

Eagle V1.2 Imaging System

Instructions for Use

For use exclusively by authorized healthcare professionals in accordance with

SBI-CIP 20-002:

A prospective multi-center clinical study evaluating the use of PD G 506 A and the Eagle V1.2 Imaging System for the visualization of carcinoma during breast conserving surgery

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1. Introduction

For use only by qualified investigators who have completed the Investigator Training Program in accordance with SBI-CIP 20-002, the Eagle V1.2 Imaging System is intended for performing intraoperative white light and Fluorescence Imaging of surgical cavities and excised tissues, including breast tissue obtained during breast cancer surgery.

As sponsor of clinical trial SBI-CIP 20-002, *SBI ALApharma Canada Inc.* supports clinical trial sites and investigators in addition to providing the information in this Instructions for Use document and SBI-CIP-20-002 Investigator's Brochure. Read this document before using the Eagle V1.2 Imaging System, the Handheld Fluorescence Camera, or accessories.

The primary component of the Eagle V1.2 Imaging System is the Handheld Fluorescence Camera (**HFC**); a battery operated, portable, and handheld optical imaging device intended for use in the operating room environment. Refer to Section 6.2 for full details.

In study protocol SBI-CIP-20-002, Fluorescence Imaging of surgical cavities and excised tissues is specifically intended to be performed on patients who have consumed appropriate doses of the investigational drug PD G 506 A (aminolevulinic acid hydrochloride [ALA HCl] granules for oral solution). Aminolevulinic acid (ALA) a non-fluorescent non-protein amino acid that is converted into the fluorophore protoporphyrin IX (PpIX) as part of the heme biosynthesis pathway. The Eagle V1.2 Imaging System's fluorescent excitation blue-violet light (405 nm) is maximally absorbed by PpIX fluorophores accumulated in malignant tissues. The resulting red fluorescence emission (600 – 660 nm) from PpIX in malignant tissues and green fluorescence emission (500 – 545 nm) from connective tissues and stroma are displayed in real time on the Handheld Fluorescence Camera's display screen.

The HFC, Handheld Fluorescence Camera, operates with a number of accessories to ensure specified performance and safety during use:

- i. **CSS** – Custom Sterile Sleeve
 - o A sterile sheath to entirely cover the Handheld Fluorescence Camera during use within the sterile field of an operating room (OR). Refer to Section 2.2.1 and Section 6.3.1 for full details.
- ii. **ECH** – External Communication Hub
 - o Mirrors the Handheld Fluorescence Camera's display on to the display monitor and facilitates the transfer/export of saved data on the Handheld Fluorescence Camera. Refer to Section 2.2.2 and Section 6.3.2 for full details.
- iii. **DIS** – Dark Imaging Sheet
 - o A non-fluorescent plastic sheet providing a consistent and standardized surface background for Fluorescence Imaging of excised tissues inside the Dark Imaging Box. Refer to Section 2.2.3 and Section 6.3.3 for full details.
- iv. **DIB** – Dark Imaging Box
 - o A mechanical assembly providing the optimal dark environment needed to perform Fluorescence Imaging of excised tissue. Refer to Section 2.2.4 and Section 6.3.4 for full details.
- v. **CCD** – Contact Charging Device

- o A charging cradle for the Handheld Fluorescence Camera, providing a secure, flat surface for the HFC to rest while charging. Refer to Section 2.2.5 and Section 6.3.5 for full details.
- vi. **PSC – Protective Storage Cradle**
 - o A reusable stand to securely store and protect the Handheld Fluorescence Camera when not in use. Refer to 2.2.6 and Section 6.3.6 for full details.

1.1. Intended Use/Indications for use – Eagle V1.2 Imaging System

The Eagle Imaging System is intended for capturing and viewing white light and fluorescence images and videos produced with conventional white light illumination, and excitation light at 405nm and emission light at 500-545 nm and 600-660 nm, respectively. The Eagle Imaging System is indicated for use in imaging a surgical cavity or excised human tissue specimens, including breast tissue specimens obtained during breast cancer surgery, and can be used in patients that have received fluorescent imaging contrast agents with the appropriate optical characteristics.

1.2. Intended Use/indication for use – PD G 506 A

PD G 506 A as an optical imaging agent for real-time visualization of malignant tissue during breast conserving surgery (lumpectomy, partial mastectomy) for breast cancer.

1.3. Clinical Need

Breast conserving surgery (BCS) is performed on patients with breast cancer to resect and completely remove the primary malignancy while conserving as much of the surrounding normal tissue as possible. Currently, surgeons rely on a multitude of methods to assess the adequacy of tissue margins intra-operatively including visual assessment and palpation, specimen radiology, intraoperative ultrasound and intraoperative histopathology. There is no consensus on intraoperative resection adequacy and definitive margin assessment requires histopathological assessment, which is not real-time or practical in the intra-operative setting. Despite intra-operative measures to obtain clean margins in BCS, the need for re-excision via a subsequent surgery is not uncommon.

Re-excisions increase poor cosmesis, complications, discomfort, stress, adjuvant delay, medical costs and risk of local recurrence. Re-excisions due to final positive margins also increase the risk of disease local recurrence and decrease disease-specific survival. Optimizing surgery to improve resection guidance and positive margin assessment during initial BCS would be highly impactful, leading to a decreased need for subsequent surgeries.

In a number of clinical trials, ALA a non-fluorescent non-protein amino acid that is converted into the fluorophore protoporphyrin IX (PpIX) as part of the heme biosynthesis pathway and preferentially accumulates in malignant tissue has been administered orally for the purpose of fluorescence-based imaging of a variety of other cancer types such as rectal carcinomas, malignant gliomas, and palpable breast tumours.

Optimizing surgery with the use of ALA and an appropriate Fluorescence Imaging device to improve resection guidance and positive margin assessment during initial BCS would be highly impactful, leading to a decreased need for subsequent surgeries.

1.4. Principles of Operation

The inability to differentiate tissues of interest during surgical procedures represents a challenge for surgeons. For example, during surgical resection of solid tumors, visualization of cancer in the resected

tissue specimens and surgical cavity, beyond what can be visualized based on conventional surgical and imaging approaches, would provide surgeons with clinically useful real-time information. In patients undergoing breast conserving surgery, the presence of cancer in the margin of the resected lumpectomy and/or in the surgical cavity that is undetected by standard of care is a significant clinical challenge for surgeons and pathologists, and a risk to patients. The Eagle V1.2 Imaging System, when used in combination a cancer-specific contrast agent, can address these challenges by enabling real-time fluorescence visualization of otherwise occult cancerous tissue.

Using blue-violet light excitation (405 nm), the Eagle V1.2 Imaging System can visualize protoporphyrin IX (PpIX) fluorescence emitted by cancer cells in patients who have received aminolevulinic acid (ALA), a non-fluorescent prodrug contrast agent, prior to surgery [1]. Metabolism of ALA in the body leads to the selective accumulation of PpIX in cancer cells. Under the blue-violet excitation light emitted by the Eagle V1.2 Imaging System, the red PpIX fluorescence from cancer cells is detected simultaneously against background normal tissues (which do not produce significant levels of PpIX) autofluorescence thereby producing a composite fluorescence image (or video) in which PpIX fluorescent cancer cells and tissues appear red in color in contrast to healthy surrounding tissues comprised primarily of connective tissue, which appear predominantly green in color; noting that adipose tissue can appear dull-brown in color in fluorescence images of breast tissues.

1.4.1. ALA and Protoporphyrin (PpIX) Production

The ALA-induced accumulation of PpIX in cancer cells is what enables the Eagle V1.2 Imaging System to visualize malignant tissues. The following section describes PpIX synthesis in malignant and healthy tissues and how exogenous administration of ALA leads to selective accumulation of PpIX in cancer cells thereby producing fluorescence contrast between cancer cells and surrounding healthy tissues using the Eagle V1.2 Imaging System.

ALA is a naturally occurring, endogenous substance, which belongs to the group of sensitizers used in photodynamic diagnosis. It is the first compound in the heme synthesis pathway. Heme biosynthesis begins within the mitochondrion, where ALA synthase catalyzes the condensation of succinyl-CoA and glycine to form ALA. Aminolevulinic acid dehydratase (ALAD) condenses 2 molecules of ALA to form the monopyrrole PBG. PBG deaminase catalyzes the polymerization of 4 molecules of PBG to hydroxymethylbilane. Hydroxymethylbilane is further metabolized to uroporphyrinogen I and III (by uroporphyrinogen cosynthase). Uroporphyrinogen decarboxylase sequentially removes a carboxylic group from the acetic side chains of each of the pyrrole rings to yield coproporphyrinogen. Coproporphyrinogen oxidase removes a carboxyl group from the propionic groups on 2 of the pyrrole rings to yield protoporphyrinogen IX. Protoporphyrinogen oxidase forms PpIX by removing 6 hydrogen atoms from protoporphyrinogen IX. Finally, ferrochelatase mediates the insertion of ferrous iron into the porphyrin macrocycle, forming heme. Heme biosynthesis is regulated by a negative feedback loop in which ALA synthase mitochondrial transport is inhibited by heme. Administration of excess exogenous ALA avoids the negative feedback control, and accumulation of PpIX occurs in target tissue.

Coproporphyrinogen oxidase removes a carboxyl group from the propionic groups on 2 of the pyrrole rings to yield protoporphyrinogen IX. Protoporphyrinogen oxidase forms PpIX by removing 6 hydrogen atoms from protoporphyrinogen IX. Finally, ferrochelatase mediates the insertion of ferrous iron into the porphyrin macrocycle, forming heme. Heme biosynthesis is regulated by a negative feedback loop in which ALA synthase mitochondrial transport is inhibited by heme. Administration of excess exogenous ALA avoids the negative feedback control, and accumulation of PpIX occurs in target tissue.

ALA HCl for oral solution is usually administered 3 hours (range 2 to 4 hours) before anesthesia prior to surgery. The investigational drug PD G 506 A is 1.5 g ALA hydrochloride (HCl) granules (chemical name: 5-

amino-4-oxo-pentanoic acid hydrochloride) for oral solution. When reconstituted in water, it can be administered exogenously to overload the cellular porphyrin metabolism and generate a build-up of PpIX.

When ALA HCl is administered exogenously by oral route, the abundantly produced red fluorescent PpIX cannot be quickly converted to its final product, heme, by the enzyme ferrochelatase and therefore accumulates in cells. PpIX accumulates in cancer cells to a higher extent than in healthy cells. This is primarily attributed to differences in the overall metabolic activity, increased ALA uptake, and a relative deficiency in activity of ferrochelatase and other heme biosynthesis enzymes in cancer cells. The preferential and selective accumulation of PpIX in cancer cells, relative to healthy cells, provides an opportunity to visualize PpIX fluorescence in cancer cells in real-time during breast cancer surgery (Figure 1).

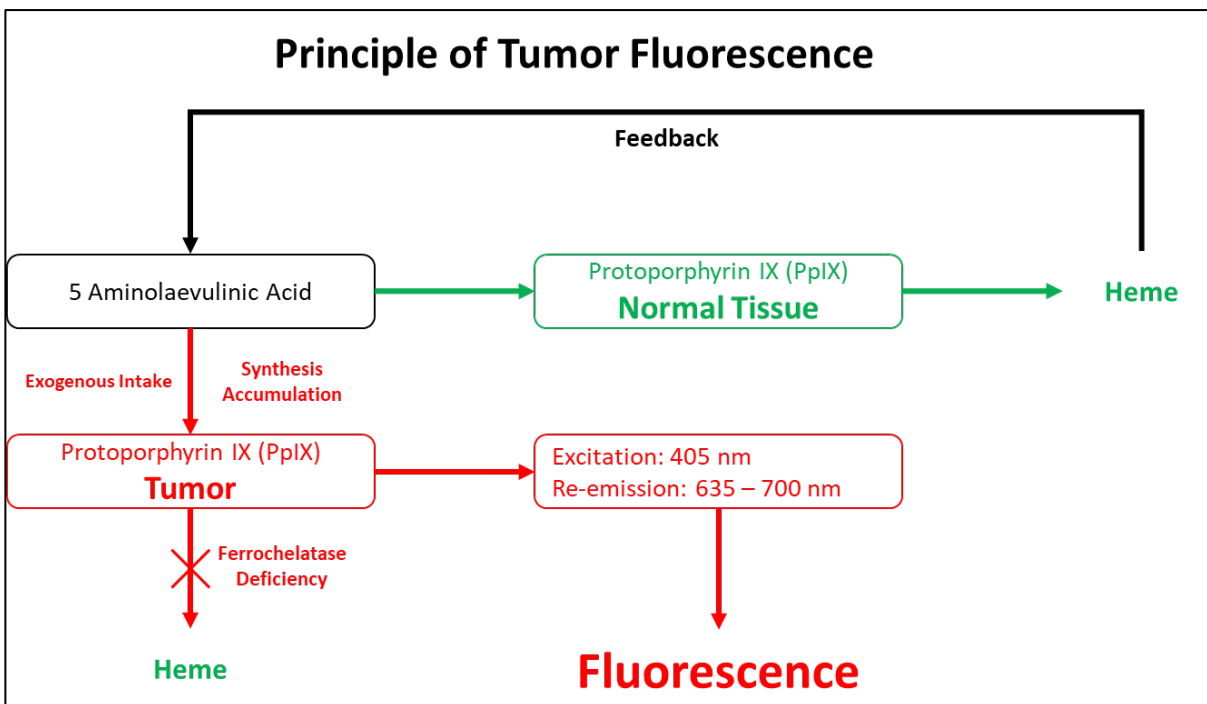


Figure 1 – Principles of Fluorescence

1.4.2. Fluorescence Imaging

The Eagle V1.2 Imaging System is a handheld intraoperative white light and Fluorescence Imaging device and accessories intended to be used during surgical procedures. Fluorescence imaging is a type of optical imaging technique used to visualize and document biological processes or structures. Fluorescence imaging relies on exogenous or endogenous fluorophores, molecules that emit light of a longer wavelength when exposed to light of a different (shorter) wavelength. When a fluorophore absorbs light, the energy of the molecule is briefly raised to higher excited states. The subsequent return to the ground state results in the emission of fluorescent light. The emitted fluorescent light, resulting from the absorbed photon of energy has a specific wavelength and can be detected and measured. Typically, Fluorescence Imaging is performed using steady-state fluorescence, where fluorophores are excited by a constant source of light, emit fluorescence, and the emitted fluorescent photons, or intensity, are detected as a function of wavelength. The Eagle V1.2 Imaging System uses steady-state Fluorescence Imaging. The main components a Fluorescence Imaging system are the following:

The main components a Fluorescence Imaging system are the following:

1. **Fluorophores:** Fluorescent molecules that can re-emit light upon light excitation.
2. **Excitation source:** Illumination source with a specific wavelength of light which is absorbed by the fluorophores, exciting the molecules and resulting in the emission of light at a longer wavelength. Emitted fluorescence can span ultraviolet, visible light, near-infrared light and infrared and beyond.
3. **Optical filter(s):** Restricts the amount of reflected and scattered excitation light, emitted fluorescent light and ambient light reaching the detector as well as the amount of excitation light reaching the imaging target during Fluorescence Imaging.
4. **Detector:** An instrument or sensor that detects and conveys (optical) information used to make an image.
5. **Display:** An output device that translates captured information and presents in a visual form.

1.4.2.1. Eagle V1.2 Fluorescence Imaging System

The following diagram (Figure 2) depicts the system architecture of the Eagle V1.2 Fluorescence Imaging System.

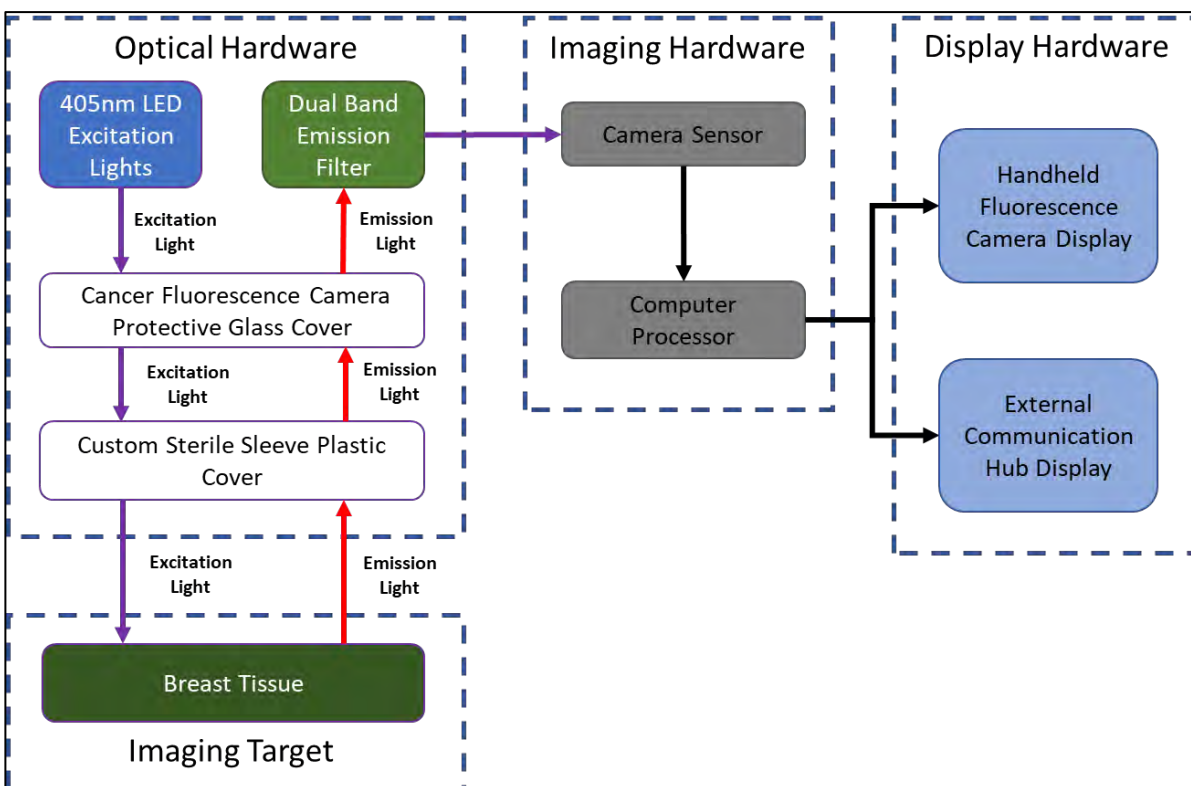


Figure 2 – Eagle V1.2 Imaging System

1.4.2.2. Fluorophores – Protoporphyrin IX (PpIX) and Connective Tissue

PpIX is a fluorophore that accumulates in cancer cells when a supply of exogenous ALA is supplied. When excited by 405 nm, PpIX emits red fluorescent light with a peak wavelength of approximately 635 nm. This red fluorescence can be used to visualize and locate the presence of PpIX fluorescent cancerous tissue. See (Figure 11). In addition, tissue autofluorescence is also emitted under 405 nm excitation. In breast tissue, autofluorescence is typically green in color, largely attributed to autofluorescence of connective tissues and redox cofactors such as nicotinamide adenine dinucleotide (NADH) and flavin adenine dinucleotide (FAD). The Eagle V1.2 Imaging System captures both the background green tissue autofluorescence and the PpIX red fluorescence simultaneously and in real-time.

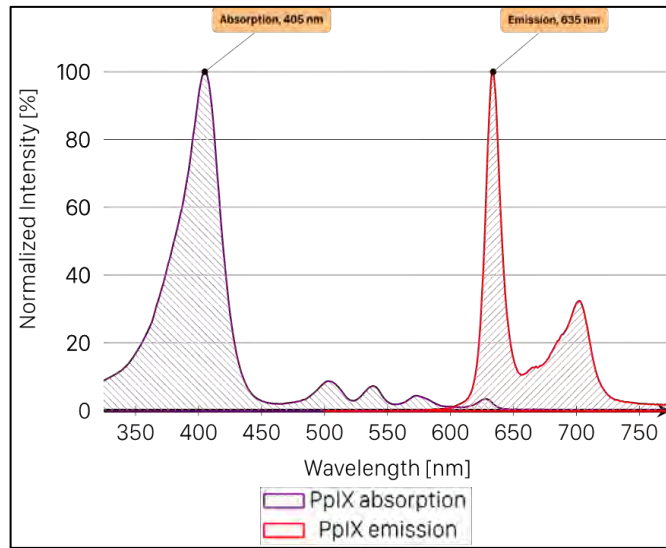


Figure 3 – PpIX Excitation and Emission

1.4.2.3. Excitation Source – 405 nm Illumination

PpIX has maximum light absorption from blue-violet light at 405 nm (Figure 12). The Eagle V1.2 Imaging System utilizes safe blue-violet (peak: 405-410 nm) emitting LEDs and an excitation filter to emit narrow wavelength band centered around 405 nm to induce maximum PpIX fluorescence as well as background tissue autofluorescence (Figure 4).

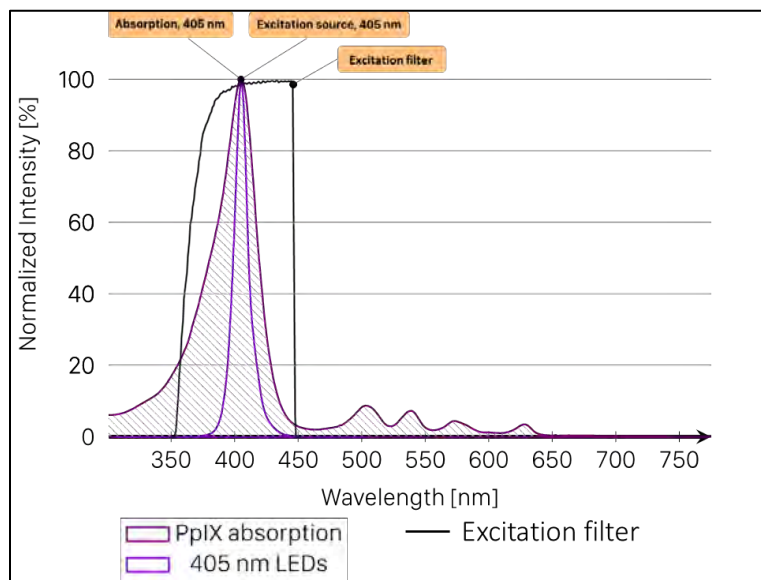


Figure 4 – Excitation Light

1.4.2.4. Optical Filters – Dual Bandpass Filter

In order to effectively visualize and image PpIX fluorescence, the 405 nm excitation light must be blocked from the imaging sensor. To accomplish this, a custom dual bandpass emission filter is placed in front of the camera image sensor thus preventing reflected or backscattered excitation light as well ambient room lighting from entering the image sensor. The two wavelength bands of fluorescence emission transmitted to the device's imaging sensor are green (500 – 545 nm) and red (600 – 660 nm) (Figure 5).

