Diversatek Healthcare

MiVu™

Esophageal Endo Cap Mucosal Integrity Testing System

Instructions for Use

Read carefully prior to use

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

DiversatekHealthcare.com

Part Number: MI-ESO-CAP-195-EN-US Rev C

Notes, Notices, and Cautions in this 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 and/or Labeling

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.
Use-by Date:	Expiration date. (YYYY-MM-DD)
Do Not Re-use:	Marked on single use items to denote the device is single use only. The materials used in the manufacture of the device may not withstand repeated reprocessing. The device may not perform as intended by the manufacturer if it is reused. This may lead to failure of the device to perform as intended and/or material degradation.
Non-Sterile:	Indicates a medical device that has not been subjected to a sterilization process.
Do not discard	Device cannot be disposed in the regular waste stream. Special care for disposal is required.
Not made with natural rubber latex:	Not made with natural rubber latex.
Endoscope Diameter	The diameter of the endoscope supported by the device.
Part Number:	Device identifier / part number as noted.
Lot Number:	Lot number as noted.
Serial Number:	Production identifier / serial number as noted.
Manufacturer:	Name and location of legal manufacturer.

	Temperature Limit:	Indicates the temperature limits to which the medical device can be safely exposed.
	Do not use if package is damaged.	Device should not be used if the packaging has been damaged.
	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 for sale by or on the order of a physician.

MiVu™ Mucosal Integrity Testing System Classifications

	Type BF Applied Part:	This symbol indicates that the patient applied part is Type BF, (floating from electrical ground) which offers a specific level of safety.
	Class I Equipment:	Requires protective grounding.
	Ordinary Protection:	Not protected against ingress of moisture. Equipment is not suitable for use with flammable anesthetics.

Abbreviations and Acronyms

A/D:	Analog-to-Digital converter; an electronic circuit or device that converts an analog input signal into a digital signal.
PriZm®	PriZm® manometry acquisition system.
Zvu®	Diversatek Healthcare's software suite for data acquisition and analysis with the PriZm® system.
Esophageal Endo Cap	Endoscope cap for MiVu™ Esophageal Testing. Patient applied sensor device.

DISCLAIMER: The information in this manual is subject to change without notice. Diversatek Healthcare makes no representations or warranties with respect to the contents hereof, and specifically disclaims any implied warranties of merchantability or fitness for a particular purpose. Diversatek Healthcare reserves the right to revise this publication and to make changes from time to time in the content hereof without obligation of Diversatek Healthcare to notify any person of such revisions or changes.

Trademarks used in this text: *PriZm®, Zvu®, and MiVu™* are trademarks of Diversatek Healthcare, Inc.; *Dell* is a trademark of Dell Inc.; *Intel*, *Pentium* are registered trademarks of Intel Corporation; *Microsoft* and *Windows* are registered trademarks of Microsoft Corporation.

Other trademarks and trade names may be used in this document to refer to either the entities claiming the marks and names or their products. Diversatek Healthcare, Inc. disclaims any proprietary interest in trademarks and trade names other than its own.

Contents

1 Introduction

1.1 How to Use This Guide

This guide is designed to help you use the MiVu™ Mucosal Integrity Testing System. It is intended for healthcare professionals trained in performing clinical procedures utilizing the MiVu System and the Zvu® Software.

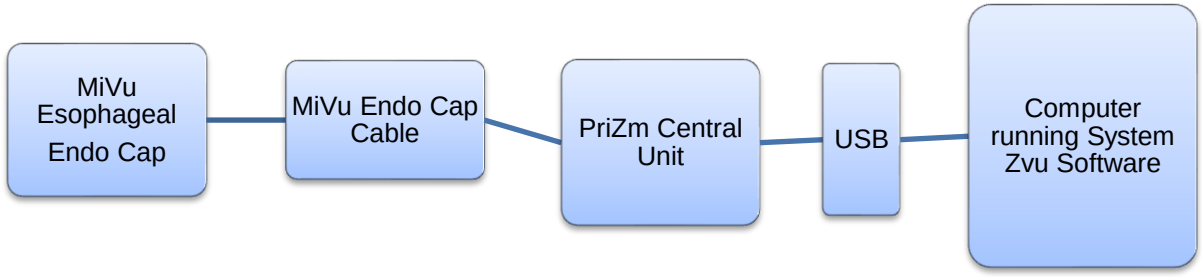
Note: Additional information concerning the features and use of the rolling cart and other system components can be found in the PriZm® System Installation and User's Guide (H20-0195).

