Diversatek Healthcare

ZepHr® Reflux Monitoring System

User's Guide

Diversatek Healthcare

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Notes, Notices, and Cautions in User's Guide

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

Symbols Marked On Devices

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.
Caution	Caution, consult accompanying documents
Use-By Date (YYYY-MM-DD):	Expiration date for single use and reusable probes.
Do Not Reuse:	Marked on single use probes.
Non-Sterile:	The product associated with this symbol is not sterilized after manufacturing.
Not made with natural rubber latex:	The product associated with this symbol is not made with natural rubber latex.
Event 1 or Enter Key:	The key on the Recorder that acts as an Enter key for accepting the current selection on the display. The key also records Event 1 during data acquisition. See section 4 Record the Patient Study for details on setting the Event 1 value.
Event 2 or Left Key:	The key on the Recorder that acts as a left arrow key for moving the focus on the display to the left. If the focus is already fully to the left, the Left Key will act as an Enter key for accepting the current selection on the display. The key also records Event 2 during data acquisition. See section 4 Record the Patient Study for details on setting the Event 2 value.
Event 3 or Right Key:	The key on the Recorder that acts as a right arrow key for moving the focus on the display to the right. If the focus is already fully to the right, the Right Key will act as an Enter key for accepting the current selection on the display. The key also records Event 3 during data acquisition. See section 4 Record the Patient Study for details on setting the Event 3 value.
Begin Meal Key:	The key on the Recorder that records the beginning of an eating period during data acquisition.
End Meal Key:	The key on the Recorder that records the end of the eating period during data acquisition.

	Light Key:	To conserve battery power, the Recorder turns off the display light after a certain period of no user input. Pressing the Light Key will turn on the light.
	Diary Key:	Pressing the Diary Key will create a Diary event during data acquisition. The Diary event can be used in conjunction with a patient's handwritten diary to record events or observations not handled with Event 1, Event 2, and Event 3. See section 4.7.1 Record Symptoms for details on using the Diary feature.
	Upright or Up Key:	The key on the Recorder that acts as an up arrow key for moving the focus on the display upward. Pressing the Upright Key also records the time that the patient's torso moves to an upright position during data acquisition.
	Recumbent or Down Key:	The key on the Recorder that acts as a down arrow key for moving the focus on the display downward. Pressing the Recumbent Key also records the time that the patient's torso moves to a 45° or greater reclining position during data acquisition.
	International Protection Rating:	The device provides no protection from the ingress of liquids or solids.
	EC Representative:	Authorized Representative in EU.
	Manufacturer:	Name and address of device manufacturer.
	Serial Number:	The manufacturer's serial number uniquely identifying the device.
	Part /Reference Number:	The manufacturer's part number of the device for re-order.
	Medical Device:	Indication the device is a medical device.
	Do Not Discard:	The device contains electronics and must be disposed of in accordance with local regulations.

Recorder Classifications

	Type BF Applied Part:	This symbol indicates that the patient applied part (probe) is Type BF (floating from electrical ground) which offers a specific level of safety.
	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.

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 probe produces analog output. The Recorder converts that output to digital data and saves it to the patient's data file. The A/D channel refers to the probe channel.
EGJ:	Esophagogastric Junction.
LES:	Lower Esophageal Sphincter. A ring of smooth muscle fibers at the junction of the esophagus and stomach. Also called cardiac sphincter or gastroesophageal sphincter.
MII:	Multichannel Intraluminal Impedance.
UES:	Upper Esophageal Sphincter. Often used to reference the cricopharyngeal and inferior pharyngeal constrictor muscles at the proximal esophagus.
USB:	Universal Serial Bus. USB is a standard port that enables the user to connect external devices (such as printers, CD writers, memory card readers, etc.) to a Windows system.
Z:	Impedance.
Catheter (Probe):	Patient applied sensor device.

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1 Introduction

1.1 How to Use This Guide

"Recorder" in this manual refers to the ZepHr Recorder.

This guide is designed to help you learn how to use the Recorder 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 7.1 Technical Support.

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

- Mouse click and double-click.
- Open desktop folders and double-click desktop icons to run 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 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*.