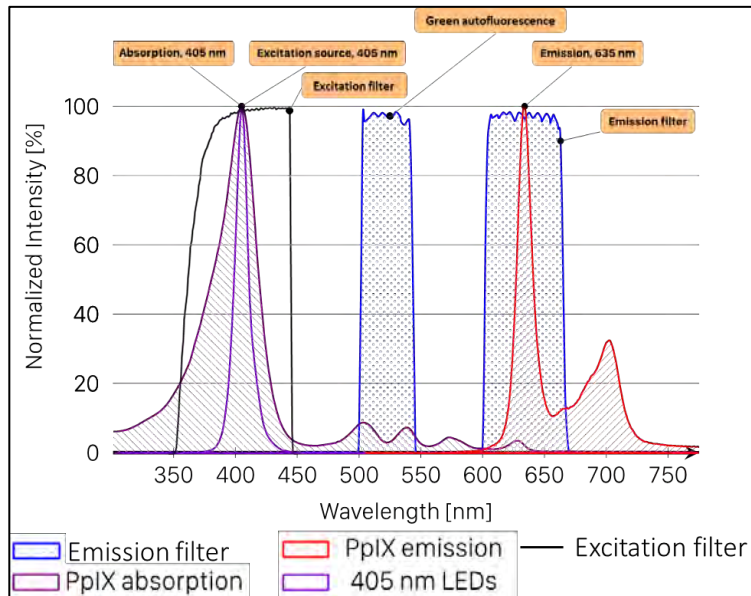


Figure 5 – Dual Bandpass Filter

First, the red bandpass region is for visualizing the red fluorescence emitted from fluorophores such as PpIX. Second, the green bandpass region is for visualizing green autofluorescence emitted from components of healthy tissue such as collagen and elastin in connective tissue and redox cofactors NADH and FAD. The addition of the green fluorescence channel is to (visually) contrast and accentuate the red fluorescence produced by the accumulation of PpIX in cancerous cells and differentiate the PpIX fluorescent cells from healthy tissue, seen as green, in real-time.

1.4.2.5. Detector – C-MOS Camera Sensor

Once fluorescence is induced, an image sensor is required to detect this light information from the fluorescence source and generate an image for real-time visualization and documentation. The Eagle V1.2 Imaging System utilizes a C-MOS (Complementary Metal Oxide Semiconductor) sensor as a detector.

1.4.2.6. Display

Finally, colour display screens present all the captured fluorescence information in a real-time visual form to the user e.g. images or video. The Eagle V1.2 Imaging System uses two forms of display, a colour active matrix organic light emitting diode (AMOLED) display on the Handheld Fluorescence Camera (HFC) and an external colour liquid crystal display (LCD) monitor, which is larger for viewing by multiple members of the surgical team.

1.1. Regulatory Information

The Eagle V1.2 Imaging System has received the following authorizations in order to conduct clinical trial SBI-CIP-20-002 in accordance with applicable United States and Canadian regulatory requirements per FDA and Health Canada:

Table 1 Investigational Authorizations		
Investigational Product	USA	Canada
Drug Product: <i>PD G 506 A</i>	In accordance with <u>21 CFR PART 312 INVESTIGATIONAL NEW DRUG APPLICATION</u> , an IND was submitted to the FDA to approve <i>PD G 506 A</i> drug use in clinical trial <i>SBI-CIP 20-002</i>	In accordance with <u>Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications</u> a CTA was submitted to Health Canada to approve <i>PD G 506 A</i> drug use in clinical trial <i>SBI-CIP 20-002</i>
Imaging Device: <i>Eagle V1.2 Imaging System</i>	In accordance with <u>21 CFR PART 812 INVESTIGATIONAL DEVICE EXEMPTIONS</u> , an IDE is not required to approve <i>Eagle V1.2 Imaging System</i> for use in clinical trial <i>SBI-CIP 20-002</i>	In accordance with <u>Guidance Document Applications for Medical Device Investigational Testing Authorizations</u> an ITA was submitted to Health Canada to approve <i>Eagle V1.2 Imaging System</i> use in clinical trial <i>SBI-CIP 20-002</i>

1.2. Terminology Used

Table 2 Terminology Used	
Term / Acronym	Definition / Meaning
EtO	EtO Sterilization is a low-temperature process that uses Ethylene Oxide gas to reduce the level of infectious agents.
Tx	Transmit
Rx	Receive
ALA	aminolevulinic acid
P/N	Part Number
GB	Gigabyte
Type-C	USB-C (formally known as USB Type-C) is a 24-pin USB connector system with a rotationally symmetrical connector
Cm	centimeter

2. Eagle V1.2 Imaging System Contents

Table 3 Eagle V1.2 Imaging System

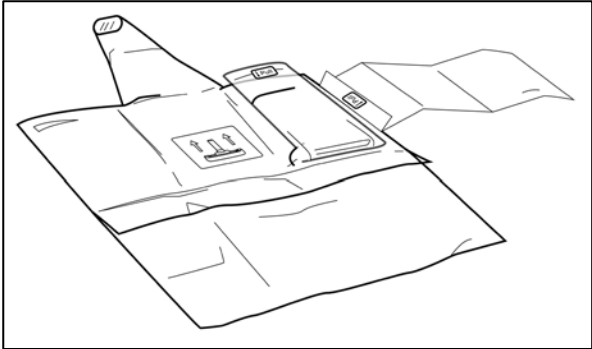
Component	Depiction	Part Number (P/N)
HCF – Handheld Fluorescence Camera		P/N 10055 Refer to Section 2.1 and Section 6.2 for full details.
CSS – Custom Sterile Sleeve		P/N 10180 Refer to Section 2.2.1 and Section 6.3.1 for full details.
ECH – External Communication Hub		P/N 10206 Refer to Section 2.2.2 and Section 6.3.2 for full details.

Table 3 Eagle V1.2 Imaging System

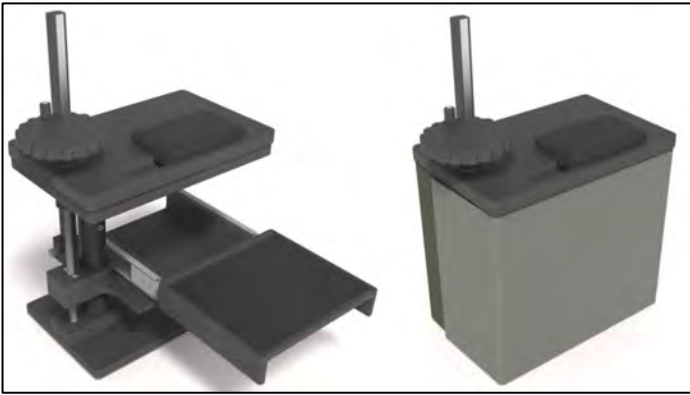
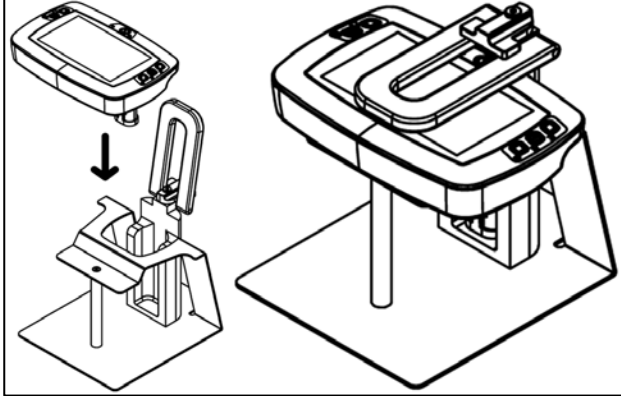
Component	Depiction	Part Number (P/N)
DIS – Dark Imaging Sheet		P/N 10171 Refer to Section 2.2.3 and Section 6.3.3 for full details.
DIB – Dark Imaging Box		P/N 10117 Refer to Section 2.2.4 and Section 6.3.4 for full details.
CCD – Contact Charging Device		P/N 10066 Refer to Section 2.2.5 and Section 6.3.5 for full details.

Table 3 Eagle V1.2 Imaging System

Component	Depiction	Part Number (P/N)
PSC – Protective Storage Cradle		P/N 10095 Refer to Section 2.2.6 and Section 6.3.6 for full details.

2.1. HCF – Handheld Fluorescence Camera

The Handheld Fluorescence Camera (HFC) is the primary element of the Eagle V1.2 Imaging System.

The HFC is a portable, handheld and battery-operated imaging device, equipped with an AMOLED color display screen, and an optical head integrated with excitation and emissions optics to enter and image the surgical cavity.

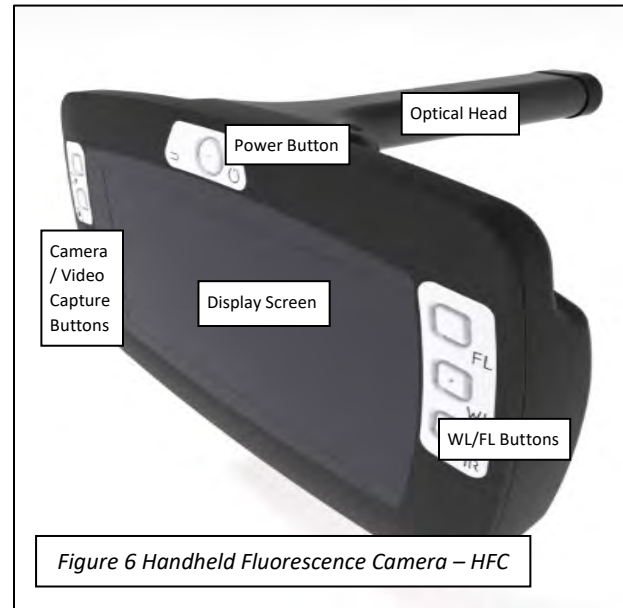
The optical head contains an ambient light sensor to detect ambient lighting conditions described in 6.2.2.2.5.1, and a range finder to detect imaging range as described in section 6.2.2.2.2.

Located in the center above the display screen, the HFC has a single power  button to turn the device on, and to sleep or wake the display screen once powered on. Refer to section 6.2.1.1 for full details.

Located on the left of the display screen, the HFC has a camera  and video  button, used to capture and save images and videos respectively. Refer to section 6.2.1 for full details.

Located on the right of the display screen, the HFC has White Light  and Fluorescence  buttons, to enable white light LEDs for White Light Imaging or blue-violet LEDs for Fluorescence imaging, respectively. For full details refer to section 6.2.2.2.4 for White Light Imaging and section 6.2.2.2.5 for Fluorescence Imaging.

The HFC lithium ion battery is rechargeable using the Contact Charging Device (CCD) described in Section 2.2.5 and Section 6.3.5.



2.1.1. HFC Optical Head

The HFC optical head shown in Figure 7 integrates two camera sensors, one dedicated for White Light Imaging and one dedicated for Fluorescence Imaging. During White Light Imaging described in section 6.2.2.2.4, two white light LEDs illuminate the field of view. During Fluorescence Imaging described in section 6.2.2.2.5, four blue-violet light LEDs illuminate the field of view.

2.1.1.1. Emissions Filter

A custom infrared emission filter (95% Transmission of wavelengths 420 – 700 nm and 815 – 900 nm and blocking all other NIR light >700nm) placed in front of the white light camera sensor ensures only light in the visible spectrum is captured.

A custom optical emission filter (>95% transmission of wavelengths 500 – 545 nm and 600 – 665 nm and blocking NIR light >700nm) placed in front of the fluorescence camera ensures only the resulting red fluorescence emission from PpIX in malignant tissues, and green fluorescence emission from connective tissues and stroma are captured.

2.1.1.2. Range Finder

The Range Finder positioned in the center of the optical head measures the distance of the optical head from the imaging target. The software user interface controlled by the HFC Display Screen (Section 6.2.1) instructs the operator to move closer or move away from the imaging target to achieve optimal imaging ranges. Refer to section 6.2.2.2.1 for full details on the Range Finder.

2.1.1.3. Ambient Light Sensor

The Ambient Light Sensor positioned in the bottom left corner of the HFC Optical Head measures the ambient light level in the imaging environment. The software user interface (Section 6.2.2) controlled by HFC Display Screen (Section 6.2.1) instructs the operator when correct ambient lighting conditions are achieved for Fluorescence Imaging (Section 6.2.2.2.5). Refer to Section 6.2.2.2.5.1 for full details on the Ambient Light Sensor.

2.1.1.4. Temperature Sensor

The temperature sensor continually monitors the temperature of the optical head, ensuring the HFC does not overheat and its operating parameters continually remain in tolerance. During imaging (Section 6.2.2.2) the Software User Interface (Section 6.2.2) controlled by the HFC Display Screen (Section 6.2.1) displays a temperature gauge to communicate device temperature to the operator. Refer to section 6.2.2.2.1 for full details on the temperature gauge.

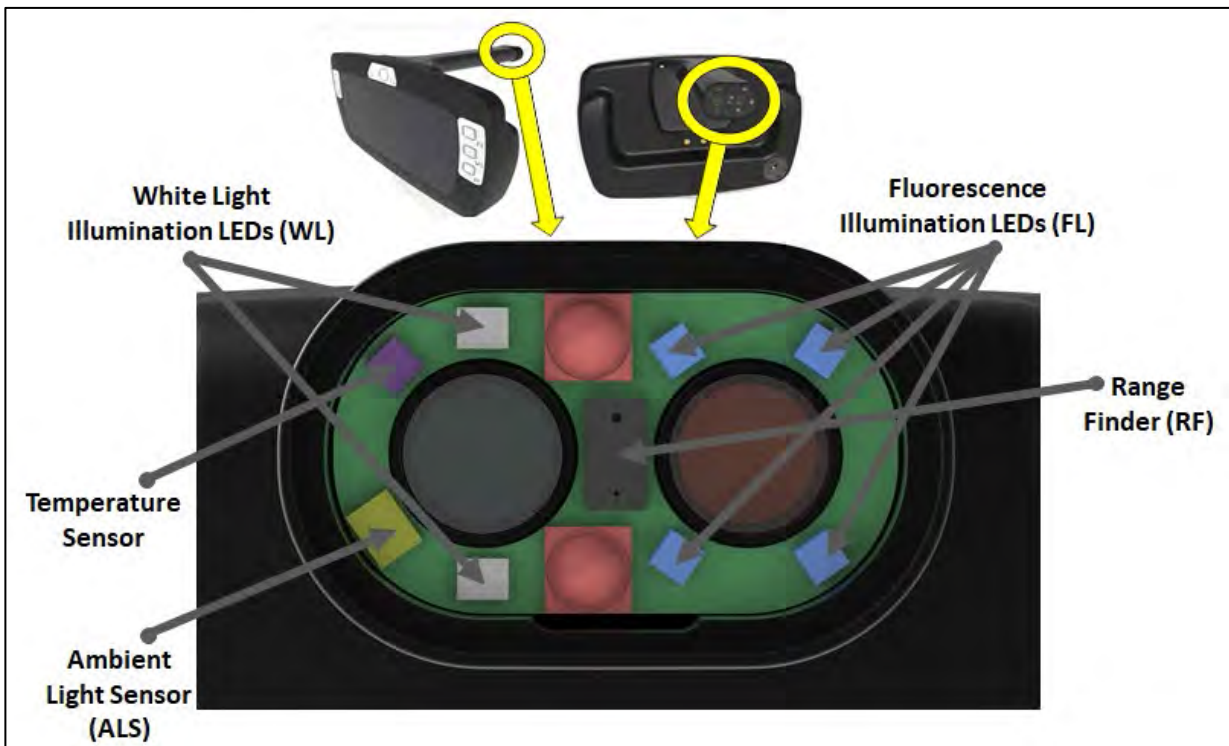


Figure 7 HFC Optical Head

2.2. Accessories and Consumables

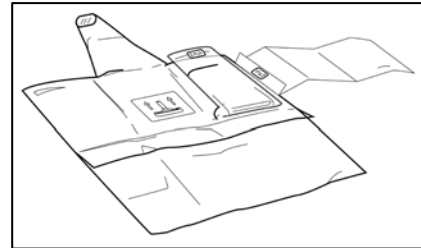
2.2.1. CSS – Custom Sterile Sleeve

The Custom Sterile Sleeve is a single use, ethylene-oxide (EtO) sterilized sheath to entirely cover the Handheld Fluorescence Camera while imaging surgical cavities. Refer to Section 6.3.1 for CSS Instructions for Use.

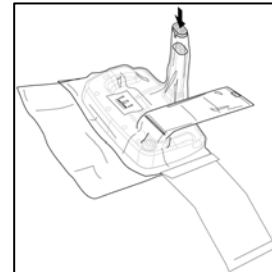
Table 4 CSS Features

1. The single use CSS is made from a clear, biocompatible plastic material that has been sterilized using EtO.

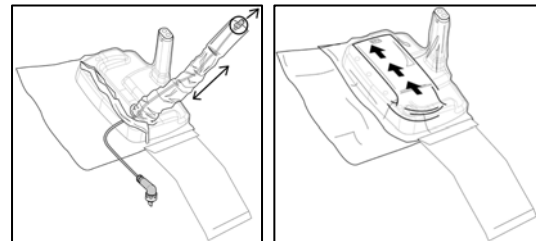
The CSS is shaped to contour the Handheld Fluorescence Camera.



2. The portion of the CSS fitting over the HFC optical head is equipped with an optical window ensuring the optical head is protected during imaging while maintaining the HFC optical performance parameters.



3. The CSS is designed to accommodate ECH wired configuration or ECH wireless configuration.
When ECH wired configuration is used (see Section 6.3.2.3), the HFC USB Cable is sheathed using the CSS 6-foot-long telescopic HFC USB Cable Cover.
When ECH wireless configuration is used (see Section 6.3.2.2), the telescopic-folded HFC USB Cable Cover is secured by the CSS Tape.



4. The CSS Tape is exposed by removing its adhesive backing with the pull tab, and laid across the sheathed HFC to seal and close the CSS (see Section 6.3.1).

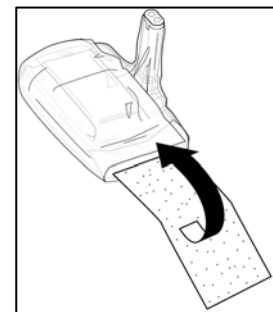
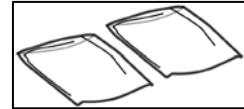
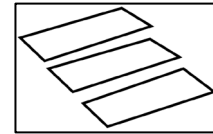


Table 4 CSS Features

- Each CSS is accompanied by 2 small sterile bags to handle the HFC USB Hatch
5. with sterile technique (see Section 6.3.1) while establishing ECH wireless configuration (Section 6.3.2.2) or ECH wired configuration (Section 6.3.2.3).



- Each CSS is accompanied by 3 pieces of tape. Tape is used to secure the sterile bag around the HFC USB Cable for ECH Wireless Configuration (see Section 6.3.2.2), and to secure the HFC USB Cable for both ECH Wireless and Wired Configuration (see Section 6.3.2.3).
- 6.



7. Refer to Section 4.2 for details on the CSS device label.
8. The CSS is a single use device. The CSS cannot be re-sterilized.

2.2.2. ECH – External Communication Hub

Intended to cast the Handheld Fluorescence Camera's display through a wired or wireless connection on to the ECH Display monitor, the External Communication Hub (ECH) is comprised of

1. ECH Display Monitor
2. ECH PC – A Small Form Factor Computer with encrypted USB Flash Drive (32 Gb) and Numeric Pad
3. ECH Router
4. ECH DVI Link Assembly, and ECH USB Cable
5. ECH Power Supplies and Extension Cables
6. ECH Power Bar
7. Cart (ECH Cart)

The External Communication Hub also facilitates the transfer/export of saved images from the Handheld Fluorescence Camera to external media. Refer to Section 6.3.2 for ECH Instructions for Use.

Table 5 ECH Features

1. The ECH Display Monitor casts the Handheld Fluorescence Camera's display.



2. The ECH PC facilitates HFC display casting and saving data stored on the HFC as a backup.



Table 5 ECH Features

3. The ECH backs up all captured images and videos from the HFC onto the encrypted USB flash drive.



4. The ECH Numeric Pad allows the operator to enter a PIN to login and setup the ECH.

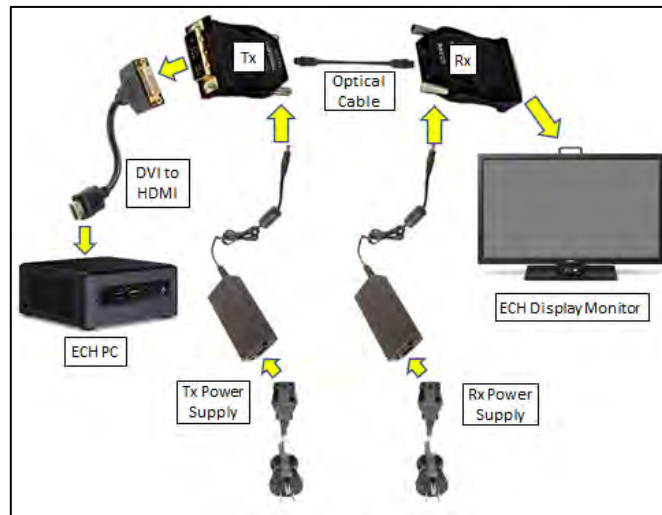


5. When connected to the ECH PC using an ethernet cable, the ECH Router allows HFC display casting wirelessly. Refer to Section 6.3.2.1 for details on ECH Wireless Configuration.



6. The ECH DVI Link Assembly sends HFC imaging data received by the ECH PC to the ECH Display Monitor. The ECH DVI Link Assembly is comprised of

- DVI Link Transmitter (Tx)
- DVI Link Receiver (Rx)
- Tx Power Supply
- Rx Power Supply
- Optical Cable
- DVI to HDMI Cable



7. The HFC USB Cable with ECH Link Cable connects the HFC to the ECH PC for ECH Wired Connection. See Section 6.3.2.3 for details on ECH Wired Connection.

To establish the ECH Wireless Configuration per Section 6.3.2.2, the HFC USB Cable is connected to the ECH PC provisionally.

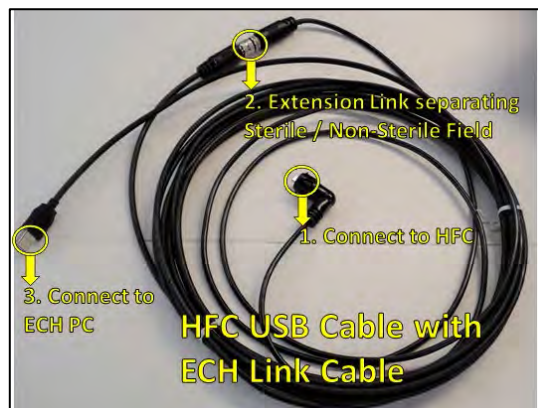


Table 5 ECH Features

A maximum of 5 power supplies connect to the ECH Power Bar:

- 8.**
- 1) ECH Display Monitor
 - 2) ECH PC
 - 3) ECH DVI Link Rx
 - 4) ECH DVI Link Tx
 - 5) ECH Router



9.

The ECH portable Cart holds and secures all ECH components and is accompanied by a 15-foot-long Hospital Medical Power Extension Cord.



10. Refer to Section 4.3 for details on the ECH device label.

11. The ECH can be cleaned and disinfected with Intermediate Level Disinfection wipes in accordance with Section 5.2.

2.2.3. DIS – Dark Imaging Sheet

The DIS is a single use, ethylene-oxide (EtO) sterilized non-fluorescent plastic sheet providing a consistent and standardized surface background for Fluorescence Imaging of excised tissues in the sterile field, or inside the Dark Imaging Box (Section 2.2.4 and Section 6.3.4). Refer to Section 6.3.3 for DIS Instructions for Use.

Table 6 DIS Features

1. The DIS measures 10.5” (inches) long by 8.3” (inches) wide.

The rigid DIS is made from a black non-reflective, non-fluorescent, non-absorbent material to prevent artifacts and provide a consistent and standardized surface background for Fluorescence Imaging. The durable non-creasing material prevents contamination of specimens placed on it.



3. The bottom of the DIS is labeled with “*This Side Down / Ce Côté En Bas*” to indicate that the bottom of the DIS is not intended for placing specimen.

THIS SIDE DOWN
CE CÔTÉ EN BAS

4. The DIS can be used alone in the sterile field, or together inside the Dark Imaging Box per Section 6.3.4.



5. Refer to Section 4.4 for details on the DIS device label.
6. The DIS is a single use device. The DIS cannot be re-sterilized.