See contact information on the cover page or in section 7 Technical Support.

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

List and Description of Components of the MiVu™ Mucosal Integrity Testing System

a) PriZm Central Unit and USB cable
b) Zvu Software, computer, and monitor
c) MiVu Endo Cap device
d) MiVu Endo Cap Cable



1.2 CAUTION: Safety Instructions

The MiVu™ System is a sensitive electronic instrument. Please use the following safety guidelines to help ensure your own personal safety and to help protect your MiVu System 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 users of the device are advised to thoroughly understand the use of the equipment and familiarize themselves with the location and function of all controls and alarms prior to using the equipment.

⚠ CAUTION: The MiVu Mucosal Integrity Testing System is indicated for use by gastroenterologists, surgeons, and medical personnel trained in endoscopic procedures during an endoscopy to obtain real-time measurement of esophageal epithelial impedance. The device is not for use as a sole diagnostic screening tool.

⚠ CAUTION: Do not attempt to use the MiVu Endo Cap Cable unit with any system other than the PriZm System. Failure to do so could damage the unit or result in injury to the user or patient.

⚠ CAUTION: Do not use the MiVu System in association with an MRI machine. The MiVu System contains sensitive electronics not designed to operate in the extensive magnetic fields of an MRI machine.

⚠ CAUTION: Do not use the MiVu System in emergency situations or for patient treatment or monitoring. The system is designed for diagnostic use only in non-emergency situations.

⚠ CAUTION: Do not get the MiVu System, the MiVu Endo Cap Cable or other signal conditioning devices wet. These devices are not waterproof.

⚠ CAUTION: Do not attempt to open or service the MiVu System or any of its components. There are no user serviceable parts inside.

⚠ CAUTION: Discard all used disposable items in accordance with local biohazard requirements. Refer to section 5.2 Decommissioning and Disposal for additional information.

⚠ CAUTION: Dispose of the MiVu System in accordance with local ordinances and regulations. Refer to section 5.2 Decommissioning and Disposal for additional information.

⚠ CAUTION: Do not drop the MiVu System or the MiVu Endo Cap Cable unit.

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

⚠ CAUTION: Do not use the MiVu System in an oxygen rich environment.

⚠ CAUTION: Any serious incidents that occur in relation to the MiVu System should be reported to Diversatek and the Competent Authority.

⚠ CAUTION: Do not use the MiVu System in close proximity to common RF emitters such as RFID readers, NFC systems, wireless power transfer/charger systems, electrocautery, MRI, electrosurgical and diathermy equipment as this may affect the performance of the MiVu System and the data collected. Refer to section 7.3 for additional information.

NOTICE: Do not store the MiVu System or any of its components in extreme temperatures. The MiVu System is best stored between 50° and 104°F (10° to 40°C).

1.3 Product Description

1.3.1 Overview and Intended Use

The MiVu Mucosal Integrity Testing System is intended to evaluate esophageal epithelial integrity to determine esophageal abnormalities by means of a device with direct electrical contact with the esophageal mucosal epithelium. The system includes associated signal conditioning hardware and software for measuring and displaying information.

Diversatek Healthcare's MiVu Mucosal Integrity Testing System utilizing the MiVu Esophageal Endo Cap is used in conjunction with an endoscope procedure. The MiVu Esophageal Endo Cap acquires impedance readings across a 3 cm length. The MiVu Esophageal Endo Cap is mounted on the working end of the endoscope and allows for direct visual placement of the device's sensors on the tissue area of interest.

The MiVu System consists of the patient-contacting MiVu Esophageal Endo Cap and the external components of the system including cables, and data acquisition hardware (PriZm) and firmware systems to facilitate the mucosal conductivity measurements. A computer, Diversatek Healthcare's custom Zvu® Software, and a monitor are the final components of the system and are used to display and analyze the impedance information of the mucosa to the clinician.

1.3.2 Indications for Use

The MiVu Mucosal Integrity Testing System is indicated for use by gastroenterologists, surgeons, and medical personnel trained in endoscopic procedures during an endoscopy to obtain real-time measurement of esophageal epithelial integrity as an adjunct for the evaluation of esophageal disorders. The device is not for use as a sole diagnostic screening tool.

The system software requires skilled interpretation by a physician to make a diagnosis.

The MiVu System is approved for adult use only.

The MiVu System is for prescription use only.

Please refer to the PriZm System Installation and User's Guide (H20-0195) for additional information.

