

molli[®]

MOLLI 2

User Manual

 **CAUTION:** Federal law restricts this device to sale by or on the order of a physician. **R ONLY**



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For additional information or assistance, please contact MOLLI Surgical Inc.

This User Manual is written for MOLLI 2 Tablet software version 2.X.X and MOLLI 2 Wand firmware version B.X.

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Introduction

The MOLLI 2 User Manual is intended to provide information for correct operation of MOLLI 2. Do not operate MOLLI 2 before reading the instructions.

The MOLLI 2 device is a wire-free, radiation-free marking system and clinical method for locating soft-tissue lesions during surgery. MOLLI 2 consists of the MOLLI Introducer needle with a preloaded magnetic MOLLI Marker and the MOLLI 2 (Wand and Tablet) to guide the user to the implanted Marker. MOLLI 2 is designed to maintain the workflow benefits of radioactive seed localization (RSL) while eliminating unnecessary patient radiation exposure and the costly burden of managing radioactive seeds.

Indications for Use

The MOLLI Marker is intended to be placed percutaneously in soft tissue to temporarily mark a surgical site intended for surgical removal. The MOLLI Marker can only be implanted for less than 30 days. Using imaging guidance (such as ultrasound or radiography) or aided by non-imaging guidance (MOLLI 2 System), the MOLLI Marker is located and surgically removed with the target tissue. The MOLLI 2 System is intended only for the non-imaging detection and localization of the MOLLI Marker that has been implanted in a site intended for surgical removal.

Contraindications

- MOLLI 2 is intended only for use in localizing the MOLLI Marker in soft tissue. MOLLI 2 is contraindicated for use in ocular, cardiac, neurological and spinal clinical applications.

Warnings

- No modification of MOLLI 2 is allowed.
- The use of any software other than those specified in this User Manual violates the safety, effectiveness, and design controls of MOLLI 2 and such use may result in an increased risk to users and patients.
- MOLLI 2 should not be used in an oxygen-rich environment, or in conjunction with flammable anesthetics.
- Remove magnetic tissue expanders from patients prior to using MOLLI 2.

- The MOLLI 2 Wand & Cable must be used with a legally marketed sterile sheath when brought into a sterile field. Please refer to the “Sterile Use” section for more information.
- Do not reuse or resterilize the sheath.
- Do not use magnetized surgical tools while simultaneously localizing the Marker as it will interfere with the Wand’s detection of the Marker’s magnetic field. Please refer to the “Preventing Magnetic Interference with MOLLI 2” section.
- Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Use of accessories, transducers and cables other than those specified or provided by MOLLI Surgical could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- Portable RF (Radio Frequency) communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of MOLLI 2, including cables specified by MOLLI Surgical. Otherwise, degradation of the performance of this equipment could result.

Cautions

- Federal law restricts this device to sale by or on the order of a physician (21 CFR §801.109(b)(1)).
- Read all warnings, cautions, and instructions provided before using.
- This product should only be used by a physician who is knowledgeable of the indications, contraindications, limitations, typical findings and possible side effects of MOLLI 2.
- Incorrect handling, excessive force, or dropping MOLLI 2 may cause malfunction or permanent damage. Handle with care.
- If any signs of damage is evident on any components of the MOLLI 2 and/or MOLLI 2 is not functioning as expected, discontinue use and contact MOLLI Surgical customer service or your local representative.

- MOLLI 2 is disconnected from Mains power by disconnecting the power supply. Do not position the device such that it is difficult to carry out disconnection if using power supply.
- Changes in the medical equipment or the environment may cause inaccuracies in MOLLI 2. Exposure of MOLLI 2 to temperatures outside of ambient conditions may cause inaccurate readings.
- Do not bring the MOLLI 2 Wand tip and MOLLI Marker in contact with each other (less than 2 mm).
- The MOLLI 2 Wand should be removed from patient contact if there is a requirement to use a defibrillator.
- Do not attach any non-MOLLI devices to the Tablet's accessible ports. This could result in a hazardous situation, and will void product warranty.
- Do not touch the accessible contacts of the MOLLI 2 Tablet connectors and the patient at the same time.
- Do not attempt to remove the Cable from the MOLLI 2 Tablet.
- The MOLLI 2 Tablet should remain in the non-sterile field. Arrange the operating room and personnel accordingly. Ensure all cable routing does not create tripping hazards.
- Sterilization methods other than those recommended could damage the Wand, void the warranty, and could result in injury to the operator or patient. Do not autoclave the MOLLI 2 Wand. Steam or dry heat sterilization will damage the MOLLI 2 Wand, void the warranty, and could result in injury to the operator.
- Do not submerge the Tablet or Cable within any solution.
- Do not scratch or abrade the Wand when cleaning. Scratching or abrading the Wand may compromise future sterilizations.
- Dispose of all MOLLI 2 components as per local laws, care facility laws or hospital laws for routine/nonhazardous electronic waste.

MR Safety Information



MOLLI 2 is MR Unsafe and poses a projectile risk.