2.2.4. DIB – Dark Imaging Box

The Dark Imaging Box (DIB) is designed to cradle the Handheld Fluorescent Camera in a fixed position providing controlled and consistent conditions for imaging tissue specimens. The Dark Imaging Sheet is required to be placed on the Dark Imaging Box Tray per 6.3.3. Refer to Section 6.3.4 for DIB Instructions for Use.

Table 7 DIB Features

1. Made from stainless steel and aluminium, the Dark Imaging Box has a wide base to stabilize the platform during imaging.



2. The DIB Cradle at the top of the Dark Imaging Box secures the Handheld Fluorescent Camera in ECH Wireless (Section 6.3.2.2) or ECH Wired configuration (Section 6.3.2.3).



Table 7 DIB Features

Using the DIB Wheel, the DIB Imaging Platform is vertically adjustable to achieve correct imaging ranges as guided by the Range Finder per Section 6.2.2.2.2.

3. The DIB ruler indicates the distance in cm (centimeters) between the tip of the HFC Optical Head and the DIB Imaging Platform.



The DIB Tray is a sliding removeable tray for easy handling and orientation of imaging specimen, designed with a recess to secure the Dark Imaging Sheet into position per Section 6.3.3.

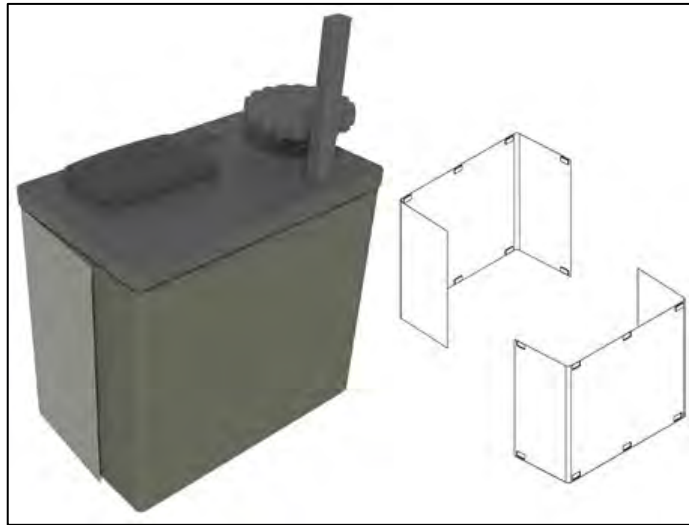
- 4.



Table 7 DIB Features

The single use disposable DIB Covers enclose the specimen for a controlled and consistent imaging environment.

5. Magnets embedded around the top and bottom of the DIB align with the metal tabs on the DIB Covers to lock them in place.



6. Refer to Section 4.5 for details on the DIB device label.

7. The DIB can be cleaned and disinfected with Intermediate Level Disinfection wipes in accordance with Section 5.3.

2.2.5. CCD – Contact Charging Device

The Contact Charging Device (CCD) is a charging cradle for the Handheld Fluorescence Camera, providing a secure surface for the HFC to rest while charging. Refer to Section 6.3.5 for CCD Instructions for Use.

Table 8 Contact Charging Device Features

1. The Contact Charging Device is powered by the CCD Power Supply, a USB Type-C power supply plugged into the back side of the CCD.



2. When plugged into the USB Type-C power supply, the front side of the Contact Charging Device has a white LED that illuminates.

Two (2) charging pins on the top side of the CCD mate with the HFC.



Table 8 Contact Charging Device Features

The HFC is charged by placing it in the Contact Charging Device.

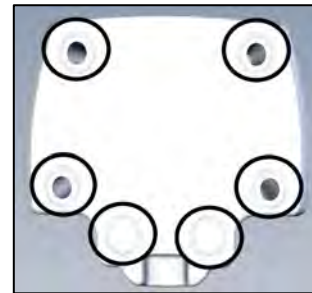
The retainer guard on the back side of the CCD secures the HFC

3. while charging.

The HFC battery begins charging when the HFC makes contact with the two charging pins on the top side of the CCD.



- 4.** The bottom side of the Contact Charging Device has 6 anti-slip rubber feet to ensure it sits securely on a flat surface positioned in the non-sterile area of the imaging environment.



- 5.** Refer to Section 4.6 for details on the CCD device label.

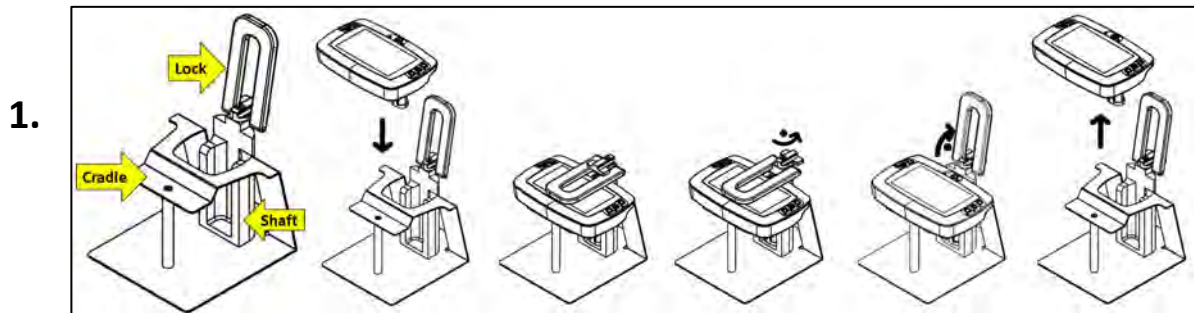
- 6.** The CCD can be cleaned and disinfected with Intermediate Level Disinfection wipes in accordance with Section 5.3.

2.2.6. PSC – Protective Storage Cradle

The Protective Storage Cradle is designed to Safeguard the Handheld Fluorescence Camera and optical head when not in use (including during a surgical procedure) or during transportation. Refer to Section 6.3.6 for PSC Instructions for Use.

Table 9 Protective Storage Cradle Features

Made from stainless steel and acetal, the PSC has a cradle to rest the body of the HFC, a protective shaft to safeguard the HFC optical head, and a lock to secure the HFC once in position.



2. Refer to Section 4.7 for details on the PSC device label.

3. The PSC can be cleaned and steam sterilized in accordance with Section 5.5.

3. Safety Information

This section is intended to provide users with safety information in order to operate the device safely and as intended.

3.1. Certifications

3.1.1. HFC – Handheld Fluorescence Camera

- *ISO 10993-1:2018* Evaluation of Medical Devices – Part 1: Evaluation of and Testing Within a Risk Management Plan

- *ISO 17664:2017* Processing of Health Care Products – Information to be Provided by the Medical Device Manufacturer for the processing of Medical Devices

- *IEC 60601-1:2005* Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance

- *IEC 60601-1-6:2010* Medical Electrical Equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability

- *IEC 62366-1:2015* Medical Devices – Part 1: Application of Usability Engineering to Medical Devices

- *IEC 60601-2-18:2019* Medical Electrical Equipment – Part 2-18: Requirements for the Basic Safety and Essential Performance of Endoscopic Equipment

- *IEC 60601-1-2:2014* Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests

- *IEC 62471* Photobiological Safety of Lamps and Lamp Systems

- *IEC 62133-2* Secondary Cells and batteries containing alkaline or other non-acid electrolytes: Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems

3.1.2. CSS – Custom Sterile Sleeve

- *ISO 10993-1:2018* Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process

- *ISO 11135:2014* Sterilization of Health Care Products -Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices

3.1.3. ECH – External Communications Hub

- *ISO 17664:2017* Processing of Health Care Products – Information to be Provided by the Medical Device Manufacturer for the processing of Medical Devices

-
- *IEC 60601-1* Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
-

- *IEC 60601-1-2* Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
-

3.1.4. DIS – Dark Imaging Sheet

- *ISO 11135:2014* Sterilization of Health Care Products -Ethylene Oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices
-

3.1.5. DIB – Dark Imaging Box

Not Applicable.

3.1.6. CCD – Contact Charging Device

- *IEC 60601-1* Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
-
- *IEC 60601-1-2* Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
-

3.1.7. PSC – Protective Storage Cradle

- *ISO 17664:2017* Processing of Health Care Products – Information to be Provided by the Medical Device Manufacturer for the processing of Medical Devices
-
- *ISO 17665-1:2006* Sterilization of Health Care Products – Moist Heat – Part 1: Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices
-

3.2. Classification

In accordance with [21 CFR PART 312 INVESTIGATIONAL NEW DRUG APPLICATION](#), an IND was submitted to the FDA to approve PD G 506 A drug use in clinical trial SBI-CIP 20-002.

In accordance with [Guidance Document for Clinical Trial Sponsors: Clinical Trial Applications](#) a CTA was submitted to Health Canada to approve PD G 506 A drug use in clinical trial SBI-CIP 20-002.

In accordance with [Guidance Document Applications for Medical Device Investigational Testing Authorizations](#) an ITA was submitted to Health Canada to approve Eagle V1.2 Imaging System use in clinical trial SBI-CIP 20-002.

The Handheld Fluorescence Camera is intended for use only by qualified investigators in accordance with SBI-CIP-20-002.

The Handheld Fluorescence Camera is classified as “IP67” for fluid ingress, and has protection against exposure to liquids.

The Eagle V1.2 Imaging System complies with Part 15 of the FCC Rules (USA) and ICES-3(B)/NMB-3(B) (Canada).

Handheld Fluorescence Camera has an operational duty cycle of 5 minutes *on*, 15 minutes *off*.

3.2.1. Federal Communication Interference Statement

We SBI ALApharma, 305-123 Edward St, Toronto, ON, M5G 1E2, Canada, 289-800-9455, declare under our sole responsibility that the Handheld Fluorescence Camera complies with Part 15 Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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

WARNING: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and radiates radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications.

3.2.2. Industry Canada Statements

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

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

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

3.2.3. Electromagnetic Compatibility

The Handheld Fluorescence Camera meets the requirements of Safety EMC Testing per IEC 60601-1-2:2014 4th Edition / EN 60601-1-2:2015. 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 Handheld Fluorescence Camera.



Warning

The device is equipped with sensitive electronic components. While imaging, avoid strong electrical or electromagnetic fields, e.g. mobile phones, microwave ovens, etc.; or it may lead to temporary imaging error or inaccuracy.

To avoid the risk of increased electromagnetic emissions or decreased immunity from such emissions, use only accessories, including power cables, recommended by *SBI ALApharma Canada Inc.* Connection of accessories not recommended by *SBI ALApharma Canada Inc.* will void product warranty and could result in malfunctioning of the HFC or other devices located in the area.

Additionally, user of the HFC can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HFC as recommended in Section 10.

Some RF emitters (e.g. RFID) in the intended environment of use might be concealed. The device could potentially be exposed to fields from these RF emitters without user awareness. Take the following precautions to prevent electromagnetic interference:



Caution

- Maintain a minimum distance between portable and mobile RF communications equipment (transmitters) and the HFC as recommended in Section 10.
- Move to a different environment to image if experiencing imaging artifacts, such as noise or distortion of the image



Note

The emissions characteristics of the HFC make it suitable for use in industrial areas and hospitals (CISPR 11 class A). The HFC is not intended for use in a residential environment and does not comply with IEC 60601-1-11:2015 *General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.*

If you experience imaging artifacts, such as noise or distortion of the image, move to a different environment to image. If problems persist contact *SBI ALApharma Canada Inc.* to troubleshoot the problem.

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

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

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

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

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

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

3.2.4. Radiation Output

The Handheld Fluorescence Camera uses a miniature pulsed laser-based range finder to determine the correct distance between the device and 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

3.3. Warning, 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:

Warnings



Warning

Messages with this heading provide information and actions to take in order to prevent Eagle V1.2 Imaging System safety hazards.

Cautions



Caution

Messages with this heading provide information and actions to take in order to operate Eagle V1.2 Imaging System correctly and prevent misuse.

Notes



Note

Messages with this heading provide information and actions to take in order to increase the user's understanding of Eagle V1.2 Imaging System correctly.

3.3.1. General Warnings

Warning Description



Always observe device labelling which includes this document and device labels. Refer to section 4 for information on all device labels.



Do not use accessories or cables other than those specified in this Instructions for Use. Using unspecified accessories or cables may result in increased emissions or decreased immunity of the Handheld Fluorescence Camera.

Warning Description



Do not connect the Handheld Fluorescence Camera to a power supply using cables that have not been approved by *SBI ALApharma Canada Inc.*



Do not attempt to open, modify, or disassemble the Handheld Fluorescence Camera which is ready for use once unpacked and charged.



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



Do not operate the Handheld Fluorescence Camera in oxygen-rich environments.



Avoid exposing the Handheld Fluorescence Camera to magnetic fields, electrostatic discharge and thermal ignition sources during use.



Do not point the illumination LEDs directly into eyes.



Do not drop the Handheld Fluorescence Camera or subject the HFC to high force impact or shock.



Protect the Handheld Fluorescence Camera by storing it in the Protective Storage Cradle, or in its original shipping package when not in use for prolonged periods of time.



Be aware of surroundings to avoid trip or other hazards when operating the Handheld Fluorescence Camera in a dark environment



Do not use the Handheld Fluorescence Camera or accessories without following appropriate cleaning, disinfection, and sterilization instructions in Section 5.



Follow institutional procedures and processes for handling intraoperative medical equipment.



Follow institutional procedures and processes for sterile technique.



The safety and effectiveness of the Handheld Fluorescence Camera for diagnostic or treatment purposes has not been evaluated.



Do not perform imaging outside of the Handheld Fluorescence Camera's Circle of Interest described in 6.2.2.2.3.



Do not utilize image information outside of the Handheld Fluorescence Camera's Circle of Interest for image interpretation described in Section 6.2.2.2.5.2.

Warning Description



The Handheld Fluorescence Camera utilizes auto-exposure to optimize the exposure settings based on lighting conditions. Images captured on the HFC are relative, not quantitative, and may not represent absolute fluorescence levels.



Avoid strong electrical or electromagnetic fields, e.g. mobile phones, microwave ovens, etc.; which may result in temporary imaging error or inaccuracy.

3.3.2. General Cautions

Caution Description



Reflective objects (e.g. retractors or other metal objects) can produce red light reflections that can appear similar to PpIX Fluorescence.



Sources of ambient light reflecting off of surfaces in the field of view may contaminate HFC images.



Always verify ambient lighting conditions using the Ambient Light Sensor before performing Fluorescence Imaging.



Always respect the Range Finder icons when performing Imaging.



Do not operate the Handheld Fluorescence Camera using eyewear with color tint, polarization, or other factors which may distort the interpretation of colors on acquired images.



The Handheld Fluorescence Camera should not be used by individuals confirmed to be color blind as the typical green and red color information comprising the acquired images may be misinterpreted.



Ensure the optical head is clean prior to imaging. Acquired images may appear distorted, out of focus, or otherwise compromised if the optical head is not clean prior to imaging.



Prior to charging the device, ensure the CFC Power Cable is undamaged before plugging into a wall outlet.



Only use cables and power supplies provided by *SBI ALApharma Canada Inc.* with the Eagle V1.2 Imaging System.



The optical head may get warm after prolonged use. The device will disable activated LEDs (white light or blue-violet light) if device temperature exceeds 41°C or 106°F.

Caution Description

Some RF emitters (e.g. RFID) in the intended use environment may be concealed. The device could potentially be exposed to fields from these RF emitters without user awareness. Take the following precautions to prevent electromagnetic interference:



1. Maintain distance between portable and mobile RF communications equipment (transmitters) and the Handheld Fluorescence Camera
2. Move to a different environment to image if experiencing imaging artifacts, such as noise or distortion of the image

3.3.3. General Note

Note Description



While charging, the device is inoperable with exception to reviewing acquired images and videos.



The Handheld Fluorescence Camera is restricted for use exclusively by authorized healthcare professionals in accordance with SBI CIP 20-002.



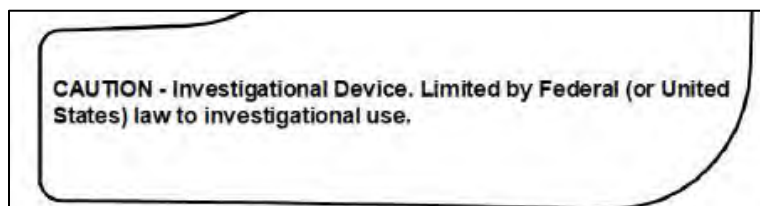
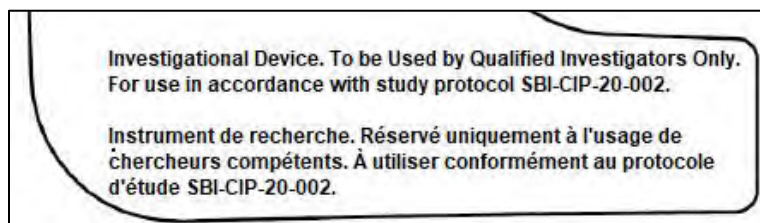
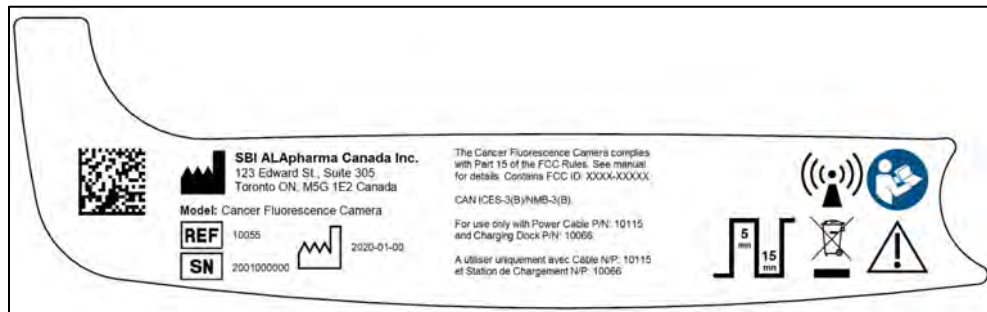
The Handheld Fluorescence Camera is solely intended for imaging surgical cavities and excised tissue.

4. Labelling

This section provides users with information on device and accessory labelling.

4.1. HFC – Handheld Fluorescence Camera Device Label

The following labels are applied to the HFC.

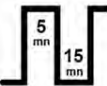


4.1.1. Symbols on HFC Device Label

Table 10 Symbols on HFC Device Label

#	Symbol	Meaning	Source
1.		Unique Device Identifier	N/A
2.	 SBI ALApharma Canada Inc. 123 Edward St., Suite 305 Toronto ON, M5G 1E2 Canada	Manufacturer Information	ISO 7000 - 3082
3.	Model: Cancer Fluorescence Camera	Device Model Name	N/A

Table 10 Symbols on HFC Device Label

#	Symbol	Meaning	Source
4.	 10055	Reference Number	ISO 7000 - 2493
5.	 2001000000	Serial Number	ISO 7000 - 2498
6.	 2020-01-00	Date of Manufacture	ISO 7000 - 2497
7.	CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use. Investigational Device. To be Used by Qualified Investigators Only. For use in accordance with study protocol SBI-CIP-20-002. Instrument de recherche. Réserve uniquement à l'usage de chercheurs compétents. À utiliser conformément au protocole d'étude SBI-CIP-20-002.	Indicating the device is to be used by qualified investigators only, in accordance with SBI-CIP-20-002	N/A
8.	Contains / Contient des: FCC ID: 2AFDI - ITCOQ626S	FCC ID	N/A
9.	Contains / Contient des: IC: 9049A - ITCOQ626S	ISED ID	N/A
10.	For use only with Power Cable P/N: 10115 and Charging Dock P/N: 10066. A utiliser uniquement avec Câble N/P: 10115 et Station de Chargement N/P: 10066	Warning for power cable use	N/A
11.		Duty Cycle	N/A
12.		WEEE Symbol. Dispose Electrical and Electronic Equipment.	EN 50419
13.		Non-ionizing electromagnetic radiation	IEC 60417 - 5140
14.		Consult the instructions for use	ISO 7010 - M002
15.		Caution	ISO 7000 - 0434A

4.2. CSS – Custom Sterile Sleeve Device Label

The following label is applied to the Custom Sterile Sleeve.



4.2.1. Symbols on CSS Device Label

Table 11 Symbols on CSS Device Label

#	Symbol	Meaning	Source
1.	 SBI ALApharma Canada Inc. 123 Edward St., Suite 305 Toronto ON, M5G 1E2 Canada	Manufacturer Information	ISO 7000 - 3082
2.	CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use. Investigational Device. To be Used by Qualified Investigators Only. For use in accordance with study protocol SBI-CIP-20-002. Instrument de recherche. Réservé uniquement à l'usage de chercheurs compétents. À utiliser conformément au protocole d'étude SBI-CIP-20-002.	Indicating the device is to be used by qualified investigators only, in accordance with SBI-CIP-20-002	N/A
3.	Model: Custom Sterile Sleeve	Device Model Name	N/A
4.	 10174	Reference Number	ISO 7000 - 2493
5.	 0000E000	Lot Number	ISO 7000 - 2492

Table 11 Symbols on CSS Device Label

#	Symbol	Meaning	Source
6.	 YYYY-MM-DD	Date of Manufacture	ISO 7000 - 2497
7.	 YYYY-MM-DD	Date of Expiry	ISO 7000 - 2607
8.		Indicating the product was EO Sterilized	ISO 7000 - 2501
9.		Indicating the product should not be used if the packaging has been damaged or opened	ISO 7000 - 2606
10.		The product is for single use only	ISO 7000 - 1051
11.		The product is not made with natural rubber latex	ISO 15223-1
12.		The product is not to be re-sterilized	ISO 7000 - 2608
13.		The product is a type B Applied part	IEC 60417 - 5840
14.		Consult the instructions for use	ISO 7010 - M002
15.	 (01) 0 7540294 00004 9 (10) 0000E000 (11) 200724 (17) 210724	Unique Device Identifier	N/A

4.3. ECH – External Communications Hub Device Label

The ECH is a composition of several hardware components. Each hardware component described in Section 2.2.2 bears its own label.

4.4. DIS – Dark Imaging Sheet Device Label

The following label is applied to the Dark Imaging Sheet.



4.4.1. Symbols on DIS Label

Table 12 Symbols on DIS Label

#	Symbol	Meaning	Source
1.	 SBI ALAlpha Canada Inc. 123 Edward St., Suite 305 Toronto ON, M5G 1E2 Canada	Manufacturer Information	ISO 7000 - 3082
2.	CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use. Investigational Device. To be Used by Qualified Investigators Only. For use in accordance with study protocol SBI-CIP-20-002. Instrument de recherche. Réservé uniquement à l'usage de chercheurs compétents. À utiliser conformément au protocole d'étude SBI-CIP-20-002.	Indicating the device is to be used by qualified investigators only, in accordance with SBI-CIP-20-002	N/A
3.	Model: Dark Imaging Sheet	Device Model Name	N/A
4.	REF 10165	Reference Number	ISO 7000 - 2493
5.	LOT 0000E000	Lot Number	ISO 7000 - 2492

Table 12 Symbols on DIS Label

#	Symbol	Meaning	Source
6.	 YYYY-MM-DD	Date of Manufacture	ISO 7000 - 2497
7.	 YYYY-MM-DD	Date of Expiry	ISO 7000 - 2607
8.		Indicating the product was EO Sterilized	ISO 7000 - 2501
9.		Indicating the product should not be used if the packaging has been damaged or opened	ISO 7000 - 2606
10.		The product is for single use only	ISO 7000 - 1051
11.		The product is not made with natural rubber latex	ISO 15223-1
12.		The product is not to be re-sterilized	ISO 7000 - 2608
13.		Consult the instructions for use	ISO 7010 - M002
14.		Unique Device Identifier	N/A

4.5. DIB – Dark Imaging Box Device Label

The following label is applied to the Dark Imaging Box.