1.3.3 Contraindications

There are no known contraindications beyond those for routine endoscopic procedures. The MiVu Mucosal Integrity devices must be used in accordance with the indications for use.

There are no known contraindications for patient contact reactions. The MiVu Esophageal Endo Cap is not made with natural rubber latex.

1.3.4 Potential Complications

Potential complications associated with gastrointestinal endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest.

1.3.5 Biocompatibility

The patient contacting components of the MiVu System utilize common materials with no known biocompatibility issues. However, the following cautions should be observed:

CAUTION: The MiVu Esophageal Endo Cap utilizes nickel that is plated with gold. This use of nickel may pose risks for people with certain allergies to nickel.

The MiVu Esophageal Endo Cap is free from natural latex rubber, BPA (bisphenol A), phthalates, and CMR (carcinogenic, mutagenic or toxic to reproduction) substances.

2 Getting Started

The following chapters describe how to connect the different accessories to the PriZm System and the basic procedural steps of a mucosal integrity study.

2.1 User Manuals

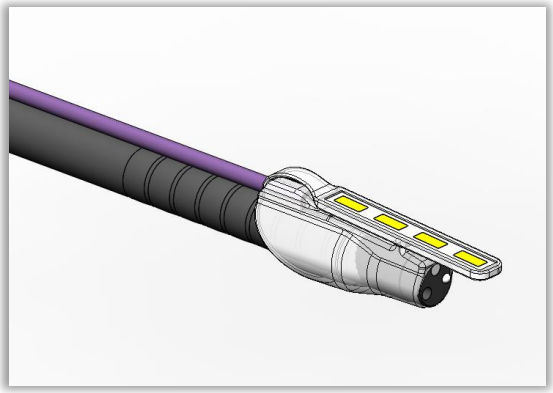
In addition to this manual, please refer to the H20-0195: PriZm System Installation and User's Guide for additional information. An electronic copy is installed on the system PC with the Zvu® Software.

2.2 Disinfecting System Components Prior to First Use

All reusable accessories need to be cleaned and disinfected prior to use. See chapter 4 for further instructions.

3 MiVu™ Esophageal Endo Cap Configuration

This configuration of the MiVu Mucosal Integrity System is intended for obtaining data concerning the integrity of the esophageal mucosa. The single-use MiVu Esophageal Endo Cap utilizes a small strip of three impedance sensors on a tubular tip that is placed over the working end of an endoscope. This allows for direct control of the placement of the sensors without impeding the optics and working channel of the endoscope.



During the endoscopic procedure, the physician will take multiple impedance readings of the mucosa to span a minimum of 10 cm, which the Zvu software will use to construct a composite esophageal integrity image. Once enough readings are obtained over a 10 cm section of the esophagus, the Zvu software will use the impedance values to calculate the disease probabilities for GERD (Gastro-Esophageal Reflux Disease), non-GERD and EoE (Eosinophilic Esophagitis). A study report may then be generated. The study data are used as one of the inputs for developing the patient's treatment plan.

The accessories for this configuration consist of the MiVu Endo Cap Cable and the MiVu Esophageal Endo Cap device. This chapter describes how to connect the accessories to the MiVu PriZm System and the basic procedural steps for a study.

Note: For MiVu Mucosal Integrity study acquisition, Diversatek Healthcare recommends that two people be present to conduct the study. While the physician is operating the endoscope with the Esophageal Endo Cap device attached, an assistant must operate the software to capture measurements. It is also important to communicate clearly about the status of the measurement quality indicators displayed by Zvu, including device positioning information and when to capture a measurement.

3.1 Connecting to the PriZm System

3.1.1 MiVu™ Endo Cap Cable

The MiVu Endo Cap Cable is a signal conditioning accessory for use with the MiVu System.

All patient-connected sensors utilized with the MiVu System are Type BF patient applied parts. Type BF indicates that the patient applied part is floating from electrical ground. These parts should only be connected to the appropriate ports on the PriZm Central Unit. Connectors are keyed to prevent inappropriate connection not intended by the design.

3.1.1.1 Connecting MiVu Endo Cap Cable to the PriZm® Central Unit

The MiVu Endo Cap Cable will connect to the PriZm Central Unit using the Port 1 connector. When the device is properly connected, the Port 1 indicator LED on the side panel of the PriZm Central Unit will illuminate in blue.

