



*High Resolution Impedance
Manometry Probe*

Installation and User's Guide

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Part Number:
HRIM-195-EN-US Rev D

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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



Attention -
Consult
Accompanying
Documents:

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.



Not Sterile:

The product associated with this symbol is not sterilized after manufacturing.



Manufacturer:

Name and location of legal manufacturer.



Serial Number:

Production identifier / serial number as noted.



Reference Number:

Device identifier / part number as noted.



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.



Medical Device

Indication the device 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.

Classifications

HRiM:

High Resolution Impedance Manometry.

inSIGHT Ultima®
PriZm®

Data acquisition system.

Probe

Patient applied sensor device.

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Contents

- 1 Introduction..... 1**
 - 1.1 How to Use This Guide..... 1
 - 1.2 CAUTION: Safety Instructions..... 2
 - 1.3 Product Description..... 4
 - 1.3.1 *Intended Use* 4
 - 1.3.2 *Contraindications*..... 4
 - 1.3.3 *Conditions of Warranty*..... 5
 - 1.3.4 *Biocompatibility*..... 5
- 2 System Components and Connections 6**
 - 2.1 Zvu® HRiM Probe System Configuration and User Guides 6
 - 2.2 Connecting the HRiM Probe to the Ultima Central Unit or PriZm Central Unit..... 7
 - 2.3 Basic Operation of the Probe 9
 - 2.3.1 *Operation* 9
 - 2.3.2 *Procedure*..... 9
 - 2.4 General Handling Precautions of the Probe 10
- 3 Reprocessing (Cleaning and Disinfection) 11**
 - 3.1 Important notes about cleaning 11
 - 3.2 Validated cleaning and disinfection solutions..... 13
 - 3.3 Cleaning Procedure 14
 - 3.4 High-Level Disinfection Procedure 16
 - 3.5 Device Storage 17
 - 3.6 Sterilization 17
- 4 Preventative Maintenance..... 18**
 - 4.1 Preventative Maintenance Steps 18
 - 4.2 Service 18
 - 4.3 Decommissioning and Disposal 18
- 5 Appendix..... 19**
 - 5.1 Technical Support 19
 - 5.2 Declaration of Conformity 20
 - 5.3 EMC Information..... 21
 - 5.3.1 *Environments of Intended Use* 21
 - 5.3.2 *Essential Performance* 21
 - 5.3.3 *Adjacent and Stacked Use Warning*..... 21
 - 5.3.4 *List of Cables* 21
 - 5.3.5 *Accessories Warning*..... 22
 - 5.3.6 *Electromagnetic Emissions* 22

5.3.7 *Electromagnetic Immunity* 23
5.3.8 *High Resolution Manometry Probe*..... 25

1 Introduction

1.1 How to Use This Guide

This guide is designed to help you install a Diversatek Healthcare Zvu® High Resolution Impedance Manometry (HRiM) Probe quickly and easily. It is intended for healthcare 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 5.1: Technical Support.

For detailed instructions on using the HRiM Probe refer to the application software and 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® HRiM 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 instructions 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® HRiM Probe and inSIGHT Ultima® System and PriZm® System are intended for use by gastroenterologists, surgeons, other trained physicians, and medically trained personnel as an aid in documenting and diagnosing digestive disorders. This system includes analysis software but requires interpretation by a physician to make a diagnosis.



CAUTION: Do not attempt to open or service the Zvu HRiM 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 4.3 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 HRiM Probe and cable 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: When using the esophageal HRiM Probe, in order to minimize the risk of nosebleed, use adequate lubrication with a water soluble lubricant for Probe intubation.



CAUTION: Use the HRiM Probe only with the approved Diversatek Healthcare inSIGHT Ultima System, PriZm System and application software, otherwise, patient injury or damage to the system or the Probe may occur.



CAUTION: Do not use the Zvu HRiM Probe with other non-Diversatek Healthcare equipment, otherwise, patient injury or damage to the Probe may occur.



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



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



NOTICE: Do not store the HRiM 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 HRiM 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 Intended Use

The Zvu® Esophageal High Resolution Impedance Manometry (HRiM) Probe is intended for use by gastroenterologists, surgeons, and medically trained personnel for gastrointestinal tract studies to obtain a high resolution mapping of peristaltic activity or pressure 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 esophageal motility disorders.

This device is indicated for use on adult populations only.

1.3.2 Contraindications

Esophageal manometry is contraindicated in the following situations:

- Suspicion or known pharyngeal or esophageal obstruction (e.g., tumors)
- Patients with severe clotting disorders
- Patients with known esophageal problems such as deep ulcers, varices, and Zenker's diverticula
- Deviated septum
- 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® Esophageal High Resolution Impedance Manometry Probe should only be used by or under the supervision of physicians thoroughly trained in esophageal 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® Esophageal High Resolution 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: The HRiM 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® HRiM Probe System Configuration and User Guides

The Zvu® Esophageal High Resolution Impedance Manometry (HRiM) Probe, when used in conjunction with the inSIGHT Ultima or PriZm Systems and Zvu Software provides pressure and impedance data useful as an aid in making a diagnosis of esophageal motility disorders. Refer to the user guides listed below for the inSIGHT Ultima System, PriZm System and Zvu Software for more detail.