4.5.1. Symbols on DIB Label

Table 13 Symbols on DIB Label

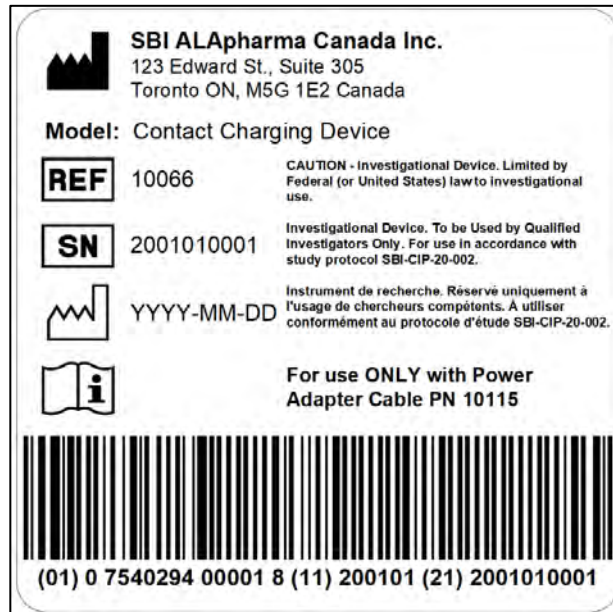
#	Symbol	Meaning	Source
1.	 SBI ALApharma Canada Inc. 123 Edward St., Suite 305 Toronto ON, M5G 1E2 Canada	Manufacturer Information	ISO 7000 - 3082

Table 13 Symbols on DIB Label

#	Symbol	Meaning	Source
2.	CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use. Investigational Device. To be Used by Qualified Investigators Only. For use in accordance with study protocol SBI-CIP-20-002. Instrument de recherche. Réserve uniquement à l'usage de chercheurs compétents. À utiliser conformément au protocole d'étude SBI-CIP-20-002.	Indicating the device is to be used by qualified investigators only, in accordance with SBI-CIP-20-002	N/A
3.	Model: Dark Imaging Box	Device Model Name	N/A
4.	 10117	Reference Number	ISO 7000 - 2493
5.	 2001020001	Serial Number	ISO 7000 - 2498
6.	 YYYY-MM-DD	Date of Manufacture	ISO 7000 - 2497
7.		Consult the instructions for use	ISO 7000 - 1641
8.	 (01) 0 7540294 00003 2 (11) 200514 (21) 2001030001	Unique Device Identifier	N/A
9.	 Product is Non-Sterile	Product is Non-Sterile	ISO 7000 - 2609

4.6. CCD – Contact Charging Device, Device Label

The following label is applied to the Contact Charging Device.

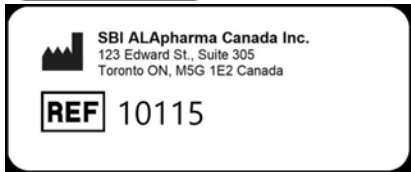


4.6.1. Symbols on CCD Label

Table 14 Symbols on CCD Label

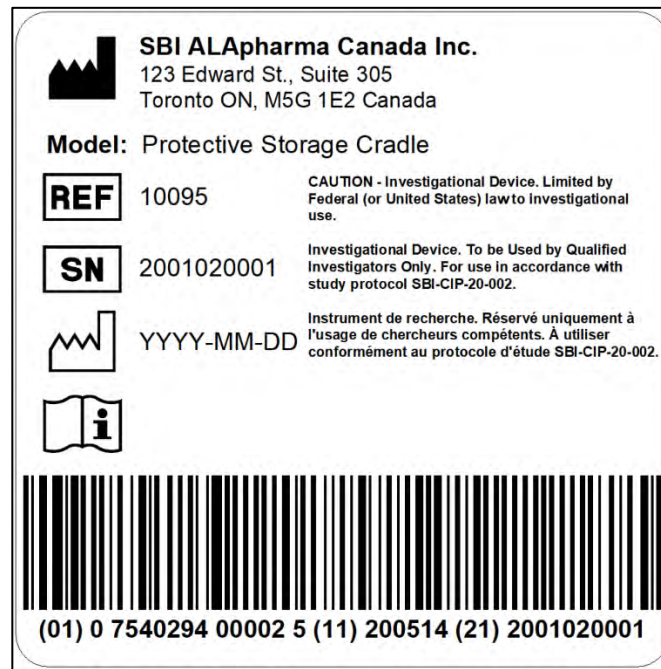
#	Symbol	Meaning	Source
1.	 SBI ALApharma Canada Inc. 123 Edward St., Suite 305 Toronto ON, M5G 1E2 Canada	Manufacturer Information	ISO 7000 - 3082
2.	CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use. Investigational Device. To be Used by Qualified Investigators Only. For use in accordance with study protocol SBI-CIP-20-002. Instrument de recherche. Réserve uniquement à l'usage de chercheurs compétents. À utiliser conformément au protocole d'étude SBI-CIP-20-002.	Indicating the device is to be used by qualified investigators only, in accordance with SBI-CIP-20-002	N/A
3.	Model: Contact Charging Device	Device Model Name	N/A
4.	 10066	Reference Number	ISO 7000 - 2493
5.	 2001010001	Serial Number	ISO 7000 - 2498
6.	 YYYY-MM-DD	Date of Manufacture	ISO 7000 - 2497

Table 14 Symbols on CCD Label

#	Symbol	Meaning	Source
7.	For use ONLY with Power Adapter Cable PN 10115	The device is to be charged with power Adapter Cable PN 10115 ONLY	N/A
8.		Consult the instructions for use	ISO 7000 - 1641
9.	 (01) 0 7540294 00006 3 (10) 0000L000 (11) 200727 (17) 210727	Unique Device Identifier	N/A
10.	 	CCD Power Supply Label	N/A

4.7. PSC – Protective Storage Cradle Device Label

The following label is applied to the Protective Storage Cradle.



4.7.1. Symbols on PSC Device Label

Table 15 Symbols on PSC Device Label

#	Symbol	Meaning	Source
1.	 SBI ALApharma Canada Inc. 123 Edward St., Suite 305 Toronto ON, M5G 1E2 Canada	Manufacturer Information	ISO 7000 - 3082
2.	CAUTION - Investigational Device. Limited by Federal (or United States) law to investigational use. Investigational Device. To be Used by Qualified Investigators Only. For use in accordance with study protocol SBI-CIP-20-002. Instrument de recherche. Réservé uniquement à l'usage de chercheurs compétents. À utiliser conformément au protocole d'étude SBI-CIP-20-002.	Indicating the device is to be used by qualified investigators only, in accordance with SBI-CIP-20-002	N/A
3.	Model: Protective Storage Cradle	Device Model Name	N/A
4.	 10095	Reference Number	ISO 7000 - 2493
5.	 2001020001	Serial Number	ISO 7000 - 2498
6.	 YYYY-MM-DD	Date of Manufacture	ISO 7000 - 2497

Table 15 Symbols on PSC Device Label

#	Symbol	Meaning	Source
7.		Consult the instructions for use	ISO 7000 - 1641
8.		Unique Device Identifier	N/A

5. Cleaning and Disinfection

	Warning	Failure clean, disinfect, and sterilize the Eagle V1.2 Imaging System may result in cross-contamination, and patient or user exposure to microbiological contamination.
	Warning	Do not clean, disinfect, or sterilize the Eagle V1.2 Imaging System when energized. Power off the device before cleaning, disinfecting, or sterilizing. Cleaning, disinfecting, or sterilizing when energized may be hazardous to the operator and/or destructive to the system.
	Warning	Use only approved cleaning and sterilization procedures
	Warning	Do not reuse the Eagle Custom Sterilize Sleeve or Dark Imaging Sheet. They are single use only accessories.
	Caution	Improper cleaning/sterilization may reduce image quality.
	Caution	Prior to disinfection or sterilization, ensure surfaces are cleaned to remove organic matter as described in the sections below.
	Note	The user should dispose of the cleaning, disinfection, and sterilization materials according to biohazard waste control processes at their Institution.
	Note	Follow precautions established in your facility when handling any medical device that has been used intraoperatively and has been in contact with body fluids, tissues, or blood.

In accordance with the *Spaulding Classification* scheme, the Handheld Fluorescence Camera is classified as a critical medical device that is intended to contact normally sterile tissue, thereby introducing a likelihood of microbial transmission and risk of infection if the device is not sterile. Therefore, it is essential that the Handheld Fluorescence Camera be cleaned, sterilized, and rinsed before use or reuse to prevent

cross-contamination, and patient or user exposure to microbiological contamination as described in Section 5.1.

The *External Communications Hub* described in sections 2.2.2 and 6.3.1.2 positioned in the sterile field is cleaned and disinfected using intermediate level disinfection wipes as described in section 5.2.

The *Protective Storage Cradle* described in sections 0 and 6.3.5 positioned in the sterile field is cleaned using intermediate level disinfection, and steam sterilized as described in section 5.5.

The *Contact Charging Device* described in sections 2.2.1 and 6.3.5 positioned in the non-sterile field is cleaned and disinfected using intermediate level disinfection wipes as described in section 5.3.

Table 16 Infrastructure, Materials, & Equipment Required for cleaning, disinfection, and sterilization				
#	Eagle V1.2 Imaging System Component	Cleaning, Disinfection, and Sterilization Method	Item	Description
1.	Handheld Fluorescence Camera	Cleaning followed by Chemical Sterilization before use. Clean and Disinfect Before and After Use.	Dedicated workspace divided into non-sterile and sterile areas	To perform cleaning and sterilization
			Soap and Water	To clean
			Glutaraldehyde	Chemical sterilant
			Latex gloves, masks, hair bonnets, gowns	Personal protective equipment
			Basin	To hold chemical sterilant
			Timer and Thermometer	To time and monitor the sterilization process
			Lint-free cloth	To wipe down the sterilized device
			Sterile blue cloth	To wrap the sterilized device

Table 16 Infrastructure, Materials, & Equipment Required for cleaning, disinfection, and sterilization

#	Eagle V1.2 Imaging System Component	Cleaning, Disinfection, and Sterilization Method	Item	Description
2.	External Communications Hub	Cleaned and disinfected using intermediate level disinfection wipes	Enzymatic Detergent Solution	To clean and disinfect the Contact Charging Device
3.	Protective Storage Cradle	Cleaned Using Intermediate Level Disinfection, and Steam Sterilized (Autoclave)	Intermediate Level Disinfection Wipes	To clean the Protective Storage Cradle
			Autoclave	To steam sterilize the Protective Storage Cradle
4.	Contact Charging Device	Cleaned and disinfected using intermediate level disinfection wipes	4X Intermediate Level Disinfection Wipes	To clean and disinfect the Contact Charging Device
5.	Dark Imaging Box	Cleaned and disinfected using intermediate level disinfection wipes	4X Intermediate Level Disinfection Wipes	To clean and disinfect the Contact Charging Device
6.	Custom Sterile Sleeve	N/A – This component is Single Use	N/A	N/A
7.	Dark Imaging Sheet	N/A – This component is Single Use	N/A	N/A

5.1. HFC – Handheld Fluorescence Camera Cleaning and Sterilization

Before use, the Handheld Fluorescence Camera must be sterilized.

SBI ALApharma Canada Inc. has validated and therefore recommends the use of mild soap and water as an effective cleaning agent before sterilizing the Handheld Fluorescence Camera with glutaraldehyde (2.5% solution).

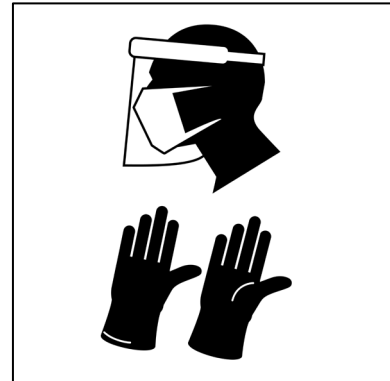
Following immediate use and before re-sterilization, *SBI ALApharma Canada Inc.* recommends to clean and disinfect the Handheld Fluorescence Camera with Intermediate Level Disinfection wipes.

5.1.1. Cleaning the HFC

Table 17 *Handheld Fluorescence Camera Cleaning Instructions*

1. Prior to sterilization, the HFC must be thoroughly cleaned with mild soap and water to remove organic matter.

2. Wear appropriate PPE (e.g. impervious gloves such as latex gloves, masks, hair bonnets, gowns).



3. Before cleaning, ensure that the hatch covering the USB-c port is closed and secured in place.

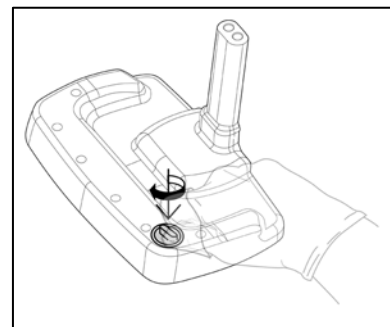
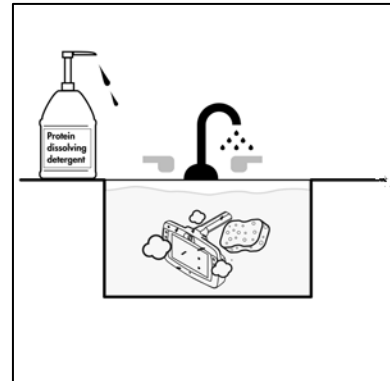


Table 17 *Handheld Fluorescence Camera Cleaning Instructions*

4. Thoroughly clean the HFC using mild soap and water.



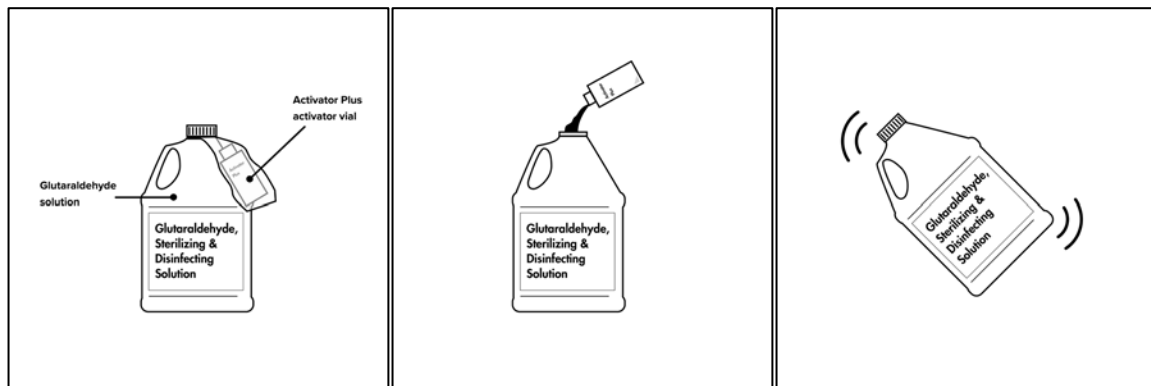
5. With the naked eye, visually inspect the device in a well-lit area at a distance of approximately 12 inches to ensure all surfaces are clean. If necessary, repeat the cleaning steps above until the HFC is clean.

5.2.1. Sterilizing the HFC

Table 18 *Handheld Fluorescence Camera Sterilization Instructions*

The glutaraldehyde (2.5% solution) liquid chemical sterilant should be used according the manufacturer's instructions, including requirements for appropriate ventilation, use of PPE, training and quality control.

- 1.

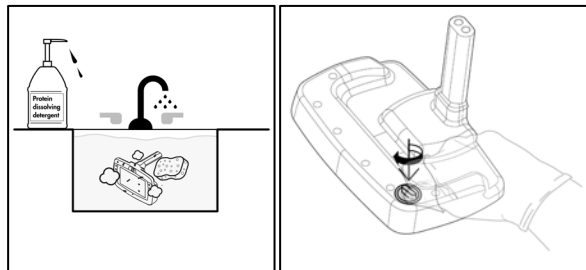


2. Liquid chemical sterilization should be performed in a dedicated workspace divided into a non-sterile and sterile area.

Table 18 Handheld Fluorescence Camera Sterilization Instructions

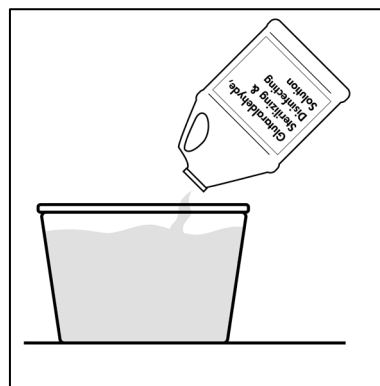
3.

Before sterilizing, ensure the device has been properly cleaned according and that the USB-c hatch is closed and secured in place.



4.

In the non-sterile area of the dedicated workspace, prepare a basin containing liquid chemical sterilant according to the manufacturers instructions to achieve the appropriate dilution

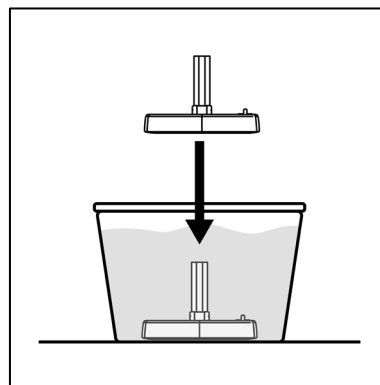


5.

Ensure the HFC is cleaned and completely dry prior to immersing in the sterilant.

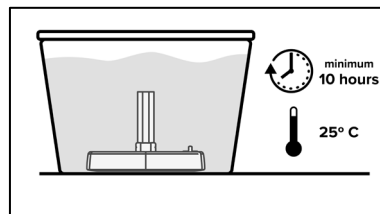
6.

Fully immerse the HFC in the liquid chemical bath ensuring all surfaces of the device are fully immersed.



7.

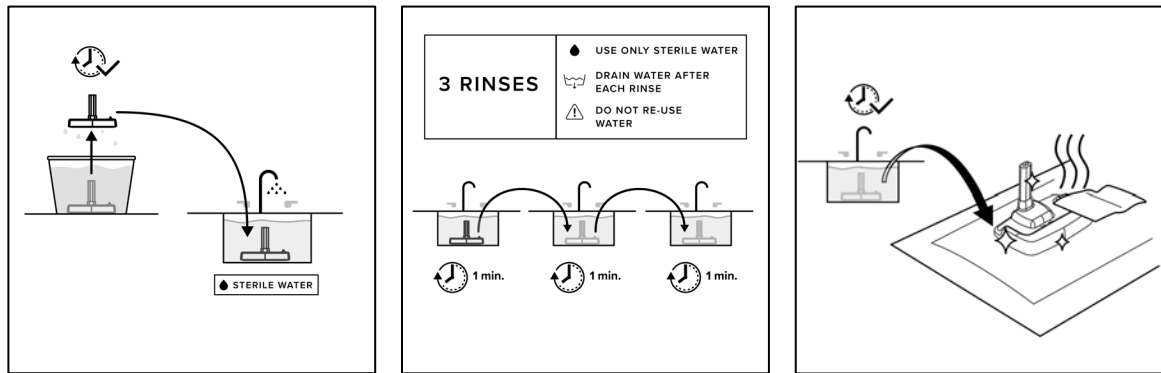
Soak the device for 10 hours, monitoring (e.g. temperature) as per the sterilant manufacturer's recommendations



8.

Remove the HFC using sterile technique and rinse according to the sterilant manufacturer's instructions.

Table 18 Handheld Fluorescence Camera Sterilization Instructions



9. Completely dry the HFC by wiping with a sterile lint-free cloth.

10. Visually inspect the device to verify there are no signs of corrosion, discoloration, pitting, or cracked of seals. Visually inspect the HFC to ensure the optical glass (Item X in Figure X) is free of any visible material (e.g. fibers) or smudges (e.g. water stains). Use sterile lint-free cloth to wipe the optical glass if required.

11. In the sterile area of the dedicated workspace, wrap the HFC in a sterile blue cloth.

12. The HFC is now sterile and ready for use.

5.2. ECH – External Communications Hub Cleaning and Disinfection



Warning

Do not clean or disinfect the ECH or any of its components when energized. Unplug all cable connections before cleaning or disinfecting. Cleaning or disinfecting when energized may be hazardous to the operator and/or destructive to the device(s).



Caution

Prior to disinfection, ensure surfaces are cleaned to remove organic matter as described in the sections below.

Thoroughly clean and disinfect all External Communications Hub component surfaces including the ECH Display, ECH PC, ECH Pad, ECH Stand, ECH Power Supplies, and cables using Intermediate Level Disinfection Wipes.

5.2.1. Cleaning ECH

Table 19 External Communication Hub Cleaning Instructions

- 1.** Wear impervious gloves such as latex gloves when handling Intermediate Level Disinfection Wipes.
- 2.** Before cleaning, ensure the ECH and all components are UNPLUGGED from their power supplies, and ensure the all power supplies are UNPLUGGED from electrical outlets.
- 3.** Use at least two new Intermediate Level Disinfection Wipes to clean and remove all visible soil and debris from all ECH component surfaces including the ECH Display, ECH PC, ECH Pad, ECH Stand, ECH Power Supplies, and cables.
- 4.** Thoroughly clean crevices and areas that are difficult to reach. Where required, fold or bunch Intermediate Level Disinfection Wipes to push into crevices, corners, and areas that are difficult to reach.
- 5.** As necessary, use additional Intermediate Level Disinfection Wipes if they become soiled during the cleaning process.
- 6.** In a well-lit area, visually inspect (at a distance of approximately 12 inches) the ECH including the ECH Display, ECH PC, ECH Pad, ECH Stand, ECH Power Supplies, and cables to ensure all surfaces are clean.
- 7.** If necessary, repeat the cleaning steps above until the ECH and its components are clean

5.2.2. Disinfecting ECH

Do not continue with disinfecting the ECH including the ECH Display, ECH PC, ECH Pad, ECH Stand, ECH Power Supplies, and cables unless the cleaning process described in Section 5.2.1 is completed. Effective disinfection can only be achieved after completing the cleaning process.

Table 20 External Communication Hub Disinfection Instructions

- 1.** After cleaning, use at least two new Intermediate Level Disinfection Wipes to thoroughly wet ALL SIDES and surfaces of the ECH including the ECH Display, ECH PC, ECH Pad, ECH Stand, ECH Power Supplies, and cables.
- 2.** Thoroughly wipe crevices and areas that are difficult to reach. Where required, fold or bunch Intermediate Level Disinfection Wipes to push into crevices, corners, and areas that are difficult to reach.
- 3.** Use additional Intermediate Level Disinfection Wipes as necessary to ensure ALL SIDES and surfaces of the ECH including the ECH Display, ECH PC, ECH Pad, ECH Stand, ECH Power Supplies, and cables have been wet.
- 4.** Once wet, allow ECH Display, ECH PC, ECH Pad, ECH Stand, ECH Power Supplies, and cables to dry.

Table 20 External Communication Hub Disinfection Instructions

5. The ECH and its components are now disinfected and ready for use. Observe sterile technique when transporting equipment from re-processing locations to points of use.

5.3. Dark Imaging Box Cleaning and Disinfection



Caution

Prior to disinfection, ensure surfaces are cleaned to remove organic matter as described in the sections below.

Before and after use, thoroughly clean and disinfect all surfaces of the Dark Imaging Box using Intermediate Level Disinfection Wipes.

