



# MolecuLight

LOOK TO HEAL™

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MolecuLightDX® User Manual for Wi-Fi certification

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## 1 Introduction

The MolecuLightDX is a cordless, handheld device indicated for standard digital imaging and fluorescence imaging.

The MolecuLightDX's standard digital imaging capability can acquire and document standard digital images of dermatological wounds, and aid clinicians in measuring their surface area, length, and width.

The MolecuLightDX's fluorescence digital imaging capability can acquire (in real-time) and document intrinsic fluorescence emission of dermatological wounds between 500-545 nm and 600-665 nm when illuminated by violet 405 nm excitation light under acceptable environmental lighting conditions.

The MolecuLightDX is capable of capturing high-resolution still images and/or video using the standard digital imaging and fluorescence digital imaging.

MolecuLight Inc. provides technical support, a User Manual, and Quick Start Guides to aid you with the use of the MolecuLightDX. Please review this User Manual thoroughly before operating your device.

## 2 Indications for Use

The MolecuLightDX is intended for use as a handheld imaging tool that allows clinicians diagnosing and treating skin wounds, at the point of care, to

- (i) View and digitally record images of a wound,
- (ii) Measure and digitally record the size of a wound, and
- (iii) View and digitally record images of fluorescence emitted from a wound when exposed to an excitation light.

The fluorescence image, when used in combination with clinical signs and symptoms, has been shown to increase the likelihood that clinicians can identify wounds containing bacterial loads  $>10^4$  CFU per gram as compared to examination of clinical signs and symptoms alone. The MolecuLightDX device should not be used to rule-out the presence of bacteria in a wound.

The MolecuLightDX does not diagnose or treat skin wounds.



### Caution

Do not use the MolecuLightDX for purposes other than imaging or video documentation of wounds using the iX Imaging App. Do not use any other Apps which may be present on the MolecuLightDX.













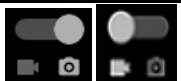
## 3 Warnings, Cautions, and Notes

Please read the following safety information before using the MolecuLightDX Imaging Device.

The MolecuLightDX is an imaging device that does not require contact with the patient. It captures images/videos and utilizes safe levels of violet wavelength light to illuminate a wound for fluorescence imaging. The MolecuLightDX Imaging Device does *not* require the use of exogenous imaging contrast agents. Some patients may experience some warmth from the device during exposure.

The Range Finder Sensor contains a fully-enclosed laser. No hazardous laser radiation is emitted during use. No eye or skin protection is required for the user or patient when operating the MolecuLightDX.

### 3.1 Definitions and Symbols for Device Operation

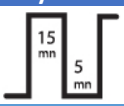
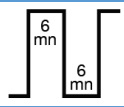

Term	Definition	
ST-Image	Standard image akin to normal photography.	
FL-Image	Fluorescence image captured with the violet excitation light and emission filter.	
Patient Directory	List of patients	
View Patient	Screen with patient details and list of wounds for the patient.	
View Wound	Screen with wound details including a scrollable browser of previously captured images.	
Review	Screen to view images in full screen	
Splash screen	Loading screen	
Login	Screen where user logs into their account	
Standard User	Clinician using the device during patient care with restricted privileges.	
Super User	Clinician using the device during patient care with additional privileges (delete, edit etc.)	
Account Administrator	Administrator with rights to add users, modify users, and set-up and configuration of the devices.	
Symbol	Meaning	Function
	Patient	Icon to indicate patient name.
	Calendar	Tap to select a specific audit log date to display.
	Search	Tap to search current screen or list.
	Filter	Tap to display a menu with filter options.
	More	Tap to display a menu with additional options for the current screen.
	Add	Tap to add either a user/patient/wound/image.
	Selected/Unselected	Selected boxes include the checkmarks. (black box does not exist on UI, only to visualize white box).
	Delete	Tap icon to delete an image.
	Information	To icon to view the image or patient details.
	Close	Tap icon to close current pop-up/screen.
	Torch OFF	Tap icon to turn the torch ON in Standard mode.
	Torch ON	Tap icon to turn the Torch OFF in Standard mode.
	Video/Still	Video/Still enabled when light grey. Tap to toggle between video and camera.

	<b>Video Not Available/Still</b>	Video is not enabled when this icon is displayed. To enable video, go to Settings and enable the Video Capture option.
	<b>Standard Mode</b>	Tap icon to enter Standard mode. Blue = Active, White = Inactive
	<b>Fluorescence Mode</b>	Tap icon to enter Fluorescence mode. Blue = Active, White = Inactive
	<b>FL available</b>	In Standard mode, icon indicates the room is dark enough to move to fluorescence mode.
	<b>Ambient Light Warning</b>	Warns the image was captured with suboptimal ambient lighting conditions.
	<b>Range Finder Warning</b>	Warns the image was captured outside of the recommended range.
	<b>Save</b>	Tap to save new patients/users or edits made on some screens.
	<b>Saved confirmation</b>	Appears on the screen for 1 second when a user taps the <b>SAVE</b> button.
	<b>Deleted confirmation</b>	Appears on the screen for 1 second anytime the user taps <b>OK</b> button.

### 3.2 Symbols Used on the MolecuLightDX Imaging Device Label

The following table lists the symbols and statements used on the MolecuLightDX Imaging Device label (silver label).

Symbol	Meaning
	Caution, consult accompanying documents
	Read User Manual
	Date of manufacture
	Catalog number
	Serial number
	Certification of safety testing
<b>Rx only</b>	Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Dispose of the MolecuLightDX in accordance with your country's legal requirements for the disposal of electrical and electronic waste
	RF transmitter for wireless transmission

Symbol	Meaning
	Device duty cycle (if device is continuously on for 15 minutes in Fluorescence Imaging Mode, violet LEDs should be turned off for 5 minutes before Fluorescence Imaging Mode is used again)
	Device duty cycle when the <b>DX</b> is used in the sterile surgical sleeve (if device is continuously on for 6 minutes in Fluorescence Imaging Mode, violet LEDs should be turned off for 6 minutes before Fluorescence Imaging Mode is used again)
	CE Marking indicates European Conformity to essential requirements of applicable European product directives; 0123 represents MolecuLight Inc.'s Notified Body
Statement	Meaning
<b>CAN ICES-3(B)/NMB-3(B)</b>	Self-Declaration of Compliance (SDoC) to Industry Canada ICES-003(B)
<b>The MolecuLight DX Imaging Device complies with Part 15 of the FCC Rules</b>	For further information related to this statement, refer to Section TBD for specific certification and Section TBD for electromagnetic compatibility
<b>For use only with Power Adapter ATS018T-P050. A utiliser uniquement avec Câble ATS018T-P050</b>	For further information related to accessories and consumables, refer to Section TBD.
<b>Contains FCC-ID: 2AFDI-ITCOQ626S IC: 9049A-ITCOQ626S</b>	MolecuLightDX contains a SOM with FCC and IC ID

### 3.3 Federal Communication Interference Statement

We MolecuLight Inc, 425 University Ave, suite 700, Toronto M5G 1T6, Ont, Canada, 647 362 4684, declare under our sole responsibility that the handheld device indicated for standard digital imaging and fluorescence imaging complies with Part 15 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.

This product does not contain any user serviceable components. Any unauthorized product changes or modifications will invalidate warranty and all applicable regulatory certification and approvals, including authority to operate this device.

**WARNING:** 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 and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

### 3.4 Industry Canada Statements

This device complies with Industry Canada license-exempt RSS standard(s).

Operation is subject to the following two conditions: (1) This device may not cause interference, and (2) This device must accept any interference, including interference that may cause undesired operation the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

### 3.5 Electromagnetic Compatibility

This device complies with Part 15 of the US FCC Rules. This device complies with Canadian ICES-003 (B). The emissions characteristics of the MolecuLight DX make it suitable for use in industrial areas and hospitals (CISPR 11 class A). MolecuLight DX is intended for use in a residential environment and does comply with IEC 60601-1-11:2015 General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

#### Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the ME SYSTEM

The MolecuLight**DX** is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MolecuLight**DX** can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MolecuLight**DX** as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d=1.2\sqrt{P}$	800 MHz to 2.7 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.24
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance  $d$  in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where  $P$  is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

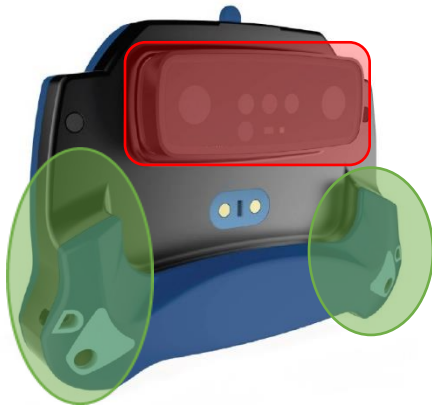
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects and people.



## 4 Holding the device

The images below indicate where to hold the MolecuLightDX device with green circles.

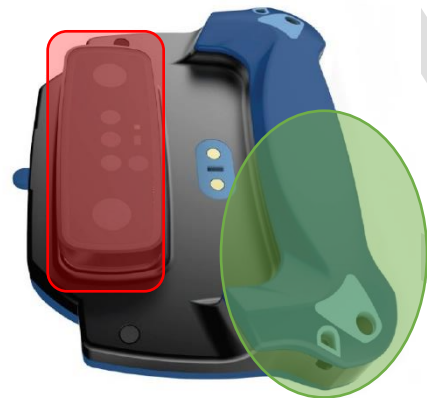
When holding the device, it is important to ensure that you do not cover the illumination zone on the back of the device. The images below indicate where the illumination zone is with a red circle.



Landscape orientation, back of device, two hands



Landscape orientation, front of device, two hands



Portrait orientation, back of device, one hand



Portrait orientation, back of device, two hand

## 5 Docking Station

The docking station charges the device battery when not in use.

