Lumicell™ Direct Visualization System (DVS)

INSTRUCTIONS FOR USE

LUMICELL®

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1

Introduction

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

The physician using Lumicell DVS must be trained in breast-conserving surgery.

The Lumicell Direct Visualization System (DVS) Instructions for Use contain information necessary for the safe and proper use of Lumicell DVS.

Carefully read the Instructions for Use.

Prior to using Lumicell DVS, read these Instructions for Use in its entirety. Follow all instructions contained within this document, as failure to understand and apply these instructions may result in:

- Patient or user discomfort
- Damage to equipment

1.1 Product Description

Lumicell™ Direct Visualization System (DVS) is a fluorescence imaging system designed to excite and capture the emissions from LUMISIGHT™, an optical imaging agent. The Lumicell DVS and LUMISIGHT combination product is indicated for fluorescence imaging in adults with breast cancer as an adjunct for the detection of cancerous tissue within the resection cavity following removal of the primary specimen during lumpectomy surgery (also known as breast-conserving surgery).

Lumicell DVS consists of a light source, handheld probe, and touchscreen which operates the patient-calibrated cancer detection software. The light source and touchscreen are each powered by a power source, all of which sit on a transportable point-of-care workstation, allowing for movement between operating rooms. The handheld probe is sterilized between each use and plugs into the light source and USB hub. A Sterile Cover for the handheld probe reduces the patient's risk of infection by providing a sterile barrier between the patient and the device.

This manual provides users of Lumicell DVS with detailed instructions for proper use, maintenance, and storage. See the Prescribing Information of LUMISIGHT for contraindications and warnings before selecting patients to receive LUMISIGHT.

1.2 System Components

Lumicell DVS	Consists of the workstation, touchscreen, power source, light source, and handheld probe. P/N: 810-00217.
Touchscreen (non-sterile)	Computer that operates the patient-calibrated cancer detection software to analyze and display images, highlight regions suspected to contain cancer, and store results. P/N: 160-00221.
Power Source (non-sterile)	Isolation transformer that provides power to the light source and touchscreen while isolating the patient from the primary power source. Users turn on the power source after plugging the Lumicell DVS power cable into a hospital-grade outlet and before turning on the other components. P/N: 192-00203.
Light Source (non-sterile)	Provides the fluorescence excitation light to the handheld probe. P/N: 810-00212.
USB Hub (non-sterile)	Connects the handheld probe to the touchscreen. Users plug the USB cable into the USB hub during setup and before turning on the software. P/N: 160-00210.
Handheld Probe with cables (sterile reprocessed)	Shines light onto the tissue and collects fluorescent light reflected from the injected imaging agent. A light guide connects it to the light source, and a USB cable connects it to the touchscreen. The handheld probe and cables are detachable from the workstation, also referred to as BF applied part (body floating applied part), and are decontaminated and sterilized (See Section 10). P/N: 810-00211.
Sterile Probe Cover (supplied separately)	The Sterile Probe Cover (P/N 840-00204), or "probe cover", is a disposable sheath provided by Lumicell to cover the handheld probe and cables during each procedure. It consists of a primary cover (applied first) and secondary cover (applied second). The sterile cover is part of the probe's optics, making it necessary to focus the camera when operating Lumicell DVS. The Sterile Probe Cover is sterilized in manufacturing with ethylene oxide (EO) and is detachable from the workstation.
Sterile Two-sided Calibration Plate (supplied separately)	Sterile Two-sided Calibration Plate (P/N: 840-00205), or "calibration plate", is a disposable component provided by Lumicell that is sterilized using ethylene oxide (EO) and is detachable from the workstation.
Sterile Workstation Drape (supplied separately)	Sterile Workstation Drape (Universal Medical Inc. SKU #: C-ARM4065B or equivalent) is an optional, disposable component to cover the workstation during each procedure. It is not provided by Lumicell. See manufacturer's information for the Sterile Workstation Drape. This drape is detachable from the workstation.
Sterilization Tray	A reusable metal tray (P/N: 810-00218) for sterilizing the handheld probe. The sterilization tray is also used to transport the sterilized, handheld probe between the OR and central processing. The tray is detachable from the workstation.

Lumicell DVS

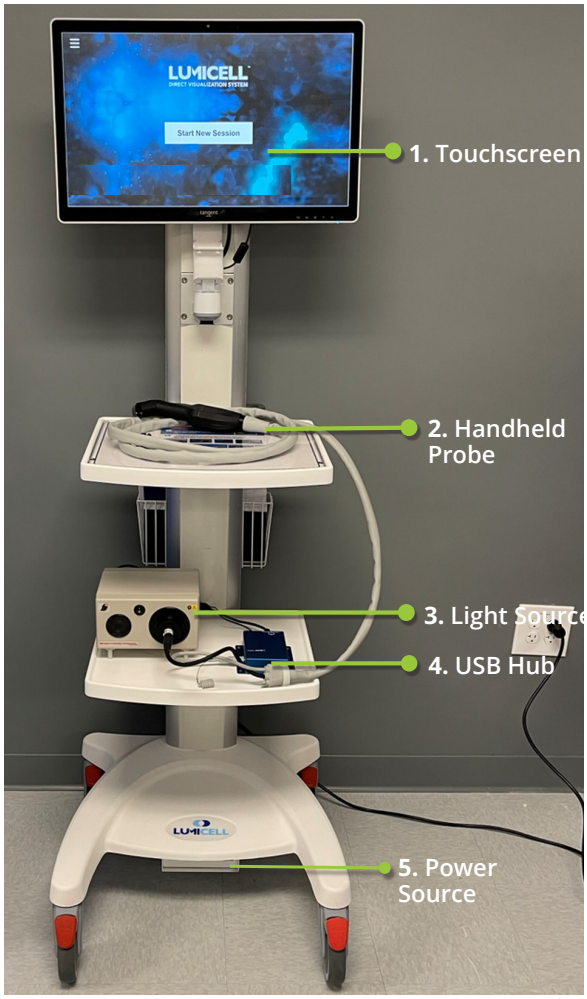

Fig.1. **Lumicell DVS**

Handheld Probe

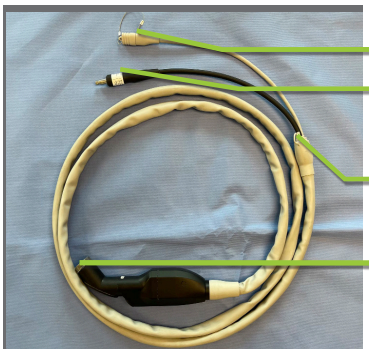

Fig.2. **Handheld probe**

Two-sided Calibration Plate

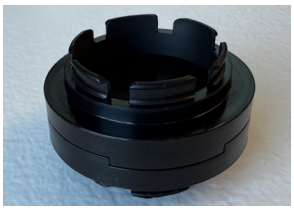

Fig.3. **Dark plate side**

Fig.4. **Bright plate side**

Light Source

Fig.5. **Light source**

1.3 Glossary Terms

Calibration	A setup step required prior to imaging that flat-field corrects the light pattern and prepares the handheld probe camera before use. Users must calibrate both plates of the calibration plate: the bright (white) plate and dark (black) plate.
Establish baseline	A process where users capture six images from different orientations in the lumpectomy cavity for the system to establish the baseline fluorescence signal and set the cancer detection threshold for the specific patient.
Insertion Portion	Portion of the handheld probe which is intended to be inserted into a natural or surgically created body opening or which is intended to be inserted into the instrument channel of an endoscope. See Section 14 "General Specifications".
Sterilization Tray	An instrument tray that holds the handheld probe during sterilization and storage. The metal clips are designed to protect and organize the handheld probe and cables within the tray. The perforated slotted base and lid assist with circulation of gas during sterilization.
Main Lumpectomy Specimen	The initial tissue mass that a surgeon removes with intent of capturing tumor.
Shave	Lumpectomy margin tissue removed after the main lumpectomy specimen, sometimes due to a positive signal as indicated by Lumicell DVS.
Sterile Surgical Towel	A standard, sterile, preferably reduced lint, operating room towel used to prevent light contamination with the handheld probe.
Working Length	Length of the insertion portion. See Section 14 "General Specifications".

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2

General Policy

2.1 Indication for Use

Lumicell Direct Visualization System (DVS) is indicated for use in adults with breast cancer as an adjunct for the intraoperative detection of cancerous tissue within the resection cavity following removal of the primary specimen during lumpectomy surgery.

Lumicell DVS is used with LUMISIGHT (pegulicianine) for fluorescence imaging of the lumpectomy cavity.

2.2 Intended Use and Users

Intended Use: The combination product consists of an optical imaging agent, LUMISIGHT (pegulicianine) for injection (NDA 214511), and a fluorescence imaging device, Lumicell Direct Visualization System (DVS). Lumicell DVS is intended for use in adults with breast cancer as an adjunct for the intraoperative detection of cancerous tissue within the resection cavity following the removal of the primary specimen during lumpectomy surgery.

Lumicell DVS is used with LUMISIGHT for fluorescence imaging of the lumpectomy cavity.

LUMISIGHT is an optical imaging agent indicated for fluorescence imaging in adults with breast cancer as an adjunct for the intraoperative detection of cancerous tissue within the resection cavity following removal of the primary specimen during lumpectomy surgery.

Intended Users: Surgeons using Lumicell DVS must be trained in proper operation of the system prior to performing any procedures.

Federal law (USA) restricts this device to sale by or on the order of a physician. Rx only.

Users of Lumicell DVS include:

1. The surgeon, who will operate the handheld probe and scan the tissue surfaces during imaging. Surgeons using Lumicell DVS shall have appropriate qualifications to perform breast-conserving surgery.
2. Surgical support staff, which includes the non-sterile user (i.e., circulating nurse) and the sterile user (scrub technicians). The sterile user will perform all sterile tasks, like applying calibration plates and the sterile probe cover. The sterile user will also interact with the software user interface when the system has a sterile workstation drape applied. When not using the sterile workstation drape, the non-sterile user will interact with the software user interface.
3. Reprocessing technicians, who clean and sterilize the handheld probe and cables in between surgeries.

Contact Lumicell for training information.

2.3 Contraindications

There are no known contraindications for Lumicell DVS. LUMISIGHT is contraindicated in patients with a history of hypersensitivity reaction to pegulicianine. Reactions have included anaphylaxis. Refer to LUMISIGHT's Prescribing Information for full safety information.

2.4 Warnings

This section provides general precautions related to using Lumicell DVS. Additional warnings and cautions related to specific instructions are highlighted throughout this Instructions for Use. If you have any questions after reading this section, do not hesitate to contact Lumicell using the contact information located on the last page of this document, or call 1-833-4LUMDVS (1-833-458-6387).

⚠ WARNING

- **Lumicell DVS is for adjunctive use and not a replacement for the standard of care lumpectomy procedure and pathology.**
- **False positives and false negatives may occur during use of LUMISIGHT imaging to detect residual cancer. Absence of signal in the lumpectomy cavity does not rule out the presence of residual cancer. Additionally, positive signal has been observed in some non-cancerous tissue.**
- **Lumicell DVS detection of breast cancer may not be generalizable to all subpopulations at increased risk for positive margins.**
- **Supply of such technical documentation relating to the instrument shall not be construed as constituting manufacturer's authorization of users' personnel, regardless of their levels of technical training, to open or repair the instrument.**
- **Before use, physicians must be trained in breast-conserving surgery and the proper use of Lumicell DVS. For details on how to perform the intraoperative imaging examination of the tumor bed, please refer to the Lumicell DVS label and Instructions for Use manual.**
- **Blue dyes used for sentinel lymph node (SLN) mapping procedures interfere with LUMISIGHT imaging. The potential of other dyes to interfere with LUMISIGHT imaging has not been evaluated. Avoid administration of dyes used for SLN mapping procedure before imaging the lumpectomy cavity in patients receiving LUMISIGHT.**
  - Note: Technetium-99 is not a blue dye and can be used with LUMISIGHT and the Lumicell DVS.
- **Read Prescribing Information for all warnings related to LUMISIGHT.**
- **To avoid infection risk when using reusable equipment, properly and completely disinfect and reprocess the handheld probe and cables after each use.**
- **To avoid infection risk when using sterile single-use equipment, ensure to use the sterile probe cover properly.**

⚠ WARNING

- **The light generated by Lumicell DVS is not dangerous to the human eye (Exempt Group, IEC 62471 Test Report), but it may be uncomfortable or distracting. Avoid shining the light toward the eyes of anyone near the device.**
- **DO NOT apply excessive pressure or torque with the handheld probe while inside the cavity.**
  - Use enough pressure to achieve in-focus images (See Section 6.2 for more details)
- **Failure to follow instructions could result in discomfort to the patient or user.**
- **ONLY connect this equipment to mains with protective earth to avoid the risk of electric shock.**
- **Grounding can only be achieved when the equipment is connected to an equipment receptacle marked "Hospital Only" or "Hospital Grade".**
- **DO NOT use the system if there are any visible signs of damage or failure.**
- **DO NOT use this system next to or stacked with other equipment.**
  - Using this system next to or stacked with other equipment could result in improper operation. If such use is necessary, observe this equipment and the other equipment to verify that they are both operating normally.
- **DO NOT use accessories, transducers, and cables other than those specified or provided by this system's manufacturer. Such use could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment. These effects could lead to improper operation.**
- **DO NOT use portable RF communications equipment (including peripherals such as antenna cables and external antennas) within 30 cm (12 inches) of any part of the System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.**
- **DO NOT connect non-Lumicell equipment to sockets (outlets) on the power source. This can result in a reduced level of safety.**
- **DO NOT position the system such that you cannot disconnect the AC Mains plug.**

2.4 Warnings (cont.)

This section provides general precautions related to using Lumicell DVS. Additional warnings and cautions related to specific instructions are highlighted throughout this Instructions for Use. If you have any questions after reading this section, do not hesitate to contact Lumicell using the contact information located on the last page of this document, or call 1-833-4LUMDVS (1-833-458-6387).

