Diversatek Healthcare

MiVu™ *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 800.558.408 or 303.470.7020

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

DiversatekHealthcare.com

Part Number: MI-195-EN-US Rev B

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

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.
Use-by Date:	Expiration date. (YYYY-MM-DD)
Do Not Reuse:	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.
Not Sterile:	The product associated with this symbol is not sterilized after manufacturing.
Temperature limitation:	Storage temperature limitations as noted.
Keep dry:	Keep device dry during storage.
Not made with natural rubber latex:	Not made with natural rubber latex.
Medical Device	Indication the device is a medical device.
Part Number:	Device identifier / part number as noted.
Lot Number:	Lot number as noted.
Serial Number:	Production identifier / serial number as noted.
Manufactured By:	Name and location of legal manufacturer.

	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 to sale by or on the order of a physician.

MiVu™ Mucosal Integrity Testing System 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 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.
Balloon Probe	Patient applied sensor device.
Zvu®	Diversatek Healthcare's software suite for data acquisition and analysis with the PriZm® system.

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: *inSIGHT Ultima®, 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

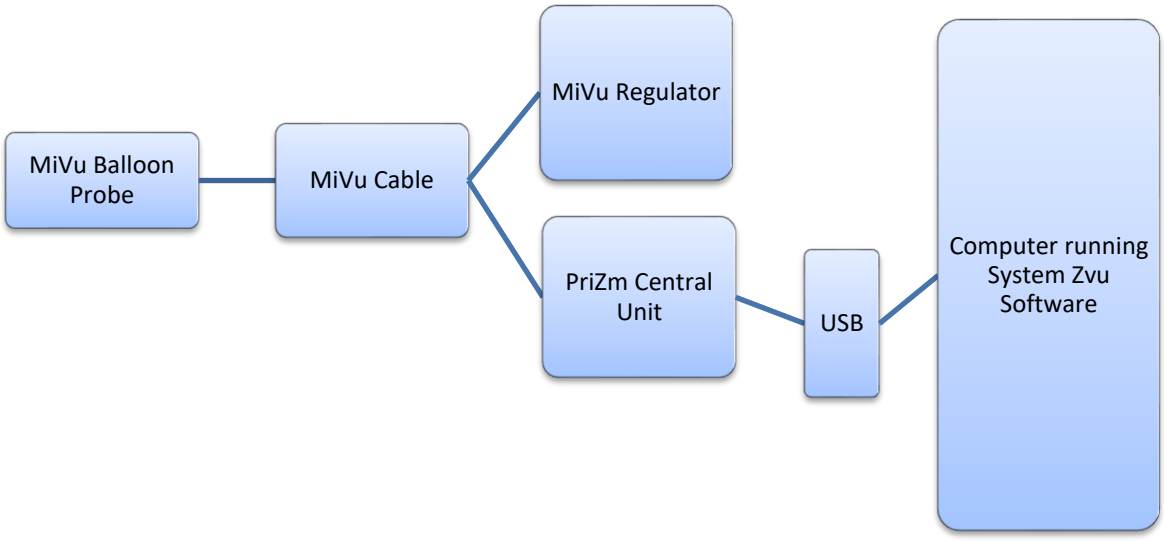
This guide is designed to help you use the MiVu™ Mucosal Integrity Testing System. It is intended for health-care professionals trained in performing clinical procedures utilizing the MiVu System and the Zvu® Software. Additional information is also found in the PriZm® System Installation and User's Guide (H20-0195).

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

The 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) MiVu Mucosal Integrity Balloon Probe
b) MiVu Cable
c) MiVu Regulator
d) PriZm Central Unit and USB cable
e) Zvu Software, computer, and monitor



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 System is 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 skilled interpretation by a physician to make a diagnosis.

⚠ CAUTION: Do not attempt to use the MiVu 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 MiVu System, MiVu 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 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.

NOTICE: Do not store the MiVu System or any of its components in extreme temperatures. The MiVu System is best stored between 33° and 160°F (1° to 70°C).

