



MolecuLight *i:X*TM Imaging Device User Manual

Trademarks

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Patent Information

The MolecuLight *i:X* Imaging Device (hereafter referred to as the device, MolecuLight *i:X* or MolecuLight *i:X* Imaging Device) contains patented technology developed by MolecuLight Inc.:

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Contact Information

The MolecuLight *i:X* and its accessories are designed and manufactured by MolecuLight Inc.

MolecuLight Inc.

101 College St., Suite 200 Room 228

Toronto, Ontario, Canada

M5G 1L7

Telephone: +1-647-362-4684

Fax: 647-362-4730

Email: info@moleculight.com

www.moleculight.com

The European authorized representative for the MolecuLight *i:X* is Atlantic Bridge Limited.

Atlantic Bridge Limited

19 Willowside

Woodley, Berkshire, RG5 4HJ

United Kingdom

Telephone: +44 (0) 118-969-7047

Email: info@atlanticbridge.co.uk

Website: www.atlanticbridge.co.uk



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1 Introduction

Congratulations on your purchase of the MolecuLight *i:X*TM Imaging Device. The handheld MolecuLight *i:X* Imaging Device allows you to rapidly visualize potentially harmful bacteria in real-time during wound assessment and includes a wound measurement application for quick wound area measurements. MolecuLight is confident that as you use the MolecuLight *i:X* Imaging Device you will find new and helpful information about the bacterial load in and around wounds during the clinical examination process, helping you to better manage wound treatment for your patients.

The device is designed to aid and simplify clinical assessment, microbial sampling and treatment of wounds provided by clinicians at the *point-of-care*. Its compact, handheld size and intuitive and simple user interface are designed for use across hospitals and wound care clinical settings.

MolecuLight Inc. provides technical support, a User Manual, a Quick Start Guide and other educational references to aid you with the use of the MolecuLight *i:X* Imaging Device. Please review this User Manual thoroughly before operating your device.

2 Warnings, Cautions, and Notes

Please read the following safety information before using the MolecuLight *i:X* Imaging Device.

The MolecuLight *i:X* 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 MolecuLight *i:X* Imaging Device does *not* require the use of exogenous imaging contrast agents. It is a Class II medical device per Health Canada Regulations.

MolecuLight *i:X* is intended for use by trained health care professionals.

There are no known contraindications or side effects associated with the use of the MolecuLight *i:X*.

Some patients may experience some warmth from the device during exposure.

The Range Finder Sensor (see Figure 2, item 14) 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 MolecuLight *i:X*.

Refer to Section 2.1.3 for the meaning of acronyms used throughout this User Manual.



2.1 Warnings, Cautions, and Notes

Warnings, cautions, and notes are used to describe serious and non-serious safety conditions of the device. The symbols used to describe these safety conditions are:



Warning

Messages with this heading indicate serious adverse reactions, potential safety hazards, and limitations in use imposed by a condition labeled with a warning. The warning identifies steps that should be taken if the incident occurs.



Caution

Messages with this heading indicate information regarding any special care to be exercised by the user and/or patient for the safe and effective use of the device. All caution statements should be followed to ensure data and device integrity.



Note

Messages with this heading provide additional information that increase the user's understanding of the operation of the device.

2.1.1 General Warning Messages



Warning

The use of an accessory or cable with the MolecuLight *i:X* Imaging Device other than those specified in Section 3 may result in increased emissions or decreased immunity of the MolecuLight *i:X* Imaging Device.



Warning

The MolecuLight *i:X* Imaging Device comes fully assembled and ready for use. No modification of this equipment is allowed. Modification of the device will void the terms of the warranty.



Warning

Do not stack the MolecuLight *i:X* Imaging Device.



Warning

MolecuLight *i:X* is intended to be used in a hospital/clinic by trained health care professionals. Avoid exposure to magnetic fields, electrostatic discharge and thermal ignition sources during use of the device.



Warning

Do not charge or use the device in areas with potentially explosive atmospheres such as fueling areas or in areas where the air contains chemicals or particles.



Warning

Do not point the violet wavelength LEDs directly into eyes (see Figure 2, item 12).



Warning

MolecuLight *i:X* is not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide.



Warning

Protect MolecuLight *i:X* against dust and moisture by storing it in its original shipping package overnight or when not in use for prolonged periods of time.



Warning

Avoid strong physical shocks and dropping.



Warning

Any damage to the device (crack or other visible deformity) may affect the functional, intended use and/or safety of the MolecuLight *i:X*. Contact MolecuLight for guidance at support@moleculight.com.



Warning











Do not soak or immerse MolecuLight *i:X* in water or other liquids.



Warning

Be aware of surroundings when operating MolecuLight *i:X* in a dark environment. The environment should be safe to prevent tripping or bumping into any objects during fluorescence imaging procedures.

2.1.2 General Caution Messages

-  **Caution** Do not attempt to use the device while it is charging. The device will not function.
-  **Caution** Keep the Illumination Zone clean and avoid covering the Violet Wavelength LEDs and camera sensor window with your fingers, as this may affect illumination and image quality (see Figure 2, item 15).
-  **Caution** Prior to charging the device, ensure the MolecuLight Power Cable P/N 1142 (described in Section 3.1) is undamaged before plugging into a wall outlet. Use of an extension cord or an electrical power bar is discouraged.
-  **Caution** When charging is complete, the MolecuLight Power Cable P/N 1142 should initially be disconnected from the wall electrical outlet and then removed from the MolecuLight *i:X* Imaging Device.
-  **Caution** Use of controls, adjustments or procedures other than those specified in this User Manual may result in hazardous laser light radiation exposure from the Range Finder Sensor (Section 2.5).
-  **Caution** The MolecuLight *i:X* Imaging Device is restricted to use by trained health care professionals and should be protected from unauthorized use.
-  **Caution** The Heat Sink (Figure 2, item 7) may get warm after prolonged use. The device will shut down if temperature exceeds 46°C or 115°F.
-  **Caution** Improper cleaning/disinfection of the device may result in distorted images.
-  **Caution** Images/videos should be regularly downloaded and saved to avoid loss of patient information.
-  **Caution** Non-MolecuLight Apps may appear on the MolecuLight *i:X* for download. Do not download any non-MolecuLight Apps in order to maintain the device configuration intended for use.









2.1.3 Acronym Table

Acronym	Meaning
RF	Radio Frequency
ST-image™	An image captured in Standard Imaging Mode
ST-video™	A video captured in Standard Imaging Mode
FL-image™	An image captured in Fluorescence Imaging Mode
FL-video™	A video captured in Fluorescence Imaging Mode
LED	Light Emitting Diode

2.2 Symbols

2.2.1 Symbols Used on the MolecuLight *i:X* Imaging Device Label

The following table lists the symbols and statements used on the MolecuLight *i:X* Imaging Device label (silver label).

Symbol/Statement	Meaning
	Caution, consult accompanying documents
	Read User Manual
	Date of manufacture
	Catalog number
	Serial number
	Certification of safety testing
	Dispose of the MolecuLight <i>i:X</i> in accordance with your country's legal requirements for the disposal of electrical and electronic waste
	RF transmitter for wireless transmission

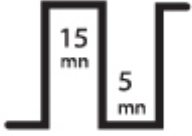





Symbol/Statement	Meaning
	Device duty cycle (if device is continuously on for 15 minutes in Fluorescence Imaging Mode, violet LEDs should be turned off for 5 minutes before Fluorescence Imaging Mode is accessed again)
	CE Marking indicates European Conformity to essential requirements of applicable European product directives; 0123 represents MolecuLight Inc.'s Notified Body
CAN ICES-3(B)/NMB-3(B)	Self-Declaration of Compliance (SDoC) to Industry Canada ICES-003(B)
The MolecuLight <i>i:X</i> Imaging Device complies with Part 15 of the FCC Rules	For further information related to this statement, refer to Section 2.3 for specific certification and Section 2.4 for electromagnetic compatibility
For use only with MolecuLight Power Cable P/N: 1142 A utiliser uniquement avec Câble N/P: 1142	For further information related to accessories and consumables, refer to Section 3
Includes FCC ID:BCG-A1421 and IC:579C-A1421	In reference to iPod touch (part of the MolecuLight <i>i:X</i> , referred to as the Display Screen)

Table 1: Symbols and statements on MolecuLight *i:X* Imaging Device label

2.2.2 Symbols Used on MolecuLight *i:X*

The following table lists the symbols used in the labeling of MolecuLight *i:X*.

Symbol	Source/Compliance	Meaning
	IEC 60417-5010	Power Button
	MolecuLight symbol	Display Screen Power Button
	MolecuLight symbol	System Status
	IEC 60417-5546	Battery Status








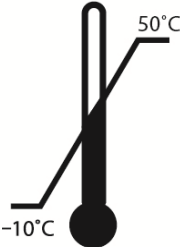

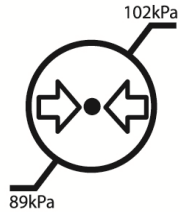
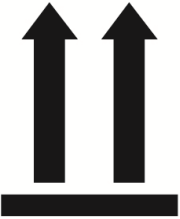


Symbol	Source/Compliance	Meaning
	IEC 60417-5031	MolecuLight <i>i:X</i> Charging Port (D.C)
	MolecuLight symbol	Range Finder
	MolecuLight symbol	Ambient Light Status
	MolecuLight symbol	Port for Charging Display Screen and Data Transfer
	MolecuLight symbol	Fluorescence Imaging Mode
	MolecuLight symbol	Standard Imaging Mode
	MolecuLight symbol	Home Button (for Display Screen)

Table 2: MolecuLight *i:X* symbols



2.2.3 Symbols Used on MolecuLight *i:X* Packaging

The following table lists the symbols and statements used on the MolecuLight *i:X* packaging label and indicates storage and transportation conditions.

Symbol	Source	Meaning
	ISO 15223-1:2012	Maintain within -10°C to 50°C (14°F to 122°F) ambient temperature
	ISO 15223-1:2012	Maintain within 10% to 70% humidity
	ISO 15223-1:2012	Maintain within 89 kPa to 102 kPa for atmospheric pressure
	ISO 7000:2014	Face up
	ISO 7000:2014	Recyclable
	WEEE symbol, EU Directive 2012/19/EU	Dispose of the MolecuLight <i>i:X</i> in accordance with your country's legal requirements for the disposal of electrical and electronic waste







Symbol	Source	Meaning
	ISO 15223-1:2012	Non sterile
	ISO 15223-1:2012	Fragile
	MolecuLight symbol	Do not stack or compress
	ISO 15223-1:2012	Keep dry

Table 3: MolecuLight *i:X* transportation and storage conditions



2.2.4 Symbols Used for MolecuLight DarkDrape Label

The following table lists the symbols and statements used on the MolecuLight DarkDrape label.




















Symbol	Source		Meaning
	ISO 15223-1:2012		Catalog number
	ISO 15223-1:2012		Batch code
	ISO 15223-1:2012		Date of manufacture
	ISO 7010:2011		Read User Manual
	ISO 15223-1:2012		Caution, consult accompanying documents
	ISO 15223-1:2012		Do not use if package is damaged
	ISO 15223-1:2012		For single use only
	ISO 15223-1:2012		Non sterile
	IEC 60417 - 5840		Type B applied part
	European Marking	Conformity	Manufacturer's declaration that the product meets the requirements of the applicable EC directives

Table 4: Symbols and statements on the MolecuLight DarkDrape label



2.2.5 Symbols Used for MolecuLight DarkDrape Package Label

The following table lists the symbols and statements used on the MolecuLight DarkDrape packaging label.

Symbol	Source	Meaning
	ISO 15223-1:2012	Catalog number
	ISO 15223-1:2012	Batch code
	ISO 15223-1:2012	Date of manufacture
	ISO 7010:2011	Read User Manual
	ISO 15223-1:2012	Fragile
	ISO 15223-1:2012	Caution, consult accompanying documents
	ISO 15223-1:2012	Keep dry
	ISO 15223-1:2012	Do not use if package is damaged
	ISO 15223-1:2012	For single use only






Symbol	Source	Meaning
	ISO 15223-1:2012	Non sterile
	IEC 60417 - 5840	Type B applied part
	European Conformity Marking	Manufacturer's declaration that the product meets the requirements of the applicable EC directives

Table 5: Symbols and statements on the MolecuLight DarkDrape package label (10-pack and 50-pack)

2.3 Certifications

The MolecuLight *i:X* Imaging Device complies with the following standards:

- Safety Testing per IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+A1:2013 including Canadian National Differences per CAN/CSA-C22.2 No. 60601-1:14 and US National Differences per ANSI/AAMI ES 60601-1:2005/A1:2012
- Safety EMC Testing per IEC 60601-1-2:2007 3rd Edition including FCC Part 15 Subpart B: 2015 & ICES-003:2012 / EN 60601-1-2:2007
- Safety LED testing per IEC 60601-2-57:2011 and IEC 62471:2006 / EN 60601-2-57:2011 and EN 62471:2008
- Usability Testing per IEC 60601-1-6:2010+A1:2013 / EN 60601-1-6:2010 and EN 62366:2008
- Risk Management per ISO 14971:2007 / EN ISO 14971:2012
- Quality Management System Requirements per ISO 13485:2003 / EN ISO 13485:2012

The MolecuLight DarkDrape complies with ISO 10993-1:2009 / EN ISO 10993-1:2009: Biological evaluation of medical devices.

2.3.1 Classifications

MolecuLight *i:X* has an operational duty cycle of 15 minutes *on*, 5 minutes *off*. The implication for this duty cycle is that if the MolecuLight *i:X* is continuously used in Fluorescence Imaging Mode for 15 minutes, the device will need to be switched to Standard Imaging Mode for 5 minutes before selecting Fluorescence Imaging Mode again to allow for optimal performance of the Violet Wavelength LEDs.

The medical device classification of the MolecuLight *i:X* in Canada is Class 2 medical device. Alone, the MolecuLight *i:X* does not require patient contact for use. The MolecuLight DarkDrape (used in combination with the MolecuLight Adapter and MolecuLight *i:X* to achieve an optimal lighting environment for imaging wounds) is a Type B patient applied part which complies with medical device biocompatibility requirements.

The MolecuLight *i:X* is classified as “IPX0” for fluid ingress, therefore it has no inherent protection against damage from exposure to liquids.

2.4 Electromagnetic Compatibility

The MolecuLight *i:X* Imaging Device meets the requirements of IEC 60601-1-2:2007 3rd edition / EN 60601-1-2:2007. Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and must be used according to the instructions in this User Manual.

While unlikely, it is possible that high levels of emitted radio-frequency (RF) electromagnetic interference (EMI) from other portable and mobile RF communications equipment or nearby radio-frequency sources could result in performance disruption of the MolecuLight *i:X* Imaging Device.

To avoid the risk of increased electromagnetic emissions or decreased immunity from such emissions, use only accessories recommended by MolecuLight (i.e. MolecuLight Power Cable, see Section 3.1). Connection of accessories not recommended by MolecuLight will void product warranty and could result in malfunctioning of the MolecuLight *i:X* Imaging Device or other devices located in the area.

This device complies with Part 15 of the US FCC Rules.

This device complies with Canadian ICES-003 (B).

2.5 Information on Laser Radiation Output

The MolecuLight *i:X* Imaging Device uses a miniature pulsed laser-based range finder to determine the optimal distance between the device and the wound for superior image quality. The laser module in the range finder emits light at 850 nm which is invisible to the human eye. The laser’s individual pulse duration is 3.33 ns and the pulse train is 52.3 ms at a 200 ms repetition rate. The laser complies with 21 CFR 1040.10 and 1040.11 except for deviations pursuant to Laser Notice No.50.



The laser is a Class 1 certified laser



Caution Do not point the laser (from the Range Finder sensor) into eyes (Figure 2, item 14).

