Mammotome

User Instructions & Operations Guide

Mammotome AutoCore™

Single Insertion Core Biopsy System

MAHC | MAP1210 | MAP1410
MAI1210 | MAI1410

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Chapter 1 : Introduction

Please read all information carefully. Failure to properly follow the instructions may lead to unintended consequences. This document provides instructions for use (IFU) for the Mammotome AutoCore™ Single Insertion Core Biopsy System. These are not surgical instructions.

Device Description

The Mammotome AutoCore™ Single Insertion Core Biopsy System is a single insertion, automated, spring-loaded core needle device. It consists of a reusable motorized battery-powered holster, charging base, disposable probes, and optional introducer stylet and cannula (**Figure 1**).

NOTE: The Mammotome AutoCore™ holster has an expected useful life of 1,000 reprocessing cycles.

IA – Optional Introducer Stylet
IB – Optional Introducer Cannula
II – Holster
III – Probe
IV – Charging Base
V – Adapter Cord

Figure 1

The AutoCore device is intended to be used in Ultrasound breast biopsy procedure rooms which are commonly found in hospitals, clinics, and other medical centers. The specific equipment within the procedure room may change from facility to facility (and country to country), but the following items will be in all or most procedure rooms:

Ultrasound machine with a transducer and monitor.

Procedure rooms vary in size and layout from facility to facility.

In the US, a core needle biopsy procedure is typically performed by a radiologist. Technologists/nurses perform a small number of procedures, however, mainly assist the radiologist or surgeon during the procedure. Pathologists are not present in the procedure room and work entirely in a laboratory. The extracted tissue samples are either stored in formalin or refrigerated and then sent to the pathologist for evaluation. The pathologists diagnose the presence or lack of disease.

Compatible Markers

IMPORTANT: The biopsy site identifiers (markers) listed in **Table 1** may be used with the Mammotome AutoCore™ system to radiographically mark the location of the biopsy procedure. **NOTE:** DO NOT USE A MARKER NOT APPROVED FOR USE WITH THE MAMMOTOME AUTOCORE™ SYSTEM.

Table 1. Compatible Markers

Marker Brand Name	Product Code	12G Introducer	14G Introducer
HydroMARK®	4010-02-15-T1	X	X
	4010-02-15-T3	X	X
	4010-02-15-T4	X	X
	4010-02-18-T3		X
CorMARK	MAM3014	X	X
	MAM3015	X	X
MammoSTAR	STAR1401	X	X
	STAR1402	X	X
	STAR1403	X	X
BiomarC	40313	X	X
	40321	X	X
	40316	X	X

Indications for Use

The Mammotome AutoCore™ Single Insertion Core Biopsy System is indicated for use by trained users to obtain tissue from the breast or lymph nodes for diagnostic sampling of breast abnormalities. This instrument is for diagnostic use only and is not indicated for therapeutic use.

The extent of a histologic abnormality cannot always be reliably determined from the palpation or imaged appearance. Therefore, the extent of removal of the palpated or imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality, e.g., malignancy. When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Intended Use

The device is intended to obtain tissue samples for diagnostic analysis.

Intended Patient Population

The Mammotome AutoCore™ Single Insertion Core Biopsy System is intended for use on patients aged twelve and older.

Contraindications

Mammotome AutoCore™ Single Insertion Core Biopsy System is not intended for use except as specifically indicated.

The instrument is contraindicated for patients who may experience increased risk of complications during removal of tissue samples as per a physician's judgment. For example, patients with bleeding disorders or those receiving anticoagulant therapy may be at increased risk.

Warnings

Please read all the contents of this IFU for the Mammotome AutoCore™ Single Insertion Core Biopsy System before operation. Follow all warnings and instructions as stated in this guide and retain this guide for future reference.

General

- Federal (USA) law restricts the sale of this device to, or on the order of, a physician only.
- This device should only be used by physicians trained in percutaneous needle techniques for tissue collection.
- **DANGER:** There is a risk of fire if the Mammotome AutoCore™ Single Insertion Core Biopsy System is used in the presence of flammable anesthetics and/or in an oxygen-rich environment. Avoid at all costs.
- No modification of this equipment is allowed. Changes or modifications not expressly approved by the party responsible for compliance can void the user's authority to operate the equipment.
- Do not attempt to service the Mammotome AutoCore™ Single Insertion Core Biopsy System. Products manufactured or distributed by companies not authorized by Devicor Medical Products, Inc. may not be compatible with the Mammotome AutoCore™ system.
- As with any medical procedure, there is potential risk for infection.
- Take care not to puncture breast implants or the patient's chest wall.
- Avoid inadvertently hitting a blood vessel when making the incision.
- Avoid hitting a nerve when using the device.
- Do not use this system in conjunction with Magnetic Resonance Imaging (MRI).
- Products manufactured or distributed by companies not authorized by Devicor Medical Products, Inc. may not be compatible.
- Inspect all packaging before use. If product packaging is compromised or the product is dropped while/after removing packaging, use the following protocol:
    - **Holster:** Follow **Cleaning the Holster** and **Disinfecting the Holster** procedures.
    - **Probe:** Throw away the probe, as it is no longer a sterile instrument.
    - **Introducer:** Throw away the introducer, as it is no longer a sterile instrument.
- Take care to avoid pressing the sample button on the holster unintentionally during repositioning and removal of the probe needle in/from the patient and take care to avoid unintentionally firing in the patient. Failure to follow this instruction could lead to patient or user injury.

Holster and Charging Base

- Keep the holster cavity and charging base clear of all foreign objects and dust.
- This medical device emits electromagnetic energy that may interfere with other nearby medical devices, which may cause those devices to malfunction and/or seriously harm the patient.

