Artwork and Signature File for:

MAN-07992 “LOCALIZER SURGICAL PROBE IFU (ML-0008)”

Artwork consists of:

- ONE, 5.5” W X 8.5” H (8.5" X 11" LANDSCAPE FOLDED)

REV AUTHORED BY STEVE HOLMES DATE 5/25/2023	HOLOGIC®	SIGNATURES ON FILE	
REV DRAFTED BY STEVE HOLMES DATE 5/25/2023			
PROPRIETARY: This document contains proprietary data of Hologic, Inc. No disclosure, reproduction or use of any part thereof may be made except by written permission from Hologic.	TITLE AW, LOCALIZER SURGICAL PROBE IFU (ML-0008)	DOCUMENT NUMBER AW-29125	REV 006
REV. RELEASE DATE: 6/14/2023		SIZE A	SHEET 1 OF 1

LOCalizer™

Surgical Probe

Instructions for Use

R_x ONLY

Health Beacons, Inc.
250 Campus Drive
Marlborough, MA 01752
+1 (800) 442-9892

MAN-07992 Rev. 006
5/2023

HOW SUPPLIED

The LOCalizer Surgical Probe is provided sterile and is intended for single patient use only. The Surgical Probe is not made with natural rubber latex.

COMPLIANCE WITH STANDARDS

When used with the LOCalizer Reader, the Surgical Probe complies with IEC60601-1 requirements for type B applied part and meets electromagnetic compatibility requirements of IEC60601-2.

INTERFERENCE

This device complies with part 15 of the FCC rules.
Operation is subject to the following two conditions:

1 This LOCalizer Reader and LOCalizer Surgical Probe may not cause harmful interference, and
2 This LOCalizer Reader and LOCalizer Surgical Probe must accept any interference received, including interference that may cause undesired operation.

The user is responsible to maintain FCC compliance.
Any changes or modifications not expressly approved by Health Beacons Inc. could void the user's authority to operate the equipment.

Use the LOCalizer Surgical probe only with a LOCalizer Reader and Tag.

The LOCalizer Reader and Surgical Probe are MR unsafe. Keep away from magnetic resonance imaging (MRI) equipment.

SYMBOLS

Symbol	Description	Standard
	Use by Date	ISO 15223-1, Reference 5.1.4
YYYY-MM-DD	Date format: YYYY represents the year MM represents the month DD represents the day	Hologic
	Date of Manufacture	ISO 15223-1, Reference 5.1.3
	Caution	ISO 15223-1, Reference 5.4.4
	Consult Instructions for Use	ISO 15223-1, Reference 5.4.3
	Do not use if package is damaged	ISO 15223-1, Reference 5.2.8
	Do not re sterilize	ISO 15223-1, Reference 5.2.6
	Do not re-use	ISO 15223-1, Reference 5.4.2
R_X ONLY	Prescription use only	FDA 21 CFR 801.109
STERILE R	Sterilized using irradiation	ISO 15223-1, Reference 5.2.4
	Manufacturer	ISO 15223-1, Reference 5.1.1
IP54	Protection against limited dust ingress. Protection from water splashed in any direction, limited ingress permitted.	IEC 60529
REF	Catalog Number	ISO 15223-1, Reference 5.1.6
LOT	Batch Code	ISO 15223-1, Reference 5.1.5
	Type B applied part	IEC 60417, Reference 5840
MR	Not safe for magnetic resonance imaging	ASTM F2503 Reference no. Table 2, Symbol 7.3.3;7.4.9.1; Fig. 9
QTY	Quantity	Hologic

DESCRIPTION

RFID Localization System

The Tag Applicator, LOCalizer™ Reader and LOCalizer Surgical Probe are components of the RFID Localization System. The Tag is intended to be placed in breast tissue, within 6 cm of the breast surface, using the Tag Applicator. The Tags, when used in conjunction with the LOCalizer Reader and LOCalizer Surgical Probe, can be used as a guide for the surgeon to follow in the excision of tissue.

RFID Localization System (RFLS) components are listed below:

System Component	Description	Part Number
LOCalizer Reader	RFID Reader	HB100
LOCalizer Surgical Probe	Attachment probe for use with LOCalizer RFID reader	HB110
Tag Applicator	Needle applicator with preloaded RFID Tag	HB200-XX* HB300-XX*

* XX indicates the length of the applicator needle in cm. Contact distributor for available sizes in your area.