### Setting up the docking station:

1. Plug the AC utility cord into a wall outlet.



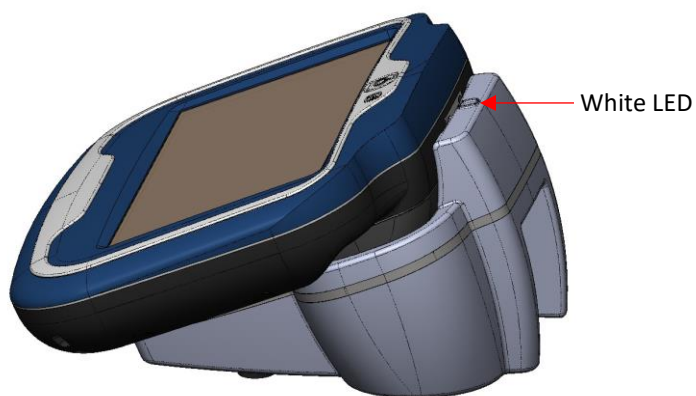
2. Plug the AC utility cord into the ACDC power adapter.



3. Plug the ACDC line cord into the USB-C connector on the docking station.



4. Once the docking station has power, a white LED indicator will be displayed automatically.



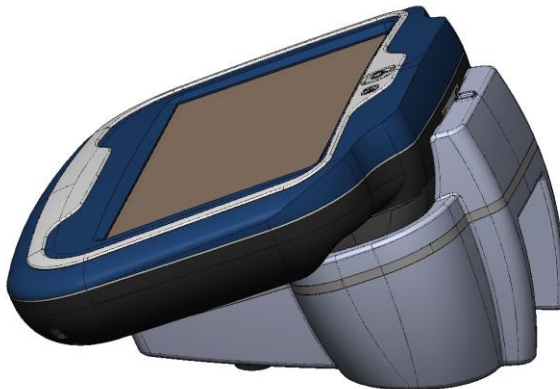
5. Ensure the docking station is placed on a stable, flat surface.

#### Attaching the device to the docking station:

1. Ensure the docking station is placed on a stable, flat surface.
2. Ensure the USB-C charging cable is not attached to the device before placing it on the docking station.  
**NOTE:** The device will not sit properly on the docking station with a USB-C cable attached to the device.
3. Ensure the device USB-C charging port cover is closed.
4. Log out of the device.
5. Place the device on the docking station as pictured above. Edges on the docking station and device connect in order to prevent the device from sliding off the docking station.
6. When the device is charging, the battery LED (to the right of the power button) will be flashing green.
7. The battery LED will flash different colours depending on the device condition:
  - a. blink quickly red: connected to a charger and battery level is low
  - b. blink quickly amber: connected to a charger and battery level is medium
  - c. blink quickly green: connected to a charger and battery level is good
  - d. green: connected to a charger and charging is complete

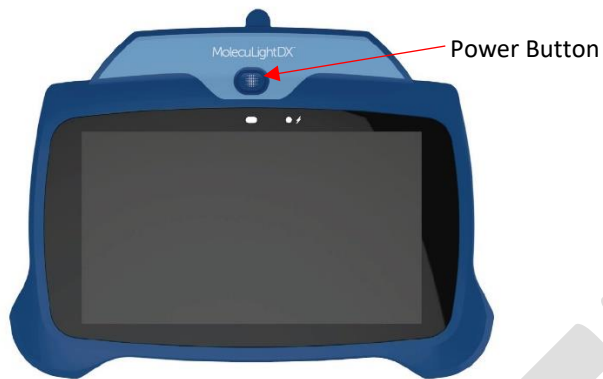


8. When the device is placed properly on the docking station, the device should look like the following:



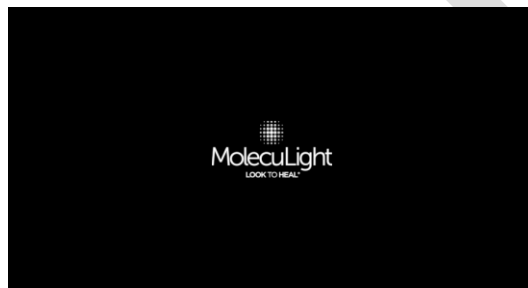
## 6 Turning the device on

1. Press and hold the power button for 4 seconds.

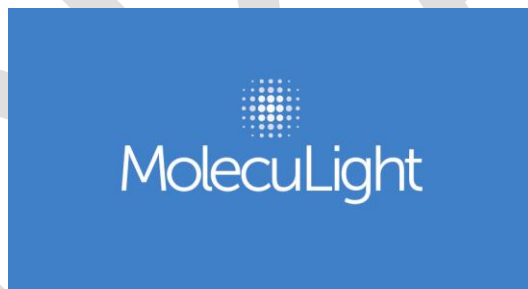


2. While the device is powering on, the following screens will be displayed on the device:

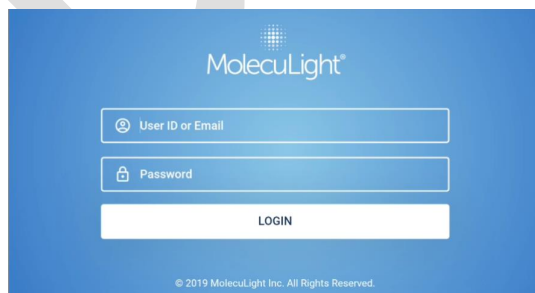
- a. MolecuLight logo screen



- b. MolecuLight screen saver screen



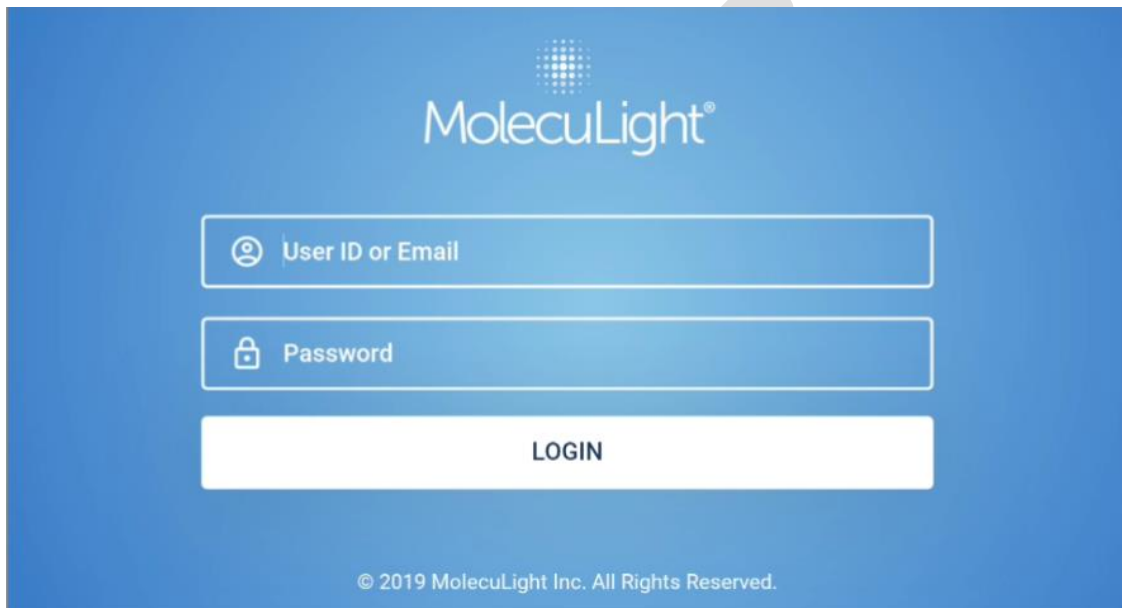
- c. MolecuLight [Login screen](#)



3. The power button LED will indicate the device status:

- a. off: device is OFF
- b. blink green: transitioning from OFF to ON
- c. green: ON or STANDBY state (all hardware operating parameters are normal)
- d. amber: ON or STANDBY (hardware operating parameters are outside of normal range, device needs service)
- e. red: OFF (hardware operating parameter(s) are out of normal range, critical error, device will not power up, device needs servicing)

## 7 Login

The image shows the MolecuLight login interface. At the top center is the MolecuLight logo, which consists of a grid of dots above the brand name. Below the logo are two input fields: the first is labeled 'User ID or Email' with a person icon, and the second is labeled 'Password' with a lock icon. Below these fields is a large white button with the text 'LOGIN'. At the bottom of the screen, there is a copyright notice: '© 2019 MolecuLight Inc. All Rights Reserved.'

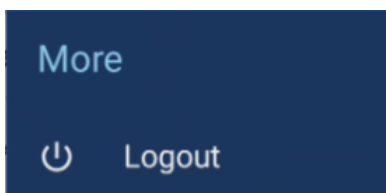
1. Tap the **User ID or Email** field. A keyboard will be displayed.
2. Type your user ID or email.
3. Tap the **Password** field.
4. Type your password.
5. Tap **LOGIN**.
6. The Patient Directory screen will be displayed.

## 8 Logout

1. From any screen, tap **More**.



2. Tap **Logout**.



3. The Login screen is displayed.

## 9 Patient Directory screen

The Patient Directory screen is the first screen you see after logging in. If the patient you are looking for is not already on the device, you must [add a patient](#).



Number	Description
1	<b>Patient Directory list.</b> All patients will be listed in this directory list. Patients are added to the bottom of the list as they are added.
2	<b>Add icon.</b> Tap <b>Add</b> to add a patient. See <a href="#">Adding a Patient</a> .
3	<b>More icon.</b> Tap <b>More</b> to display a menu. The only option in the menu on the Patient Directory screen is Logout.
4	<b>Filter icon.</b> Tap <b>Filter</b> to display a menu. The menu options will allow you to filter the patients in the list by either active or inactive, see <a href="#">Filtering the Patient Directory</a> and <a href="#">Editing Patient (View Patient screen)</a> .
5	<b>Search icon.</b> Tap <b>Search</b> to display a search bar. See <a href="#">Searching the Patient Directory</a> .