⚠ WARNING

- **DO NOT connect an additional multiple-socket outlet or extension cord to the system.**
- **To prevent risk of electrical shock, make sure the Lumicell touchscreen and light source are connected to the power source.**
- **Before and after moving the system, ensure all cables are arranged in an orderly manner and positioned outside of foot traffic areas to prevent users from tripping.**
- **Keep hands away from the wheels of Lumicell DVS to avoid pinching or crushing hands or fingers while moving the system.**
- **To prevent overheating, turn off the Light Source if the High Internal Temperature Indicator (yellow LED) is illuminated.**
- **DO NOT touch monitor and patient simultaneously.**
- **Equipment cannot be altered. Hazards can result from unauthorized modification of the equipment.**
- **Lumicell DVS has been designed and tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to the IEC 60601-1-2:2020 standard when used in the professional healthcare environment.**
- **Do not use Lumicell DVS equipment near magnetic equipment. Strong magnetic fields from nearby equipment could result in performance disruption.**

⚠ CAUTION

- Use a sterile surgical towel and turn off lights to minimize possible interference from stray light. Stray light can interfere with system's cavity reading.
- Legibility of markings: Label legibility is intended to be read at no more than 0.5 meters away.
- High levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from nearby equipment could result in performance disruption. Such disruption will result in an error message being displayed with instructions on how to resolve the error.
- The plug at the end of the workstation power cord is considered the disconnect device. When connected, the system should be positioned so that the plug is accessible for removal.

3

Preparing for Imaging Session

Materials You Will Need

- LUMISIGHT (pegulicianine) for injection
- Lumicell DVS (P/N: 810-00217), which includes:
  - Workstation (touchscreen, light source, power source)
  - Handheld probe (P/N: 810-00211)
    - *Handheld probe is provided non-sterile and must be sterilized prior to use*
- Disposable sterile two-side calibration plate (P/N: 840-00205)
- Disposable sterile probe cover (P/N: 840-00204)
- Disposable sterile workstation drape (Optional)

3.1 Confirm LUMISIGHT Injection Window

a) Ensure LUMISIGHT has been injected **2 to 6 hours** before performing imaging.

Refer to the prescribing information for instructions on preparing and injecting LUMISIGHT.

Inject 2 to 6 hours before imaging

3.2 Open Handheld Probe

a) Using sterile technique, remove the handheld probe from the sterile tray and place the handheld probe in the sterile field.

b) Uncoil the handheld probe cables.

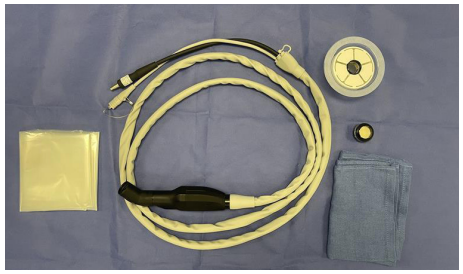

Fig.6. **Place probe in sterile field**

⚠ Warning

Prior to use, inspect the handheld probe and cables for signs of functional damage, including:

- Cracks, deep scratches, or condensation on the distal window
- Degradation of seams or seals, sharp edges, or other structural damage.

Sterilization may result in minor cosmetic changes - such as discoloration - that do not affect device performance.

Do not use the device if functional damage is suspected.

Contact Lumicell Technical Support at 1-833-4LUMDVS (1-833-458-6387) for product support, including return authorization.

c) While maintaining sterility of the handheld probe, pass the sterile handheld probe cables out of the sterile field to the circulating nurse.

Fig.7. **Pass cables out of sterile field**

3.3 Position Lumicell DVS and lock wheels

a) Position Lumicell DVS so the surgeon has a clear view of the touchscreen.

b) Lock the wheels of Lumicell DVS'.

If Lumicell DVS needs to be moved during the procedure, unlock and relock the wheels after relocation.

Fig.8. **Lock wheels**

3.4 Plug in Handheld Probe Cables

IMPORTANT
Steps 3.4-3.5b must be performed by a non-sterile circulating nurse.

a) Plug the black light guide into the front of the light source.

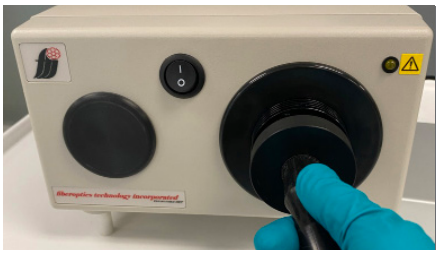

Fig.9. **Plug light guide into light source**

b) Plug the gray USB cable into the USB hub located beside the light source on Lumicell DVS.

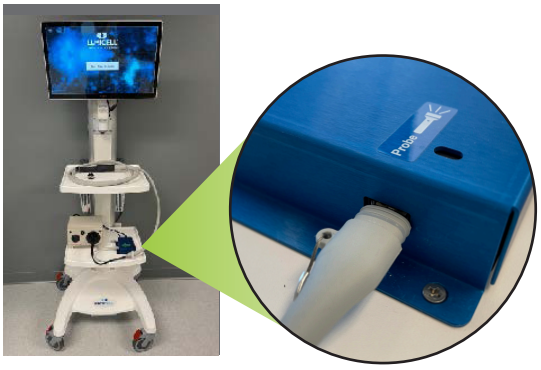

Fig.10. **Plug handheld probe USB cable into USB hub**

3.5 Power on Lumicell DVS

NOTE

The power source supplies power to the entire Lumicell DVS. Turn on the power source first, otherwise the remaining system components will not turn on.

a) Plug the power source into a grounded electrical outlet in the wall.

b) Turn on the power source by pressing the ON side of the switch located at the front base of Lumicell DVS.

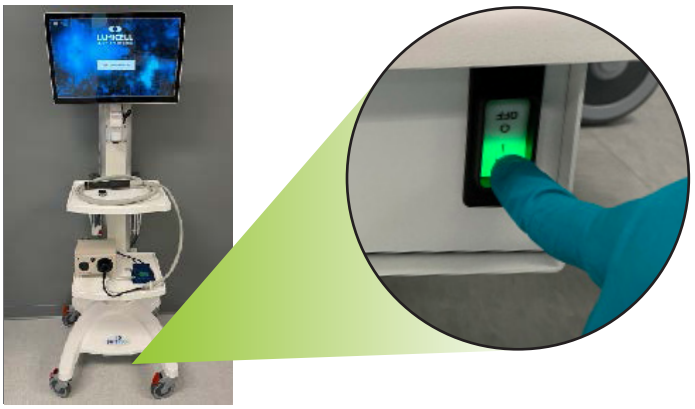

Fig.11. **Turn on power source**

c) Turn on the light source by pressing the "I" side of the power switch.

⚠ WARNING

Avoid direct eye exposure to handheld probe light.

Fig.12. **Turn on light source**

d) Turn on the touchscreen by pressing the button located under the lower right corner of the screen.

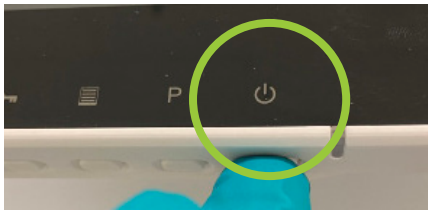

Fig.13. **Turn on touchscreen**

3.6 Log into Lumicell DVS

a) Press the "Key" button on the lower right-hand corner of the touchscreen to bring up the login screen.

Enter login credentials to open the patient-calibrated cancer detection software.

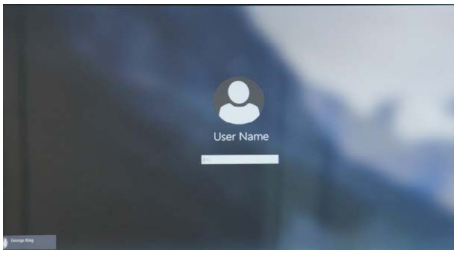

Fig.14. **Log in screen**

3.7 Prepare Lumicell DVS

a) *[Optional]* Using sterile technique, apply the Sterile Workstation Drape. Pull the sides down to cover the entire workstation and ensure drape is tight around monitor so it is easy to touch and visible to the surgeon.

⚠ WARNING

Maintain sterile technique while applying the drape.

Fig.15. **Sterile workstation drape**

b) Tap "Start New Session." The system warmup time begins once "Start New Session" is selected.

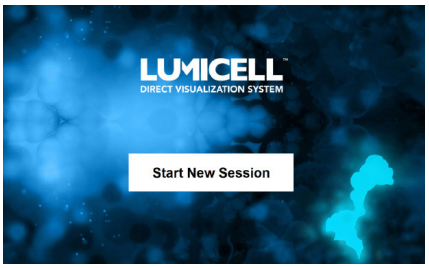

Fig.16. **Start new session**

c) Enter Patient Information. The fields with asterisks (*) are required. Press Continue.

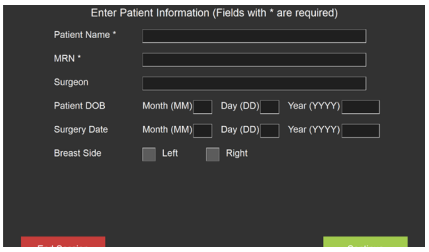

Fig.17. **Enter patient information**

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4

Calibrating the System

Materials you will need

- Disposable Two-sided Calibration Plate (P/N: 840-00205)
- Handheld Probe (P/N: 810-00211)

IMPORTANT

- If using the sterile workstation drape as described in Section 3, follow sterile technique throughout the rest of the imaging session. If not using the sterile workstation drape, the non-sterile user must operate the workstation while the sterile user handles the probe and calibration plates inside the sterile field.
- See Section 11 "Troubleshooting" for any issues with bright and dark plate error messages.

NOTE

Retrieving and applying the two-sided calibration plate requires a sterile user and a non-sterile user. The non-sterile user must perform Step 4.1, and then the sterile user attaches the calibration plates to the sterile probe.

4.1 Retrieve and Open Two-Sided Calibration Plate

a) Locate the two-sided calibration plate dispenser carton and remove a pouch from the carton.

b) Confirm that the ethylene oxide (EO) indicator on the pouch has turned green, indicating that the plate has been sterilized.

c) Empty the calibration plate into the sterile field.

IMPORTANT

If using the sterile workstation drape, the following steps must be performed by a sterile user within the sterile field. If not using the sterile workstation drape, the sterile user must apply the calibration plates while the non-sterile user clicks through the software prompts.

4.2 Calibrate Bright Plate

a) Following the on-screen instructions, snap the calibration plate onto the handheld probe with the white side (i.e., bright plate) facing the probe.

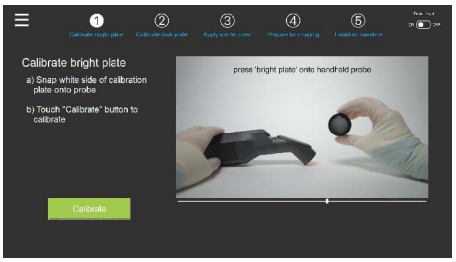

Fig.18. **Bright plate calibration screen**

Fig.19. **Bright plate attached**

4.2 Calibrate Bright Plate *continued*

b) Tap "Calibrate," and the software will confirm successful bright plate calibration.

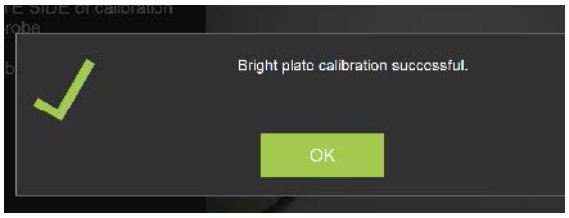

Fig.20. **Bright plate calibration confirm screen**

4.3 Calibrate Dark Plate

a) Remove the calibration plate from the probe at an angle, flip the plate over, and snap the plate onto the probe with the black side (i.e., dark plate) facing the probe.

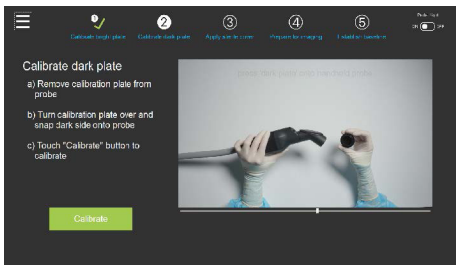

Fig.21. **Dark plate calibration screen**

Fig.22. **Dark plate attached**

b) Tap "Calibrate," and the software will confirm successful dark plate calibration. Do not remove dark plate until software confirms calibration is successful.