- Clean and disinfect the Mammotome AutoCore™ Single Insertion Core Biopsy System before the first use and after each use following the instructions provided in **Chapter 3: Cleaning and Disinfection**. Do not attempt to clean, disinfect, or sterilize any parts of this system using alternate methods, such as autoclave, ultrasound bath, automated washer-disinfection, radiation, or any other method not described within this document. Do not immerse this system in liquid.
- After cleaning, be sure the holster is fully dry before placing it back onto the charging base to avoid electrical shock.
- Portable RF communications equipment, including antennas, can affect medical electrical equipment. Such devices should be used no closer than 30cm (12in) to any part of this device.
- 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 radiofrequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
- The battery may only be replaced or disposed of by an authorized Service and Repair facility.

Probe and Optional Introducer

- Inspect the disposable packaging label for the expiration date prior to use. Do not use the disposable device if the expiration date has passed.
- This device is packaged and sterilized for single use only.
- Do not reuse, reprocess, or resterilize the probe or introducer. Reusing, reprocessing, or resterilization may compromise the structural integrity of the device and/or lead to device failure, which may result in patient injury, illness, or death. In addition, reprocessing or resterilization of single use devices may create a risk of contamination and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient.
- Avoid scraping the needle tip against the tip protector during removal. Keep the tip protector on the probe needle (and optional introducer) until you are ready to perform the tissue sampling procedure.
- Take care to avoid injury while removing the tip protector. Once the tip protector has been removed, it should be properly disposed of. Do not try to put the protector back onto the probe needle or introducer.
- Keep hands clear of the sample aperture and probe needle tip at all times.
- If the needle is bent, do not use it. Dispose of the probe in the appropriate container.
- Avoid pressing the holster button during probe removal. Failure to follow this instruction could lead to patient or user injury.
- Cobalt can be found in some steel metals used in this device.
- Persons allergic to cobalt and/or nickel may suffer an allergic reaction.

- This medical device contains a magnet that may interfere with other nearby medical devices, which may cause those devices to malfunction and/or seriously harm the patient.

Precautions

- To ensure that the probe and holster are correctly and securely attached, make sure an audible “click” is heard and tactile feedback is felt during attachment. If the probe is incorrectly attached or misaligned, it can detach from the holster during the procedure.
- Take care to avoid excessive side-loading force during use. This can cause the stylet to fail to fully retract, which interrupts the delivery of the sample.

Adverse Reactions

Potential complications are limited to the region surrounding the biopsy site and include hematoma, hemorrhage, infection, and pain. Follow best medical practices.

Chapter 2 : Instructions for Use

First Time Use

Be sure the holster is adequately charged (the holster battery charge indicator LED will be illuminated green if it is adequately charged) for the procedure(s) to be performed. If the holster battery charge indicator LED is illuminated yellow or red, allow the holster to charge before beginning a procedure.

1. Remove the holster and the charging base from the packaging.
2. Use only with supplied AC power adapters, cords, and other accessories provided in the package at the time of purchase. Use of third-party AC power adapters, cords, and other accessories may have a negative impact on system performance, including EMC. The AC adapter's connection to the wall outlet serves as the means for isolation. Do not place the charging base and AC adapter in a location where it is difficult to remove them if they need to be disconnected from the wall outlet.

NOTE: Inspect the devices for non-cosmetic damage (i.e., bent needle/introducer tip) prior to use. If damage is found, return the device to the manufacturer, or dispose of the device properly. Do not use if the device is showing damage or wear.

NOTE: Ensure the device is in good working order prior to use to ensure the device is not compromised by electromagnetic disturbances.

3. Clean and disinfect the holster prior to initial use. Follow the instructions detailed in **Chapter 3: Cleaning and Disinfection**.
4. Completely charge the holster prior to initial use by placing the holster in the charging base for 12 hours.

NOTE: After charging for 12 hours, the holster battery power indicator LED will flash green while the holster is seated in the charging base and will illuminate solid green when removed from the charging base.

NOTE: See **Charging the Holster** below for detailed charging instructions.

Charging the Holster

1. Connect the adapter cord into the charging base.

NOTE: Use only with supplied AC power adapters, cords, and other accessories provided in the package at the time of purchase.

NOTE: Do not stack the charging base on top of any other devices.

NOTE: Ensure charging base is plugged into an outlet that is easily accessible in case there is a need for rapid disconnection of power.

2. Plug the charging base AC adapter into a power source. Confirm that the charging base power indicator LED is illuminated green (**Figure 2**).

3. Place the holster into the charging base (**Figure 2**).

NOTE: If a foreign object is detected by the charging base or the charging base overheats during wireless charging of the holster, the charging base fault indicator LED flashes red (**Figure 3**).

Figure 2

Figure 3

NOTE: As shown in **Figure 4**, the holster battery charge indicator LED flashes slowly while seated in the charging base and charging. The color of the holster battery charge indicator LED indicates its remaining battery charge.

Green (I): The holster has sufficient battery charge to complete at least 2 procedures and/or is fully charged.

Yellow (II): The holster has sufficient battery charge to complete at least 1 procedure, but fewer than 2 procedures.

Figure 4

Red (III): The holster does not have sufficient battery charge to complete 1 full procedure. Allow the holster to charge before beginning a procedure.

4. After every use, return the holster to the charging base once the disposable probe (and optional introducer) has been unarmed, removed, and properly disposed of, and the holster has been cleaned and disinfected per the instructions provided in **Chapter 3: Cleaning and Disinfection**.

Loading the Probe

1. Ensure the holster is adequately charged as described in **Charging the Holster** and remove the holster from the charging base.
2. Open the disposable probe (and optional introducer) using standard sterile techniques.

NOTE: Do not use if the package is damaged.

WARNING: If any part of the probe (or introducer) touches a non-sterile surface, the probe (or introducer) cannot be used and must be disposed of properly.

WARNING: The tip protector should remain on the outer (or introducer) cannula until the probe (or introducer) is ready for the insertion procedure.

NOTE: Take care to avoid dropping the probe while inside its packaging, as damage to the probe could result.

NOTE: Do not open the probe packaging and release the probe onto a sterile tray or other surface. Damage to the probe could result.

3. Grasp the probe body and align the alignment tab with the alignment notch on the holster.
4. Push the holster into the probe until the alignment tabs engage with the holster assembly (**Figure 5**). There will be tactile feedback and an audible “click” when the holster and probe are attached correctly.