5.3.1. Cleaning Dark Imaging Box

Table 21 Dark Imaging Box Cleaning Instructions

1. Wear impervious gloves such as latex gloves when handling Intermediate Level Disinfection Wipes.
2. Before cleaning, ensure the Dark Imaging Sheet (Section 2.2.2 and Section 6.3.3), the DIB Front Cover, and DIB Back Cover (Section 6.3.4) are removed and detached from the DIB, and discarded. The Dark Imaging Sheet, DIB Front Cover, and DIB Back Cover are to be discarded after single use.
3. Use at least two (2) new Intermediate Level Disinfection Wipes to clean and remove all visible soil and debris from the DIB including its Base, Cradle, Adjustment Wheel, Ruler, and Imaging Platform.
4. Thoroughly clean crevices and areas that are difficult to reach. Where required, fold or bunch Intermediate Level Disinfection Wipes to push into crevices, corners, and areas that are difficult to reach.
5. As necessary, use additional Intermediate Level Disinfection Wipes if they become soiled during the cleaning process.
6. In a well-lit area, visually inspect (at a distance of approximately 12 inches) the DIB including its Base, Cradle, Adjustment Wheel, Ruler, and Imaging Platform to ensure all surfaces are clean. If necessary, repeat the cleaning steps above until the DIB is clean.

5.3.2. Disinfecting Dark Imaging Box

Do not continue with disinfecting the DIB unless the cleaning process described in Section 5.3.1 is completed. Effective disinfection can only be achieved after completing the cleaning process.

Table 22 Dark Imaging Box Disinfection Instructions

1. After cleaning, use at least two new Intermediate Level Disinfection Wipes to thoroughly wet ALL SIDES and surfaces of the DIB including its Base, Cradle, Adjustment Wheel, Ruler, and Imaging Platform.

Table 22 Dark Imaging Box Disinfection Instructions

2. Thoroughly wipe crevices and areas that are difficult to reach. Where required, fold or bunch Intermediate Level Disinfection Wipes to push into crevices, corners, and areas that are difficult to reach.
3. Use additional Intermediate Level Disinfection Wipes as necessary to ensure ALL SIDES and surfaces of the DIB including its Base, Cradle, Adjustment Wheel, Ruler, and Imaging Platform have been wet.
4. Once wet, allow the DIB to dry.
5. The DIB is now disinfected and ready for use. Observe sterile technique when transporting equipment from re-processing locations to points of use.

5.4. CCD – Contact Charging Device Cleaning and Disinfection



Warning

Do not clean or disinfect the Contact Charging Device, its power supply, or its cables when energized. Unplug all cable connections before cleaning or disinfecting. Cleaning or disinfecting when energized may be hazardous to the operator and/or destructive to the device(s).



Caution

Prior to disinfection, ensure surfaces are cleaned to remove organic matter as described in the sections below.

Thoroughly clean and disinfect all surfaces of the Contact Charging Device, the CCD Power Supply, and the cables using Intermediate Level Disinfection Wipes.

5.4.1. Cleaning CCD

Table 23 Contact Charging Device Cleaning Instructions

1. Wear impervious gloves such as latex gloves when handling Intermediate Level Disinfection Wipes.
2. Before cleaning, ensure the CCD is UNPLUGGED from the CCD Power Supply, and ensure the CCD Power Supply is UNPLUGGED from the electrical outlet.
3. Use at least two new Intermediate Level Disinfection Wipes to clean and remove all visible soil and debris from the CCD, the CCD Power Supply, and all cables.
4. Thoroughly clean crevices and areas that are difficult to reach. Where required, fold or bunch Intermediate Level Disinfection Wipes to push into crevices, corners, and areas that are difficult to reach.
5. As necessary, use additional Intermediate Level Disinfection Wipes if they become soiled during the cleaning process.
6. In a well-lit area, visually inspect (at a distance of approximately 12 inches) the CCD, the CCD Power Supply, and all cables to ensure all surfaces are clean. If necessary, repeat the cleaning steps above until the CCD, the CCD Power Supply, and all cables are clean.

5.4.2. Disinfecting CCD

Do not continue with disinfecting the CCD, the CCD Power Supply, or cables unless the cleaning process described in Section 5.4.1 is completed. Effective disinfection can only be achieved after completing the cleaning process.

Table 24 Contact Charging Device Disinfection Instructions

1. After cleaning, use at least two new Intermediate Level Disinfection Wipes to thoroughly wet ALL SIDES and surfaces of the CCD, the CCD Power Supply, and Cables.
2. Thoroughly wipe crevices and areas that are difficult to reach. Where required, fold or bunch Intermediate Level Disinfection Wipes to push into crevices, corners, and areas that are difficult to reach.
3. Use additional Intermediate Level Disinfection Wipes as necessary to ensure ALL SIDES and surfaces of the CCD, the CCD Power Supply, and Cables have been wet.
4. Once wet, allow the CCD, the CCD Power Supply, and Cables to dry.
5. The CCD, the CCD Power Supply, and Cables are now disinfected and ready for use. Observe sterile technique when transporting equipment from re-processing locations to points of use.

5.5. PSC – Protective Storage Cradle Cleaning and Sterilization

Before use, clean and sterilize the Protective Storage Cradle.

5.5.1. Cleaning Protective Storage Cradle

Table 25 Protective Storage Cradle Manual Cleaning Instructions

1. Prepare Prolystica 2x Concentrate Presoak and Cleaner enzymatic detergent solution per manufacturer's instructions (1/8 fl. oz./gal to 1/2 fl. oz./gal) with lukewarm tap water (22°C to 30°C temperature range).
2. Immerse the device(s) in the prepared solution and soak for one (1) to five (5) minutes.
3. Use a non-linting wipe or cloth saturated with the detergent solution to wipe all device surfaces until visibly clean.
4. Rinse the device(s) in a tap water (or better) bath for at least 30 seconds.
5. Thoroughly dry all surfaces of the device(s) using non-linting wipes or cloths, changing wipes/ cloths when necessary to ensure the devices are completely dry.
6. Visually inspect each device for the absence or presence of remaining soil in a well-lit area. If soil is present, repeat the manual cleaning steps until all visible soil is removed.

5.5.2. Sterilizing Protective Storage Cradle

Do not continue with sterilizing the Protective Storage Cradle unless the cleaning process described in section 5.5.1 is completed. Effective sterilization can only be achieved after completing the cleaning process.

Steam sterilize the Protective Storage Cradle according to the following instructions.

Table 26 Protective Storage Cradle Sterilization Instructions

- 1.** Place Protective Storage Cradle in a double-wrapped sterilization configuration

Subject PSC to full cycles of either

- 2.**
 - 1) Four (4) minutes of exposure time at 132°C using prevacuum air removal
 - 2) Three (3) minutes of exposure time at 134°C using prevacuum air removal

Subject PSC to dry times of either

- 3.**
 - 1) 20 to 30 minutes of dry time after 132°C with four (4) minutes exposure using prevacuum air removal following Four (4) minutes of exposure time at 132°C using prevacuum air removal
 - 2) 20 minutes of dry time after 134°C with three (3) minutes exposure using prevacuum air removal following three (3) minutes of exposure time at 134°C using prevacuum air removal

-
- 4.** The PSC is now disinfected and ready for use. Observe sterile technique when transporting equipment from re-processing locations to points of use.
-

6. Operating the Handheld Fluorescence Camera, and Eagle V1.2 Imaging System Accessories

6.2. HFC – Handheld Fluorescence Imaging Device Overview and Operation

6.2.1. Tactile Interface

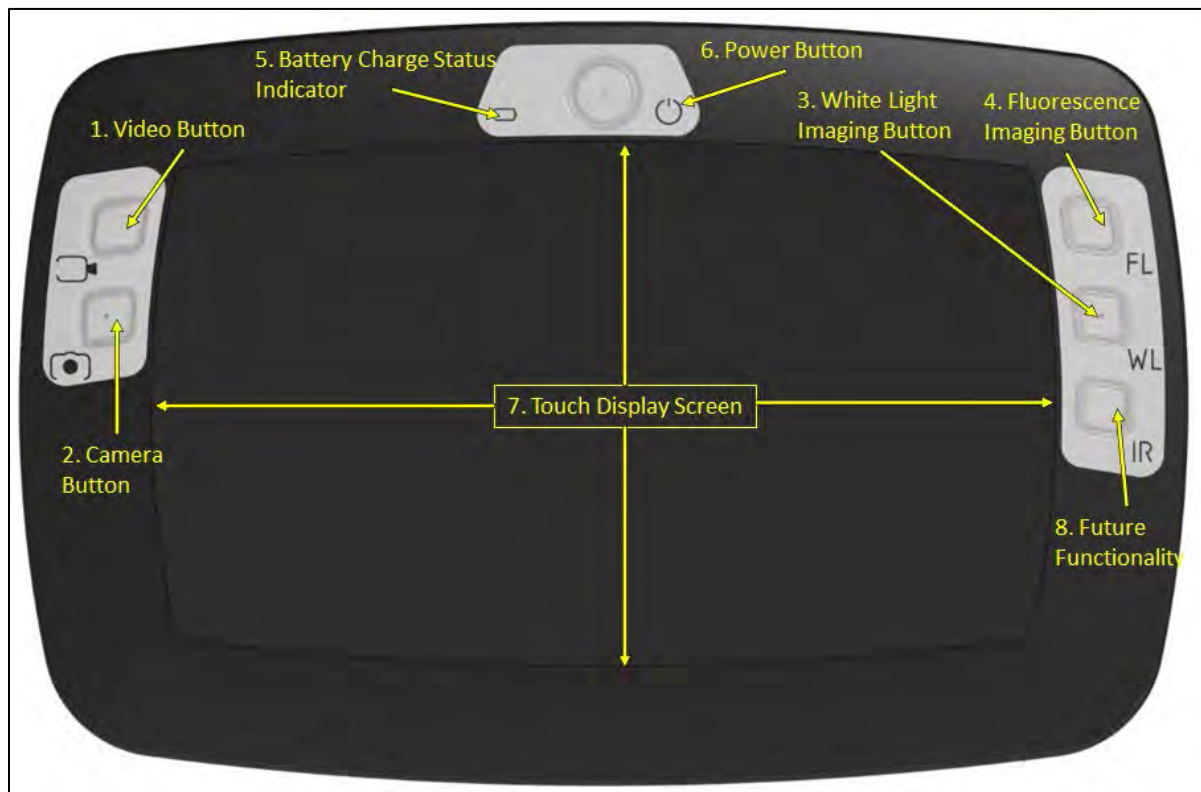
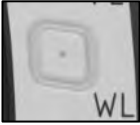


Table 27 Tactile Interface Buttons

#	Icon	Name	Description
1.		Video Button	Pressing the video button  during <i>White Light</i> or <i>Fluorescence Imaging</i> begins video recording. Pressing the Video Button again stops and saves the video recording.
2.		Camera Button	Pressing the camera button  captures an image during <i>White Light Imaging</i> or <i>Fluorescence Imaging</i> . Pressing the camera button during a <i>White Light</i> or <i>Fluorescence Imaging</i> video recording captures an image.

Table 27 Tactile Interface Buttons

#	Icon	Name	Description
3.		White Light Imaging button	Pressing this button initiates <i>White Light Imaging Mode</i> (section 6.2.2.2.4) from <i>Imaging Mode</i> (Section 6.2.2.2)
4.		Fluorescence Imaging button	Pressing this button initiates <i>Fluorescence Imaging</i> (Section 6.2.2.2.5) from <i>Imaging Mode</i> (Section 6.2.2.2)
5.		Battery Status LED	Communicates battery charging status and battery level (Section 6.2.1.3)
6.		Power Button	Used to power on, power off, and sleep the HFC Display Screen (Section 6.2.1.2)
7.	N/A	Touch Display Screen	Touch Display Screen to control the Software User Interface described in Section 6.2.1.2
8.		Future Functionality	Non functioning button for future functionality
9.		System Status LED	Communicates the power status (Section 6.2.1.4)

6.2.1.1. Power On

Table 28 Power On Instruction

1. Hold the Power Button  (located in the center top right of the Tactile Interface 6.2.1) for 3 seconds to power on the Handheld Fluorescence Camera.

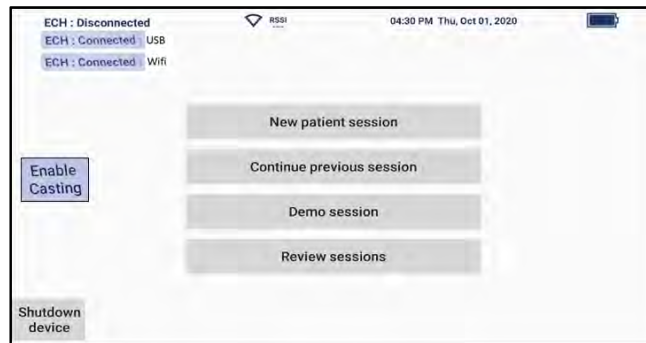


Table 28 Power On Instruction

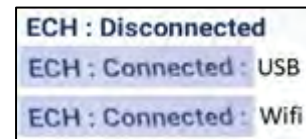
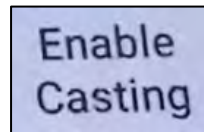
2. During device start-up the *SBI ALApharma Canada Inc.* splash screen will be displayed.



3. Soon after, the Session Menu (section 6.2.2.1) is displayed.



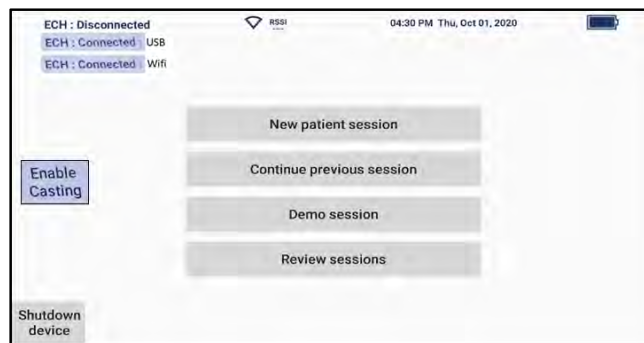
4. Refer to Sections 6.3.2.2 and 6.3.2.3 for information on using the "Enable Casting" button and ECH connection status.



6.2.1.2. Shutdown / Power Off

Table 29 Power Off Instruction

1. Access the Session Menu (section 6.2.2.1) to power off the device.

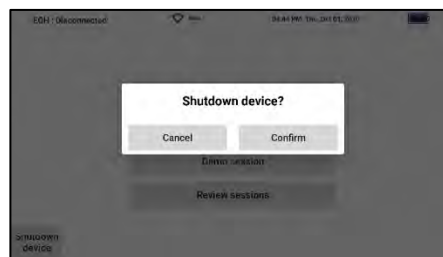


2. From the Session menu to power off the device, press "Shutdown device"



Table 29 Power Off Instruction

3. When prompted, press  to return to the Session Menu, or press  to shutdown the device.



6.2.1.3. Battery Status LED

The Battery Status LED (Table 27 item 61)

- blinks *Amber* in color if the device is charging and the battery level is greater than 20% and less than 80%.
- blinks *Green* in color if the device is charging and the battery level is greater than 80% less than 100%.
- is solid *Green* color if the HFC is charging and the battery level reaches 100%

The blink rate of the Battery Status LED

- is one (1) blink per two (2) seconds if the battery is being charged from a PC.
- is two (2) blinks per second if the battery is being charged directly from the CCD Power Supply
- is four (4) blinks per second if the battery is being charged from the CCD per Section 6.3.5
- is *Red* in color once every 5 (five) seconds if the battery is less than or equal to 5% when HFC is powered off and when the battery is not charging
- is *OFF* when the HFC is powered off and the battery is greater than 5%

6.2.1.4. System Status LED

The System Status LED (Table 27 item 9)

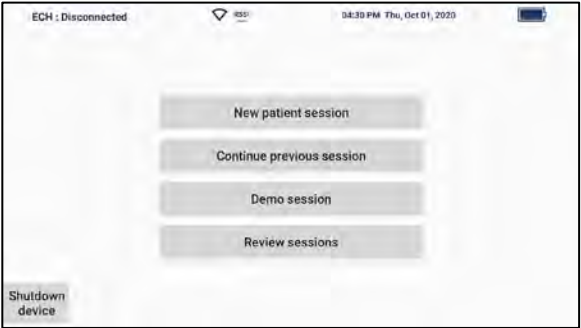
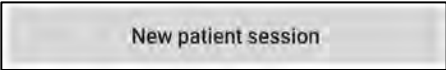
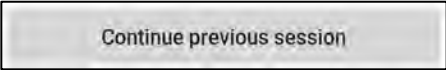
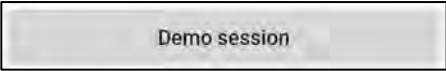
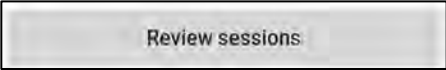
- is *Green* in color while in the power on or standby state if the device is functioning normally
- is *Amber* in color while in the power on or standby state if the device detects a hardware warning that requires attention
 - this typically occurs when the temperature sensor in the HFC Optical Head is approaching thermal operating limits
- is *Red* in color a critical hardware error is detected
 - in case of a critical hardware failure, the firmware power offs the device and may prevent the device from powering on
 - this typically occurs when temperature sensors in the HFC Optical Head have reached thermal operating limits. When this occurs, white light and blue-violet LED are shut down and the System Status LED is Red in color
- blinks *Red* if there is a diagnostics failure during Power on
- Is *OFF* when the HFC is powered off

6.2.2. Software User Interface

6.2.2.1. Session Menu

Begin imaging or review captured images and videos from the Session Menu.

Table 30 Session Menu Instruction

After powering on, the Session Menu is displayed.		
To begin imaging, press		
1.	New patient session	
	Continue previous session	
	Or	
	Demo session	To review saved images and videos, press
	Review sessions	
2.	Press “New patient session” to begin a new imaging session.	
3.	Press “Continue previous session” to continue the last imaging session.	
4.	Press “Demo session” to begin a demo imaging session.	
5.	Press “Review sessions” to review saved images and videos.	

6.2.2.1.1. New Patient Session

Images and videos saved in a new patient session are saved into a session, accessed through “Review Session” menu

Table 31 New Patient Session Instruction

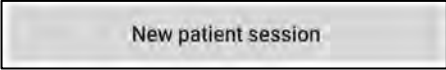
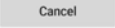
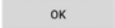
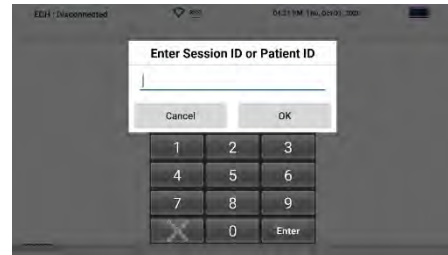
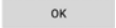
1.	Press “New patient session” to begin a new imaging session.	
----	---	--

Table 31 New Patient Session Instruction

Before imaging, enter the Session ID or Patient ID using the onscreen keypad.

2. Press  to return to the Session Menu.
Press  to begin imaging.



Imaging Mode is initiated after pressing .

3. White Light (Section 6.2.2.2.4) or Fluorescence Imaging (Section 6.2.2.2.5) can now be performed.

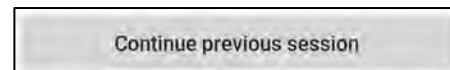


6.2.2.1.2. Continue Previous Session

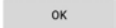
Continue a previous session to continue saving images and videos to the session. Images and videos saved from a continued session are organized into a sub-session. All sessions and captured images and videos are accessed through the “Review Session” menu.

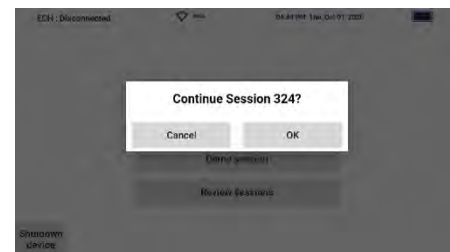
Table 32 Previous Session Instruction

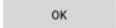
1. Press “Continue previous session” to continue the last imaging session.



Press  to return to the Session Menu.

2. Press  to continue the last session, and begin imaging.



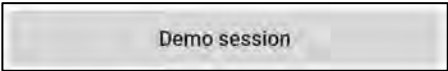
Imaging Mode is initiated after pressing .

3. White Light (Section 6.2.2.2.4) or Fluorescence Imaging (Section 6.2.2.2.5) can now be performed.



6.2.2.1.3. Demo Session

A Demo Session doesn't require entry of a Session ID or patient ID and images are saved to Sessions named with prefix "000".

Table 33 Demo Session Instruction	
1. Press "Demo session" to begin a demo session.	
2. Imaging Mode is initiated after pressing  White Light (Section 6.2.2.2.4) or Fluorescence Imaging (Section 6.2.2.2.5) can now be performed.	

6.2.2.1.4. Review Session and Review Images/Videos

Images and videos captured under *White Light Imaging* or *Fluorescence Imaging* are automatically saved. From the *Sessions Menu*, press **Review sessions** to review saved data.

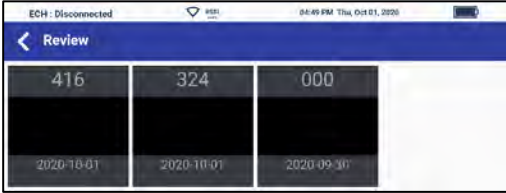
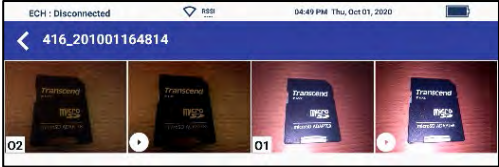
Table 34 Review Images and Videos Instruction	
1. Press "Review sessions" to review saved images and videos.	
2. All sessions are shown. Press a session to explore it. Press the Back button  to return to the Session Menu.	
3. Sessions may be comprised of sub-sessions. Press the Back button  to return to the previous screen.	
4. Saved images and videos are found within a session or sub-session Press the Back button  to return to the previous screen.	

Table 34 Review Images and Videos Instruction

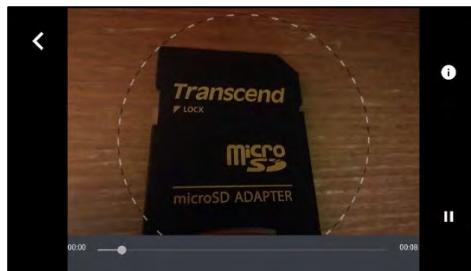
5. Pressing on a saved image will open the image.
Press the Back button  to return to the session.



6. Pressing on a saved video will open the video.
Pressing the Play button  will play the video.



- Pressing the Pause button  will pause video playback.
Press and drag the playback slider to the desired position to select video playback start point.
Press the Back button  to return to the session.

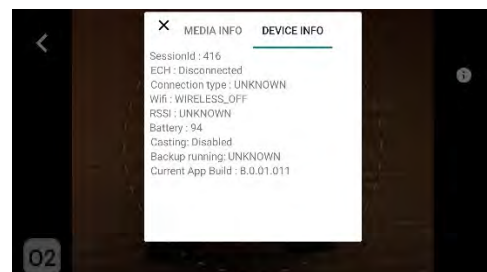


7. Pressing on the Information button  on an opened image or video will display the Media information.



- Pressing on the Device Info tab from the Information window will display the Device Information.

Press  to close the Information tab.



6.2.2.2. Imaging Mode

Imaging Mode is enabled once a new patient session has been created (Section 6.2.2.1.1), a previous session is continued (Section 6.2.2.1.2), or a Demo Session has been started (Section 6.2.2.1.3).

Figure 8 shows the *Imaging Mode* user interface.