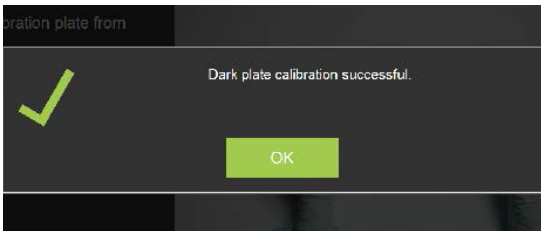

Fig.23. **Dark plate calibration confirm screen**

c) Remove the calibration plate from the probe at an angle. Dispose of the calibration plate following institutional practices for managing disposable materials exposed to biological hazards.

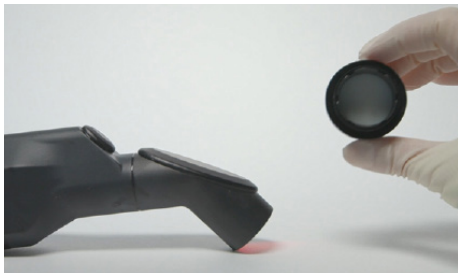

Fig.24. **Remove plate from handheld probe**

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5

Applying the Sterile Probe Cover

Materials you will need

- Handheld Probe (P/N: 810-00211)
- Disposable Sterile Probe Cover (P/N: 840-00204)
- Tool to clip cable to table (not supplied by Lumicell)

⚠ WARNING

- **The light generated by Lumicell DVS is not dangerous to the human eye (Exempt Group, IEC 62471 Test Report), but it may be uncomfortable or distracting. Avoid shining the light toward the eyes of anyone near the device.**

NOTE

Applying the sterile probe cover requires collaboration between a sterile user and a non-sterile user. The non-sterile user must perform Sections 5.1 – 5.3, and then the sterile user must perform the remaining steps.

5.1 Retrieve Sterile Probe Cover

a) Locate the Lumicell sterile probe cover dispenser carton and remove a tray from the perforated opening.

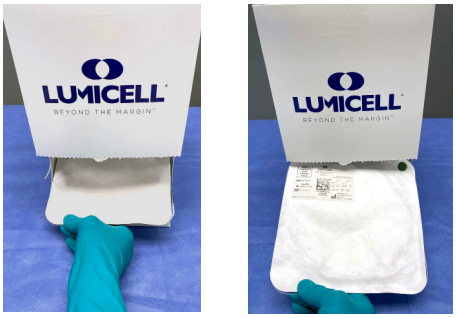

Fig.25. **Sterile probe cover dispenser carton.**

5.2 Inspect Outer Tray Label

a) Check the outer tray label's expiration date to ensure the cover has not expired.

Fig.26. **Sterile probe cover outer tray**

b) Confirm that the ethylene oxide (EO) indicator in the top right corner has turned green, indicating that the cover has been sterilized.

Fig.27. **Green EO indicator on outer tray of sterile probe cover**

5.3 Remove Contents from Outer Tray

a) Remove the outer tray lid completely by peeling from the bottom left corner.

Fig.28. **Sterile probe cover outer tray peel lid open**

b) Empty the contents of outer tray (i.e., inner tray) into the sterile field.

Fig.29. **Sterile probe cover empty outer tray**

⚠ WARNING

Discard and do not use any elastic bands that may be packaged with the sterile cover.

IMPORTANT

The following steps must be performed by a sterile user in the sterile field.

5.4 Open the Sterile Cover Inner Tray

a) Keeping the tray upright, use the pull tab to peel open the lid.

Fig.30. **Sterile probe cover inner tray**

b) Remove and dispose of the blue clip protector from the tray.

Ensure the sterile probe cover remains in the tray; tray is required to aid in sterile probe cover application.

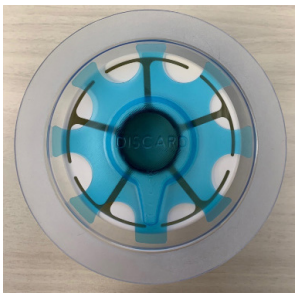

Fig.31. **Remove blue clip protector**

5.5 Snap the Sterile Probe Cover onto the Handheld Probe

a) Before the next step, ensure that system calibration with calibration plates has already been completed from the previous section. If not, complete the calibration step then return to sterile cover application.

b) While holding the tray, press the handheld probe into the sterile probe cover clip until it snaps (you will hear a click).

Fig.32. **Handheld probe into sterile probe cover**

⚠ WARNING

Incorrect application can lead to false positives or false negatives while imaging.

c) Lift the handheld probe with sterile probe cover attached and dispose of tray.

Discard the tray and packaging according to standard hospital protocol.

Fig.33. **Remove sterile probe cover from tray**

5.6 Apply the Primary Cover

a) Push the handheld probe through the middle of the applicator hoop and pull the applicator hoop down over the handheld probe and cables.

Continue pulling the applicator hoop down to unroll the primary cover over the probe and cables.

Fig.34. **Push sterile probe cover over handheld probe**

b) Once the applicator hoop exits the sterile field, a non-sterile user can pull the ring further along the cables to fully unroll the primary cover over the entire cable.

The applicator hoop is designed to detach from the bag. Pull down the cover across the length of the cable without the hoop if it detaches early.

Fig.35. **Pull sterile probe cover down cables**

5.7 Apply the Secondary Cover

a) Pull the secondary cover from the tip of the handheld probe and pull it over the entire handheld part of the device.

Fig.36. **Second sterile probe cover over handheld probe tip**

⚠ WARNING

Incorrect application of secondary cover can lead to false positives or false negatives while imaging.

b) Use a sterile cable clip or another tool to clip sterile cover and cable to the surgical table.

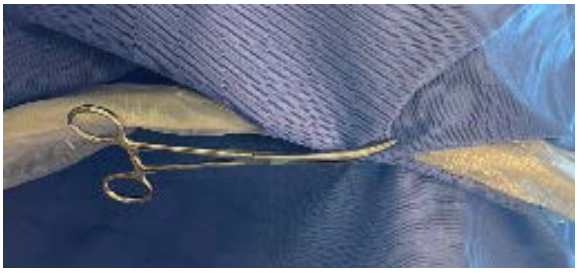

Fig.37. **Clip sterile cover to table**

⚠ WARNING

Incorrect application can lead to false positives or false negatives while imaging, or a foreign body entering the patient cavity.

NOTE

If the sterile cover tears, replace it with a new sterile cover. If the probe is not contaminated, the probe does not need to be replaced since it is sterile.

6

Conducting Imaging Session

⚠ WARNING

- **The light generated by Lumicell DVS is not dangerous to the human eye (Exempt Group, IEC 62471 Test Report), but it may be uncomfortable or distracting. Avoid shining the light toward the eyes of anyone near the device.**
- **DO NOT apply excessive pressure or torque with the handheld probe while inside the cavity.**

Perform imaging within 2 to 6 hours of LUMISIGHT injection.

6.1 Prepare the Cavity and Operating Room

a) Tap “Next” on the touchscreen to proceed to the “Prepare for imaging” screen.

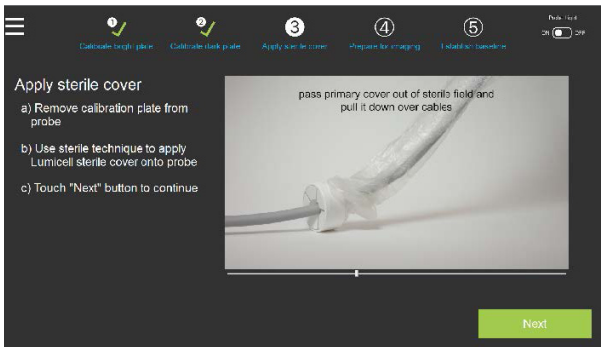

Fig.38. **Apply sterile cover screen**

b) If needed, position Lumicell DVS next to the surgical table per the surgeon's preference. Relock the workstation's wheels/casters when the system is positioned in the desired location.

Fig.39. **Position workstation**

c) Turn off room lights and head lamps to reduce background light.

Fig.40. **Lock wheels/casters**

⚠ WARNING

- **Before and after moving the system, ensure all cables are arranged in an orderly manner and positioned outside of foot traffic areas to prevent users from tripping.**
- **Keep hands away from the wheels of Lumicell DVS to avoid pinching or crushing hands or fingers while moving the system.**

6.1 Prepare the Cavity and Operating Room *Continued*

d) Confirm hemostasis within the surgical cavity. If needed, irrigate and dry the cavity with suction. This will help to ensure that the images are clean and clear.

Fig.41. **Irrigate the cavity**

⚠ CAUTION

- **Prevent light contamination into the probe by using a surgical towel to block room light where the light is visible through the skin (see images on next page).**
  - To ensure the camera is not absorbing room light, place the towel over the skin, rather than over the cavity opening since towels can leave debris in the surgical cavity.
- **Foreign substances in the surgical cavity, like sponges and surgical marker ink, may have fluorescent properties that interfere with imaging.**
  - When possible, limit the use of sponges until after imaging is complete and the transfer of surgical ink into the surgical cavity. Prep resistant markers may help limit the transfer of surgical ink.

6.2 Establish the Patient Baseline

NOTE

- Make continuous clean cuts when removing the main lumpectomy specimen. It is easier to create uniform probe contact with smooth, flat tissues.
- To ensure accurate imaging, always make sure the viewing window is free of air and fluid bubbles.
- If image appears foggy, clean the probe window. If that does not resolve the fogginess, obtain a new probe and restart imaging session.
- To avoid light contamination, use a sterile surgical towel to cover the outside of the breast and turn operating room lights off.

⚠ CAUTION

- **Ensure good contact with tissue.**
  - Making good contact between the handheld probe tip and tissue is a mandatory part of imaging. Achieve good contact by applying uniform pressure on the handheld probe and pressing into the tissue.

Fig.42. **Handheld probe contact**

  - To create better contact between the tissue and handheld probe, Lumicell recommends one of the following techniques:
    - Apply gentle counter-pressure to the handheld probe tip from outside the body using the opposite hand. Avoid applying excessive pressure to prevent potential tissue or skin damage.
    - Use thyroid retractors or baby abdominal retractors to open the cavity and make the tissue taut.
    - Note that the technique used to create good contact with handheld probe is similar to the technique used with an ultrasound probe.
- **Take care while establishing the baseline.**
  - To establish a patient-specific cancer detection threshold, capture six unique images from the lumpectomy cavity. Your initialization images should evenly sample the area you are evaluating for residual cancer. These images are used to determine the baseline for identifying a positive signal, which guides the resection of suspicious tissue.
  - To ensure an effective baseline process:
    - Always use the same imaging technique while establishing the baseline as during real-time imaging to detect residual cancer.
    - Avoid taking images of nipple, fascia, and muscle while establishing the baseline.
- **Establish a new baseline for each distinct cavity.**
  - Each tumor cavity requires its own baseline. If imaging multiple, unconnected cavities (e.g., during a bilateral lumpectomy), establish a new baseline for each cavity.

⚠ WARNING

- **DO NOT apply excessive pressure or torque with the handheld probe while inside the cavity.**

6.2 Establish the Patient Baseline *Continued*

NOTE

Establish the baseline immediately after the main lumpectomy specimen is removed.

a) Tap the green "Baseline" button. Ensure that all lights are off before starting imaging. Lights must be off for baseline and real-time imaging.

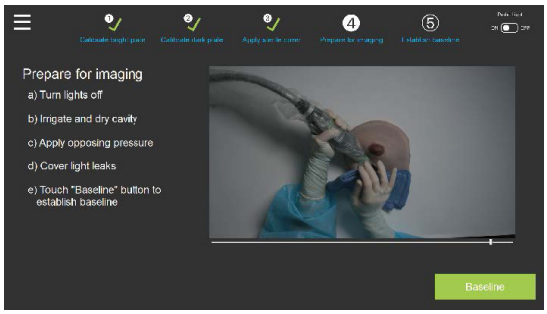

Fig.43. **Preparing for imaging screen**

b) Introduce the handheld probe into the cavity and press into the cavity wall.

Fig.44. **Insert handheld probe into cavity**

c) Using your free hand, cover light leaks with the surgical towel while applying opposing pressure to the handheld probe.

Fig.45. **Block light with surgical towel**

NOTE

The top of the probe near the bend corresponds to the 12 o'clock position on the imaging feed.

Fig.46. **Orient handheld probe**

d) With the handheld probe positioned in the first desired cavity location, tap the camera icon to capture the first image (image order does not matter).

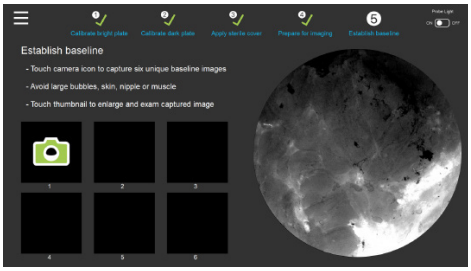

Fig.47. **Establish baseline screen first image**

e) Move the handheld probe to the second cavity location, apply opposing pressure, and cover light leaks with the surgical towel.

Then, tap the camera icon to capture the second image.