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

1.2 CAUTION: Safety Instructions

The Recorder is a sensitive electronic instrument. Please use the following safety guidelines to help ensure your own personal safety and to help protect your ZepHr 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. 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 ZepHr 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. Use of this device for other than the intended use is strictly prohibited.

⚠ CAUTION: Single use catheters are designated as such for the protection of the patient. If single use catheters are reused the risk of cross contamination with other patients is possible. Do not reuse single use catheters.

⚠ CAUTION: Probe pouches are marked with the expiration date on the label. Do not use expired probes.

⚠ CAUTION: Do not get the Recorder wet as the device is not waterproof.

⚠ CAUTION: Do not expose the Recorder to x-rays, metal detectors, MRI, or other strong radiation.

⚠ CAUTION: Do not drop the Recorder.

⚠ CAUTION: Do not attempt to open or service the Recorder.

⚠ CAUTION: Remove and discard the used batteries after each completed study.

⚠ CAUTION: Electromagnetic interference is possible between Z probes and implanted devices such as pacemakers, internal defibrillators and gastric stimulators. Monitoring of all implanted devices is advised. Consult with the manufacturer of the implanted device for any possible interference issues.

⚠ CAUTION: Follow instructions provided with all types of probes used with the ZepHr System.

⚠ CAUTION: Discard all used disposable probes in accordance with local biohazard requirements. Refer to section 3.5 Decommissioning and Disposal for additional information.

⚠ CAUTION: The Recorder incorporates a lithium device. Dispose of the Recorder in accordance with local regulations or return to manufacturer. Refer to section 3.5 Decommissioning and Disposal for additional information.

You can contact Technical Support either by email or telephone.

- Email address is technicalsupport@diversatekhc.com.
- The telephone number is 303-470-7020.

⚠ CAUTION: Instruct the patient to not wear the strap around their neck while in bed.

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

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

⚠ CAUTION: Do not apply liquid directly to the recorder. Please refer to the cleaning instructions in section 3.2 Cleaning Procedure.

⚠ CAUTION: Only use Diversatek Healthcare approved probes, buffer solution and accessories with the ZepHr Recorder. 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 ZepHr Recorder in association with an MRI machine. The ZepHr Recorder contains sensitive electronics not designed to operate in the extensive magnetic fields of an MRI machine.

⚠ CAUTION: Do not use the ZepHr Recorder 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 ZepHr Recorder in an oxygen rich environment.

⚠ CAUTION: Any serious incidents that occur in relation to the ZepHr Recorder and/or probes should be reported to Diversatek and the Competent Authority.

⚠ CAUTION: The infusion (air) port on the side of infused probes is for probe locating only and not for the infusion of any medications or other substances other than air from a Sphincter Locator accessory.

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

NOTICE: Use of non-Diversatek Healthcare approved memory cards can cause unpredictable intermittent device operation.

NOTICE: Insertion of AA alkaline batteries powers "ON" the Recorder. The batteries must be removed to switch "OFF" the Recorder. Removing batteries is not synonymous with ending the study.

NOTICE: Always use new alkaline batteries for each study.

NOTICE: Do not store or use the ZepHr System in extreme temperatures. The ZepHr System is best stored between 32° and 104°F (0° to 40°C). See section 6.8.

NOTICE: The ZepHr recorder should be kept dry. The carrying case provides some protection from water ingress, however, it is best to protect the unit from any exposure to fluids.

NOTICE: Use only with Diversatek Healthcare Z/pH and pH-only probes.

NOTICE: The ZepHr Recorder contains no user serviceable parts. The device must be sent to Diversatek Healthcare for servicing.

1.3 Product Description

1.3.1 Indications for Use

The ZepHr Recorder (registered as Accessory Model MII), when used in conjunction with a pH probe, can be used as an aid in differentiating acid vs. non-acid reflux events. In addition, the ZepHr Recorder is intended to measure motor function of the proximal gastrointestinal tract including swallow effectiveness and directional bolus transport by means of intraluminal impedance recording when used in conjunction with a Z/pH probe. The ZepHr Recorder is not intended for use in biliary studies.