1.3 Product Description

1.3.1 Overview

Diversatek Healthcare's MiVu™ Mucosal Integrity Testing System consists of a patient-contacting balloon probe with the remainder of the system outside the patient. The external components of the system include cables, an inflation regulator, and data acquisition hardware/firmware systems to facilitate the mucosal conductivity measurements of the system. 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 esophageal mucosa to the clinician.

1.3.2 Intended Use and Indications for Use

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

The MiVu Mucosal Integrity Testing System is indicated for use by gastroenterologists, surgeons, and medically trained personnel 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 a skilled interpretation by a physician to make a diagnosis. 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, but it must be used in accordance with the indications for use.

There are no known contraindications for patient contact reactions. The MiVu Balloon Probe 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 MiVu System components utilize common materials with no known biocompatibility issues. However, the following cautions should be observed:

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

2 Getting Started

The MiVu™ Mucosal Integrity Testing System consists of the PriZm® System, the MiVu Cable and the MiVu Balloon Probe. This chapter describes how to connect the MiVu Cable to the PriZm and attach the MiVu Balloon Probe. It also covers proper positioning of the MiVu Balloon Probe within the patient and describes the user controls available to the operator.

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 section 4 for further instructions.

2.3 Connecting to the PriZm System

2.3.1 MiVu™ Cable

Diversatek Healthcare's MiVu Cable is a signal conditioning accessory for use with the PriZm Motility System. The PriZm provides impedance signal conditioning.

All patient connected balloon probes/sensors utilized with the PriZm Motility 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 of the signal conditioning units, i.e., they must not be connected to any port on the central unit directly. Connectors are keyed to prevent inappropriate connection not intended by the design.

2.3.1.1 Connecting to the PriZm® Central Unit

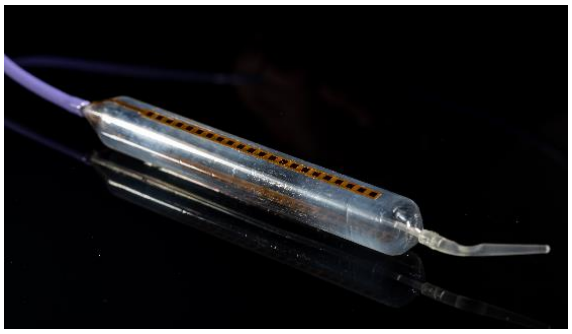
The MiVu™ Cable will connect to the PriZm Central Unit using the Port 1 connector. When the device is properly connected, the Port 1 indicator LED on the side panel of the PriZm Central Unit will illuminate in blue.

Port 1 Connector

Port Status LEDs

2.3.1.2 Connecting the MiVu™ Balloon Probe to the MiVu Cable

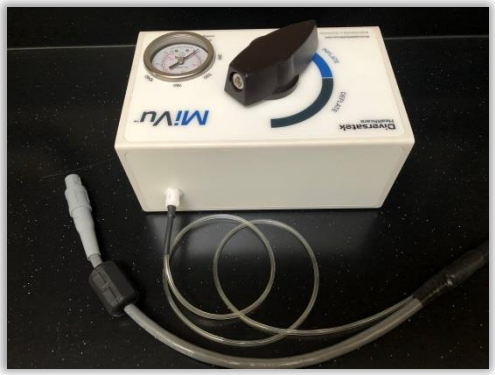
The MiVu Balloon Probe is the only patient-contacting and single-use component of the MiVu System.



Refer to the images below.

a) Connect the MiVu Inflation Syringe to the Extension Tube.
b) Connect the Extension Tube to the luer fitting on the MiVu Regulator.
c) Connect the clear air supply line from the MiVu Cable to the output port fitting on the MiVu Regulator.