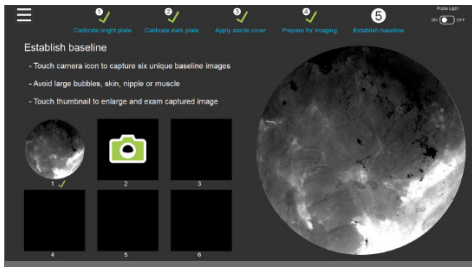

Fig.48. **Establish baseline screen second image**

NOTE

Each baseline image must be unique. Your initialization images should evenly sample the area you are evaluating for residual cancer. Reorient the handheld probe to capture a new location in each image.

f) Repeat this process for the third through sixth images.

g) Tap "Review," and review the six images to ensure:

- No large bubbles are present (see next step)
- The tissue is in focus
- The six baseline images are unique orientations

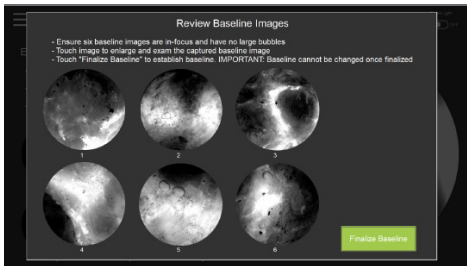

Fig.49. **Review baseline images**

6.2 Establish the Patient Baseline *Continued*

h) Images with large bubbles should be recaptured.

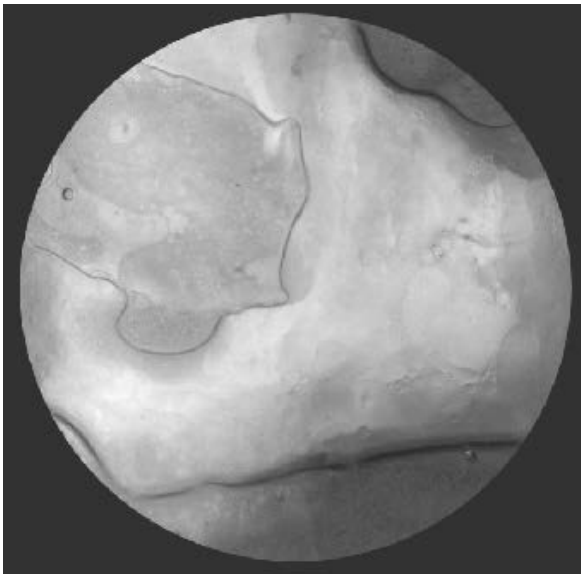

Fig.50. **Large Bubbles**

IMPORTANT

Baseline cannot be changed after continuing from the Review Baseline screen. Review images carefully to ensure that they are acceptable.

i) If you would like to recapture any of the baseline images, tap on the image, tap "Delete Image", and then recapture the image.

If the images are acceptable, tap “Finalize Baseline.”

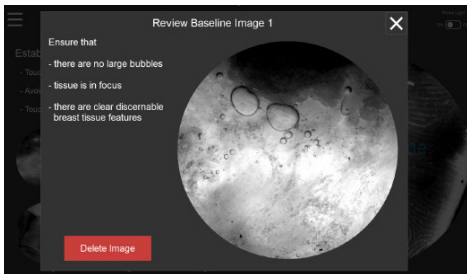

Fig.51. **Delete image (if needed)**

6.3 Detect Residual Cancerous Tissue

NOTE

- **Scan the ENTIRE cavity first to determine the extent of any red signal (potentially cancerous tissue) before capturing images or removing tissue.**
  - If red signal extends to the edge of the viewing window, scan adjacent areas to find the borders of the red area to understand the extent of the signal and guide effective and complete shaves.

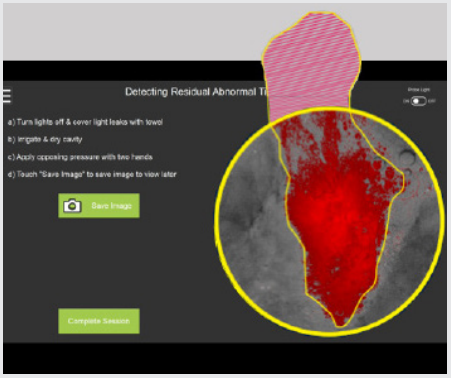

Fig.52. **Red signal extent**

- **Use the same pressure and contact with the handheld probe on the tissue as was used while establishing the baseline.**
- **Ensure red signals are stable and persistent.**
  - Bubbles or poor tissue contact can cause transient red signals. When observing a red signal, ensure that you are using proper technique (i.e., achieving good tissue contact, avoiding bubbles, avoiding light leaks) and that the red signal is stable and persistent.
- **Avoid exposing patient tissue to the handheld probe light for more than 30 seconds per field of view.**
  - Extended exposure to the handheld probe light can cause red signals to decrease. As a result, signals just above the detection threshold might not be detected.
- **Nipple-areola complex, skin, and muscle may cause a false positive. The system is not intended to guide removal of nipple, skin, or muscle.**

a) Ensure that all operating room (OR) lights stay off. If needed, irrigate and then dry the cavity with suction.

Fig.53. **Irrigate and dry the cavity**

6.3 Detect Residual Cancerous Tissue *Continued*

b) Scan ALL orientations of the lumpectomy cavity to identify suspicious tissue, indicated by red signal. Scan the entire cavity to determine the extent of any red signal before removing tissue.

While scanning, continue applying opposing pressure and covering light leaks with the surgical towel.

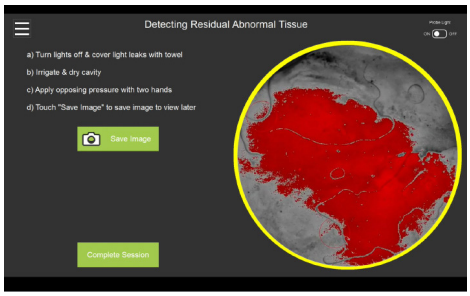

Fig.54. **Scan cavity**

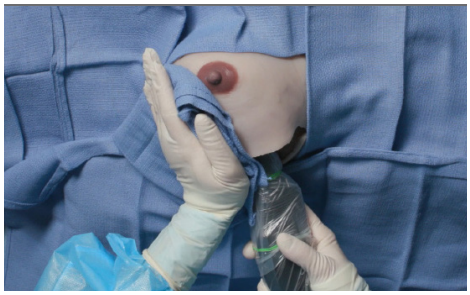

Fig.55. **Apply opposing pressure**

⚠ WARNING

- **Lumicell DVS is for adjunctive use and is not a replacement for the standard of care.**
- **DO NOT apply excessive pressure or torque with the handheld probe while inside the cavity.**
  - Excessive pressure on tissue can cause tissue perforation or damage. Additionally, applying excessive force or torque can result in device damage.
- **Do not restart a session once shaves have been removed.**
  - Establishing the baseline must occur immediately after the main lumpectomy specimen is removed. If a session cannot be resumed after removing shaves, do not restart the session or re-establish the baseline.

NOTE

During normal imaging, blood and other biological fluids may dry on the sterile probe cover tip, obscuring the image. When this occurs, soak sterile gauze in a saline solution. Then, using a circular motion, use the gauze to wipe the sterile probe cover tip until the dried fluid is no longer visible.

c) Red signal indicates that the device has detected a region suspected to contain residual cancer. Lumicell DVS can detect fluorescence at depths up to 5mm. Use clinical judgement to determine whether to remove a guided shave.

d) To capture and save an image during scanning, tap the green “Save Image” button.

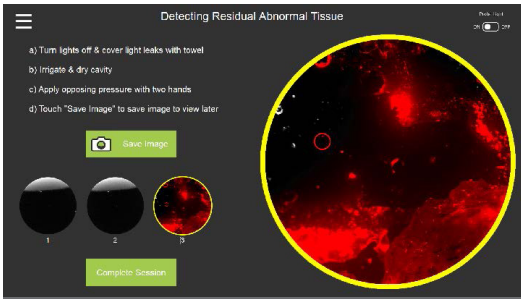

Fig.56. **Save image**

e) Add the orientation for saved images by tapping the gray box next to the orientation text, and then select "Done". The orientation of previously saved images can be edited by tapping the desired thumbnail.

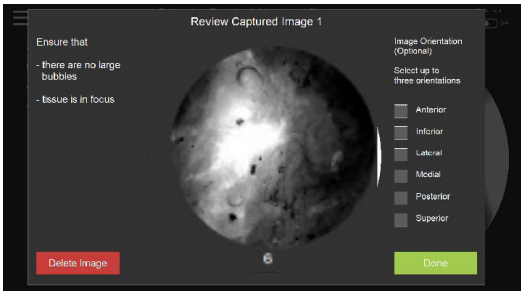

Fig.57. **Add information about image**

f) When scanning is complete, tap the green "Complete Session" button in the lower left-hand corner of the touchscreen.

Then tap "End Session" again in the dialog box.

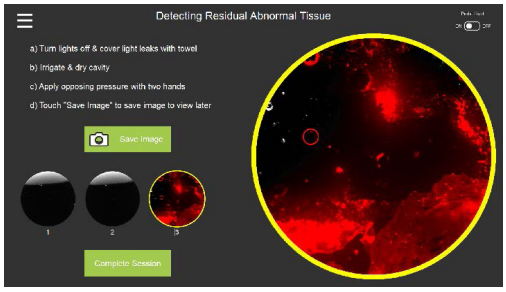

Fig.58. **Complete session**

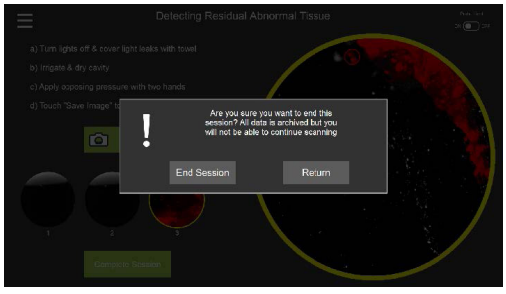

Fig.59. **End session**

6.4 Viewing, Importing, and Deleting Sessions

a) To view archived sessions, tap the three lines in the top left corner. Then, tap "View archived sessions".

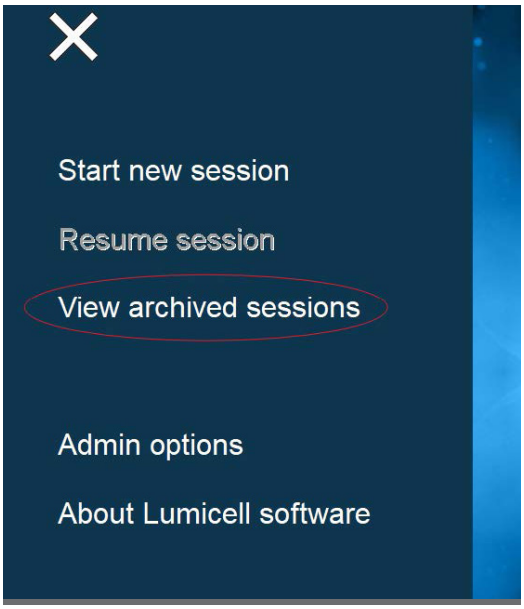

Fig.60. **View archived sessions**

b) On the Archived Sessions page, tap a session.

c) To view the session images and data, tap "View Report". This will bring up a PDF of the report. Tap the "X" in the top right corner to close the report.

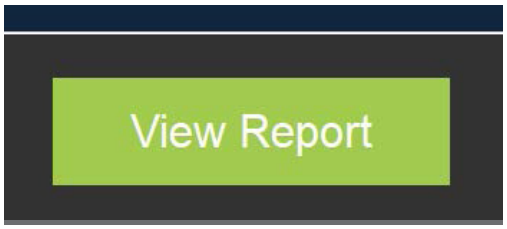

Fig.61. **View archived sessions**

d) To Import a session, tap the "Import" button, double-click a file, then tap "Import". See Section 6.5 for instructions on USB drives.

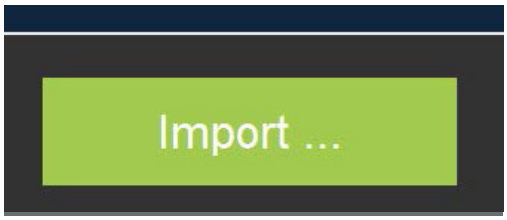

Fig.62. **Import a session**

e) To delete a session, tap the "Delete" button in the bottom right corner. A popup will appear "Are you sure you want to delete selected session(s)? A deleted session cannot be recovered. To save the data, export the session(s) before deleting." To permanently remove data, tap "Delete", otherwise tap "Cancel".

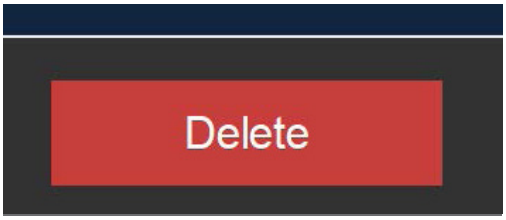

Fig.63. **Delete a session**

6.5 Exporting Sessions

NOTE

Only encrypted USB drives can be used with Lumicell DVS. Encrypted USB drives are not provided by Lumicell. Obtain approval from your facility before using encrypted flash drives.

a) Obtain an encrypted USB drive. If the handheld probe is still attached to the USB hub, remove it. Plug the encrypted USB drive into the USB hub.