3 Contents

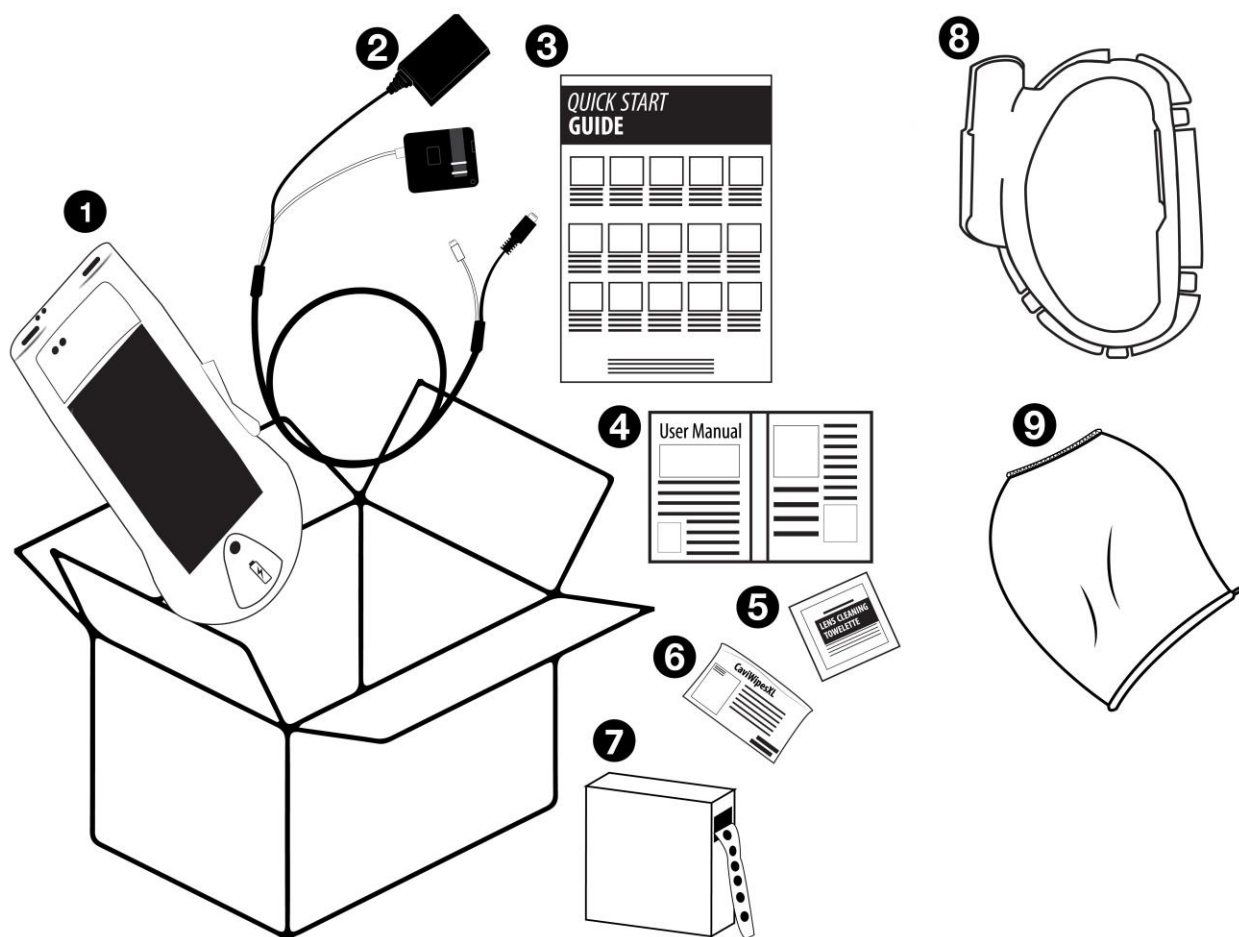


Figure 1: MolecuLight *i:X* Imaging Device and its components

3.1 MolecuLight *i:X* System Contents

The MolecuLight *i:X* Imaging Device comes fully assembled and ready for use. The standard system configuration includes items 1-7 illustrated in Figure 1 and detailed in Table 6 below. These items allow the MolecuLight *i:X* Imaging Device to be used in a patient care setting.

# in Figure 1	Item	Description
1	MolecuLight <i>i:X</i> Imaging Device	Device operates on Apple iOS software
2	MolecuLight Power Cable	Cable to charge the MolecuLight <i>i:X</i> Imaging Device and download images/videos to a computer; Includes geography-specific plug adaptors (where applicable)
3	Quick Start Guide	Step by step guide for MolecuLight <i>i:X</i> use
4	User Manual	Provides detailed instructions on use of the MolecuLight <i>i:X</i>
5	Optical Lens Wipes	5 x Optical lens cleaning towelettes, individually packaged for cleaning display screen and optical windows (ProWorks)
6	CaviWipes	1 package of 45 CaviWipes (Metrex) disinfecting wipes to clean the device between uses
7	MolecuLight Wound Stickers	1 box of 2,000 stickers for wound area measurement with the MolecuLight <i>i:X</i>

Table 6: List of items included with the MolecuLight *i:X* System (P/N 1153)



Note

The MolecuLight DarkDrape and MolecuLight Adapter (Figure 1, items 8-9) are not part of the MolecuLight *i:X* System configuration. They are optional accessories that may be ordered separately.

3.2 MolecuLight *i:X* Accessories and Consumables

MolecuLight *i:X* accessories and consumables are listed below in Table 7 along with suggested vendors from which the items may be purchased (if not available from MolecuLight).

To reorder items available from MolecuLight, contact MolecuLight by email: info@moleculight.com.

# in Figure 1	Item	Description	MolecuLight Part #	Reorder from MolecuLight
2	MolecuLight Power Cable	Cable to charge the MolecuLight <i>i:X</i> Imaging Device and download images/videos to a computer; Includes geography-specific plug adaptors (where applicable)	1142	Yes
3	Quick Start Guide	Step by step guide for MolecuLight <i>i:X</i> use	1149	Yes
4	User Manual	Provides detailed instructions on use of the MolecuLight <i>i:X</i>	1189	Yes

# in Figure 1	Item	Description	MolecuLight Part #	Reorder from MolecuLight
5	Optical Lens Wipes (Box of 100)	Box of 100 optical lens cleaning towelettes, individually packaged for cleaning display screen and optical windows (ProWorks)	1182	Yes
6	CaviWipes	Disinfecting wipes to clean the device between uses (Metrex)	N/A	No; available from Metrex, K-Dental, Amazon.com, Fisher Scientific
7	MolecuLight Wound Stickers	1 box of 2,000 stickers for wound area measurement with the MolecuLight <i>i:X</i>	1266	Yes
8	MolecuLight Adapter	Reusable Adapter to connect MolecuLight DarkDrape to the MolecuLight <i>i:X</i> to create an optimal lighting environment for imaging wounds	1215	Yes
9	MolecuLight DarkDrape (Case of 50)	Case of 50 MolecuLight DarkDraperes, individually packaged for one-time use to create an optimal lighting environment for imaging wounds	1212	Yes
N/A	eo TECHSPEC Lens Cleaning Solution	Lens cleaning solution to clean the device's optical components (Edmund Optics)	N/A	No; available from Edmund Optics, Fisher Scientific, VWR, Staples.com, Amazon.com
N/A	Fisherbrand Lens Paper (4"x6")	Len paper to clean the device device's optical components (Fisher Scientific)	N/A	No; available from Fisher Scientific, VWR, Staples.com, Amazon.com

Table 7: List of recommended MolecuLight *i:X* accessories and consumables



Warning

Do not connect the MolecuLight *i:X* Imaging Device to a power supply using cables that have not been approved by MolecuLight.



Note

Lens Cleaning Solution and Lens Paper may be used instead of the Lens Cleaning Towelette.

Detailed information about cleaning and disinfecting the MolecuLight *i:X* is provided in Section 12.

4 MolecuLight *i:X* Imaging Device

Overview

4.1 MolecuLight *i:X* Imaging Device Description and Use

The MolecuLight *i:X* Imaging Device allows clinicians to quickly, safely and easily visualize potentially harmful bacterial presence and distribution on skin and in wounds, in real-time at the *point-of-care*. The device is non-contact and no imaging contrast agents are required for fluorescence imaging.

The MolecuLight *i:X* Imaging Device is a handheld medical device comprised of a high-resolution color LCD display and touch-sensitive screen with integrated optical and microelectronic components. MolecuLight *i:X* uses its patented technology to enable real-time standard light and fluorescence imaging of bacteria and tissue components in wounds and surrounding healthy skin of patients.

The MolecuLight *i:X* Imaging Device captures real-time images (JPEG format) and videos (MOV format) in *Standard Imaging Mode*[™] and *Fluorescence Imaging Mode*[™]. These modes are identified as follows:

1. Standard Imaging Mode[™] (or ST-Mode): Real-time imaging as per standard photography.

In Standard Imaging Mode, MolecuLight *i:X* is able to capture the following images:

- a. ST-image[™]: An image captured in Standard Imaging Mode
- b. ST-video[™]: A video captured in Standard Imaging Mode



Note Wound measurement is only possible on an ST-Image (see Section 10).

2. Fluorescence Imaging Mode[™] (or FL-Mode): Real-time imaging in Fluorescence Imaging Mode as a result of violet light illumination.

In Fluorescence Imaging Mode, MolecuLight *i:X* is able to capture the following images:

- a. FL-image[™]: An image captured in Fluorescence Imaging Mode
- b. FL-video[™]: A video captured in Fluorescence Imaging Mode

The device provides image-guidance during visual assessment of wounds.

The device can capture an ST-image[™], ST-video[™], FL-image[™], and FL-video[™] of wounds to quickly identify the presence and extent of harmful bacteria. This helps to guide the clinical team towards a more comprehensive wound examination through guided or ‘targeted’ debridement and sampling of potentially harmful bacteria. Images can be appended to a patient’s clinical care record by exporting the images in JPEG format or printing them (see Section 9.9).



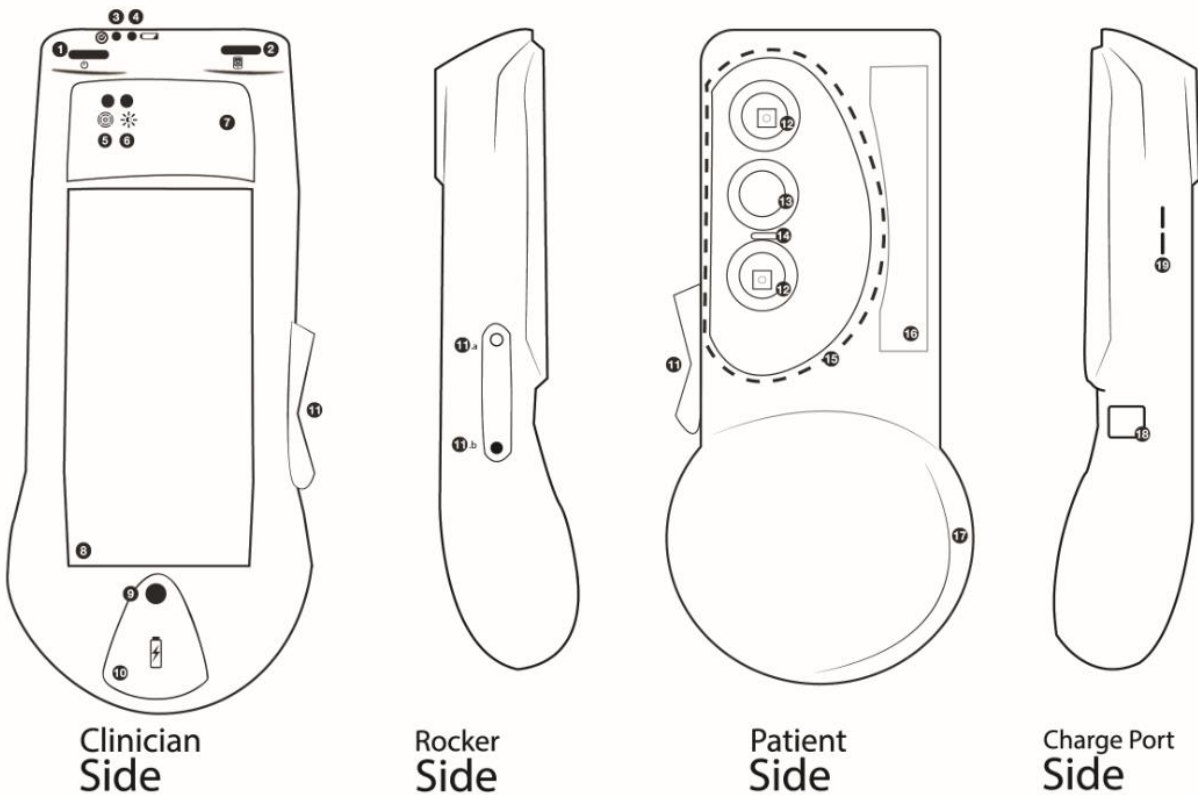


Figure 2: Clinician side, side views and Patient side of MolecuLight i:X Imaging Device

1. **Power Button:** pressing button turns the device ON/OFF
2. **Display Screen Power Button:** pressing button turns Display Screen ON/OFF
3. **System Status LED:** indicates overall device performance
4. **Battery Status LED:** indicates device battery charge
5. **Range Finder LED:** indicates optimal distance from wound
6. **Ambient Light Status LED:** indicates optimal lighting environment for Fluorescence Imaging Mode
7. **Heat Sink:** dissipates heat during use



Warning Heat Sink may get warm after prolonged use

8. **Display Screen:** provides touch functionality and displays images in real-time
9. **Home Button:** pressing button turns Display Screen ON
10. **Port for Charging Display Screen and Data Transfer:** to be used with the white connecting cable on the MolecuLight Power Cable, boot should be lifted for access
11. **Rocker Switch for Standard Imaging Mode and Fluorescence Imaging Mode:** allows the user to switch between Standard Imaging Mode and Fluorescence Imaging Mode
12. **Violet Wavelength LEDs:** provide illumination when in Fluorescence Imaging Mode
13. **Camera Sensor Window:** protects the camera sensor which allows image and video capture



14. **Range Finder Sensor:** detects optimal distance from wound, and
Ambient Light Sensor: detects optimal lighting conditions for Fluorescence Imaging Mode
15. **Illumination Zone:** area includes camera sensor window, Violet Wavelength LEDs, Ambient Light Sensor and Range Finder Sensor

**Note**

Keep the Illumination Zone clean and avoid covering the Violet Wavelength LEDs and camera sensor window with your fingers

16. **Label:** lists certifications, references User Manual, indicates date of manufacture, contains MolecuLight Inc.'s address, provides device model and serial number
17. **Holding Contour:** allows the user to grip the device securely
18. **MolecuLight i:X Charging Port:** allows device charging with black power supply cable on the MolecuLight Power Cable
19. Buttons for future functionality

MolecuLight's training program includes the following to ensure user knowledge of how to operate the device:

- Reading this User Manual in its entirety
- Following the Quick Start Guide (Appendix C) and the MolecuLight i:X Imaging Device Overview (Appendix B)
- Following the MolecuLight DarkDrape & MolecuLight Adapter Instructions for Use (Appendix D) and the MolecuLight i:X Wound Measurement Quick Start Guide (Appendix E)

**Caution**

The MolecuLight i:X Imaging Device is restricted to use by trained health care professionals and should be protected from unauthorized use.

4.2 How MolecuLight i:X Creates Images in FL-Mode

The MolecuLight i:X includes two high-efficiency violet wavelength emitting LEDs that illuminate wounds and surrounding skin for high-resolution and real-time fluorescence imaging of bacteria and tissues, without the need for contrast agents. When wounds are illuminated by violet light, endogenous collagens in the connective tissue matrix emit a green colored fluorescent signal. Some bacteria emit a red colored fluorescence signal due to the production of endogenous porphyrins, and others emit a cyan colored fluorescence signal due to the production of endogenous pyoverdine. The MolecuLight i:X Imaging Device simultaneously captures fluorescence from both bacteria and tissues and creates a composite image on the high-resolution color LCD Display Screen. The user can easily and instantly visualize the presence and location of bacteria within and around a wound.

Figure 3 illustrates how MolecuLight i:X uses violet light illumination to create real-time fluorescence images.

**Caution**

Keep the Illumination Zone clean and avoid covering the Violet Wavelength LEDs and camera sensor window with your fingers, as this may affect illumination and image quality (see Figure 2, item 15).

**Note**

The red color may appear orange to some users.

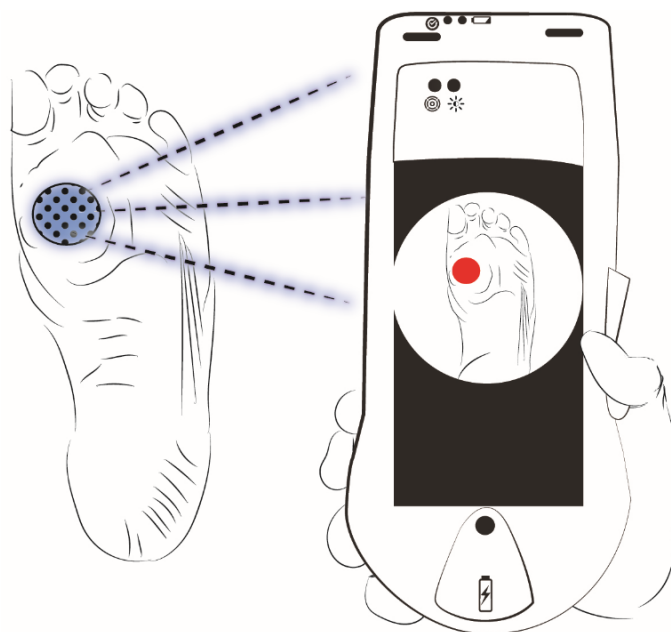


Figure 3: MolecuLight i:X Real-time Imaging

Violet Wavelength LEDs homogeneously illuminate the wound, resulting in the generation of a red or cyan fluorescence signal when bacteria are present due to the presence of endogenous porphyrins or pyoverdine.