### 9.1 Adding a Patient

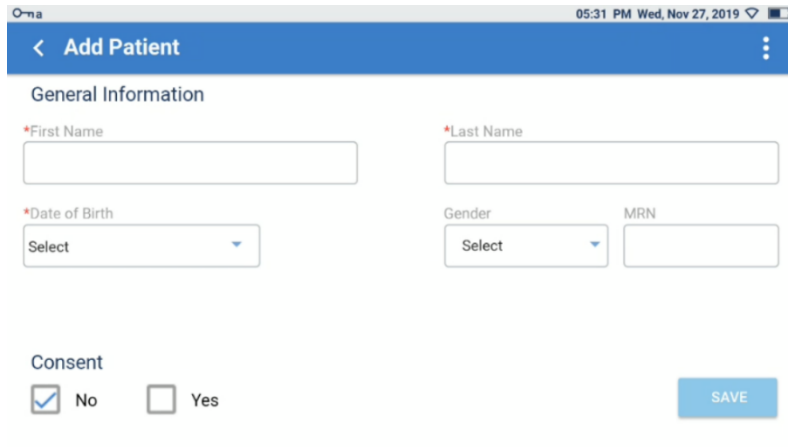
The first screen displayed after logging in, is the [Patient Directory screen](#).

**NOTE:** When adding a patient, only fields on the Add Patient screen marked with a red asterisk are required to save a patient.

1. On the Patient Directory screen, tap **Add**.



2. On the Add Patient screen, tap the **First Name** text field to automatically display a keyboard. Using the keyboard enter the patient's first name.



3. Tap **Next** on the keyboard to go to the next text field.



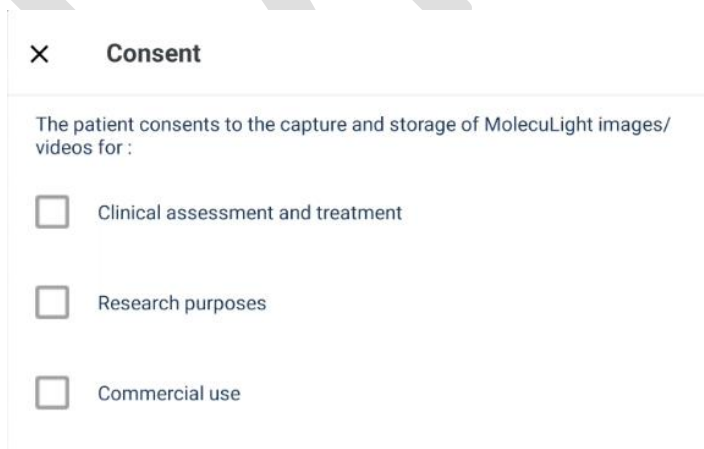
4. If a patient agrees to the capture and storage of images and videos for either clinical assessment and treatment, research purposes and/or commercial use tap **Yes** for Consent.

**NOTE:** Default consent is No when adding a new patient.

5. The Consent popup will be displayed.

**NOTE:** You must select **Clinical assessment and treatment** before the **Research purposes** and **Commercial use** options can be selected.

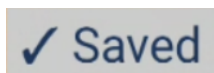
**NOTE:** If the patient does not provide consent you cannot create a wound or capture an image for the patient.



6. Tap **SAVE**.



7. New user is saved, and a confirmation message is displayed.



## 9.2 Filtering the Patient Directory

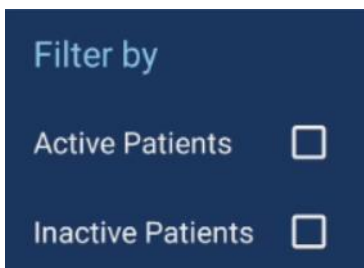
When a new patient is added, their status defaults to Active. You can edit a patient's status to Inactive at any time from the [Edit Patient screen](#).

When a patient's status is Inactive, you will not be able to add a wound or any images to existing wounds.

1. On the Patient Directory screen, tap **Filter**.



2. A menu is displayed.



3. Tap either **Active Patients** or **Inactive Patients** checkbox to filter the list. The Patient Directory is automatically filtered according to your selection.

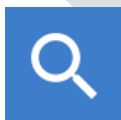
**NOTE:** The filter you select will remain enabled until you uncheck the filter checkboxes, go to a different screen (ie. Add Patient screen) or log out of the device.

## 9.3 Searching the Patient Directory

Search the Patient Directory to easily find a patient using either their name or MRN.

You can also search the Patient Directory when a [filter](#) is enabled.

1. On the Patient Directory screen, tap **Search**.



2. A search bar will be displayed at the top of the screen.



3. Tap inside the search bar and a keyboard will be displayed. Enter text to search by either the patient name or MRN.
4. Tap **Search** on the keyboard. The patient list will be filtered according to what was entered.

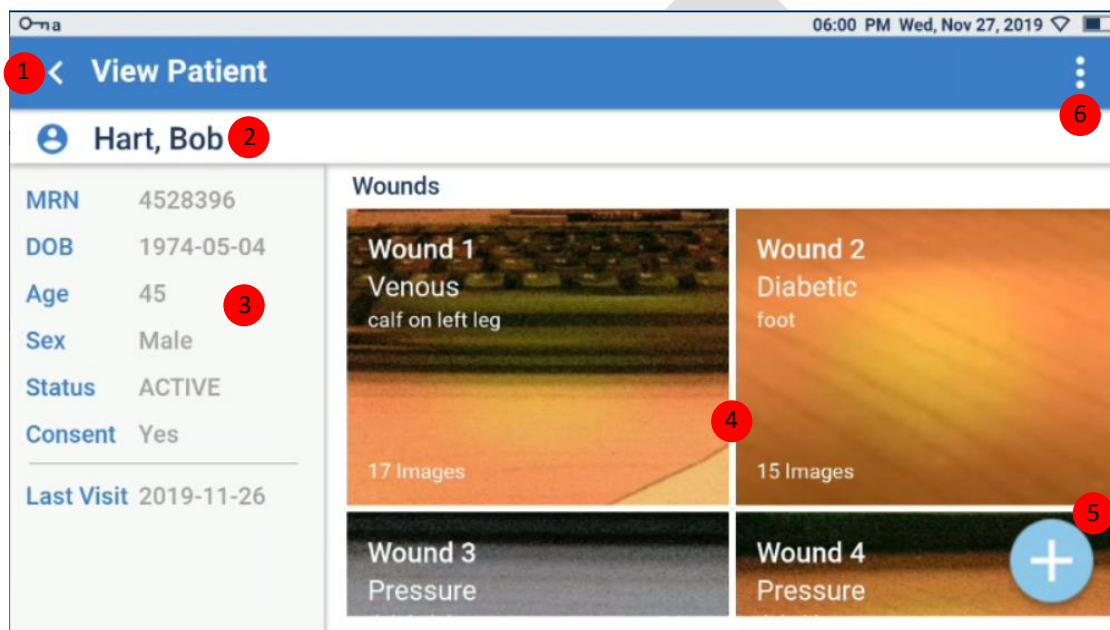




5. Do either of the following:
  - a. Tap to select a patient from the filtered list to load the View Patient screen for that patient.
  - b. Cancel the search by tapping **X** from within the search bar.



## 10 View Patient screen



Number	Description
1	<b>Back icon.</b> Tap <b>Back</b> to return to the Patient Directory screen.
2	<b>Patient name.</b> Displays the current patient name as Last Name, First Name.
3	<b>Patient information.</b> Displays the MRN, Date of Birth (DOB), Age, Sex, Status (Active or Inactive), Consent (Yes/No) and date of the last visit.
4	<b>Wound thumbnails.</b> Wound thumbnails list displayed for the current patient. Tap any wound to open the Wound screen.
5	<b>Add icon.</b> Tap <b>Add</b> to add a wound for the current patient.
6	<b>More icon.</b> Tap <b>More</b> to display a menu. An Edit Patient and Logout option are available on the menu. See <a href="#">Editing Patient</a> .

### 10.1 Selecting a Wound

Once a wound has been added for a patient, tap to select a wound to view the images captured for that wound.

1. On the View Patient screen, tap a wound thumbnail.
2. The Wound screen will be displayed. Images that have been captured will be displayed as a thumbnail.

## 10.2 Adding a Wound

If a wound is not already listed for the current patient, you must add a new wound.

1. On the View Patient screen, tap **Add**.

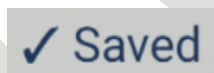


2. On the Add Wound screen, tap the **Wound Location** text field and using the keyboard enter the wound location.

3. Tap the **Wound Type** drop-down menu and select a wound type from the list.  
**NOTE:** Only fields marked with a red asterisk are required to save a new wound.
4. Tap **SAVE**.



5. New wound is saved, and a confirmation message is displayed.



## 10.3 Searching the Wound list

1. On the View Patient screen, if the patient has more than 2 wounds, a scrollable list will become available.
2. Using a tap, drag and finger swipe from the bottom to top of the screen, scroll through the wound thumbnail list.
3. Tap the wound thumbnail to load the Wound screen for that wound.

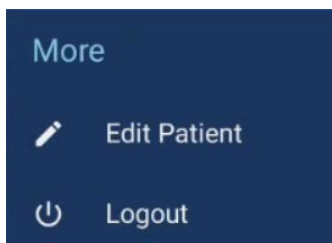
## 10.4 Editing Patient

You can edit an existing patient if data was entered incorrectly, if their consent has changed or if their status has changed.

