

HEALTH BEACONS LOCALIZER READER AND RFID LOCALIZATION SYSTEM

User Manual

CAUTION:

- Federal law restricts these devices to sale by or on the order of a physician.
- Read all warnings, cautions, and instructions provided with this equipment before using.
- Read the instructions, warnings, and cautions provided with the Tag Applicator and Localizer Surgical Probe before using. Specific instructions pertaining to Tag implantation and preparation and use of the Surgical Probe are not included in this Manual.

DESCRIPTION

RFID Localization System:

The Tag Applicator, **LOCALIZER** Reader, and **LOCALIZER** Surgical Probe are components of the Health Beacons RFID Localization System. The Tag is intended to be temporarily placed in breast tissue, within 6 cm of the breast surface, using the Applicator needle. It is implanted up to thirty days prior to removal. The Tags, when used in conjunction with the Health Beacons **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 Reader	HB110
Tag Applicator	Needle applicator with preloaded RFID Tag	HB200

The **LOCALIZER** Instrument Drape (HB120) is also available for use with the **LOCALIZER** Reader in a sterile environment.

LOCALIZER Reader:

The **LOCALIZER** Reader locates and reads (RFID) Tags which have been implanted using the Health Beacons Tag Applicator. The **LOCALIZER** Reader displays the distance between the Tag and the Probe under use. Tag location is also indicated by an audible sound of which the pitch and volume increase in proportion to a decrease in the "**LOCALIZER** to Tag" distance.

The **LOCALIZER** Reader is a portable, battery-operated system and is supplied non-sterile. The Tag Applicator and **LOCALIZER** Surgical Probe (available separately) are provided sterile. This manual includes guidelines for the use of the Probes in the sterile field.

INDICATIONS FOR USE

The Tag of the RFLS is intended for percutaneous placement in the breast to temporarily (<30 days) mark 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.

LOCALIZER READER OVERVIEW

The Health Beacons LOCALIZER Reader (**Figure 1**) is composed of:

- 1 handheld LOCALIZER Reader
- 2 AA Alkaline batteries (IEC-LR6)

The LOCALIZER Reader includes an integrated Loop Probe (A) that is used to locate and read Tags from the skin surface. It can also be used with the LOCALIZER Surgical Probe attachment (D) to locate and read Tags within the surgical incision. Probe details are included in Table 1. Subsequent sections of this manual describe in detail probe and LOCALIZER Reader use.