Contact Information

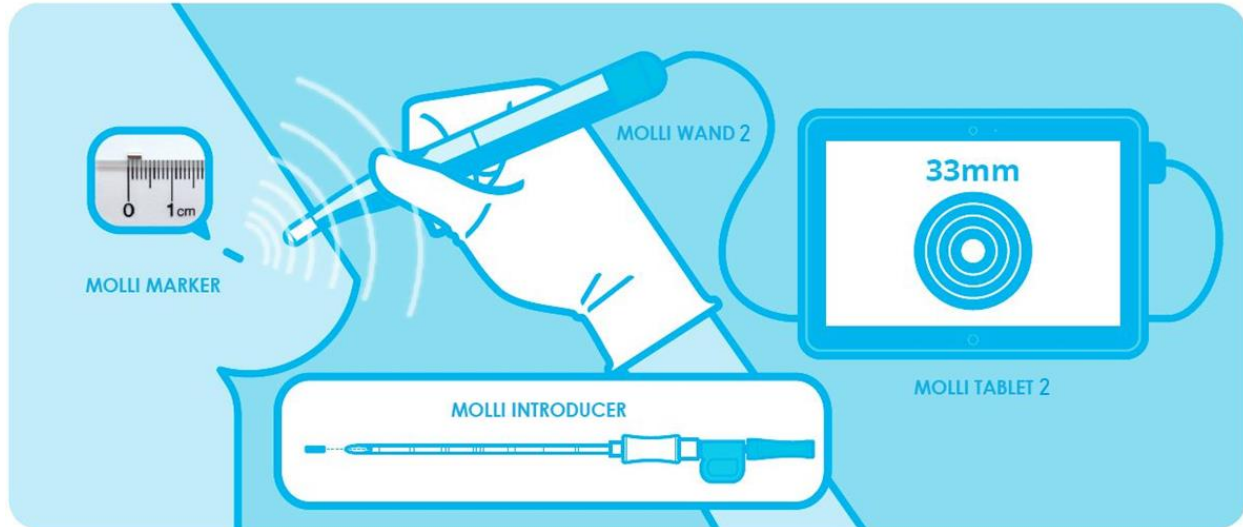
For questions or comments about the device and its application, or other issues related to MOLLI 2 requiring assistance, please contact your local representative.



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Product Description



MOLLI 2 consists of:

MOLLI 2 Wand



MOLLI 2 Tablet



MOLLI 2

MOLLI 2 provides three forms of feedback to localize the MOLLI Marker: distance (mm), graphical display (bullseye), and an audible tone. The detection range is from 5 mm to 45 mm.

MOLLI 2 is neither a diagnostic or a therapeutic device and does not emit energy. The MOLLI 2 Wand is connected to the MOLLI 2 Tablet via a cable that is 2.8 m long. The MOLLI 2 Tablet can be powered either by internal battery or via the power adapter provided by MOLLI Surgical (length of 1.5 m). All cables are IEC 60601-1-2 compliant and only originally equipped cables should be used (see “Technical Specifications”). The MOLLI 2 Wand is the applied part as per IEC 60601 definitions. A legally marketed sterile sheath must be placed over the MOLLI 2 Wand and the cable.

MOLLI Marker & MOLLI Introducer

MOLLI 2 is intended to be used with a MOLLI Marker, a single-use passive implant composed of a magnetic material which provides a signal detectable by the MOLLI 2 Wand. MOLLI Markers are visible under both ultrasound and radiographic imaging. A MOLLI Marker comes preloaded inside a MOLLI Introducer and is provided to the user sterilized. The single-use MOLLI Introducer needles are available in a variety of lengths.

For more information, refer to the provided User Manual for the MOLLI Marker & Introducer (MAR-003).

Setup

⚠ WARNING: The MOLLI 2 Wand & Cable must be used with a legally marketed sterile sheath when brought into a sterile field.

⚠ CAUTION: The MOLLI 2 Tablet should remain in the non-sterile field. Arrange the operating room and personnel accordingly. Ensure all cable routing does not create tripping hazards.

⚠ CAUTION: Do not attempt to remove the MOLLI Cable from the MOLLI 2 Tablet.

NOTE: The default setup includes the MOLLI 2 Tablet attached to the tabletop stand.

NOTE: Please have ultrasound or radiographic imaging available if localization using MOLLI 2 is not possible.

1. Before use, visually inspect the Wand and Tablet for any signs of physical damage such as cracking or splitting. If physical damage is evident, discontinue use and contact MOLLI Surgical customer service or your local representative.
2. Power on the Tablet by pressing the power button. Check that the Tablet is charged prior to use. If not, connect the power adapter to the Tablet to charge the Tablet.

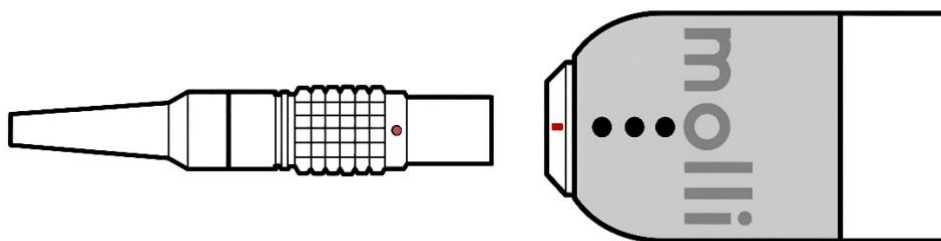


NOTE: The complete battery charging time of the Tablet is approximately 2-3 hours and the battery run time is approximately 8 hours.