Components:

- Zvu® HRiM Probe
- inSIGHT Ultima® System or PriZm® System
- Zvu Software

Manual Part Number	Title
H12R-0195	inSIGHT Ultima System with Zvu Installation and User's Guide
HRIM-195	High Resolution Manometry Probe Installation and User's Guide
H20-0195	PriZm System Installation and User's Guide
Zvu	See the electronic help information accessible from the Help icon within the software.

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

The Zvu HRiM 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



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 Probe

2.3.1 Operation

The Zvu® Esophageal High Resolution Impedance Manometry (HRiM) Probe, when used in conjunction with the inSIGHT Ultima System or PriZm System and Zvu Software, provides pressure and impedance data to aid in making a diagnosis of esophageal motility disorders. Refer to the user guides for the inSIGHT Ultima System, PriZm System and Zvu Software for more detail.

2.3.2 Procedure

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

1. For esophageal manometry studies, ensure the water in the water calibration tube is fresh (water should be changed daily) and is appropriately conductive by using a mixture of tap water and normal saline depending on the ionic content of the local water supply. Water should be at room temperature (20-40°C) when calibrating.
2. Connect the HRiM Probe to the inSIGHT Ultima System or PriZm System:
 - Align and connect the Probe to the Probe Accessory Cable. Alignment features on 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.
3. Power on all hardware.
4. Launch the Zvu Software.
5. Enter patient information into the software and use a workflow created for the model of probe being used.
6. Follow the software prompts to begin the acquisition process and perform the pressure calibration and pressure/impedance operational verification.
7. After successful calibration and operational verification, intubate the Probe and acquire the manometry study according to the on-screen prompts.
8. Upon completion of the study, extubate the Probe from the patient.

9. Disconnect the Probe from the cable and tighten the cap on the Probe handle.
10. 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.
11. 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, 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® HRiM Probe needs to be “reprocessed” to include enzymatic cleaning followed by high level disinfection (HLD). Thorough rinsing, preferably under running water, is recommended upon removal from the patient. Do not allow the Probe to dry after the procedure 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 Zvu® HriM Probe.

3.1 Important notes about cleaning



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



Note: The HriM 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.



CAUTION: Reprocess the HriM 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 submerge 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, alcohols, peracetic acid (such as Rapicide PA) with the Probe. Do not expose to alcohol, wound benzene, cresols, phenols, acetone, hydrogen peroxide (H₂O₂), mercury compounds, chlorides, sodium hypochlorite (bleach), xylenes, trichloroethylenes, Freon, or Bomix. These solutions will damage the sensors and voids the warranty.



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 HRiM 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® HRiM Probe. Failure to use one of 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
Cidex® (2.4% glutaraldehyde)	Full Strength	45 minutes @25°C	60 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 from the use of unapproved solutions or procedures is not covered under warranty.

3.3 Cleaning Procedure

The Zvu® High Resolution Impedance Manometry 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.
3. 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.
4. 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.
5. Immerse the entire Probe into the cleaning solution according to the soak times indicated in the table above.

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 and contact Technical Support.

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

6. Replace gloves before removing the Probe from the cleaning solution.
7. 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 (from the 70 cm mark to the tip) for at least 1 minute.
8. 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.
9. 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.
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. Do not soak the Probe longer than the maximum soak time as indicated in the table above.
6. Replace gloves before removing the probe from the disinfection solution.
7. After the appropriate soak time has elapsed, remove the Probe and rinse thoroughly with potable water or distilled water for a minimum of 1 minute.
8. 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.
9. Allow the Probe to dry for a minimum of 5 minutes in ambient air before storage.

3.5 Device Storage

The Zvu® HRiM 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.

3.6 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 Preventative Maintenance

4.1 Preventative Maintenance Steps

The Zvu® HRiM 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. Remove debris, clean out liquids and allow to dry before use.
- Inspect the Probe connection cable to ensure that there is no damage such as bent pins, broken or exposed wires, or debris. Do not use the cable if there is any signs of damage.

4.2 Service

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

4.3 Decommissioning and Disposal

The HRiM 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

5 Appendix

5.1 Technical Support

You can 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.
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WEBSITE:	www.diversatekhealthcare.com
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E-MAIL:	Product Information and Demonstrations: sales@diversatekhc.com
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	Clinical Support: clinicalsupport@diversatekhc.com
--	---

	Technical Support: technicalsupport@diversatekhc.com
--	--

TELEPHONE (24/7):	800.558.6408
Std hrs 7am – 5pm MST	303.470.7020
On-Call hrs 5pm – 7am MST	

For faster resolution to your problem, please gather as much of the applicable information as possible before contacting a service technician.

- 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.

5.2 Declaration of Conformity

The Zvu® Esophageal High Resolution Manometry 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

5.3 EMC Information

5.3.1 Environments of Intended Use

The High Resolution Impedance Manometry 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).

5.3.2 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 gastrointestinal tract 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.

5.3.3 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.

5.3.4 List of Cables

The 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.

5.3.5 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.

5.3.6 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.

5.3.7 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	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	2	0.3	28
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Specifications

5.3.8 High Resolution Manometry Probe

Diversatek Healthcare Part Number:	HRIM-201
Channel Types:	Pressure and Impedance
Dimensions:	
Diameter:	12Fr (4.19 mm)
Length:	189 cm (tip to connector)
Pressure sensor pitch	1 cm
Impedance sensor pitch	2 cm
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)