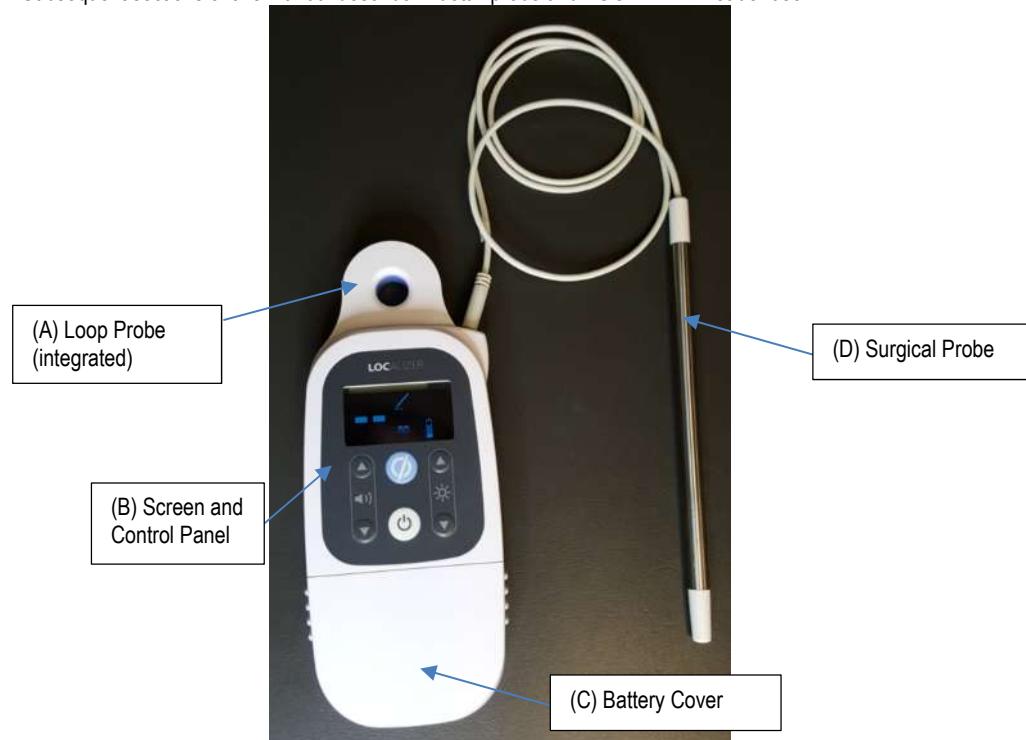


Figure 1. LOCALIZER Reader with Surgical Probe connected (Instrument Cover not shown)

Table 1. Probe Specifications

Probe	Part No.	Probe Dimensions	Max Reading Depth	Positional Accuracy
Loop Probe (integrated)	n/a	27 mm inner diameter 39 mm outer diameter	6 cm	±5 mm*
Surgical Probe	HB110	175 mm long 8 mm diameter	3 cm	±5 mm**

*As measured from center of the Loop probe to end of Tag (Figure 3)

**As measured from end of the Surgical probe to end of Tag (Figure 4)

WARNINGS

- The LOCALIZER Reader is designed only for use with the Health Beacons Tags and LOCALIZER Surgical Probe.
- The RFID Localization System is not intended for use with patients with cardiac pacemakers

- If any resistance is felt during advancement of the Surgical Probe or Tag Applicator (during implantation), carefully correct the orientation but never apply strong forces in order to overcome the obstacle.
- When using the Surgical Probe to identify location intraoperatively, avoid disrupting the Tag's location.
- Do NOT use if the package or **LOCALIZER** Reader is damaged.
- The **LOCALIZER** Reader is a non-sterile device. Drape with the sterile **LOCALIZER** Instrument Cover (Product HB120) 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 increases the probability that the **LOCALIZER** Reader will malfunction due to potential adverse effects on components.
- Use of the **LOCALIZER** Reader 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 the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation
- The **LOCALIZER** Reader may suffer degraded accuracy or erroneous detection or indication 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, WLAN 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.
- With the exception of battery replacement, no modification or repair of this equipment is allowed. If the **LOCALIZER** Reader stops working or is damaged it should be replaced.
- The user is responsible to maintain FCC compliance. Any changes, modifications, or use of non-Health Beacons probes could void the user's authority to operate the equipment.

PRECAUTIONS

General:

- Failure to thoroughly review and adhere to the information contained in this User Manual may pose a potential hazard to the patient and/or user and may void the warranty.
- 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.

LOCALIZER Reader:

- Handle all components in a manner that will prevent accidental contamination.
- The **LOCALIZER** Reader is designed to locate the low frequency 134 kHz Health Beacons Tags. Do not use the **LOCALIZER** Reader with RFID markers other than the Health Beacons Tags. Other markers may give some response but the detection range and accuracy may be affected. Most markers at other frequencies will not be readable.
- Metal items, such as surgical tools, that 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 being read.
- Ensure the **LOCALIZER** Reader battery is fully charged prior to use. A back-up **LOCALIZER** Reader is recommended in the case of instrument malfunction or battery depletion.
- Do not immerse **LOCALIZER** Reader in liquid.
- The **LOCALIZER** Reader is sensitive to degraded performance in the vicinity of HF Surgical Equipment such as Electrosurgery cutting tools and instruments, and should not be used while HF Surgical Equipment is in use.
- 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 (15 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 inductive coupling 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. Other sensitive devices such as Low Frequency RFID readers may likewise be affected by the operation of the **LOCALIZER** Reader in the same vicinity.

ADVERSE REACTIONS

None known.

