Diversatek Healthcare

inSIGHT Ultima®

Central Unit for Zvu® Manometry

Installation and User's Guide

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Part Number: H12R-0195 Rev. 9

Notes, Notices, and Cautions in User's Guide

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

Symbols Marked On Devices

Refer to Instruction Manual:	The operator must read, understand, and follow all instructions in the accompanying documents including all warnings, cautions, and precautions before using the medical device.
General Warning Sign:	General warning sign to alert the user to potential hazards.
Use-By Date (YYYY-MM-DD):	Expiration date for single use and reusable catheters.
Do Not Reuse:	Marked on single use devices.
Non-Sterile:	The product associated with this symbol is not sterilized after manufacturing.
No Pushing:	Do not push at this location. Doing so may cause the cart to overbalance and become unstable.
EC REP EC Representative:	Authorized Representative in EU
Manufacturer:	Name and address of device manufacturer.
SN Serial Number:	The manufacturer's serial number uniquely identifying the device.
REF Part / Reference Number:	The manufacturer's part number of the device for re-order.
MD Medical Device:	Indication the device is a medical device.
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.

inSIGHT Central Unit 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.
	Power Source Classification:	Class I Equipment - Requires protective earth grounding.
	Ingress Protection:	Not protected against ingress of moisture. Equipment is not suitable for use with flammable anesthetics.
Rx Only	Prescription Only:	Device restricted for use by or on the order of a physician.

Definitions, Abbreviations and Acronyms

A/D:	Analog-to-Digital converter; an electronic circuit or device that converts an analog input signal into a digital signal. A channel on a Catheter produces analog output. The inSIGHT converts that output to digital data and saves it to the patient's data file. The A/D channel refers to the Catheter channel.
HRiM:	High Resolution Impedance Manometry.
inSIGHT	inSIGHT peripheral acquisition system.
LCD:	A computer monitor which uses a liquid crystal display to display the output of a computer to the user.
USB:	Universal Serial Bus. USB is a standard data I/O interface that enables the user to connect peripheral devices to a personal computer.
Catheter (Probe)	Patient applied sensor device.

Contents

1 Introduction

1.1 How to Use This Guide

This guide is designed to help you install the inSIGHT Ultima system and the ZVU software quickly and easily. It is intended for health-care professionals trained in performing clinical procedures. Regularly scheduled clinical training courses are offered for your convenience. See contact information on the cover page or in Section 6.1: Technical Support.

⚠ CAUTION: The assembly and installation of a rolling cart system must be performed by a trained manufacturer's representative since some assembly is required.

For detailed instructions on using the inSIGHT Ultima System and ZVU Software refer to the help screens incorporated into the software.

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

- Mouse click and double-click. If using a touch screen, then touching the screen is the same as a mouse click and touching the screen twice in rapid succession in the same spot is the same as a double-click.
- Open desktop folders and double-click desktop icons to invoke applications.
- Use Windows Explorer to browse and manage files and folders.
- Maximize, minimize, resize, and move application windows.
- Use dialog boxes and message boxes.
- Use menu bars to execute menu commands.

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 inSIGHT Ultima System and the accompanying signal conditioning devices are sensitive electronic instruments. Please use the following safety guidelines to help ensure your own personal safety and to help protect your inSIGHT 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 user of the device is 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 inSIGHT 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: The assembly and installation of a rolling cart system must be performed by a trained manufacturer's representative.

⚠ CAUTION: Do not get the inSIGHT System or signal conditioning devices wet - these devices are not waterproof.

⚠ CAUTION: Plug the inSIGHT System into voltages as stated on the InSIGHT Ultima Central Unit Nameplate.

⚠ CAUTION: To avoid the risk of electric shock, this equipment must only be connected to an AC Main supply with protective earth ground. This equipment is not intended to receive AC mains power from any other device.

⚠ CAUTION: For Desktop Systems: The inSIGHT System must receive AC Main power supply from a medical grade isolation transformer. The isolating transformer is specified as a part of the Medical Electrical System.

⚠ CAUTION: For Desktop Systems: Warning: Connecting electrical equipment to multiple socket outlets effectively leads to creating a Medical Equipment System, and can result in a reduced level of safety. Do not use the socket outlets for other devices that are not part of the inSIGHT System.

⚠ CAUTION: For Desktop Systems: Do not plug another multiple socket outlet power strip into the accessory outlets provided with the isolation transformer. Only the devices provided with the inSIGHT System should be powered through the isolation transformer.

⚠ CAUTION: Do not attempt to open or service the inSIGHT System or signal conditioning devices. There are no user serviceable parts inside.

⚠ CAUTION: No modification of this equipment is allowed.

⚠ CAUTION: Follow instructions provided with all types of catheters used with the inSIGHT System and Signal Conditioning devices.

⚠ CAUTION: Discard all used disposable catheters in accordance with local biohazard requirements. Refer to section 5.5 Decommissioning and Disposal for additional information.

⚠ CAUTION: Reusable catheters should be cleaned and disinfected according to manufacturer's and your institution's guidelines after each use.

⚠ CAUTION: Dispose of the inSIGHT System and signal conditioning device in accordance with local ordinances and regulations. Refer to section 5.5 Decommissioning and Disposal for additional information.

⚠ CAUTION: Electromagnetic interference is possible between impedance (Z) catheters and implanted devices such as pacemakers and internal defibrillators. Monitoring of all implanted devices is advised.

⚠ CAUTION: Inspect the catheter for damage such as bent or broken pins. Also, verify the integrity of the Catheter between the tubing and each sensor. Do not connect the Catheter to the equipment if there is visible damage. Refer to the Catheter manufacturer's cautions and warnings found in the Catheter manufacturer's user guide.

⚠ CAUTION: In order to minimize the risk of nosebleed, use adequate lubrication with a water soluble lubricant for catheter intubation.

⚠ CAUTION: To clean the monitor, use a cloth that has been slightly dampened in a solution of warm water and mild detergent. Avoid solvents which may damage the product cases. Follow hospital protocol. Do not apply liquid directly to monitor.

⚠ CAUTION: Only use Diversatek Healthcare approved accessories with the inSIGHT System. Damage to the system, the accessory, and/or patient injury may occur.

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

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

⚠ CAUTION: Do not use the inSIGHT System or other signal conditioning 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 inSIGHT System in an oxygen rich environment.

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

⚠ CAUTION: Do not connect any multiple socket-outlet or extension cord to the output side of the isolation transformer.

⚠ CAUTION: Do not connect any devices **not** associated with the inSIGHT Ultima System to the output side of the isolation transformer. The isolation transformer should only be used with the inSIGHT Ultima System components.

NOTICE: Use of non-Diversatek Healthcare approved USB devices may cause unpredictable intermittent device operation.

NOTICE: Use of an uninterruptible power system is suggested if the quality of power is questionable.

NOTICE: Do not store the inSIGHT System or signal conditioning devices in extreme temperatures. The inSIGHT System and signal conditioning devices are best stored between 50° and 104°F (10° to 40°C).

NOTICE: Do not drop the inSIGHT System or the signal conditioning devices.

NOTICE: Do not run other software, update software or the operating system, or add/remove peripherals during data acquisition.