The LOCalizer Instrument Drape (HB125) is provided separately for use with the LOCalizer Reader in a sterile environment.

LOCalizer Surgical Probe

The LOCalizer Surgical Probe is a sterile, single patient use hand-held attachment that, when used with the LOCalizer Reader, can locate and read embedded Tags up to a depth of 3 cm within a surgical incision. The Surgical Probe is approximately 175 mm long and 8 mm in diameter (Figure 1).

A Probe Connector
B Cable
C Probe Handpiece

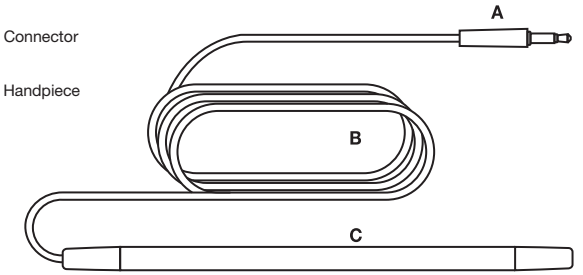


Figure 1. LOCalizer Surgical Probe

INDICATIONS FOR USE

The Tag of the RFLS is intended for percutaneous placement in the breast to mark (>30 days) a lesion intended for surgical removal. Using image guidance (such as ultrasound or radiography) or aided by non-imaging guidance (RFLS), the RFID Tag is located and surgically removed with the target tissue.

The RFLS is intended only for the non-imaging detection and localization of the Tag that has been implanted in a lesion intended for surgical removal.

CONTRAINDICATIONS

The RFID Localization System is not intended for use under conditions where breast lesion localization is contraindicated.

The RFID Localization System is not intended for use in the heart, eyes, brain or spinal cord.

The Tag should not be placed in a tissue site with clinical evidence of infection.

The Tag should not be placed in muscle tissue.

ADVERSE EVENTS

The potential risks associated with implantable breast lesion localization tags, such as the RFLS include but are not limited to: bleeding upon placement, infection, and MRI interference. These adverse events do not include all adverse events that could occur with breast surgery in general but are important considerations for breast lesion localizers when used for percutaneous placement in the breast to mark a lesion intended for surgical removal.

WARNINGS

The Surgical Probe is designed only for use with the LOCalizer Reader and Tags.

If any resistance is felt during advancement of the Surgical Probe, carefully correct the orientation but never apply strong forces in order to overcome the obstacle.

When using the Surgical Probe intraoperatively, avoid touching or moving the Tag with the Surgical Probe.

The Surgical Probe has been designed for SINGLE USE only. Reusing this medical device bears the risk of cross-patient contamination. The residue of biologic material can promote the contamination of the device with pyrogens or microorganisms which may lead to infectious complications.

DO NOT RESTERILIZE. After sterilization, the sterility of the product is not guaranteed because of an indeterminable degree of potential pyrogenic or microbial contamination which may lead to infectious complications. Cleaning, reprocessing and/or re-sterilization of the present medical device increases the probability that the device will malfunction due to potential adverse effects on components that are influenced by thermal and/or mechanical changes.

Do NOT use if the package is open or damaged.

Use the Surgical Probe prior to the expiration date shown on the product label.

The LOCalizer Reader is a non-sterile device. Drape with the sterile LOCalizer Instrument Cover (Product HB125) when using in a sterile environment. Do NOT sterilize the LOCalizer Reader as sterility cannot be guaranteed. Cleaning, reprocessing and sterilization of this LOCalizer Reader could cause the LOCalizer Reader to malfunction due to adverse effects on components

Use of the LOCalizer Reader next to or stacked with other equipment should be avoided because it could result in improper functioning. 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 Health Beacons could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

The LOCalizer Reader may suffer erroneous signal detection or degraded distance accuracy of an RFID Tag due to electromagnetic interference from HF Surgical Equipment, other RFID readers, or wireless charging devices.

Portable RF communications equipment such as cell phones or tablets should be used no closer than 30 cm (12 inches) to any part of the LOCalizer Reader to avoid degradation of the performance of this equipment.

.

PRECAUTIONS

This product should only be used by a physician who is completely familiar with the indications, contraindications, limitations, typical findings and possible side effects of using a system for lesion localization that employs a marker at the site of the lesion and a reader for marker retrieval.