Figure 5

5. If properly assembled, all 3 holster status indicator LEDs will flash white while initialization is in progress. When initialization is complete, all 3 LEDs will illuminate white (**Figure 6**).

Figure 6

Sampling Tissue

Ensure proper preparation of the biopsy site using appropriate surgical techniques. Take appropriate protections before making the incision, including use of personal protective equipment (PPE).

See **Procedure for Optional Introducer** if the Mammotome AutoCore™ introducer is to be used for this sampling.

Begin the Sampling Procedure

Step	Action
1	Puncture the skin with an appropriate tool to make a small incision.
2	Remove the tip protector from the outer cannula.
3	Arm the device outside the breast by pressing the sample button once. The first holster status indicator LED will flash white during arming and illuminate white when arming is complete (**Figure 7**).

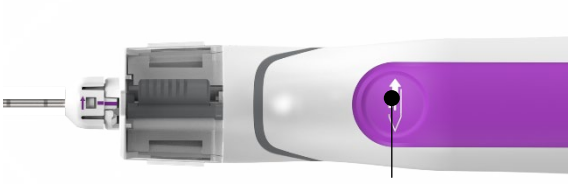

Figure 7

Choose Standard or Alternate Operation

Sample tissue by firing the device inside the breast following **Standard Operation**, or outside the breast following **Alternate Operation**.

NOTE: Do not "test" the device by firing it prior to the procedure. Tip damage and user and/or patient injury could result.

Step	Standard Operation (Inside the Breast)	Alternate Operation (Outside the Breast)
4	Insert the needle of the probe into the patient's breast through the incision made in **Step 1** above. Use image guidance to insert and/or rotate the probe needle to target the desired region of the lesion.	Fire the inner stylet outside of the breast by pressing the sample button a second time. The first status indicator LED will remain illuminated white. The second status indicator LED will flash white during firing and illuminate white when firing is complete (**Figure 8**).
5	Position the tip of the probe needle at the outer edge of the lesion.	Insert the needle of the probe into the patient's breast through the incision made in **Step 1** above. Use image guidance to position the tip of the probe needle at the outer edge of the lesion.
6	Fire the inner stylet by pressing the sample button for a second time. The first status indicator LED will remain illuminated white. The second status indicator LED will flash white during firing and illuminate white when firing is complete (**Figure 8.**)	Proceed to **Step 7**.

Figure 8

Step	Standard and Alternate Operation
7	Fire the outer cannula by pressing the sample button a third time. **NOTE:** This retrieves the tissue sample. The first and second status indicator LEDs will remain illuminated white. The third status indicator LED will flash white during firing and sample collection and illuminate white when firing and sample collection are complete (**Figure 9**).

Figure 9

NOTE: To increase target accuracy and view sample(s) inside the specimen collection cup, the probe and holster assembly may be rotated ± 90° from the neutral orientation during the procedure.

Collecting Additional Samples

1. Re-arm the device by pressing the sample button once. Use image guidance to rotate the probe and/or reposition the tip of the probe needle as needed. Repeat these steps (beginning at **Step 6** of **Standard Operation** or **Alternate Operation**) until sufficient sample is collected.
2. View the specimen collection cup as necessary during and/or after the procedure to ensure that adequate sample(s) have been acquired and are present in the cup.

NOTE: The specimen collection cup can store up to 6 samples. Empty the cup when full (see instructions, below).

3. Remove the probe from the biopsy site.

Procedure for the Optional Introducer

NOTE: Do not use if the package is damaged.

1. Insert the introducer stylet and cannula into the desired location in the breast following the incision made in **Step 1** above (under **Begin the Sampling Procedure**).
2. Remove the introducer stylet from the introducer cannula, detaching the stylet from the cannula as follows:
    a. Twist the stylet via the hub to separate the stylet hub from the cannula hub until released (**Figure 10**).

Figure 10

    b. Slide the introducer stylet through the introducer cannula until released (**Figure 11**).

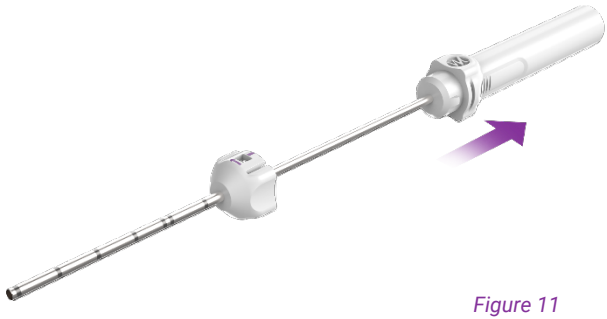

Figure 11

NOTE: Grip the introducer cannula hub and introducer stylet hub at all times.

3. Insert the probe needle into the introducer cannula (**Figure 12**) until you feel a hard stop at the cannula hub.

Figure 12

4. Grip the cannula hub and gently push the probe forward until the probe tab is secured in the window of the introducer cannula hub (**Figure 13**).

Figure 13

NOTE: Ensure that the introducer cannula is properly locked to the probe after probe insertion through the introducer cannula. Failure to properly lock may result in inadequate tissue or poor tissue quality.

5. Sample as needed as defined following the **Procedure for Sampling Tissue**.

Detaching the Probe from the Introducer

1. Gripping the cannula hub, rotate the probe counterclockwise until the tab on the probe needle guide is clear of the window on the introducer cannula hub (**Figure 14-1**).
2. Slowly slide the probe needle out from the introducer cannula until released (**Figure 14-2**).

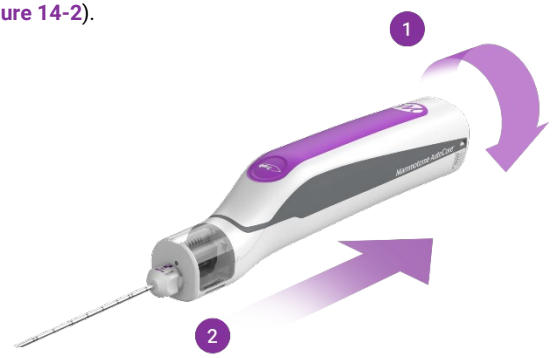

Figure 14

3. Mark the site through the introducer cannula as needed with a biopsy site marker as per the manufacturer's instructions.
4. Remove the introducer cannula and marking device from the tissue after confirmation of marker deployment.