NOTICE: Microsoft Windows does not allow the Hibernate, System Standby, or Hard Disks Power-Off features to be deactivated through software, so ZVU® cannot deactivate these features. Turning on any of these features may cause the termination of acquired data while the items are shut down. **Data loss may occur.** Use caution when turning on these features.

1.3 Product Description

1.3.1 Indications of Use

The inSIGHT Ultima Gastrointestinal Motility System is intended for use by gastroenterologists, surgeons, and medically trained personnel as an aid in documenting and diagnosing digestive motility disorders. It may be used for esophageal and anorectal studies. The system includes analysis software, but requires a skilled interpretation by a physician to make a diagnosis.

1.3.2 Contraindications

Esophageal manometry is contraindicated in the following situations:

- Suspicious or known pharyngeal or upper esophageal obstruction (e.g., tumors)
- Patients with severe clotting disorders
- Patients with known esophageal problems such as deep ulcers, varices, Zenker's diverticula, and strictures

Anorectal manometry is contraindicated in the following situations:

- Patients with known anal obstructions.

Small bowel manometry is contraindicated in the following situations:

- Those associated with esophagogastroduodenoscopy (EGD).
- Massively dilated small bowel is a relative contraindication due to risk of perforation.
- Known multiple jejunal diverticulosis.

1.3.3 Features

The inSIGHT Ultima System was designed with the end user in mind. The inSIGHT Ultima System offers the following features:

- Specialized modules focused on specific clinical procedures.
- Guided Protocols to guide the operator step by step through the procedure.
- On-screen *Help* buttons accessible by users at any time during a procedure if detailed instructions are needed.
- Compatible with a flat panel LCD display to save space and facilitate transportation.
- Works with a touch screen display that may eliminate the need for a keyboard and mouse during data acquisition.
- A flexible system that supports various configurations to meet the clinician's requirements.

1.3.4 Biocompatibility

The inSIGHT Ultima System components utilize common materials with no known biocompatibility issues. However, the following cautions should be observed:

CAUTION: Some catheters have applied parts made with 316L stainless steel. This type of stainless steel, although medical grade, contains 10-14% nickel which may pose risks for people with certain allergies to nickel.

2 System Components

The following sections describe the various components of the inSIGHT Ultima System.

2.1 User Manuals

All of the user manuals for the inSIGHT Ultima System are provided in electronic versions that are installed along with the ZVU Software suite. The following table lists the various manuals provided. Please refer to these manuals for additional information.

Manual Part Number	Title
H12R-0195	inSIGHT Ultima System Installation and User's Guide

2.2 Main System Components

The inSIGHT Ultima Motility System consists of the following main components. Optional signal conditioning units are available. Refer to the manuals accompanying those units for additional information.

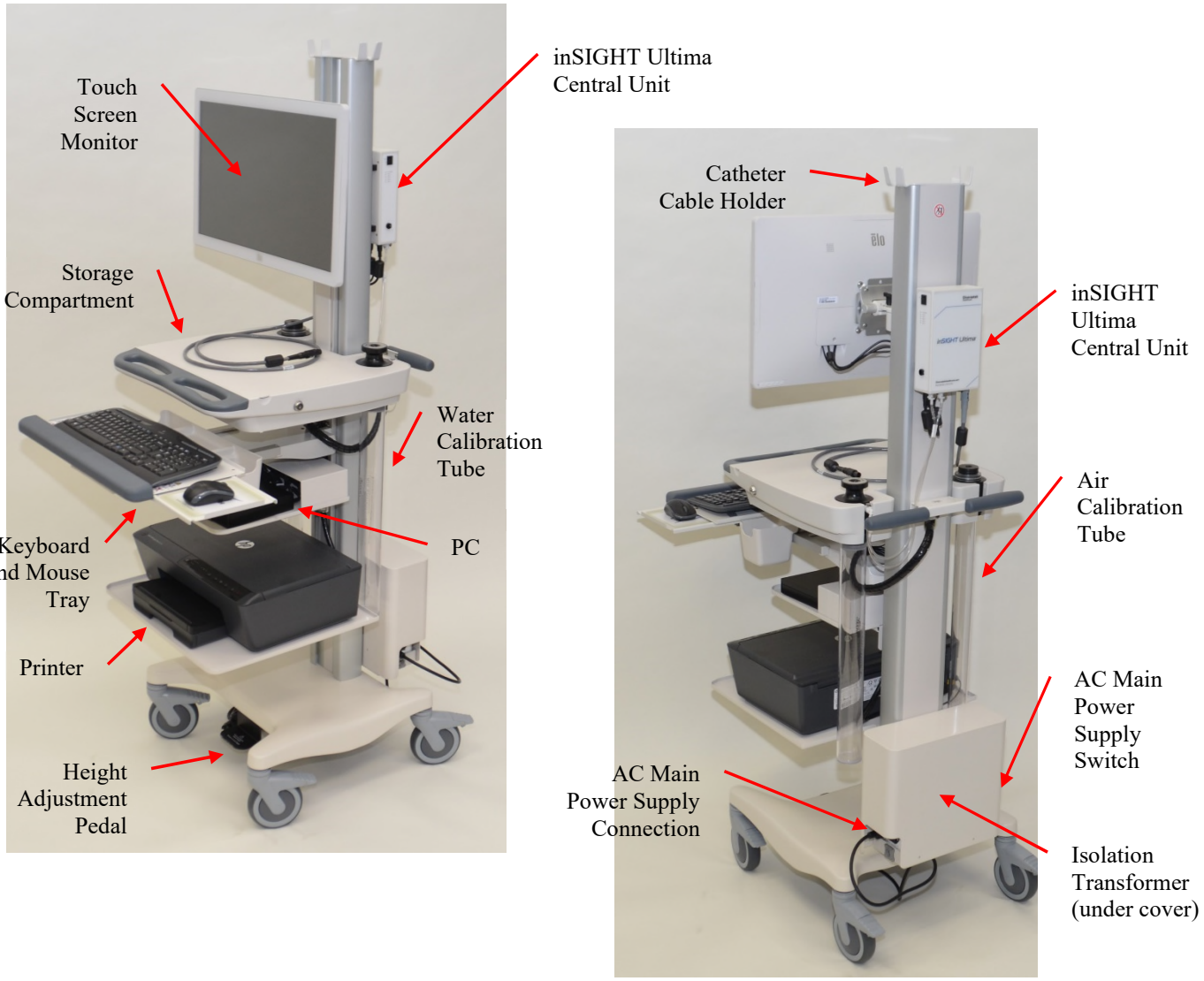
inSIGHT Ultima Central Unit:	Provides patient isolation for safety; translates data format and transfers data to host computer.
Host Computer:	Provides computer processing capabilities to acquire, store, and analyze recorded patient data.
Touch Screen Monitor:	The display shows the waveform data that is being acquired from the patient.
Catheters and Transducers:	Patient applied parts to collect biomedical data and convert it into a format that can be displayed and analyzed using a computer.
Isolation Transformer:	Safety device required for use with system. Provides electrical isolation of the system and minimizes potential leakage current.
Printer:	Optional accessory for producing hard copy reports.

2.3 Configurations

The inSIGHT System is available in two configurations: Cart and Desktop. The active medical components are the same for both the cart and desktop configurations. The rolling cart is offered for those customers who require additional mobility.