4.3 MolecuLight DarkDrape and MolecuLight Adapter Device Description and Use

Used together, the MolecuLight DarkDrape and the MolecuLight Adapter provide a convenient and optimal environment for imaging wounds when room lights cannot be turned off or windows cannot be blocked.

The MolecuLight DarkDrape provides a light-blocking shield that may be draped over a wound. The MolecuLight Adapter provides an attachment that allows the MolecuLight i:X to connect to the MolecuLight DarkDrape. After the MolecuLight DarkDrape is securely attached to the MolecuLight Adapter, the MolecuLight Adapter slides onto the MolecuLight i:X and clicks into place.

Please see Section 12.4 for MolecuLight Adapter cleaning instructions.

Please see Appendix D for the MolecuLight DarkDrape and MolecuLight Adapter Instructions for Use.

-  **Warning** Do not reuse the MolecuLight DarkDrape. It is for single use only.
-  **Caution** Do not overtighten the drawstring when securing the MolecuLight DarkDrape to the patient.
-  **Caution** Avoid touching the wound with the MolecuLight DarkDrape.
-  **Caution** Be aware of compromised visibility of the imaging target when using the MolecuLight DarkDrape to avoid injuring the patient.
-  **Note** Ensure the MolecuLight DarkDrape does not obstruct the imaging field of view.
-  **Note** The MolecuLight DarkDrape is designed for fluorescence imaging on the lower leg or foot.

5 Intended Use and Indication for Use

The MolecuLight *i:X* instantly visualizes the presence of potentially harmful levels of bacteria through endogenous autofluorescence without the need for contrast agents or contact with the patient. The intended use of the device is to assist health care professionals during the management of patients with wounds by enabling real-time visualization of potentially harmful bacteria. The device is intended to be used as part of routine clinical wound assessment processes which may include examination for characteristic signs and symptoms of infection. Under violet light illumination, the MolecuLight *i:X* can capture and document images or videos of wounds and surrounding areas where fluorescent bacteria may be present. The bacterial fluorescence signals detected by the device provide health care professionals with a visual indication of bacterial presence, load, and location within and around wounds. This information can be used to guide health care professionals in their selection, application, and response monitoring of wound therapies.

The indication for use of the device is to instantly visualize the presence of potentially harmful bacteria commonly found within or around wounds including *S. aureus*, *P. aeruginosa*, *E. coli*, Coagulase-negative staphylococci, *Enterococcus spp*, *Proteus spp*, *Klebsiella pneumoniae*, Beta-hemolytic streptococci (Group B) and *Enterobacter spp* during clinical assessment, treatment, and monitoring of treatment response of wounds.

6 Device Basics

The device consists of two primary elements:

1. MolecuLight *i:X* Imaging Device – contains the electronics required to support its imaging functionality, including optical filters, camera sensor, range finder and ambient light sensors and the violet light source. It also contains several LEDs to indicate the status of various operational components of the device.

The MolecuLight *i:X* Imaging Device contains a rechargeable battery which needs to be kept charged in order for MolecuLight *i:X* to work properly. Refer to Section 9.8 for details about charging the MolecuLight *i:X*.

Primary features on the MolecuLight *i:X* Imaging Device include:

- Rocker Switch
 - Two Power Buttons
 - Four Status indicator LEDs (see Figure 4)
 - Two Charging Ports
2. Display Screen – displays both standard light and fluorescence images on a touch-sensitive color LCD screen, which can be controlled by the user touching the screen in order to control the imaging functionality of the device.

The Display Screen leverages iPod technology and has the following characteristics:



- 4-inch (diagonal) widescreen display with Multi-Touch technology
- 1136-by-640-pixel resolution at 326 pixel per inch
- 800:1 contrast ratio (typical)
- 500 cd/m² max brightness (typical)
- Fingerprint-resistant oleophobic coating

The Display Screen contains a rechargeable battery, which needs to be kept charged in order for MolecuLight *i:X* to function properly. Refer to Section 9.8 for details about charging the Display Screen.

For instructions about using the device's Display Screen functionality, please refer to Section 9.10.



Note

The Display Screen and the MolecuLight *i:X* Imaging Device each contain separate rechargeable batteries. Both batteries need to be charged separately in order for MolecuLight *i:X* to work properly. Refer to Section 9.8 for details about charging the MolecuLight *i:X*.

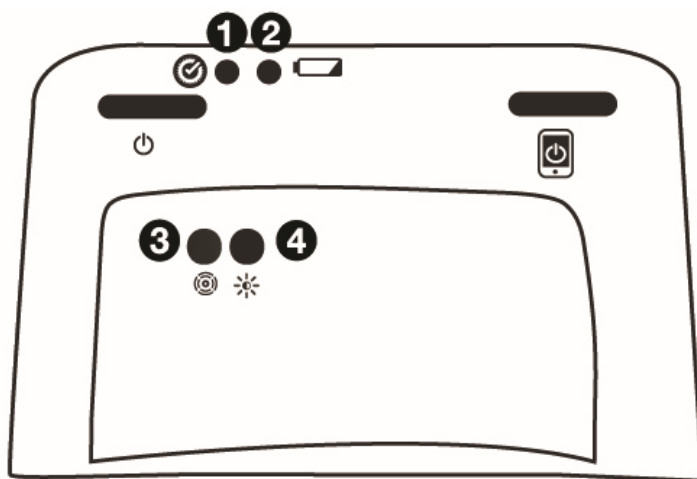


Figure 4: Schematic rendering of MolecuLight *i:X* Imaging Device showing 1- System Status LED, 2- Battery Status LED 3- Range Finder LED and 4- Ambient Light Status LED

6.1 Power Button

The MolecuLight *i:X* Imaging Device has a Power Button for controlling the ON/OFF state of the electronics in the device.



The Power Button can toggle the MolecuLight *i:X* to one of the following states:

- **OFF:** the MolecuLight *i:X* is powered off
- **ON:** the MolecuLight *i:X* is powered on (Violet Wavelength LEDs turn on after Fluorescence Imaging Mode is selected)



**Note**

The ON/OFF state of the MolecuLight *i:X* is independent of the ON/OFF/SLEEP state of the Display Screen. Refer to Section 9.10 for details about the ON/OFF state of the Display Screen.

The Power Button functions as follows:



Action	Effect
If the MolecuLight <i>i:X</i> is OFF, press and hold the Power Button for 3 seconds	Switches MolecuLight <i>i:X</i> from OFF to ON.
If the MolecuLight <i>i:X</i> is ON, press and hold the Power Button for 3 seconds	Switches MolecuLight <i>i:X</i> from ON to OFF.
If the MolecuLight <i>i:X</i> is ON during Fluorescence Imaging Mode for greater than 90 seconds	Switches Violet Wavelength LEDs from ON to OFF automatically (to conserve battery).  Note You will need to move the Rocker Switch to Standard Imaging Mode and then back to Fluorescence Imaging Mode to activate the Violet Wavelength LEDs.
If the MolecuLight <i>i:X</i> is ON and you don't touch MolecuLight <i>i:X</i> for 30 minutes	Switches the MolecuLight <i>i:X</i> from ON to OFF automatically after 30 minutes (timing out to conserve battery).  Note If the Rocker Switch is in the Fluorescence Imaging Mode position when powering the MolecuLight <i>i:X</i> ON, you need to move the Rocker Switch to Standard Imaging Mode and then back to Fluorescence Imaging Mode to turn on the Violet Wavelength LEDs.
Reset function (to be used when the device or any of its functions are not functioning as intended)	To reset the MolecuLight <i>i:X</i> , switch the device off, then hold the Power Button for 8 seconds. The System Status LED will blink red initially, then yellow and then red again twice. This sequence indicates a reset was performed. Remove finger from button once this sequence is observed. Press the Power Button again for 2-3 seconds to turn on the device.

Table 8: Power Button functions

6.1.1 Status Indicator LEDs

The MolecuLight *i:X* is designed with four sensors to guide you in capturing optimal images/videos. Each sensor has a corresponding indicator light (LED) on the MolecuLight *i:X*.

6.1.1.1 System Status LED



MolecuLight *i:X* periodically executes a self-diagnosis to ensure it is operating properly. The System Status LED indicates the overall operational state of the MolecuLight *i:X* Imaging Device.

Indicator	Meaning
Solid Green Light	MolecuLight <i>i:X</i> Imaging Device is functioning as expected.
Solid Yellow Light	You can continue imaging, however follow up with MolecuLight as soon as possible.
Solid Red Light	The device has malfunctioned. Stop using the device immediately and contact MolecuLight to troubleshoot the problem.
Red Light, Yellow Light, and 2 Red Light flashes	The device is going through a reset (after the Power Button has been pressed).

Table 9: System Status LED



Note

When the device is OFF, no System Status LED color is visible. When you power on the device, the System Status LED blinks green 5 times for 2 seconds, staying solid green on the 5th blink. Blinking indicates that the device is performing its self-diagnostic routine.

6.1.1.2 Range Finder LED



MolecuLight *i:X* is equipped with a pulsed laser-based Range Finder sensor which is used to determine the distance between MolecuLight *i:X* and the wound. The Range Finder LED indicates to the user when the device is held at the correct distance for optimal imaging.

LED Indicator	Meaning
Green Light	The optimal distance (8-12 cm) between MolecuLight <i>i:X</i> and the wound being imaged has been reached. See Figure 8.
Amber Light	<p>The distance between MolecuLight <i>i:X</i> and the wound is out of its optimal range (i.e. closer than 8 cm or further than 12 cm) and/or the Range Finder sensor is unable to determine the device-to-wound distance.</p> <p>The user can adjust the device-to-wound distance to obtain a Green Light for imaging.</p>

Table 10: Range Finder LED



Note

The Range Finder LED turns green when the distance between Range Finder and the wound is within 8-12 cm.

The Range Finder LED should be used when in FL-Mode. It is also strongly recommended to be used when in ST-Mode to obtain images with similar sizes (for presentation or comparison purposes).

The Range Finder LED should always be used when measuring wound area per Section 10.



Caution

Capturing a FL-image or FL-video outside the recommended device-to-wound distance may result in suboptimal fluorescence and/or image quality.



Caution

A defect in the Range Finder's function may result in distorted/inaccurate images/videos. See Section 15 Troubleshooting & Support, question 18 on how to verify the Range Finder function.

6.1.1.3 Ambient Light Status LED



FL-images and FL-videos need to be captured in a dark environment for optimal fluorescence image quality. The Ambient Light Status LED indicates if the level of ambient light in the examination room is optimal for Fluorescence Imaging to aid users in capturing optimal fluorescence images and videos.



Note

The Ambient Light Status LED is only ON in Standard Imaging Mode. It turns off in Fluorescence Imaging Mode.

For use with Fluorescence Imaging Mode, view the Ambient Light Status LED immediately after turning off room lights and prior to toggling the Rocker Switch to Fluorescence Imaging Mode.


Indicator	Meaning
Green Light	The ambient light level in the imaging environment is adequate for fluorescence imaging.
Amber Light	<p>The ambient light level is too high and fluorescence images should not be captured.</p> <p>The user should reduce the ambient light settings by turning off the room lights, blocking windows, turning off computer monitors or other means until the Ambient Light Status LED turns green.</p> <p> Note If you are unable to obtain optimal ambient light for Fluorescence Imaging Mode, MolecuLight recommends using MolecuLight DarkDrape (used in conjunction with MolecuLight Adapter). For more information, refer to Section 4.3 or contact MolecuLight.</p>

Table 11: Ambient Light Status LED



Note

The Ambient Light Status LED is not active or ON when the Violet Wavelength LEDs are turned on for imaging in Fluorescence Imaging Mode. In Fluorescence Imaging Mode, the Ambient Light Status LED is OFF.



Caution

A defect in the Ambient Light Status LED may result in inaccurate images.



Caution

Ignoring the Ambient Light Status LED indicator may result in inaccurate images.

6.1.1.4 Battery Status LED



The Battery Status LED indicates the MolecuLight *i:X* Imaging Device battery charge level.



Note

This LED indicates the battery status for the MolecuLight *i:X* Imaging Device only. The Display Screen's battery status and charging status operates independently of this functionality and is displayed on the screen.

Indicator	Meaning
Solid Green Light	The MolecuLight <i>i:X</i> battery is fully charged or at high power (over 80% power).
Solid Yellow Light	The MolecuLight <i>i:X</i> battery power is between 20-80% power and MolecuLight <i>i:X</i> charging is advised.
Solid Red Light	The battery power has dropped below 20% power and the MolecuLight <i>i:X</i> requires immediate charging.

Table 12: Battery Status LED

When the MolecuLight *i:X* Imaging Device is OFF, the Battery Status LED is OFF, except when the battery is critically low and not charging, at which point the LED blinks red every 2 seconds.

When the MolecuLight *i:X* Imaging Device is charging, the Battery Status LED blinks to indicate charging status of the device.

6.1.2 Rocker Switch

The Rocker Switch enables the user to toggle between Standard Imaging Mode and Fluorescence Imaging Mode. When the Rocker Switch is in its “down” position, MolecuLight *i:X* is in Fluorescence Imaging Mode. When the Rocker Switch is in its “up” position, MolecuLight *i:X* is in Standard Imaging Mode.

To enable Standard Imaging Mode:

1. Turn on the device (if it is not already on).
2. Toggle the Rocker Switch to its “up” position (Figure 5).
 - MolecuLight *i:X* is in Standard Imaging Mode.

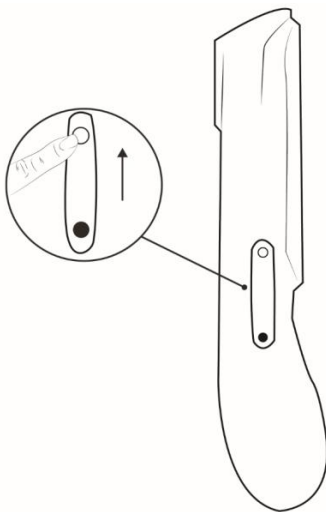


Figure 5: Rocker Switch in Standard Imaging Mode (in ‘up’ position)

To enable Fluorescence Imaging Mode:

1. Toggle the Rocker Switch to its “down” position (Figure 6).
 - MolecuLight *i:X* is in Fluorescence Imaging Mode.
 - Violet Wavelength LEDs turn on.

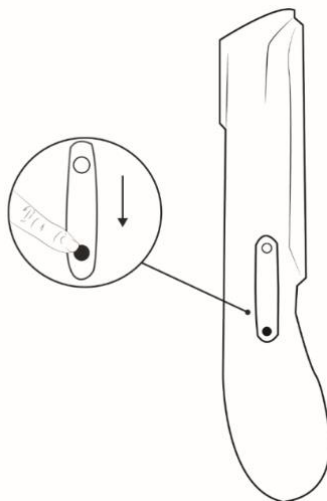


Figure 6: Rocker Switch in Fluorescence Imaging Mode (in ‘down’ position)

7 Quick Start Guide

Please see Appendix C for the MolecuLight *i:X* Quick Start Guide.

8 Environmental Conditions That Affect Use

MolecuLight *i:X* is intended to be used in a hospital/clinical setting.



Caution

MolecuLight *i:X* is not suitable for use in the presence of flammable anesthetic mixtures with air, oxygen or nitrous oxide.

8.1 Lighting

The level of ambient light in the imaging environment dramatically affects the quality of both the Standard Imaging Mode and Fluorescence Imaging Mode images acquired with the MolecuLight *i:X* Imaging Device. A green Ambient Light Status LED indicates when the lighting conditions are optimal for imaging in Fluorescence Imaging Mode. During Standard Imaging Mode the Ambient Light Status LED will be amber. Check the Ambient Light Status LED prior to toggling the Rocker Switch to FL-Mode.

If you are unable to obtain optimal ambient light for Fluorescence Imaging Mode, MolecuLight recommends using MolecuLight DarkDrape (used in conjunction with MolecuLight Adapter). For more information refer to Section 4.3.



Caution

Be aware of surroundings when using the MolecuLight *i:X* in dark environments during Fluorescence Imaging Mode. Failure may result in bodily injury due to tripping.

8.2 Operating Temperature

The device is designed to operate in environment temperatures between 10-30°C (50-86°F).

8.3 Storage

Store MolecuLight *i:X* at room temperature in a secure location between uses.

