Diversatek Healthcare

Zvu®

HRaM Anorectal Manometry Probe

Installation and User's Guide

Diversatek Healthcare
Technical Research & Training Center
9150 Commerce Center Circle, Suite 500
Highlands Ranch, CO 80129 USA

P 800.558.6408

technicalsupport@diversatekhc.com
clinicalsupport@diversatekhc.com
clinicaleducation@diversatekhc.com

Part Number:
HRAM-195-EN-US Rev F

DiversatekHealthcare.com

Notes, Notices, and Cautions in User's Guide

NOTE:	A NOTE indicates important information that helps you make better use of your system.
NOTICE:	A NOTICE indicates either potential damage to hardware or loss of data and tells you how to avoid the problem.
CAUTION:	A CAUTION indicates a potential for property damage, personal injury, or death.

Symbols Marked On Devices

	Refer to Instruction Manual:	The operator must read, understand, and follow all instructions in the accompanying documents including all warnings, cautions, and precautions before using the medical device.
	General Warning Sign:	General warning sign to alert the user to potential hazards.
NON STERILE	Non-Sterile:	The product associated with this symbol is not sterilized after manufacturing.
LATEX	Not made with natural rubber latex:	The product associated with this symbol is not made with natural rubber latex.
	Manufacturer:	Name and location of legal manufacturer.
	Date of Manufacture:	Indicates the date when the medical device was manufactured.
SN	Serial Number:	Production identifier / serial number as noted.
REF	Reference Number:	Device identifier / part number as noted.

	Lot Number:	Indicates the manufacturer's lot number so that the lot can be identified.
	Use-by Date (YYYY-MM-DD):	Indicates the date after which the medical device is not to be used.
	Do Not Reuse:	Indicates a medical device that is intended for one single use only.
	Direct Current Voltage:	The type of input voltage required by the device and the voltage levels needed.
	Do Not Discard:	The device contains electronics and must be disposed of in accordance with local regulations.
	MR Unsafe:	This device is unsafe to use in a magnetic resonance (MR) environment.
Rx Only	Prescription Use Only:	Caution: Federal law restricts this device to use by or on the order of a physician.
	EC Representative:	Authorized Representative in EU
	Medical Device:	Indicates the item is a medical device.

Classifications

	Type BF Equipment	This symbol indicates that the patient applied part is Type BF, (floating from electrical ground) which offers a specific level of safety.
	Class II Equipment	Requires protective grounding.
	Ingress Protection	IPX5/IPX7 Liquid ingress protection effective against water projected by a nozzle and immersion up to 1 m depth.

Definitions, Abbreviations and Acronyms

HRaM:	High Resolution Anorectal Manometry.
inSIGHT Ultima® PriZm®	Data acquisition system.
Probe	Patient applied sensor device.

Contents

1 Introduction

1.1 How to Use This Guide

This guide is designed to help you install the Diversatek Healthcare Zvu® High Resolution Anorectal Manometry (HRaM) Probe quickly and easily. It is intended for health-care professionals trained in performing clinical procedures. Diversatek Healthcare offers regularly scheduled product training courses for your convenience. See contact information on the cover page or in Section 6.1: Technical Support.

For detailed instructions on using the HRaM Probe refer to the supporting reference guides.

This User's Guide assumes the user has basic computer skills common to Microsoft software applications.

This guide uses visual clues and typographical conventions to attract attention to, and clarify instructions.

Keyboard keystrokes are written in **bold face.**

Labels in the software such as a menu, toolbar, button, shortcut names, etc. are written in *italics*.

The guide is divided into different sections featuring specialized tasks for quick, easy reference.

1.2 CAUTION: Safety Instructions

The Zvu® HRaM Probe is a sensitive electronic instrument. Please use the following safety guidelines to help ensure your own personal safety and to help protect your Probe and working environment from potential damage.

⚠ CAUTION: The user must be qualified in gastrointestinal diagnostic procedures, trained in the use of the system, and must be familiar with all labeling and instruction for use associated with the equipment. Many device injuries are due to user error and failure to follow the instructions for use. The user of the device is advised to thoroughly understand the use of the equipment, and familiarize themselves with its operation prior to using the equipment.

⚠ CAUTION: The Zvu® HRaM Probe and inSIGHT Ultima® System and PriZm® is intended for use by gastroenterologists, surgeons, other trained physicians, and medically trained personnel as an aid in documenting and diagnosing elimination disorders. This system includes analysis software, but requires skilled interpretation by a physician to make a diagnosis.

⚠ CAUTION: Do not attempt to open or service the Zvu HRaM Probe or inSIGHT Ultima System or PriZm system. There are no user serviceable parts inside.

⚠ CAUTION: Warning: No modification of this equipment is allowed.

⚠ CAUTION: Follow instructions provided with the inSIGHT Ultima System, PriZm System and Signal Conditioning devices.

⚠ CAUTION: The Probe is reusable and must be cleaned and disinfected according to this user guide and your institution's guidelines after each use.