NOTE: If the power adapter is to remain connected to the Tablet during use, ensure Tablet is positioned such that cable routing does not create a trip hazard.

NOTE: If a power outage occurs during surgery, MOLLI 2 will continue to run on battery power without being compromised.

3. Using a sterile technique, cover the Wand and Cable in a sterile sheath for use in the sterile field (see “Sterile Use” section below).
4. Connect the MOLLI 2 Wand to the MOLLI 2 Tablet via the Cable by aligning the red dot on the end of the Cable to the red dot and/or 3 aligned circles on the end of the Wand. The system will inform the user if the Wand is detected.



NOTE: If the system is unable to detect the Wand, refer to the “Troubleshooting” section. If the problem persists, discontinue use and contact MOLLI Surgical customer service or your local representative.

NOTE: Ensure that the Cable is moved out of the way and clamped down with strain relief to prevent tripping if needed.

5. The system is ready for the Wand Check (see “Wand Check Procedure” section).

Sterile Use

The MOLLI 2 Wand & Cable *must* be used with a legally marketed sterile sheath when brought into a sterile field (or setting). The MOLLI 2 Wand does *requires* sterilization between procedures. The Wand must be cleaned and thoroughly sterilized before use. See the MOLLI Wand and MOLLI 2 Wand Reprocessing Instructions for in-detail instructions.

Sterile Sheaths

The Wand & Cable may be used in a sterile field after a sterile sheath is placed over the Wand and Cable. Sterile sheaths are available from MOLLI Surgical Inc. for US customers only or from a multitude of vendors. For reference, the MOLLI 2 Wand has a tip diameter of 0.39" (10 mm) which extends to a maximum diameter of 0.88" (22 mm). The length of the sheath should be greater than 90" (2.30 m).

Suggested Draping Procedure

Sterilized Wand

Suggested installation sequence of a sterile Wand into a sterile sheath is as follows:

1. A professional in the sterile field holds the sterile MOLLI 2 Wand and the sterile sheath.
2. A professional outside the sterile field holds the Cable.
3. The sterile professional inserts the Wand into the sheath and passes the rear end of the drape (without pulling it out to its full length) to the non-sterile professional.
4. The non-sterile professional takes the rear end of the sheath in one hand and the Cable in the other hand, reaches into the unextended sheath with the Cable and inserts the cable connector into the MOLLI 2 Wand connector.
5. The non-sterile professional then pulls the drape up the Cable to its full length.

Disposal

 **WARNING:** Do not resterilize or reuse the sheath.

The single-use sheath must be disposed immediately after sterile use, as per hospital policy.

Wand Check Procedure

A Wand Check is automatically initiated each time the Wand is connected to the Tablet. It is an initial scan for magnetic fields that may interfere with MOLLI 2's performance. When completed, localization may proceed.

NOTE: *If you are stuck in the Wand Check procedure see the Troubleshooting section for probable causes and possible resolutions.*

NOTE: *If at any time during operation, you feel that a Wand Check is required, without a prompt from the software, you can initiate it with a tap on the Wand Check icon located in the top left corner of the Tablet screen. If you ever tap the icon by mistake, hold the Wand in free space away from any objects and the Wand Check system will automatically return to localization mode.*



Use

⚠ WARNING: Do not use magnetized surgical tools while simultaneously localizing the Marker as it will interfere with the Wand's detection of the Marker's magnetic field.

⚠ CAUTION: Read all warnings, cautions, and instructions provided before using.