Store the MolecuLight DarkDrape at room temperature in a dry place.



9 Operating Instructions

9.1 Proper Imaging Technique

A standardized wound imaging protocol is critical to the accuracy and objectivity of digital wound evidence and image capture. Images should be acquired while holding the device stable in the hands of the user and while the patient is not moving (to avoid movement artifacts in the images). See Figure 7.

To capture images with MolecuLight *i:X* (in either Standard Imaging Mode or Fluorescence Imaging Mode):

- Hold the device 8-12 cm away from the wound. The Range Finder LED is green when the distance between MolecuLight *i:X* and the wound is optimal.
- Ensure that the wound is centered in the camera's field of view.
- Hold MolecuLight *i:X* such that the plane of the wound is parallel to the plane of MolecuLight *i:X*. See Figure 8.



Note

The optical glass windows (see Figure 7) must be clean for optimal Standard Imaging Mode and Fluorescence Imaging Mode image capture. Refer to Section 12 for information about cleaning MolecuLight *i:X*.



Caution

Patient movement while the device is in close proximity to the patient may result in distorted images.



Caution

Angling the device incorrectly may result in poor image quality. The Illumination Zone on the device should point directly at wound and be held at the recommended distance. Failure to do so may result in poor image quality. Refer to Figure 8.

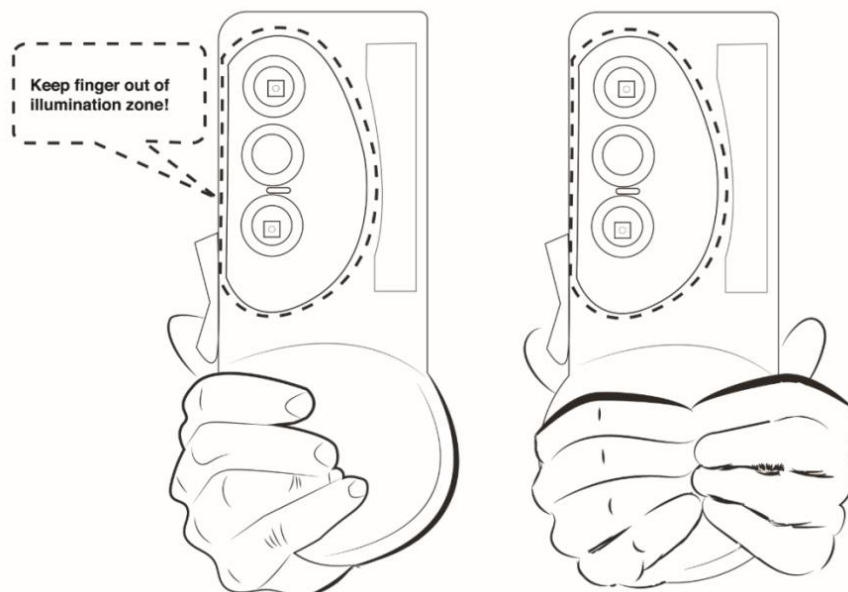


Figure 7: How to hold the device with one hand (left) and two hands (right)



Note

Hands are positioned away from the Violet Wavelength LEDs and are outside of the Illumination Zone demarcated by the raised ridge.

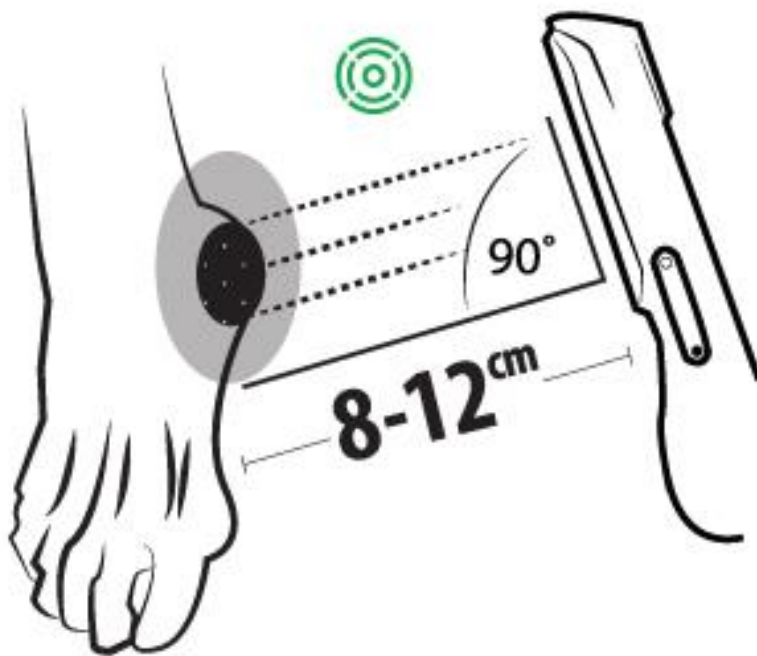


Figure 8: Overview of optimal distance and angling of the device relative to the wound

9.2 Handling MolecuLight *i:X*

MolecuLight *i:X* does not require direct contact with the patient or wound during operation. The optimal distance for imaging is 8-12 cm from the wound.

MolecuLight *i:X* does not require the administration of any exogenous imaging contrast agents for imaging in Fluorescence Imaging Mode.

MolecuLight *i:X* can be easily cleaned between uses. Instructions for cleaning and disinfection can be found in Section 12.

MolecuLight recommends the use of standard powder-free latex or nitrile gloves when using MolecuLight *i:X* to reduce the risk of bacterial contamination.



Caution

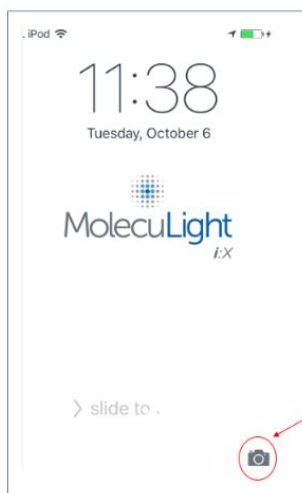
Residue from (some) medical gloves on optical components may result in distorted images.

9.3 Imaging with MolecuLight i:X (iX Camera App)

The MolecuLight iX Camera App is a simple and intuitive application that allows you to quickly and easily capture images and videos on your MolecuLight i:X Imaging Device.



Warning Only use the iX Camera App to capture wound images and/or videos.



Caution Do not “swipe up” the camera icon circled in red above. This is not the iX Camera App that is intended for use.

The iX Camera App is easily accessible by following two simple steps:

1. Push and hold the Home Button on the MolecuLight i:X.

The MolecuLight i:X Display Screen turns on.

If the screen is locked, use ‘slide to unlock’ at the bottom of the display to unlock the screen.



Note The MolecuLight i:X Imaging Device and the Display Screen must be powered on. Refer to Section 6.1 for details.

2. Press the iX Camera App icon.



The iX Camera App opens and is ready for use.

The iX Camera App allows you to:

- Capture an image
- Capture a 30 second video
- Review previously acquired images/videos via Image Library
- Delete images/videos


9.3.1 Capture an Image

The iX Camera App allows you to capture both a ST-image and FL-image by selecting the Camera icon.



9.3.1.1 Capture an ST-image

To capture an image in Standard Imaging Mode:

1. Move the Rocker Switch to the Standard Imaging Mode position.
2. Select the Camera  icon. The Camera icon turns blue when selected.
3. When using the iX Camera App wound measurement functionality, refer to instructions provided in section 10 and Appendix E.
4. View the Range Finder LED.



The Range Finder LED advises when the optimal distance between (8-12 cm from the wound) the target and MolecuLight *i:X* is reached. If you wish to capture images in FL-Mode and ST-Mode with similar fields of view, this feature will be critical to observe.

5. Aim the MolecuLight *i:X* Imaging Device towards the wound (with the screen facing the user) and center the wound in the camera's field of view.

A square briefly appears in the center of the field of view to indicate that the camera focus is being set. If the autofocus is not satisfactory, tap on the screen on the target of interest to manually focus on the wound.

6. To take an image, tap anywhere within the blue rectangle indicating 'CAPTURE IMAGE'.

You will hear a click sound and the screen will flash indicating that the ST-image was captured and saved on the MolecuLight *i:X*.



Caution Hold MolecuLight *i:X* steady while imaging; shaking hands may result in distorted images.

9.3.1.2 Capture an FL-image

To capture an image in Fluorescence Imaging Mode:

1. Turn off the lights in the examination room. A dark environment is required to capture a good quality image.



Note If lights cannot be turned off, use (optional) MolecuLight DarkDrape and MolecuLight Adapter. Refer to Section 4.3 for details.





Caution Do not use MolecuLight Wound Stickers when capturing images in Fluorescence Imaging Mode.

2. View the Ambient Light Status LED.



3. The Ambient Light Status LED provides feedback as to whether or not the ambient light level is optimal. The green color indicates that conditions are optimal to capture an image. If the

LED is amber, try turning off additional light sources (e.g. computer monitors) and covering windows until the LED turns green or use a MolecuLight DarkDrape.

4. Move the Rocker Switch to the Fluorescence Imaging Mode position.
5. Select the Camera  icon and ensure you are already within the iX Camera App.
If the Display Screen is *off*, press the Home Button to access the iX Camera App icon. 
6. View the Range Finder LED.



The Range Finder LED advises when the optimal distance (8-12 cm from the wound) between the target and MolecuLight *i:X* is reached. The Range Finder LED is green when the distance is optimal.

7. Aim MolecuLight *i:X* towards the wound (with the screen facing the user). A square briefly appears in the center of the field of view to indicate that the camera focus is being set. If the autofocus is not satisfactory, tap on the screen on the target of interest to manually focus on the wound.
8. To take an image, tap anywhere within the blue rectangle indicating 'CAPTURE IMAGE'.


You will hear a click sound and the screen will flash indicating that the FL-image was captured and saved on the MolecuLight *i:X*.



Caution


Covering LEDs with your fingers will result in poor image quality. The Illumination Zone on MolecuLight *i:X* (see Figure 7) represents the intended keep-out zone for the LEDs.

9.3.1.3 Capture a video

The iX Camera App allows you to capture both an ST-video and FL-video by selecting the Video  icon.

9.3.1.4 Capture an ST-video

To capture a video in Standard Imaging Mode:

1. Move the Rocker Switch to the Standard Imaging Mode position.
2. Select the Video  icon. The Video icon turns blue when selected.
3. View the Range Finder LED.



4. The Range Finder LED indicates when the optimal distance between (8-12 cm from the wound) the target and MolecuLight *i:X* is reached. If you wish to capture videos in FL-Mode and ST-Mode with similar fields of view, this feature will be important to use.

**Note**

Monitor the Range Finder LED throughout the whole video recording session to maintain an appropriate imaging distance.

5. Aim MolecuLight *i:X* towards the wound.

A square briefly appears in the center of the field of view to indicate that the camera focus is being set. If the autofocus is not satisfactory, tap on the screen on the target of interest to manually focus on the wound.

6. To take a video, tap anywhere within the blue rectangle indicating 'START RECORDING'.

The ST-video begins recording and a time counter will appear on the screen.

7. To stop the recording, tap the screen within the blue rectangle indicating 'STOP RECORDING'. The time counter stops.

The ST-video stops recording and is saved on the MolecuLight *i:X*.

**Note**

30 seconds is the maximum video length that can be acquired at one time.

**Note**

Images and videos are saved in the Image Library.



9.3.1.5 Capture an FL-video

To capture a video in Fluorescence Imaging Mode:

1. Turn off the lights in the examination room. A dark environment is required to capture a good quality image.

**Note**

If lights cannot be turned off, use (optional) MolecuLight DarkDrape and MolecuLight Adapter. Refer to Section 4.3 for details.


**Caution**

Do not use MolecuLight Wound Stickers when capturing images in Fluorescence Imaging Mode.

2. View the Ambient Light Status LED.



The Ambient Light Status LED provides feedback as to whether or not the ambient light level is optimal. If the LED is amber, try turning off additional light sources (e.g. computer monitors) and covering windows until the LED turns green, or use the MolecuLight DarkDrape.

3. Move the Rocker Switch to the Fluorescence Imaging Mode position (see Figure 6).
4. Select the Video  icon. The Video icon is blue when selected.
5. View the Range Finder LED.



The Range Finder LED advises when the optimal distance (8-12 cm from the wound) between the target and MolecuLight *i:X* is reached. The Range Finder LED is green when the distance is optimal.



Note Monitor the Range Finder LED throughout the whole video recording session to maintain an appropriate imaging distance.

6. Aim MolecuLight *i:X* towards the wound. A square briefly appears in the center of the field of view to indicate that the camera focus is being set. If the autofocus is not satisfactory, tap on the screen on the target of interest to manually focus on the wound.

7. To take a video, tap anywhere within the blue rectangle indicating 'START RECORDING'.

The FL-video begins recording and a time counter appears on the screen.

8. To stop the recording, tap the screen within the blue rectangle indicating 'STOP RECORDING' and the time counter will stop.

The FL-video stops recording and is saved on the MolecuLight *i:X*.



Note 30 seconds is the maximum video length that can be acquired at one time.




Note Images and videos are saved in the Image Library.



9.4 Viewing Images and/or Videos

The *iX* Camera App allows you to browse through the Image Library and view individual images/videos. The Image Library displays images and videos that have been saved. The most recently saved image/video is displayed at the bottom of the Image Library.

When the Image Library  icon is selected, all images appear and are available for viewing in thumbnail format.

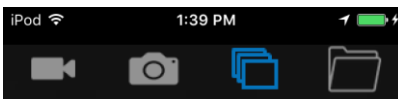


Caution There may be a minor delay once the Image Library icon is selected before the image thumbnails appear.

Swipe up or down to scroll through recent images/videos in the Image Library.

Swiping up scrolls to older image(s)/video(s) and swiping down scrolls to newer image(s)/video(s).

To view previously acquired images and videos within the menu bar:



1. Select the Image Library icon by tapping on it.



2. Tap the image/video to be displayed.

The selected image/video is displayed. A video is indicated by the overlaid play icon.

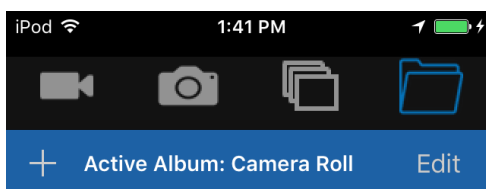



9.5 Managing Images and/or Videos

For users who wish to group images into particular folders, the Album feature provides an easy and convenient way to group images together by creating and designating an Active Album.

An Active Album simply means that newly acquired images and videos will be added to the Active Album selected.

By default, the Active Album to view saved images/videos on the MolecuLight *i:X* is the Camera Roll.



The Album  feature may be selected from the Menu bar where previously created Albums may be browsed and selected to become the “Active Album” at any time.



Note

The Active Album must be selected prior to taking images/videos. Images/videos cannot be moved between Albums.



Warning

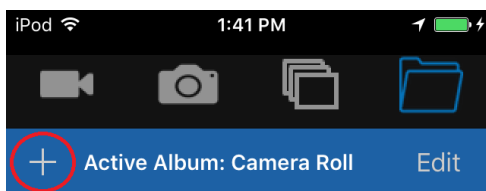
Due to iOS restrictions, when downloading images to a computer through explorer/finder, individual albums will not appear and users may manually sort photos using the unique image ID text overlay saved on images.

9.5.1 Creating a New Album

To create a new Album:


1. Choose the Album icon. 

2. Select '+' on the bottom left side of the Menu bar:



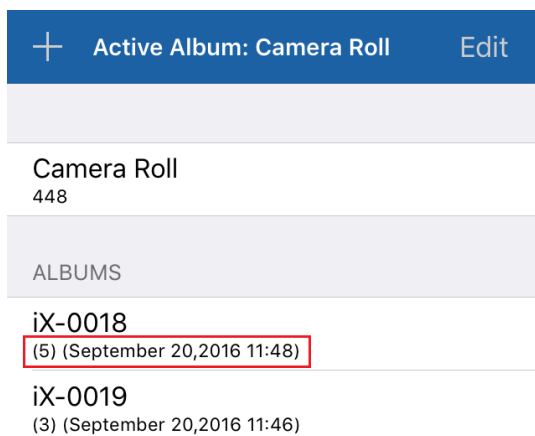
3. Select 'Create' when prompted with 'Create New Album: iX-....?'
4. The App automatically generates the Album name with prefix 'iX-' followed by the next 4-digit number in the sequence.




9.5.2 Accessing Previous Albums

To select a previously created Album to add new images within it, choose the Album icon: 

1. Select the desired Album from the list.
2. The selected Album becomes the Active Album and is labelled as the 'Active Album' across the Menu Bar.