⚠ CAUTION: Dispose of the Probe and the inSIGHT Ultima System and PriZm System in accordance with local ordinances and regulations. Refer to section 5.3 Decommissioning and Disposal for additional information.

⚠ CAUTION: Electromagnetic interference is possible between Probes and implanted devices such as pacemakers and internal defibrillators. Monitoring of all implanted devices is advised.

⚠ CAUTION: Inspect the HRaM Probe for damage such as bent or broken connector pins. Also, verify the integrity of the Probe between the tubing and each sensor. Do not connect the Probe to the equipment if there is visible damage.

⚠ CAUTION: Only use the HRaM Probe with the approved Diversatek Healthcare inSIGHT Ultima System, PriZm system and application software. If other equipment is substituted, damage to the system, the Probe, and/or patient injury may occur.

⚠ CAUTION: Do not use Diversatek Healthcare accessories with other non-Diversatek Healthcare equipment. Damage to the system, the accessory, and/or patient injury may occur.

⚠ CAUTION: Do not use the HRaM Probe or inSIGHT Ultima System or PriZm System in association with an MRI machine. The Probe contains sensitive electronics not designed to operate in the extensive magnetic fields of an MRI machine. Patient injury or Probe damage may occur.

⚠ CAUTION: Do not use the HRaM Probe or inSIGHT Ultima System or PriZm System devices in emergency situations or for patient treatment or monitoring. The system is designed for diagnostic use only in non-emergency situations.

⚠ CAUTION: Do not use the HRaM Probe or inSIGHT Ultima System or PriZm System during the operation of high frequency devices such as RF ablation devices.

⚠ CAUTION: Do not use the HRaM Probe or inSIGHT Ultima System or PriZm system in an oxygen rich environment.

⚠ CAUTION: Any serious incidents that occur in relation to the HRaM Probe or inSIGHT Ultima System or PriZm System should be reported to Diversatek and the Competent Authority.

NOTICE: Do not store the HRaM Probe or inSIGHT Ultima System or PriZm System in extreme temperatures. The Probes are best stored between 50° and 104°F (10° to 40°C).

NOTICE: Do not drop the HRaM Probe. The pressure sensors along the Probe body are very sensitive. Always take care to handle the Probe gently.

1.3 Product Description

1.3.1 Indications for Use

The Zvu® High Resolution Anorectal Manometry (HRaM) Probe is intended for use by gastroenterologists, surgeons, and medically trained personnel for gastrointestinal tract studies to obtain a high resolution mapping of pressures within the organs, and to allow storage of the corresponding data.

The device is used in conjunction with a manometry system from Diversatek Healthcare. Studies performed with this system require skilled interpretation by a physician to aid in making a diagnosis of anorectal motility disorders.

This device is indicated for use on adult populations only.

1.3.2 Contraindications

Anorectal manometry is contraindicated in the following situations:

- Patients with severe clotting disorders
- Anal obstruction
- Severe anal pain and anal stricture
- Other abnormal anatomical conditions making intubation difficult

GI Tract procedures are contraindicated in the following situations:

- Patients with severe clotting disorders
- Peritonitis
- Other abnormal anatomical conditions making intubation difficult

1.3.3 Conditions of Warranty

The Zvu® High Resolution Anorectal Manometry Probe should only be used by or under the supervision of physicians thoroughly trained in anorectal manometry procedures and studies.

The warranty on the Probe covers damage on materials and deviations from the specifications, provided the damage is not attributable to improper handling or poor/incorrect cleaning. In particular, the warranty excludes any damage that may result from mechanical influence on the sensor(s), Probe or the connector due to negligence on the part of the user.

The manufacturer does not assume any liability or warranty for damages due to improper repair or changes to the Zvu® Anorectal Manometry Probe performed by unauthorized persons.

1.3.4 Biocompatibility

The Probe utilizes components made of common materials with no known biocompatibility issues. However, the following cautions should be observed:

CAUTION: HRaM Probe has applied parts made with 304 stainless steel. This type of stainless steel, although medical grade, contains 8-11% nickel which may pose risks for people with certain allergies to nickel.

NOTE: Not made with natural rubber latex.

2 System Components and Connections

2.1 Zvu® HRaM Probe System Configuration and User Guides

The Zvu® High Resolution Anorectal Manometry (HRaM) Probe, when used in conjunction with the inSIGHT Ultima or PriZm Systems, inSIGHT Acquisition and BioVIEW® software provides pressure data useful for diagnosing anorectal diseases and conditions. Refer to the user guides for the inSIGHT Ultima System, PriZm System and BioVIEW software for more detail.