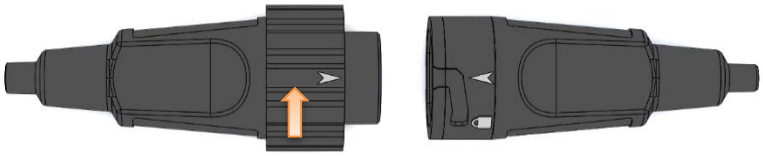
Port 1 Connector

Port Status LEDs

3.1.1.2 Connecting the MiVu Esophageal Endo Cap to the MiVu Endo Cap Cable

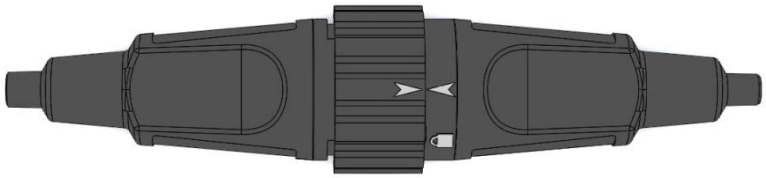
The MiVu Esophageal Endo Cap connects to the MiVu Endo Cap Cable and is secured by a locking ring. Do not try to force the connectors together if the two connectors do not slide together easily. The connectors are keyed so they can only fit together in one orientation.

a) Align the arrows on the two connectors so they are pointing to each other. The locking ring on the cable rotates, so you may need to twist the locking ring (up, in the image at left) so they align.

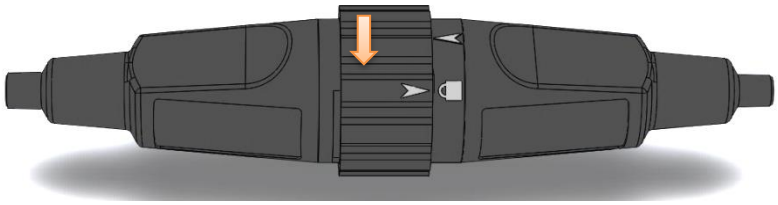


Left – MiVu Endo Cap Cable Right - MiVu Endo Cap device

b) Slide the two connectors together so they are fully seated. Do not try to force the connectors together, if the two connectors do not slide together easily. Check the alignment of the connectors and twist the locking ring so they align.



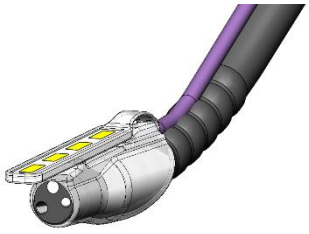
c) Twist the locking ring so the arrow on the locking ring points to the lock symbol on the Endo Cap device (down, in the image at left).



3.1.1.3 Positioning the MiVu™ Esophageal Endo Cap on the endoscope

The MiVu Esophageal Endo Cap is designed to fit over the working end of the endoscope without obstructing the optics or working channel of the scope.

a) Use a small amount of lubricant on the sides of the endoscope. Slide the Endo Cap tip onto the working end of the endoscope as shown in the images on the right. Make sure the face of the endoscope end is flush with the opening of the tip. The tip should have a snug fit on the endoscope. The sensors should be aligned at the 12 o'clock position, as controlled by the Big Wheel of the endoscope.



3.2 Mucosal Integrity Conductivity Test (MI) Procedure using the MiVu Esophageal Endo Cap

This section describes the basic procedural steps to record the necessary data for a Mucosal Integrity - Esophageal study using the MiVu™ Mucosal Integrity Testing System with the MiVu Esophageal Endo Cap and Zvu® Software.

Note: The MiVu Endo Cap device utilizes a security feature that limits the device to a single use. When the Acquire button in Zvu is first clicked when using the MiVu Endo Cap, the device has a one-hour period during which it must be used. During this period, Zvu will allow a study to be restarted in case there are unforeseen interruptions, such as a loss of power. After the hour period, if a study acquisition is attempted using the same device, Zvu will report the device has been used and will not allow the study acquisition to begin.

3.2.1 Preparation

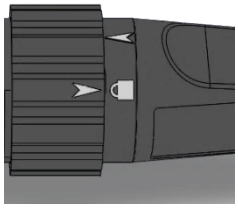
a) Remove the MiVu Esophageal Endo Cap from the box and inner tray.

b) Inspect the device for any signs of damage. If damage is present, do not use the device.

c) Attach the Endo Cap tip to the working end of the endoscope making sure the tip has a tight grip to the scope.

d) Lay the Endo Cap wire along the length of the endoscope to the scope's handle.

e) Attach the device connector to the mating connector on the MiVu Endo Cap Cable and twist the cable's locking ring to secure them together. The arrow on the locking ring will point to the lock symbol on the probe connector.