When browsing through previously created Albums, a description below the Album name provides information about the number of images and videos and the time and date of the last acquired image within a particular album:

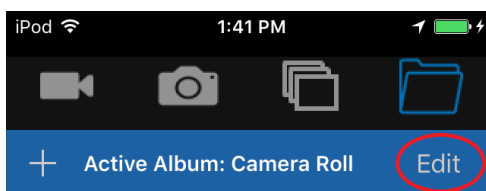





- 
Note Once an image is in the Camera Roll it cannot be moved into another Album.
- 
Note At any time, the user may go back to the Album icon and select to save images only in the Camera Roll.
- 
Note When the total number of created Albums reaches 9999, a new Album “iX-0001” shall be created even if an old Album with the same name exists. This does not overwrite the previous Album.

9.5.3 Deleting Albums

To delete an Album:

1. An Album may be deleted by selecting the ‘Edit’ function within the Album folder.

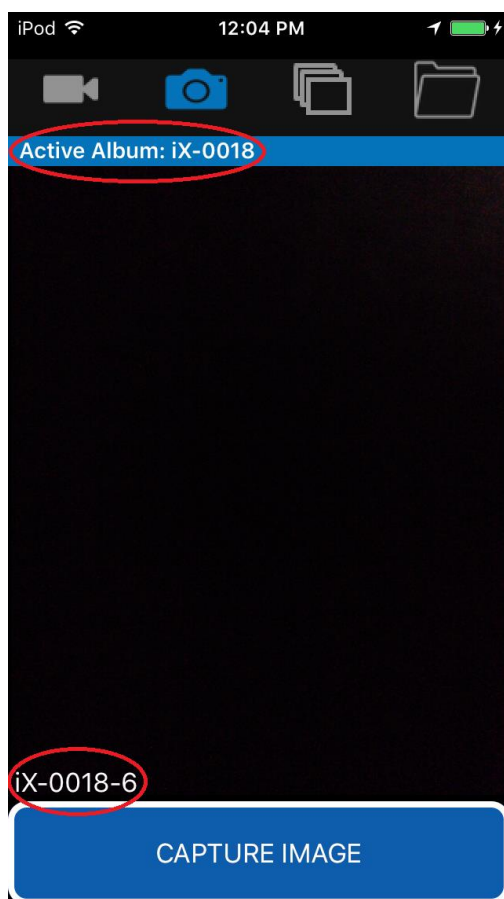


2. If user selects the Edit button, a minus sign  appears next to each album.
3. When the minus sign  is selected, a Delete  button will appear.
4. If Delete button is selected a confirmation message appears.
5. Once user confirms to delete the Album, they will be asked whether or not to also delete the images within that Album. If user chooses not to delete the images after the Album is deleted, the images will be found in the Camera Roll.
6. Select the Edit button again to exit the Edit function.

9.5.4 Capture Image and Video Capture Screens:

The Capture Image and Video Capture screens will show the Active Album across the top of the image (under the Menu Bar) and the unique Image ID across the bottom left side of the image as depicted below.

1. First select an Album from the Album list, then return to the Capture Image (Camera icon) or Video Capture (Video icon) screens, the name of the Active Album is displayed.
2. The Active Album shows which Album subsequent images/video will be stored.
3. In addition, a unique Image ID containing the Album name followed by “*photo number*” appears on the bottom left side of the image. This Image ID will appear at the bottom of the saved photo and will automatically increment each time a new photo is taken.



9.6 Zooming in and out and Panning

9.6.1 Zooming in and out

To zoom in and out on a displayed image:

1. Select the image. The image will fill the full screen.
2. Place your thumb and pointer finger at opposing points of the image.
3. Keep both fingers on the screen and gently move your fingers away from each other.

This action “zooms in” on the part of the image between the two fingers, enlarging the portion of the image between the two fingers.



Note The speed at which your fingers spread influences the rate of zoom.

4. To zoom back out, reverse the motion and gently “pinch” your fingers towards each other while keeping contact with the screen.

This action “zooms out” on the part of the image between the two fingers, reducing the display of the portion of the image between the two fingers.



Note It is not possible to zoom in and out on video recordings.

9.6.2 Panning

To pan a displayed image:

On a zoomed in image, drag the screen with one finger to move around the image or hold your finger near the edge of the screen to pan to that side. Move your finger closer to the edge to pan more quickly.




Note It is only possible to pan a displayed ST-image or FL-image that has been zoomed. It is not possible to pan a recorded video. It is not possible to pan during image capture.

9.7 Deleting Images and Videos

To delete an image or video:

1. Select the image or video on the Display Screen.

2. Tap the Trash icon. 

You will be prompted with “Allow ‘iX Camera’ to delete this photo?” or “Allow ‘iX Camera’ to delete this video?”

3. Select either ‘Don’t Allow’ or ‘Delete’.

Selecting ‘Delete’ will delete the image or video.



Note Images are not permanently deleted using this method. Images can still be recovered on the device from the deleted images folder.

9.8 Charging MolecuLight *i:X*

The Display Screen and the MolecuLight *i:X* Imaging Device each contain a rechargeable battery. Both batteries need to be charged separately in order for MolecuLight *i:X* to work properly. The cables for charging both batteries are provided as one item (MolecuLight Power Cable) so that the MolecuLight *i:X* Imaging Device and Display Screen may be charged concurrently.

9.8.1 Charge the MolecuLight *i:X* Imaging Device

To charge the MolecuLight *i:X* Imaging Device:



Figure 9: Charging MolecuLight *i:X* Imaging Device and Display Screen with MolecuLight Power Cable

1. Connect the MolecuLight *i:X* Imaging Device to the black power supply cable on the MolecuLight Power Cable (P/N 1142) as in Figure 9. The black power supply cable charges the MolecuLight *i:X* Imaging Device.

The MolecuLight *i:X* Imaging Device begins charging. The Battery Status LED indicates the battery power as described in Section 6.1.1.4.

2. When the Battery Status LED is solid green and no longer blinking, disconnect the MolecuLight Power Cable from the wall. Then remove the black power supply cable from the device and store the MolecuLight *i:X* for its next use.



Note

Connection to wall outlet should be easily and readily accessible and not blocked when MolecuLight *i:X* requires charging.



Note

MolecuLight recommends charging the MolecuLight *i:X* whenever it is not in use so that it is fully charged for its next use.



Note

It takes up to 5 hours to fully charge the MolecuLight *i:X* once it is fully depleted. It takes approximately 2 hours to charge to 80%.

9.8.2 Charge the MolecuLight *i:X* Display Screen

To charge the MolecuLight *i:X* Display Screen:

1. Connect the white connecting cable on the MolecuLight Power Cable (P/N 1142) to the port on the MolecuLight *i:X* Display Screen as shown in Figure 9.
2. Connect the USB power adapter to the other end of the white connecting cable as shown in Figure 9.
3. Plug the USB power adapter into an electrical outlet.
4. When the battery status on the Display Screen indicates that it is fully charged, disconnect the MolecuLight Power Cable from the electrical outlet and then remove the MolecuLight Power Cable from the device.



Note

MolecuLight recommends charging the MolecuLight *i:X* Display Screen whenever it is not in use so that it is fully charged for its next use.

9.9 Uploading Images and Videos to Computer

You can upload images and videos to a computer using supported applications on your Mac or PC.

To upload images and videos to a computer:

1. Connect the white connecting cable on the MolecuLight Power Cable (P/N 1142) to the port on the MolecuLight *i:X* Display Screen. Connect the USB connector end of the white connecting cable to your computer as shown in Figure 10. When prompted to 'allow' or 'trust' the computer on the MolecuLight *i:X* Display Screen, you may do so.

Communication between MolecuLight *i:X* and your computer will be established automatically.



Note

If the USB connector end of the white connecting cable is connected to the USB power adapter, disconnect it.

2. Do not use iTunes to copy or move images from MolecuLight *i:X* to your computer. If you have iTunes on your computer, you will automatically be prompted to access the images/videos via iTunes.
3. Close the iTunes window, select Finder (Mac) or Windows Explorer (PC) and select the MolecuLight Device under Portable Devices. You will be able to access your images within the MolecuLight Device folder.



Note

If you delete photos or videos during data transfer, they are removed from the Image Library.



Note

Images are not permanently deleted using this method. Images can still be recovered on the device from the deleted images folder.



Note

You will require an Apple ID (consult with your Institution's IT department), for accessing future MolecuLight Apps.

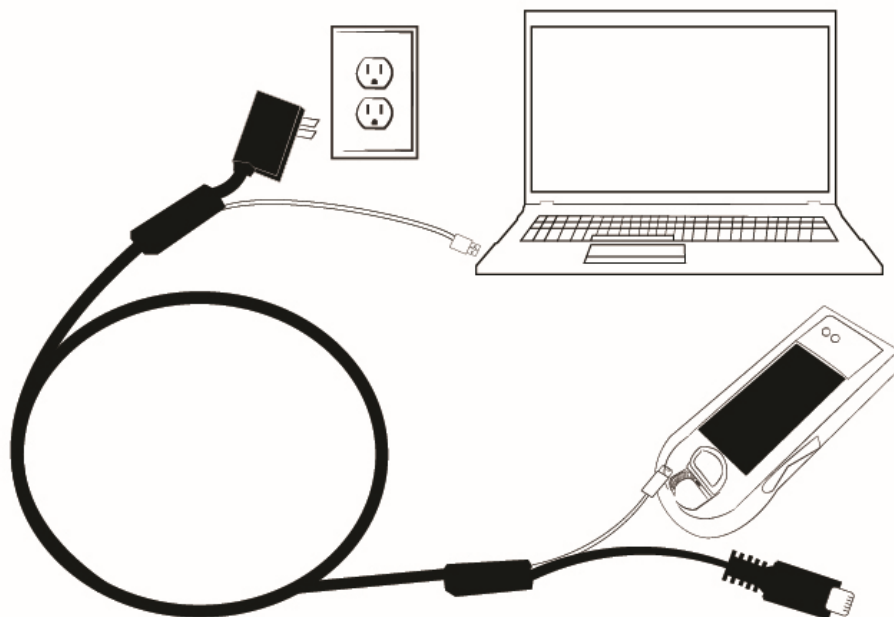


Figure 10: Connecting MolecuLight *i:X* to a computer to transfer images/videos

9.10 Display Screen Functionality



Figure 11: MolecuLight *i:X* Display Screen

9.10.1 Basic Display Screen Functionality for MolecuLight *i:X* Use

Most of the buttons required to use the Display Screen are located on the touchscreen user interface. The Home Button is the only physical button that controls the Display Screen.

9.10.1.1 Home Button

Pressing the Home Button takes you to the Home Screen and provides access to the iX Camera App.

You are able to lock the Display Screen while not using the MolecuLight *i:X*. Locking the Display Screen saves battery life and prevents the device from responding if you inadvertently touch the screen.

To lock the Display Screen:

1. Press the Display Screen Power Button. The MolecuLight *i:X* screen becomes dark and the device is locked.



Note The Display Screen locks automatically if you don't touch the screen for 5 minutes.

To unlock the Display Screen:

1. Press the Home Button.
2. Drag the 'slide to unlock' slider to the right. The MolecuLight *i:X* unlocks.

To turn on the Display Screen:

1. If the Display Screen has been fully powered off, press and hold the Display Screen Power Button.
2. When the Apple logo appears, wait for the MolecuLight *i:X* Display Screen to power on.
3. When the 'slide to unlock' slider appears, drag the 'slide to unlock' slider to the right which unlocks the MolecuLight *i:X*, and access the iX Camera App.

To turn off the Display Screen:

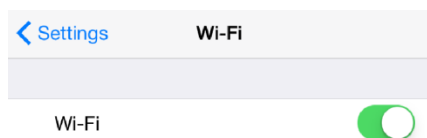
1. Press and hold the Display Screen Power Button.
2. When the 'slide to power off' slider appears, then drag the slider to the right.
3. The MolecuLight *i:X* Display Screen powers off.

9.10.2 Connect to a Wi-Fi Network

Wi-Fi is a technology that allows you to wirelessly connect to a local-area network.


To connect to a Wi-Fi network:

1. From the MolecuLight *i:X* Home Screen, swipe right to the center page and tap Settings.
The Settings screen is displayed.
2. Tap Wi-Fi.
The Wi-Fi screen is displayed.
3. Slide the Wi-Fi ON/OFF switch to ON.



MolecuLight *i:X* automatically searches for available Wi-Fi networks.

4. Tap the name of your desired Wi-Fi network.
5. If the Wi-Fi network is password-protected, a prompt appears to enter a password.
6. Enter the password for the Wi-Fi network.
7. Tap Join.

When your device is connected to a Wi-Fi network, a checkmark appears to the left of the network name. The Wi-Fi symbol  also appears in the status bar at the top left of your display.



Note

If you leave proximity to a connected Wi-Fi network and lose the connection to it, MolecuLight *i:X* reconnects when you return to the same location.

9.10.3 Connect to the Internet

MolecuLight *i:X* connects to the Internet by joining Wi-Fi networks. When joined to a Wi-Fi network that is connected to the Internet, MolecuLight *i:X* connects to the Internet automatically.

9.10.4 Create a Passcode



Note

It is advised to follow your IT department protocol before setting up a passcode.

Default factory settings for the MolecuLight *i:X* Imaging Device do not require the use of a passcode.

To create a passcode for MolecuLight *i:X*, go to Settings > Passcode.



10 Measuring Wound Area

The iX Camera App wound measurement functionality features wound border detection and wound area measurement capabilities. The wound border may be traced automatically (Auto Mode) or manually (Manual Mode). Wound area measurement should only be performed on images captured in Standard Imaging Mode with the use of MolecuLight Wound Stickers. Refer to Appendix E for additional details on the iX Camera App wound measurement functionality.



Note

The wound measurement functionality should only be used on images captured in Standard Imaging Mode and should not be used on images captured in Fluorescence imaging mode.



Note

The use of 2 MolecuLight Wound Sticker may produce an average wound area measurement error of 5%, when the image is taken with MolecuLight Wound Stickers in the plane of the wound.



Note

In the absence of MolecuLight Wound Stickers, no area measurement is provided.



Caution

The use of only 1 MolecuLight Wound Sticker may produce an average wound area measurement error of 15%



Caution

Only MolecuLight Wound Stickers should be used for the wound measurement functionality.








Caution

Do not place MolecuLight Wound Stickers on the wound.

10.1 Auto Mode




The iX Camera App can automatically trace and measure the area of a wound. The following steps are required for automated wound area measurements:

1. Ensure the Standard Imaging Mode wound image is captured with 2 MolecuLight Wound Stickers (P/N 1266) placed close to and within the plane of the wound. Measurement accuracy will be degraded if the MolecuLight Wound Stickers are off plane, in which case they may appear elliptical. For optimal results, ensure the MolecuLight Wound Sticker placement is such that the stickers appear at the top and bottom of the Display Screen when holding the MolecuLight *i:X* in a portrait (vertical) orientation.
2. When capturing an image, ensure the MolecuLight *i:X* Camera Sensor is parallel to the wound and the MolecuLight Wound Stickers are in field of view.
3. Open the image of interest from the Image Library. Select the Auto Trace  icon.
4. The Auto Trace feature traces the border of the wound with a thin white line (the MolecuLight Wound Stickers will be highlighted with a blue circle during this auto detection process).
5. When selecting Auto Trace, additional icons are available to expand  or contract  the detected border. Pressing these icons expands or contracts the wound border as desired.
6. Once the desired wound border is achieved, a Checkmark  icon is available to 'Accept and Save' the wound border and the wound area will appear in cm².

At any point, the user can select the Auto Trace  icon to exit Auto Mode.






Note

Once the user has pressed the Expand  icon until it reaches the largest detection threshold range, the Expand  icon will disappear, leaving the Contract  icon.




Note

Once the user has pressed the Contract  icon until it reaches the smallest detection threshold range, the Contract  icon will disappear, leaving the Expand  icon.







Note

The wound area measurement is not displayed unless the user selects the Checkmark  icon.


10.2 Manual Mode

If Auto Mode is not tracing an accurate wound boundary, the iX Camera App also allows for manual tracing of the wound border to measure wound area. The following steps are required for manual wound area measurements:


1. Ensure the Standard Imaging Mode wound image is captured with 2 MolecuLight Wound Stickers (P/N 1266) placed close to and within the plane of the wound. Measurement accuracy will be degraded if the MolecuLight Wound Stickers are off plane, in which case they may appear elliptical. For optimal results, ensure the MolecuLight Wound Sticker placement is such that the stickers appear at the top and bottom of the Display Screen when holding the MolecuLight i:X in a portrait (vertical) orientation.
2. When capturing an image, ensure the MolecuLight i:X Camera Sensor is parallel to the wound and the MolecuLight Wound Stickers are in field of view.
3. Open the image of interest from the Image Library. Select the Manual Trace  icon.
4. Use your index finger or a stylus to draw the border of the wound.
5. Select the Checkmark  icon if the trace is acceptable.
6. If the trace is not acceptable, press the Manual Trace  icon once to exit Manual Mode and press it again to reenter Manual Mode.
7. Once the desired wound border is drawn, a Checkmark  icon is available to 'Accept and Save' the wound border and the wound area will appear in cm².