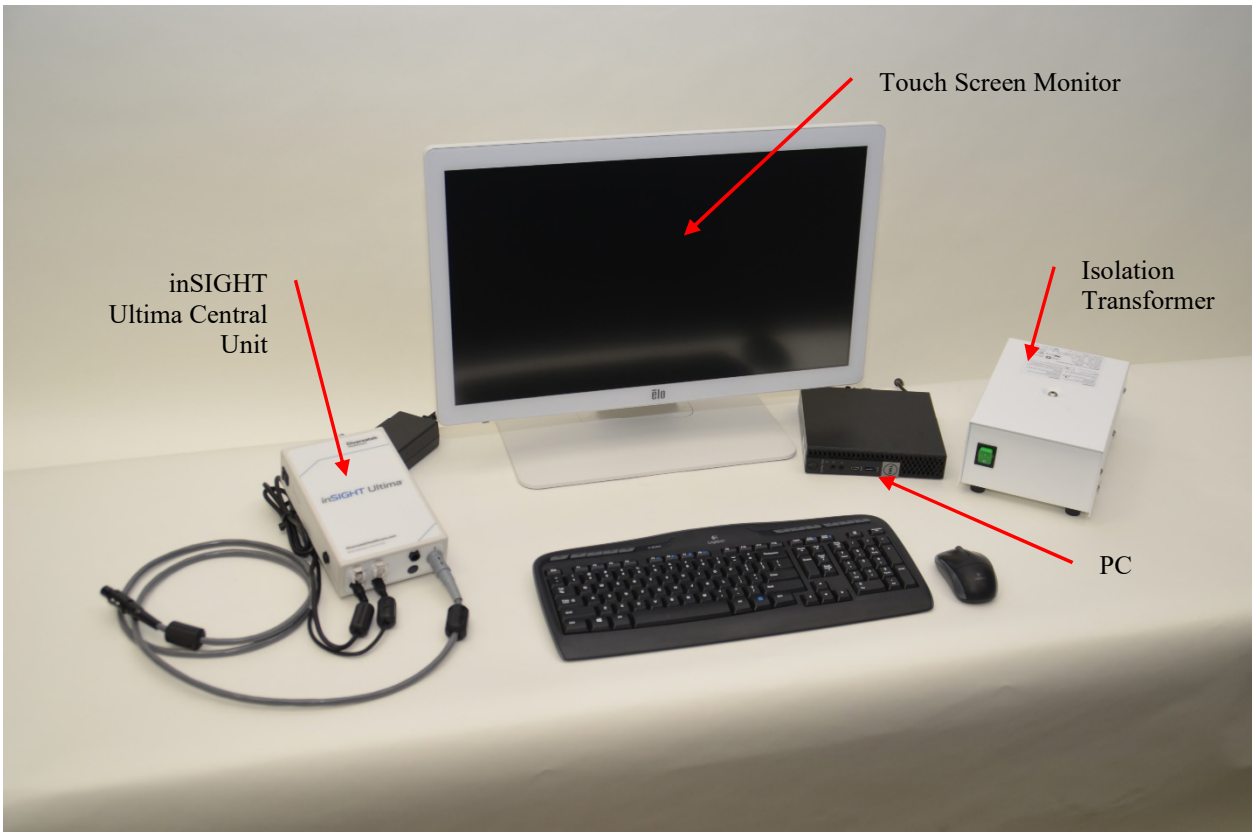
2.3.1 Cart Configuration

The inSIGHT Ultima Motility System is offered with an optional rolling cart. The following diagram shows the locations of the main components.



2.3.2 Desktop Configuration

The inSIGHT Ultima Motility System is offered in a desktop configuration. The following diagram shows the main components.



Items not shown:

- Water Calibration Tube
- Air Calibration Tube
- Hand-held Pressure Gauge
- Printer

2.4 Electrical Configuration

⚠ CAUTION: A suitable medical grade isolation transformer is required for this system.

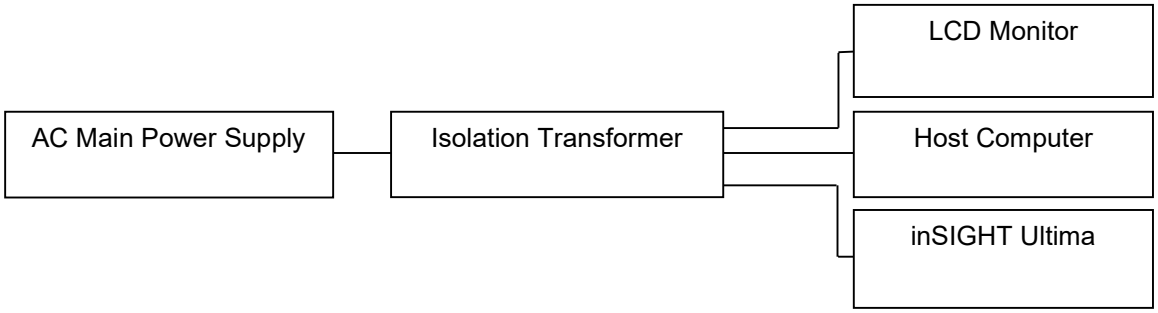


Figure 1: Electrical Configuration

Connect the system components together according to the following manner (refer to Figure 1 above):

- Connect all AC power cords to the isolation transformer.

2.5 Isolation Transformer Setup (for Desktop Configuration)

An isolation transformer is a critical safety device that helps to isolate the patient from electrical hazards. The following precautions must be followed for the isolation transformer to provide the best protection possible.

⚠ CAUTION: The inSIGHT Ultima System must receive AC Main power supply from a medical grade isolation transformer. The supplied isolating transformer is specified as a part of the Medical Electrical System.

⚠ CAUTION: Connect all devices of the inSIGHT Ultima System to the output side of the isolation transformer as described in section 2.4 above.

⚠ CAUTION: Do not connect any devices **not** associated with the inSIGHT Ultima System to the output side of the isolation transformer. The isolation transformer should only be used with the inSIGHT Ultima System components.

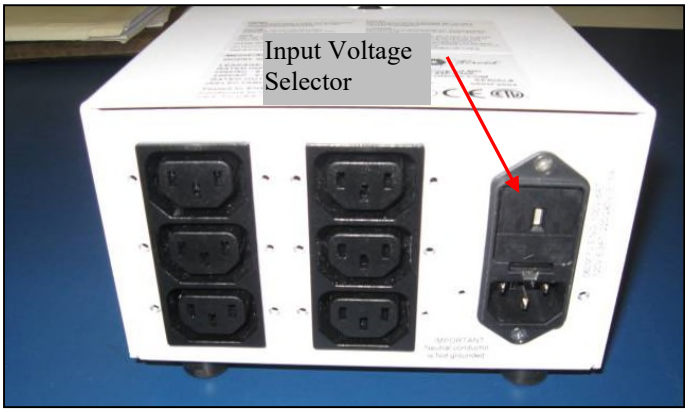
⚠ CAUTION: Do not connect any multiple socket-outlet or extension cord to the output side of the isolation transformer.