Components:

- Zvu® HRaM Probe
- inSIGHT Ultima® System or PriZm® System
- inSIGHT Acquisition software
- BioVIEW software

Manual Part Number	Title
H12R-0190	inSIGHT Ultima System Installation and User's Guide
HRAM-195	High Resolution Anorectal Manometry Probe Installation and User's Guide
H20-0195	PriZm System Installation and User's Guide
H06-0140	inSIGHT (Acquisition) Software User's Guide
PL-14-12	Standard HRaM Editing Techniques

2.2 Connecting the HRaM Probe to the Ultima Central Unit or PriZm Central Unit

The Zvu® High Resolution Anorectal Manometry (HRaM) Probe is connected to the inSIGHT Ultima Central Unit or PriZm Central Unit through an accessory cable that is unique to the Diversatek Healthcare Probe. Cables used for connecting other probes to the inSIGHT Ultima Central Unit and PriZm Central Unit are not compatible with the Diversatek Healthcare Probe, nor is this accessory cable compatible with those probes.

Note: The two ends of the accessory cable utilize different connectors. They are color coded to match the mating connector. In addition, the connectors are keyed differently to only fit in the proper mating connector. Do not try to force the connector if it does not fit properly or the colors do not match.

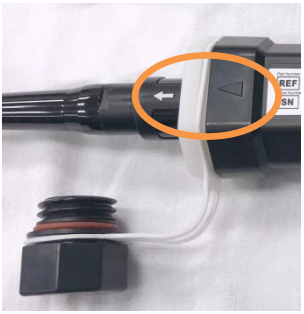
inSIGHT Ultima Central Unit or PriZm Central Unit

Connect the gray connector of the accessory cable into the matching gray colored Port 1 connector on the inSIGHT Ultima Central Unit or PriZm Central Unit (see images below, Ultima and PriZm Central Units are very similar).

Port 1 – High Resolution Probe accessory cable connection

High Resolution Probe

Connect the black connector of the accessory cable into the matching black connector on the Probe (see the image at right). Align the white arrow of the cable connector with the triangle on the housing above the Diversatek Healthcare label.



2.3 Basic Operation of the HRaM Probe

2.3.1 Operation

The Zvu® High Resolution Anorectal Manometry (HRaM) Probe, when used in conjunction with the inSIGHT Ultima® System or PriZm® System and BioVIEW® software provides pressure data ton aid in making a diagnosis of anorectal motility disorders. Refer to the user guides for the inSIGHT Ultima System, PriZm System and BioVIEW software for more detail.

2.3.2 Procedure

This section describes the basic steps of what should be done before and after acquiring an anorectal manometry study.

1. Connect the HRaM Probe to the inSIGHT Ultima System or PriZm System:
   - Align and connect the Probe to the Probe Accessory Cable. Alignment features in the connectors are to avoid misalignment. Do not force the cable plug into the Probe connector.
   - Align and connect the accessory cable into Port 1 of the inSIGHT Ultima or PriZm.
2. Power on all hardware.
3. Launch the inSIGHT Acquisition software.
4. Enter patient information into the software and use a protocol created for the model of probe being used.
5. Follow the software prompts to begin the acquisition process and perform the pressure calibration and operational verification.
6. Attach the balloon per the Balloon Attachment Steps in section 4.1 and verify it holds air.
7. Insert the Probe with deflated balloon and acquire the manometry study according to on-screen prompts.
8. After completion of the study, extubate the Probe from the patient.
9. Remove the balloon per the Balloon Removal Steps in section 4.2.
10. Disconnect the Probe from the cable and tighten the cap on the Probe handle.
11. Immediately rinse the Probe in water. Do not allow the Probe to dry after the procedure. Allowing the Probe to dry without rinsing can make the removal of proteins more difficult and negatively affect the usable life of the Probe.
12. Follow the specific reprocessing instructions in the section below to properly clean and disinfect the Probe after each use.

2.4 General Handling Precautions of the Probe

CAUTION: **Do Not** squeeze the Probe sensors.

CAUTION: **Do Not** stretch, fold, twist, crush, lean on or kink the Probe. Do not bend the Probe tighter than a 2 inch (5cm) diameter.

CAUTION: **Do Not** ultrasonically clean the Probe.

CAUTION: **Do Not** use a Probe with visible damage such as torn sensors, cracked or separated tubing, or visible wiring.

CAUTION: The Probe is supplied non-sterile and must be cleaned and disinfected prior to the first patient use and after each subsequent patient use.

CAUTION: Use only the validated reprocessing methods described in this guide to clean and disinfect the Probe.

CAUTION: During reprocessing, do not subject the probe to any temperatures over 50°C / 122°F as this may damage the probe.

3 Reprocessing (Cleaning and Disinfection)

Prior to first use and immediately after every patient study, the Zvu® High Resolution Anorectal Manometry (HRaM) Probe needs to be "reprocessed" to include enzymatic cleaning followed by a high level disinfection (HLD). Thorough rinsing, preferably under running water, is recommended upon removal from the patient. Do not allow the Probe to dry without cleaning as this may cause a buildup of proteins that can damage the Probe or reduce performance.