1. On the Patient Directory screen, tap on any information for the patient you want to edit. The [View Patient screen](#) will be displayed.
2. Tap **More**.



3. Tap **Edit Patient**.



4. On the Edit Patient screen, tap a field to select it—a keyboard will be displayed if a text box is selected. Tap the Date of Birth drop-down arrow to display a calendar. Tap the Gender drop-down arrow to display a menu with gender options.

You can change the status of a patient from Active (default) to Inactive by selecting the appropriate radio button. You can change the status of their consent by selecting the appropriate checkbox.

**NOTE:** If a patient has Inactive Status assigned, you will not be able to add either a wound or any images to existing wounds.

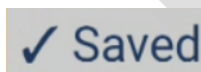
The screenshot shows the 'Edit Patient' screen with the following fields and options:

- General Information**
  - \*First Name: Text box containing 'Maya'
  - \*Last Name: Text box containing 'Smiths'
  - \*Date of Birth: Drop-down menu showing '1970-01-01'
  - Gender: Drop-down menu showing 'Select'
  - MRN: Text box
  - Patient Status: Radio buttons for 'Active' (selected) and 'Inactive'
  - Consent: Checkboxes for 'No' (checked) and 'Yes'
- SAVE** button

5. Tap **SAVE**.



6. Edits are saved and a confirmation message is displayed.



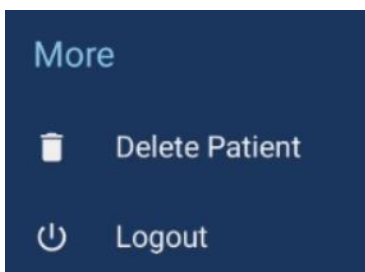
## 10.5 Deleting Patients

You may want to delete patients if your device storage reaches its capacity or if the patient no longer has an active wound.

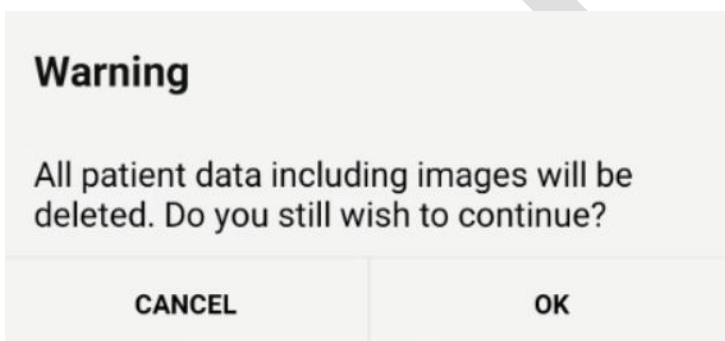
1. On the Patient Directory screen, tap on any information for the patient you want to edit. The [View Patient screen](#) will be displayed.
2. Tap **More**.



3. Tap **Edit Patient**. The [Edit Patient screen](#) will be displayed.
4. Tap **More**.
5. Tap **Delete Patient**.



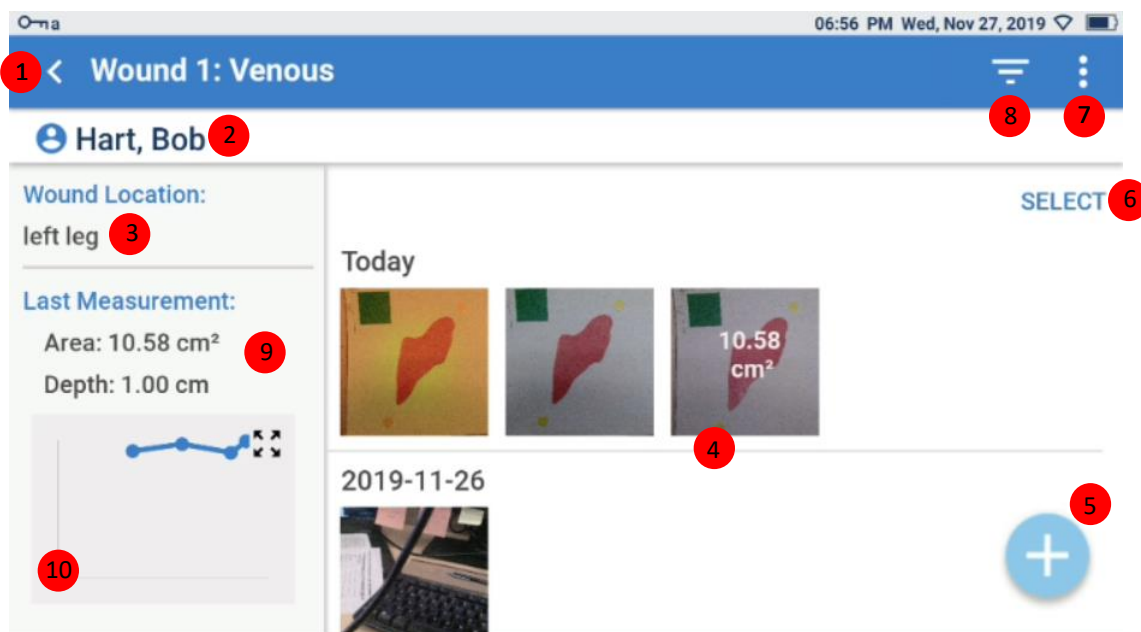
6. On the warning dialog, tap **OK**.



7. Patient is deleted and a confirmation message is displayed.



## 11 Wound screen



Number	Description
1	<b>Back icon.</b> Tap <b>Back</b> to return to the Patient Directory screen.
2	<b>Patient name.</b> Displays the current patient name as Last Name, First Name.
3	<b>Wound location.</b> Displays the location of wound.
4	<b>Image thumbnails.</b> Image thumbnails list displayed for today and previous visits by date. Videos are displayed with a play icon. Tap any thumbnail to load the image into full screen review.
5	<b>Add icon.</b> Tap <b>Add</b> to add an image to the current wound.
6	<b>SELECT.</b> Allows you to delete or move images. Tap <b>SELECT</b> to display checkboxes on each thumbnail, then tap the thumbnails you wish to delete or move. Once the thumbnails are selected, tap the <b>More</b> icon to display a menu with the delete and move options. <b>NOTE:</b> Once <b>SELECT</b> is tapped, it will be displayed as <b>CANCEL</b> . Tap <b>CANCEL</b> to exit the delete/move mode.
7	<b>More icon.</b> Tap <b>More</b> to display a menu. An Edit Wound and Logout option are available on the menu. See <a href="#">Editing a Wound (Open/Close)</a> .
8	<b>Filter icon.</b> Tap <b>Filter</b> to display a menu. The menu options will allow you to filter the images in the current wound by either FL-Image, ST-Image and Videos or any combination. Images will be filtered according to your selection. <b>NOTE:</b> The filter will be disabled when exiting the screen or by deselecting the options in the menu.
9	<b>Last Measurement.</b> The surface area and depth from the most recent wound measurement image are displayed.
10	<b>Wound Area Graph.</b> All surface area measurements from measurement images of the wound are displayed on this graph in order to track wound area progression. See <a href="#">Reviewing Measurements</a> .

### 11.1 Capturing Images

Once a wound is created and the Wound screen is loaded, you can capture any type of image for the selected wound. See the [Imaging screen](#) for more details on capturing images.

Modes include:

- Standard (camera/video)
- Fluorescence (camera/video)
- Measurement

1. On the Wound screen, tap **Add**.

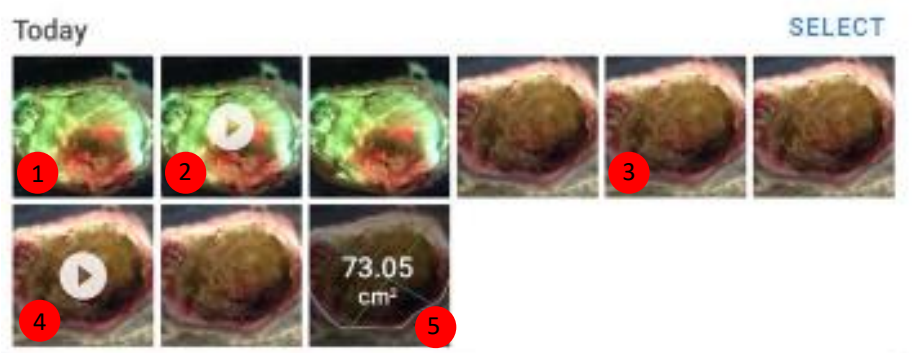


2. On the [Imaging screen](#), capture the required image(s).
3. When image capture is completed, tap **Back** to return to the Wound screen. A thumbnail of the just captured image(s) will be displayed under today's visit folder.

### 11.2 Reviewing Images

An image thumbnail will be displayed on the Wound screen for each image captured. Images will be organized according to the date of capture.