Note

The wound area measurement is not displayed unless the user selects the Checkmark  icon.

10.3 Saving a Wound Measurement

When a wound border is traced (in either Auto or Manual Mode), a Checkmark  icon is available and when selected, a pop-up message will appear prompting the user to 'Accept and Save' the image. The user should select 'OK' when the wound border trace accurately represents the border of the wound. Once 'OK' is selected, the image with the wound border and reported area measurement will be saved as a new image to the same Album as the original image.

11 Interpretation of Fluorescence Images

MolecuLight *i:X* allows real-time visualization of the presence and distribution of bacteria in wounds (for more details, see Sections 4.2 and 5). When the device is used in FL-Mode as described in Step 5 of the Quick Start Guide in Appendix C, fluorescence images of a wound may be obtained.

The fluorescence images obtained with the MolecuLight *i:X* Imaging Device have distinct fluorescence colors which are associated with bacteria and other different wound components. Users may see the following characteristic fluorescence colors when imaging wounds:

Color	Indicator
Red*	Typically associated with the presence of potentially harmful levels of bacteria
Green	Typically associated with connective tissues in skin
Dark/black areas	Typically associated with blood, highly vascularized tissues, necrotic tissue, highly pigmented tissue (freckles, moles, etc.) or poorly illuminated areas
White	Typically associated with materials in the field of view that are white (bed sheet, clothing, paper, wound measuring ruler, etc.) or oversaturation of color signal
Cyan	Typically associated with the presence of <i>Pseudomonas aeruginosa</i>

Table 13: Color indicators for interpretation of fluorescence images



Note* Red color of bacteria may appear orange to some users.

Figure 12 provides examples of the Standard Imaging Mode (ST-Image) and corresponding Fluorescence Imaging Mode (FL-Image) from typical diabetic foot ulcers (DFUs) showing the characteristic red and green fluorescence colors typically seen during use of the MolecuLight *i:X* Imaging Device for assessing a DFU.

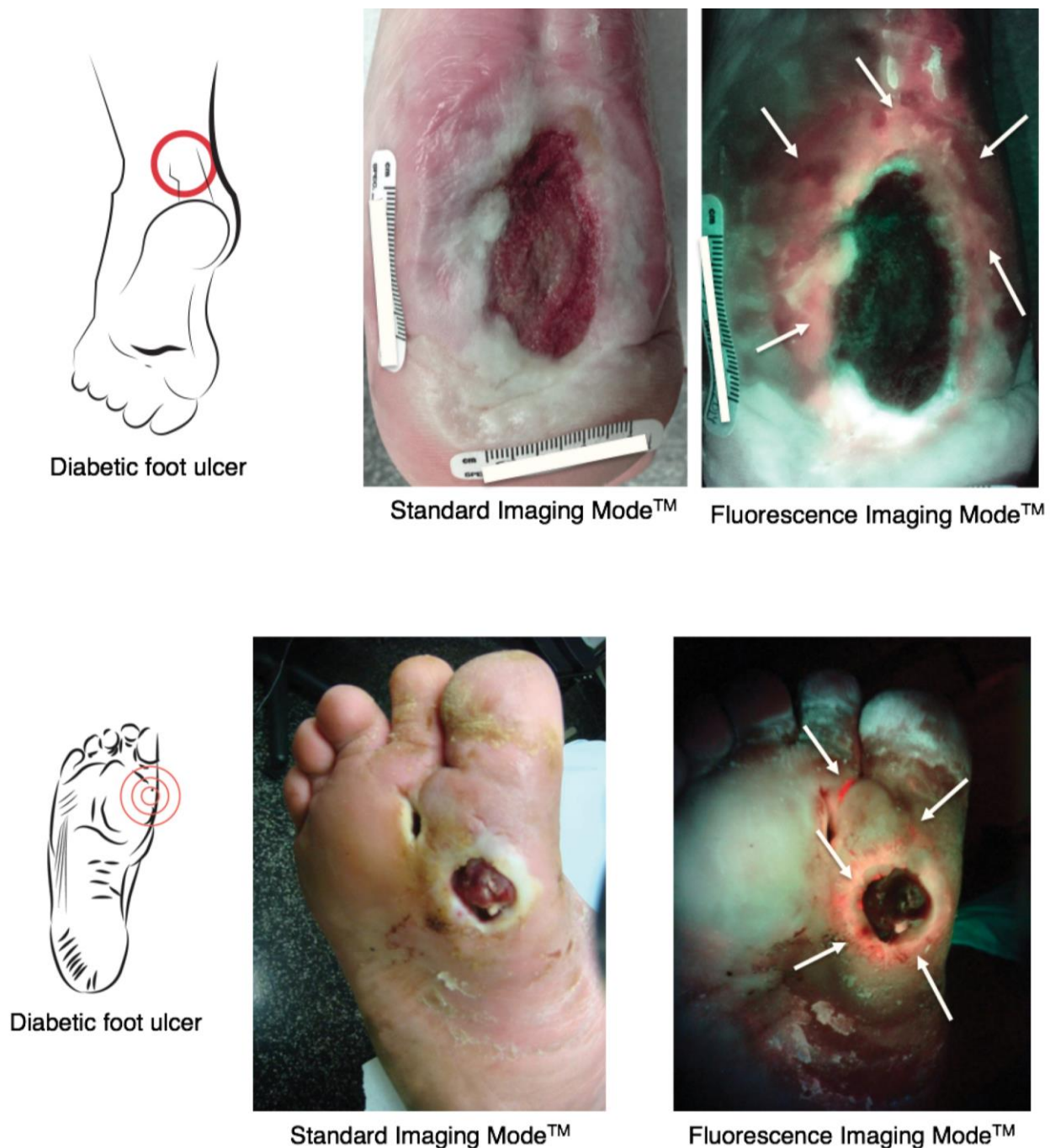


Figure 12: Examples of MolecuLight *i:X* images in Standard Imaging Mode and Fluorescence Imaging Mode. Red color indicates the presence of bacteria (shown by arrows).

11.1 Color Blindness

Correct interpretation of the images acquired with the MolecuLight *i:X* Imaging Device requires that the user can differentiate between green and red colors. A typical test for red-green color blindness involves looking at color swatches (see the examples in Figure 13). Individuals who do not suffer from red-green color blindness will be able to see the number 56 in the left-hand color swatch shown below, and the number 74 in the right-hand color swatch shown below.

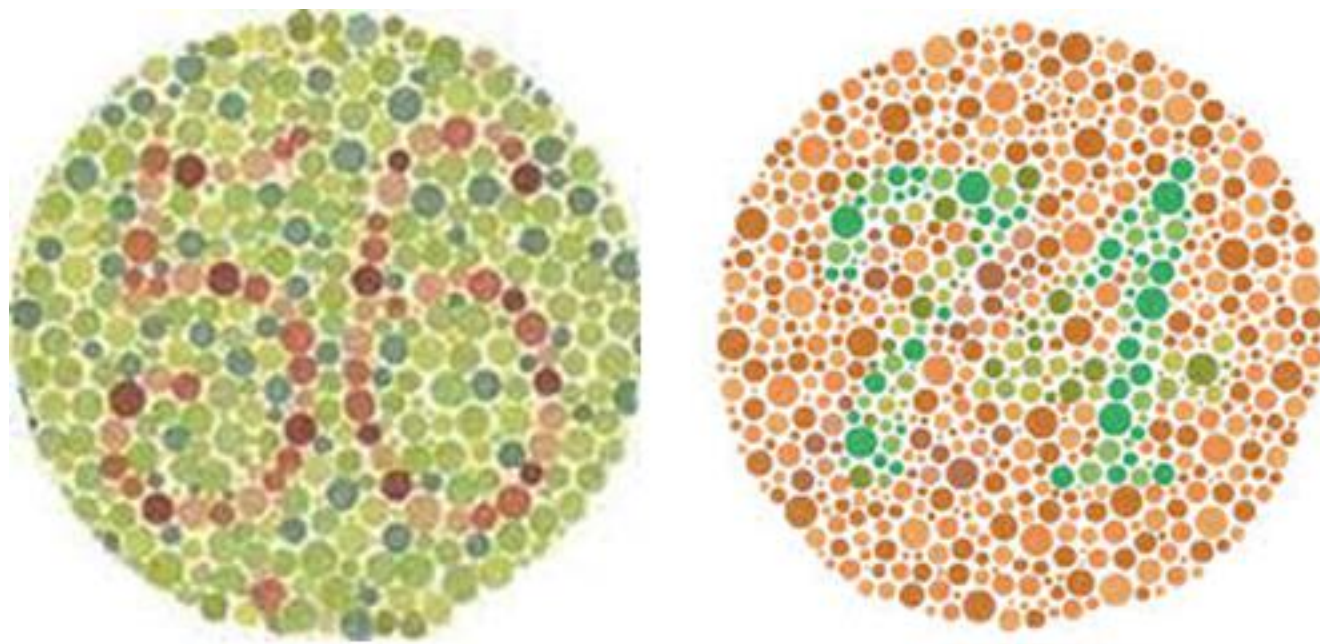


Figure 13: Color figure swatches used in a typical clinical color-blindness test



Caution

MolecuLight *i:X* should not be used by individuals confirmed to be color blind.



12 Cleaning and Disinfecting

MolecuLight *i:X*

Clean and disinfect MolecuLight *i:X* before and after it is used and between wound assessment procedures. Failure to do so may result in cross-contamination, and patient or user exposure to bacterial contamination. MolecuLight recommends disinfecting wipes noted in Section 3.2 for cleaning and disinfecting.

The MolecuLight DarkDrape is for single use only and must not be used more than once. The MolecuLight Adapter can be reused after being appropriately cleaned and disinfected.



Warning Do not reuse the MolecuLight DarkDrape. It is a single use only accessory.

12.1 Pre-Clean the MolecuLight *i:X*

Wear impervious gloves such as latex gloves when handling disinfecting wipes. Use a disinfecting wipe to remove all debris from the MolecuLight *i:X* by gently wiping ALL SIDES and surfaces (see Figure 2), including the Display Screen and optical components identified within the red perimeters in Figure 14.

12.2 Disinfect the MolecuLight *i:X*

Use another disinfecting wipe to thoroughly wet ALL SIDES and surfaces (see Figure 2) of the MolecuLight *i:X*, including the Display Screen and optical components identified within the red perimeters in Figure 14. Let the MolecuLight *i:X* remain wet for 3 minutes at room temperature. Allow the MolecuLight *i:X* to dry.

12.3 Clean the MolecuLight *i:X*

Use a Lens Cleaning Towelette to thoroughly clean the Display Screen and optical components identified within the red perimeters in Figure 14. There should be no visible debris, fingerprints or material on the Display Screen or any of the optical components after cleaning. Allow the MolecuLight *i:X* to dry.

The MolecuLight *i:X* is now clean, disinfected and ready for use.



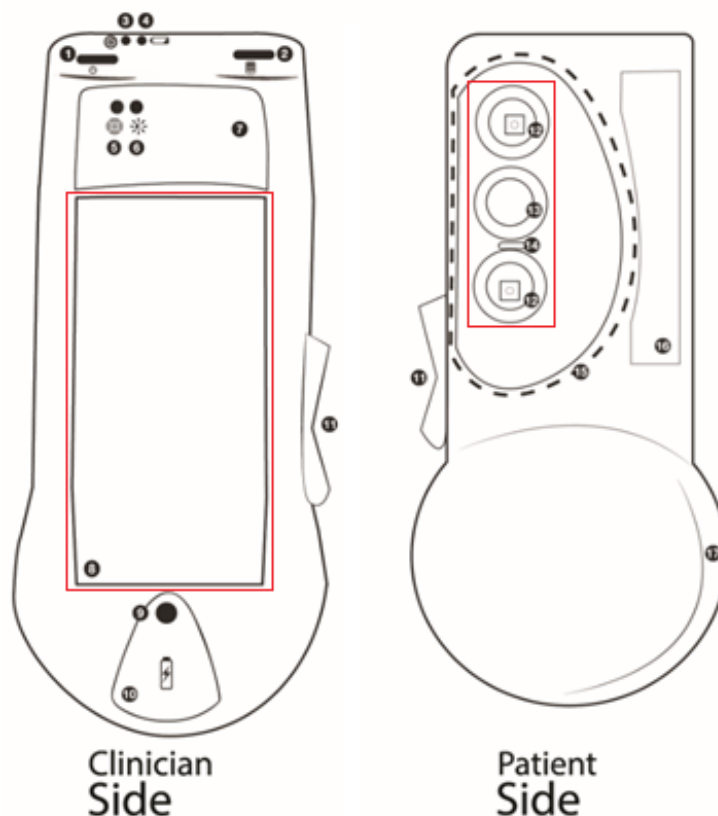


Figure 14: Image showing optical components (red) on Clinician Side and Patient Side of MolecuLight *i:X*

On the Clinician Side, red perimeter indicates location of the Display Screen.

On the Patient Side, red perimeter includes: Optical window for Violet Wavelength LED, Camera Sensor Window, Range Finder & Ambient Light Sensor (listed from top to bottom as depicted)



Warning Do not soak or immerse MolecuLight *i:X* in water.



Note Prior to cleaning optical components, ensure surfaces are disinfected as described in Section 12.2.



Caution Improper cleaning/disinfection may result in distorted images.



Note The user should dispose of the cleaning and disinfection materials as well as MolecuLight DarkDrape (if used) according to the biohazard waste control processes at their Institution.

12.4 Pre-Clean the MolecuLight Adapter

Use a disinfecting wipe to remove all debris from the MolecuLight Adapter by gently wiping all sides and surfaces, including tabs.

12.5 Disinfect the MolecuLight Adapter

Use another disinfecting wipe to thoroughly wet ALL SIDES, surfaces and tabs of the MolecuLight Adapter. Let the MolecuLight Adapter remain wet for 3 minutes at room temperature. Allow the MolecuLight Adapter to dry. The MolecuLight Adapter is now clean, disinfected and ready to use.

13 Maintenance of MolecuLight *i:X*

MolecuLight *i:X* periodically executes a self-diagnosis to ensure it is operating properly, without requiring user input. The System Status LED indicates the overall operational state of the MolecuLight *i:X* Imaging Device.

If the System Status LED turns to amber or red (green is the indication that the device is functioning as intended), you may need to send the device to MolecuLight for servicing. Contact MolecuLight at support@moleculight.com.

Otherwise, except for regular cleaning (Section 12), there are no maintenance or calibration activities that need to be performed.

For more information and details on service pricing, contact MolecuLight at support@moleculight.com.

14 Disposal of MolecuLight *i:X*

Comply with your country's legal requirements for the disposal of electrical and electronic waste to dispose of the MolecuLight *i:X*. The two rechargeable lithium ion batteries that power the MolecuLight *i:X* must be recycled appropriately by following your country's disposal regulations. For more information about recycling MolecuLight products, please contact your local recycling program or MolecuLight at info@moleculight.com.



15 Troubleshooting and Support

15.1 Frequently Asked Questions

About who to contact:

1. Where do I call/email with questions?
 - Contact MolecuLight at info@moleculight.com or call +1-647-362-4684.
2. How can I purchase a device?
 - Contact MolecuLight at info@moleculight.com or call +1-647-362-4684.

About imaging bacteria:

3. How does the device detect bacteria?
 - The device illuminates wounds with a narrow band of violet light that causes bacteria commonly found in and around wounds to fluoresce based on the presence of endogenous molecules called fluorophores (e.g. porphyrins, pyoverdine, etc.). Refer to Section 4.2 for additional information.
4. Which type of bacteria can be detected?
 - Evidence from clinical studies indicates the MolecuLight *i:X* can reliably detect the following bacteria species that are relevant for clinical wound care: *Staphylococcus aureus*, MRSA, *Pseudomonas aeruginosa*, *Escherichia coli*, Coagulase-negative staphylococci, *Enterococcus spp*, *Proteus spp*, *Klebsiella pneumonia*, Beta-hemolytic streptococci (Group B) and *Enterobacter spp*.

About acquiring images:

5. How long does it take to get an image?
 - Images appear immediately. ST-images and FL-images are captured instantly from a wound and displayed in real-time on the device's Display Screen and when the 'CAPTURE IMAGE' button is pressed.
6. How can I access the images/videos?
 - Images/Videos are located in the Camera Roll and Albums. Refer to Section 9.4 for additional information.
 - You can transfer these images/videos from your device to any computer using the white connecting cable on the MolecuLight Power Cable (P/N 1142). Refer to Section 9.9 for instructions.