When a popup appears when the USB is detected, tap "OK".

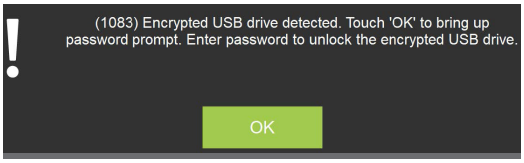

Fig.64. **Encrypted USB Drive Detected**

b) Enter the password in the BitLocker (D:) pop-up in the top right corner. Tap "Unlock".

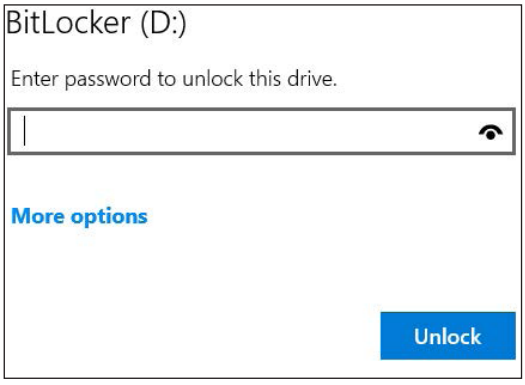

Fig.65. **Enter encrypted USB password**

c) On the "Archived Sessions" page, tap a session, then tap "Export...".

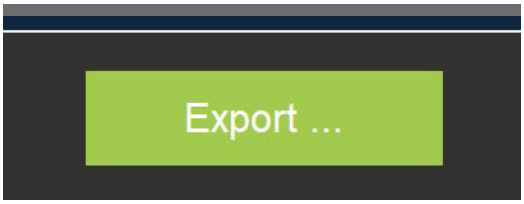

Fig.66. **Tap Export**

d) Tap "USB Drives" on the left-hand menu and tap the USB drive that was just unlocked. Tap a folder on the right-hand side, if desired.

Fig.67. **Tap USB Drive**

6.5 Exporting Sessions *Continued*

e) To exclude patient protected health information (PHI) in the export, tap "Anonymize data". To export the raw images (without bright and dark plate correction), tap "Export raw data".

Tap "Export". A loading screen will appear then disappear when export is complete.

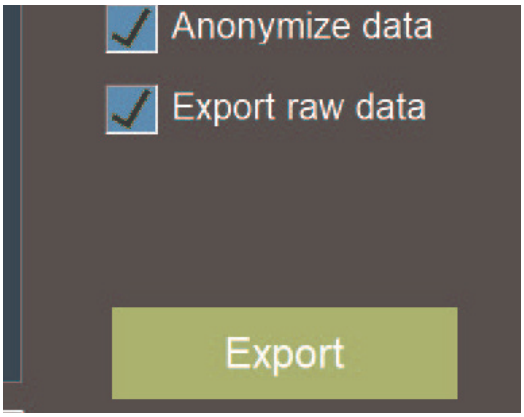

Fig.68. **Export Data Options**

f) Tap the "X" buttons in the top right corners to return to the main menu.

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7

Removing and Disposing Sterile Probe Cover and Sterile Workstation Drape

⚠ CAUTION

The sterile probe cover and sterile workstation drape are bio-hazards after surgery.

Carefully remove sterile probe cover from the handheld probe and workstation drape, if used, from Lumicell DVS and dispose of the drape and cover following institutional practices for managing disposable materials exposed to biological hazards.

7.1 Removing and Disposing Sterile Probe Cover and Workstation Drape

a) Pop the clip off of the handheld probe by pressing the clip's corner at an angle.

Fig.69. **Remove handheld probe clip**

b) Gently pull the applicator hoop back over the handheld probe to remove both the primary and secondary cover layers.

Avoid tearing or stretching the covers to ensure that biological material remains on the outer sides of the covers.

Fig.70. **Pull off cover**

c) Dispose of the cover, clip and applicator hoop following institutional practices for managing disposable materials exposed to biological hazards.

d) Remove workstation drape from Lumicell DVS, if used. Dispose of drape according to institutional practices for managing disposable materials exposed to biological hazards.

8

Shutting Down the System

a) Exit the patient-calibrated cancer detection software by tapping the menu and then the tapping "Exit Application" button.

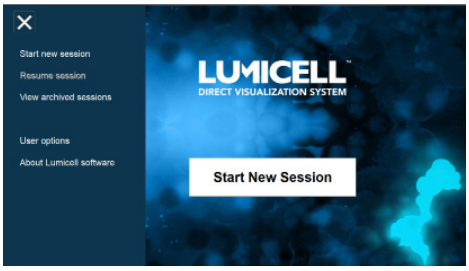


Fig.71. **Exit application**

b) Turn off the touchscreen by tapping the “Start” menu button in the bottom right corner and then tapping "Shutdown.”

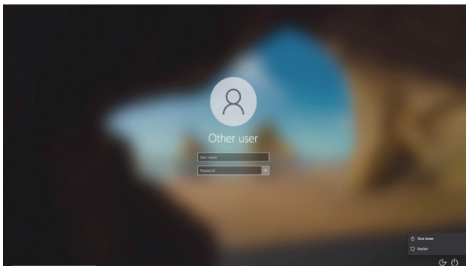


Fig.72. **Shutdown touchscreen**

8 Shutting Down the System *Continued*

c) Turn off the Light Source by pressing the "O" side of the switch.

Fig.73. **Light source**

d) Unplug the handheld probe light guide from the light source and the USB cable from the USB hub.

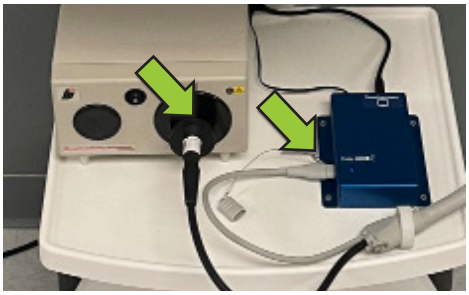


Fig.74. **Unplug handheld probe cables**

e) Turn off the power source by pressing the OFF side of the power switch located at the front base of the Lumicell DVS workstation.

Then, unplug the power source from the wall outlet.

Fig.75. **Power source**

f) Attach the USB protective cap onto the end of the USB connector and ensure that the vent cap is closed.

9

Point-of-Use (POU) Cleaning

⚠ WARNING

Improper or incomplete disinfection of the handheld probe and cables increases risk of patient or healthcare provider infection.

NOTE

You must clean the handheld probe, handheld probe window, cables, and workstation at the point of use after each imaging session, prior to reprocessing in the Central Sterile Services Department.

9.1 Clean Handheld Probe, Cables, and Sterilization Tray within 1 Hour of Use

a) As soon as possible (and within 1 hour after use) in the operating room, use enzymatic spray or enzymatic wipes to remove visible soil from the handheld probe, handheld probe window, cables (USB cable and light guide), and sterilization tray.

Fig.76. **Clean handheld probe and cables**

⚠ WARNING

DO NOT use any other solutions or cleaning agents to clean the handheld probe, handheld probe window, cables, and sterilization tray.

9.2 Clean Workstation, Touchscreen, and Light Source

a) Use CaviWipes™ or Sani-Cloth™ to remove visible soil from Lumicell DVS, including the workstation, light source, and power source.

⚠ WARNING

DO NOT use any other solutions or cleaning agents to clean the workstation, touchscreen, light source, or power source.

9.3 Prepare Handheld Probe and Cables for Transport

a) Place the pre-treated handheld probe and cables in the sterilization tray.

To avoid mechanical damage to the handheld probe, transport via your facility's established policies, protocols, and procedures.

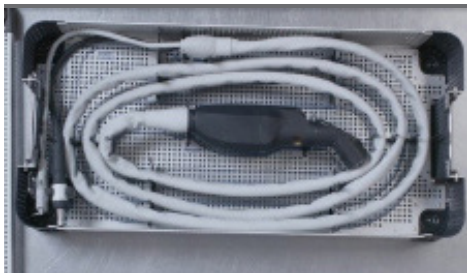


Fig.77. **Sterilization tray**

10

Decontamination and Sterilization

⚠ Warning

Cleaning must always be performed prior to sterilization.

Inspect the handheld probe and cables for signs of functional damage, including:

- Cracks, deep scratches, or condensation on the distal window
- Degradation of seams or seals, sharp edges, or other structural damage.

Sterilization may result in minor cosmetic changes - such as discoloration - that do not affect device performance.

Do not use the device if functional damage is suspected.

Contact Lumicell Technical Support at 1-833-4LUMDVS (1-833-458-6387) for product support, including return authorization.

NOTES

Cleaning must occur within 1 hour following use to effectively remove soil.

Wear personal protective equipment (PPE) according to hospital's policies and procedures for all decontamination and sterilization steps.

Dispose of any accessories, like the calibration plate, if they are left in the tray.

NOTE

Automatic cleaning with a washer-disinfector is recommended for the sterilization tray. If a washer-disinfector is not available, proceed to Section 10.2 for manual cleaning of the sterilization tray. **Automatic washing is for the tray only. The handheld probe cannot be cleaned with an automatic washer.**

10.1 Clean Sterilization Tray - Automatic Method

a) Remove the handheld probe from the sterilization tray and set the handheld probe aside for cleaning in Sections 10.3 and 10.4

b) Rinse the sterilization tray under running, cold tap (utility) water to remove excess contamination.

c) Transfer the device(s) onto an appropriate rack system (e.g., three-level manifold rack accessory) contained inside the washer-disinfector for processing.

Ensure the lid of the tray is not on the tray. Place the lid in an open spot in the washer-disinfector.

d) Select the automated washer cycle parameters as listed in the table below. Run the washer-disinfector.

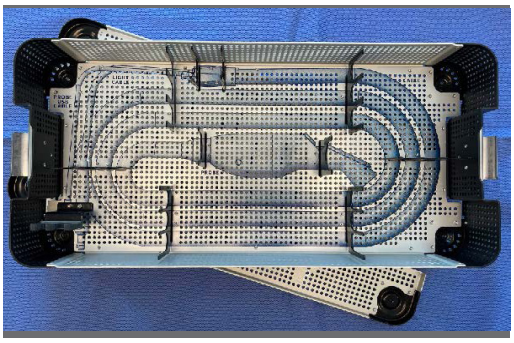


Fig.78. **Sterilization tray**

Stage	Time (minutes)	Temperature	Detergent Type and Concentration (if applicable)
Pre-wash 1	02:00	Cold Tap Water	N/A
Enzyme Wash	04:00	Hot Tap Water	Enzymatic solution per manufacturers instructions
Rinse1	01:00	≥ 43°C (109° F) Tap water (set point)	N/A
Pure Water Rinse	01:00	≥ 43°C (109° F) RO/DI water (set point)	N/A
Thermal Disinfection	01:00	90°C (194° F) RO/DI water	N/A
Drying	07:00	100°C (212° F)	N/A

10.1 Clean Sterilization Tray - Automatic Method *Continued*

e) Remove the tray from the washer-disinfector and use a lint-free cloth to dry the tray, as needed.

f) Visually inspect the sterilization tray for contamination. Repeat steps a through f if contamination is observed. Set aside according to hospital policy to reunite with probe in Section 10.5.

10.2 Clean Sterilization Tray - Manual Method

a) Remove the handheld probe from the sterilization tray and set the handheld probe aside for cleaning in Sections 10.3 and 10.4.

b) Rinse the sterilization tray under running, cold tap (utility) water to remove excess contamination.

c) Prepare enzymatic detergent per the manufacturer's recommendations.

d) Fully immerse the sterilization tray in the prepared detergent bath and allow the tray to soak for 1 minute or according to the detergent manufacturer's instructions.

e) While submerged, use a soft-bristled brush to remove visible soil from the sterilization tray including all crevices and hard-to-reach areas.

f) Remove the sterilization tray from the prepared detergent bath and rinse it under running critical water (e.g., RO/DI water) to remove detergent residuals.

g) Use a lint-free cloth to dry the sterilization tray.

h) Visually inspect the sterilization tray for contamination. Repeat steps a through h if contamination is observed. Set aside according to hospital policy to reunite with probe in Section 10.5.

⚠ WARNING

- **Do not submerge or rinse connector end with faucet (~2 ft. of cable measured from the tip of the optical fiber). Submerging connector end can damage probe.**

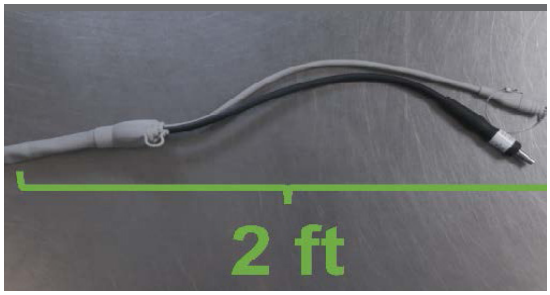


Fig.79. **Connector End**

10.3 Rinse Handheld Probe Under Running Tap Water

a) Prior to cleaning, ensure USB protective cap and vent caps are still in place on the end of the USB cable.

If caps come off at any point during cleaning, thoroughly dry the probe and cables, re-cap, and continue the cleaning procedure.