Each thumbnail type will be displayed as follows:

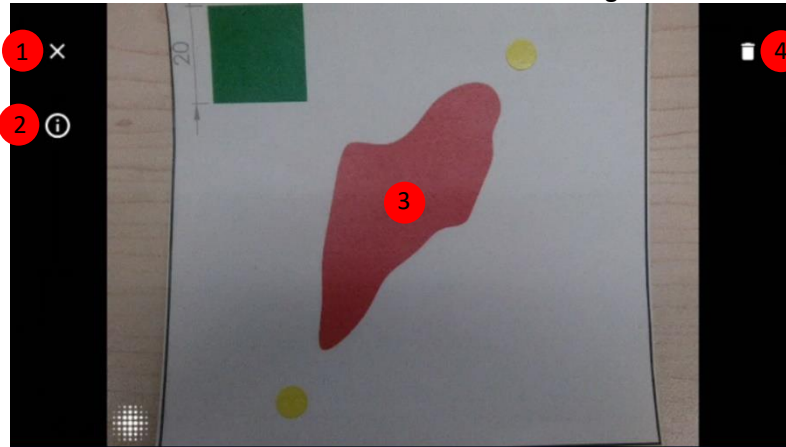


Number	Image Type
1	Fluorescence still image
2	Fluorescence video image
3	Standard still image
4	Standard video image
5	Measurement image

**To load an image into Review:**

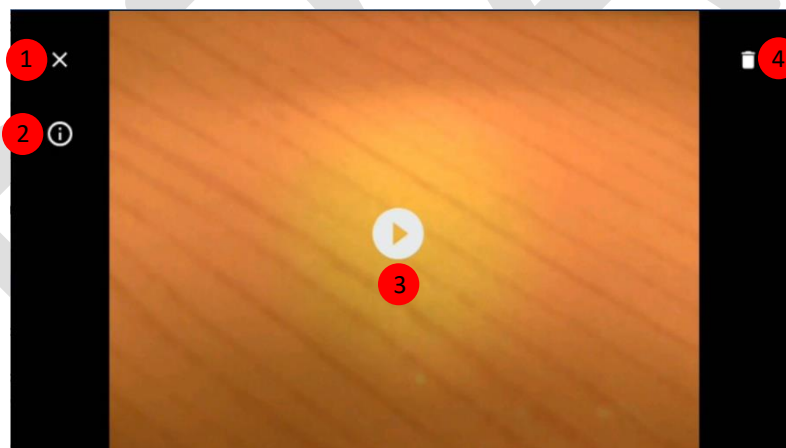
1. On the Wound screen, tap a thumbnail to load the image into Review in full screen.

**Review screen for Standard and Fluorescence still images:**

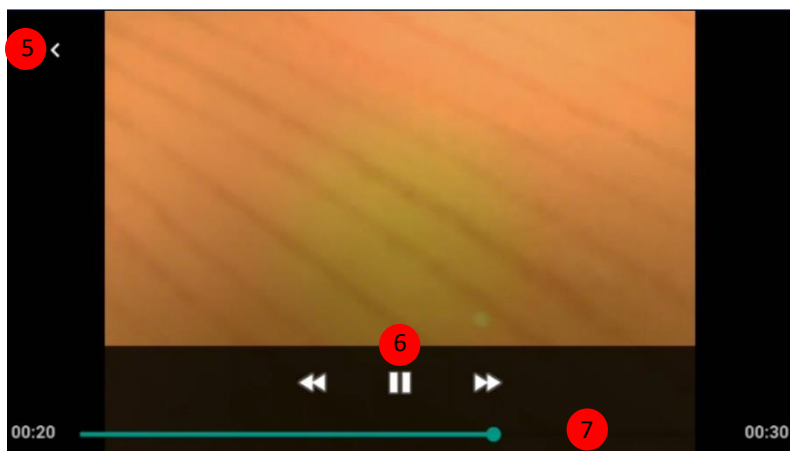


Number	Description
1	<b>Close icon.</b> Tap <b>Close</b> to return to the Wound screen.
2	<b>Info icon.</b> Tap <b>Info</b> to display the Image Details; includes patient name, date of birth, wound location, date/time of image capture, and user who captured the image.
3	<b>Review screen.</b> Displays the image in full screen.
4	<b>Delete icon.</b> Tap <b>Delete</b> to delete the current image.

**Review screens for Standard and Fluorescence videos:**



**Screen 1: Tap Play to load the video**



Screen 2: Includes video controls

Number	Description
1	<b>Close icon.</b> Tap <b>Close</b> to return to the Wound screen.
2	<b>Info icon.</b> Tap Info to display the Image Details; includes patient name, date of birth, wound location, date/time of image capture, and user who captured the image.
3	<b>Play icon.</b> Only displayed for videos, tap to load the video.
4	<b>Delete icon.</b> Tap Delete to delete the current image.
5	<b>Back icon.</b> Tap Back to return to Review screen 1.
6	<b>Video controls.</b> Controls include play/pause toggle, fast forward and fast rewind. Tap the main area to dismiss the video controls.
7	<b>Video position and length.</b> Displays where in the video the video is currently playing and how long the video is. Tap to drag the position indicator to adjust what is currently displayed.

#### Image Details from Info icon

### 11.3 Reviewing Measurements

To the left of the Wound screen, wound surface area measurements are displayed. The last measurement surface area and depth are displayed as well as a graph showing wound size progression over time.





#### To view the wound area graph:

1. Tap on the expand icon on the wound size graph on the left of the Wound screen.



2. The wound area graph displays all the wound surface area measurements taken of that wound over time. Surface area is displayed in cm<sup>2</sup> and the date of the measurement is seen on the bottom of the graph.

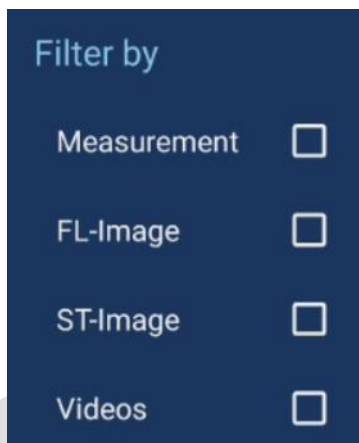
#### 11.4 Filtering Images

The software allows you to filter the thumbnail list on the Wound screen by image type, still or video and any combination of the options available.

1. On the Wound screen, tap Filter.



2. A menu is displayed.



3. Tap any option checkbox to filter the list. The Wound screen thumbnails list is automatically filtered according to your selection.

**NOTE:** The filter you select will remain enabled until you uncheck the filter checkboxes, go to a different screen (ie. Imaging or View Patient screens) or log out of the device.

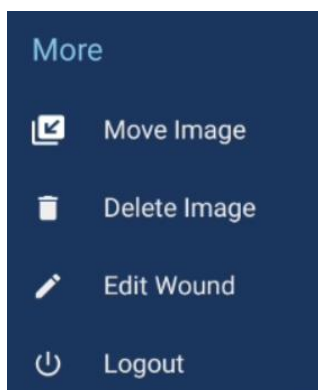
#### 11.5 Moving Images

You can move an image to a different wound for the same patient.

4. On the Wound screen, tap **SELECT**. A checkbox is displayed on the top right corner of all thumbnails for all visits.
5. Tap to select a thumbnail.
6. Tap **More**.



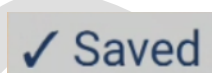
7. A menu is displayed.



8. Tap **Move Image**.
9. Tap a wound checkbox from the list.

 A white dialog box with a black border titled "Select New Location". It contains a list of four wound entries, each with a checkbox on the right: "Wound 1 - Venous left leg", "Wound 2 - Diabetic foot", "Wound 3 - Pressure djddjjdd", and "Wound 4 - Pressure djddjjdd". At the bottom are two buttons: "CANCEL" and "OK".

10. Tap **OK**.
11. Image is moved to new wound and a confirmation message is displayed.



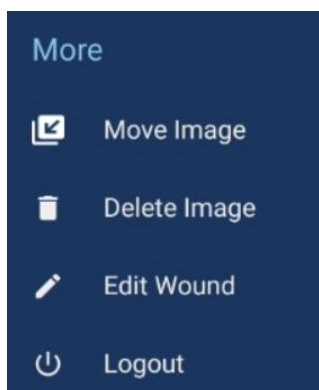
## 11.6 Deleting Images

You can delete an image from a wound from the [Review screen](#), but also from the Wound screen.

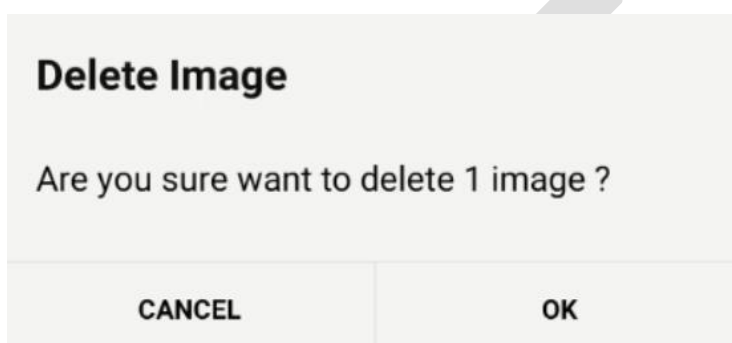
1. On the Wound screen, tap **SELECT**. A checkbox is displayed on the top right corner of all thumbnails for all visits.
2. Tap to select a thumbnail.
3. Tap **More**.



4. A menu is displayed.



5. Tap **Delete Image**.
6. On the warning dialog, tap **OK**.



7. Image is deleted and a confirmation message is displayed.

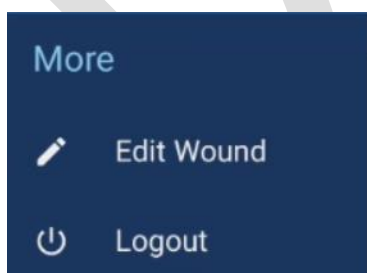


## 11.7 Editing a Wound

1. On the View Wound screen, tap **More**.



2. Tap **Edit Wound**.



3. On the Edit Wound screen, tap a field to select it, then make your edits.

When editing a wound, an additional option to edit a **Wound Status** is available. You can change the status of a wound from **Open** to **Closed** and vice versa.

**NOTE:** When a wound is closed, you cannot capture images.

0-na 08:13 PM Wed, Nov 27, 2019

< Edit Wound

Onset Date

\*Wound Type

Wound Status ☒ Open ☐ Closed

\*Wound Location

SAVE

7. Tap **SAVE**.

SAVE

8. Edits are saved and a confirmation message is displayed.

✓ Saved

## 12 Imaging Screen



Number	Description
1	<b>Back icon.</b> Tap <b>Back</b> to return to the Wound screen.
2	<b>Info icon.</b> Tap <b>Info</b> to display Patient Details—including name, date of birth and wound location.