About operating the MolecuLight *i:X*:

7. Does the device require any consumables to obtain FL-Images?
 - Consumables are not required for operation of the device in optimal lighting conditions.
 - If you are unable to obtain optimal ambient light for Fluorescence Imaging Mode, MolecuLight recommends using MolecuLight DarkDrape (used in conjunction with MolecuLight Adapter). For more information, refer to Section 4.3, or contact MolecuLight at info@moleculight.com or +1-647-362-4684.
8. Who is qualified to use the device?
 - Trained health care professionals in wound care.
9. How do I clean the device?
 - The MolecuLight *i:X* can be wiped clean using disinfecting wipes. Ensure excess fluid from the wipes does not enter any openings and that the device is thoroughly dry before use. A lens towelette to clean the optical components and Display Screen should also be used. For further information, please see Sections 3 and 12.
10. How do I take care of the device?
 - MolecuLight *i:X* is an optical imaging device and must be handled with care at all times.
 - i. Do not drop, knock or shake the device. Ensure there is no dirt, moisture or scratches over the camera sensor window, LEDs and Display Screen.
 - ii. Do not immerse the device in liquid.
 - iii. Place the MolecuLight *i:X* with its screen facing up on a clean, dry, flat surface when not in use.
11. Is the device safe with laser light exposure and violet light illumination?
 - Yes, the device is classified in Risk Group 1 and the laser is Class 1 meaning there is not sufficient energy produced to damage skin or eyes in normal use. It is advised to not point the device towards the eyes.
12. How do I turn on the device?
 - There are 2 dark gray power buttons to turn the device on. Press and hold each for 3 seconds to turn on the device and the Display Screen respectively.
13. Why is the Display Screen off?
 - The Display Screen is turned on via the Display Screen Power Button. Push this button to turn on the Display Screen. If it does not turn on, the Display Screen battery may need to be charged via the charging port located below the Home Button using the white connecting cable on the MolecuLight Power Cable (P/N 1142).
 - The Display Screen could also be locked. Press and release the Display Screen Power Button or the Home Button to reveal the screen.



14. Why can't I see red fluorescence on the screen?

- There may not be any red fluorescence signal generated by the target you are imaging.
- Ensure that the System Status LED is green, which indicates that the device optics and electronics are functioning properly. For further information, contact support@moleculight.com.
- The Rocker Switch may be set to imaging in Standard Imaging Mode.

15. What is the System Status LED?

- This LED informs you that the device electronics and optics are functioning as designed. This LED should be green. If the color changes to amber or red, contact MolecuLight as soon as possible. Refer to Section 6.1.1.1.

16. What does the Battery Status LED indicate?

- This LED indicates the battery power of the device (for the optics and electronics) and is green when the charge is >80%. Note that there is also a battery status for the Display Screen itself in the top right corner of the screen that is independent of the device.

17. What does the Range Finder LED indicate?

- The Range Finder notifies you when the optimal distance between the device and the wound is reached, i.e. 8-12 cm. This is critical to follow in FL-Mode and it is also advised to observe the Range Finder LED when in ST-Mode so that the images obtained will have a similar field of view.

18. How do I check if the Range Finder is working properly?

- You can use a ruler at various distances from the device to verify the Range Finder LED Status. At a 5 cm distance, the LED should be amber, at 10 cm, the LED should turn green and at 15 cm the LED should turn amber again. If the results are incorrect, do not use the device and contact MolecuLight at support@moleculight.com or call +1-647-362-4684.

19. What does the Ambient Light Status LED indicate?

- For optimal image quality in FL-Mode, it is important that the lighting conditions are in a dark environment. The Ambient Light Status LED will notify you when conditions are optimal (the LED will be green).

20. How do I check if the Ambient Light Status LED is working?

- The Ambient Light Status LED should be amber in a bright environment and turn green in a dark environment. Make sure all lighting is off in order for the LED to turn green. If you have any questions, contact MolecuLight at support@moleculight.com or call +1-647-362-4684.



21. The Ambient Light Status LED turns off when the device is in FL-Mode. Is this intended?

- Yes, this is the normal operation. The ambient light sensor which is used to measure the ambient light conditions is also sensitive to the light emitted from the device during FL-Mode operation, therefore the indicator LED turns off in this mode to ensure it does not provide a false reading. The lighting conditions should be adjusted such that the Ambient Light Status LED is green prior to using FL-Mode.
- If you are unable to obtain optimal ambient light for FL-Mode, MolecuLight recommends using MolecuLight DarkDrape (used in conjunction with MolecuLight Adapter). For more information, refer to Section 4.3, or contact MolecuLight at info@moleculight.com or +1-647-362-4684.

22. How do I know that my Device is working properly?

- The System Status LED indicates the functionality of the electronics and optics of the device. This LED is green when the device is turned on and operating properly. If it is amber or red, contact MolecuLight at support@moleculight.com.

23. How long does it take to charge the device?

- The device charges to approximately 80% of its total capacity after 2 hours of charging and will be fully charged after approximately 5 hours.

About operating the wound measurement app:

24. Why do I need to use the MolecuLight Wound Stickers?

- In the absence of MolecuLight Wound Stickers, no area measurement is provided. The use of 2 MolecuLight Wound Sticker may produce an average wound area measurement error of 5%, when the image is taken with MolecuLight Wound Stickers in the plane of the wound. The use of only 1 MolecuLight Wound Sticker may produce an average wound area measurement error of 15%.



15.2 iX Camera App Troubleshooting

iX Camera App Error Message	Description	Cause	Action
“iX Camera” Would Like to Access the Camera <Don’t Allow> <OK>	Message from iOS to confirm the user is granting the App access to the camera hardware to allow capture of images and video.	This message appears the first time the App is opened. Once the user selects <OK> this setting will be saved and the message will no longer appear.	Select <OK>
“iX Camera” Would Like to Access Your Photos <Don’t Allow> <OK>	Message from iOS to confirm the user is granting the App access to the Image Library to view and store images and video.	This message appears the first time the App is accessing the Image Library. Once the user selects <OK> this setting will be saved and the message will no longer appear.	Select <OK>
Camera Access Not Enabled	iOS has detected that access to the camera hardware has been disabled by the user.	This message can be caused by the user either selecting <Don’t Allow> when it was prompted to give access to the camera or the user manually changed the settings in the “Settings Privacy Camera” menu.	Go to “Setting Privacy Camera” and locate the toggle switch for the iX Camera and swipe to the enable position.
Image Library Access Not Enabled	iOS has detected that access to the Image Library has been disabled by the user.	This message can be caused by the user either selecting <Don’t Allow> when it was prompted to give access to the Image Library or the user manually changed the settings in the “Settings Privacy Photos” menu.	Go to “Setting Privacy Photos” and locate the toggle switch for the iX Camera and swipe to the enable position.



iX Camera App Error Message	Description	Cause	Action
Video Maximum Recording Reached	This message notifies the user that video is no longer being captured due to reaching the 30 second timeout limit. The video has been saved.	The maximum recording duration of 30 seconds has been reached.	Video has been saved, no action required if user was finished recording video. If not finished, the user can Press "START RECORDING" again to start recording a new video.
Allow "iX Camera" to delete this photo? <Don't Allow> <Delete>	iOS has detected that the user has selected to delete an image.	This message appears when the user selects the "Trash" icon while viewing an image.	User can select <Don't Allow> to return to browsing without deleting, or <Delete> to delete the image from the Image Library.
Allow "iX Camera" to delete this video? <Don't Allow> <Delete>	iOS has detected that the user has selected to delete a video.	This message appears when the user selects the "Trash" icon while viewing a video.	User can select <Don't Allow> to return to browsing without deleting, or <Delete> to delete the video from the Image Library.

Table 14: iX Camera App error messages

If you are having any difficulty with your MolecuLight *iX* or have any questions that require troubleshooting, contact MolecuLight at support@moleculight.com. A representative will respond to your inquiry.

If you have any questions about operating the device, contact MolecuLight:

MolecuLight Inc.
101 College St., Suite 200 Room 228
Toronto, ON Canada
M5G 1L7
Telephone: +1-647-362-4684
info@moleculight.com
www.moleculight.com

16 Warranty

MolecuLight warrants this product to be free from any defects in material and workmanship for a period of one year from the date of purchase by the initial purchaser.

Contact MolecuLight at support@moleculight.com to report any defects and obtain a returned material authorization (RMA) number and shipping instructions prior to returning the device to MolecuLight.

All shipping charges and duties for returned goods are the responsibility of the purchaser.

Upon inspection and evaluation of the returned unit by MolecuLight, your MolecuLight *i:X* Imaging Device will either be replaced or repaired (during the warranty period).



Caution Any evidence of tampering or disassembly shall void this warranty.



Caution Any evidence of damage (crack, discoloration) shall void this warranty.



Appendix A: Specifications

The device was tested to the following specifications:

- Safety Testing per IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+A1:2013 including Canadian National Differences per CAN/CSA-C22.2 No. 60601-1:14 and US National Differences per ANSI/AAMI ES 60601-1:2005/A1:2012
- Safety EMC Testing per IEC 60601-1-2:2007 3rd Edition including FCC Part 15 Subpart B: 2015 & ICES-003:2012 / EN 60601-1-2:2007
- Safety LED testing per IEC 60601-2-57:2011 and IEC 62471:2006 / EN 60601-2-57:2011 and EN 62471:2008
- Usability Testing per IEC 60601-1-6:2010+A1:2013 / EN 60601-1-6:2010 and EN 62366:2008
- Risk Management per ISO 14971:2007 / EN ISO 14971:2012
- Quality Management System Requirements per ISO 13485:2003 / EN ISO 13485:2012

Specifications for MolecuLight *i:X* operating conditions:

Specification	Value
Temperature	10 °C to 30 °C
Relative humidity	10-70%
Atmospheric pressure	89-102 kPa

Specifications for MolecuLight *i:X* transportation and storage conditions:

Specification	Value
Temperature	-10 °C to 50 °C
Relative humidity	10-70%
Atmospheric pressure	89-102 kPa

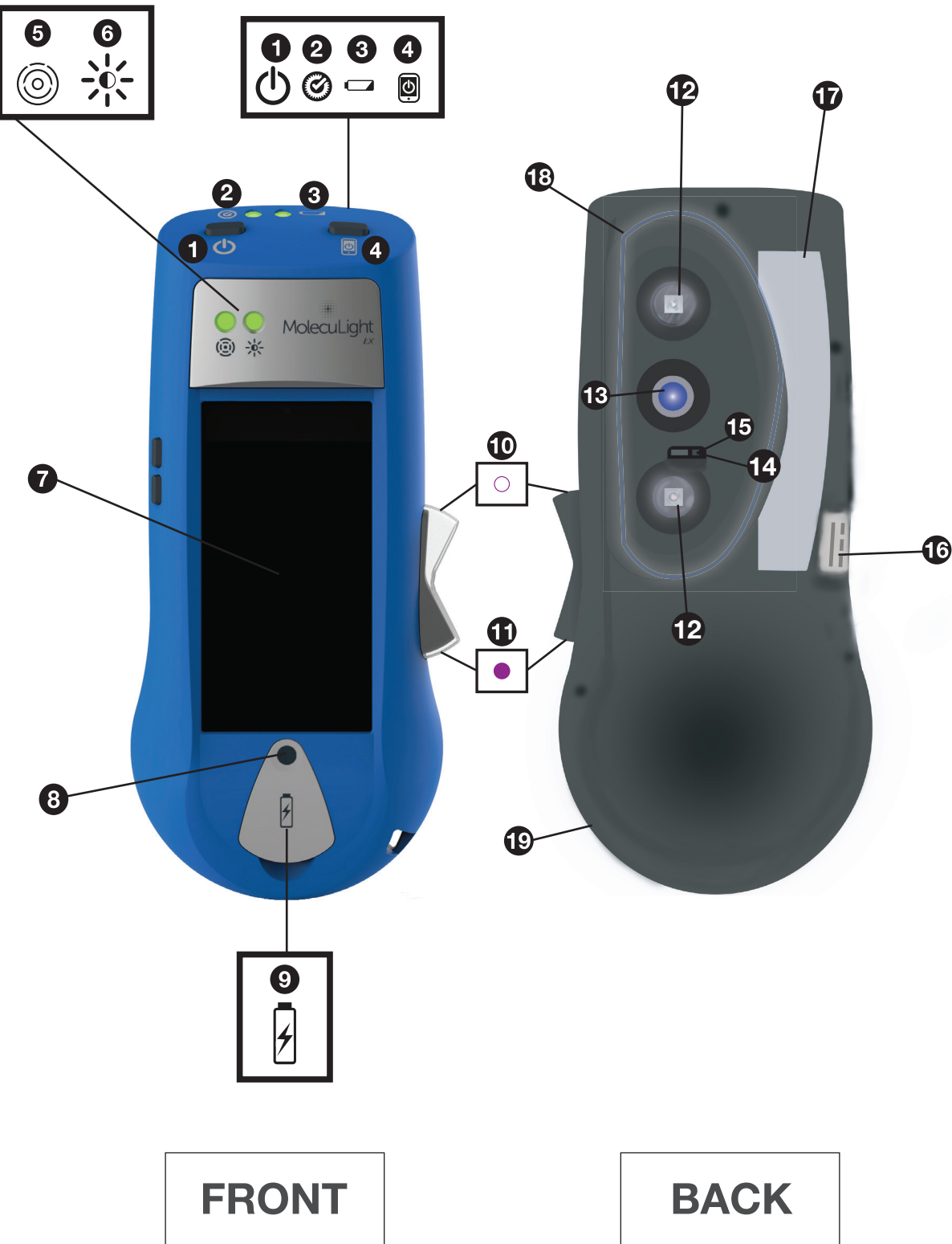
MolecuLight *i:X* dimensions:

Dimension	Value
Height	21 cm
Width (maximum)	9.5 cm
Depth (maximum)	4 cm
Weight	398 g

The electrical specifications for the MolecuLight Power Cable P/N 1142 are as follows:

Model: PSA05F-050QAL6	
Input	Output
100-240 V	5 V
0.18 A	1 A
60 Hz	
Model: PSA10F-050	
Input	Output
100-240 V	5 V
0.35 A	2 A
60 Hz	

APPENDIX B: DEVICE OVERVIEW

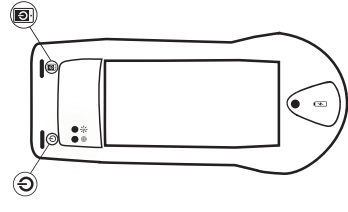
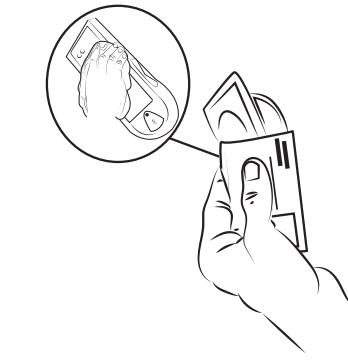
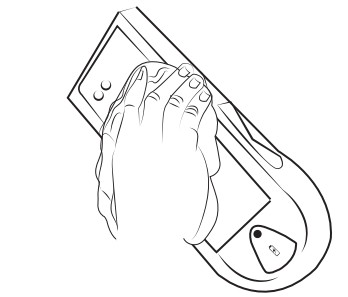
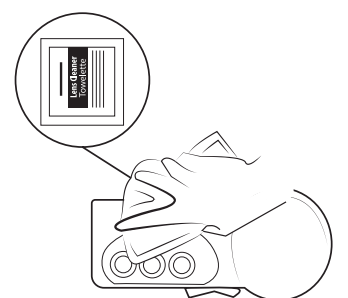
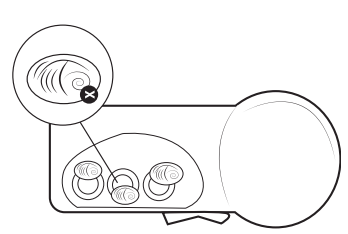