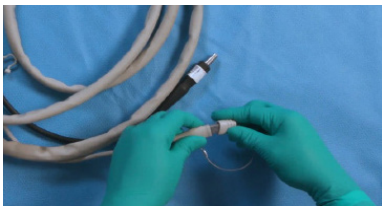


Fig.80. **USB connector**

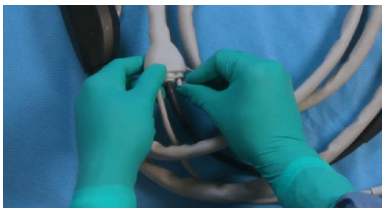


Fig.81. **Vent cap**

b) Keeping the USB and vent caps dry, rinse the handheld probe and cables under cold, running tap water to remove excess soil (recommended to rinse for at least 30 seconds). **Do not rinse USB cap or vent cap.**

Fig.82. **Rinse probe**

c) Wipe excess soil from connector end of cables as outlined in Figure 82 (~2 feet of cable measured from the tip of the optical fiber) using a lint-free cloth wet with cold utility (tap) water.

Fig.83. **Wipe connector end**

10.4 Perform Manual Cleaning in Enzymatic Solution

⚠ WARNING

- **Do not submerge or rinse connector end with faucet (~2 ft. of cable measured from the tip of the optical fiber, Figure 82). Submerging connector end can damage probe.**

a) Following the detergent manufacturer's instructions, mix enzymatic neutral pH detergent solution in lukewarm tap water (temperature range 27°C to 44°C / 81°F to 111°F). **Do not use ortho-Phthalaldehyde (OPA) or unspecified cleaner**.

b) Submerge the handheld probe and most of the cable, except the last ~2 feet of the cable, in the prepared solution. Do not immerse the vent cap or USB cap.

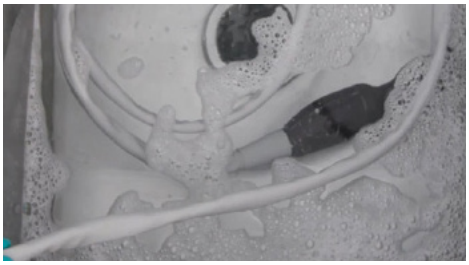


Fig.84. **Submerge handheld probe and cables**

c) While submerged, use a soft-bristled brush to remove visible soil from the handheld probe, including all cracks, crevices, and hard-to-reach areas. **Do not use a brush on probe window.**

Fig.85. **Brush handheld probe**

⚠ CAUTION

Be careful not to scratch the handheld probe window. Do not use brush on probe window.

d) While submerged, use a lint-free cloth soaked with detergent solution to remove visible soil from the window of the probe.

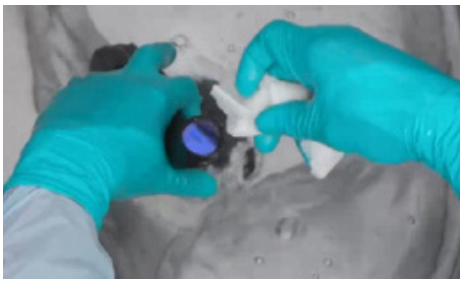


Fig.86. **Wipe probe window**

10.4 Perform Manual Cleaning in Enzymatic Solution *Continued*

e) Use a lint-free cloth soaked in enzymatic solution to remove soil from the connector end, probe, and cables. **Do not immerse USB cap or vent cap.**

f) Allow the handheld probe and submerged end of the cables to soak in the detergent for 1 minute or according to detergent manufacturer's instructions. **Do not immerse USB cap or vent cap.**

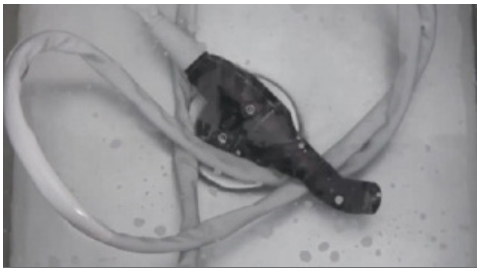


Fig.87. **Soak handheld probe and cables**

g) Remove the handheld probe and cables from the solution and rinse under running RO/DI water while keeping the USB end dry. Rinse must be with RO/DI water. Do not use tap water. Do not rinse USB cap or vent cap.

h) Using a clean, lint-free cloth wet with RO/DI water, wipe the section of the cable as outlined in Figure 82 (~2 feet of cable measured from the tip of the optical fiber) that was not rinsed in the previous step.

Fig.88. **Wipe connector end with RO/DI-soaked cloth**

i) Use a clean, lint-free cloth to dry the handheld probe and cables, including the vent cap and USB end.

Fig.89. **Dry handheld probe and cables**

j) Visually inspect the device to confirm that visible soil has been removed from all surfaces and crevices.

If any visible soil remains, repeat manual cleaning (Sections 10.3-10.4).

10.5 Sterilize

⚠ WARNING

Improper sterilization of the handheld probe and cables might render the device non-sterile prior to next use, increasing the risk of infection to the patient or healthcare provider.

NOTES

Handheld probe, cables, and tray must be cleaned as described in Sections 10.1-10.4 prior to sterilization.

a) Place the dry handheld probe and cables in the Lumicell sterilization tray, following the sequence depicted on the right and detailed on the bottom of the sterilization tray. Place lid on tray.

⚠ CAUTION

Ensure the handheld probe and cables are completely dry. The sterilizer will not start if there is any residual moisture on the components.

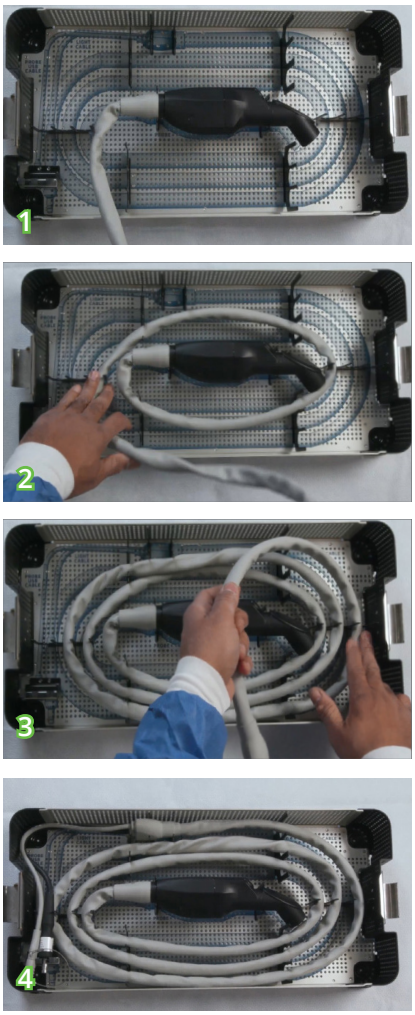


Fig.90. **Place in sterilization tray**

10.5 Sterilize *Continued*

b) Wrap the tray according to the sterilization wrap IFU.

> ⚠ **CAUTION**
>
> Ensure there are no tears in the wrap. Rewrap the tray if the wrapping is ripped or torn.

c) Document sterilization cycle according to hospital policy. Only approved sterilization cycles according to Section 10.7 can be used.

d) Load the wrapped Lumicell sterilization tray into the sterilization chamber according to the manufacturer's instructions.

Ensure the chamber does not tear the wrap while loading the tray. Lumicell recommends the use of a transport tray.

e) Select an approved sterilization cycle to sterilize the handheld probe and cables. **Do not use autoclave or other unapproved methods.**

Follow instructions for use for the sterilization process to ensure sterility and protect the handheld probe and cables from accidental damage.

f) Confirm sterilization cycle parameters have been completed per hospital policy, then remove the Lumicell sterilization tray from the chamber. Confirm that the wrap did not tear. If the wrap is torn, rewrap and resterilize.

> ⚠ **CAUTION**
>
> Do not knock or bump the tray against the chamber during removal. This could cause tears or rips in the wrap and compromise sterility.

10.6 Store Sterilized Handheld Probe and Cables

a) Follow hospital policy for storage requirements and maximum shelf life of sterilized medical devices. Follow wrap manufacturer's instructions and do not exceed the wrap's labeled maintenance of sterility.

10.7 Approved Sterilization Methods

NOTE

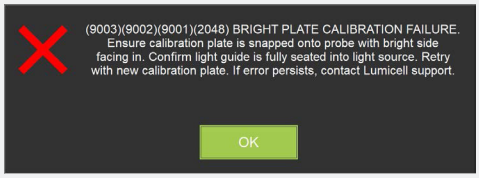
The sterilizers and cycles in the following table are the approved sterilization methods for the handheld probe and sterilization tray. Do not use other, unapproved methods for sterilization.

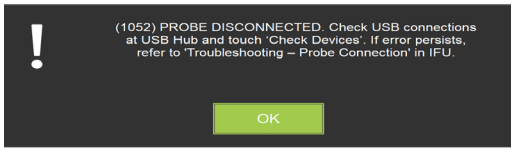
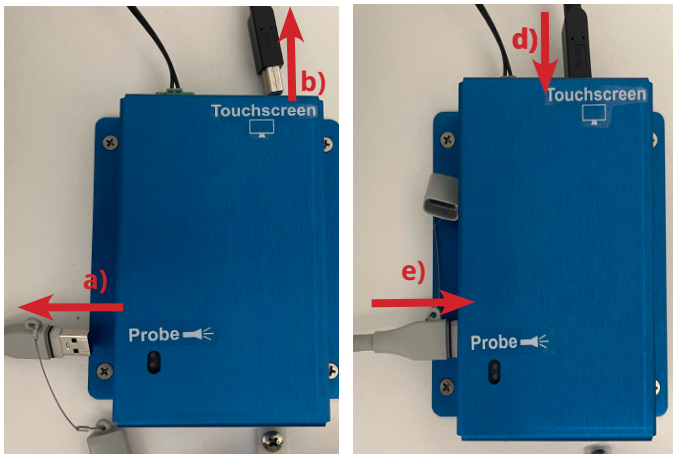
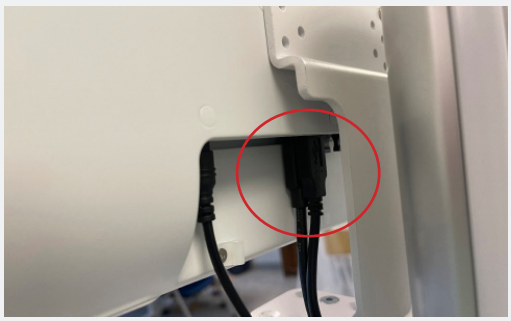
Brand	Sterilizer	Cycles				
STERRAD®		Duo	Standard	Express	Flex	
	100NX	✓				
	NX					
	100S					
STERIS®		Standard/ Lumen	Non Lumen	Flexible	Fast Non Lumen	Fast
	V-PRO® 1	✓				
	V-PRO® 1 Plus	✓	✓			
	V-PRO® maX	✓	✓	✓		
	V-PRO® maX 2	✓	✓	✓	✓	
	V-PRO® 60	✓	✓	✓		
	V-PRO® s2	✓	✓	✓		✓

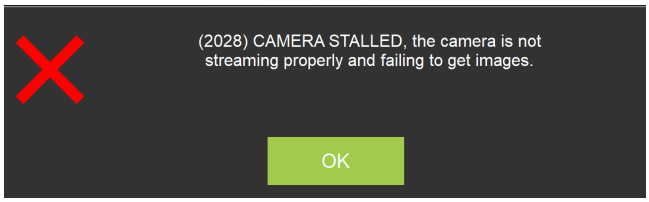
11

Troubleshooting

The following troubleshooting steps may help correct any issues with Lumicell DVS. If troubleshooting steps do not correct the issue, contact Lumicell for support using the contact information on the last page of this document or call 1-833-4LUMDVS (1-833-458-6387).

Issue	Action(s) to take
Warning! Signal below/ above expected limit  *Fig.91.* **Warning signal below limit**  *Fig.92.* **Warning signal above limit**	This is normal when the handheld probe is outside the lumpectomy cavity, but these warnings should not appear while inside the cavity. If one of these warning appears, follow these steps for corrective action: a) Confirm light source is on. b) Confirm surgical lights are pointed away from the table and that the surgeon is using the surgical towel to minimize light disruption. c) If the problem persists after completing steps a and b, cancel current session, then start a new session and workflow starting at Section 3.7b.
Bright/dark plate fail  *Fig.93.* **Calibration plate fail** Error Codes 2048/2049: BRIGHT/DARK PLATE FAILURE. Ensure calibration plate is snapped onto probe with bright/dark side facing in. Confirm light guide is fully seated into light source. Retry with same plate, then retry with new calibration plate. If error persists, contact Lumicell.	a) Ensure that the calibration plate is properly secured on the handheld probe. b) For bright plate calibration, ensure the white side of the calibration plate is facing toward the probe. c) For dark plate calibration, ensure the black side of the calibration plate is facing toward the probe. d) Confirm that the light source is turned on and the probe's optical light guide is fully seated into the light source. e) Retry calibration with the same plate. If calibration fails, try again with a different calibration plate. f) If repeated attempts to calibrate the system are unsuccessful, discontinue use of the probe and contact Lumicell.