This section describes the necessary reprocessing steps, lists the approved solutions to use and provides important notes to reduce the chance of damaging the Probe.

3.1 Important notes about cleaning

Note: The HRaM Probe is not disinfected prior to shipment. A proper cleaning and disinfection cycle is required before the initial use.

Note: The HRaM Probe must be reprocessed immediately after each patient use. Do not allow the Probe to dry after a patient procedure. Allowing the Probe to dry without rinsing can make the removal of proteins more difficult and negatively affect the usable life of the Probe. Rinse the Probe with water immediately after removing the probe from the patient. Failure to do so can result in damage to the device.

Note: The HRaM Probe utilizes a lumen to inflate a balloon. Even though the lumen is only charged with air during the study, it is critical that the lumen be flushed when cleaning and disinfecting the Probe. Follow the additional steps in section 3.5 Lumen Reprocessing for proper cleaning and disinfection of the lumen.

CAUTION: Reprocess the Probe using only the cleaning and disinfection solutions approved by Diversatek Healthcare as listed below. Failure to use approved solutions can result in damage to the device.

CAUTION: Do not submerse the Probe connector in liquid without securing the cap tightly in place. Immersing the Probe connector without the cap properly installed will damage the sensitive electronics inside the connector housing.

CAUTION: Do not use ultrasonic cleaners with the Probe. This will damage the sensors and voids the warranty.

CAUTION: During reprocessing, do not subject the probe to any temperatures over 50°C / 122°F as this may damage the probe.

CAUTION: Do not use acetones, peracetic acid (such as Rapicide PA) with the Probe. Do not expose to wound benzene, cresols, phenols, acetone, hydrogen peroxide (H_20_2), mercury compounds, chlorides, sodium hypochlorite (bleach), xylenes, trichloroethylenes, Freon, or Bomix. These solutions will damage the sensors and voids the warranty. Do not use alcohols on the outside of the Probe. Use Isopropyl Alcohol only to flush the lumen as directed below.

CAUTION: Sterilization using any method is not permitted. Do not use any autoclave, (gamma) irradiation, or low-temperature plasma sterilization.

NOTICE: The USER is responsible for cleaning and disinfection of the Diversatek Healthcare Zvu® High Resolution Manometry Probes. Only the procedures and solutions described below are validated and qualified for proper cleaning and disinfection of the Probe. Additionally, please pay attention to the protocols, regulations and guidelines of your facility.

When handling the HRaM Probe remember the following:

- **Do Not** squeeze or pull the sensor(s).
- **Do Not** clean with brushes, needles, or wires.
- **Do Not** stretch or pull on the Probe.
- **Do Not** bend the Probe too tightly. Never coil, twist, or knot the Probe.
- **Do Not** coil the Probe tighter than 15 cm / 6 inches in diameter.

- When placing the Probe in the storage case, take care not to crush, pinch, kink or cut the pressure sensors or tubing. This can permanently damage the Probe.
- **Do Not** allow the Probe to swing into any surfaces such as counters, cabinets or the like.
- **Do Not** use ultrasonic cleaners.
- **Do Not** use a combined cleaning/disinfecting solution unless specifically listed in the table below. Ensure the Probe has been thoroughly cleaned prior to disinfection. Failing to thoroughly clean the Probe can cause residue to permanently adhere onto the Probe which can affect the Probe's performance.
- **Do Not** use mechanical washing systems. The manual instructions below are the only approved cleaning and disinfecting methods.
- **Do Not** use thermal disinfection.
- Follow the instructions as provided by the chemical manufacturers for room temperature cleaning and disinfection.
- Use only approved solutions for cleaning and disinfection to avoid damaging the Probe.

3.2 Validated cleaning and disinfection solutions

The following table lists the cleaning and disinfection solutions validated by Diversatek Healthcare for use with the Zvu® HRaM Probe. Failure to use these approved solutions may damage the Probe and void the warranty.

Validated Cleaning Detergents	Dilution Formula (from Chemical Manufacturer's IFU)	Recommended Minimum Soak Time	Maximum Soak Time
Enzol®	1 oz/1 gal	5 minutes	30 minutes
EmPower™	1 oz/1 gal	5 minutes	30 minutes
Endozime® AW Plus	½ oz /1 gal	5 minutes	60 minutes
Revital-Ox™	⅛ - ½ oz /1 gal (1-4 mL / L)	5 minutes	30 minutes

Validated Disinfection Solutions	Dilution Formula (from Chemical Manufacturer's IFU)	Validated Soak Time	Maximum Soak Time
Cidex® OPA (non-glutaraldehyde)	Full Strength	12 minutes @20°C	30 minutes
Revital-Ox™ RESERT®(1)	Full Strength	8 minutes	30 minutes

(1)Also available as Revital-Ox™ RESERT® High Level Disinfectant – Chemosterilant and as Resert XL HLD High Level Disinfectant depending on geographical location.

Diversatek Healthcare does not guarantee the effectiveness of these agents.