HOW SUPPLIED

The Health Beacons **LOCALIZER** Reader is provided nonsterile and is intended for reuse.

LOCALIZER READER CONTROLS

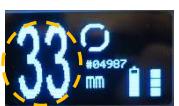
The LOCALIZER Reader contains the display and controls for the System and are located on the front face of the instrument. The LOCALIZER Reader allows the user to adjust the system's settings, and produces signals in the form of a displayed distance in millimeters and an audible pitch that represents the intensity of a Probe's signal.



Figure 2. LOCALIZER Reader Controls and Displays (described below)

Table 2. LOCALIZER Reader Controls and Displays

Control/ Display	Description
	Turns power ON/OFF <ul style="list-style-type: none">• To switch ON, press and hold until the display comes ON.• To switch OFF, press the ON/OFF button. "SHUTTING DOWN" will appear on the display for a few seconds and the LOCALIZER Reader will shut off.
	Toggles between Loop Probe and Surgical Probe
	Increases/ decreases the volume of the audible signal

Control/ Display	Description
Brightness Adjustment 	Increases/ decreases the brightness of the backlight level
Display – Distance Output 	Displays the distance to the Tag in millimeters
Display – Tag ID # 	Displays the Tag ID
Display – Unit Indicator 	Displays the unit of measurement is in millimeters (mm)
Active Probe Icon 	Displays the Probe which is currently active, Loop (left) or Surgical Probe (right)
Battery Indicator 	Indicates current battery level The battery level decreases as the battery discharges. The symbol flashes on and off when the battery needs to be replaced. When the battery reaches a critical level, the device is disabled
Intensity Indicator 	Indicates Intensity of Tag signal The Intensity Indicator can be used alternatively to the audio tone to assess location

Sound and backlight

The selected sound and display light levels are stored when the instrument is turned off and recalled when it is turned on again. When the battery is critically low, the sound level is automatically lowered to extend operating lifetime.

LOCALIZATION PROCEDURE

Power on the LOCALIZER Reader.

- a. The firmware version number is displayed.
- b. There is a brief delay while the integrated loop probe is tested
- c. If the Surgical probe is installed, there is a corresponding delay while the surgical probe is tested.

2. Use the up and down arrows on the brightness control to adjust the screen to the desired intensity.

3. Check the battery charge indicator to ensure there is adequate charge. It is highly encouraged to change the batteries before each procedure. Batteries can be replaced following directions in the "CARE AND MAINTENANCE" section.

NOTE: The LOCALIZER Reader can be turned ON with a critically low battery but will not continue operation

4. Use the Loop Probe on the LOCALIZER Reader to identify the general location of the Tag from the surface of the breast. The sound level and pitch increases as the LOCALIZER Reader approaches the Tag. The scale shows the approximate distance to the nearest point of the Tag in millimeters. When using the Loop probe the range of the LOCALIZER Reader is 1 – 60 mm.

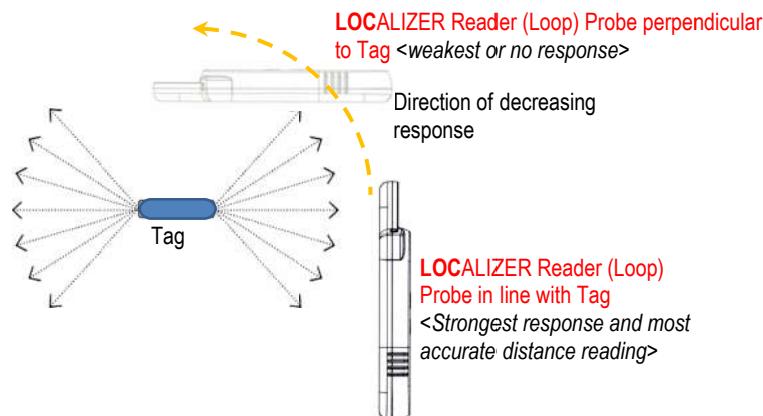


Figure 3. Assessing Tag location/ position with Loop Probe using signal strength (not to scale)

NOTE: The sound and distance display rise to a maximum when the Tag is in line with and directly under the sensing head surface. Identification of the Tag location can be refined by moving the Probe until both ends of the Tag are detected.