Removing the Specimen Collection Cup

WARNING: Avoid pressing the holster button during specimen collection cup removal. Failure to follow this instruction could lead to patient or user injury.

NOTE: The specimen collection cup can store up to 6 tissue samples. Empty the cup when full.

1. Rotate the device 180° about its neutral axis so that the specimen collection cup and holster are underneath the probe.
2. Using a thumb and finger, gently apply force to the right locking/release tab until the tab is unlocked/released (**Figure 15-1**).
3. Rotate the cup about the left locking/release tab (used as a hinge) (**Figure 15-2**).
4. Move the cup downward and away from the probe.

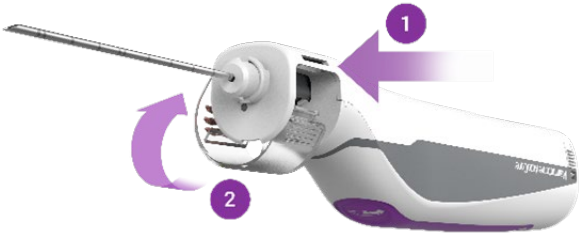

Figure 15

a. **Option 1:** Place the entire specimen collection cup with contained tissue samples directly into a Formalin cup (**Figure 16**).

b. **Option 2:** Use sterile forceps to remove the tissue samples from the specimen collection cup and place individually into a Formalin cup (**Figure 17**).

Figure 16

Option 1: Place the specimen collection cup containing the tissue samples into a Formalin cup.

Figure 17

Option 2: Use sterile forceps to remove the tissue samples from the specimen collection cup and place individually into a Formalin cup.

NOTE: The Formalin cup must contain at least 60 mL in volume (or greater) prior to placement of the specimen collection cup or tissue samples (**Figure 18**).

Figure 18

5. If additional samples are needed, reattach the specimen collection cup to the probe as follows (**Figure 19**):

    a. Align the orientation feature on the cup with the corresponding feature on the probe.

    b. Using a thumb and finger, gently pinch the locking tabs on the specimen collection cup toward one another and firmly press the cup into place on the probe.

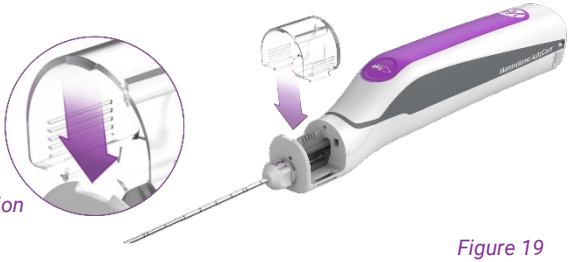

Figure 19

Removing the Probe from the Holster

NOTE: The probe is intended for **single use only**. Dispose of the probe immediately after use or if the probe touches a non-sterile surface.

WARNING: Avoid pressing the holster button during probe removal. Failure to follow this instruction could lead to patient or user injury.

1. Using a thumb and finger, pinch the probe's locking tabs toward one another to release the holster (**Figure 20**).
2. Lift the probe upwards, away from the holster to separate it from the holster (**Figure 20**).

Figure 20

Cleaning and Disposal

1. Dispose of the used probe (and optional introducer, if used) per the facility protocol.
2. Clean the holster and charging base following the instructions provided in **Chapter 3: Cleaning and Disinfection**.
3. Disinfect the holster following the instructions provided in **Chapter 3: Cleaning and Disinfection**.
4. Allow the holster and charging base to fully dry.
5. Place the holster on the charging base and ensure that it is charging per the instructions provided in **Charging the Holster**.

Chapter 3 : Cleaning and Disinfection

Cleaning and disinfection of the Mammotome AutoCore™ Single Insertion Core Biopsy System must follow these instructions. Do not attempt to clean or disinfect the system using other methods.

Introduction

This chapter includes detailed cleaning and disinfection instructions for the Mammotome AutoCore™ Single Insertion Core Biopsy System.

Users in North America should also refer to appropriate sections of *AORN Standards & Recommended Practices* for additional guidance on cleaning and disinfection. All other localities should refer to appropriate guidelines.

The cleaning agents and disinfectants specified for use in these instructions have been validated for use with the Mammotome AutoCore™ Single Insertion Core Biopsy System.

There are no limitations for time of storage of any cleaned/disinfected device prior to use and no additional support systems are required.

The Mammotome AutoCore™ holster has an expected useful life of 1,000 reprocessing cycles. The charging base has an expected useful life of 500 reprocessing cycles.

The following wipes (**Table 2**) are suitable for cleaning and disinfecting the Mammotome AutoCore™ holster and charging base.

Table 2. Cleaning and disinfection wipes

Product	Active Ingredients	Concentration	Wet Contact Time
Super Sani-Cloth® Germicidal Disposable Wipe by Nice-Pak / PDI, Inc.	Isopropyl Alcohol	55.0%	Cleaning: 2.5 minutes Disinfection: 2 minutes
	Alkyl (60% C14, 32% C16, 5% C12, 5% C18) dimethyl benzyl ammonium chlorides	0.25%	
	Alkyl (68% C12, 32% C14) dimethyl ethyl benzyl ammonium chloride (0.25%)	0.25%	
Incidin™ OxyWipe S by Ecolab®	Hydrogen Peroxide	1 - 2.5%	Cleaning: 2.5 minutes Disinfection: 5 minutes
	Glycolic Acid	1 – 2.5%	
	Salicylic Acid	0.1 - 0.25%	

Cleaning the Holster and Charging Base

Using a wipe specified in **Table 2** above, wipe the holster and charging base to remove visible contamination. Additional wipes may be necessary to remove all visible contamination. Begin the holster cleaning process less than 45 minutes after each use. Clean the charging base only as needed.