Issue	Action(s) to take
Probe Connection The touchscreen might display a camera or framing error if there are any issues with the imaging feed, or if the USB 3 cable is disconnected from the touchscreen.  *Fig.94.* **Probe Disconnect Error** Error Codes: 1050: PROBE DISCONNECTED. Check USB connections at USB Hub then "Continue". 1052: PROBE DISCONNECTED. Check USB connections at USB Hub and touch 'Check Devices'. 2005: SYSTEM ERROR. YOU WILL BE LOGGED OUT. Log in to retry.	a) Unplug the gray, probe USB cable from the USB hub. b) Unplug the black, touchscreen cable from the USB hub. Note: do not unplug cables from the back of the touchscreen.  *Fig.95.* **USB Hub order of re-plugs** c) Wait 10 seconds. d) Replug the black, touchscreen cable into the USB hub. e) Replug the gray, USB cable into the USB hub. f) Wait 5 seconds, then tap "Retry". g) If issue persists, check USB connection in the back of the touchscreen, then contact Lumicell at 1-833-4LUMDVS (1-833-458-6387).
Light Source Errors The touchscreen might display the following errors when the light source is off or disconnected: 1046: LIGHT SOURCE POWER OFF. Switch light source power ON and 'Continue'. If error persists, touch "End Session". 1047: LIGHT SOURCE DISCONNECTED. check 2 USB connections (1 at Touchscreen and 1 at Light source) and Continue. If error persists, touch "End Session".	a) Switch light source to the "On" position as detailed in Section 3.5c. b) Ensure cables are secure in the light source and back of the touchscreen.  *Fig.96.* **Light source and camera cables in touchscreen**

Issue	Action(s) to take
Camera Stalled During Calibration This error occurs when the system is experiencing intermittent data streaming issues from the camera during calibration, commonly from electromagnetic interference from other equipment, like electrocautery.  *Fig.97.* **Camera Stalled Errors** Error Code: 2028: CAMERA STALLED. The camera is not streaming properly and failing to get images.	a) Clear the error and turn off nearby electromagnetic equipment (e.g., electrocautery). Recapture bright and/or dark plate image(s), as prompted by the software. b) If the error persists, check USB connections and reconnect probe USB according to the "Probe Connection" troubleshooting step.
Camera Stalled This warning occurs when the system is experiencing intermittent data streaming issues from the camera, commonly from electromagnetic interference from other equipment, like electrocautery.  *Fig.98.* **Camera Stalled Errors** Error Code: 1085: Camera is stalled. It is not streaming properly and struggling to get images.	a) The camera will continue to try to connect to the computer, and the warning may go away on its own. If you are not actively imaging, leave the system as-is to allow it to re-establish streaming. b) If the warning message is disruptive to imaging, reduce possible sources of electromagnetic interference by relocating or shutting off nearby electromagnetic equipment (like electrocautery) and allow the system to re-establish streaming. c) If the warning message persists, check USB connections and reconnect probe USB according to the "Probe Connection" troubleshooting step.

Issue	Action(s) to take
Light Source Idle Errors Error Codes: 1048: LIGHT SOURCE POWER OFF. Before starting a new session, switch light source power ON, and touch 'Check Devices' to establish connection. 1049: LIGHT SOURCE DISCONNECTED. Before starting a new session, check 2 USB connections (1 at Touchscreen and 1 at Light source), and touch 'Check Devices' to establish connection.	a) See "Light Source Errors" section for actions to take.
Light Source Disconnected Error Codes 2016/17: LIGHT SOURCE DISCONNECTED. Ensure light source power ON, check USB connection at touchscreen and at light source then touch 'Continue'. If error persists, touch "End Session" and contact Lumicell support.	a) See "Light Source Errors" section for actions to take.
Camera Overheating Error Codes 1051/1053: PROBE OVERHEATING. Remove any towels covering probe, disconnect from USB Hub for 5 seconds, reconnect and touch Continue. (or before starting a new session, touch 'Check Devices').	a) Remove gray cable from the USB hub for 5-10 seconds. b) Reseat gray cable in USB hub and tap "Retry". c) If error message persists, replace the handheld probe.
Computer Disk Full Error code 2004: DISK SPACE FULL. Manage saved sessions to create space prior to new session.	a) Tap the menu button from the main screen. b) Tap "View Archived Sessions" c) Work with the surgeon or IT department to delete sessions and free space on the hard drive.
Start Session Failure Error Codes 2031/2032: RESUME SESSION ERROR. Check USB connections at USB Hub then retry.	a) See "Probe Connection" section for troubleshooting steps. b) If the issue persists, see "Light Source Errors" troubleshooting steps.

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12

Maintenance, Storage, and Transport

Preventive maintenance is recommended to be performed annually by Lumicell to ensure Lumicell™ DVS performance and safety.

Contact Lumicell to schedule service or maintenance as needed. Contact information is on the last page of this document or call 1-833-4LUMDVS (1-833-458-6387).

DO NOT perform service or maintenance on the system. Service or maintenance will be performed and properly documented by Lumicell personnel.

12.1 Proper Usage

Lumicell DVS must be used as outlined in these instructions for use. Do not allow unauthorized users to access the system, even when not in use. The operating system used with Lumicell DVS is password-protected to prevent unauthorized use. To reset a password, contact your hospital administrator.

12.2 Storage, Operating, and Transport Conditions

Store Lumicell DVS in a limited access area while not in use. The recommended storage, operating, and transport (shipping) temperature ranges for each component is listed in the table below.

Condition	Reusable System	Disposables
Operating	41°F-82.4°F (5°C-28°C) 20-80% RH (non-condensing) Up to 15,000 ft	41°F-82.4°F (5°C-28°C) 20-80% RH (non-condensing)
Storage	41°F-122°F (5°C-50°C) 20-80% RH (non-condensing) Up to 50,000 ft	41°F-122°F (5°C-50°C) 20-80% RH (non-condensing)
Transport (shipping)	-4°F-122°F (-20°C-50°C) 25-90% RH (non-condensing) Up to 14,000 ft	-22°F-140°F (-30°C-60°C) 15-90% RH (non-condensing)

If you suspect that Lumicell DVS has been tampered with during storage, contact Lumicell immediately. See the last page of this document for Lumicell contact information or call 1-833-4LUMDVS (1-833-458-6387).

⚠ WARNING

- **Before and after moving the system, ensure all cables are arranged in an orderly manner and positioned outside of foot traffic areas to prevent users from tripping.**
- **Keep hands away from the Lumicell DVS's wheels to avoid pinching or crushing hands or fingers while moving the system.**

12.3 Transportation within Hospital

a) Lock wheels when stored and not in use.

b) To unlock, step on red wheel locks to release brakes. Release all four wheels, then move the workstation by using the handle.

c) Once positioned in place, step on all four wheel brakes to lock it back in place.

Fig.99. **Wheels unlocked**

Fig.100. **Wheels locked**

12.4 Supply Replenishment

The following components of Lumicell DVS require replenishment:

- Two-sided Calibration Plate
- Sterile Workstation Drape
- Sterile Probe Cover

Email a request for more supplies to support@lumicell.com. Include the facility name, shipping address, and the shipping contact's name and phone number.

The sterile workstation drape is optional and not provided by Lumicell. Order C-ARM4065B from Universal Medical, or equivalent.

If the handheld probe is damaged and requires replacement, contact Lumicell.

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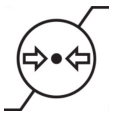
13

Symbols Key

Equipment with a Lumicell label should be used exclusively with Lumicell DVS. If a label is missing, notify Lumicell personnel. See the last page of this document for Lumicell contact information or call 1-833-4LUMDVS (1-833-458-6387).

Labeling Symbols Key



Atmospheric pressure limitation: To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage (ISO 7000-2621).

Batch code: To identify the manufacturer's batch or lot code, for example on a medical device or the corresponding packaging. The code shall be placed adjacent to the symbol (ISO 7000-2492).

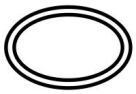
Catalogue number: To identify the manufacturer's catalogue number, for example on a medical device or the corresponding packaging. The catalogue number shall be placed adjacent to the symbol (ISO 7000-2493).

Caution: An advisory notice. Failure to follow instructions may result in damage to the system (EN 980, Clause 5.11, ISO 15223-1, Clause 5.4.4, IED 60601, Tables D.a, Symbol 10, ISO 7000-0434).

Date of manufacture: To indicate the date on which a product was manufactured (ISO 7000-2497).

Do not reuse: Indicates a medical device that is intended for one use or for use on a single patient during a single procedure. (EN 980, Clause 5.2, ISO 15223-1, Clause 5.4.2, ISO 7000-1051 Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied).

Do not use if package is damaged: To indicate that the device must not be used if the package holding the device is damaged, for example on packaging of medical devices (ISO 7000-2606).



Double sterile barrier system: To indicate that there are two sterile barrier systems (ISO 7000-3704).

Labeling Symbols Key (cont.)

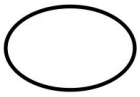
Humidity limitation: To indicate the acceptable upper and lower limits of relative humidity for transport and storage (ISO 7000-2620).

Keep away from sunlight: To indicate that transport package shall not be exposed to sunlight (ISO 7000-0624).

No latex: Product is not made with natural rubber latex (ISO 15223-1).

Operator's Manual: To identify the location where the operator's manual is stored or to identify information that relates to the operating instructions. To indicate that the operating instructions should be considered when operating the device or control close to where the symbol is placed (ISO 7000-1641).

Serial number: To identify the manufacturer's serial number, for example on a medical device or its packaging. The serial number shall be placed adjacent to the symbol (ISO 7000-2498).



Single sterile barrier system: To indicate that there is a single sterile barrier system (ISO 7000-3707).

Sterilized by ethylene oxide (ISO -7000 - 2501).

Symbol for Manufacturer: The manufacturer contact information appears next to this symbol. (EN980, Clause 5.12, ISO 15223-1, Clause 5.1.1, ISO 7000-3082).

Temperature limit: To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used (ISO 7000-0632).

Type of BF applied part: To identify a type BF applied part complying with IEC 60601-1 (IEC 60417-5333).

Use by date: To indicate that the device should not be used after the date accompanying the symbol, for example on a medical device or its packaging (ISO 7000-2607).

Warning: Failure to follow instructions could result in injury to the patient or user.

℞ only

Prescription only: The symbol for prescription device. Federal (USA) law restricts this device to sale by or on the order of a physician.

14

Technical Specifications

14.1 General Specifications

Optical	
Excitation Wavelength	630 nm ± 5 nm (Red)
Emission Signal Passthrough	662.5 - 737.5 nm
System Illumination Power	265 ± 45 mW
Maximum Irradiance	130 mW/ cm^2
Detection Depth	≤ 5 mm
Field of View (Area)	4 - 6 cm^2
System Spatial Resolution (Smallest Detectable Feature)	≤ 300 µm x 300 µm
Magnification	0.245x ± .002
Distortion	< 300 µm
Depth of Field (Resolution at 5 mm defocus)	≤ 800 µm x 800 µm at 5 mm defocus
Overall System Uniformity	> 20% ratio of darkest to brightest regions
Excitation Crosstalk	≤ 41 counts
Sensitivity	Limit of Quantification (LOQ) ≤ 10 nM
Linearity	$R^2 \geq 0.98$
Imaging Agent	LUMISIGHT

Electrical and Safety	
Electrical Rating (Light Source)	100-240 VAC, 50-60Hz, <1.0 Amp @ 115 V
Electrical Rating (System)	115 VAC, < 4.4 Amp
System Noise	<45 dB

14.1 General Specifications *Continued*

Physical	
Working Length	Typical: 1.72 in (43.7 mm) Maximum: 3.24 in (82.3 mm) See Figure 101.
Maximum insertion portion (working length) width	1.28 in (32.5 mm)
Probe tip diameter (with sterile cover)	1.14 inch (29.1 mm)
System (Workstation) Weight	110 lbs

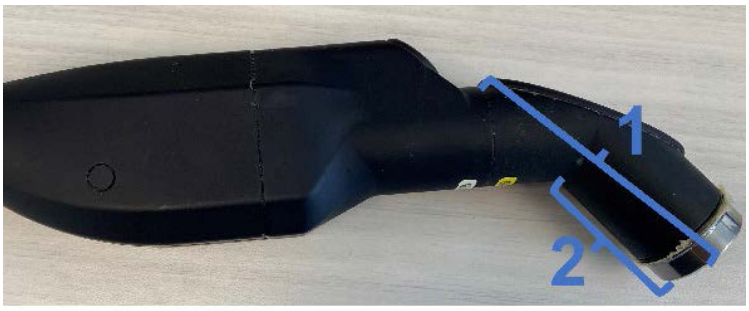


Fig.101. **Typical working length (2) and maximum working length (1).**

14.2 Electromagnetic (EMC) Specifications

Guidance and Manufacturer's Declaration – Electromagnetic Disturbance Compliance		
Lumicell DVS is intended for use where its impact on the electromagnetic disturbance environment is specified below. The customer or user of the Lumicell DVS should ensure that it is only used in an environment where such compliance is required.		
Emission Test	**Compliance**	**Electromagnetic Environment Guidance**
Radiated RF Emissions	CISPR 11, Group 1, Class A	Lumicell DVS is suitable for use in all professional healthcare facility environments. Not for use in domestic environments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Conducted RF Emissions	CISPR 11, Group 1, Class A	
Harmonic Distortion	IEC 61000-3-2	
Voltage Fluctuations and Flicker	IEC 61000-3-3	