NOTE: The Tag's unique identification number is displayed once the probe is close enough to the implanted Tag.

5. Use the up and down arrows on the volume control to adjust the audio tone to the desired volume.
6. If excising the Tag and lesion, plan and mark the surgical area with the approximate location of the Tag.
7. In preparation for surgery, place the sterile LOCALIZER Instrument Cover over the LOCALIZER Reader per the Instrument Cover Instructions for Use.
8. NOTE: The LOCALIZER Reader can be used on an un-breached breast surface in a non-sterile setting. In a sterile setting, the Instrument Cover is required on the LOCALIZER Reader. The Surgical Probe is only intended for sterile use. Connect the Surgical Probe into the jack on the top of the LOCALIZER Reader by introducing it through the drape portal. When connected, the LOCALIZER Reader automatically identifies the Surgical Probe as the active probe, performs a self-test and the LOCALIZER Reader screen displays the Surgical Probe icon. When the Surgical Probe is attached, the range of LOCALIZER Reader is 0-30 mm.

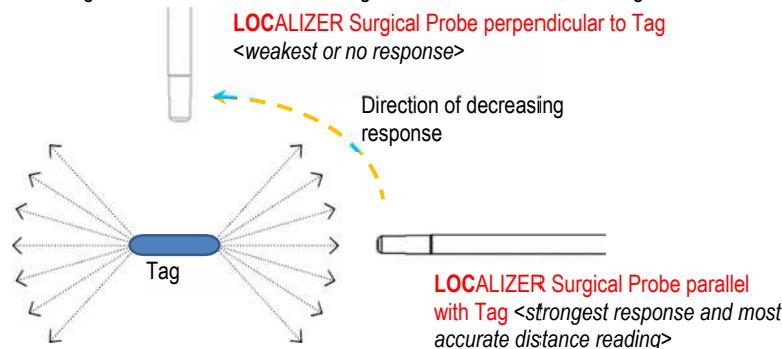


Figure 4. Assessing Tag location/ position with Surgical Probe using signal strength (not to scale)

NOTE: Readings will vary depending on the orientation of the Tag, because the signal emitted is directional along the long axis of the Tag. The **LOCALIZER** Reader will receive the strongest response and most accurate distance reading when the Surgical Probe is parallel with the Tag. The **LOCALIZER** Reader signal strength decreases as the Surgical Probe head moves toward perpendicular to the Tag and the distance accuracy may decrease.

9. During the surgical approach, the **LOCALIZER** Reader may be toggled between the Loop Probe and Surgical Probe by depressing the probe toggle switch. The active probe is indicated on the display.
10. Excise intended tissue with implanted Tag.
11. Confirm the Tag is present in the excised specimen using the **LOCALIZER** Reader or imaging (ultrasound or radiography).