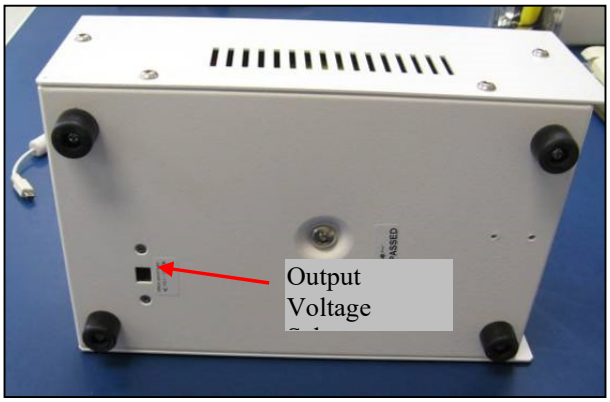
NOTE: See the appendix for the isolation transformer specifications.

2.5.1 **Voltage Settings** (for Desktop Configuration)

The Input and Output voltage settings must be configured before connecting the isolation transformer into the AC Main power supply. The Input voltage selector is set through a four-position key that is located within the fuse holder of the power entry module (see below). When setting the voltage selector, the desired voltage will be visible in the window. The Output voltage selector is set through a two-position switch on the bottom of the unit (see below). Refer to the following table for the proper Input and Output voltage settings for your region. If your input voltage for your area is not listed below, please contact Technical Support for assistance.

Region	Input	Output
North America (120 V~)	120 V~	115 V~
Europe (230-240 V~)	240 V~	230 V~
Japan (100 V~)	100 V~	115 V~
Other 220 V~	220 V~	230 V~





2.6 Connecting the System to a Data Network

The inSIGHT Ultima System does not need to be connected to a data network for it to function properly and achieve its intended use. Attachment to a network provides for convenient sharing of data files, back-up of data, and printing to network printers. There are no known hazardous situations resulting from a failure of the network coupling.

The IT data network port utilized by the inSIGHT Ultima System conforms to the conventional Ethernet standard IEEE 802.3. There are no required characteristics or configuration of the IT network.

If the inSIGHT Ultima System is connected to a data network, please be aware of the following:

⚠ CAUTION: Connection of the inSIGHT Ultima System to a network/data coupling that includes other equipment could result in previously unidentified risks to patients, operators or third parties. All risks should be identified, analyzed, evaluated and controlled. Subsequent changes to the network/data coupling could introduce new risk and require additional analysis such as unauthorized access. Changes to the network/data coupling include:

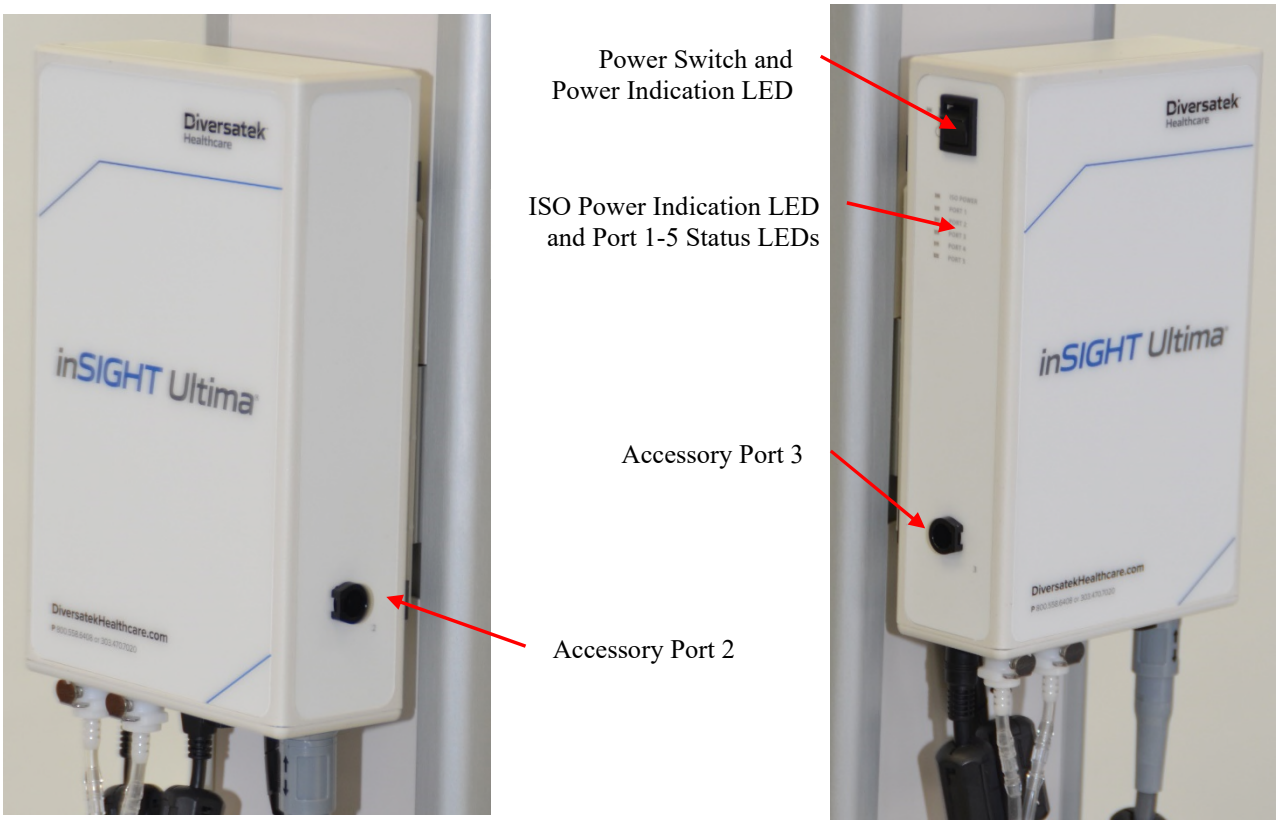
- Changes in network/data coupling configuration
- Connection of additional items to the network/data coupling
- Disconnecting items from the network/data coupling
- Update of equipment connected to the network/data coupling
- Upgrade of equipment connected to the network/data coupling

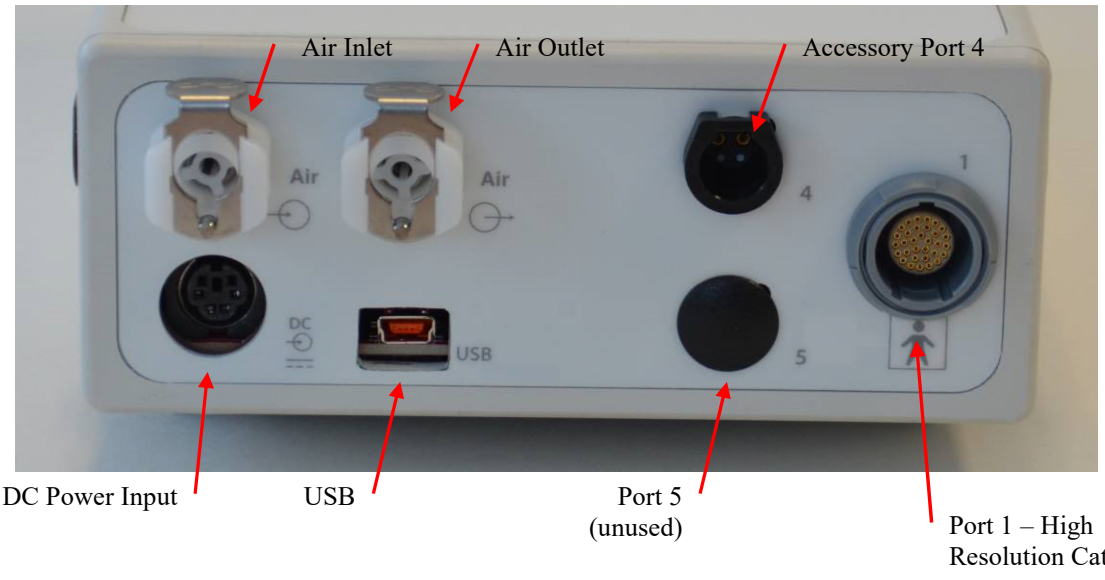
Please refer to the current revision of IEC 60601-1 for the requirements applicable to Medical Electrical (ME) Systems.