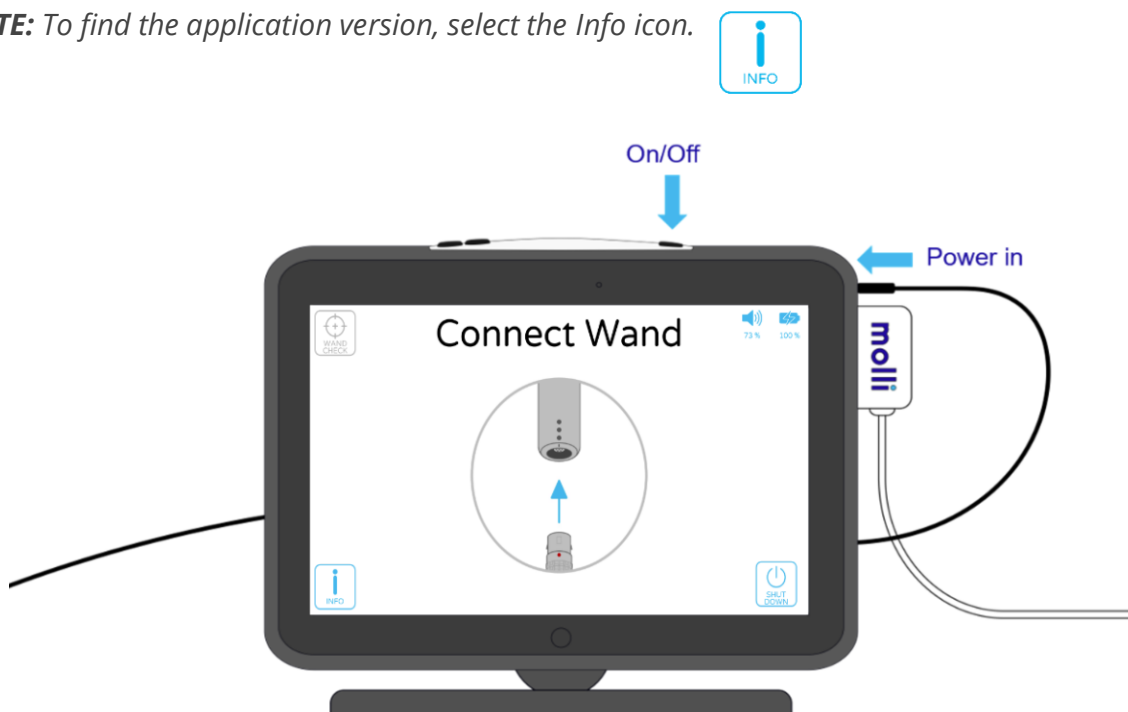
⚠ CAUTION: Do not bring the Wand tip and Marker in contact with each other (less than 2 mm).

⚠ CAUTION: The MOLLI 2 Wand should be removed from patient contact if there is a requirement to use an external defibrillator.

NOTE: MOLLI 2 is intended for use by suitably qualified, trained and authorized physicians and/or operating room staff. MOLLI Surgical Inc. takes no responsibility for the possible use or misuse by inadequately qualified staff.

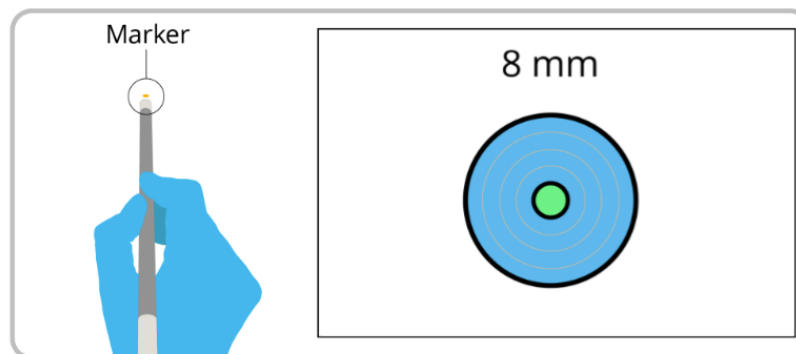
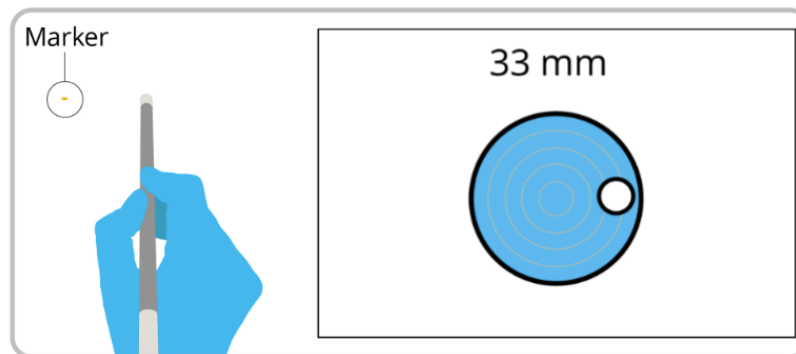
NOTE: Please have ultrasound or radiographic imaging available if localization using MOLLI 2 is not possible.

NOTE: To find the application version, select the Info icon.



Instructions for localization:

1. Move the tip of the Wand towards the suspected lesion location. Feedback indicates distance from Wand tip to the center of the Marker.
2. Three forms of feedback are provided:
 - **Sound** – Increase in audible pitch indicates the Wand is approaching the Marker, and conversely, a decrease indicates Wand is getting farther away from the Marker. Auditory feedback occurs only when the distance between the Wand and the Marker is changing.
 - **Distance** –The number represents the non-directional radial distance between the tip of the Wand and the MOLLI Marker from 5 mm to 45 mm.
 - **Bullseye** –The bullseye consists of a white dot which moves to provide the relative position of the Wand tip to the MOLLI Marker. The center of the bullseye represents the center of the MOLLI Marker, and the white dot represents the tip of the Wand. If the MOLLI Marker is directly in front of the Wand tip the white dot on the bullseye will turn green. Refer to the graphics below:



NOTE: MOLLI 2 will display measurements when the distance between the tip of the Wand and the center of the Marker is between 5 and 45 mm. The distance is a combination of the lateral and depth displacement of the Marker from the Wand tip. The distance measurement is representative of depth only at the minimum distance. If the Tablet reads ">50 mm", bring the Wand closer to the Marker until a distance is displayed.