14.2 Electromagnetic (EMC) Specifications *Continued*

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment Guidance
Electrostatic Discharge	IEC 61000-4-2	± 8kV contact ± 2kV, ± 4kV, ± 8 kV air[1]	Floors should be wood or concrete. If floors are covered with a synthetic material, the relative humidity should be at least 30%
Radiated RF EM Fields	IEC 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80% AM at 1kHz	Mains power quality should be that of a typical commercial or hospital environment. Use of Lumicell DVS in environments that exceed the tested levels for electromagnetic disturbances may result in unpredictable system operation. Use in such environments is not recommended.
Proximity Fields from RF Wireless Communications Equipment	IEC 610004-3	Per Clause 8.10 IEC 60601-1-2 30 A/m 50Hz or 60 Hz	
Radiated Power Frequency Magnetic Fields	IEC 61000-4-8	Per Clause 8.10 IEC 60601-1-2 30 A/m 50Hz or 60 Hz	
Proximity Magnetic Fields	IEC 61000-4-39	N/A[2]	
Electrical Fast Transients/ Bursts	IEC 61000-4-4	± 2 kV 100 kHz repetition frequency	
Surges, Line To Line	IEC 61000-4-5	± 0.5 kV, ± 1 kV	
Surges, Line To Ground	IEC 61000-4-5	± 0.5 kV, ± 1 kV, ± 2 kV	
Conducted Disturbances Induced by RF Fields	IEC 61000-4-6	3 V 0.15 – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% AM at 1 kHz	
Voltage Dips	IEC 61000-4-11	0% UT[3]: 0.5 cycle, @ 0°, 45°, 90°, 135°. 180°, 225°, 270° and 315° 0% UT: 1 cycle, @ 70° UT: 25/30 cycles, @ 0°	
Voltage Interruptions	IEC 61000-4-11	0% UT: 250/300 cycle	

[1]The ± 15kV air discharge level was not tested as the environment in an operating room is not conducive to ESD events therefore in accordance with Annex E of 60601-1-2, testing to levels greater than the reasonably foreseeable maximum of ± 8kV are not likely to result in increased safety of Lumicell DVS.

[2]Lumicell DVS is not intended for use in close proximity to equipment generating high magnetic fields and therefore this requirement has not been tested.

[3]UT is the AC Mains voltage prior to the application of the test level.

15

Clinical Data Summary

This section summarizes the results from the safety and effectiveness assessment for LUMISIGHT and Lumicell DVS combination product.

15.1 Summary of Clinical Safety

This Summary of Clinical Safety includes human data relevant to the safety and tolerance of the following two FDA approved products ("combination product"): LUMISIGHT (pegulicianine, previously referred to as LUM015), an optical imaging agent and Lumicell DVS, a fluorescence imaging device.

15.1.1 Safety Evaluation Plan

Safety was evaluated in 710 subjects with breast cancer, 56 subjects with other solid tumors, and 24 healthy patients who received LUMISIGHT. Thus, a total of 790 subjects were exposed to LUMISIGHT, 766 of whom were subjects with cancer. Pivotal Study CL0007 included a total of 406 subjects (51% of the evaluable safety population).

Particular adverse events (AEs) related to LUMISIGHT that were expected were allergic reactions/ anaphylaxis. Study personnel administering LUMISIGHT in each study were provided with guidance and instructions to treat any AE of allergic reaction or anaphylaxis. Surgeons were also given guidance to premedicate subjects if there was suspicion of a high risk of allergic reactions based on medical history.

Patients included in the safety database were representative of the overall breast cancer population. All breast cancer types were included in the safety studies (i.e., invasive ductal, invasive lobular, and ductal carcinoma in situ (DCIS)).

15.1.2 Safety Results Summary

The safety profile of LUMISIGHT when administered as a single 1 mg/kg dose was characterized in clinical studies that enrolled a total of 726 subjects (703 with breast cancer).

- The expected AE of chromaturia was the most frequently reported AE, occurring in 85% of subjects.
- There were no deaths. Life-threatening AEs (0.3%), serious AEs (SAEs) (1.1%), and AEs leading to discontinuation (1.0%) were reported infrequently.
- No unanticipated adverse device effect (UADEs) were reported.
- 85% of AEs were mild in severity and resolved without sequelae.
- Hypersensitivity reactions occurred in 1.4% of patients. This included 4/726 (0.6%) patients who experienced signs and symptoms consistent with anaphylaxis.
- Adverse reactions occurring in <1% of patients were skin discoloration after extravasation, nausea, dyspnea, pyrexia, and vomiting.

15.2 Summary of Clinical Effectiveness

15.2.1 Effectiveness Evaluation Plan

The effectiveness of the LUMISIGHT and Lumicell DVS combination product was assessed in a multi-center, well controlled study:

- **Pivotal Study CL0007**: a two-arm randomized, hypothesis-tested IDE study (N = 406 subjects)

Pivotal Study CL0007 was designed to evaluate the use of LUMISIGHT and Lumicell DVS in combination as an adjunct to the standard of care (SoC) breast-conserving surgery (BCS or lumpectomy). All subjects included in the effectiveness analysis were injected intravenously with LUMISIGHT at a dose of 1 mg/kg and completed the surgical intervention as per the study protocol. Once the surgeon completed the SoC BCS, subjects were randomized to either the device arm or control arm. For subjects in the device arm, Lumicell DVS was used to scan the lumpectomy cavity to detect regions suspicious to contain residual cancer (activated by LUMISIGHT) and to assist in its removal by Lumicell DVS-guided shaves, as performed by the

surgeon where indicated. In the control arm, subjects had no Lumicell DVS-guided imaging.

During the analysis, each tissue removed was identified as part of the SoC BCS or guided by Lumicell DVS, so the pathology margin assessments prior to and after using Lumicell DVS is known. With this approach, the patient serves as their own control.

In the Pivotal Study CL0007, injection of any dye for sentinel node mapping prior to imaging with the Lumicell DVS was an exclusion criterion. Blue dyes that are sometimes used for sentinel lymph node mapping procedures (e.g., isosulfan blue) generate a fluorescent signal that interferes with the signal from LUMISIGHT.

15.2.2 Endpoints for Effectiveness Evaluation

The primary endpoints used for the effectiveness evaluation in Pivotal Study CL0007 were as follows:

- **Removal of residual cancer**: The proportion of subjects who have residual cancer found in at least one Lumicell DVS-guided shave (also known as a therapeutic shave) among all subjects. Residual cancer was defined as tumor found by pathology in a therapeutic shave after the SoC surgical procedure is completed; that is, tumor that current SoC surgery failed to remove.
- **Diagnostic performance measures**: Tissue-level sensitivity and tissue-level specificity.

A series of post hoc analyses and secondary endpoints are presented in this section also.

15.2.3 Effectiveness Results Summary

15.2.3.1 Primary Effectiveness Endpoints

Removal of Residual Cancer

Table 1 presents the tumor removal rate for the Pivotal Study CL0007. The lower bounds of the 95% CI had tumor removal rates higher than the performance target of greater than 3% as predefined in the statistical analysis plan (SAP) for Pivotal Study CL0007.

Table 1. Tumor Removal Rate in Pivotal Study Device Arm

Primary Endpoint	Result
Proportion of subjects who had residual cancer in at least one Lumicell DVS-guided shave among all subjects in the device arm (subject level), % (n/N) (95% CI)	7.6 (27/357) (5.0, 10.8)

Abbreviations: CI = confidence interval; Lumicell DVS-guided = guided by imaging with Lumicell DVS.
Note: CI: Binomial Clopper–Pearson (Exact).

Diagnostic Performance Analysis: Tissue-Level Sensitivity and Specificity

The diagnostic performance of the LUMISIGHT and Lumicell DVS combination product to detect and guide the removal of residual cancer was evaluated by the primary endpoints of tissue-level sensitivity and tissue-level specificity. A generalized estimating equation (GEE) approach was applied to address potential within-subject correlations because multiple data points are generated from each subject.

The tissue-level sensitivity in the Pivotal Study CL0007 was 49.1% (95% CI: 36.4%, 61.9%), and did not meet the preset performance goal of 40% by 3.6 percentage points at the lower bound of the 95% CI (i.e., 36.4%; Table 2).

The tissue-level specificity was 86.5% (95% CI: 84.5%, 88.3%)(Table 2). The performance goal of 60% was met

in Pivotal Study CL0007 by 24.5 percentage points (i.e., 84.5%) at the lower bound of the 95% CI (Table 2).

Table 2. Cross-Study Comparison of Sensitivity and Specificity of Lumicell DVS in Predicting Residual Cancer in the Cavity Following the Hierarchical Approach for Truth Standard

	Pivotal Study CL0007 Device Arm
Truth standard positives	69
Truth standard negative	2277
True positives	34
True negatives	1940
GEE Estimator	
Sensitivity (%) (95% CI)	49.1 (36.4, 61.9)
Specificity (%) (95% CI)	86.5 (84.5, 88.3)
Youden Index (95% CI)	0.36 (0.21, 0.50)

Abbreviations: CI = confidence interval; GEE = generalized estimating equation.

15.2.3.2 Secondary Effectiveness Endpoints

Secondary effectiveness endpoints were analyzed in Pivotal Study CL0007 related to meaningful clinical impact. These analyses included:

- Conversion of SoC positive margin patients to final negative margins patients.
- Lumicell DVS-guided removal of residual cancer in subjects having negative SoC margins.
- Average volume of Lumicell DVS-guided shaves and contribution to total excision volume.

Conversion of SoC Positive Margin Patients to Final Negative Margins Patients

In Pivotal Study CL0007, of 62 subjects (17.4%, 62 out of 357 subjects, 95% CI: 13.6%, 21.7%) with positive margins after the SoC surgery (i.e., before intervention with Lumicell DVS), 14.5% (9 out of 62 subjects; 95% CI: 6.9%, 25.8%) had final pathology-negative margins because of removing Lumicell DVS-guided shaves. Thus, Lumicell DVS may potentially prevent approximately 15% of second surgeries due to SoC positive margins by guiding the removal of additional shaves.

Lumicell DVS-guided Removal of Residual Cancer in Subjects Having Negative Standard of Care Margins

In addition, 19 out of 295 subjects in CL0007 who had negative margins after the SoC procedure had residual cancer found in at least one Lumicell DVS-guided shave in subjects with negative margins (6.4%; 95% CI: 3.9%, 9.9%). Two of the 19 subjects that initially had negative margins after SoC BCS had final positive margins in Lumicell DVS-guided shaves and went on to receive a second surgery.

In summary, without the use of the LUMISIGHT and Lumicell DVS combination product, these 19 subjects in Pivotal Study CL0007 would have completed their initial surgical procedure with cancer remaining in the lumpectomy cavity and likely would have not received a second surgery because the SoC margins were negative.

Average Volume of Lumicell DVS-guided Shaves and Contribution to Total Excision Volume

The mean (± standard deviation [SD]) SoC total excision volume (prior to using Lumicell DVS) removed in the mITT Population was 89.0 cm^3 (± 93.7 cm^3).

Among the 166 patients with at least one Lumicell DVS-guided shave, the mean Lumicell DVS-guided shave volume was 22 cm^3 (± 20 cm^3), accounting for 20% (± 15%) of the total volume of resection.

Previously (Chagpar et al. 2015, Dupont et al. 2021) it has been shown that when 30.0% of additional tissue is removed during BCS, there is no substantial impact to the patient's perceived cosmetic outcomes or reported postoperative complication. Thus, the results from the pivotal study indicate that the additional volume of Lumicell DVS-guided shaves to the volume of the SoC BCS (less than 30%) should not substantially impact cosmetic outcomes or reported postoperative complications.

15.3 Overall Clinical Conclusions

In Pivotal Study CL0007, major safety concerns (anaphylaxis or hypersensitivity events) were identified but considered acceptable and manageable with the mitigation approach for LUMISIGHT. No device related adverse events were reported across the clinical study program.

The effectiveness of the combination product in the Pivotal Study CL0007 clearly demonstrated success in detecting and guiding the removal of residual cancer in 27 patients that would have otherwise remained undetected after SoC BCS. Additionally, 14.5% of patients with pathology positive margins after SoC BCS were converted to final negative margins by removing a Lumicell DVS-guided shave, potentially saving a potential second surgery. In the pivotal study, 7.6% of patients had additional cancer removed that was undetected during the initial SoC surgery.

Moreover, in approximately 49.0% of patients (176 out of 357 patients) the combination product confirmed either no residual cancer was present or a negative margin outcome. Results from the pivotal study also show that in 41 patients with residual cancer removed, 27 had a more complete resection guided using LUMISIGHT, with 20 of those 27 patients having residual cancer only found by Lumicell DVS.

In summary, the LUMISIGHT and Lumicell DVS combination product demonstrated a capacity to reliably and consistently remove some residual cancer that remained undetected in patients with breast cancer in a disease population with high unmet needs. The Pivotal Study reliably evidenced consistent results of diagnostic performance with limitations of sensitivity counterbalanced by improvements over SoC margin detection rates.

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