3 Controls and Connections

3.1 inSIGHT Ultima Central Unit

The inSIGHT Ultima Central Unit is the main component of the inSIGHT system. It provides data buffering to the inSIGHT Acquisition Software running on the PC.





3.1.1 Ports, Switches and Indicators

- USB - Connection port for the USB cord attaching the system to the PC.
- Power Switch – This controls the DC power supplied by the external medical grade power supply brick.

NOTE: This switch controls the power supplied to the inSIGHT Ultima Central Unit and all attached signal conditioning units.

- DC Power Input – This is the DC power input receptacle.

CAUTION: To avoid the risk of electric shock, this equipment must only be connected to an AC Main power supply with protective earth ground.

CAUTION: The inSIGHT System must receive AC Main power supply from a medical grade isolation transformer. The supplied isolating transformer is specified as a part of the Medical Electrical System.

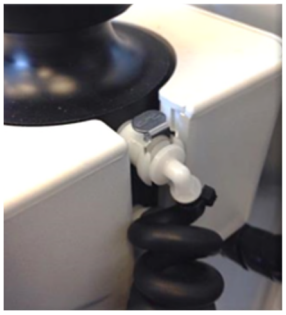
- Air Inlet and Outlet Ports – Air supply and pressure sensing ports for the automated calibration tube feature.
- Port 1 – A patient isolated connection port for attaching to the High Resolution Catheters.
- Ports 2-4 – Non-patient isolated Accessory Ports for attaching external device adapters. Patient connected external device adapters have their own built-in patient isolation.
- Port 5 – Unused. Reserved for future expansion.
- Power Indication LED – A green LED that is illuminated when the Power Switch is in the ON position and the DC input is measured to be at the appropriate voltage levels.
- ISO Power Indication LED – A green LED that is illuminated when the isolated power of the internal High Resolution Catheter Adapter board is determined to be at the appropriate levels for operation.
- Port 1 Indication LED – A blue LED that is illuminated when the High Resolution Catheter is attached to Port 1 and communicating properly.
- Port 2-5 Indication LEDs – Blue LEDs that are illuminated when an external device adapter module is plugged in and communicating properly. These LEDs will blink if the InSIGHT Ultima Central Unit detects the device adapter module was plugged in but communication was not established. If blinking, try re-plugging in the device or use a different port. Contact Technical Support for assistance.

3.1.2 Automated Air Calibration

The ZVU Software is able to utilize the automated air calibration feature of the inSIGHT Ultima System. Inside the inSIGHT Ultima is a small air pump that ZVU turns on to pressurize the air calibration tube. ZVU then monitors the inSIGHT Ultima's calibration sensor to detect the calibration points. The releasing of the air is accomplished through two tiny vent holes, one located in each of the two air lines.

To use the automated calibration feature of the inSIGHT Ultima two air lines must be installed between the inSIGHT Ultima and the air calibration tube cap.

a) Disconnect the sphygmomanometer from the air calibration tube. To release the fitting, press down on the metal tab of the port on the calibration tube.



b) Connect the straight fitting ends of the two air lines to the two ports on the inSIGHT Ultima. The air lines are identical and can be plugged into either port. The fittings are fully seated when the metal tab on the port clicks up.

c) Connect the elbow fitting of the two tubes to the two ports on the air calibration tube. The air lines are identical and can be plugged into either port. Twist the fittings so the barbed end of the fitting points upward and the tubing is not kinked.

To perform a manual calibration, disconnect ***both*** connectors from the air calibration tube only. Leave the air lines connected to the inSIGHT Ultima. Connect the sphygmomanometer to either of the connector ports on the air calibration tube.

3.2 Signal Conditioning Units

The inSIGHT Ultima Motility System is designed to be very flexible. Signal conditioning modules have been developed to allow for processing a variety of signals related to the GI tract. These include pressure and impedance.

3.2.1 High Resolution Catheter Adapter

Integrated into the inSIGHT Ultima Central Unit is the High Resolution Catheter Adapter. This adapter provides pressure and impedance signal conditioning for the High Resolution catheters as well as electrical patient isolation.

3.3 System Cart

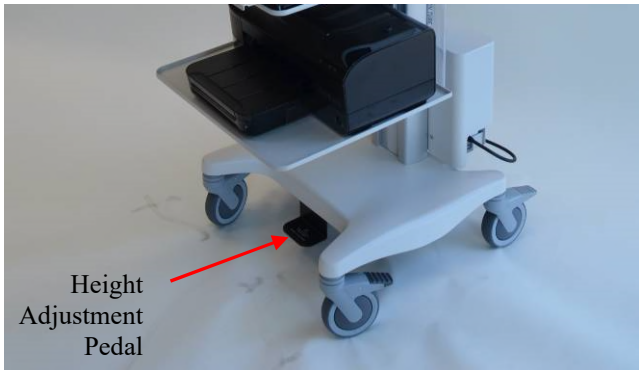
The inSIGHT Ultima System is available as a rolling cart system. This cart is designed with ergonomic features to make the use of the system more comfortable, efficient and effective. These include an adjustable working height and adjustable monitor mount. The following describes the main features and how to use them.

⚠ CAUTION: The assembly and installation of a rolling cart system must be performed by a trained manufacturer's representative since some assembly is required.

3.3.1 Adjustable Working Height

The rolling cart is designed so the height of the work area can be easily adjusted for comfortable use. The cart pillar incorporates a gas-assisted mechanism to make the adjustment of the work area easier to move. Please note the work area will not move independently and will require some effort to move it up and down. The gas-assist mechanism makes this task easier by counterbalancing most of the weight.

To move the work area up or down, release the locking mechanism by stepping on the foot pedal at the front center of the cart base.



3.3.2 Monitor Adjustments

The touchscreen monitor mount can be swiveled left and right as well as tilted up and down to provide a comfortable viewing arrangement. The monitor can be easily swiveled left and right by grabbing the side of the monitor and pushing or pulling to the desired location. The monitor can be swiveled fully to either side.

In addition, the monitor can be tilted up and down. The tilt positioning is held in place by a locking handle located on the top of the monitor mount at the back of the monitor. Twisting the handle will loosen or tighten the lock. When adjusting the tilt, hold the bottom of the monitor with one hand while loosening the tilt lock to keep the monitor from swinging down rapidly. Once the monitor is positioned to the desired tilt, tighten the locking handle.

