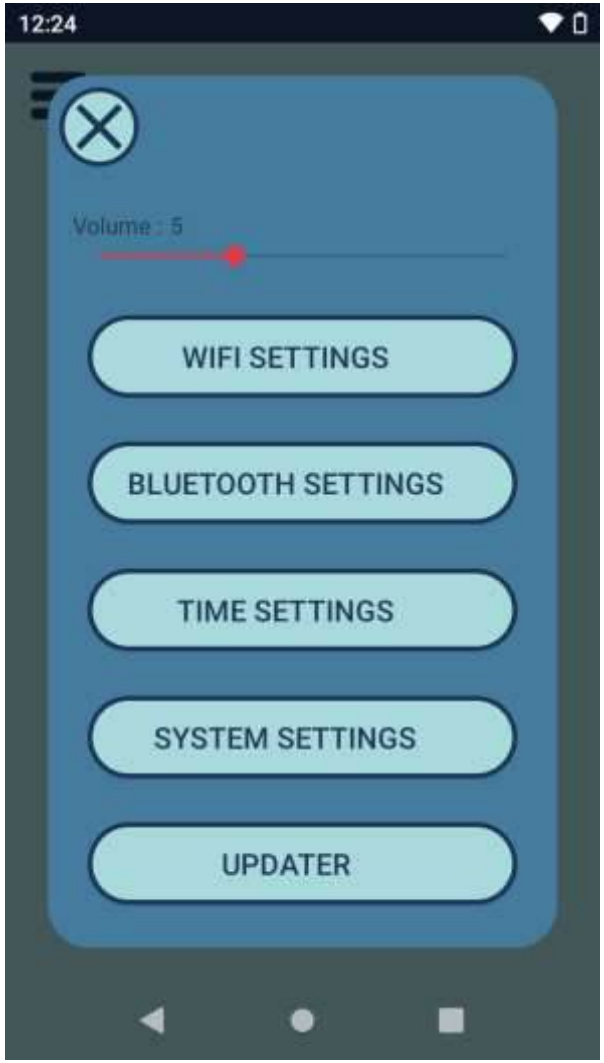


Figure 54: Connect to Bluetooth

To connect the IRIS to Bluetooth, tap the Menu icon> Settings>Bluetooth Settings.

PAIR NEW BLUETOOTH DEVICE

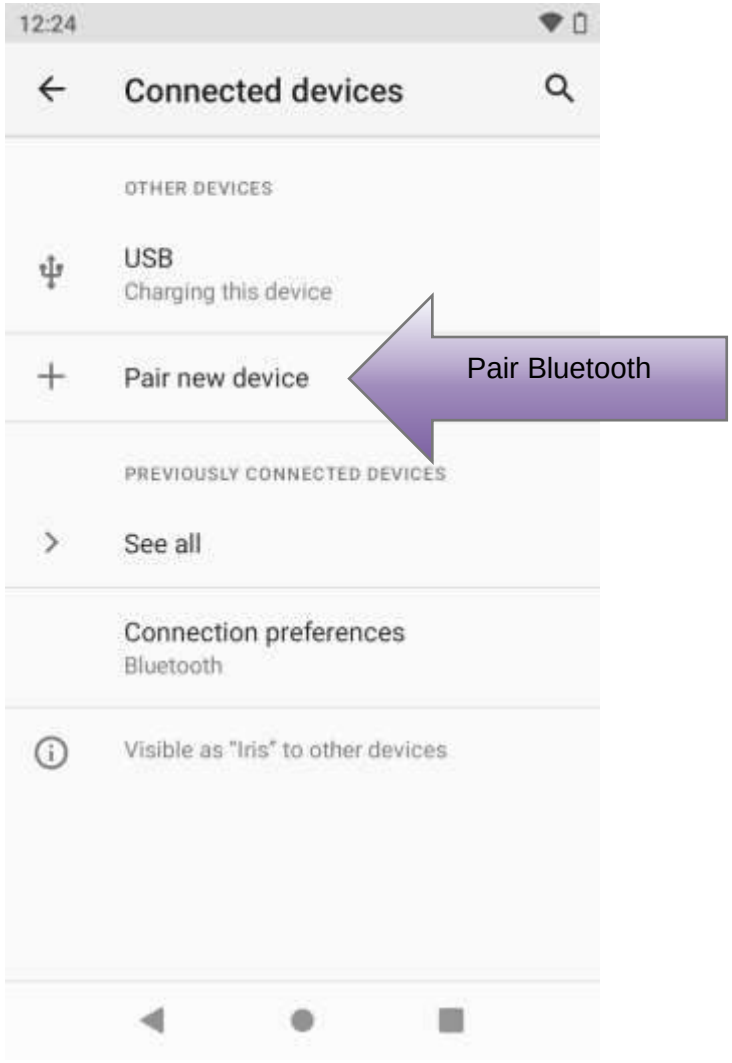


Figure 55: Pair Bluetooth

Tap Pair New Device.