NOTE: Ensure the speaker grill on the rear of Tablet is clear of obstruction. Ensure that the Tablet display is visible to the surgeon.

3. Scan the targeted area and move the Wand as close to the Marker as possible. MOLLI Surgical Inc. suggests the following steps to localize the Marker:
 - Raster scan the surface of the targeted area until the Wand is within 45 mm of the Marker as indicated on the Tablet.
 - Move the Wand in one direction to minimize the distance displayed.
 - Once a local minimum is achieved, move the Wand in the orthogonal direction to look for a smaller distance.
 - Repeat the above two steps as required.
 - Once the Marker has been localized, the position can be confirmed by pressing the Wand down into the surface.
4. After surgery, turn off the Tablet by pressing the power button on the Tablet and refer to the "Cleaning, Disinfection and Sterilization" section.

Bracketing Cases

NOTE: The recommended minimum spacing between any two or more implanted Markers is 40 mm. When the Wand tip is equidistant to any two Markers, numerical distance feedback may be inaccurate. User should rely on audio and graphical feedback to localize Markers.

1. In accordance with the localization instructions above, begin the scan from the peripheral edges of the cavity moving inwards.
2. Once the first MOLLI Marker is localized (when the white dot on the bullseye turns green), mark its position (i.e. with a stitch, pen mark, etc).
3. To localize additional markers, begin the scan from the other side of the cavity, repeating the movements above until all markers are identified.

Performance and Accuracy

MOLLI 2 indicates the presence of magnetic fields around the Wand tip and acts as a proximity detector. The MOLLI Marker's magnetic field is stronger nearer to the Marker. The numerical distance reading on the Tablet decreases as the magnetic field strength increases (moving the Wand towards the Marker). The audible tone increases in pitch as the magnetic field strength increases.

The maximum distance to the MOLLI Marker that can be measured by the System is 45 mm. The accuracy of MOLLI 2's distance feedback for a single Marker is as follows:

Distance from Wand tip to the Marker	≥5 mm – 19 mm	≥20 mm – 29 mm	≥30 mm – 39 mm	≥40 mm – 45 mm
Accuracy rate	± 2 mm	± 3 mm	± 4 mm	± 5 mm

The recommended minimum spacing between any two or more implanted Markers is 40 mm. At this spacing or greater, the accuracy is maintained. At a spacing less than 40 mm between any two Markers, users should solely rely on audio feedback to localize the Marker.

The medical team can always revert to standard forms of imaging guidance, such as ultrasound and radiography to extract the MOLLI Marker.

Preventing Magnetic Interference with MOLLI 2

MOLLI 2 complies with IEC 60601-1-2:2020 (ed 4.1) standard for power frequency magnetic field interference; this ensures that performance is not degraded by reasonably foreseeable maximum levels of electromagnetic disturbances from medical electrical equipment and systems in the intended use environments. Additionally, MOLLI 2 has a built-in check for detecting magnetic disturbance called the Wand Check Procedure.

Wand Check Procedure: The Wand Check is performed at the beginning of each surgery and is automatically initiated any time the MOLLI 2 Wand is connected to the MOLLI 2 Tablet. The Wand Check Procedure takes approximately 10 seconds to scan the environment to determine if there is magnetic disturbance.

Fixing Wand Check Failure: If the Wand Check fails, MOLLI 2 will not allow you to proceed. However, if you have followed the on-screen prompts correctly and repeated Wand Check attempts still fail, this indicates that there is a presence of magnetic field disturbance. This magnetic disturbance may arise from magnetic tools or instruments within the surgical environment. Please check non-electrical surgical tools before use as follows:

Checking non-electrical surgical tools before use: Please check surgical tools for magnetization if they are expected to be used close to the Wand. This can be done by a simple test before using the tool: hold the Wand stationary and bring the tool as close as would be clinically expected. If the System's displayed distance decreases, do not use the surgical tool in proximity to the Wand.

NOTE: *If you must use a particular surgical instrument that is interfering with MOLLI 2, you can safely use it if you are not simultaneously localizing.*

Cleaning and Sterilization

Tablet & Cable

The Tablet and Cable must be cleaned with a legally marketed surface disinfectant (CaviWipes[®] or similar) following each use.

 **CAUTION:** *Do not submerge the Tablet or Cable within any solution.*

1. Clean the outside surfaces of the Tablet and Cable using a surface disinfectant (CaviWipes[®] or similar) as per the disinfectant manufacturer's instructions.
2. Visually inspect all cleaned surfaces for signs of contamination. Repeat cleaning until all surfaces are free of visible contamination.

Wand

All Wands require cleaning immediately after use followed by sterilization. Ensure that the sheath is removed and disposed, according to hospital policy, prior to reprocessing. Select sterilization per your Hospital Infection Prevention and Control policy.

Follow the step-by-step instructions provided in the subsequent sections of this manual for proper cleaning and sterilization. Alternatively, consult the MOLLI Wand and MOLLI 2 Wand Reprocessing Instructions.