3.2.2 Data Acquisition

Please refer to the PriZm® User's Manual (H20-0195) for additional information concerning the operation of the PriZm System and the Zvu® Software. Refer to the MiVu™ Guide: Endo Cap Acquisition and Analysis for details on data acquisition.

After powering up the PriZm System, launch the Zvu Software. In the Patient Management module, add the patient data, create a Mucosal Integrity - Esophageal workflow and select the probe type being used. Add a study to the patient using the workflow just created and click the Save button to save the changes. Finally, click the Acquire button and follow the on-screen prompts for acquiring the study. Please refer to the Zvu help menu for additional information about using Zvu.

Note: Prior to intubating the patient, start acquisition in Zvu to verify the MiVu System components are communicating properly.

a) Begin the upper endoscopy procedure. As the endoscope passes through the oral cavity, the sensor surface should be in contact with the patient's tongue. As the endoscope approaches the larynx and the esophageal inlet, the sensor surface is oriented anteriorly.
b) Gently introduce the tip of the Endo Cap posterior to the arytenoids, into the esophageal inlet, avoiding contact with the larynx. Do not use excessive force.
c) Rinse and suction the esophagus as needed to remove excess fluid or foam.
d) Place the tip of the endoscope 2 cm above the squamocolumnar junction (SCJ).
e) While visually observing the video endoscopic image on the monitor, rotate the Endo Cap sensor surface to between 6 o'clock and 9 o'clock position.
f) Adjust the sensor position as needed to achieve all "Green", Measurement Quality Indicator bubbles on the Zvu Acquisition Screen. Capture the measurement and repeat if necessary.
g) Withdraw the endoscope 3 cm to the next measurement location. Repeat step (e).
h) A minimum of four (4) measurement levels must be taken to activate the Disease Probability calculation.
i) After all measurements are taken, gently withdraw the endoscope. Should the Endo Cap device appear to be moving off the endoscope, gently pull the Endo Cap conduit tubing to keep it from slipping further. Stop the extraction if there is any resistance that might lead to patient injury.

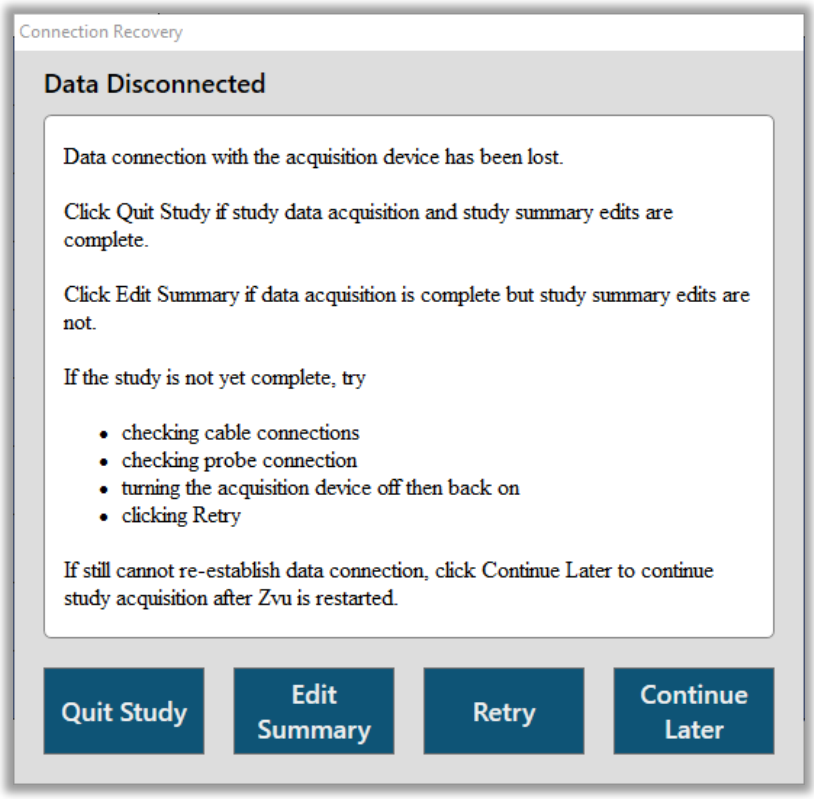
Note: Perform the mucosal impedance study before taking biopsies of tissue so the compromised tissue and the presence of blood does not impact the mucosal impedance readings.