Enzol® and Cidex® are registered trademarks of Advanced Sterilization Products.
Endozime® is a registered trademark of The Ruhof Corporation.
EmPower™ is a trademark of Metrex Research LLC.
Revital-Ox™ RESERT® is a registered trademark of Steris Corporation.

Only use the approved cleaning and disinfecting solutions listed above. Damage to the Probe through the use of unapproved solutions or procedures is not covered under warranty.

3.3 Cleaning Procedure

The Zvu® HRaM Probe should be immersed into the cleaning solution according to the times indicated in the table above. Immersing the Probe for longer periods of time is not recommended and can damage the Probe. Follow all solution preparation instructions as indicated by the chemical manufacturer.

1. Users should wear appropriate protective gear (goggles and gloves at a minimum) as recommended by facility policy throughout the cleaning process.

2. Install the cap onto the connector handle and hand-tighten securely. Tighten the cap until resistance is felt from the cap sealing o-ring, then continue to tighten until the cap comes to a hard stop against the handle. The cap sealing o-ring should no longer be visible. Do not overtighten with extreme force.

3. Remove the balloon and retention bands. Please refer to section 4.2 HRaM Balloon Removal Steps for instructions.

4. Rinse the entire Probe with potable water or distilled water for at least 1 minute. The water temperature must be less than 50°C / 122°F.

5. Prepare the cleaning solution according to the manufacturer's instructions and place in a large (approximately 17x12x8) polypropylene tub or similar receptacle. The container should be sized to allow immersion of the complete Probe without excessive bending or kinking of the device.

6. Immerse the entire Probe into the cleaning solution according to the soak times indicated in the table above. Flush the lumen with at least 10 ml of cleaning solution at the beginning of the probe immersion and keep the lumen filled with cleaning solution during the entire probe soak time. Flush the lumen again with at least 10 ml of cleaning solution at the end of the Probe immersion. (Refer to section 3.5 Lumen Reprocessing below for additional information.)

   Longer soaking times in the cleaning solution are allowable when more residue is present after the procedure. Do not soak the Probe longer than the maximum soak time as indicated in the table above.

   Towards the end of the soaking time, take a clean soft gauze soaked with cleaning solution and gently wipe the sensor area of the submerged Probe to help remove tougher deposits of soil. Do not aggressively scrub the Probe as this may damage the delicate sensors.

   If the Probe is still visibly soiled after the maximum soak time, remove the Probe from the cleaning solution, and rinse thoroughly in potable water or distilled water for at least 1 minute. Gently pat the Probe dry. Return the Probe to the soaking solution and repeat the steps above to remove the remaining soil. Do Not repeat the soaking cycle more than once. If visible soil remains after the second cleaning cycle, **STOP** the reprocessing steps and contact Technical Support.

The Probe must be thoroughly clean and free of visible soil before the high level disinfection step.

7. Replace gloves before removing the Probe from the cleaning solution.

8. Purge the lumen with air using the syringe.

9. After immersion, the entire Probe must be rinsed again with potable water or distilled water. Rinse from the handle towards the tip. Thoroughly rinse the handle and Probe tubing, then rinse the patient contact area for at least 1 minute. Flush the lumen with at least 10 ml of potable water or distilled water.

10. Following the rinse, gently pat the Probe with a soft gauze or lint-free cloth, taking care not to squeeze or pull on the sensors. Pat the Probe until visibly dry. Purge the lumen with air using the syringe.

11. Visually inspect the Probe after cleaning for damage, corrosion, cuts, separation of tubing, punctures, and cracked seals. If any damage is found, **STOP** the reprocessing steps and contact Technical Support.

3.4 High-Level Disinfection Procedure

Carefully follow the instructions below. Not following these instructions may result in ineffective disinfection or damage to the Zvu® Probe. Follow all solution preparation instructions as indicated by the chemical manufacturer.

1. Users should wear appropriate protective gear (goggles and gloves at a minimum) as recommended by facility policy throughout the disinfection process.

2. Ensure the Probe has been thoroughly cleaned prior to disinfection. The presence of soil on the device after cleaning can make the disinfection less effective and lead to infection in patients. Additionally, failing to thoroughly clean the Probe can cause soil and residue to permanently adhere onto the Probe which can affect the Probe's performance and the efficacy of the high-level disinfection.

3. Install the cap onto the connector handle and hand-tighten securely. Tighten the cap until resistance is felt from the cap sealing o-ring,

then continue to tighten until the cap comes to a hard stop against the handle. The cap sealing o-ring should no longer be visible. Do not overtighten with extreme force.

4. Prepare the disinfecting solution according to the manufacturer's instructions and place in a large (approximately 17x12 x8) polypropylene tub or similar receptacle. The container should be sized to allow immersion of the complete Probe without excessive bending or kinking of the device.