If the Cable is still connected to the Wand, disconnect the Cable and only perform the following reprocessing steps on the Wand.

Wand - Cleaning Process

Follow these steps to ensure cleaning is done correctly. Cleaning must be conducted prior to sterilization.

 **CAUTION:** Do not scratch or abrade the Wand during reprocessing. Scratching or abrading the Wand may compromise future sterilizations.

Materials: Legally marketed enzymatic detergent, running water.

1. Rinse the outside surface of the Wand (including the connector end of the Wand) with a brisk stream of lukewarm tap water (98 °F to 105 °F / 36.5 °C to 40.5 °C) for 1 minute.
2. Prepare diluted enzymatic cleaner solution, suitable for surgical instruments, according to the manufacturer's recommendation.
3. Wipe the Wand for at least 1 minute, with a soft, lint-free cloth wetted with the diluted enzymatic cleaner solution.
4. Visually inspect the Wand for contaminated areas.
5. Repeat steps 3 to 4 until visual inspection reveals the Wand is clean.
6. Rinse the Wand with a brisk stream of lukewarm tap water (98 °F to 105 °F / 36.5 °C to 40.5 °C) for 30 seconds.
7. Air-dry or dry the Wand with a clean, lint-free towel to ensure the Wand is completely dry before proceeding to sterilization.
8. Visually inspect the Wand for any signs of physical damage, such as cracking or splitting. If physical damage is evident, discontinue use and contact MOLLI Surgical customer service or your local representative.
9. Proceed to sterilization, see instructions below.

Wand - Sterilization Process

⚠ CAUTION: Sterilization methods other than those recommended could damage the Wand, void the warranty, and could result in injury to the operator or patient. **DO NOT AUTOCLAVE THE MOLLI 2 WAND.** Steam or dry heat sterilization will damage the MOLLI 2 Wand, void the warranty, and could result in injury to the operator or patient.

The Wand, with Cable removed, can be sterilized using one of the following methods:

1. STERRAD® 100S short sterilization cycle (~55 minutes) **OR**
2. Ethylene oxide (EO) sterilization cycle **OR**
3. STERRAD® NX standard sterilization cycle (28 minutes) **OR**
4. STERIS® V-PRO® Non-Lumen sterilization cycle **OR**
5. STERRAD® 100NX standard sterilization cycle

Ethylene Oxide Process Parameters

Concentration: 735 mg/L

Temperature: 55 °C

Exposure: 120.0 minutes

Relative Humidity: 50-70%

Aeration Time: 12.0 hours

Aeration Temperature: 55 °C*

**Aeration temperature tolerance is defined by the sterilizer manufacturer ± 3 °C*

The Wand can be packaged in a standard packing material as long as the pack is large enough to contain the Wand without stressing the package seals. Store the sterilized Wand per hospital policy.

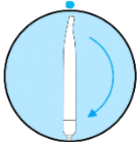
Troubleshooting

General Troubleshooting Guidelines

If the Tablet malfunctions, check for conditions that may have caused the problem:

- Check the Tablet for visible signs of physical damage.
- Verify that the Cable is connected and attached properly.

Use the table below to help identify and correct specific conditions.

Problem	Probable Cause	Possible Resolutions
Stuck in Wand Check procedure Move Wand 	Magnetic interference	This magnetic interference may arise from magnetic tools within the surgical environment. Please check surgical tools for magnetization by holding the MOLLI 2 Wand stationary and bring the tool as close as would be clinically expected. If the System's displayed distance decreases, do not use the surgical tool in proximity to the MOLLI 2 Wand. If this fix is not practical, ultrasound or radiographic imaging may be used to localize the MOLLI Marker.

Problem	Probable Cause	Possible Resolutions
"Wand Error" or "Tablet Error" displayed	Damaged components detected by system	If available, try using another MOLLI 2 Wand. Alternatively, ultrasound or radiographic imaging may be used to localize the MOLLI Marker. If neither are available, abort the procedure and contact your MOLLI Surgical customer representative.
Display appears dark or unresponsive	Tablet is OFF	Turn Tablet power ON (See Setup)
	Battery is discharged	Charge battery by connecting to charger
	Tablet won't charge	Recheck all power connections
Low battery symbol on Tablet 	Tablet is low on battery	Recharge battery via Tablet charger
No sound from Tablet	Volume is turned down	Increase level of volume; use volume buttons located on the top of the Tablet. 
	Volume is muted 	Unmute system; press the volume icon, or volume buttons located on top of tablet. 

Problem	Probable Cause	Possible Resolutions
Tablet is unresponsive to Wand	Tablet failed to recognize Wand	Unplug and reinsert Wand plug into the Tablet to reset the Wand-Tablet interface
	Tablet has malfunctioned	Restart the system by holding down the power button on top of system (See “Setup”)

For ALL other problems, please contact MOLLI Surgical 24-hour helpline (1-833-MOLLI-MD, 1-833-665-5463) for support.