SELECT NEW BLUETOOTH DEVICE TO PAIR

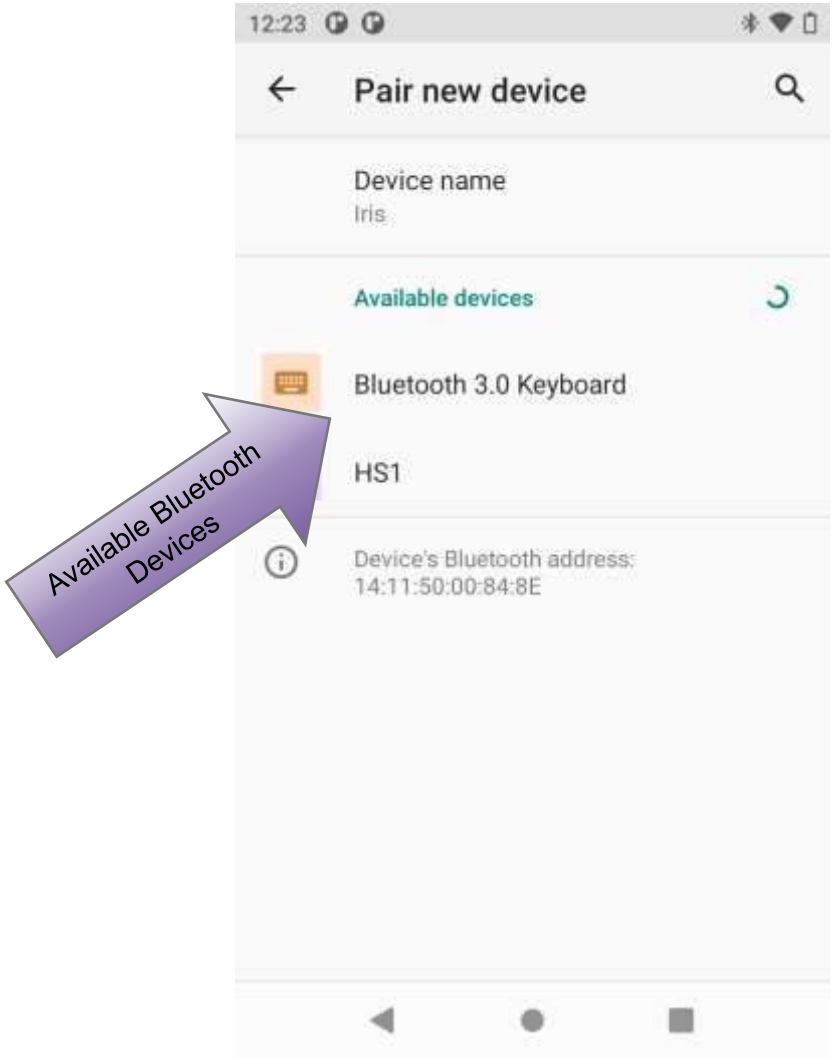


Figure 56: Select New Bluetooth Device to Pair

Tap on the device to pair.