3	<b>Camera/video icon.</b> Default setting is camera. Tap the <b>Camera/Video</b> toggle to switch from camera to video mode and vice versa. <b>NOTE:</b> Video is available for Standard and Fluorescence mode. <b>NOTE:</b> If video is unavailable, go to Settings and enable the <b>Video Capture</b> option.
4	<b>Torch icon.</b> Tap <b>Torch</b> toggle to enable/disabled. Available in Standard mode.
5	<b>Saved thumbnail.</b> When an image is captured, a thumbnail is displayed. Tap the thumbnail to view the just captured image in full screen.
6	<b>Range.</b> For Fluorescence mode, capture images within the acceptable range to ensure the best results. Capture images only when the range icon appears green. <b>NOTE:</b> If you hold the device too far or too close, messages will be displayed on the image area to instruct you to move the device closer or farther away, when in fluorescence mode.
7	<b>Active field of view.</b> Screen will display what is currently in front of the device camera.
8	<b>Capture button.</b> Tap <b>Capture</b> to save what is displayed in the field of view. An audible shutter sound will be heard when an image is captured.
9	<b>Fluorescence icon.</b> Tap <b>Fluorescence</b> to capture a Fluorescence image. White icon = inactive, blue icon = active.
10	<b>Standard icon.</b> Tap <b>Standard</b> to capture a Standard image. Standard is the default mode when entering the Imaging screen. White icon = inactive, blue icon = active.
11	<b>Measurement icon.</b> Tap <b>Measurement</b> to capture a measurement image. White icon = inactive, blue icon = active.

### 12.1 Focus

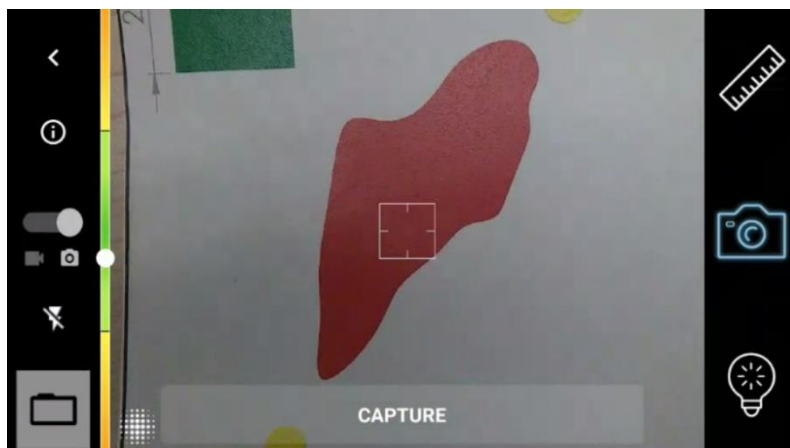
The software provides a focus feature you can engage by tapping the screen while viewing the active field of view. A white square graphic will be displayed in the field of view while the camera is actively focusing.

The software also provides an auto motion focus feature whereby the camera will automatically focus whenever motion is detected.

The focus graphic will default to the center of the screen and applies to both Camera and Video image capture.

#### Using focus to capture an image/video:

1. Locate the desired target in the field of view.
2. Ensure the distance between the device and the target is in the acceptable range (green).
3. Tap the screen where the target area is to engage the focus feature.



4. Tap **CAPTURE** or **START RECORDING**.

**NOTE:** When capturing a video, you can refocus at any time during the video to focus on a different area of a target.

## 12.2 Range Finder

A pulsed laser-based range finder sensor is used to determine the distance between the device and a target. The range finder indicates to the user when the device is held at the correct distance for optimal imaging.

Acceptable range for Fluorescence mode is 8-12 cm. When the device is at an acceptable distance, the range finder icon appears green. When it is out of range, the range finder icon appears amber.



In Range



Out of Range

In Fluorescence mode, prompts will appear on the screen telling the user to move closer or farther away from the wound in order to enter the correct range.

When the device is out-of-range (icon appears amber), an out-of-range warning icon will be displayed in the field of view on the top right corner.



**NOTE:** The range finder warning icon will be imbedded onto the image when saved.

## 12.3 Ambient Light Sensor

Fluorescence images and videos need to be captured in a dark environment for optimal fluorescence image quality. The ambient light sensor indicates the correct level of ambient light in the imaging environment for fluorescence imaging. Until the correct ambient light levels are met for fluorescence imaging, the FL Available icon will not be displayed.

The ambient light can be reduced by turning off the room lights, blocking windows and turning off computer monitors. When the ambient light levels are met for fluorescence imaging, the following icon will be displayed when in Standard mode:



Tap the Fluorescence available icon to enter Fluorescence mode.

If the user attempts to enter Fluorescence mode when the ambient light is too high in the imaging environment and the FL available icon is not present, the following warning will appear:

Screenshot.

If the user enters Fluorescence mode while the ambient light is too high in the imaging environment, an ambient light sensor warning icon will be displayed in the field of view on the top right corner.



**NOTE:** The ambient light sensor warning icon will be imbedded onto the image when saved.

#### 12.4 Standard Images and Videos

Standard digital imaging capabilities allow you to acquire and document standard digital images of dermatological wounds.

The software allows you to capture a still image or a video in Standard mode. Still images are captured in \*.jpeg format and videos are captured in \*.mov format.

**To capture a Standard still image:**

1. From the Imaging screen, tap the Standard mode icon.



Inactive



Active

2. Tap the Video/Still toggle to set it to Still capture mode.



3. Aim the device parallel to the wound.
4. Ensure the distance from the wound is acceptable and that the range finder indicator is green.
5. Centre the target in the middle of the field of view.
6. Tap the screen to focus on the target.
7. Tap **CAPTURE**.
8. A thumbnail will be displayed on the bottom left of the Imaging screen when the image is saved.
9. (Optional) Tap the thumbnail to [review](#) your image in full screen. To exit full screen mode, tap **Close**.



10. Continue to capture images or tap **Back** to return to the Wound screen.

**To capture a Standard video:**

1. From the Imaging screen, tap the Standard mode icon.



Inactive    Active

2. Tap the Video/Still toggle to set it to Video capture mode.



3. Aim the device parallel to the wound.
4. Ensure the distance from the wound is acceptable and that the range finder indicator is green.
5. Centre the target in the middle of the field of view.
6. Tap the screen to focus on the target.
7. Tap **START RECORDING**. The device will begin recording and display a counter on the field of view to count down from the maximum allowable video length of 30 seconds.
8. (Optional) Tap **STOP RECORDING** before the 30 seconds to capture a shorter video.
9. A thumbnail will be displayed on the bottom left of the Imaging screen when the video is saved.
10. (Optional) Tap the thumbnail to [review](#) your video in full screen. To exit full screen mode, tap **Close**.



11. Continue to capture videos or tap **Back** to return to the Wound screen.

## 12.5 Fluorescence Images and Videos

Fluorescence digital imaging capabilities allow you to acquire (in real-time) and document intrinsic fluorescence emission of dermatological wounds between 500-545 nm and 600-665 nm when illuminated by violet 405 nm excitation light under acceptable environmental lighting conditions.

A dark environment is required to capture a good quality image in Fluorescence mode, so turn off room lights.

The software allows you to capture a still image or a video in Fluorescence mode. Still images are captured in \*.jpeg format and videos are captured in \*.mov format.

### To capture a Fluorescence still image:

1. Turn off the room lights.
2. From the Imaging screen in Standard mode, tap the FL available icon to enter Fluorescence mode.



FL  
available



Inactive



Active

3. Tap the Video/Still toggle to set it to Still capture mode.



4. Aim the device parallel to the wound.
5. Ensure the distance from the wound is acceptable and that the range finder indicator is green.
6. Centre the target in the middle of the field of view.
7. Tap the screen to focus on the target.



8. Tap **CAPTURE**.
9. A thumbnail will be displayed on the bottom left of the Imaging screen when the image is saved.
10. (Optional) Tap the thumbnail to [review](#) your image in full screen. To exit full screen mode, tap **Close**.



11. Continue to capture images or tap **Back** to return to the Wound screen.

#### To capture a Fluorescence video:

1. Turn off the room lights.
2. From the Imaging screen in Standard mode, tap the FL available icon to enter Fluorescence mode.



FL  
available



Inactive



Active

3. Tap the Video/Still toggle to set it to Video capture mode.



4. Aim the device parallel to the wound.
5. Ensure the distance from the wound is acceptable and that the range finder indicator is green.
6. Centre the target in the middle of the field of view.
7. Tap the screen to focus on the target.
8. Tap **START RECORDING**. The device will begin recording and display a counter on the field of view to count down from the maximum allowable video length of 30 seconds.
9. (Optional) Tap **STOP RECORDING** before the 30 seconds to capture a shorter video.
10. A thumbnail will be displayed on the bottom left of the Imaging screen when the video is saved.
11. (Optional) Tap the thumbnail to [review](#) your image in full screen. To exit full screen mode, tap **Close**.



12. Continue to capture images or tap **Back** to return to the Wound screen.

#### 12.6 Measurement Image

Measurement imaging allow the user to capture a still measurement image in Measurement mode, which displays the wound surface area, length, width and a manually entered depth (optional). Measurement images are captures in \*.jpeg format.

##### To capture a Measurement image:








1. From the Imaging screen, tap the Measurement mode icon.



Inactive      Active

2. Aim the device parallel to the wound.
3. Ensure the distance from the wound is acceptable and that the range finder indicator is green.
4. Centre the target in the middle of the field of view.
5. Tap the screen to focus on the target.
6. Tap **CAPTURE**.
7. The captured image will appear in a Measurement Image screen. Users will have the ability to perform either an Auto or Manual measurement.