TROUBLESHOOTING

Little or No Tag Response	<ul style="list-style-type: none"> • <i>The Tag is out of LOCALIZER Reader detection range</i> Reposition the LOCALIZER Loop or Surgical Probe until a signal is detected. • <i>The Tag signal is receiving interference from another Tag or device</i> Remove alternative source of signal or use alternate imaging guidance such as ultrasound or radiography to confirm Tag location. • <i>The Tag is broken</i> An alternate imaging guidance such as ultrasound or radiography should be used to ensure the entire Tag is removed with tissue removal.
Tag distance reading is incorrect	<ul style="list-style-type: none"> • <i>Positioning of the Reader</i> Resolution of system allows discrimination of two ends of Tag. Reposition the LOCALIZER Loop or Surgical Probe and look for readings from both ends of Tag. Readings at these positions have the highest accuracy.
Tag presence is indicated and incorrect	<ul style="list-style-type: none"> • <i>Interference of transmitting equipment</i> If a Tag detection is indicated when no Tag is within the normal detection distance , check for other RFID readers , wireless chargers or other nearby equipment that may be transmitting in the region of 134 kHz.
Tag location cannot be determined	<ul style="list-style-type: none"> • <i>Readings are difficult to interpret</i> Resolution of system allows discrimination of two ends of Tag. Reposition the LOCALIZER Loop or Surgical Probe and look for readings from both ends of Tag to determine Tag location.
The LOCALIZER Reader is unresponsive	<ul style="list-style-type: none"> • <i>The LOCALIZER Reader has a critically low battery</i> Replace batteries.
Display shows: "LOW BATTERY UNIT IS DISABLED"	<ul style="list-style-type: none"> • <i>Battery is too depleted to continue operation</i> Replace batteries.
Display shows: "INVALID SIGNAL DETECTED"	<ul style="list-style-type: none"> • <i>This condition may occur if an interfering signal from another RFID reader or wireless charger is received.</i> Check for and remove other RFID readers, wireless chargers or other nearby equipment that may be transmitting in the region of 134 kHz • <i>This condition may occur if multiple Tags were placed in the same operative breast and the LOCALIZER Reader can't discern one Tag signal from the other</i> Re-position the Reader in multiple locations to identify more than one Identification number. Use the identification numbers to determine each Tag's placement.
Display shows: "PROBE ERROR"	<ul style="list-style-type: none"> • <i>The Selected Probe does not pass self-test</i> -For the Surgical probe, replace the Probe -For the Loop probe, replace the LOCALIZER Reader
Display Shows	<ul style="list-style-type: none"> • <i>When adjusting the Audio Volume, if the Battery is nearly depleted, (Battery Icon Blinking) the maximum audio volume is reduced in order to enhance</i>

“ADJUST VOLUME LOW BATTERY VOLUME”	any remaining battery capacity. Replace batteries.
Display Shows “ERROR CODE xx”	<ul style="list-style-type: none"> • <i>An Internal error has occurred</i> This is generally a permanent fatal error, and the LOCALIZER Reader must be replaced. Before returning the LOCALIZER Reader for service, try removing and replacing the battery. This may clear an error.

CARE AND MAINTENANCE

Surface care:
As needed, use a damp cloth or sponge, with mild detergent if necessary. Do not use abrasives or solvents, as these may degrade the case. Do not submerge the LOCALIZER Reader in liquid.

Batteries:

Periodic battery replacement is necessary for the unit to continue to operate correctly. To replace batteries, slide open the battery compartment to install commercially available AA batteries. Approximate battery life expectancy under normal use conditions is 8 hours. These times may be reduced at high display intensity and audio volume. Use only good quality AA Alkaline cells (IEC-LR6).

REPLACEABLE COMPONENTS

The Surgical Probe can be replaced by ordering REF HB110
The Instrument Cover can be replaced by ordering REF HB120.

REPAIRABLE COMPONENTS

None

TECHNICAL INFORMATION

Environmental, Storage, and Transportation Conditions:

	Operational Conditions	Temporary Storage and Transport Conditions*
Ambient temperature	5° - 30° C (41° - 86° F)*	-20° - 50°C (-4°-122°F)
Relative humidity	30% - 75%, non-condensing	15% - 93%, non-condensing
Atmospheric Pressure	70 kPa – 102 kPa	50kPa - 106kPa

*For best service life of AA Alkaline Cells used in LOCALIZER Reader, storage temperature should be 5° - 30°C
To avoid potential damage from cells leaking, remove battery if the LOCALIZER Reader will not be used within 2 months.

Interference:

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 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 Reader only with a Health Beacons LOCALIZER Surgical Probe and Tag.

Electromagnetic Emissions and Immunity:

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:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Consult the dealer or an experienced radio/TV technician for help.

The LOCALIZER Reader is compliant to applicable emissions and immunity standards listed below.