Maintenance & Service

MOLLI 2 must be serviced by MOLLI Surgical Inc. To ensure proper performance, the MOLLI 2 Tablet and MOLLI 2 Wand should be checked for any signs of damage or wear before each use and storage. This includes inspecting the housing, power cord, integrity of connectors, and integrity of switches. Should abnormalities such as discoloration or physical damage such as cracks or splitting be discovered by the user, the user should contact MOLLI Surgical Inc. Do not use a damaged Wand or Tablet.

Preventative maintenance is limited to external cleaning of Tablet and confirmation of power up functional diagnostics. The MOLLI 2 Tablet and MOLLI 2 Wand do not require any specific routine service. There are no user-serviceable components within the MOLLI 2 Tablet, MOLLI 2 Wand, or power adapters. Should any issues arise which are not solved through common troubleshooting steps, please contact the MOLLI technical support line (1-833-665-5463) for help. Refer servicing, maintenance, and repairs to authorized service users.

NOTE: *If a Tablet or Wand is to be shipped from your institution for repair, then please clean and disinfect the Tablet or Wand as described in this manual before packing for shipment. Indicate on the outside of the shipping container that the Tablet or Wand has been cleaned and disinfected.*

Disposal

The single-use sheath must be disposed immediately after sterile use, as per hospital policy.

Dispose of MOLLI 2 as per local laws, care facility laws, or hospital laws for routine/nonhazardous electronic waste or contact MOLLI technical support for help.

To ship a Tablet or Wand from your institution to MOLLI Surgical for disposal, contact MOLLI technical support.

For Users with an Existing MP1001 MOLLI Wand

For users using a MP1001 MOLLI Wand, the MOLLI 2 Tablet comes equipped with the same visual and audible feedback found on previous MT1001 MOLLI Tablets. The software will automatically detect when a MP1001 MOLLI Wand is connected. The MOLLI 2 Tablet is compatible with MP1001 MOLLI Wand Firmware version 2.1. Refer to the MP1001 MOLLI Wand User Manual for use of the MP1001 MOLLI Wand bullseye feedback.

NOTE: *The MOLLI 2 Software bullseye feedback cannot be used with a MP1001 MOLLI Wand.*

General Specifications

Model / Type Reference	MOLLI 2
Mode of Operation	Continuous

Tablet Details

Part Number	MT2001
Instrument Weight	2.5 kg
Instrument Dimensions (W x H x D)	260 mm x 220 mm x 200 mm

Tablet Power Supply Specifications

Power Supply Make / Model	Adapter Tech / ATM036T-A150
Power Supply Input Connector	IEC 60320 C8
Power Supply Input	100-240V AC ~ 50-60Hz 1-0.45A
Power Supply Output	15V 2.4A
Power Supply Input Cable (AC)	0.7 m cable with IEC 60320 C7 Connector
Power Supply Output Cable (DC)	1.5 m cable permanently affixed to power supply

NOTE: Use only the MOLLI-supplied power supply to power the Tablet. Use of any other power supply will void the IEC 60601-1 safety compliance and IEC 60601-1-2 EMC compliance of the device. Should any additional, spare or replacement cables or power supplies be required please contact MOLLI Surgical.

Wand Details

Part Number	MP2001
Protection against electrical shock	Class II

Applied part isolation	Type B
Ingress protection rating	IP37 (when Wand is disconnected from the system for cleaning purposes)

Tablet - Wand Interface Cable Specifications

Cable Length	2.8 m shielded white cable
Cable Connector	Push-pull locking circular connector
Tablet - Wand Cable Connection	Cable is permanently affixed to the Tablet

NOTE: Only the originally equipped Tablet - Wand Interface cable should be used. Should any repair or replacement be required please contact MOLLI Surgical. Cable is not user-serviceable.

MOLLI Accessories

Specified Accessories	None - Wand is an applied part and required for operation
Non-specified Accessories	None - Cables or accessories which have not been provided by MOLLI Surgical should not be used. See "Warnings" for details.

Technical Specifications

	Operating Temperature: 10 to 35°C (50 to 95°F) Storage / Transportation temperature: -20 to 60°C (-4 to 140°F)
	Operating/transportation/storage humidity: 0 to 95%
	Operating/transportation/storage pressure: 70 to 106 kPa

Electromagnetic Compatibility

MOLLI 2 complies with IEC 60601-1-2:2020 (ed 4.1) standard. MOLLI is intended for use in the electromagnetic environment specified below. MOLLI users should assure that it is used in such an environment. The essential performance of MOLLI 2 was evaluated to ensure it maintains the measurement accuracy as specified in the table on page 18 in the Performance and Accuracy section, as the pass/fail criteria.

Certain electromagnetic disturbances (e.g. static discharge/shock, use of an electrocautery system) may temporarily affect the connection between the MOLLI 2 Tablet and Wand. This behavior is rare but expected, and the MOLLI 2 Tablet will reconnect with the MOLLI 2 Wand within 2 seconds and will not require any input or action from the user.

It is recommended to keep the Wand cable away from other cables to prevent increased occurrence of certain electromagnetic disturbances.

MOLLI 2 does not require specific exclusions from active HF (High Frequency) surgical equipment or high RF (Radio Frequency) areas.