CONNECTED BLUETOOTH DEVICES

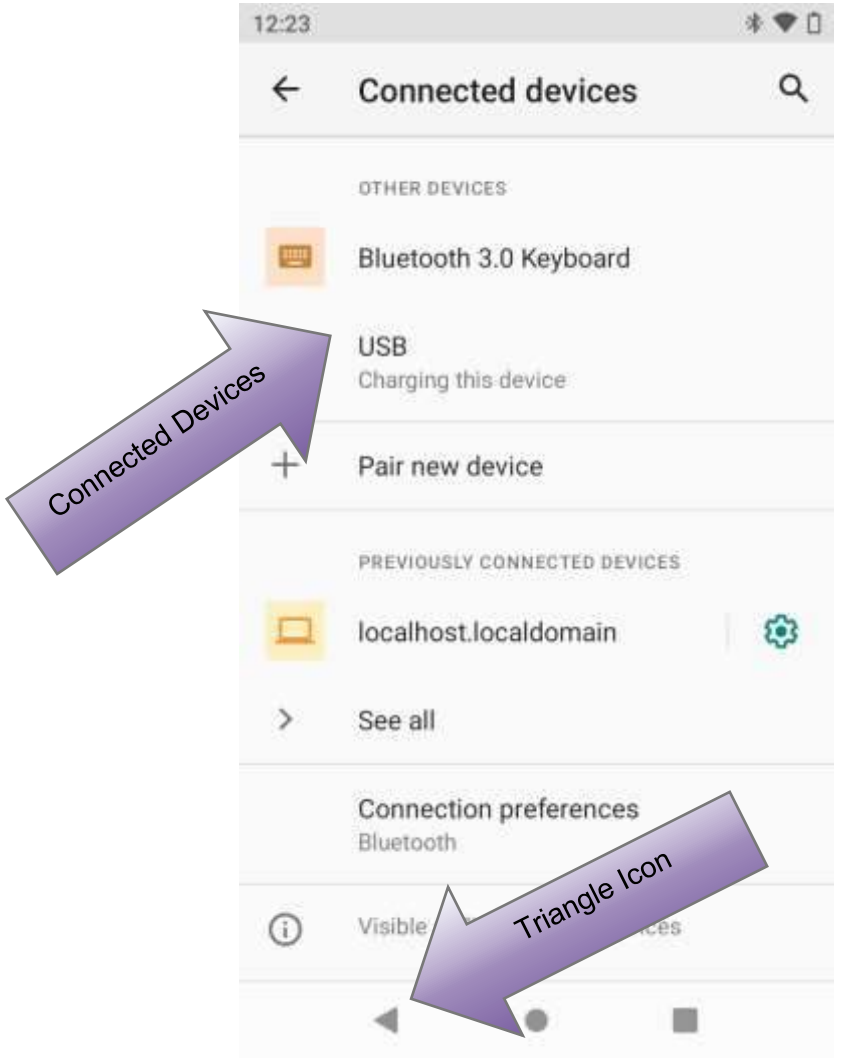


Figure 57:Select Device to Pair With

The paired device should be listed under “Currently Connected.”
To return to the IRIS tap the triangle icon.

UPDATE IRIS SOFTWARE

Figure 58: Settings Menu

To update the IRIS software, tap on the Options Menu icon then select Settings>Updater.

IRIS UPDATER

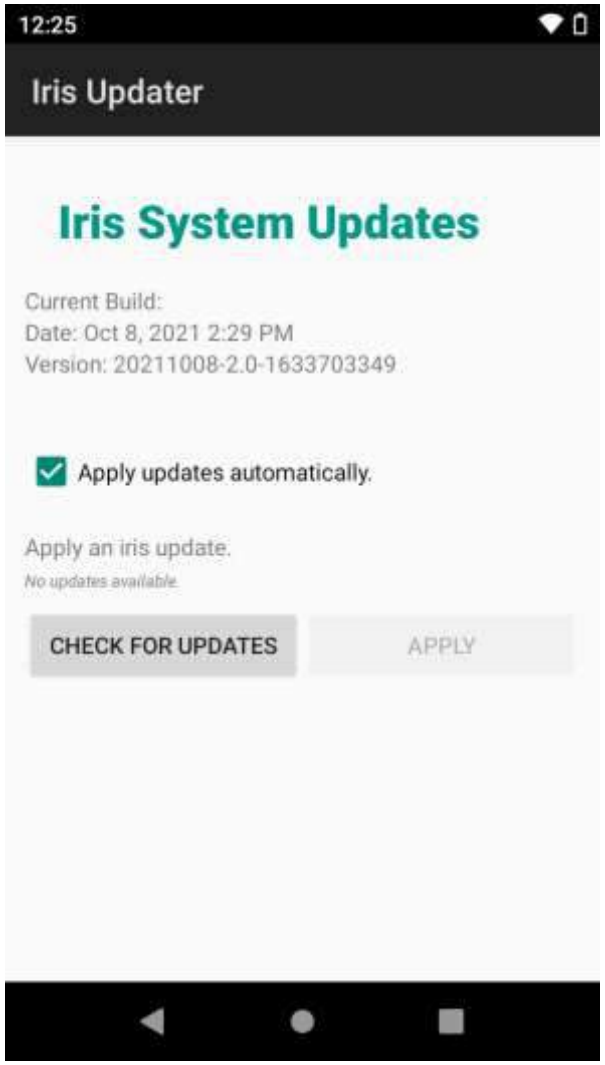


Figure 59: Update Screen

1. Tap Check for Updates to see if there are any available updates.
2. Tap Apply to update the software (if an update is available).
3. The update will automatically install, and the app will restart.
4. If there are no updates currently available, the app will display “No updates available”.