3.3.3 Casters and Caster Locks

The system cart utilizes five inch diameter casters with hard rubber treads. These provide for smooth travel over hard flooring as well as carpeting. The large diameter wheels also provide good stability when traveling over small obstructions like cords and elevator thresholds.

All four casters are braking type where the wheel is prevented from rolling when the foot lever is pressed down to engage. All four casters should be locked to fully immobilize the cart from moving.

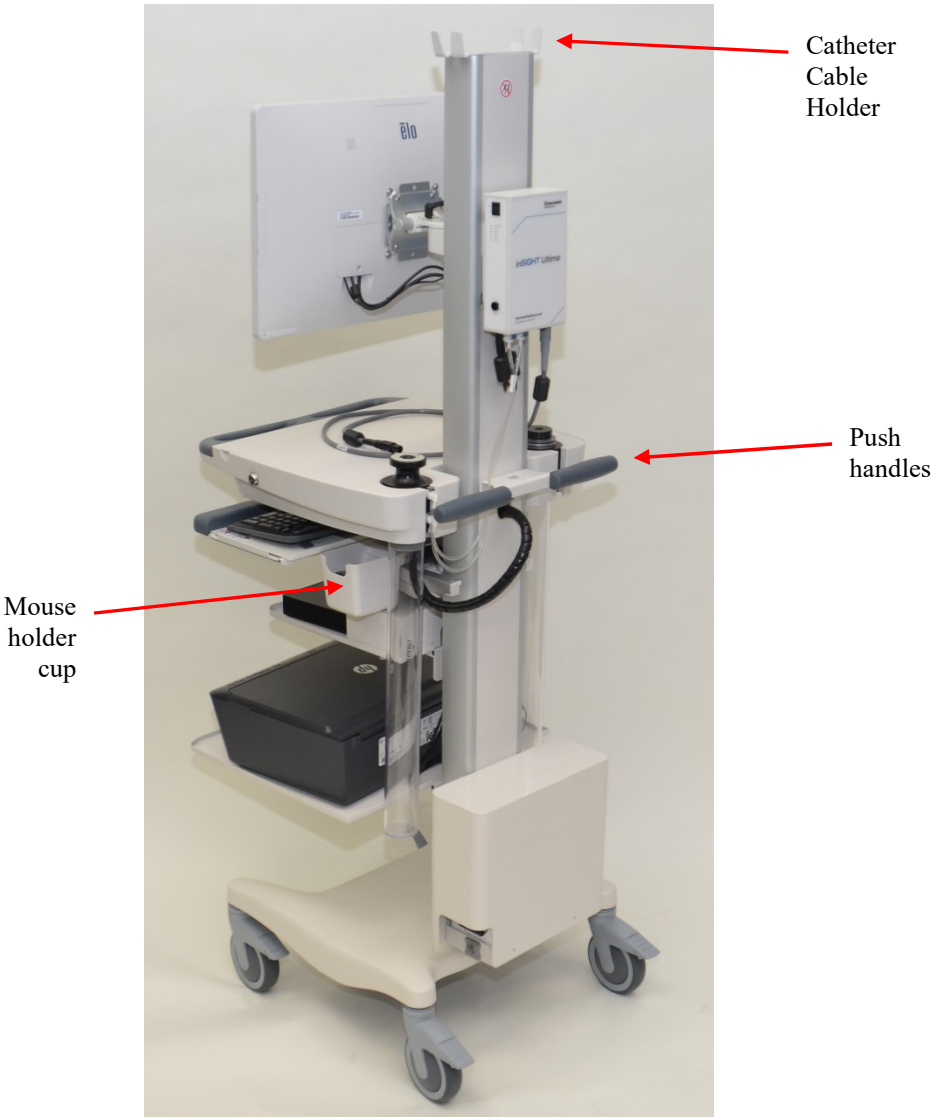
NOTE: To fully immobilize the cart it is best that all four casters are locked.

CAUTION: When the caster locks are applied, do not lean or press against the top-most area of the pillar. Doing so may cause the cart to overbalance and become unstable. Note the following sign on the back of the pillar.

3.3.4 Moving the Cart

When moving the cart long distances care must be taken to prepare the cart for movement. The following items are suggested:

- Place the mouse into the mouse holder cup behind the keyboard and slide the mouse tray in.
- Slide the keyboard tray in.
- Unplug the AC Main power supply cord from the wall outlet and drape the cord over the back push handles or the catheter cable holder at the top of the pillar.
- Align the front casters by pushing the cart a short distance using the back push handles, and then lock the front casters to keep them from swiveling. Locking the casters will make the cart easier to steer when pushed from behind.
- Push the cart using the back push handles with the cart in front of you. This arrangement will provide the best control and stability.



3.4 Basic Operation of the System

This section is intended to provide a brief introduction of the steps necessary to safely bring the inSIGHT Ultima System to an operational mode and how to terminate operation when finished.

3.4.1 Plugging in the System

The inSIGHT Ultima System utilizes a hospital grade AC Main power supply cord with the correct plug for your power source. The following notes about safety should be kept in mind when arranging the inSIGHT Ultima System for use.

NOTE: The AC Main power supply cord is the only recognized disconnect device. The inSIGHT Ultima System should be positioned so its disconnect device is readily accessible and can be easily disconnected in an emergency.

NOTE: Attach the AC Main power supply cord directly into a wall outlet without the use of an extension cord or power strip. This is to ensure the protective earth ground connection is not compromised.

3.4.2 Turning On the System

To bring the inSIGHT Ultima System to an operational mode, do the following:

- Plug the AC Main power supply cord (refer to section above).
- Turn on the power switch of the isolation transformer which is located on the back left side of the cart. (Refer to section 2.3.1 Cart Configuration.) It is a green switch that will illuminate when turned on and power plugged in.
- Turn on the power switch for the inSIGHT Ultima Central Unit. (Refer to 3.1 inSIGHT Ultima Central Unit.)
- Turn on the PC (front upper left corner) and monitor (along the lower right side). When the PC fully boots up, select the appropriate user ID to get to the desktop.

3.4.3 Turning Off the System

To bring the inSIGHT Ultima System to a powered off state, do the following:

- Close all open applications running on the PC. Be sure to save files where appropriate.
- Power down the PC by selecting "Shut Down" from the Windows Start Menu. When Windows completes its shutdown process it will turn off the PC.
- Turn off the touchscreen monitor.
- Turn off the inSIGHT Ultima Central Unit.
- Turn off the power switch of the isolation transformer.
- If the system cart is to be moved for storage or use elsewhere, unplug the AC Main power supply cord from the wall outlet and drape it over the back push handles or the catheter cable holder at the top of the pillar. (Refer to 3.3.4 Moving the Cart.)

4 Software

For inSIGHT Ultima Systems with a PC, all required software is pre-installed. However, in special situations, it may be necessary to install the latest update or other special software. If such a situation arises, first consult this section for guidance, and then if in doubt, please contact Technical Support.