5. Immerse the entire Probe in the disinfecting solution according to the times indicated in the table above. Flush the lumen with at least 10 ml of disinfecting solution at the beginning of the Probe immersion and keep the lumen filled with the disinfecting solution during the entire Probe soak time. Flush the lumen again with at least 10 ml of disinfecting solution at the end of the Probe soak time. Refer to section 3.5 Lumen Reprocessing below for additional information.

6. Replace gloves before removing the probe from the disinfection solution.

7. After the appropriate soak time has elapsed, purge the lumen with air using the syringe. Remove the Probe and rinse thoroughly with potable water or distilled water for a minimum of 1 minute. Flush the lumen with at least 10 ml of distilled water then purge the lumen with air using a syringe.

8. Flush the lumen with 10 ml of isopropyl alcohol then purge the lumen with air using the syringe.

9. After rinsing the entire Probe, gently pat the Probe until visibly dry using a soft gauze or lint-free cloth, taking care not to squeeze or pull on the sensors.

10. Allow the Probe to dry for a minimum of 5 minutes in ambient air before storage.

3.5 Lumen Reprocessing

The HRaM Probe utilizes a lumen to inflate a balloon. Even though the lumen is only charged with air during the study, it is critical that the lumen

be flushed when cleaning and disinfecting the Probe. The instructions above for reprocessing the Probe call out to flush the lumen at various steps. This section is intended to provide more details.

- Use at least a 10 ml size syringe for flushing the lumen.
- For all steps when flushing the lumen with cleaner, disinfectant or rinse water, use at least 10 ml of fluid.
- When soaking the Probe in the cleaner, always have the lumen filled with cleaner for the entire soak time.
- When soaking the Probe in the disinfectant, always have the lumen filled with the disinfectant for the entire soak time.
- When flushing, fill the syringe first then attach it to the lumen. Always flush the lumen so the fluid flows into the luer fitting and out the orifices at the tip of the Probe. Do not draw fluid into the syringe through the lumen.
- At the end of the reprocessing cycle, always purge the lumen with 10mL of isopropyl alcohol and air to dry before storing the device.

3.6 Device Storage

The Zvu® HRaM Probe is a reusable device that must be stored in a manner that keeps the device dry and safe from mechanical damage per your institution's practices for high-level disinfected devices.

3.7 Sterilization

Zvu® High Resolution Manometry Probes are not intended to be sterilized. The Probes should be cleaned and disinfected between each use as described above.

CAUTION: **DO NOT** sterilize Diversatek Healthcare High Resolution Manometry Probes. The sterilization process will damage the Probes.

Sterilization using any method is not permitted. Do not use any autoclave, (gamma) irradiation, low-temperature plasma sterilization, or ethylene oxide sterilization.

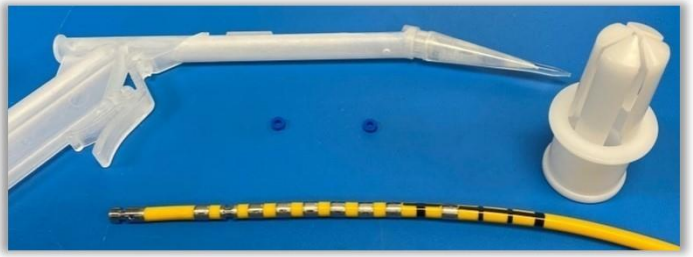
4 HRaM Balloon Attachment and Removal Instructions

The Zvu® High Resolution Anorectal Manometry (HRaM) Probe utilizes a single-use balloon that must be replaced for each patient study. Special care must be taken when attaching and removing the balloon to keep from damaging the Probe and ensuring the balloon is properly positioned and securely held in place.

Diversatek Healthcare has developed special tools that when used properly will minimize the chance of damaging the Probe. This section describes how to use these tools properly.

4.1 HRaM Balloon Attachment Steps

1. Gather equipment:
    a. One (1) Zvu® Anorectal Manometry (HRaM) Probe
    b. Two (2) Balloon Retention Bands
    c. One (1) Zvu® Anorectal Balloon
    d. One (1) Ligator



2. Insert the loading cone into the ligating drum of the Ligator and slide one band part way up the cone.

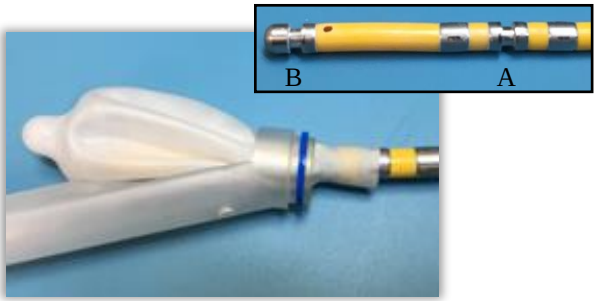
3. Place the base of the Band Pusher on a flat surface.
4. Insert the tip of the loading cone into the center of the Band Pusher fingers.

5. Push the Ligator straight down so the fingers of the Band Pusher move the band up the loading cone and onto the ligating drum.