Tubing Connections to the MiVu Regulator

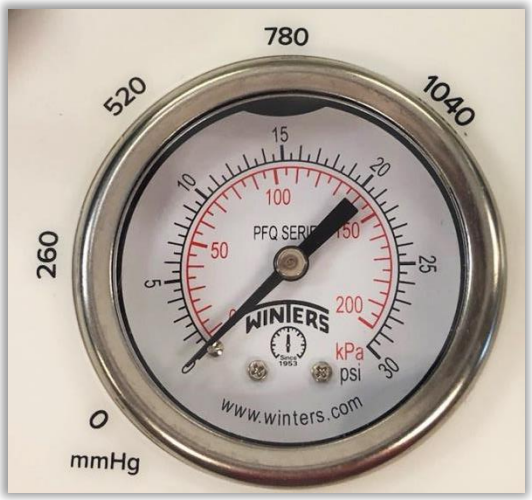


Inspect the balloon probe for any damage. Do not use a damaged balloon probe.

d) Connect the MiVu Balloon Probe to the cable so the two white tubing connectors mate. The tubing connector on the cable will produce an audible click when the two are properly mated. To disconnect the MiVu Balloon Probe from the cable, press down on the silver tab of the tubing connector then pull the two connectors apart (see image below).

2.3.2 MiVu™ Regulator Pressure Indicator

The MiVu Regulator has a pressure gauge (see image below) to display the pressure within the balloon. The dial is graduated with mmHg on the outside label, psi on the center dial in black, and kPa on the inner dial in red.



2.3.3 MiVu™ Regulator Control Handle

The control handle on the MiVu Regulator is a position switch which controls how the air flow from the MiVu Inflation Syringe to the MiVu Balloon Probe is controlled. Set the handle pointed to the Inflate position when inflating the balloon. This will allow for repeated cycling of the inflation syringe to bring the pressure up to the necessary value as displayed on the nearby gauge. Set the handle pointed to the Deflate position when deflating the balloon.

Inflate

Deflate

3 Mucosal Integrity Conductivity Test (MI) Procedure

This section describes the basic procedural steps to record the necessary data for a Mucosal Integrity Study using the Diversatek Healthcare MiVu™ Mucosal Integrity Testing System with Zvu® Software.

Note: The MiVu Balloon Probe utilizes a security feature that limits the probe to a single use. When the Acquire button in Zvu is first clicked when using a probe, the probe 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 probe, Zvu will report the probe has been used and will not allow the study acquisition to begin.

3.1 Preparation

a) Open the pouch and remove the MiVu Balloon Probe.

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

c) Remove the balloon sheath by pulling it straight off the balloon without twisting. Twisting off the sheath will damage the balloon.

d) Inspect the balloon for damage without unfolding or inflating the balloon. Look for any signs of damage including holes and loose edges of the sensor circuit.

3.2 Intubation

a) Wash esophagus with water and suction all liquid, saliva and air from stomach and esophagus prior to insertion of the balloon probe.

b) The curved tip of MiVu Balloon Probe should point down toward the esophagus as it passes through the mouth.

CAUTION: If resistance is met during the intubation procedure, do not advance the MiVu Balloon Probe without first determining the cause of the resistance and taking remedial action.

c) Gently advance the balloon probe through the oral cavity and esophagus until the marking on the balloon probe is equivalent to 2 cm above the SCJ location identified from the endoscope. The graduations along the shaft will be on the top of the tubing and are measured from the most distal impedance sensor. If there is difficulty intubating the balloon probe, lift the jaw forward to open the UES during insertion.

d) With the balloon probe in place, reinsert the endoscope to the level of oropharynx and confirm probe in esophagus.

e) After successful intubation, attach the probe device to the MI system. Connect the balloon probe to the cable connector as described in section 2.3.1.2 “Connecting the MiVu™ Balloon Probe to the MiVu Cable” above. Confirm the white tubing connectors are fully seated and the silver retaining latch has locked into place.

f) To inflate the MiVu™ Balloon Probe:
   1. Turn the switch on the MiVu Regulator to Inflate.
   2. Pump the manual syringe to inflate the balloon with air (see Notes below).
   3. Continue inflating until the pressure gauge reads 10 psi.