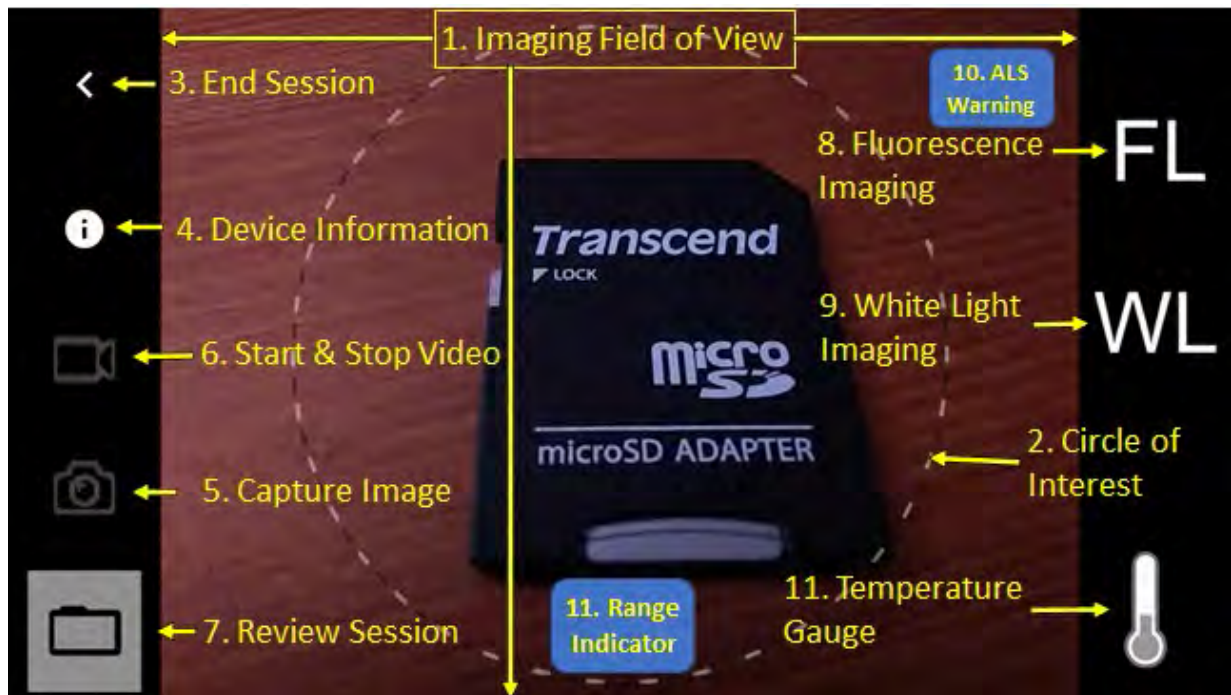


Figure 8:
Handheld Fluorescence Camera's User Interface under Imaging Mode

Table 35 Imaging Mode User Interface Icons

#	Icon	Name	Description
1.	Imaging Field of View	N/A	Indicates the borders of the imaging field of view
2.	Circle of Interest	N/A	Recommended imaging region for <i>Fluorescence Imaging</i> . Imaging in this region ensures optimal Fluorescence Imaging.
3.		End Session Icon	Pressing this button will end the current imaging session after prompting.
4.		Device Information Icon	Pressing this button will display device information.
5.		Capture Image Icon	This icon turns grey  to white  during <i>Fluorescence Imaging</i> or <i>White Light Imaging</i> indicating the camera icon is active. Pressing the active camera icon  captures an image.
6.		Capture Video Icon	This icon turns grey  to white  during <i>Fluorescence Imaging</i> or <i>White Light Imaging</i> indicating the icon is active. Pressing the active video icon  begins video recording. During video recording, the video icon is highlighted red  . Pressing the active video icon again stops and saves the video recording.
7.		Review Session Icon	Pressing this button will display the Review Session screen (section 6.2.2.1.4)
8.		Fluorescence Imaging Icon	Pressing this button initiates <i>Fluorescence Imaging</i> from <i>Imaging Mode</i> . This icon turns white  to blue  during <i>Fluorescence Imaging</i> (section 6.2.2.2.5).
9.		White Light Imaging Icon	Pressing this button initiates <i>White Light Imaging Mode</i> . This icon turns from white  to blue  during <i>White Light Imaging</i> (section 6.2.2.2.4).

Table 35 Imaging Mode User Interface Icons

#	Icon	Name	Description
10.		Ambient Light Sensor Warning Icon	This icon appears overlaid in the top right corner of the Imaging Field of View when the Ambient Lighter Warning has been accepted
11.		Range Finder (RF)	These range icons appear in the bottom center of the Imaging Field of View when the camera sensor is too close or too far from the imaging target.
12.		Temperature Gauge	The temperature gauge communicates relative temperature to the operator.

6.2.2.2.1. Temperature Gauge

The temperature gauge communicates relative temperature to the operator. When the gauge approaches full, the HFC is approaching a maximum operating temperature of 41°C. When operating temperature of 41°C is reached, the HFC automatically disables white light or blue-violet LEDs.

6.2.2.2.2. Range Finder (RF)

During White Light Imaging or Fluorescence Imaging, the Range Finder will provide real time instruction to “Move back” from or “Move closer” to the imaging target. When the optimal imaging range has been met, the Range Finder is not present on the display screen.



Capturing images or videos when the Range Finder is present may result in reduced image quality.

6.2.2.2.3. Circle of Interest

Align imaging targets during White Light Imaging and Fluorescence Imaging within the Circle of Interest. Imaging within the Circle of Interest ensures the imaging target is uniformly illuminated during White Light Imaging and Fluorescence Imaging.



Do not use fluorescence information observed outside the Circle of Interest when interpreting fluorescence images per Section 6.2.2.2.5.2.

6.2.2.2.4. White Light Imaging



Accessed through *Imaging Mode*, *White Light Imaging* can only be performed after creating a new patient session (Section 6.2.2.1.1), continuing a previous session (Section 6.2.2.1.2), or beginning a Demo Session (Section 6.2.2.1.3).

Table 36 White Light Imaging Instruction

1. Enter *Imaging Mode* per Section 6.2.2.2.

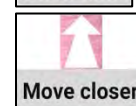
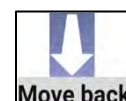
2. While in *Imaging Mode*, press the **WL button** on the right side of the HFC tactile interface (Section 6.2.1) or the White Light Imaging Icon on the right side of the Software User Interface (Section 6.2.2) to initiate *White Light Imaging*.



3. The white WL icon **WL** turns blue when the WL button on the tactile interface is pressed to begin *White Light Imaging*



4. Move back, or move closer to the imaging target as directed by the *Range Finder* icons.
Before capturing an image or video, verify correct imaging range by monitoring the onscreen *Range Finder* icons.



5. Press the **Camera button** on the left side of the HFC Tactile Interface (Section 6.2.1) or the Capture Image Icon on the left side of the Software User Interface (Section 6.2.2) to capture an image.



6. After an image is captured, annotate the image with one (1) of eight (8) annotations:
P, A S, I, M, L, 01, or 02



7. Press the **Video button** on the left side of the HFC tactile interface (Section 6.2.1) or the Video Capture Icon on the left side of the Software User Interface (Section 6.2.2) to start video recording. Press the **Video button** again to stop video recording. During video recording, pressing the **Camera button** will capture an image.



6.2.2.2.5. Fluorescence Imaging



Accessed through *Imaging Mode*, *White Light Imaging* can only be performed after creating a new patient session (Section 6.2.2.1.1), continuing a previous session (Section 6.2.2.1.2), or beginning a Demo Session (Section 6.2.2.1.3).

Table 37 Table XX Fluorescence Imaging Instruction

1. Enter *Imaging Mode* per Section 6.2.2.2.

Fluorescence Imaging must be performed in the darkness. When correct ambient lighting conditions are met, the FL icon located in the top right corner of the *Imaging Mode's* user interface is circled in blue.

- 2.

Refer to Section 6.2.2.2.5.1 if prompted with "**Warning: "ambient light is too bright for Fluorescence Imaging"**".



- 3.

While in *Imaging Mode* with the FL icon circled in blue, press the **FL button** on the right side of the HFC tactile interface (Section 6.2.1) or the Fluorescence Light Imaging Icon on the right side of the Software User Interface (Section 6.2.2) to initiate *Fluorescence Imaging*.



- 4.

The white FL icon  turns blue when the FL button on the tactile interface is pressed to begin *Fluorescence Imaging*.



- 5.

Move back, or move closer to the imaging target as directed by the *Range Finder* icons

Before capturing an image or video, verify correct imaging range by monitoring the onscreen *Range Finder* icons.



- 6.

Press the **Camera button** on the left side of the HFC Tactile Interface (Section 6.2.1) or the Capture Image Icon on the left side of the Software User Interface (Section 6.2.2) to capture an image.



- 7.

Press the **Video button** on the left side of the HFC tactile interface (Section 6.2.1) or the Video Capture Icon on the left side of the User Interface (Section 6.2.2) to start video recording. Press the **Video button** again to stop video recording. During video recording, pressing the **Camera button** will capture an image.



6.2.2.2.5.1. Ambient Light Warning



When attempting to initiate *Fluorescence Imaging* when incorrect ambient lighting conditions are detected, the following warning appears indicating that “*ambient light is too bright for Fluorescence Imaging*”

Warning: ambient light is too bright for
fluorescence imaging

CANCEL

CONTINUE

Press **CANCEL** to return to *Imaging Mode*. Take action to correct ambient light conditions by diminishing sources of light in the imaging environment until the FL icon located in the top right corner of the *Imaging Mode's* user interface is circled in blue.



Pressing **CONTINUE** on the warning will initiate *Fluorescence Imaging* with the Ambient Light Warning icon overlaid in the top right corner of the Imaging Field of View. Any image or video captured in this condition includes the Ambient Light Warning icon to indicate that incorrect ambient lighting conditions were used to capture the image or video.



Proceeding with *Fluorescence Imaging* using incorrect ambient lighting conditions is not recommended and may result in reduced image quality.

6.2.2.2.5.2. Interpretation of Fluorescence Images

Table 38 provides exemplary white light and fluorescence images of grossly sectioned breast tissue specimens.

Areas of red PpIX fluorescence are contrasted with areas of healthy tissue autofluorescence which typically appear predominately green and brown. Areas containing connective tissue typically appear green fluorescent. Areas composed predominately of adipose tissue typically appear dull pink or brown. Tissue specimen ink applied to tissue margins typically appears black. Blood vessels and blood also typically appear black; however, they may also have a dark red hue. Areas of white indicate pixel saturation and should not be considered when interpreting the images for PpIX fluorescence.



The Handheld Fluorescence Camera utilizes auto-exposure to optimize the exposure settings based on lighting conditions. Images captured on the HFC are relative, not quantitative, and may not represent absolute fluorescence levels.

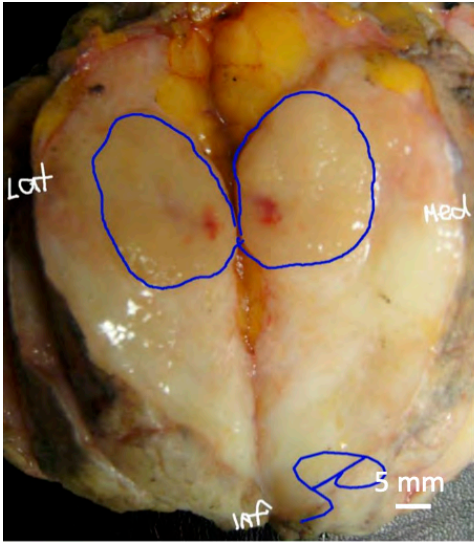
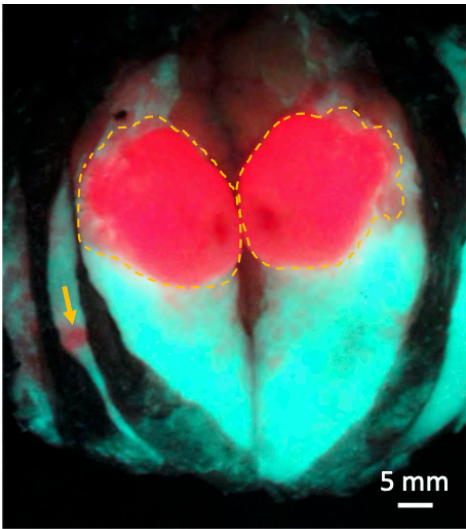
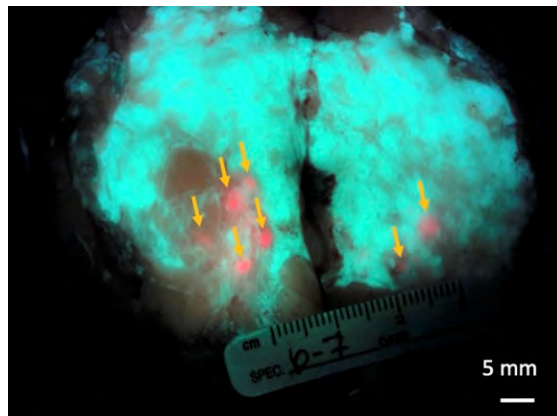
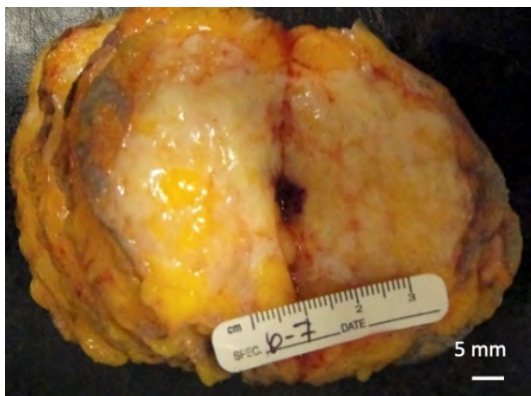
Table 38 Interpretation of Fluorescence Images	
White Light Images	Fluorescence Images
1.   Border of palpable breast tumor	  & ↓ Areas of PpIX red fluorescence

Table 38 Interpretation of Fluorescence Images

White Light Images

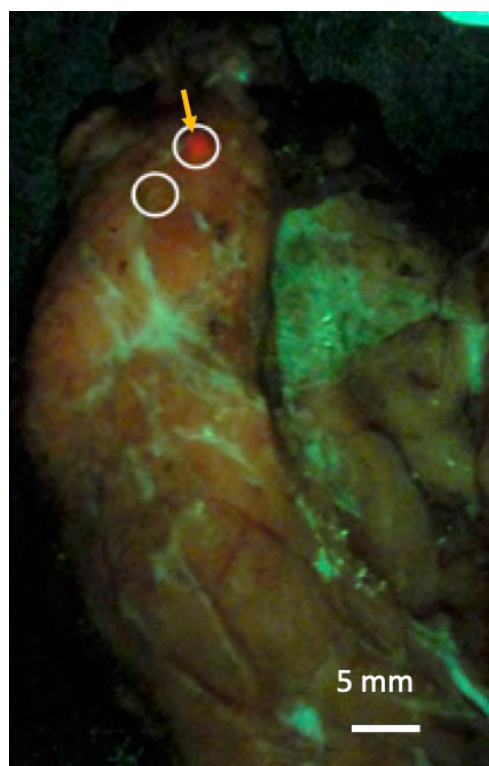
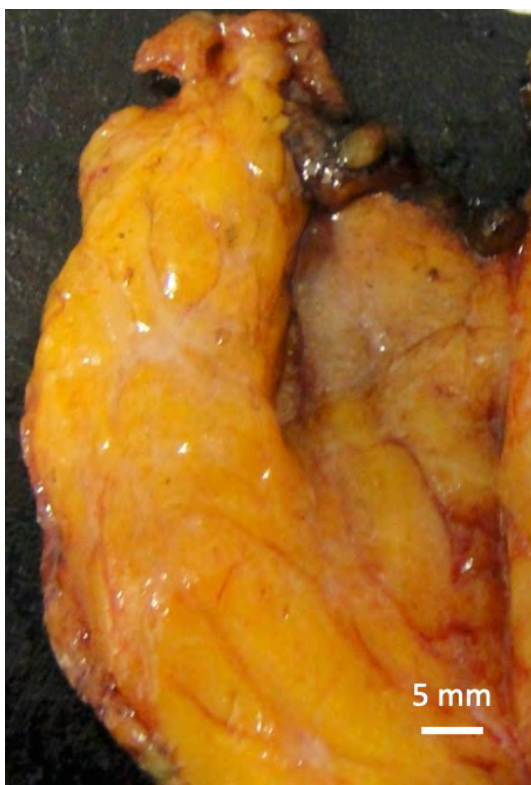
Fluorescence Images

2.



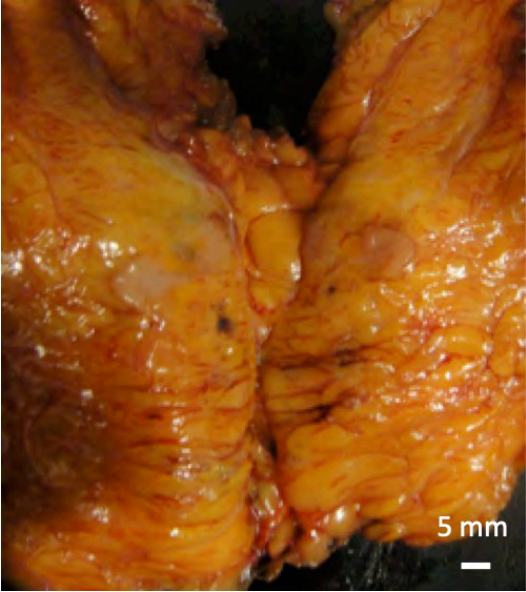
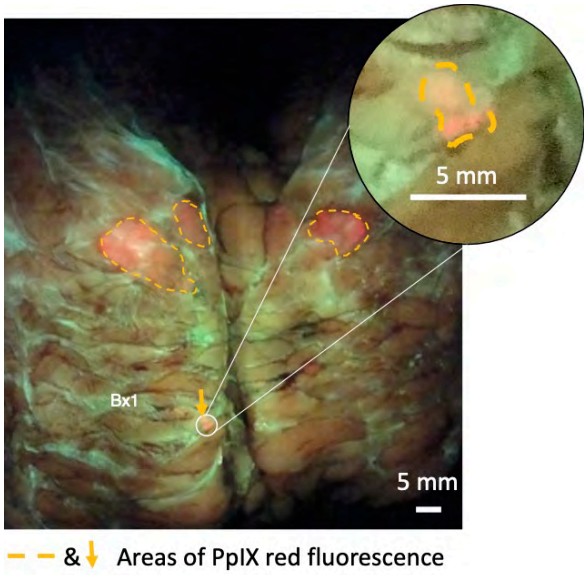
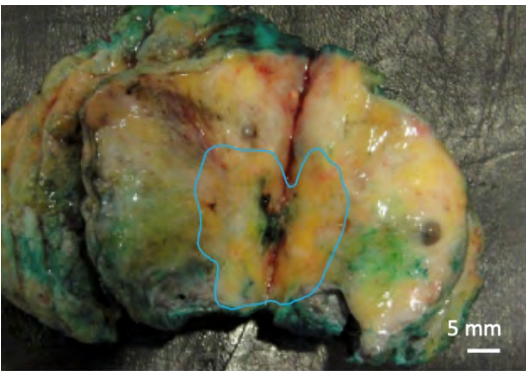
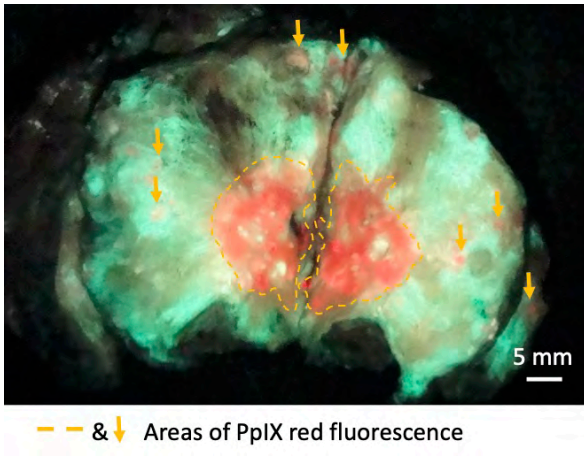
↓ Areas of PpIX red fluorescence

3.



↓ Areas of PpIX red fluorescence

Table 38 Interpretation of Fluorescence Images

White Light Images	Fluorescence Images
4. 	 — & ↓ Areas of PpIX red fluorescence
5.  — Border of palpable breast tumor	 — & ↓ Areas of PpIX red fluorescence

6.2.2.3. Saving Data

Whenever an image or video is captured under *White Light Imaging* (Section 6.2.2.2.4) or *Fluorescence Imaging* (Section 6.2.2.2.5), it is automatically saved to the ECH Flash Drive.

Saved data can be reviewed from the Sessions Menu described in section 6.2.2.1.

6.2.2.4. Exporting Data

All data is saved to the ECH Flash Drive. Install and unlock the ECH Flash Drive on a separate PC to access saved data.

6.3. Accessories Overview and Operation

6.3.1. Custom Sterile Sleeve (CSS) Instructions for Use

The Custom Sterile Sleeve can be sheathed around the Handheld Fluorescence Camera in two (2) ways to accommodate both ECH Wireless (Section 6.3.2.2) and ECH Wired (Section 6.3.2.3) Configurations. Observe sterile technique when mounting the CSS as described in the next Sections 6.3.1.1 and 6.3.1.2.

6.3.1.1. Custom Sterile Sleeve Wireless Configuration

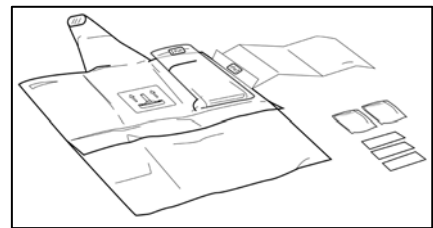
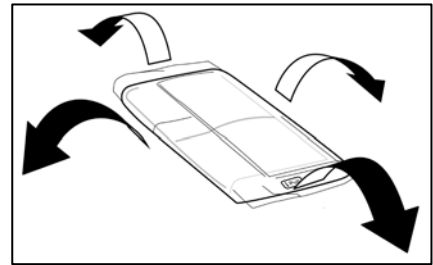
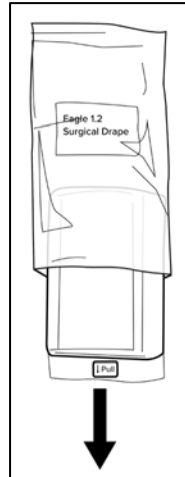
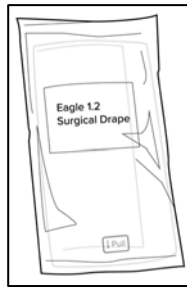
Table 39 Custom Sterile Sleeve Wireless Configuration Instructions

1. Ensure the External Communications Hub (ECH) is set up for ECH **Wireless** Configurations per Section 6.3.2.1.

Pull the CSS out of its packaging.

Unfold the CSS.

2. Prepare the CSS, two (2) small sterile bags, and three (3) pieces of tape on a flat surface in the sterile field.



3. Position the HFC on flat work surface in the sterile field.

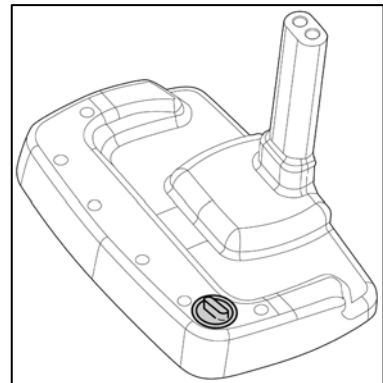
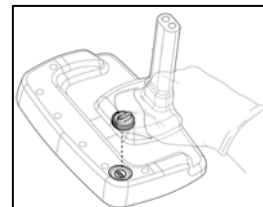
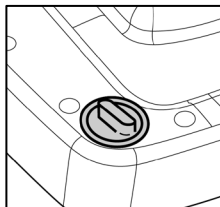
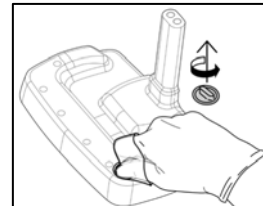


Table 39 Custom Sterile Sleeve Wireless Configuration Instructions

4.