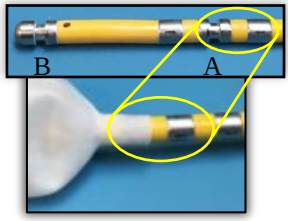
6. Remove the loading cone from the Ligator.

7. Insert the tip of the Zvu® Probe into the Zvu® Anorectal Balloon.

8. Insert the Probe and balloon into the lumen of the ligating drum and locate over slot A.



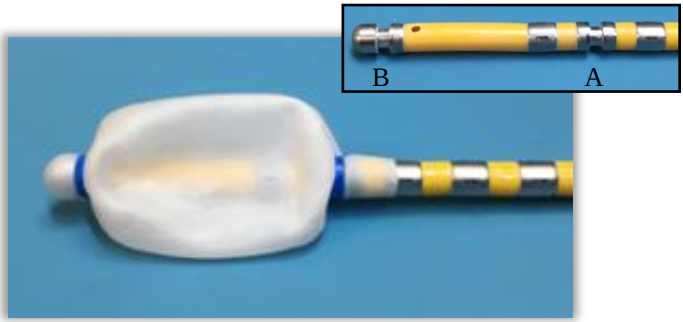
9. Position the end of the balloon so it is between slot A and the rectal sensor. Make sure the balloon neck is not covering the rectal sensor.



10. Check the alignment of the tool with the slot and avoid releasing the band over a sensor as this may damage the sensor.

11. Squeeze the trigger on the handle of the Ligator to release the band into the slot. Check that the band is properly seated.

12. Follow steps 2 through 6 for applying a second band in slot B.



4.2 HRaM Balloon Removal Steps

1. Gather equipment:
    a. One (1) Zvu® Anorectal Manometry (HRaM) Probe with Attached Balloon
    b. One (1) Band EZ-Removal Guide
    c. One (1) Band Removal Knife

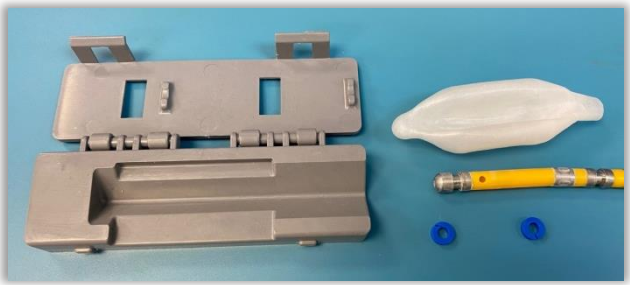
2. Remove the syringe from the lumen and gently squeeze the balloon to empty it of air. Do not cap the lumen until the balloon has been removed.

3. Place the tip of Probe into the EZ-Removal Guide, so that the tip rests against the end wall.

4. Close the lid, making sure the clips snap into place and the bands are accessible through the port holes.

5. Insert the tip of the Band Removal Knife blade under the band and pull upward to execute the cut. Repeat for the second band.

6. Remove the Probe from the EZ-Removal Guide. Slide the balloon off the tip of the Probe. Discard the Balloon and Retention Bands, EZ-Removal Guide and Band Removal Knife according to the facility's biohazard disposal policy.



7. Follow the reprocessing instructions for the Zvu® Probe listed above.

5 Preventative Maintenance

5.1 Preventative Maintenance Steps

The Zvu® HRaM Probe should be carefully examined for any damage prior to each use. This will help eliminate problems while a study is being performed and reduce the potential for patient injury.

- Check the Probe for damaged sensors (windows in sensor rings). Do Not use the Probe if there is any evidence of separation between the sensor areas and the stainless steel rings.
- Check the Probe for damaged tubing. Do Not use the Probe if there is any evidence of separation between the tubing and the stainless steel rings.
- Do Not use the Probe if there is any visible damage to the sensing portion of the Probe.
- Inspect the Probe connector for debris or liquid ingress.
- Inspect the Probe connection cable to ensure that there is no damage such as bent pins, broken or exposed wires, or debris.

5.2 Service

There are no serviceable components in the HRaM Probe. If necessary, the device should be returned to Diversatek Healthcare for repair. Contact Technical Support for information.

5.3 Decommissioning and Disposal

The HRaM Probe does not require decommissioning to remove it from service.

The device contains electronics and must be disposed of in accordance with facility policies and local regulations. For customers who do not have approved device disposal procedures, please go to the following website page for guidance:

Website URL: www.diversatekhealthcare.com/downloads
Document: Safe Disposal of Electrical/Electronic Medical Devices

6 Appendix

6.1 Technical Support

Contact Diversatek Healthcare by mail, telephone or e-mail. Please see the listings below for complete contact information.

Diversatek Healthcare strives to provide customers with the highest quality, state-of the-art instrumentation, backed by service, support and training. Service technicians are available via telephone on a 24-hour-a-day, seven-day-a-week basis.