Additional Cleaning Tool(s): Soft-bristled nylon brush (brush head approximate dimensions: width of 9mm and length of 40mm, with individual bristles 9mm long).

1. Use a specified wipe to wipe all external surfaces of the holster, including crevices.
2. Thoroughly scrub crevice areas with the clean, dry, soft-bristled nylon brush for a minimum of 1 minute and 10 seconds.

3. Use a specified wipe to thoroughly wipe the device, including crevices, ensuring that a wet surface is maintained for 2.5 minutes.

NOTE: Do not wipe the gears and electronics on the underside of the holster with the cleaning wipe.

NOTE: Additional wipes may be used to maintain the 2.5 minutes of wet contact time.

NOTE: If using Super Sani-Cloth® Germicidal Disposable Wipe by Nice-Pak/PDI. Inc., after applying the wipe, soak a lint-free cloth in sterile water and wipe all external surfaces including holster crevices.

4. Allow the holster to air dry.

5. Perform a visual check to ensure all visible contamination has been removed from the surface. If contamination is present, repeat Steps 1–4 until no visible contamination is present.

CAUTION: Do not attempt to sterilize the holster or charging base through autoclave, ethylene oxide, radiation, or plasma sterilization procedures. Do not process through an automated washer-disinfect or ultrasound bath. Do not spray the holster with fluids or submerge in fluids. Do not use liquids on the charging base; this may damage the instrument. Do not allow the detergent to come in contact with the electronic components on the underside of the holster, as this may damage the holster. If the holster is cleaned improperly, the warranty may be void. Do not transport the device in a container prior to cleaning.

Disinfecting the Holster

Disinfection of the holster must be done at point of use, immediately following the cleaning procedure. The chemical disinfectant wipes in **Table 2** are approved for use with the holster.

1. Use a specified wipe to thoroughly wipe down all surfaces of the holster that are exposed when the probe is attached to the holster, ensuring that a wet surface is maintained for the specified disinfection time of the corresponding wipe in **Table 2**. The gears and electronics on the underside of the holster should not be wiped with the disinfecting wipe.

NOTE: Pay special attention to the crevices of the device.

NOTE: Additional wipes may be used to maintain the specified disinfection wet contact time of the corresponding wipe in **Table 2**.

2. Allow the holster to air dry.

NOTE: Disinfected products should be stored in a dry, clean environment, which is protected from contamination, direct sunlight, pests, extreme temperatures, and humidity.

Chapter 4 : Electromagnetic Compatibility (EMC) and Electrical Safety

The Mammotome AutoCore™ Single Insertion Core Biopsy System requires special precautions regarding electromagnetic compatibility (EMC) and must be The Mammotome AutoCore™ Single Insertion Core Biopsy System does not have any essential performance.

Simplified EU Declaration of Conformity

Hereby: Devicor Medical Products, Inc. declares that the radio equipment type [code] is in compliance with Directive 2014/53/EU. The full text of the EU Declaration of Conformity is available at the following internet address: Mammotome.com/RED-Doc.

Guidance and Manufacturer's Declaration: Electromagnetic Emissions & Immunity

Table 3. Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The Mammotome AutoCore™ Single Insertion Core Biopsy System is intended for use in the electromagnetic environments specified below. The customer or user of the Mammotome AutoCore™ Single Insertion Core Biopsy System should assure that it is used in such an environment.		
Emission Test	Compliance	Guidance
RF Emissions CISPR 11	Class A	The Mammotome AutoCore™ Single Insertion Core Biopsy System 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.
Harmonic Emissions IEC 61000-3-2	Class A	The Mammotome AutoCore™ Single Insertion Core Biopsy System is suitable for use in non-domestic establishments.
Voltage fluctuations/flicker emissions IEC 61000-3-3	Class A	The Mammotome AutoCore™ Single Insertion Core Biopsy System is suitable for use in all non-domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
FCC Compliance Statement: "This device complies with Part 15 of the FCC rules. Operation is subject to the following two conditions: 1. This device may not cause harmful interference, and 2. This device must accept any interference received, including inference that may cause undesired operation: "This portable transmitter with its antenna complies with FCC/IC RF exposure limits for general population / uncontrolled exposure."		

Table 4. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Mammotome AutoCore™ Single Insertion Core Biopsy System is intended for use in the electromagnetic environments specified below. The customer or user of the Mammotome AutoCore™ Single Insertion Core Biopsy System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic Discharge IEC 61000-4-2	± 8KV Contact ± 2KV, ± 4KV, ± 8KV, ±15KV Air	PASS	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2KV for power supply lines, 100KHz	PASS	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 KV line(s) to lines ± 1 KV line(s) to lines ± 2 KV lines(s) to earth	PASS	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% for 0.5 cycle (0,45,90,135,180, 225, 270, 315 degrees) 0% for 1 cycle 70% for 25 cycles (50 Hz) 70% for 30 cycles (60 Hz) 0% for 250 cycles (50 Hz) 0% for 300 cycles (60Hz)	PASS	Mains power quality should be that of a typical commercial or hospital environment. If the user requires continuous operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m (50 and 60 Hz)	PASS	Power frequency magnetic fields should be at levels characteristic of a typical location in a commercial or hospital environment.

Table 4 Continued. Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The Mammotome AutoCore™ Single Insertion Core Biopsy System is intended for use in the electromagnetic environments specified below. The customer or user of the Mammotome AutoCore™ Single Insertion Core Biopsy System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	6Vrms ISM Band 150 KHz to 80 MHz 3 Vrms 150 KHz to 80 MHz	PASS	Portable and mobile RF communications equipment should be used no closer to any part of the Mammotome AutoCore™ Single Insertion Core Biopsy System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.* Recommended separation distance d = [1.17]√P 150 KHZ to 80MHz d = [1.17]√P 80 MHz to 800 MHz d = [2.33]√P 800 MHz to 2.7 GHz where P is maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic survey, a should be less than the compliance level in each frequency range [b]. Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	PASS	
Proximity Fields from RF Wireless equipment IEC 61000-4-3	Per table 8 of IEC 60601-1-2:2014	PASS	

NOTE: At 80 MHz and 800 MHz, the higher frequency range applies.