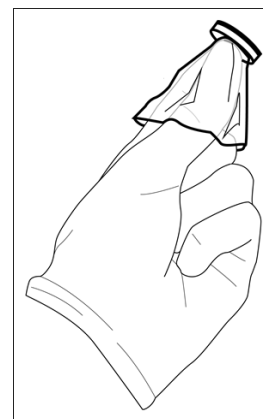
Prepare to remove the HFC USB Hatch with sterile technique by placing thumb and index finger inside one (1) small sterile bag provided with the CSS.

Pinch-grip, twist, and pull the HFC USB Hatch to remove it.



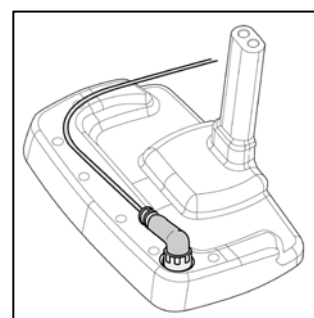
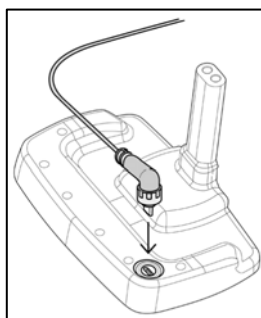
5.

Use the small sterile bag to hold the HFC USB Hatch with sterile technique.



6.

Connect the HFC USB Cable to the HFC. Position the HFC USB Cable 90° Type-C connector such that it points towards the inside of the HFC.



7.

Using provided tape, secure the opposite end of the HFC USB Cable to the work bench.

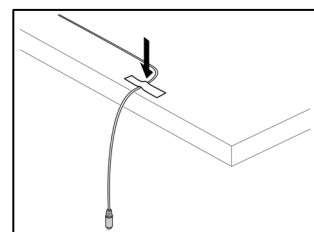
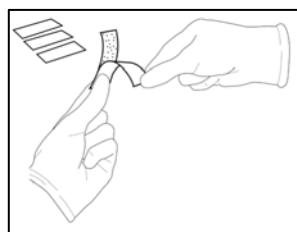
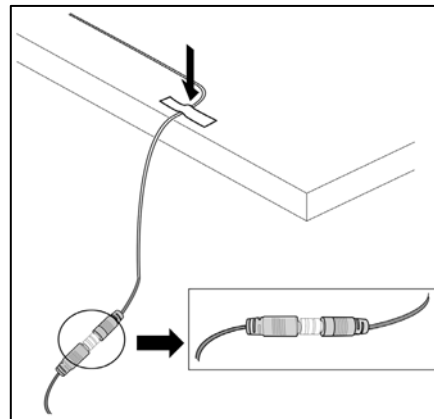


Table 39 Custom Sterile Sleeve Wireless Configuration Instructions

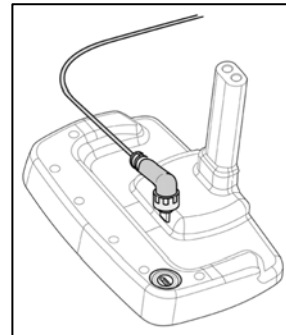
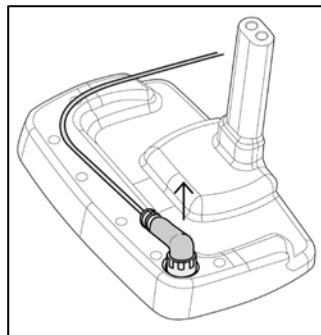
Link the HFC USB Cable to the ECH Link Cable while observing sterile technique.

8. Connect ECH Link Cable to ECH PC USB Port per Section 6.3.2.2 Step 8.

Before proceeding to the next step in this instruction, verify successful connection between the HFC and ECH per Section 6.3.2.2 Steps 8 through 14.



9. After verifying successful connection between the HFC and ECH per Section 6.3.2.2, unplug the HFC USB Cable 90° Type-C connector from the HFC.



10. Prepare to cover the HFC USB Cable 90° Type-C connector by collecting one (1) small sterile bag and one (1) piece of tape.

Cover the HFC USB Cable 90° Type-C connector with small sterile bag and seal bottom opening with tape.

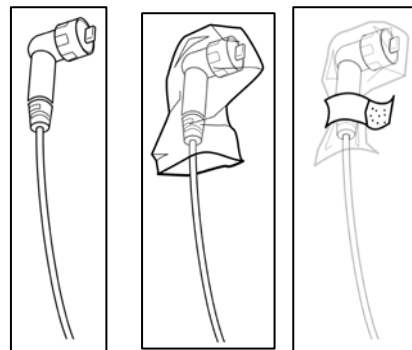
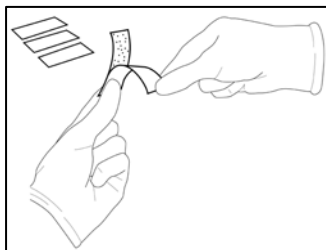
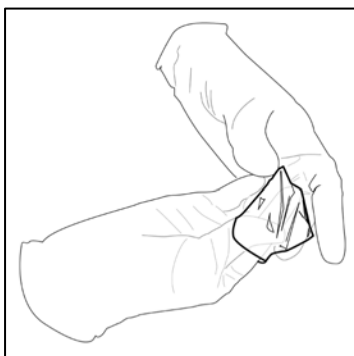
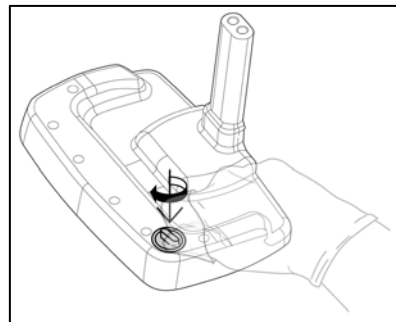
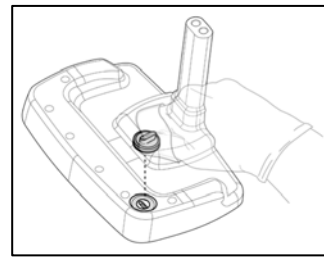


Table 39 Custom Sterile Sleeve Wireless Configuration Instructions

Prepare to re-attach the HFC USB Hatch with sterile technique.

11. While pinch-gripping the HFC USB Hatch with the small sterile bag, push and twist the HFC USB Hatch to re-attach it.

The HFC is now ready to be sheathed with the CSS.

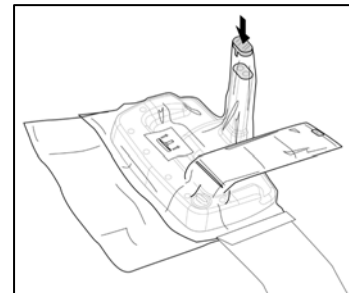
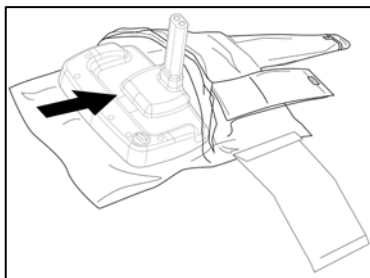


Slide the HFC into the CSS.

Fit the CSS over the HFC optical head.

12. Ensure the CSS optical window snaps onto the optical head.

Position the HFC in the top right of the CSS such that any CSS slack material hangs off the left side of the HFC, while the CSS Tape is flush with the right side of the HFC.



Pull the CSS taut over the body of the HFC.

13. Pull CSS slack material taut from the bottom and left, and wrap the HFC in a gift-wrap style.

Lay the unused telescopic HFC USB Cable Cover across the body of HFC.

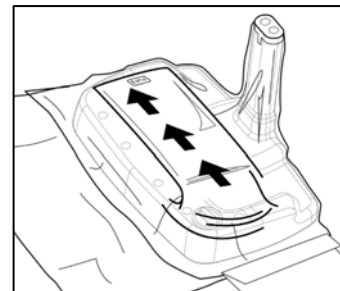
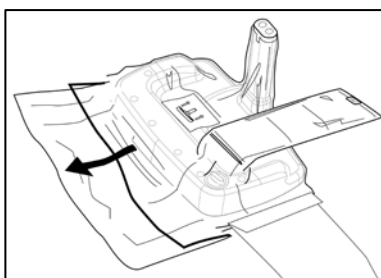
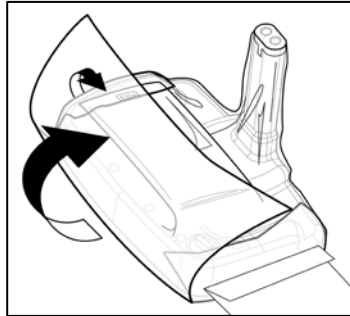
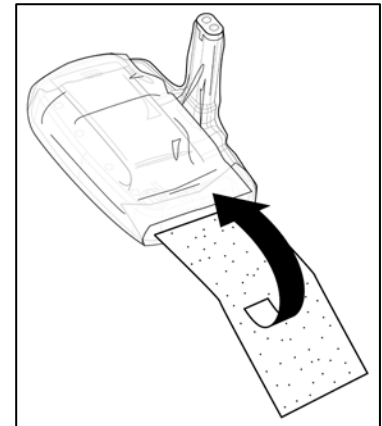
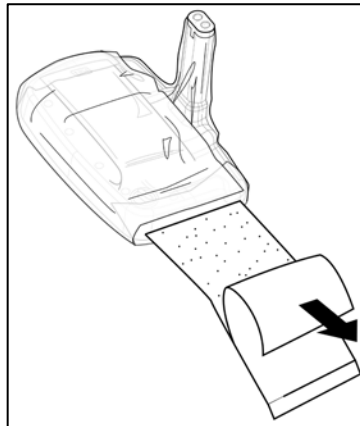


Table 39 Custom Sterile Sleeve Wireless Configuration Instructions

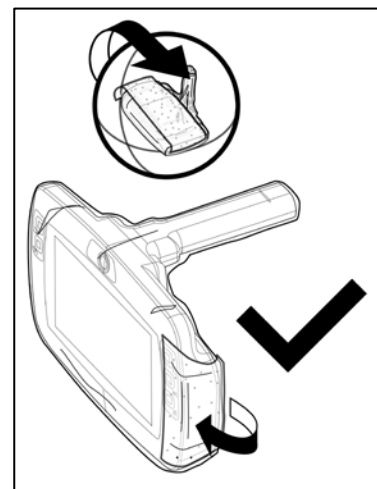
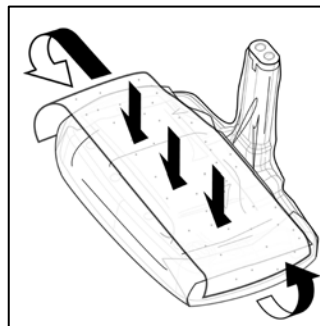
- 14.** Pull CSS slack material taut from the bottom and left, and wrap the HFC in a gift-wrap style.



- 15.** Pull off the adhesive backing from the CSS Tape while keeping the gift-wrapped CSS material in position.
Lay the CSS Tape over the gift-wrapped CSS material.



- 16.** Lay and push the CSS Tape firmly across the backside of the HFC body.
Flip the HFC around and finish adhering the CSS Tape around the right front side of the HFC.



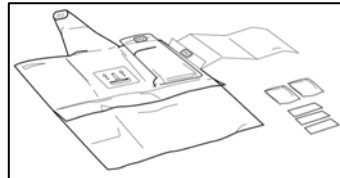
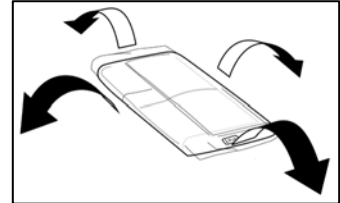
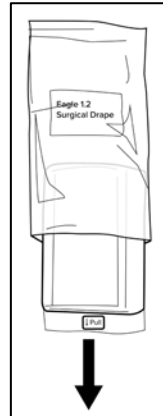
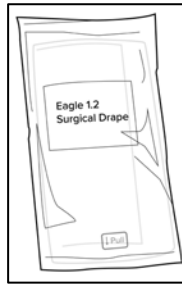
- 17.** The Handheld Fluorescence Camera is now sheathed in the Custom Sterile Sleeve using the ECH **Wireless** Configuration (Section 6.3.2.1), and ready for Imaging per Section 6.2.2.2.

6.3.1.2. Custom Sterile Sleeve Wired Configuration

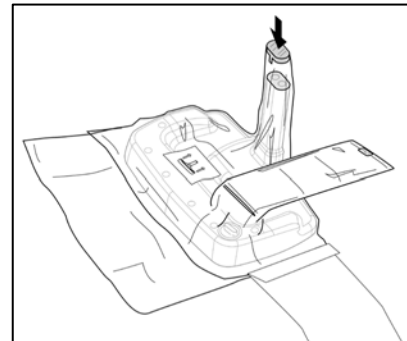
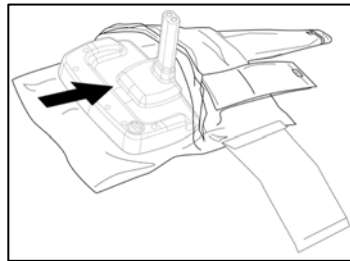
Table 40 Custom Sterile Sleeve Wired Configuration Instructions

1. Ensure the External Communications Hub (ECH) is set up for ECH Wired Configurations per Section 6.3.2.3.

2. Pull the CSS out of its packaging.
Unfold the CSS.
Prepare the CSS, two (2) small sterile bags, and three (3) pieces of tape on a flat surface in the sterile field.



3. Slide the HFC into the CSS.
Fit the CSS over the HFC optical head.
Ensure the CSS optical window snaps onto the optical head.
Position the HFC in the top right of the CSS such that any CSS slack material hangs off the left side of the HFC, while the CSS Tape is flush with the right side of the HFC.



4. Run the HFC USB Cable through the CSS 6-foot-long telescopic HFC USB Cable Cover.

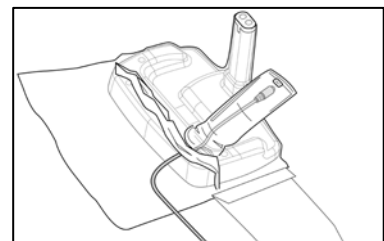
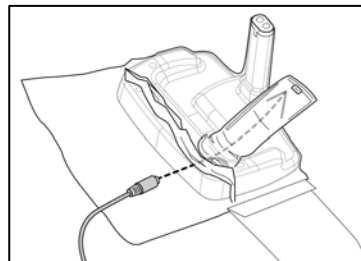
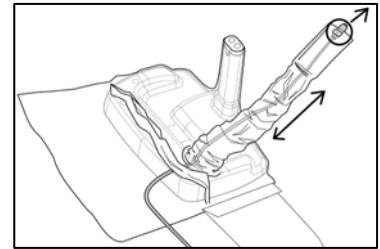
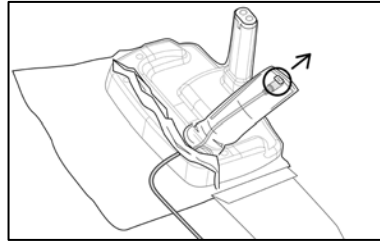


Table 40 Custom Sterile Sleeve Wired Configuration Instructions

5.

Pull to fully extend the telescopic HFC USB Cable Cover.

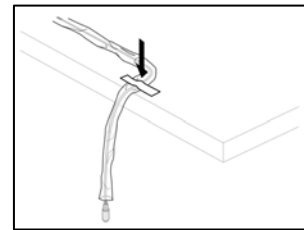
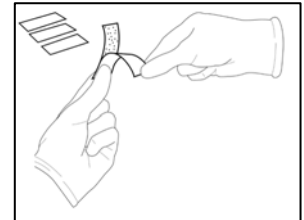
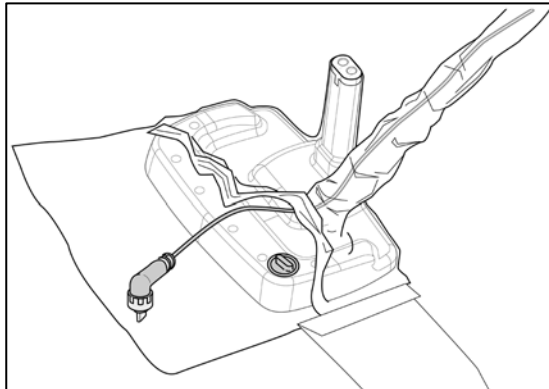
Run the HFC USB Cable through the telescopic HFC USB Cable Cover



6.

Pull to align the HFC USB Cable 90° Type-C connector with the HFC USB Hatch, leaving enough slack to orient and manoeuvre the cable easily.

Using provided tape, secure the opposite end of the HFC USB cable to the work bench, allowing sufficient slack to orient and manoeuvre the HFC during imaging.



7.

Prepare to remove the HFC USB Hatch with sterile technique by placing thumb and index finger inside one small sterile bag provided with the CSS.

Pinch-grip, twist, and pull the HFC USB Hatch to remove it.

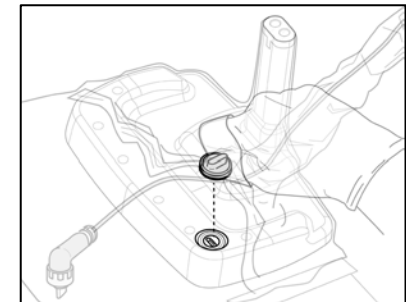
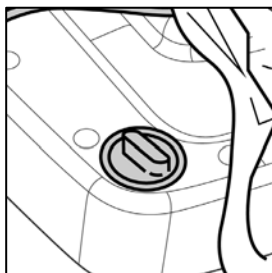
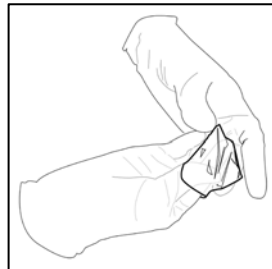
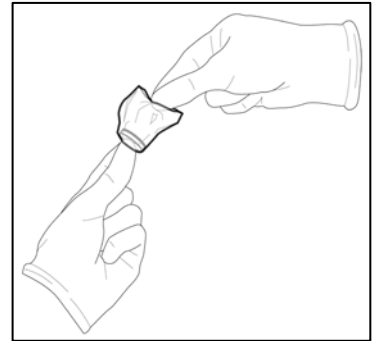


Table 40 Custom Sterile Sleeve Wired Configuration Instructions

8.

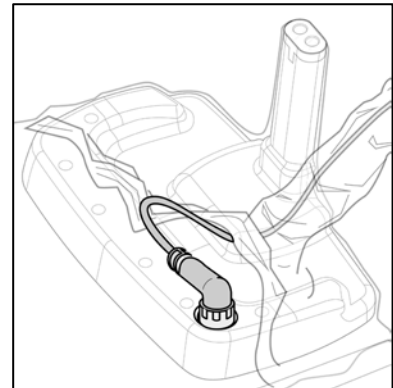
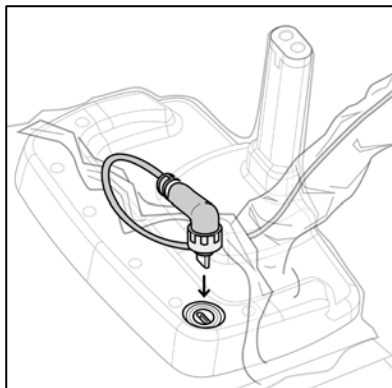
While holding the HFC USB Hatch, turn the small sterile bag inside-out to safeguard the HFC USB Hatch while not in use.



9.

Connect the HFC USB Cable to the HFC.

Position the HFC USB Cable 90° Type-C connector such that it points towards the inside of the HFC.



10.

Link the HFC USB Cable to the ECH Link Cable, while observing sterile technique.

Connect ECH Link Cable to ECH PC USB Port per Section 6.3.2.3 Step 8.

Before proceeding to the next step in this instruction, verify successful connection between the HFC and ECH per Section 6.3.2.3 Steps 8 through 14.

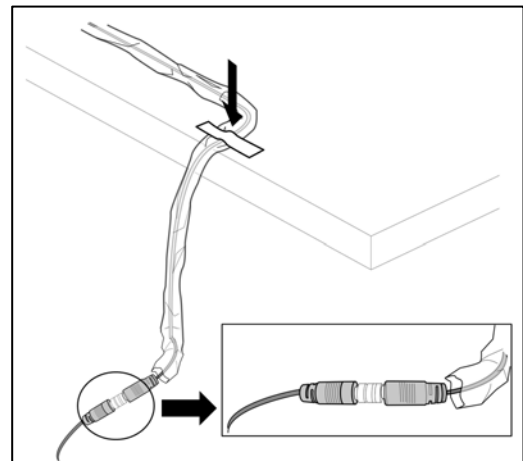
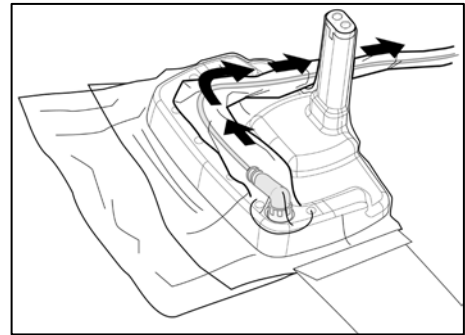
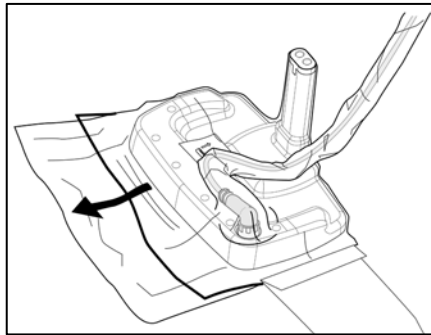


Table 40 Custom Sterile Sleeve Wired Configuration Instructions

11.

Pull the CSS taut over the body of the HFC.

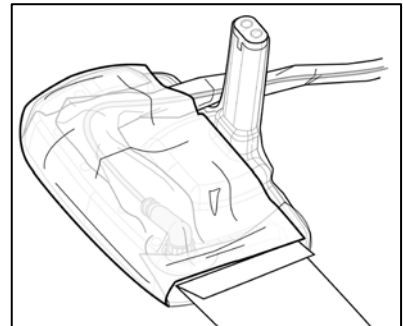
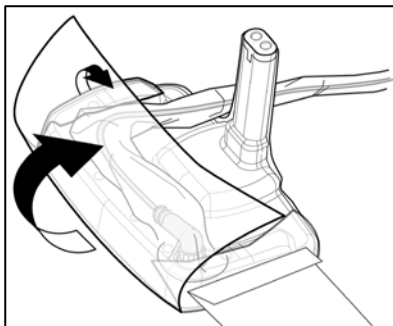
Position the sheathed HFC USB Cable along the bottom and left side of the HFC body.



12.

Ensure the HFC remains positioned in the top right of the CSS such that any CSS slack material hangs off the left side of the HFC, while the CSS Tape is flush with the right side of the HFC.

Pull CSS slack material taut from the bottom and left, and wrap the HFC in a gift-wrap style.



13.

Pull off the adhesive backing from the CSS Tape while keeping the gift-wrapped CSS material in position.

Lay the CSS Tape over the gift-wrapped CSS material.