Note: Hold the balloon catheter in place at the mouth during inflation so that it does not migrate.

Note: for patients with a narrow esophagus or fragile esophageal mucosa, do not inflate the balloon to more than 5 psi to avoid potential damage to the mucosal wall.

CAUTION: The MiVu Balloon Probe must be filled with ambient air only. Do not exceed maximum recommended inflation pressure on device label.

3.3 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™ Mucosal Integrity Acquisition and Analysis Guide for details on data acquisition.

After powering up the PriZm System, launch the Zvu Software. Create a Mucosal Integrity workflow and add a study to the patient using the workflow. 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.

3.3.1 Troubleshooting During Data Acquisition

While acquiring data, refer to the following troubleshooting table for guidance if there are any anomalies.

Condition	Possible Resolution
Difficulty intubating balloon probe	Confirm balloon protective sheath is removed.
	Confirm balloon remains tightly twisted around the balloon probe shaft. The balloon must not be inflated when intubating.
Inaccurate impedance readings or flat waveforms	If balloon probe does not properly inflate to 10 psi, check air tubing and fittings for leaks.
	Verify cable connections are secure with the balloon probe and PriZm System.

After inflating the balloon, there may be liquid or air trapped between the balloon sensors and the mucosal wall. The impedance values for air will be 10,000 ohms or greater. The impedance values for liquid will be 500 ohms or lower. Deflating and re-inflating the balloon will help to push the liquid and air out of the way of the sensors. This may need to be repeated a few times. For a large amount of liquid or air, remove the probe, suction the air and any saliva that may be in the esophagus, then re-intubate the probe, position and re-inflate.

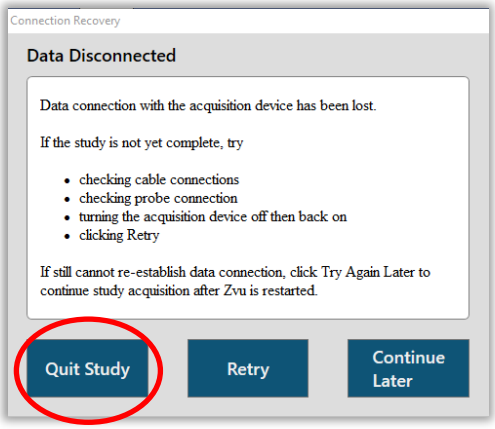
3.4 Extraction

a) Deflate the balloon of the MiVu™ Balloon Probe using the MiVu Regulator and MiVu Inflation Syringe. Set the control handle of the MiVu Regulator to Deflate and cycle the MiVu Inflation Syringe several times to completely remove all air from the balloon. Any air left in the balloon will make it more difficult to extract and may cause injury to the patient. Use endoscope to monitor balloon folds for obstruction and potential injury to patient.

b) Carefully extract the MiVu Balloon Probe from the patient. Stop the extraction if there is any resistance that might lead to patient injury.

c) Disconnect the MiVu Balloon Probe from the cable by pressing down on the silver retention tab and pulling the connector shells apart.

Note that when the probe is disconnected, the system will detect the disconnection and Zvu will display a message. Click the Quit Study button to save the acquired data and close the study. Return to the Patient Management page and open the study for analysis to complete study notations and generate reports.



d) Dispose of the MiVu Balloon Probe and MiVu Inflation Syringe according to the institution's procedure for disposable medical equipment. The MiVu Balloon Probe and MiVu Inflation Syringe are single-use devices. Do not re-use the MiVu Balloon Probe and MiVu Inflation Syringe.

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

4.1 Single-use, Disposable Items

The MiVu™ Mucosal Integrity Balloon Probe is a single-use, non-sterile device that does not require cleaning before use. This device must be disposed after use and cannot be reprocessed.

The MiVu Inflation Syringe that connects to the MiVu Regulator is a single use, non-sterile disposable device and must be disposed of after use.