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

* 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 the Mammotome AutoCore™ Single Insertion Core Biopsy System is used exceeds the applicable RF compliance level above, the Mammotome AutoCore™ Single Insertion Core Biopsy System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Mammotome AutoCore™ Single Insertion Core Biopsy System.

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

Table 5. Recommended Separation Distances

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Mammotome AutoCore™ Single Insertion Core Biopsy System			
The Mammotome AutoCore™ Single Insertion Core Biopsy System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 KHz to 80 MHz d = (3.5/v1)√P	**80 MHz to 800 MHz d = (3.5/E1)√P**	**800 MHz to 2.7 GHz d = (7/E1)√P**
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

RFID Specifications

RFID Specifications	
Operating Frequency	13.56MHz
Transmission Power	-45dBm
Operating Distance	up to 50mm

Wireless Charging Specifications

Wireless Charging Specifications	
Operating Frequency	105kHz - 205kHz
Transmission Power	-15dBm
Operating Distance	up to 4cm

Test Frequency (MHz)	Band (MHz)
Electrical Conformity	This medical equipment has passed all required testing for electric shock, fire, and mechanical hazards in accordance with UL 60601-1, IEC/EN 60601-1, CAN/CSA C22.2 No 60601-1.
Flammability	Equipment is not suitable for use in the presence of flammable anesthetic.
Dimensions	Length: 20.4 cm Width: 3.8 cm Height: 3.0 cm
Battery Location	The battery is located in the distal end of the holster.
Battery Type	Lithium Ion
AC Power Cord and Adapters	The AC power adapter is considered part of the ME Equipment. Use only with supplied AC power accessories: • Model: ME20A0503B01 • Make: SL Power Electronics • Input Voltage: 100-240Vac • Input Current: 0.5A-0.2A • Input Frequency: 50-60Hz • Output Voltage: +5Vdc • Output Current: 3A • Max Watts: 15W
Classification	Class II, internally powered Type BF equipment
Applied Part	Probes (MAP1210 and MAP1410)
Environmental Conditions	Transportation and Storage: • -18°C to +54°C (-0.4°F to 129.2°F) • 10% to 95% Relative Humidity, Non-Condensing • 500 to 1060 hPa Atmosphere Pressure Operation: • 15°C to +32°C (59°F to 89.6°F) • 30% to 75% Relative Humidity, Non-Condensing • 810 to 1042 hPa Atmosphere Pressure
Mode of Operation	Continuous operation
Ingress of Water	Holster: IPX2 Charging Base: IPX0

Holster Status Indicator LEDs

Red: If 1 or more holster status indicator LEDs are illuminated red (**Figure 21**), a hardware fault has occurred. Contact your sales representative for a replacement holster. If you cannot contact a representative directly, please contact customer service for instructions. See **Chapter 6: Additional Information** for customer service contact information. **Do not attempt to use for additional procedure(s).**

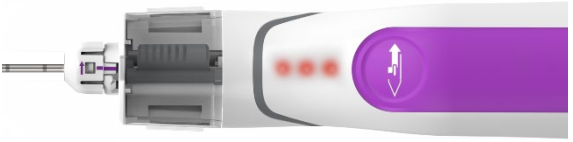

Figure 21

Yellow: If 1 or more holster status indicator LED(s) are illuminated yellow, a fault has occurred in the holster as follows:

- If 1 status indicator LED is illuminated, the fault occurred during arming or initialization (**Figure 22**). Refer to **Holster Faults Troubleshooting** section.

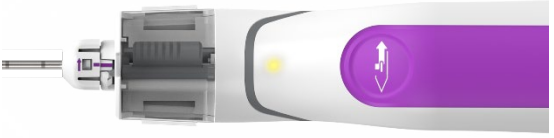

Figure 22

- If 2 status indicator LEDs are illuminated, the fault occurred during firing of the inner stylet (**Figure 23**). Refer to **Holster Faults Troubleshooting** section.

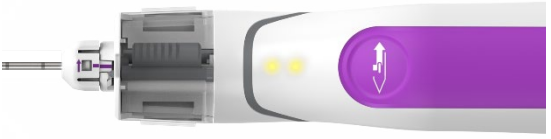

Figure 23

- If all 3 status indicator LEDs are illuminated, the fault occurred during firing of the outer cannula or sample collection (**Figure 24**). Refer to **Holster Faults Troubleshooting** section.

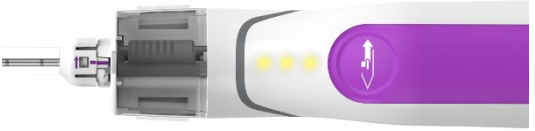

Figure 24

Holster Faults Troubleshooting:

There is an issue with the attached probe (e.g., it could be jammed or broken, etc.). Disassemble the probe from the holster and reassemble. If the fault is still present, assemble a new probe to the holster.

Purple: If all 3 status indicator LEDs are illuminated purple, the holster has overheated (**Figure 25**). Allow the holster to cool before additional use.

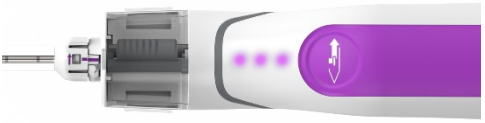

Figure 25

Orange: If all 3 status indicator LEDs on the holster flash orange for 5 seconds when the holster is seated in the charging base, the holster is approaching its maximum use life (**Figure 26**). Contact your sales representative for a replacement holster. If you cannot contact a representative directly, please contact customer service for instructions. See **Chapter 6: Additional Information** for customer service contact information.

Figure 26

Holster Power Indicator LEDs

If the power indicator LED on the holster illuminates yellow, the holster has sufficient battery charge to complete at least 1, but fewer than 2, procedures. See **Chapter 2: Charging the Holster** for additional details related to charging.