3.2.3 Post-Procedure

a) Remove the MiVu Esophageal Endo Cap tip from the end of the endoscope.

b) Disconnect the MiVu Esophageal Endo Cap from the cable by twisting the connector locking ring so the arrow on the ring points to the arrow on the device connector, then pull the connectors apart.

Note: When the Endo Cap device is disconnected from the MiVu Endo Cap Cable, the system will detect the disconnection and Zvu will display the message shown below if it is still on the Acquisition screen. If the study data are acquired and the study edits are complete, click the Quit Study button to save the acquired data and close the study. If the study data are acquired but the study summary requires editing, click the Edit Summary button.



c) Dispose of the MiVu Esophageal Endo Cap according to the institution's procedure for disposable medical equipment. The MiVu Esophageal Endo Cap is a single-use device and must not be re-used.

4 Cleaning and Disinfecting the Components of the MiVu™ Mucosal Integrity Testing System

4.1 Single-use, Disposable Items

The MiVu™ Esophageal Endo Cap is a single-use, non-sterile device that does not require cleaning before use. After use, this device must be disposed of according to local or facility regulations pertaining to biohazardous disposable medical devices.

4.2 PriZm®, Cart and Computer

Clean the outside only of the PriZm Central Unit, cart, computer, and monitor as needed with disinfectant solutions or an approved hospital grade wipe defined by the appropriate rules of the using institution. Do not immerse these items in water or any other solution as this may cause damage to the sensitive electronics inside.

NOTE: Always apply cleaning solution to a soft cloth and then wipe the equipment. Never apply liquid directly to the equipment.

4.3 MiVu™ Endo Cap Cable

The MiVu Endo Cap Cable is a non-patient contacting, reusable device that might be subjected to incidental contact of patient contaminants. As a result, it must be cleaned and low-level disinfected immediately after each procedure. This section describes the necessary steps and lists the approved solutions for use to properly clean and disinfect this equipment.

4.3.1 Important Notes about Cleaning

Note: The MiVu Endo Cap Cable is not disinfected prior to shipment. A proper cleaning and disinfection cycle is required before the initial use.

Note: The MiVu Endo Cap Cable must be reprocessed immediately after each patient use.

CAUTION: Clean and disinfect the MiVu Endo Cap Cable 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 devices.

CAUTION: **DO NOT** Sterilize the MiVu Endo Cap Cable. Steam sterilization and other methods of sterilization with a temperature above 70°C / 160°F are not permitted. Do not use any autoclave or (gamma) irradiation, and or low-temperature plasma sterilization like STERRAD® (due to high hydrogen peroxide (H_2O_2) concentration).

NOTICE: The USER is responsible for cleaning and disinfection of the MiVu Endo Cap Cable. Only the procedures and products described below are validated and qualified for proper cleaning and disinfection of the reusable components of the MiVu Mucosal Integrity Testing System. Additionally, please pay attention to the protocols, regulations, and guidelines of your facility.

4.3.2 Validated Cleaning and Disinfection Solution

The following table lists the cleaning and disinfection solution validated by Diversatek Healthcare for use with the MiVu™ Endo Cap Cable. Failure to use this approved solution may damage the devices and void the warranty.

Validated Cleaning and Disinfecting Wipes	Recommended Minimum Exposure Time for Disinfection
Super Sani-Cloth® Germicidal Disposable Wipe (Reorder numbers Q55172, Q86984, H04082, or U87295)	3 minutes

The Super Sani-Cloth® Germicidal Disposable Wipe from PDI Healthcare is a pre-moistened nonwoven durable wipe containing a quaternary ammonium chloride/alcohol-based solution. Visit pdihc.com for more info.

4.3.3 Cleaning Procedure

The MiVu Endo Cap Cable should be cleaned immediately after use.

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

2. Use a new wipe (from the list above) to thoroughly clean and scrub the entire MiVu Endo Cap Cable (includes connectors). Clean all visible soil from the cable and continue to clean until the cable is thoroughly clean and free of any visible soil. Replace the wipe as necessary to ensure the MiVu Endo Cap Cable is thoroughly cleaned. Once cleaned, place the cable on a clean surface.