CONNECTING TO EXTERNAL DISPLAY

Figure 60: External Connection

Tap the external display icon to access external monitor options. *For HDMI, the IRIS must be connected to an HDMI-compatible monitor via an HDMI cable.*

When connected to an external monitor via HDMI, the HDMI Stream display will show HDMI: Connected

SHUTTING DOWN

At any point, the IRIS can be reset or shutdown by pressing and holding the activation button for approximately three (3) seconds. The power menu will display. Tap Power Off to shut the IRIS down. Tap Restart to reset the IRIS.

RECHARGING THE BATTERIES

- Batteries should only be recharged when the battery and charger are dry
- Plug the battery into the charging adapter.
- Plug the charging adapter into an A/C outlet

NOTE: The charger can be plugged into an A/C power outlet of 100-240VAC, 50/60Hz, with the proper country adapter.

- The red ‘charging’ LED on the charger should illuminate
- A completely discharged battery should fully recharge in about two (2-4) hours.
- When the battery is fully charged, the red ‘charging’ LED will turn to green.

Figure 61. Battery Charging

- Remove the battery from the charger base and disconnect the charger from the A/C outlet when the battery has been fully charged.

NOTE: The battery will not be damaged by leaving the battery in the charging adapter after the battery is fully charged making overnight charging convenient.

- The IRIS batteries are lithium-ion batteries and cannot be charged while connected to the IRIS handle. The IRIS handle cannot be connected to supply mains.
- Remove the 12V lithium-Ion battery is the IRIS is not likely to be used for some time.
- There is an internal lithium-ion coin-cell battery (CR1220) that can only be changed by Liger Medical personnel that is trained to use the appropriate tool.

PATIENT PREPARATION

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

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 VILLA, standard complications with their use may occur. The following complications may occur during or following thermal ablation use of the IRIS:

- Infection
- Pain
- Tissue Burn

CLEANING AND INSPECTION

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 following procedure:

Handle and Battery Cleaning Procedure:

- Disassemble the IRIS into three separate parts (handle, battery, probe)
- 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. Pour/spray the cleaning solution or disinfectant onto a cloth and ensure that the cloth is evenly damp prior to cleaning the IRIS.
- Do not allow fluids to enter the IRIS. Do not sterilize the IRIS handle or battery.
- Special caution should be used not to scratch the camera lens or display.

Probe Cleaning Procedure:

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 below for directions.

- If possible, initiate instrument cleaning within 30 minutes following use.
- **Always place the silicone cap on probe connector and do not immerse the probe connector in liquid.**

CAUTION: Only use a soft brush or cloth to manually remove impurities; never use abrasive materials as they may damage the probes.

- Perform the final instrument rinse with clean water (i.e., Reverse Osmosis/De-ionized (RO/DI) water) that does not contribute to device staining or contamination.
- 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.

Manual Cleaning*

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

- **Place silicone cap on probe connector.**
- 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.

- 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.
- 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.
- Remove the probe from the detergent solution and rinse with running water.
- Visually inspect each probe for visible soil. If soil remains, repeat the cleaning procedure outlined above.

* 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. 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 sterilization or a reduction in instrument life.

PROBE STERILIZATION

- Individually double pouch each in an FDA-cleared wrap, pouch, containers or other method to maintain sterility after auto-clave.
- Place silicone cap on probe connector.
- Insert probe(s) into sterilization tray/pouch following sterilizer manufacturer guidelines for appropriate tray/pouch and packaging instructions.
- Ensure that all surfaces will be exposed to the sterilizing agent.
- Control the water purity dedicated to steam production to prevent damage to the instruments.
- 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 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.

Probe High Level Disinfection (HLD)

Materials (not provided):

- An FDA-cleared High Level Disinfectant, such as Cidex® Activated Dialdehyde Solution, in a basin large enough for submerging the probe
- Tongs
- Pure water (boiled) at room temperature
- Sterile cloths for drying and storage

Disinfection Procedure:

1. Ensure minimum effective concentration (MEC) of the HLD following manufacturer's guidelines.
2. **Place silicone cap firmly on probe connector.**
3. Immerse the end of the heating tip of the probe into a cup of disinfectant solution approximately 5 to 6 inches (11 to 13 cm) deep. Keep probes upright. Do not immerse the connector end in the solution.
4. Allow the probe to soak in HLD following manufacturer's guidelines (i.e. 45 minutes at room temperature (25°C) for Cidex®).