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™ Cable and MiVu™ Regulator

The MiVu Cable and MiVu Regulator are non-patient contacting, reusable devices that might be subjected to incidental contact of patient contaminants. As a result these components 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 Cable and MiVu Regulator are not disinfected prior to shipment. A proper cleaning and disinfection cycle is required before the initial use.

Note: The MiVu Cable and MiVu Regulator must be reprocessed immediately after each patient use.

CAUTION: Clean and disinfect the MiVu Cable and MiVu Regulator 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: 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 Diversatek Healthcare MiVu Cable and MiVu Regulator. Only the procedures and solutions 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™ Cable and MiVu™ Regulator. 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)	2 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 Cable and MiVu Regulator 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 MiVu Cable. Clean all visible soil from the MiVu Cable and continue to clean until the MiVu Cable is thoroughly clean and free of any visible soil. Replace the wipe as necessary to ensure the MiVu Cable is thoroughly cleaned. Once cleaned, place the MiVu Cable on a clean surface.

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

   Note: If the MiVu Cable or MiVu Regulator 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 Cable and MiVu Regulator must be thoroughly clean and free of visible soil before the disinfection step.

4. Following the cleaning, gently pat dry the MiVu Cable and MiVu Regulator with a soft gauze or tissue.

5. Visually inspect the MiVu Cable and MiVu Regulator 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™ Cable or MiVu™ Regulator.

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

2. Ensure the MiVu Cable and MiVu Regulator have 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 Cable. Use multiple wipes as necessary in order to fully saturate all surfaces of the MiVu Cable. Allow the disinfectant to saturate all external surfaces of the MiVu Cable for a minimum of two (2) minutes. Place the MiVu Cable on a clean surface to dry.

4. Replace gloves. Use new wipes to thoroughly contact and saturate all external parts of the MiVu Regulator. Use multiple wipes as necessary to fully saturate all surfaces of the MiVu Regulator. Allow the disinfectant to saturate all external surfaces of the MiVu Regulator for a minimum of two (2) minutes. Place the MiVu Regulator on a clean surface to dry.

5. Replace gloves. Gently pat dry the MiVu Cable and MiVu Regulator using a soft gauze or tissue.

6. Visually inspect the MiVu Cable and MiVu Regulator after disinfection for damage, corrosion, cuts, punctures, and cracked seals. If any damage is found, **STOP** the disinfecting steps and contact Technical Support.

7. Allow the MiVu Cable and MiVu Regulator 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 Cable and MiVu Regulator are reusable devices 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 Cable and MiVu Regulator are not intended to be sterilized. These reusable components of the MiVu Mucosal Integrity Testing System should be cleaned and disinfected between each use as described above.

CAUTION: **DO NOT** Sterilize the MiVu Cable and MiVu Regulator. 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, or low-temperature plasma sterilization like STERRAD® (due to high hydrogen peroxide (H_2O_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, punctures, and cracked seals. If any damage is found, do not use the system and contact Technical Support for assistance.

Contact Diversatek Healthcare for replacement parts.

5.1 Service

There are no serviceable components in the MiVu Cable, MiVu Regulator, 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 Balloon Probe is a single-use, non-sterile device. Upon completion of the procedure, dispose of the MiVu Balloon Probe per institutional guidelines for biohazardous medical waste.

The MiVu Balloon Probe contains electronics and must be disposed of in accordance with local regulations.

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

The MiVu Cable, MiVu Regulator, 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 your sales representative 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 updates.

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

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-hours a day, seven days a week basis.

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 (24/7) : Standard hours 7am – 5pm MST On-Call hours 5pm – 7am MST	800-558-6408 303-470-7020

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

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 Cable

Diversatek Healthcare Part Number:	MI-CAB-01	
Dimensions:		
Length:	6 ft	(1.8 m)
Weight:	1 lb	(0.45 Kg)
Power Source:	DC power provided by the PriZm Central Unit.	
Patient Connection:	Isolated BF patient connection.	
Channels:	10-40 Impedance	
Analog to Digital Conversion:	16 bit (provided by the PriZm Central Unit)	