3. Replace gloves. Use a new wipe to thoroughly clean and scrub the MiVu Endo Cap Cable. Clean all visible soil and continue to clean until the MiVu Endo Cap Cable is thoroughly clean and free of any visible soil. Replace the wipe as necessary to ensure the MiVu Endo Cap Cable is thoroughly cleaned. Once cleaned, place the MiVu Endo Cap Cable on a clean surface.

   Note: If the MiVu Endo Cap Cable is still visibly soiled after scrubbing with the wipe, repeat the cleaning steps above. If visible soil remains after the second cleaning cycle, **STOP** the reprocessing steps, and contact Technical Support.

   The MiVu Endo Cap Cable must be thoroughly clean and free of visible soil before the disinfection step.

4. Following the cleaning, allow the MiVu Endo Cap Cable to air dry completely.

5. Visually inspect the MiVu Endo Cap Cable after cleaning for damage, corrosion, cuts, punctures, and cracked seals. If any damage is found, **STOP** the cleaning and disinfecting steps, and contact Technical Support.

4.3.4 Low-Level Disinfection Procedure

Carefully follow the instructions below. Not following these instructions may result in ineffective disinfection or damage to the MiVu Endo Cap Cable.

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

2. Ensure the entire MiVu Endo Cap Cable has been thoroughly cleaned prior to disinfection. The presence of soil on any device after cleaning can make the disinfection less effective.

3. Use new wipes (from the list of validated wipes) to thoroughly contact and saturate all external parts of the MiVu Endo Cap Cable. Use multiple wipes, as necessary, to fully saturate all surfaces of the cable. Allow the disinfectant to saturate all external surfaces of the cable for a minimum of three (3) minutes. Place the cable on a clean surface to air dry completely.

4. Replace gloves and visually inspect the MiVu Endo Cap Cable after disinfection for damage, corrosion, cuts, punctures, and cracked seals. If any damage is found, **STOP** the disinfecting steps and contact Technical Support.

5. Allow the MiVu Endo Cap Cable to dry for a minimum of five (5) minutes in ambient air before storing in a cool, dry location.

4.3.5 Reusable Device Storage

The MiVu Endo Cap Cable 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 storage of low-level disinfected devices.

4.3.6 Do not Sterilize

The MiVu Endo Cap Cable is not intended to be sterilized. This reusable component of the MiVu Mucosal Integrity Testing System should be cleaned and disinfected between each use as described above.

⚠ CAUTION: **DO NOT** Sterilize the MiVu Endo Cap Cable. Steam sterilization and other methods of sterilization with a temperature above 70°C / 160°F are not permitted. Do not use any autoclave, (gamma) irradiation, or low-temperature plasma sterilization like STERRAD® (due to high hydrogen peroxide (H_20_2) concentration). The sterilization process will damage these devices.

5 Preventative Maintenance

The MiVu™ Mucosal Integrity Testing System should be periodically examined to ensure the devices are in working order. This will help eliminate the chance for trouble when a mucosal integrity study is being performed. Visually inspect all system components for damage, corrosion, cuts, and punctures. If any damage is found, do not use the system, and contact Technical Support for assistance.

Contact Diversatek Healthcare for replacement devices or repair services.

5.1 Service

There are no serviceable components in the MiVu Endo Cap Cable and PriZm® Central Unit. If necessary, the device should be returned to the manufacturer or manufacturer's representative for repair.

5.2 Decommissioning and Disposal

The MiVu Endo Cap is a single-use, non-sterile device. Upon completion of the procedure, dispose of the soiled device per institutional guidelines for biohazardous medical waste.

The MiVu Endo Cap Cable and PriZm Central Unit do not require decommissioning to remove from service.

The MiVu Endo Cap Cable and the PriZm Central Unit contain 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 Cybersecurity

Diversatek Healthcare will provide software upgrades through its sales representatives or technical support. Users should install all upgrades and updates within a reasonable amount of time after receipt.

To keep the software secure, please adhere to the following recommendations:

6.1 Software Environment

Maintain all operating systems by regularly downloading upgrades.

6.2 Firewall

Use a firewall on all computers running Diversatek Healthcare software. Diversatek Healthcare software does not require any ports to be open.

6.3 User Access Control

All users of Diversatek Healthcare software are recommended to have uniquely assigned accounts.

7 Technical Support

7.1 Contact Information

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.