#### To perform an Auto Measurement:

1. Measurement images are set to perform an Auto Measurement as default.
2. Using your finger or a stylus, circle the wound border. Ensure the circled region surrounds the wound and is not drawn on or within the wound border. The MolecuLightDX searches for a wound border within the circled region. For complex wound borders, closely follow the wound border contour to achieve the most accurate trace.
3. Tap the next button  to proceed with automatic wound border detection or tap the redo button  to re-circle the wound border.
4. Auto Mode detects and traces the wound border with a green line. Use the expand  and contract  buttons to increase or decrease the detected border respectively to achieve the desired wound border trace. Tap the next button  to accept the wound border trace.
  - a. If the desired wound border trace is not accurately detected using the Auto Mode, tap the back button  to re-circle the wound, or use Manual Mode as described below.
5. A depth dialog box will appear prompting the user to input a depth measurement in centimeters (cm) measured according to standard of care. Enter a depth value and tap "Ok" or tap "Skip" to skip the option to enter a depth value.
6. The following measurements will be displayed:
  - a. Area measurement in centimeters squared (cm<sup>2</sup>)
  - b. Maximum length in centimeters (cm) represented by a dark blue line
  - c. Maximum width perpendicular to the length in centimeters (cm) represented by a light blue line
  - d. If entered, a depth measurement in centimeters (cm) beside the depth icon 
7. To save the image and measurement data, tap the Save icon.

SAVE

8. At any point, tap the Manual/Auto toggle to enter Manual Mode.



9. A thumbnail will be displayed on the bottom left of the Imaging screen when image is saved.
10. (Optional) Tap the thumbnail to [review](#) your image in full screen. To exit full screen mode, tap **Close**.



#### To perform a Manual Measurement:

1. Measurement images are set to perform an Auto Measurement as default.
2. Tap the Manual/Auto toggle to enter Manual Mode.



3. Using your finger or a stylus, trace the exact border of the wound. Maintain contact with the Display Screen until closing the wound border trace.
4. Tap the next button > to accept the wound border or tap the redo button ↺ to redo the wound border trace.
5. A depth dialog box will appear prompting the user to input a depth measurement in centimeters (cm) measured according to standard of care. Enter a depth value and tap "Ok" or tap "Skip" to skip the option to enter a depth value.
6. The following measurements will be displayed:
  - a. Area measurement in centimeters squared (cm<sup>2</sup>)
  - b. Maximum length in centimeters (cm) represented by a dark blue line
  - c. Maximum width perpendicular to the length in centimeters (cm) represented by a light blue line
  - d. If entered, a depth measurement in centimeters (cm) beside the depth icon ⬇
7. To save the image and measurement data, tap the Save icon.

SAVE

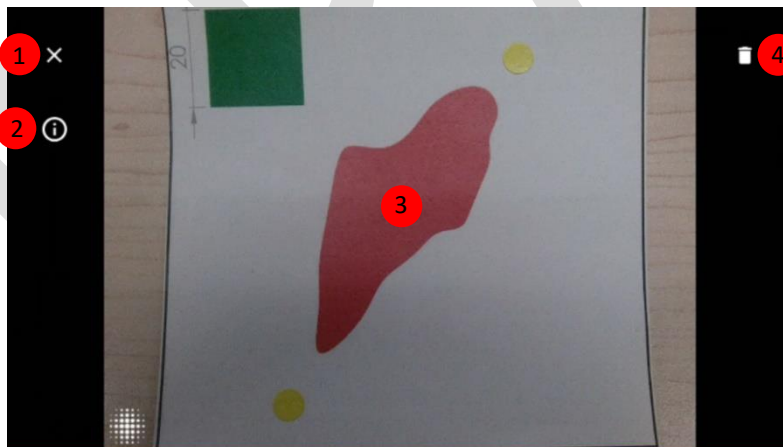
8. A thumbnail will be displayed on the bottom left of the Imaging screen when image is saved.
9. (Optional) Tap the thumbnail to [review](#) your image in full screen. To exit full screen mode, tap **Close**.

×

## 12.7 Reviewing Images

After capturing an image, a thumbnail will be saved and displayed on the bottom left corner of the [Imaging screen](#). Tap the thumbnail to view the image in full screen.

1. On the Imaging screen, capture an image of any type.
2. As the image is being saved, a green disc icon will be displayed.
3. Once the green disc icon is dismissed, tap the thumbnail.
4. The image is loaded into Review in full screen.



Number	Description
1	<b>Close icon.</b> Tap <b>Close</b> to return to the Wound screen.
2	<b>Info icon.</b> Tap Info to display the Image Details; includes patient name, date of birth, wound location, date/time of image capture, and user who captured the image.
3	<b>Review screen.</b> Displays the image in full screen.

4	<b>Delete icon.</b> Tap Delete to delete the current image.
---	---

5. (Optional) Tap **Delete**.

On the warning dialog, tap **OK**.

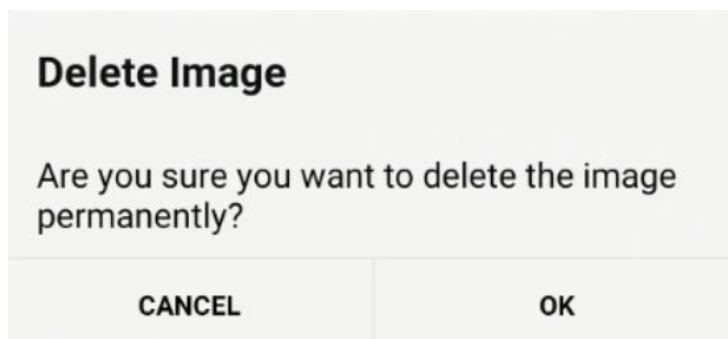


Image is deleted and a confirmation message is displayed.

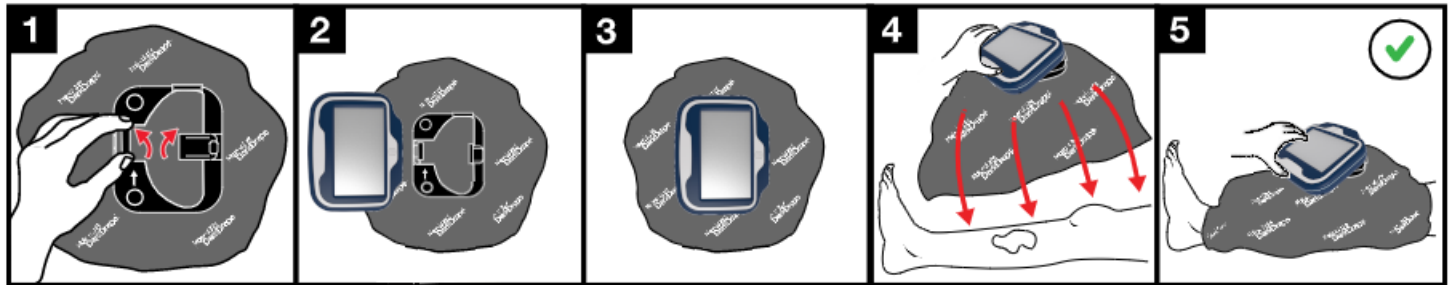


6. Tap **Back** to return to the Imaging screen.

## 13 DarkDrape

The DarkDrape is a onetime use accessory that provides a portable dark environment for the MolecuLightDX to perform fluorescence imaging of wounds when room lights cannot be turned off or windows cannot be blocked.

The DarkDrape attaches to the device by simply clipping onto the MolecuLightDX and clicking it into place. Once attached, The DarkDrape provides a light-blocking shield that may be draped over a wound, see image below.



**Warning** Do not reuse the DarkDrape. It is for single use only.



**Caution** Avoid touching the wound with the DarkDrape.



**Caution** Be aware of compromised visibility of the imaging target when using the DarkDrape to avoid injuring the patient.



**Note** Ensure the DarkDrape does not obstruct the imaging field of view.

## 14 Quick Start

### 14.1 With an existing patient and wound

1. On the Login screen, enter user ID and password, then tap **LOGIN**.
2. On the Patient Directory screen, tap to select a patient.
3. On the View Patient screen, tap to select a wound.
4. On the Wound screen, tap **Add** to add an image.
5. Tap **CAPTURE** to capture an image—image is added to wound.
6. Tap **Back** to return to previous screens and/or to select a different patient.

### 14.2 With no patient or wound

1. On the Login screen, enter user ID and password, then tap **LOGIN**.
2. On the Patient Directory screen, tap **Add** to add a new patient.
3. On the Add Patient screen, enter required patient information.
4. Tap **Yes** for Consent, then select 'Clinical assessment and treatment' (at a minimum).
5. Tap the 'x' close button on the Consent screen.
6. Tap **SAVE**.
7. On the Patient Directory screen, tap to select a patient.
8. On the View Patient screen, tap **Add** to add a wound.
9. On the Add Wound screen, enter required wound information.
10. Tap **SAVE**.
11. On the View Patient screen, tap to select a wound thumbnail.
12. On the Wound screen, tap **Add** to add an image.
13. Tap **CAPTURE** to capture an image—image is added to wound.
14. Tap **Back** to return to previous screens and/or to select a different patient.

## 15 Troubleshooting








### 15.1 Low Battery

The device may experience poor behaviour when the battery is low.

Before performing a device reset, check the battery charge status of your device. The battery charge status is displayed on any screen in the MolecuLight application in the top right corner.



Battery Charge Status	
	To indicate the charge status of the device is between 80-100%
	To indicate the charge status of the device is between 60-80%
	To indicate the charge status of the device is between 40-60%
	To indicate the charge status of the device is between 20-40%
	To indicate the charge status of the device is between 0-20%

## 15.2 Device Reset

The device may experience a software error which will require a device reset. Turning the device OFF then back ON will fix these errors.