Standards	Description	Severity Level or Limit	Criteria	Test Result
IEC 60601-1-2:2014 Product Family Standard Emissions and Immunity	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests - Edition 4	The requirements for use in the Professional healthcare facility environment were chosen by the manufacturer. See called out basic standards below	See Below	Complies
EN55011:2009 +A1:2010, FCC 15.109(a) & ICES-003	Radiated Emissions: At any one voltage & frequency (Per Table 1)	Class B Group 1, 30 MHz - 1 GHz	Limit	Complies
EN55011:2009 +A1:2010, FCC 15.107(a) & ICES-003	Conducted Emissions: At any one voltage & frequency (Per Table 1)	NA, NA EUT is battery operated only	Limit	NA
EN61000-3-2:2006 +A1:2009 +A2:2009	Power Harmonics At 230 V, 50Hz or 60 Hz (Per Table 1)	NA EUT is battery operated only	Limit	NA
EN61000-3-3:2013	Voltage Fluctuation At 230 V, 50Hz (Per Table 1)	NA EUT is battery operated only	Limit	NA
EN61000-4-2:2009 Basic test standard	Electrostatic Discharge Immunity: At any one voltage & frequency (Per Tables 1 and 7)	±15 kV Air Discharge ±8 kV Contact Discharge, VCP, HCP	per Annex I	Complies
EN61000-4-3:2006 + A2:2010 Basic test standard	Radiated Electromagnetic Fields Immunity: At any one voltage & frequency (Per Tables 1 and 4)	3V/m, 80 - 2700 MHz at 80% 1kHz AM Modulation	per Annex I	Complies
EN61000-4-3:2006 + A2:2010 Basic test standard	Radiated Electromagnetic and Proximity Fields Immunity: At any one voltage & frequency (Per Tables 4 and 9)	RF wireless communication fields on Spot Frequencies from Table 9 at 50%, Square wave Modulation 9 to 28 V/m,	per Annex I	Complies
EN61000-4-4:2012 Basic test standard	Electrical Fast Transient /Burst Immunity: 100 kHz At any one voltage & frequency (Per Table 1)	NA on AC Mains NA SIP/SOP Ports are < 1m in length EUT is battery operated only	NA	NA
EN61000-4-5:2006 Basic test standard	Surge Immunity: At any one voltage & frequency (Per Table 1)	NA CM Line-Gnd NA, DM Line-Line NA SIP/SOP Ports are not connected directly to outdoor cables.	NA	NA
EN61000-4-6:2009 Basic test standard	Conducted Immunity: At any one voltage & frequency (Per Table 7)	3V rms, 0.15 - 80 MHz on SIP/SOP 6V rms, on ISM bands port only	per Annex I	Complies
EN61000-4-8:2010 Basic test standard	Power Frequency Magnetic Field Immunity: At any one voltage at 50 or 60 Hz (Per Table 1)	30A/m @ 50Hz or 60Hz 3 orthogonal orientations	per Annex I	Complies
EN61000-4-11:2004 Basic test standard	Voltage Dips and Voltage Interruptions: At min & max rated input voltage at any rated power frequency (Per Table 1)	NA NA NA EUT is battery operated only NA	NA	NA

SYMBOLS

The following symbols may be found on the product labeling for the Health Beacons LOCALIZER Reader:



Caution



Follow instructions for use



Keep dry



Humidity limitation



Temperature limitation

Rx ONLY

U.S. federal law restricts this device to sale by or on the order of a physician



Manufacturer



Manufacture Date



Catalog number



Serial Number



Type B Equipment



Device is non-sterile



Do not dispose of the LOCALIZER Reader by placing into trash receptacles.

DISPOSAL OF EQUIPMENT

After following the cleaning recommendations above, and there are no biohazard risks involved, dispose of the LOCALIZER Reader at the end of the LOCALIZER Reader's useable life per Waste of Electrical and Electronic Equipment (WEEE) directive [Directive 2002/96/EC]. Dispose of Surgical Probe and Instrument Cover per the device Instructions for Use.

Instructions to disassemble LOCALIZER Reader into separate parts for recycling:

TBD

Manufactured For:

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Phone: (978) 254-6500
www.healthbeacons.com

Location of Manufacture: USA