5. Thoroughly rinse the probe(s) in pure water agitating and allowing them to set for a minimum of 5 minutes.
6. Repeat the previous rinsing step (6.) two more times for a total of 3 rinses using a fresh bath of pure water each time.
7. Dry with sterile lint-free cloth.
8. Store in sterile lint-free cloth until next use.

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 unit
- Signs of damage to any connector
- Accumulation of lint or debris on or around the unit

In each case, discontinue using the unit. If the unit is damaged externally or has a damaged connector, contact Liger Medical. If the unit 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 unit 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. 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 warrant period for Liger Medical products are as follows:

- Two (2) years from date of shipment

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.

TECHNICAL ASSISTANCE

For technical assistance, please call Liger Medical at the following telephone number: +1 (801) 256-6576, email sales@ligermedical.com, or visit 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:	10-40cm
Focus Mechanism:	Manual
Digital Magnification:	1x-4x
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
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:	10° to 40°C
Relative Humidity:	0% to 80% non-condensing
General Info	
Type BF 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

Electromagnetic Compatibility Guidance

Manufacturer's Declaration – Electromagnetic Emissions

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.

Emissions Test	Compliance	EMC Environment Compliance
RF Emission CISPR 11	Group 1	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.
RF Emission CISPR 11	Class A	The IRIS is suitable for use in professional healthcare environments.
Conducted RF Emissions	Not Applicable	
Radiated RF Emissions	Complies	
Harmonic Distortion IEC 6100-3-2	Not Applicable	
Voltage Fluctuation and Flicker IEC 61000-3-3	Not Applicable	

Manufacturer's Declaration – Electromagnetic Immunity

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.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
IEC 6100-4-2 – Electrostatic discharge (ESD)	±8 kV contact	Complies	Not Applicable
	±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	100% for 0.5 cycle at 0/40/90/135/180/225/270 & 315	Not Applicable	No external connections

variations on power supply input lines	100% for 1 cycle		
	30% for 25/30 cycles		
	100% for 250/300		
IEC 61000-4-8 – Rated Power-Frequency Magnetic Field (50/60Hz) magnetic field	30 A/m	Complies	See Warning 10 on Page 3 of this IFU

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
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
810 870 930	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
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 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

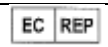
Contains Transmitter Module FCC ID: TFB-1004
Contains Transmitter Module IC: 5969A-1004
This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference 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	Standard	Clause	Symbol Title	Description
	*ISO 15223-1:2016*	*5.1.6*	*Catalogue number*	Device Name
	*ISO 15223-1:2016*	*5.1.7*	*Serial number*	Serial Number
	*ISO 15223-1:2016*	*5.1.1*	*Manufacturer*	Manufacturer & Date of Manufacture
	*ES 60601-1:2005+A1:2012*	*Table D.2 Symbol 10*	*Refer to instruction manual/booklet*	Attention! See Instructions for Use
	*ES 60601-1:2005+A1:2012*	*Table D.1 Symbol 20*	*Type BF Applied Part*	Type BF Applied Parts
	*N/A*	*N/A*	*Prescription Only*	CAUTION: Federal (USA) law restricts the sale of this device by or on the order of a physician
	*ASTM F203*	*N/A*	*Magnetic Resonance (MR) unsafe*	MRI Unsafe Keep Away from Magnetic Resonance Imaging (MRI) Equipment
	*ISO 15223-1:2016*	*5.3.7*	*Temperature limit*	Temperature Limits
IP21	*ES 60601-1:2005+A1:2012*	*Table D.3 Symbol 2*	*Solid Particle Protection*	Solid Particle Protection Level 2 (>12.5mm); Liquid Ingress Protection Level 1 (dripping water)
	*ES 60601-1:20-05+A1:2012*	*Table D.1 Symbol 4*	*Direct Current*	Rated Input Power
	*ISO 15223-1:2016*	*5.1.2*	*Authorized representative in the European Community*	Authorized Representative in the European Community

Liger Medical, LLC.
3300 N. Running Creek Way
Building G, Suite G20
Lehi, UT 84043
www.ligermedical.com



SMIDGEN
Millhouse,
Bleach Road,
Kilkenny, Eire
Ireland