OVERVIEW

- 1 Power Button: turns device ON/OFF by pressing and holding 3 seconds
- 2 System Status LED: indicates overall Device performance (Green is required)
- 3 Battery Status LED: indicates Device battery charge (Green or Amber is required for image capture)
- 4 Display Screen power button: turns Display Screen 7 ON/OFF by pressing and holding 3 seconds
- 5 Range Finder LED: indicates optimal distance of device from wound (Green is required for image capture)
- 6 Ambient Light Status LED: indicates optimal lighting environment for fluorescence imaging (Green is required for Fluorescence Imaging Mode™)
- 7 Display Screen: provides touch functionality and displays images/videos
- 8 Home Button: turns Display Screen ON
- 9 Port for charging Display Screen and downloading data: to be used with MolecuLight i:X Connecting Cable
- 10 Rocker Switch in Standard Imaging Mode™ position: allows for Standard Mode Imaging
- 11 Rocker Switch in Fluorescence Imaging Mode™ position: allows for Fluorescence Mode Imaging
- 12 Violet wavelength LEDs: provide illumination when in Fluorescence Imaging Mode™
- 13 Camera Sensor Window: protects the camera sensor which allows image and video capture
- 14 Range Finder Sensor: detects optimal distance from wound
- 15 Ambient Light Sensor: detects ambient lighting conditions
- 16 MolecuLight i:X Charging Port: allows charging of device with MolecuLight Power Cable
- 17 Label: lists certifications, references instructions
- 18 Illumination zone contains: 12 13 14 15 Fingers should be kept out of this area
- 19 Holding Contour: allows proper positioning of hands

APPENDIX C: Moleculight i:X™ Imaging Device QUICK START GUIDE

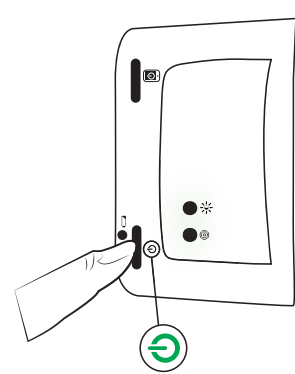
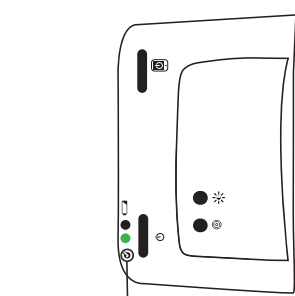
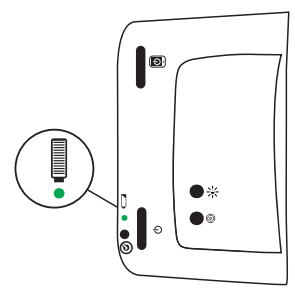
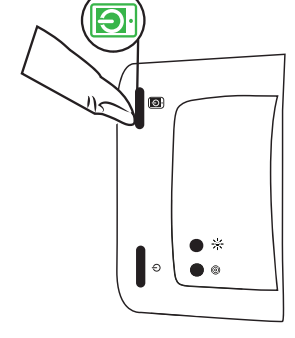
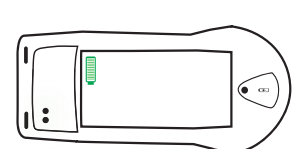
1. CLEANING

-  a. Ensure i:X is OFF or turn device OFF and Display Screen OFF.
-  b. Use a disinfecting wipe to preclean the i:X.
-  c. Use a second disinfecting wipe to clean the whole device including all crevices.
-  d. Use lens towelette to clean all glass surfaces.
-  e. Check that all windows are clean, free of all debris and fingerprints.

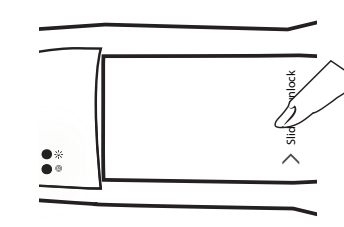
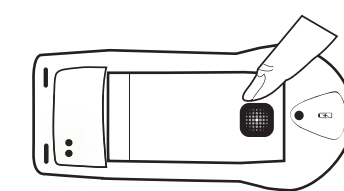
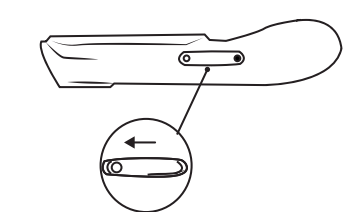
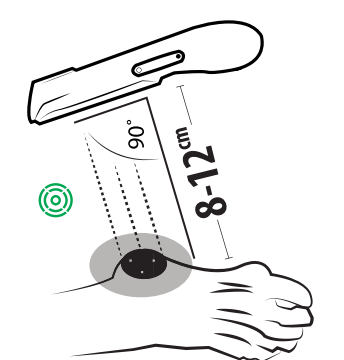
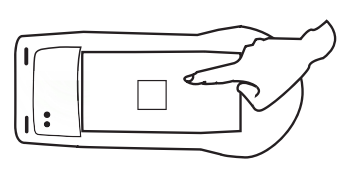
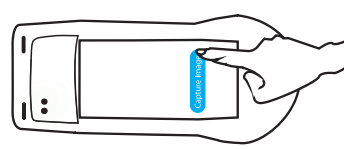
2. CHARGING

-  a. Charge device and Display Screen with the Moleculight Power Cable.
-  b. One end of the Power Cable connects to the device and the other to the Display Screen.
-  d. LED flashes when device is being charged.
-  e. Battery icon will be visible when Display Screen is being charged.

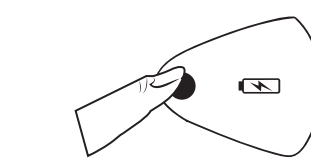
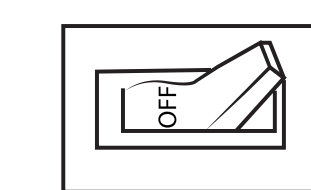
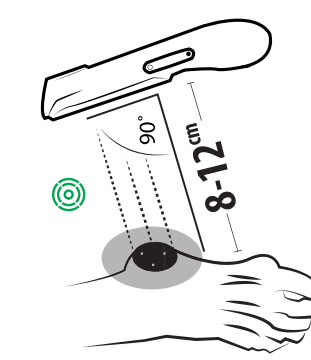
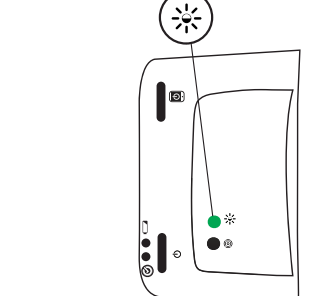
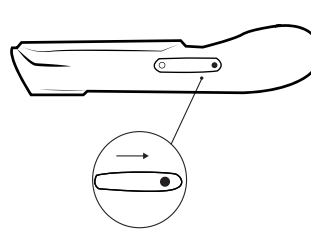
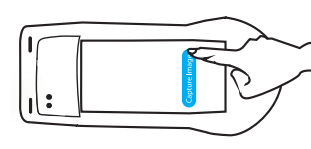
3. TURNING ON

-  a. Push power button (3 sec) to turn device on.
-  b. Check that the System Status LED will be green (if yellow or red consult User Manual).
-  c. Verify the battery status on device (green indicates maximum charge capacity).
-  d. Push screen power button (3 sec) to turn Display Screen on.
-  e. Verify Display Screen battery capacity.

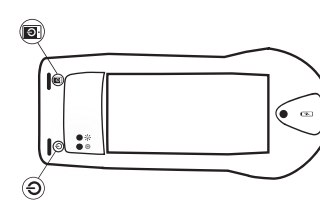
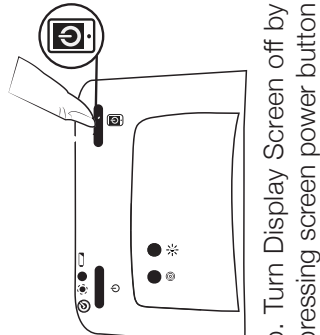
4. CAPTURING A STANDARD LIGHT IMAGE/VIDEO

-  a. Press the home button and select slider.
-  b. Select the iX Camera App on Display Screen.
-  c. Position Rocker Switch in Up position.
-  d. Use Range Finder Sensor LED to reach appropriate distance (LED turns green).
-  e. Tap on the screen to improve focus as required.
-  f. Capture image and/or video, Range Finder Sensor LED should remain green.

5. CAPTURING A FLUORESCENCE LIGHT IMAGE/VIDEO

-  a. Use home button to access screen, select slider if needed.
-  b. Turn off room lights.
-  c. Use Range Finder Sensor LED to reach appropriate distance (LED turns green).
-  d. Confirm Ambient Light Sensor LED is green before toggling Rocker Switch to FL-Mode.
-  e. Toggle to FL-Mode; Ambient Light Sensor LED turns off when FL-Mode is activated.
-  g. Capture image and/or video, Range Finder Sensor LED should remain green.

6. TURNING OFF

-  a. Turn device off by pressing power button for 3 seconds.
-  b. Turn Display Screen off by pressing screen power button for 3 seconds.



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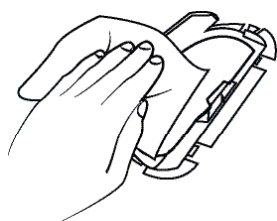
©2016 Moleculight Inc. All Rights Reserved. PN 1149 Rev 1.3.
Consult the Moleculight i:X™ User Manual for more information.

APPENDIX D: INSTRUCTIONS FOR USE

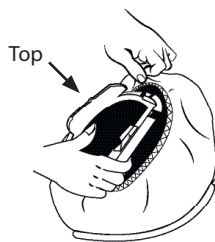
MolecuLight
DarkDrape™

MolecuLight
Adapter™

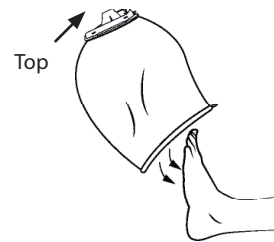
For optimal imaging with the MolecuLight *i:X*™ Imaging Device in Fluorescence Imaging Mode™



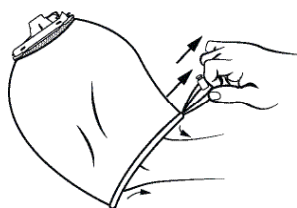
1. Use a disinfecting wipe to clean the MolecuLight Adapter.



2. Expand the MolecuLight DarkDrape into a balloon shape and attach it to the MolecuLight Adapter by securing it in between the 5 tabs.



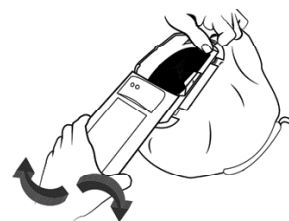
3. Carefully place the MolecuLight DarkDrape over the patient's foot. Avoid touching the wound with the MolecuLight DarkDrape. Keep orientation of the MolecuLight Adapter as shown in Step 2.



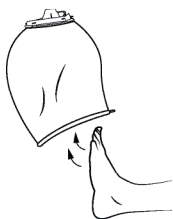
4. Secure the MolecuLight DarkDrape by pulling on the draw string and locking it in place with the push button. Avoid touching the patient's wound with the DarkDrape.



5. Slide the MolecuLight *i:X* Imaging Device over the MolecuLight Adapter until the device clicks into place. Avoid touching the patient's wound with the DarkDrape.



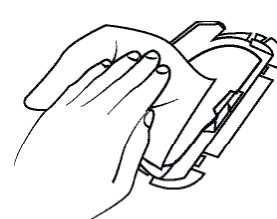
6. When imaging is complete, hold the MolecuLight Adapter tab to remove the MolecuLight *i:X*.



7. Press the push button to loosen the draw string. Carefully remove the MolecuLight DarkDrape from the patient's foot. Avoid touching the wound with the DarkDrape.



8. Remove the MolecuLight Adapter from the MolecuLight DarkDrape. The MolecuLight Adapter can be disinfected and reused. Dispose of the MolecuLight DarkDrape according to your institutional guidelines.



9. Use a disinfecting wipe to clean the MolecuLight Adapter.

*The MolecuLight DarkDrape and MolecuLight Adapter provide a convenient and optimal environment for imaging wounds with the MolecuLight *i:X* Imaging Device in Fluorescence Imaging Mode when room lights cannot be turned off.*

The MolecuLight DarkDrape is for single use only.



MolecuLight

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Consult the MolecuLight *i:X*™ User Manual for more information.

APPENDIX E: MolecuLight i:X™ Wound Measurement QUICK START GUIDE

CAPTURE IMAGE



Open the iX Camera App.



Place two **MolecuLight Wound Stickers** in the plane of the wound.

When holding the device in a portrait (vertical) orientation, ensure the **MolecuLight Wound Sticker** placement is such that the stickers appear at the top and bottom of the Display Screen as depicted.



Select the **'Camera'** icon to capture images in **Standard Imaging Mode**.

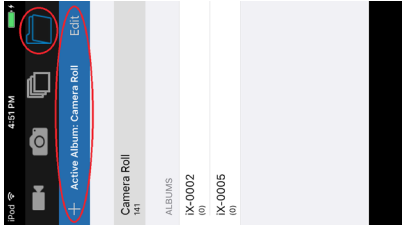


Use the **Range Finder LED** to position the MolecuLight i:X™ at the correct distance from the wound.

Ensure the MolecuLight i:X **Camera Sensor** is parallel to the wound and the **MolecuLight Wound Stickers** are in field of view.

Select **'CAPTURE IMAGE'**

ACCESS IMAGE



Album Management:
Select the **'Album'** icon to manage **Albums**.

Newly acquired images are saved to the **Active Album**.

Note: The **Camera Roll** is the default **Active Album**.

To designate an **Active Album**, select one of the **Albums** listed.

Select **'+'** to create a new **Album** or **'Edit'** to delete **Albums**.



To view the images within your **Active Album**, select the **'Image Library'** icon.

Note: There may be a slight delay before the images appear.

Use your index finger or a stylus to scroll through the images and select the image of interest.

Newly acquired images and newly saved images appear at the bottom of the **Active Album**.

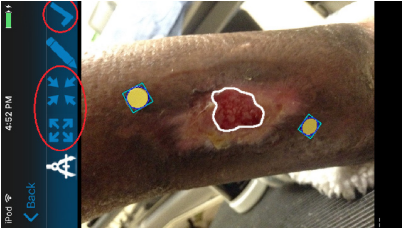
The image selected will appear on the screen.

The **Auto Trace** and **Manual Trace** icons become available.

AUTO MODE: To Automatically Trace Wound Border



Select the **'Auto Trace'** icon.



Auto Trace automatically draws a white border around the wound. The **MolecuLight Wound Stickers** will be outlined in blue.

Use the **'Expand'** or **'Contract'** icons to adjust the wound border if necessary.

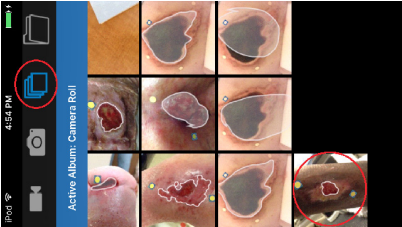
Select the **'Checkmark'** icon to accept the wound border.



The wound area measurement is displayed. An **'Accept and Save Image?'** prompt will appear.

Select **'OK'** to save the image with the overlaid wound border trace and measurement to the **Image Library**.

Select **'Cancel'** to reject the reported wound area and return to the wound border trace.



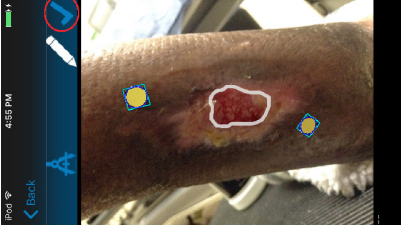
Select the **'Image Library'** icon to browse the **Camera Roll/Active Album** for images saved with area measurements.

Newly acquired images and newly saved images appear at the bottom of the **Active Album**.

MANUAL MODE: To Manually Trace Wound Border

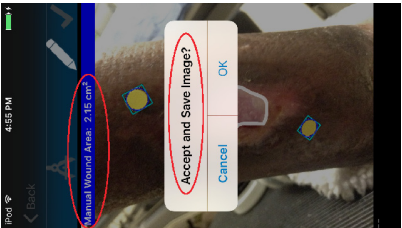


Select the **'Manual Trace'** icon.



Trace a wound border with your index finger or a stylus. The **MolecuLight Wound Stickers** will be outlined in blue.

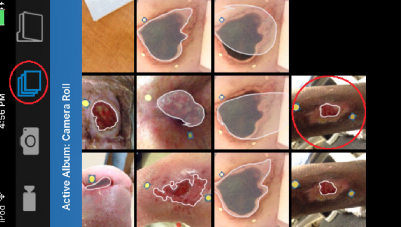
Once the trace is complete, select the **'Checkmark'** icon to accept the wound border.



The wound area measurement is displayed. An **'Accept and Save Image?'** prompt will appear.

Select **'OK'** to save the image with the overlaid wound border trace and measurement to the **Image Library**.

Select **'Cancel'** to reject the reported wound area and return to the wound border trace.



Select the **'Image Library'** icon to browse the **Camera Roll/Active Album** for images saved with area measurements.

Newly acquired images and newly saved images appear at the bottom of the **Active Album**.

ICON LEGEND



MolecuLight

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Consult the MolecuLight i:X™ User Manual for more information.