Holster Reset

To reset the holster, press and hold the sample button for 5 seconds and then release to place it into sleep mode. To wake the holster from sleep mode, press the sample button once or place the holster in the charging base to charge.

Chapter 6 : Additional Information

How Supplied

- The Mammotome AutoCore™ Holster and Charging Base are supplied in a non-sterile state.
- The Mammotome AutoCore™ Probes are sterilized using irradiation. The probes are supplied in a sterile state for single patient use and sold separately. Discard after use.
- The Mammotome AutoCore™ Introducers are sterilized using irradiation. The introducers are supplied in a sterile state for single patient use and sold separately. Discard after use.

Disposal of Holster

WEEE (The Waste Electrical and Electronic Equipment Directive)

This symbol on the product(s) and/or accompanying documents means that used electrical and electronic products should not be mixed with general household waste. For proper treatment, recovery, and recycling, please take this product(s) to designated collection points where it will be accepted free of charge. Alternatively, in some countries you may be able to return your products to your local retailer upon purchase of an equivalent new product. Disposing of this product correctly will help save valuable resources and prevent any potential negative effects on human health and the environment, which could otherwise arise from inappropriate waste handling.

Please contact your local authority for further details on your nearest designated collection point.

Penalties may be applicable for incorrect disposal of this waste, in accordance with your national legislation.

For business users in the European Union:

If you wish to discard electrical and electronic equipment, please contact your dealer or supplier for further information.

Information on disposal in other countries outside the European Union:

This symbol is only valid in the European Union. If you wish to discard this product, please contact your local authorities or dealer, and ask for the correct method of disposal.

CAUTION: Do not dispose of the holster, the electronics, or the lithium-polymer battery: they should be returned to MAMMOTOME.

Contact MAMMOTOME for instructions regarding return of the holster.

CAUTION: The lithium-polymer battery might present a fire or chemical burn hazard if mistreated. Do not disassemble, crush, or puncture the lithium-polymer battery. Do not heat the lithium-polymer battery above 140°F (60°C).

Calling for Service

Call 1-877-926-2666 (U.S. calls) or +1-513-864-9000 (international calls – English speaking only) or contact your local representative.

Customer support is also available by emailing **us.customerservice@mammotome.com**. Please include:

1. Your account name and number
2. Your contact information
3. Your question

Once received, a member of the Customer Support Team will reply within one business day.

Requesting an Additional Paper Copy of the Information for Use (IFU)

Call 1-877-926-2666 (U.S. calls) or +1-513-864-9000 (international calls – English speaking only) or contact your local representative. After a request for a paper copy of the IFU is submitted, the paper copy will be sent to the requester within 24 hours.

FCC Information

This product has been tested to comply with FCC standards and it has been approved and meets the regulated limits for ionizing radiation. The FCC ID of the holster is 2ATMT-MAHC01, and the FCC ID of the charging base is 2ATMT-MAHCB01.

NOTE: The equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Cybersecurity Statement

Mammotome is committed to the safety and security of our instruments. In response to potential threats to cybersecurity, Mammotome has formed a global product security team to assess vulnerabilities and determine responses within a coordinated vulnerability disclosure (CVD) process.

To report a potential security vulnerability and view the latest product security updates, please visit **https://www.mammotome.com**.

Additional Product Information

Visit our website at **https://www.mammotome.com** for a complete listing and description of available products.

Warranty Claims and Remedies

Devicor Medical Products, Inc. warrants this product to be free from defects in material and workmanship under normal use and preventative maintenance for the warranty period provided in packaging inserts, applicable brochure, documentation, or customer agreement. Devicor Medical Products, Inc.'s obligation under this warranty is limited to the repair or replacement. This warranty does not apply to any product, or part thereof, that has been: 1) adversely affected due to use with devices manufactured or distributed by parties not authorized by Devicor Medical Products, Inc. 2) repaired or altered outside Devicor Medical Products, Inc.'s factory in a way so as to, in Devicor Medical Products, Inc.'s judgment, affect its stability or reliability, 3) subjected to improper use, negligence or accident, or 4) used other than in accordance with the design and use parameters, instructions and guidelines for the product or with functional, operational or environmental standards for similar products generally accepted in the industry. Preventative

maintenance should be performed by qualified service personnel and is not covered by this warranty.

UNLESS SUPERCEDED BY APPLICABLE LOCAL LAW, THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING THE WARRANTIES ***OF*** MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, AND OF ALL OTHER OBLIGATIONS OR LIABILITIES ON THE PART OF DEVICOR MEDICAL PRODUCTS, INC. AND IS A PURCHASER'S EXCLUSIVE REMEDY. IN NO EVENT SHALL DEVICOR MEDICAL PRODUCTS, INC. BE LIABLE FOR SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES INCLUDING, WITHOUT LIMITATION, DAMAGES RESULTING FROM LOSS OF USE, PROFITS, BUSINESS, OR GOODWILL OTHER THAN AS EXPRESSLY PROVIDED BY A SPECIFIC LAW.

Symbols Glossary

Symbol	Symbol Title	Explanation Text for the Symbol	Standard & Reference	Standard Title
Manufacture				
	Manufacturer	Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.	ISO 15223-1:2021, 5.1.1	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
	Authorized representative in the European Community	Indicates the Authorized representative in the European Community. "EC Rep"	ISO 15223-1:2021, 5.1.2	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
	Date of manufacture	Indicates the date when the medical device was manufactured.	ISO 15223-1:2021, 5.1.3	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
	Use-by date	Indicates the date after which the medical device is not to be used.	ISO 15223-1:2021, 5.1.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1:2021, 5.1.5	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1:2021, 5.1.6	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1:2021, 5.1.7	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
	Country of manufacture	Indicates the two-letter country code. This example indicates Mexico.	ISO 15223-1:2021, 5.1.11	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
Sterility				
	Sterilized using irradiation	Indicates a medical device that has been sterilized using irradiation.	ISO 15223-1:2021, 5.2.4	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
	Do not resterilize	Indicates a medical device that is not to be re-sterilized.	ISO 15223-1:2021, 5.2.6	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or open.	ISO 15223-1:2021, 5.2.8	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
	Single sterile barrier system	Indicates a single sterile barrier system (oval); a solid line identifies a sterile barrier system and is used in combination with the **Sterilized using irradiation** symbol.	ISO 15223-1:2021, 5.2.11	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied

Symbol	Symbol Title	Explanation Text for the Symbol	Standard & Reference	Standard Title
Storage				
	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.	ISO 15223-1:2021, 5.3.7	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed.	ISO 15223-1:2021, 5.3.8	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the medical device can be safely exposed.	ISO 15223-1:2021, 5.3.9	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied
Safe Use				
 1	Carcinogenic, mutagenic, reprotoxic (CMR) substance	Indicates a medical device that contains substances that can be carcinogenic, mutagenic, reprotoxic (CMR), or substances with endocrine disrupting properties. The "1" beneath the symbol indicates the presence of cobalt.	ISO 15223: 2021- 5.4.10	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied
	Do not re-use	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1:2021, 5.4.2; also, ISO 60601-1:2012, Table D.1, #28	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied AND Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1:2021, 5.4.3; also, ISO 60601-1:2012, Table D.1, #11	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied AND Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
	Use of the "Consult instructions for use" symbol for an electronic instruction for use (eIFU). Symbol is accompanied by an eIFU indicator below the symbol.	Indicates the location for finding the instruction for use in electronic format (when the hard copy labeling does not accompany product shipment)	ISO 15223-1:2021, 5.4.3, Section A.15	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
	Follow instructions for use	Indicates to refer to instruction manual / booklet	IEC 60601-1:2012, Table D.2, #10	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
	Use of the "Follow instructions for use" symbol for an electronic instruction for use (eIFU). Symbol is accompanied by an eIFU indicator below the symbol.	Indicates the location for finding the instruction for use in electronic format (when the hard copy labeling does not accompany product shipment)		

Symbol	Symbol Title	Explanation Text for the Symbol	Standard & Reference	Standard Title
	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1:2021, 5.4.4; also, ISO 60601-1:2012, Table D.1, #10	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied AND Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
	Rx only or prescription only	Requires prescription in the United States.	FINAL RULE: Docket No. FDA-2013-N-0125, found in 81 FR 38911 - 38931:2021; 21CFR 801.15(c)(1)(i)F; 21CFR 801.109.	Use of Symbols in Labeling AND Medical devices; prominence of required label statements; use of symbols in labeling AND Prescription devices.
	Non-ionizing electromagnetic radiation	Interference may occur in the vicinity of equipment marked with this symbol.	IEC 60601-1-2:2012, 5.1.1	Medical electrical equipment - Part 1: General requirements
Miscellaneous				
	Magnetic Resonance (MR) Unsafe	Indicates an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	ASTM F2503-13, Table 2 and Figure 9	Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment
IPX2	Degrees of Ingress Protection Provided by Enclosure	Protection against vertically falling water drops when ENCLOSURE tilted up to 15°	IEC 60601-1:2012, Table D.3, Symbol 2	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance AND Degrees of protection provided by enclosures (IP Code)
IPX0		Not protected against the effects of continuous immersion in water.		
	Type BF Applied Part	Indicates F-type applied part complying with the specified requirements of this standard to provide a higher degree of protection against electric shock than that provided by Type B applied parts	IEC 60601-1:2012, Table D.1, #20	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
	Waste Electrical and Electronic Equipment (WEEE)	Indicates a separate waste collection is required for Waste of Electrical and Electronic Equipment (WEEE)	WEEE Directive 2002/96/EC Article 10 and Annex IV	Directive 2002/96/EC on Waste Electrical and Electronic Equipment

Symbol	Symbol Title	Explanation Text for the Symbol	Standard & Reference	Standard Title
	Medical device	Indicates the item is a *medical device.*	ISO 15223-1:2021, 5.7.7 For use in Europe the full definition of "medical device" is given in EU Regulation 2017/745.[23] Other jurisdictions can have unique definitions.	Medical devices - Symbols to be used with medical device labels, labeling and information to be supplied
	Metlabs MET Mark	Indicates the product shows it has been independently tested and certified to meet recognized standards for safety or performance.	IEC 60601-1, IEC 60601-1-6	n/a
	Electronic and Electrical Product Restricted Substance Use-Restriction Logo (Logo 2) (RoHS)	Indicates this electronic and electrical product contains certain hazardous substances above the limit requirement of GB/T 26572 and can be used safely during its environmental protection use period and should enter into the recycling system after its environmental protection use period.	SJ/T 11364—2014 Logo (figure) 2	Marking for the Restricted Use of Hazardous Substances in Electronic and Electrical Products
	Quantity per box	n/a	n/a	n/a
	Contains Nickel	n/a	n/a	n/a
	Allow cooling	n/a	n/a	n/a
	Approaching the end of service	n/a	n/a	n/a
	Consult the IFU	n/a	n/a	n/a
	Replace probe	n/a	n/a	n/a

REF MAHC, MAP1210, MAP1410, MAI1210, MAI1410

CC001787001

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Super Sani-Cloth Disposable Wipe is a registered trademark of Nice-Pak/PDI, Inc. Incidin OxyWipe S is a trademark of Ecolab®.

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AW001609 | CC001787001 | REV B JUNE 2024

TITLE				
Mammotome AutoCore™ Single Insertion Core Biopsy System User Instructions and Operations Guide				
ARTWORK NUMBER	**SCALE**	**REVISION**	**ECN NUMBER**	**DATE**
AW-001609	1:1	B	ECN-003147	06/25/2024
PRODUCT CODE(S)			**DRAWN BY**	
MAHC, MAP1210, MAP1410, MAI1210, MAI1410			A. Liddle	

NOTES:

1. Translations: English, French, German, Italian, Spanish, Portuguese, Polish, Dutch, Czech, Danish, Finnish, Swedish, Norwegian, Slovak, Croatian, Slovenian, Greek, Estonian, Latvian, Lithuanian
2. All translations of this IFU are generated as their own files.