Do NOT use the Surgical Probe if it is damaged.

Handle the Surgical Probe in a manner that will prevent accidental contamination.

After use, the Surgical Probe is a biohazard. Dispose in accordance with your facility's biohazardous waste procedures.

Do NOT immerse the Surgical Probe in liquid.

Metal Items, such as surgical tools, which block the path between the implanted Tag and LOCalizer Probe may alter the LOCalizer Reader readings. Ensure these items are not in the path of the Tag.

The LOCalizer Reader is sensitive to electromagnetic interference during the operation of HF Surgical Equipment such as Electrosurgery cutting tools and instruments, and should be used non-concurrently with such equipment.

The LOCalizer Reader is a sensitive radio receiver operating at 134 kHz. Its operation may be affected by other devices operating near this frequency.

The LOCalizer Reader is intended for use only in a hospital, except near active HF Surgical Equipment and other RFID equipment or wireless battery chargers.

The LOCalizer transmits RF energy at 134 kHz and is sensitive to a receive bandwidth of 120kHz to 150khz.

The LOCalizer Reader transmits a weak unmodulated magnetic field at 134 kHz (<200 microwatts ERP) to sense the presence of the Tag. Modulation of the field by the Tag is detected by the LOCalizer Reader. Other devices that generate electromagnetic fields in this frequency region may interfere with the ability of the LOCalizer to sense the location of the Tag. Interference may occur for example from other RFID readers, inductive chargers commonly used for cell phones or other devices, or magnetic induction proximity detectors. Sensitive devices such as other Low Frequency RFID readers may likewise be affected by the operation of the LOCalizer Reader in the same vicinity

STORAGE

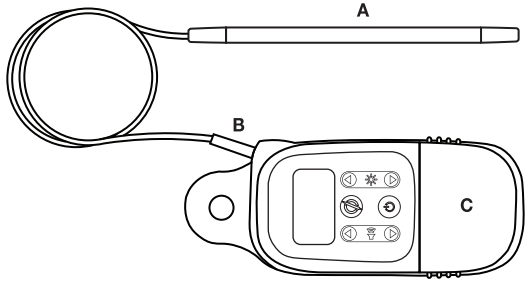
Store at ambient temperature 15˚ to 30˚C (59˚ to 86˚F)

DIRECTIONS FOR USE

NOTE: These instructions are NOT meant to define or suggest any medical or surgical technique. The individual physician is responsible for the proper procedure and techniques to be used with this product.

1. Prepare the LOCalizer Reader for use (see details in Reader / System Manual).
2. Inspect the packaging of the Surgical Probe to ensure that package integrity has not been compromised. The product is sterile unless the seal is broken or the expiration date has passed.
3. Using standard aseptic technique, open the package and remove the Surgical Probe (***Figure 1,*** **A**).
4. Uncoil the cable. Align the Probe Connector with the LOCalizer Reader receptacle (***Figure 1,*** **B**) through the sterile Instrument Cover and insert the connector firmly.

   NOTE: The Probe Icon (***Figure 2***) will illuminate on the LOCalizer Reader screen to verify proper connection.



A Surgical Probe
B Probe Connector
C LOCalizer Reader

Figure 1. LOCalizer Reader with connected Surgical Probe (Instrument Cover not shown)

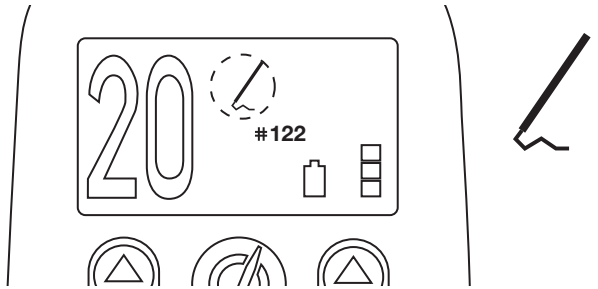


Figure 2. Active Probe Icon

5. Follow the LOCalizer Reader steps in initiation and allow the Surgical Probe to complete a self-test. If the self-test is successful, the Surgical Probe is ready for use.
6. Use the Surgical Probe intraoperatively as frequently as needed to determine the location of and distance from the implanted Tag.

   The Probe produces an audio tone that increases in pitch and volume as it gets closer to the Tag while the distance is displayed on the Reader in millimeters. Refer to LOCalizer Reader instructions for additional device operation.