4.1 System Requirements

For inSIGHT Ultima Systems, a host computer with the following requirements is recommended:

	Recommended
PC Processor	Intel 64-bit processor, 2 GHz or faster with 4 cores
Operating System:	Windows® 10 Professional
Graphics:	DirectX-11 device with Feature (DDI) level 11 or higher (includes Intel HD2500)
Memory:	8 GB
Hard Drive:	256 GB SSD (Solid State Drive)
Monitor:	Full HD 1080p (1920x1080 resolution)
USB Ports:	5 USB 2.0 compatible ports

⚠ CAUTION: These replacements must be certified to IEC 60950/62368 or IEC 60601. The user (RESPONSIBLE ORGANIZATION) is responsible for ensuring that the modified system configuration still complies with IEC 60601-1 safety requirements.

4.2 Software Installation Instructions

NOTE: Before you get started: You must have "Local" administrator privileges to load the software. If you do not have local administrator privileges, the install will not run. Please contact your local IT administrator or Technical Support if you need assistance with obtaining local administrator privileges.

To install ZVU Software, do the following:

- Power on the host computer.
- Log on as a user with Local Administrator privileges.
- Insert the ZVU installation media (CD or USB memory stick) and wait about 15 seconds. The setup program will run automatically. If the auto-start installation wizard does not start:
  - Open Windows Explorer
  - Navigate to the installation media
  - Double-click on the exe file.
  - The ZVU installation begins.
- Follow the installation prompts to complete the installation.
- After the installation is complete, exit from the installation screen.
- Remove the installation media from the PC.

4.3 Software Activation

Diversatek Healthcare is required by regulatory agencies to track the installation of ZVU Software at each customer site. To comply with regulations, ZVU requires that each installation on each computer be activated. Basic site and computer information for each installation of ZVU Software will need to be provided. No patient information is collected.

For customers outside of the United States, contact your Distributor for help with activating the software.

For customers within the United States, contact Technical Support and provide the following information:

- Machine identification code: generated by ZVU and displayed on the Activation Screen at initial start up
- Facility name
- Facility address
- Contact person at facility
- Contact person's telephone number
- Contact person's email address

Technical Support will then generate an activation code to enter on the ZVU Activation Screen.

4.4 Software Upgrades

NOTE: DO NOT install the software immediately before starting a study. If anything goes wrong with the installation, for example the installation CD is scratched and cannot finish the installation; you will need time to fix the problem. Once the old software is uninstalled, it is no longer readily available.

- To install the software update, follow the instructions accompanying the upgrade. If those instructions are not available, then follow the steps in Section 4.2 Software Installation Instructions.

4.5 Security and Authentication

The inSIGHT Ultima System software utilizes patient identifying information. In some countries, access to this kind of information must be restricted. The use of Windows Security and Authentication to limit access to the software and patient data is recommended. Software users should be required to login with a unique user ID and password that can be authenticated.

5 Cleaning and Preventative Maintenance

5.1 Cleaning Procedure

5.1.1 inSIGHT Ultima, Cart, and Accessories

Clean the outside of the inSIGHT Ultima System and all accessories 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.

5.1.2 Calibration Tubes

The air and water calibration tubes come into contact with the probe and should be cleaned on a regular basis. Please follow the recommendations listed below:

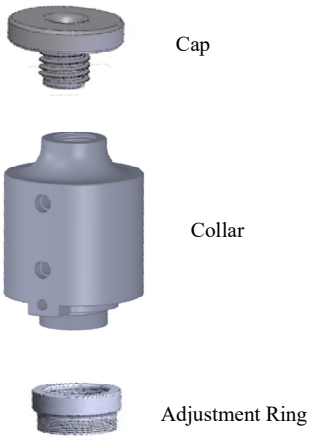
- Change the water in the water calibration tube on a daily basis.
- Clean both the air and water calibration tubes at least monthly or more frequently as required by the current hospital/clinic practices.

5.1.2.1 Water Calibration Tube Cleaning Steps

1) Lift the water calibration tube up to remove it from the cart.
2) Remove the cap from the water calibration tube and discard the water.
3) Clean the tube with mild soap and water, and then rinse well with tap water. Do not use a brush. For locations with hard water, do a final rinse with distilled water to help keep water deposits from forming. Allow to air dry.
4) Wipe the outsides and the inside opening of the cap with a hospital grade wipe.
5) Replace the cap and place the water calibration tube back into the cart.

5.1.2.2 Air Calibration Tube Cleaning Steps

1) Unscrew the clear tube from the adjustment ring. If the adjustment ring comes off with the clear tube, just remove the adjustment ring at this time.
2) Clean the tube with mild soap and water, and then rinse well with tap water. For locations with hard water, do a final rinse with distilled water to help keep water deposits from forming.
3) Using a hospital grade wipe, wipe all sides of the adjustment ring, cap, and main collar including the center areas where the probe passes through. Be sure to also wipe the white nylon washer and black neoprene washer. When reassembling, place the neoprene washer into top of the collar first, then the white nylon washer and secure with the cap.



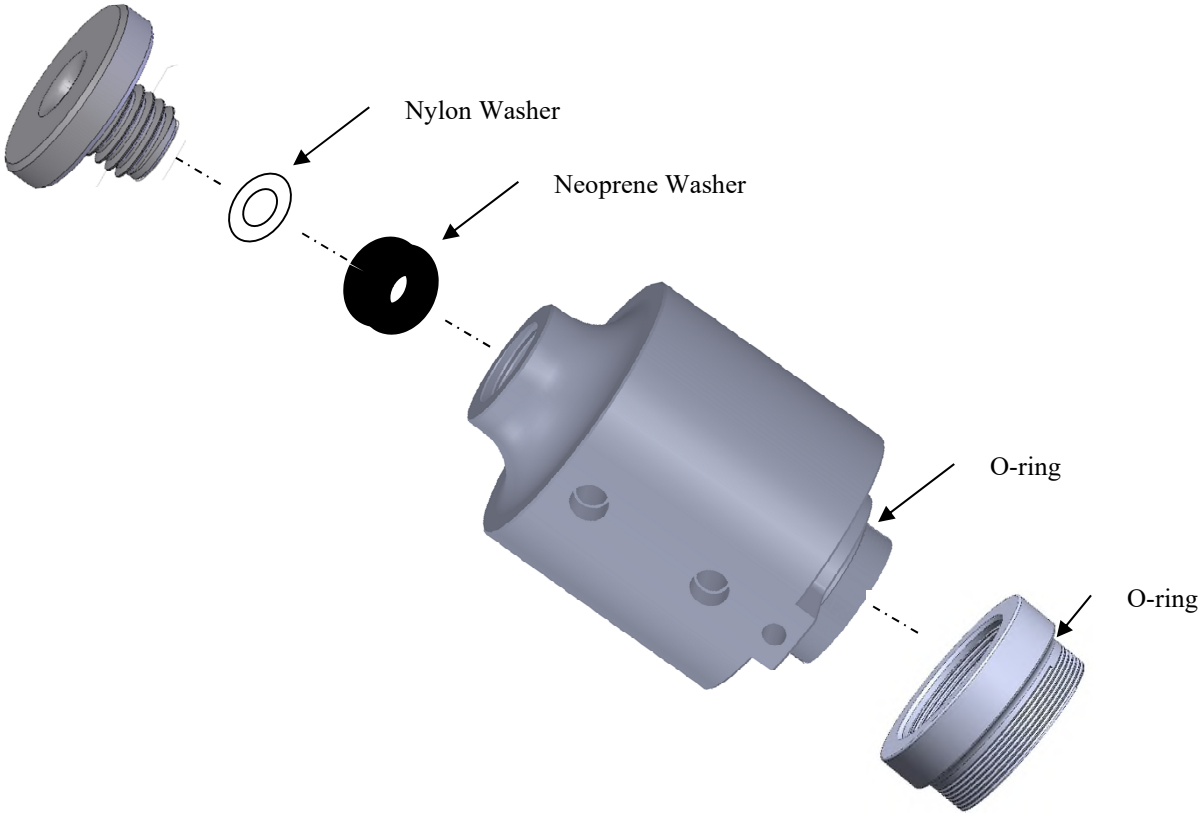
5.1.3 Probe Case Cleaning

The probe case can be cleaned as needed by wiping it with a hospital grade wipe.