MAIL:	Diversatek Healthcare, Inc. 9150 Commerce Center Circle Suite 500 Highlands Ranch, CO 80129 U.S.A.
WEBSITE:	www.diversatekhealthcare.com
E-MAIL:	Product Inquiries and Quotations: sales@diversatekhc.com Clinical Education: clinicaleducation@diversatekhc.com Clinical Support: clinicalsupport@diversatekhc.com Technical Support: technicalsupport@diversatekhc.com
TELEPHONE:	800-558-6408

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 email address or FAX number.
- Your shipping address and a PO if repair or loaner/rental equipment is involved.

7.2 EMC Information

The MiVu System incorporates the PriZm® System components which includes the PriZm Central Unit, isolation transformer, rolling cart, PC and monitor. Refer to the IFU for the PriZm System (H20-0195) for additional information.

7.2.1 Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The MiVu System is intended for use in the electromagnetic environment specified below. The customer or the user of the MiVu System should ensure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The MiVu 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	The MiVu System is suitable for use in all establishments other than domestic, and those directly connected to the public low-voltage power supply network that supplies building used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

7.2.2 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The MiVu System is intended for use in the electromagnetic environment specified below. The customer or the user of the MiVu System should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) (differential mode) ± 2 kV line(s) to earth (common mode)	± 1 kV line(s) to line(s) (differential mode) ± 2 kV line(s) to earth (common mode)	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the MiVu System requires continued operation during power mains interruptions, it is recommended that the MiVu System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The MiVu System is intended for use in the electromagnetic environment specified below. The customer or the user of the MiVu System should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the MiVu System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 0.6\sqrt{P}$ where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the MiVu System is used exceeds the applicable RF compliance level above, the MiVu System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the MiVu System. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

7.2.3 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment the MiVu System

The MiVu System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the MiVu System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the MiVu System as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.5 GHz
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

7.2.4 IEC 60601-1-2 Compliance Summary

Tests performed in accordance with (ABNT NBR) IEC 60601-1-2:

Standard	Test	Result
(ABNT NBR) IEC/CISPR 11:2012	Conducted Emissions	Approved
(ABNT NBR) IEC/CISPR 11:2012	Radiated Emissions	Approved
IEC 61000-3-2:2009 + A1: 2020	Harmonic current emissions	Approved
IEC 61000-3-3:2013 +A1: 2017	Voltage changes, fluctuation and flicker	Approved
(ABNT NBR) IEC 61000-4-2:2013	Electrostatic Discharge	Approved
(ABNT NBR) IEC 61000-4-3:2014	Radiated RF Immunity	Approved
(ABNT NBR) IEC 61000-4-3:2014	Radiated RF Immunity from wireless communications equipment	Approved
(ABNT NBR) IEC 61000-4-4:2015	Electrical Fast Transients (EFT)/burst immunity	Approved
IEC 61000-4-5: 2014 +A1: 2017	Surge Immunity	Approved
IEC 61000-4-6:2013	Conducted RF Immunity	Approved
IEC 61000-4-8:2009	Power Frequency H- Field Immunity	Approved
IEC 61000-4-11:2004 + A1: 2017	Voltage dips, short interruptions and voltage variations Immunity	Approved

7.3 Special Information Concerning Common RF Emitters

When operating the MiVu Mucosal Integrity System, special care should be taken to not use devices that emit radio frequencies (RF) in close proximity to the system components as this may affect the operation of the system or compromise the data collected. Some of the common RF emitters that could be found in the professional medical office environment include the following:

- Identification (RFID) readers
- Near-field communications (NFC) systems
- Wireless power transfer/charging systems
- Cellular phones
- Electrocautery devices
- MRI
- Electrosurgical units
- Diathermy equipment

Please keep in mind that some emitters, such as RFID readers, may be built into other systems and hidden from view. If you suspect interference from an unknown source, stop the procedure until the source can be identified.

8 Appendix

8.1 Specifications

Please refer to the PriZm® System Installation and User's Guide (H20-0195) for additional information about the system.

8.1.1 MiVu Endo Cap Cable

Diversatek Healthcare Part Number:	MI-CAB-02	
Dimensions:		
Length:	6 ft	(1.8 m)
Weight:	0.5 lb	(0.2 Kg)
Power Source:	DC power provided by the PriZm Central Unit.	
Patient Connection:	Isolated BF patient connection.	
Channels:	3 Impedance	
Analog to Digital Conversion:	16 bit (provided by the PriZm Central Unit)	

8.1.2 MiVu Esophageal Endo Cap

Diversatek Healthcare Part Number:	MI-ESO-CAP-3L
Endoscope Diameters:	9.9 mm
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)