1. With the device on, press and hold the power button for 3 seconds. Wait for the green LED around the power button to turn ON.
2. With the device off, press and hold the power button for 3 seconds. Wait for the green LED around the power button to turn ON. The device will restart and display the MolecuLight logo, a MolecuLight screen saver and then the Login screen

## 15.3 Device Hard Reset

The device may display a system or communications error that will require a hard device reset.

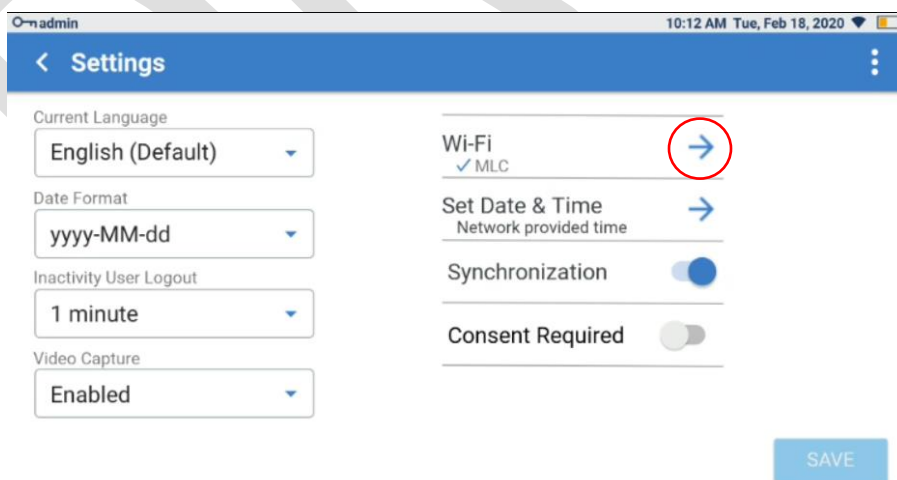
1. With the device on, press and hold the power button for 8 seconds or until the LED around the power button flash quickly from green to red.
2. Press and hold the power button for 4 seconds or until the LED flash slowly from green to red.
3. Press and hold the power button for 3 seconds or until the LED turn to solid orange.
4. Press the power button for 1 second. The LED will turn green, flash 2-3 times then the device will shutdown.
5. To turn the device back on, press and hold the power button for 3 seconds. The device will restart and display the MolecuLight logo, a MolecuLight screen saver and then the Login screen.

## 15.4 Setting Up Wi-Fi

When enabling the Wi-Fi for your current location, several additional screens are provided for Wi-Fi setup.

Speak to your IT Administrator to provide the details required to setup your Wi-Fi successfully.

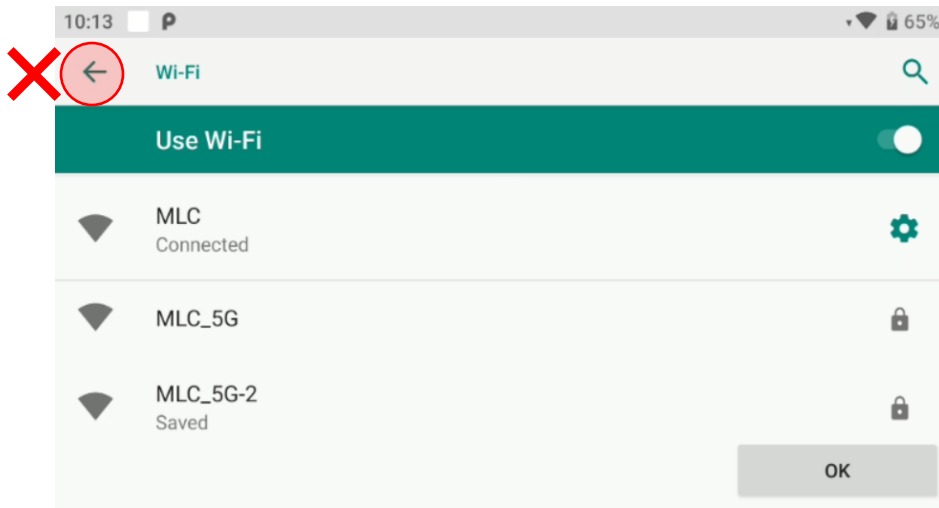
1. Log into the device as an Administrator.
2. On the User Directory, tap the more menu.
3. On the menu, tap the Settings option.
4. On the Settings screen, tap the Wi-Fi arrow.



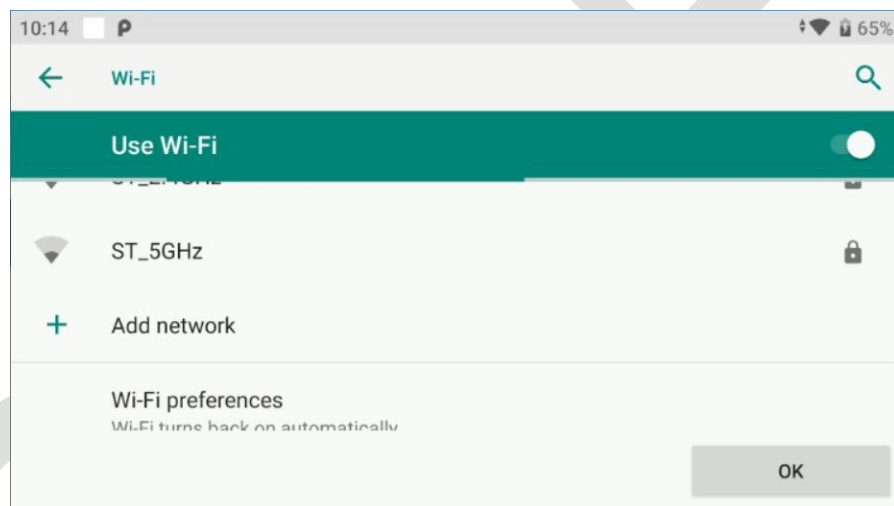
5. A Wi-Fi screen will be displayed.



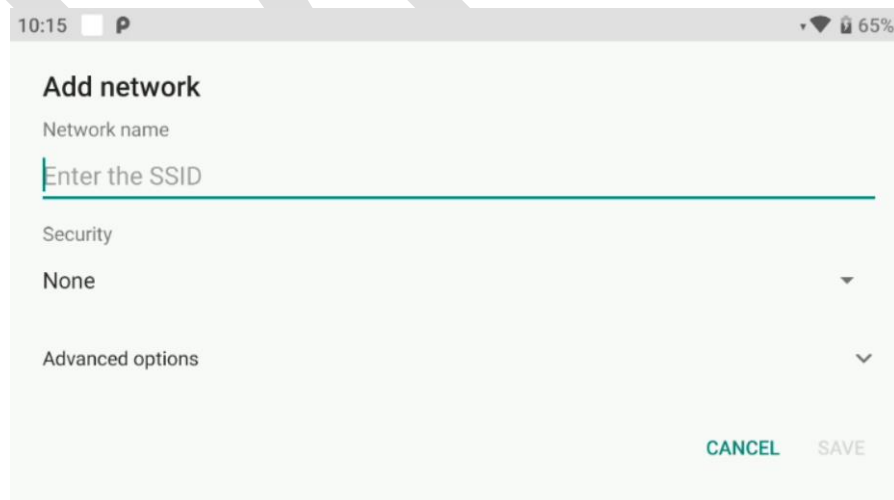
NOTE: At any point, DO NOT tap the back arrow on the top left corner of the Wi-Fi screen. If this happens, a [Device Reset](#) is required.



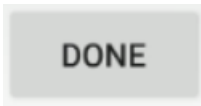
6. Scroll to the bottom of the list to find the 'Add network' option.



7. Tap the SSID text box and enter the SSID for the network you wish to connect to.



8. Tap **DONE**.



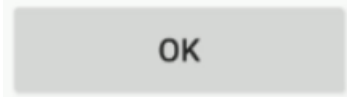
9. (Optional) Change the Security setting.

10. (Optional) Change Advanced options by tapping this option. Change settings as required.

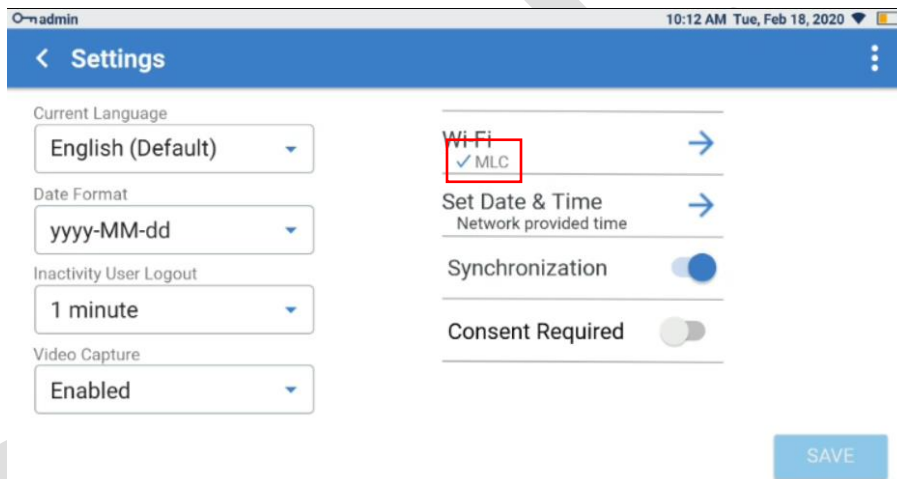
11. Tap **SAVE** when complete.



12. On the Wi-Fi screen, select the just added Wi-Fi network and then tap **OK**.



13. The just added Wi-Fi network is now displayed on the Settings screen as the active network.



14. Tap **SAVE**.



15. Settings are saved, and a confirmation message is displayed.