MOLLI 2 is MR Unsafe and should not be used near an MRI Suite.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Emissions test	Compliance	Electromagnetic environment
Radiated RF Emissions CISPR 11	Group 1, Class A ISO 14117 - Magnetic Emissions from 10Hz to 10MHz	MOLLI 2 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. MOLLI 2 is suitable for use in all establishments other than domestic, and may be used in domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded:
Conducted RF Emissions CISPR 11	Group 1, Class A	
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker Emissions IEC 61000-3-3	Complies	

NOTE: The Emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Immunity test	IEC 60601-1-2:2020 Test Level	Compliance level

Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV Contact ±15 kV Air	±8 kV Contact ±15 kV Air
Electrical Fast Transient/Burst IEC 61000-4-4	±2 kV for power supply lines	±2 kV for power supply lines
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line & ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to line & ±0.5 kV, ±1 kV, ±2 kV line to ground
Voltage Dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11 NOTE: U_T is a c. mains voltage prior to application of the test level.	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 250/300 cycles	0% U_T (100% dip in U_T) for 0.5 cycle 0% U_T (100% dip in U_T) for 1 cycle 70% U_T (30% dip in U_T) for 25/30 cycles 0% U_T (100% dip in U_T) for 250/300 cycles
Power Frequency Magnetic Field (50/60 Hz) IEC 61000-4-8	30 A/m	30 A/m

Electrosurgery Immunity	Monopolar HF Surgical • Cut Mode Capability: 375W, 500kHz • Power Coagulation Mode Capability: 110W, 450kHz	Monopolar HF Surgical • Cut Mode Capability: 375W, 500kHz • Power Coagulation Mode Capability: 110W, 450kHz
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms Inside ISM bands 150 kHz to 80 MHz (see Note c)	3 Vrms 150 kHz to 80 MHz 6 Vrms Inside ISM bands 150 kHz to 80 MHz (see Note c)
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz & Proximity Fields (IEC 60601-1-2:2020 Table 9)	3 V/m 80 MHz to 6 GHz & Proximity Fields (See Note d)

IEC 60601-1-2 Services for which the recommended separation distance is 30 cm (12 inches)

Test Frequency (MHz)	Band (MHz)	Service	Modulation	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse 18 Hz	27
450	430-470	GMRS 460; FRS 460	Pulse 18 Hz	28
710	704-787	LTE Band 13, 17	Pulse 217 Hz	9
745				
780				
810	800-960	GSM 800/900; TETRA 800; iDEN 820; CDMA 850; LTE Band 5	Pulse 18 Hz	28
870				
930				
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse 217 Hz	28
1845				
1970				
2450	2400-2570	Bluetooth; WLAN; 802.11 b/g/n; RFID 2450; LTE Band 7	Pulse 217 Hz	28
5240	5100-5800	WLAN 802.11 a/n	Pulse 18 Hz	9
5500				
5785				

Proximity Fields from RFID and NFC Equipment	134.2 kHz, 65 A/m, 2.1 kHz pulse modulation 13.56 MHz, 7.5 A/m, 50kHz pulse modulation	134.2 kHz, 65 A/m, 2.1 kHz pulse modulation 13.56 MHz, 7.5 A/m, 50kHz pulse modulation
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NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

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

NOTE a: Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which MOLLI 2 is used exceeds the applicable RF compliance level above, MOLLI 2 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MOLLI 2 device.

NOTE b: Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

NOTE c: The ISM frequency bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz, 13.553 MHz to 13.567 MHz, 26.957 MHz to 27.283 MHz, and 40.66 MHz to 40.70 MHz.

NOTE d: Test Specifications for Enclosure Port Immunity to RF Wireless Communications Equipment (IEC 60601-1-2:2020 Table 9)

FCC Compliance

FCC ID: RZ5MD101

FCC Registration Number: 0022396329

MOLLI 2 complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:

1. MOLLI 2 may not cause harmful interference, and
2. MOLLI 2 must accept any interference received, including interference that may cause undesired operation (FCC Title 47, Subpart A, Part 15.19(3)).

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment (FCC Title 47, Subpart A, Part 15.21).

NOTE: *This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures (FCC Title 47, Subpart B, Part 15.105(b)):*

- *Reorient or relocate the receiving antenna.*
- *Increase the separation between the equipment and the receiver.*
- *Connect the equipment to an outlet on a circuit different from that to which the receiver is connected.*
- *Consult the dealer or an experienced radio/TV technician for help.*

NOTE: *"Harmful interference is defined by the FCC as follows: Interference that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with FCC rules.*

Symbols

Symbol Title of Symbol

	Manufacturer
	Batch code
	Serial number
	Catalogue number
	Non-sterile

Symbol Title of Symbol

	Date of manufacture
	Do not use if package is damaged
	Keep dry
	Temperature limit
	Humidity limitation

Symbol Title of Symbol

	Do not dispose of with regular waste
	Prescription only
	Warning or caution
	Identifies a Type B applied part complying with IEC 60601-1

Symbol Title of Symbol

	Atmospheric pressure limitation
	Consult instructions for use
	MR Unsafe
	Ingress protection rating



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precision surgery made **simpler**®