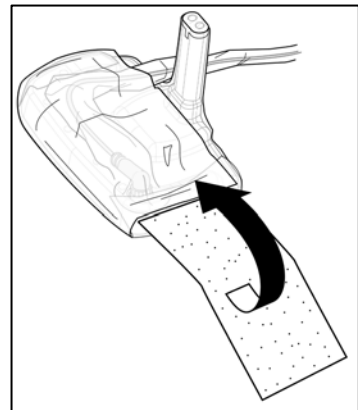
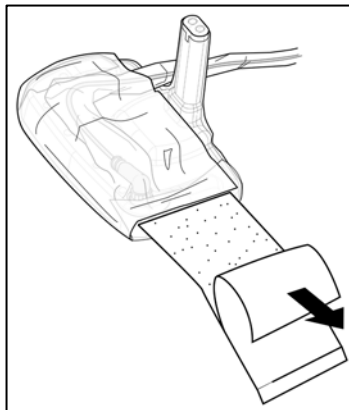
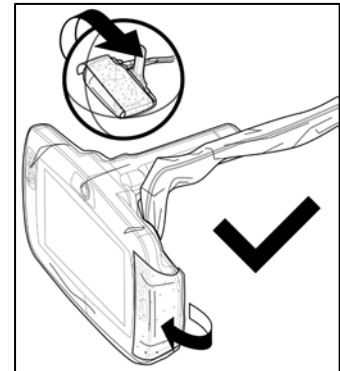
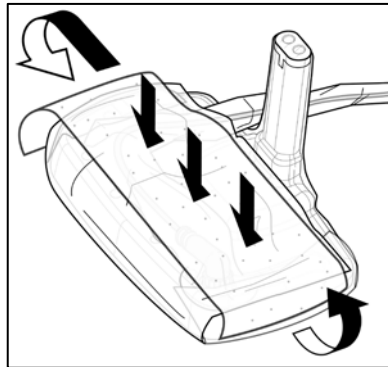


Table 40 Custom Sterile Sleeve Wired Configuration Instructions

14.

Lay and push the CSS Tape firmly across the backside of the HFC body, ensuring the CSS Tape contours along the sheathed HFC USB Cable positioned in Step 11.

Flip the HFC around and finish adhering the CSS Tape around the right front side of the HFC.



15.

The Handheld Fluorescence Camera is now sheathed in the Custom Sterile Sleeve using the ECH **Wired** Configuration (Section 6.3.2.3), and ready for Imaging per Section 6.2.2.2.

6.3.2. External Communications Hub (ECH) Instructions for Use

Once assembled according to Section 6.3.2.1 The External Communications Hub can be configured in a wireless or wired fashion to cast the Handheld Fluorescence Camera's display on to the ECH Display.

The HFC display is cast wirelessly to ECH Display Monitor when the HFC is connected to the ECH PC, using ECH Router. Follow instructions in Section 6.3.2.2 to set up the ECH Wireless Configuration.

The HFC display is cast directly to ECH Display Monitor when the HFC is connected to the ECH PC, using HFC USB Cable with ECH Link Cable. Follow instructions in Section 6.3.2.3 to set up the ECH Wired Configuration.

The ECH support connecting up to two (2) Handheld Fluorescence Cameras at once.

When two (2) Handheld Fluorescence Cameras are connected to ECH:

- the ECH automatically saves data captured on either device, to the other
- data from one HFC can be reviewed on the HFC, and vice versa until the HFC is shutdown
- only 1 HFC can be casted to the ECH

Follow instruction in Step 9 of Section 6.3.2.2 and Step 9 of 6.3.2.3 to connect two (2) Handheld Fluorescence Cameras to the ECH.

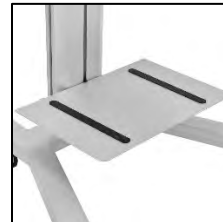
6.3.2.1. ECH Assembly Instructions

Table 41 External Communications Hub Assembly Instructions

1. Mount ECH Desk onto ECH Cart.



2. Mount ECH Shelf onto ECH Cart.



3. Mount ECH Basket onto ECH Cart



Table 41 External Communications Hub Assembly Instructions

4. Mount ECH Power Bar onto ECH Cart.



5. Plug ECH Extension Cord into ECH Power Bar.



6. Mount ECH Display Monitor onto ECH Cart. Plug ECH Display Monitor into ECH Power Bar.



7. Place ECH PC onto the ECH Desk. Connect the ECH Numeric Pad.
Install ECH Flash Drive into ECH PC.
Plug ECH PC into ECH Power Bar.



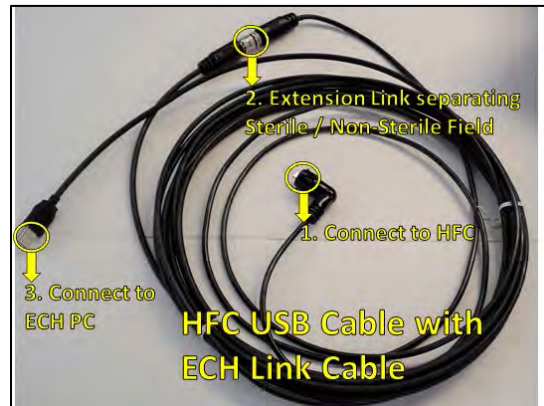
8. Plug ECH PC Power supply into ECH Power Bar.



Table 41 External Communications Hub Assembly Instructions

Link the HFC USB Cable to the ECH Link Cable.

9. Connect the ECH Link Cable to ECH PC.
Coil linked HFC USB Cable and ECH Link Cable and place on ECH Desk.



10. Slide the adjustable ECH Shelf to maximum height.



11. Place ECH Router with power supply and ethernet cable assembly onto ECH Shelf. Plug ECH Router power supply into ECH Power Bar.



Table 41 External Communications Hub Assembly Instructions

- 12.** Plug ethernet cable into ECH PC.

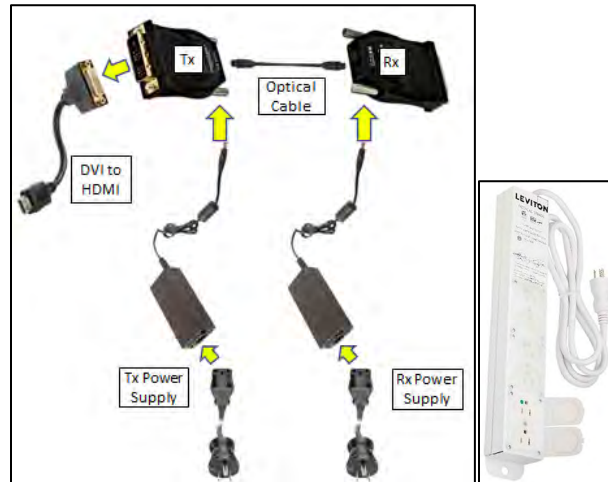


- 13.** Assemble ECH DVI Link Assembly comprised of:

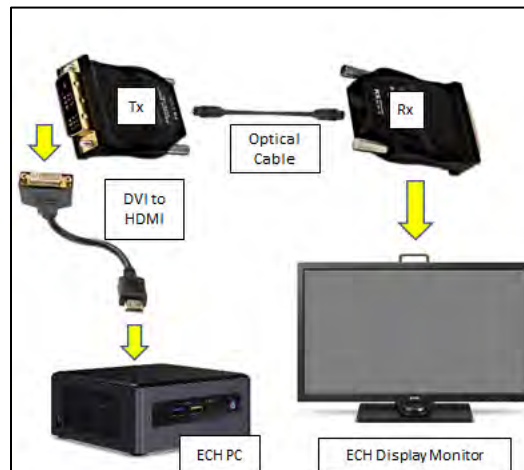
- DVI Link Transmitter (Tx)
- DVI Link Receiver (Rx)
- Tx Power Supply
- Rx Power Supply
- Optical Cable
- DVI to HDMI Cable

Plug Tx Power Supply into ECH Power Par.

Plug Rx Power Supply into ECH Power Bar.



- 14.** Plug HDMI connector into ECH PC.
Plug DVI Link Receiver (Rx) into ECH Display Monitor DVI Port.



Verify 5 power supplies are connected to the ECH Power Bar:

- 15.**
- ECH Display Monitor
 - ECH PC
 - ECH DVI Link Rx
 - ECH DVI Link Tx



Table 41 External Communications Hub Assembly Instructions

- ECH Router

- 16.** Coil cables, and use provided ECH assembly hardware for cable management.
Place power supplies and excess cabling into the ECH Basket.



- 17.** Plug ECH Extension Cord into electrical outlet.



- 18.** Power on the ECH Display Monitor, ECH PC, and ECH Router.

- 19.** The ECH is assembled, powered on and ready for casting the Handheld Fluorescence Camera's display.



Table 41 External Communications Hub Assembly Instructions

20. Setup ECH Wireless Connection following Section 6.3.2.2 or ECH Wired configuration following Section 6.3.2.3.

6.3.2.2. ECH Wireless Configuration

Table 42 External Communications Hub Wireless Instructions

1. Ensure the ECH has been assembled and is powered on according to section 6.3.2.1.

2. After ECH PC power on, enter authorization PIN on ECH Numeric Pad to login.

3. After successful login, the ECH Display Monitor shows the ECH Start Up screen.

CFC CastingVersion : 0.6

4. Shortly after, ECH prompts to *"Insert & Unlock USB Memory Stick"*. Insert ECH Flash Drive into the ECH PC USB port and/or unlock encrypted ECH Flash Drive.

Insert & Unlock USB Memory Stick

5. When the encrypted USB flash drive is unlocked and plugged into the ECH PC USB port, ECH notifies *"USB memory stick setup complete"*.

USB memory stick setup complete

6. After successful login, ECH notifies *"Hub is ready for Wireless setup – Connect First Device"*.

Hub is ready for Wireless setup
Connect First Device

7. Before proceeding, ensure the Custom Sterile Sleeve (CSS) has been configured for ECH Wireless Configurations per Section 6.3.1.1, up until Step 8.

8. Connect ECH Link Cable to the ECH PC USB Port. When a successful connection is made, ECH notifies *"Device 1 is ready for wireless, unplug Device USB cable"*.

Device 1 is ready for wireless
unplug Device USB cable

9. Unplug HFC USB Cable 90° Type-C connector from the HFC. ECH notifies *"Hub is ready for Wireless setup – Connect Second Device"*. If not connecting two (2) HFCs, press "Enter" to move to the next step.

Hub is ready for Wireless setup
Connect Second Device

If connecting two (2) HFCs, connect second ECH Link Cable into the ECH PC USB Port.

Table 42 External Communications Hub Wireless Instructions

10.	<i>"Device 2 is ready for wireless, unplug Device USB cable".</i> Unplug HFC USB Cable 90° Type-C connector from the second HFC.	Device 2 is ready for wireless unplug Device USB cable
11.	ECH notifies <i>"Hub Setup Complete"</i>	Hub Setup Complete
12.	Review the HFC Display Screen. Connected Handheld Fluorescent Camera(s) will show <i>"ECH: Connected Wifi"</i> in the top.	ECH : Connected : Wifi
13.	Press <i>"Enable Casting"</i> to cast the HFC Display Screen onto the ECH Display Monitor Wirelessly.	Enable Casting
14.	Verify the ECH Display Monitor is casting the HFC Display Screen.	

6.3.2.3. ECH Wired Configuration

Table 43 External Communications Hub Wired Instructions

1.	Ensure the ECH has been assembled and is powered on according to section 6.3.2.1.	
2.	After ECH PC power on, enter authorization PIN on ECH Numeric Pad to login.	
3.	After successful login, the ECH Display Monitor shows the ECH Start Up screen.	CFC CastingVersion : 0.6
4.	Shortly after, ECH prompts to <i>"Insert & Unlock USB Memory Stick"</i> . Insert ECH Flash Drive into the ECH PC USB port and/or unlock encrypted ECH Flash Drive.	Insert & Unlock USB Memory Stick
5.	When ECH Flash Drive is unlocked and plugged into the ECH PC USB port, ECH notifies <i>"USB memory stick setup complete"</i> .	USB memory stick setup complete
6.	After successful login, ECH notifies <i>"Hub is ready for Wired setup – Connect First Device"</i> .	Hub is ready for Wired setup Connect First Device

Table 43 External Communications Hub Wired Instructions

7.	Before proceeding, ensure the Custom Sterile Sleeve (CSS) has been configured for ECH Wired Configurations per Section 6.3.1.2, up until Step 10.	
	Connect ECH Link Cable to the ECH PC USB Port.	
8.	When a successful connection is made, ECH notifies <i>"First Device is connected to the Hub: wired"</i> .	First Device is connected to the Hub: wired
	ECH notifies <i>"Hub is ready for Wireless setup – Connect Second Device"</i> .	
9.	If not connecting two (2) HFCs, select "Enter" and move to the next step. If connecting two (2) HFCs, connect second ECH Link Cable into the ECH PC USB Port.	Hub is ready for Wired setup Connect Second Device
10.	<i>"Second Device is connected to the Hub: wired"</i> .	Second Device is connected to the Hub: wired
11.	ECH notifies <i>"Hub Setup Complete"</i> .	Hub Setup Complete
	Review the HFC Display Screen.	
12.	Connected Handheld Fluorescent Camera(s) will show <i>"ECH: Connected USB"</i> in the top left corner.	ECH : Connected : USB
13.	Press "Enable Casting" to cast the HFC Display Screen onto the ECH Display Monitor Wirelessly.	Enable Casting
14.	Verify the ECH Display Monitor is casting the HFC Display Screen.	

6.3.3. DIS – Dark Imaging Sheet

The DIS provides a black non-reflective, non-fluorescent standardized surface background imaging in the sterile field or with the Dark Imaging Box per Section 6.3.4.

Table 44 Dark Imaging Sheet Instructions

1.	When used in the sterile field, place the DIS on a flat surface with the side labelled <i>"This Side Down / Ce Côté En Bas"</i> facing down.	THIS SIDE DOWN CE CÔTÉ EN BAS
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Table 44 Dark Imaging Sheet Instructions

2. Place imaging specimen on the DIS and perform imaging per Section 6.2.2.2.



When using the Dark Imaging Sheet with the Dark Imaging Box, place the DIS with imaging specimen on the DIB Imaging Tray with the side labelled "*This Side Down / Ce*

3. *Côté En Bas*" facing down.

Perform imaging per Section 6.2.2.2.



6.3.4. DIB – Dark Imaging Box

The Dark Imaging Box is intended to be positioned on a flat surface in the non-sterile field.

Table 45 Dark Imaging Box Instructions

1. Before use, clean and disinfect the Dark Imaging Box according to Section 5.3.
2. Position the Dark Imaging Box on a flat surface in the non-sterile field.
3. Pull the DIB Tray out in preparation of receiving the Dark Imaging Sheet.
4. Place the Dark Imaging Sheet into the DIB Tray recess, and push the DIB Tray in.
5. Enclose the Dark Imaging Box by aligning the DIB Covers around the Dark Imaging Box. The DIB Covers magnetize to the Dark Imaging Box.
6. Place the Handheld Fluorescent Camera into the DIB Cradle and perform imaging per Section 6.2.2.2.

6.3.5. CCD – Contact Charging Device

The Handheld Fluorescence Camera is required to be fully charged before use.

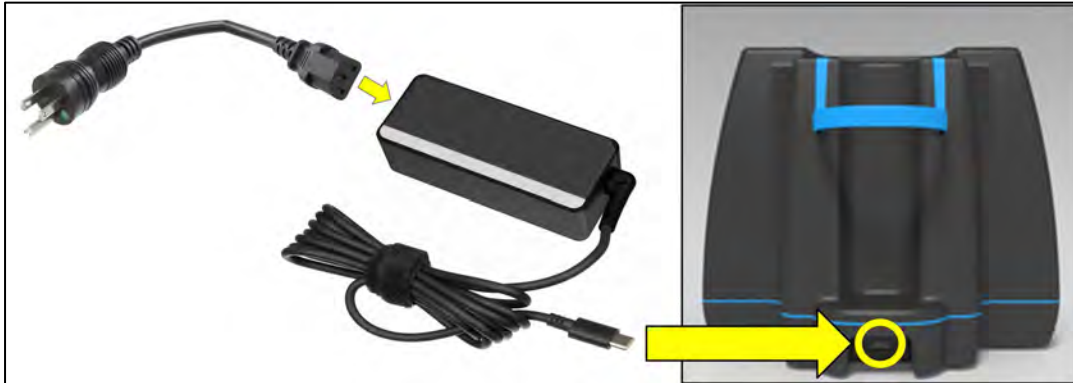
-  While charging, the device is inoperable with exception to reviewing acquired images and videos.
 -  While charging, connection to the ECH is not supported.
-

Table 46 Charging Instructions

- 1.** Before use, clean and disinfect the Contact Charging Device according to Section 5.3.
-

Assemble the CCD Power supply and plug the USB Type-C connector into the CCD USB Type-C port.

2.



- 3.** The white LED on the front side of the Contact Charging Device is illuminated when power is supplied.

Pug the CCD Power cord into electrical outlet.

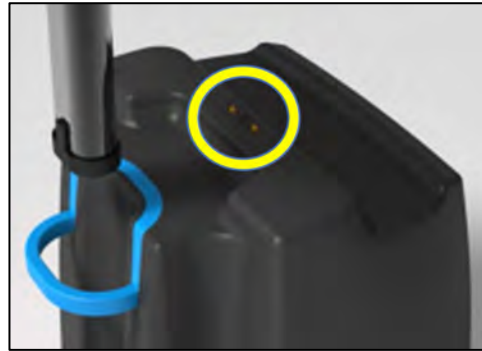


Table 46 Charging Instructions

4. Place the Handheld Fluorescent Camera into the Contact Charging Cradle, with the HFC Optical Head pointing down.



5. The HFC battery begins charging when the HFC makes contact with the two charging pins on the top side of the CCD.



6. Refer to Section 6.2.1.3 for details on the Battery Status LED to understand how to determine battery charge levels, and battery charge status.

6.3.6. PSC – Protective Storage Cradle

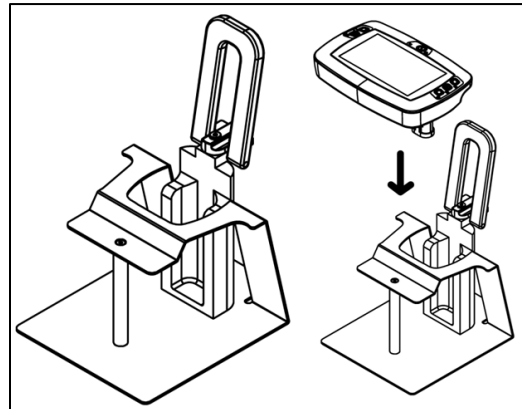
Use the Protective Storage Cradle to Safeguard the Handheld Fluorescence Camera when not in use or during transportation.

Table 47 Charging Instructions

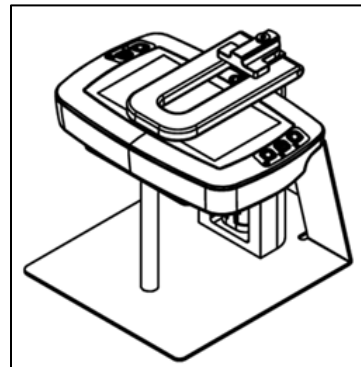
1. Before use, clean and disinfect the Protective Storage Cradle according to Section 5.5.

2. To protect the Handheld Fluorescent Camera, place the Protective Storage Cradle on a flat surface and open the Protective Storage Cradle lock.

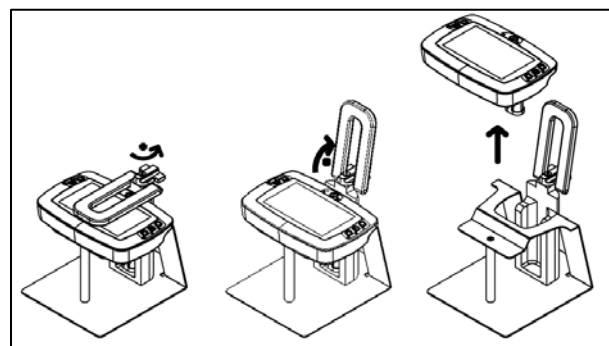
Place the Handheld Fluorescent Camera into the Protective Storage Cradle, with the HFC Optical Head pointing down.



3. Rest the HFC on the PSC cradle, and close the PSC lock. The HFC is now locked into the PSC.



4. To remove the HFC from the PSC, open the PSC lock and remove the HFC.



7. Workflow

7.1. Unpack

- 1) Unpack and remove all Eagle V1.2 Imaging System components.
- 2) Charge HFC with CCD per Section 6.3.5.
- 3) Set up the ECH per Section 6.3.2.1 and verify HFC connection.

7.2. Imaging Workflow

- 1) Clean, disinfect, and sterilize all Eagle V1.2 Imaging System components per Section 5.
- 2) Mount the CSS on the HFC per Section 6.3.1
- 3) Verify successful HFC connection with ECH per Section 6.3.2.2 or 6.3.2.3.
- 4) Perform imaging per Section 6.2.2.2
- 5) Use the Dark Imaging Sheet and Dark Imaging Box as necessary per Section 6.3.3 and Section 6.3.4.

7.3. Post Imaging

- 1) Dispose of CSS, DIS, and DIB Covers.
- 2) Clean, disinfect, and sterilize Eagle V1.2 Imaging System components per Section 5.

8. Care and Maintenance

8.1. Transport and Handling

Per section 6.3.6 Store the Handheld Fluorescent Camera in the Protective Storage Cradle when not in use.

9. Performance Specifications

9.1. HFC – Handheld Fluorescence Camera

- Operating Temperature:_____ 18 – 25 °C
- Operating Relative humidity:_____ 10 – 70%
- Operating Atmospheric pressure:_____ 89 – 102 kPa
- Height:_____ 13 cm
- Width:_____ 19 cm
- Depth:_____ 13 cm
- Weight:_____ 591 g
- Input (Charging Current, Voltage):_____ 2.5 A, 5 VDC
- Battery Capacity:_____ 6500 mAh
- Operating Voltage:_____ 3.7 VDC

9.2. CSS – Custom Sterile Sleeve

- FCC ID: 2AFDI – ITCOQ626S
- ISED ID: 9049A – ITCOQ626S
- Operating Temperature: 18 – 25 °C
- Operating Relative humidity: 10 – 70%
- Operating Atmospheric pressure: 89 – 102 kPa
- Height: 2 cm
- Width: 28 cm
- Depth: 39 cm

9.3. ECH – External Communications Hub

- Operating Temperature: 18 – 25 °C
- Operating Relative humidity: 10 – 70%
- Operating Atmospheric pressure: 89 – 102 kPa
- RAM: 8 GB
- Memory: 256 GB
- Operating System: Windows 10
- FCC ID: ZJEST-WKP302
- WLAN: 2.4 GHz

9.3.1. ECH PC Power Supply

- Output: 65 W, 19 V, 3.40 A

9.3.2. ECH Router Power Supply

- Output: 6 W, 12 V, 1.0 A

9.3.3. DVI Link Power Supply

- Output: 10 W, 5 V, 2.0 A

9.3.4. ECH Router Wireless

- Frequency: 5.0 GHz
- Wi-Fi Speed: AC2200 – AC4400
- Wi-Fi: 802.11AC

9.4. CCD – Contact Charging Device

- Operating Temperature: 18 – 25 °C
- Operating Relative humidity: 10 – 70%
- Operating Atmospheric pressure: 89 – 102 kPa
- Height: 15 cm
- Width: 18 cm
- Depth: 15 cm
- Weight: 400 g
- Output Current: 2.5 A
- Output Voltage: 5 V

END OF
Eagle V1.2 Imaging System Instructions for Use