The probe case insert can be cleaned as needed with an alcohol wipe before placing the reprocessed probe in the case for storage.

5.2 Air Calibration Tube Seals

The air calibration tube utilizes several o-rings and gaskets to obtain an air tight seal. Over time, these parts may dry out and need to be replaced. Similarly, the neoprene washer will degrade with repeated use of the calibration tube and may leave black flecks at the bottom of the tube. These items can be easily replaced by removing the worn parts and installing new ones. Contact Customer Success to order the air calibration tube o-ring replacement kit (Part # S90-5120-H).



5.3 Preventative Maintenance

The inSIGHT Ultima System should be periodically examined to ensure the device is in working order. This will help eliminate problems while a study is being performed.

In addition to periodic cleaning mentioned above, the following should be done on a regular basis. Contact Technical Support for replacement parts.

- Check the calibration tubes for cracks or other damage. Cracked calibration tubes must be replaced.
- Inspect cables for cabling that has been pulled away from the connector, loose connectors, bent or broken pins or debris in the connector.
- Your inSIGHT Ultima system includes a computer. Care should be taken to back-up patient files from the computer.
- Run the Microsoft Windows Disc Cleanup and Disc Defragmenter as appropriate.
- Inspect mouse and keyboard to ensure that there is no damage and inspect for debris.
- Inspect reusable catheters for damage to the connector or Catheter body. Refer to the Catheter manual for cleaning and disinfecting information.

5.4 Service

There are no serviceable components in the inSIGHT Ultima System. If necessary, the device should be returned to Technical Support for repair.

5.5 Decommissioning and Disposal

The inSIGHT Ultima System does not require decommissioning to remove it from service.

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

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

6 Appendix

6.1 Technical Support

Technical Support can be reached by mail, telephone, fax, or e-mail. Please see the listings below for complete contact information.

We strive 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 and Training Center 9150 Commerce Center Circle Suite 500 Highlands Ranch, CO 80129 U.S.A.
WEBSITE:	DiversatekHealthcare.com
E-MAIL:	Product Information and Demonstrations: sales@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
FAX:	414-265-7628

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.
- Appropriate contact name, telephone number and email address for correspondence.
- Your shipping address and a Purchase Order if repair or loaner/rental equipment is involved.

6.2 Declaration of Conformity

The inSIGHT Ultima System complies with the following standards

Safety

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1:2012 (or IEC 60601-1:2012 reprint)
- EN 60601-1 3rd Edition
- Canadian National standard: CAN/CSA-C22.2 No. 60601-1:08
- US National standard: ANSI/AAMI ES60601-1: 2005 / A2:2010
- Japan standard: JIS T0601-1:2012
- Korean standard: KS C IEC 60601-1

EMC

- IEC 60601-1-2: 3rd Edition, 2007-03
- EN 60601-1-2: 2007
- EN 55011: 2009 + A1" 2010, Class A, Group 1
- CISPR 11, Ed. 5.1, 2010-05, Class A, Group 1

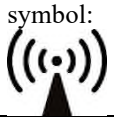
6.3 EMC Information

6.3.1 Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The inSIGHT Ultima System is intended for use in the electromagnetic environment specified below. The customer or the user of the inSIGHT Ultima System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The inSIGHT Ultima 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 inSIGHT Ultima 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	

6.3.2 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The inSIGHT Ultima System is intended for use in the electromagnetic environment specified below. The customer or the user of the inSIGHT Ultima System should assure 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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	AC Main power supply 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)	AC Main power supply 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	AC Main power supply quality should be that of a typical commercial or hospital environment. If the user of the inSIGHT Ultima System requires continued operation during AC Main power supply interruptions, it is recommended that the inSIGHT Ultima 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 AC Main power supply voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
The inSIGHT Ultima System is intended for use in the electromagnetic environment specified below. The customer or the user of the inSIGHT Ultima System should assure 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 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the inSIGHT Ultima System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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 inSIGHT Ultima System is used exceeds the applicable RF compliance level above, the inSIGHT Ultima 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 inSIGHT Ultima System. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

6.3.3 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment the inSIGHT Ultima System			
The inSIGHT Ultima System is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the inSIGHT Ultima System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the inSIGHT Ultima 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.			

6.4 Specifications

6.4.1 inSIGHT Ultima Central Unit

Part Number:	H12R-2000	
Dimensions:		
Height:	2.0 in	(5.1 cm)
Width:	5.0 in	(12.7 cm)
Depth:	8.0 in	(20.3 cm)
Weight:	2 lb	(0.9 Kg)
Power Source:	5/12 Vdc, 30W, provided by medical grade external power supply 100-240V~, 2 A, 50-60 Hz, provided by isolation transformer.	
Instrument Control:	PC software with a USB connection.	
Patient Connection:	Isolated BF patient connection through signal conditioning modules.	
Channels:	Up to 48 Channels, with up to 48 displayed simultaneously.	
Channel Types:	Provided through separate signal conditioning units: Pressure and Impedance.	
Analog to Digital Conversion:	Integral to inSIGHT Ultima, 16 bit.	
Catheter Type:	Disposable or Reusable (Contact Technical Support for suitability listing).	
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)

6.4.2 Isolation Transformer

Part Number:	ISO-MED-3	
Type:	Medical Grade	
Dimensions:		
Height:	3.5 in	(8.9 cm)
Width:	6.5 in	(16.5 cm)
Depth:	10.5 in	(26.7 cm)
Weight:	13 lb	(6 Kg)
Power Source:	Selectable: 100, 120, 220, 240 V~, 50-60 Hz	
Output:	Selectable: 115, 230 V~	
Power:	600 VA	
Amps:	5.0 Amps	
Regulation (Voltage Drop)	< 5%	
Leakage Current:	< 100 ❍A	
Approvals:	EN 60601-1	

6.4.3 Cart

Part Number:	CART5R	
Dimensions:		
Height:	66 in	(167.6 cm)
Width:	19 in	(48.3 cm)
Depth:	24 in	(61 cm)
Weight:	120 lb	(54.4 Kg)
AC Power Input:	Selectable 100/120/220/230-240V~, 5 A, 50-60 Hz (see Isolation Transformer)	
Approvals:	See Declaration of Conformity above.	