MAIL:	Diversatek Healthcare Technical Research & Training Center 9150 Commerce Center Circle - Suite 500 Highlands Ranch, CO 80129 U.S.A.
WEBSITE:	www.diversatekhealthcare.com
E-MAIL:	Product Information and Demonstrations: sales@diversatekhc.com Clinical Support: clinicalsupport@diversatekhc.com Technical Support: technicalsupport@diversatekhc.com
TELEPHONE:	800.558.6408

For faster problem resolution, please gather as much of the applicable information as possible before contacting Technical Support.

- The type and model number of the equipment in question.
- The serial number or lot number of the equipment in question.
- The version number of the software and protocols in use.
- Your shipping address and a purchase order if repair or loaner/rental equipment is involved.

6.2 Declaration of Conformity

The Zvu® Anorectal Manometry (HRaM) Probe complies with the following standards:

Safety

- IEC 60601-1: 2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1:2012 reprint)
- IEC 60601-1-6:2010 (Third Edition) + A1:2013
- EN 60601-1 3rd Edition
- US National standard: ANSI/AAMI ES60601-1:2005 + A2(R2012) + A1
- Canadian National standard: CAN/CSA-C22.2 No. 60601-1:14
- Japan standard: JIS T0601-1:2012
- Korean standard: KS C IEC 60601-1

EMC

- IEC 60601-1-2: 4th Ed., 2014-02
- EN 60601-1-2: 2007
- EN 55011: 2009 + A1: 2010, Class A, Group 1
- CISPR 11, Ed. 5.1, 2010-05, Class A, Group 1

6.3 EMC Information

6.3.1 Environments of Intended Use

The HRaM Probe is intended for use in a Professional Healthcare Facility Environment defined as physician offices, dental offices, clinics, limited care facilities, freestanding surgical centers, freestanding birthing centers, multiple treatment facilities, hospitals (emergency rooms, patient rooms, intensive care, surgery rooms except near high frequency surgical equipment, outside the RF shielded rooms of an ME system for magnetic resonance imaging).

6.3.2 Essential Performance

The inSIGHT Ultima® System or PriZm® System does not have an essential performance function which results in an unacceptable risk or is critical to patient safety. The user must be a trained clinician familiar with the acquisition of anorectal motility studies and capable of recognizing physiological data. The impact of electromagnetic interference (EMI) during acquisition is presented as waveform artifact that is not similar to physiological data, such as severe discontinuities.

6.3.3 Adjacent and Stacked Use Warning

⚠ WARNING: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

6.3.4 List of Cables

The HRaM Probe requires a custom designed cable (Part No. H12R-7610) to connect the Probe to the inSIGHT Ultima® System or PriZm® System. Please contact Diversatek Healthcare Technical Support for assistance with ordering a replacement cable.

6.3.5 Accessories Warning

⚠ WARNING: 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.

6.3.6 Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
Diversatek Healthcare declares the Probe to be in compliance to the following standards and test levels.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The Probe, an accessory of the inSIGHT Ultima System and PriZm 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.
RF emissions CISPR 11	Class A	NOTE The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

6.3.7 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity	
Diversatek Healthcare declares the High Resolution Manometry Probe to be in compliance for electromagnetic immunity to the following tests and test levels.	
Immunity test	IEC 60601 test level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact, HCP and VCP ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	50 and 60 Hz, 30A/m, x, y, and z-axes
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms in ISM bands between 150 kHz and 80 MHz 80% AM at 1kHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz

Guidance and manufacturer's declaration – electromagnetic immunity to proximity fields from RF wireless communications equipment

Diversatek Healthcare declares the Probe to be in compliance for electromagnetic immunity to proximity fields from RF wireless communications equipment to the following test levels.

⚠ WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Probe, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	460-470	GMRS 460, FRS 460	FM +/-5 kHz deviation 1kHz sine	2	0.3	28
710 745 780	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	2	0.3	28
810 870 930	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

6.4 Specifications

6.4.1 High Resolution Anorectal Manometry Probe

Diversatek Healthcare Part Number:	HRAM-200
Channel Types:	Pressure
Dimensions:	
Diameter:	16.5Fr (5.56 mm)
Length:	145 cm (tip to connector)
Pressure sensor pitch	1cm
Patient Connection:	Isolated BF patient connection through signal conditioning modules.
Channels:	Depends on specific Probe configuration.
Probe Type:	Reusable, Non-sterile
Ingress Protection:	IPX5/IPX7 Liquid ingress protection effective against water projected by a nozzle and immersion up to 1 m depth.
Operating Environment:	
Temperature:	10°C - 40°C (50°F-104°F)
Relative Humidity:	0 - 80% RH, 31° C, decreasing linearly to 50% RH at 40° C sea level to 2,000 meters.
Storage/Transportation Environment	
Temperature:	10°C - 40°C (50°F-104°F)
Relative Humidity:	0 - 80% non-condensing
Atmospheric Pressure:	18.7 kPa – 101.3 kPa (Elevation 0 m – 12192 m)