The ZepHr Reflux Monitoring System is approved for adult use only.

1.3.2 Contraindications

Reflux studies are 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

1.3.3 Biocompatibility

The ZepHr Recorder system utilizes 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.

Patient contacting components are made with materials that do not contain the following:

- Natural rubber latex
- BPA (Bisphenol A)
- Phthalates
- Other CMR substances (carcinogenic, mutagenic or toxic to reproduction)

1.3.4 Overview

The ZepHr Recorder is an ambulatory diagnostic instrument used to quantify gastroesophageal reflux and correlate reflux episodes to symptom events occurring during the study period. ZepHr Monitoring employs concurrent collection of Multichannel Intraluminal Impedance (MII/Z) data and pH data. Reflux episodes are identified by impedance based on the ability of impedance to detect all reflux episodes; both acid and nonacid. pH sensors are also employed to support the differentiation between acid and nonacid reflux episodes. If a reflux episode is detected by impedance and the pH is below 4 for at least 5 seconds during the reflux (MII) episode, the episode is characterized as acid reflux. Conversely, if a reflux episode is detected with impedance and the pH remains above 4.0, the episode is characterized as nonacid reflux.

The Recorder can be used with a combined modality impedance/pH (Z/pH) probe to assess both acid and nonacid reflux. Alternatively, the Recorder can be used to acquire pH-only studies in conjunction with 1, 2 or 3 channel pH probes.

Diversatek Healthcare manufactures a complete series of Z/pH and pH-only probe models sold under the product name ZepHr®, ComforTEC® and ComforTEC® Plus.

ZVU Software is used to configure a new study on the memory card. The configuration process supports entry of patient data, selection of a study workflow which is based upon the specific probe selected and designation of the symptom event keys to match a specific patient's symptoms. After the study is acquired, ZVU Software is used to manage the transferring of acquired data on the memory card to the analysis computer for subsequent analysis.

The ZepHr System's memory card is included with the Recorder upon purchase. If additional or replacement memory cards are needed, they should be purchased from Diversatek Healthcare to ensure compatibility and reliability.

The memory card reader is installed on the analysis computer via the USB port. Once installed, the memory card reader supports the configuration of memory cards for new studies and transferring of acquired studies.

Diversatek Healthcare's ZVU Software supports the analysis and report generation of Z/pH (acid, non-acid) and pH (acid) reflux studies.

1.3.5 ZepHr System Components

The ZepHr System consists of the following components:

1.	Host Computer (U.S.A.):	Provides computer processing capabilities to setup, store, and analyze recorded patient data.
2.	Memory Card Reader:	Removable drive that can read and write to a memory card.
3.	Memory Card:	Provides Recorder with patient specific instructions for recording a study. The Recorder writes study data per the instructions onto the memory card for later transfer by the Host Computer and ZVU Software.
4.	Recorder:	Records patient's position, symptoms, events, meal periods, and Z/pH data during an ambulatory study.
5.	Carrying Case:	Provides a convenient way for the patient to carry the Recorder during a study.
6.	ComforTEC® Z/pH (MII/pH) Probes (infused and non-infused; internal and external reference): and ComforTEC® Plus pH Probes (infused and non-infused; internal reference):	Disposable probes used to collect biomedical data and convert it into a format that can be displayed and analyzed by a computer.
7.	ZepHr System Starter Kit*:	Includes SD card reader, Zvu Software, and pH Calibration Kit (pH buffer and tubes for calibrating pH channels and verifying impedance channels before each study).
8.	AirFlo™ Sphincter Locator	Air pressure infusor for locating the upper or lower esophageal sphincter by providing uncalibrated pressure readings as the probe is pulled slowly through the sphincter.
9.	ZVU Software:	Provides an easy way for the user to setup the memory card for recording a study, transfer recorded data, display data for analysis and report the data.

*The ZepHr System Starter Kits and pH calibration kits (including pH buffer solutions and calibration tubes) are not covered by CE 2460 (not covered under the scope of notified body certification under EU medical device regulation).

1.3.6 Recorder Main Features

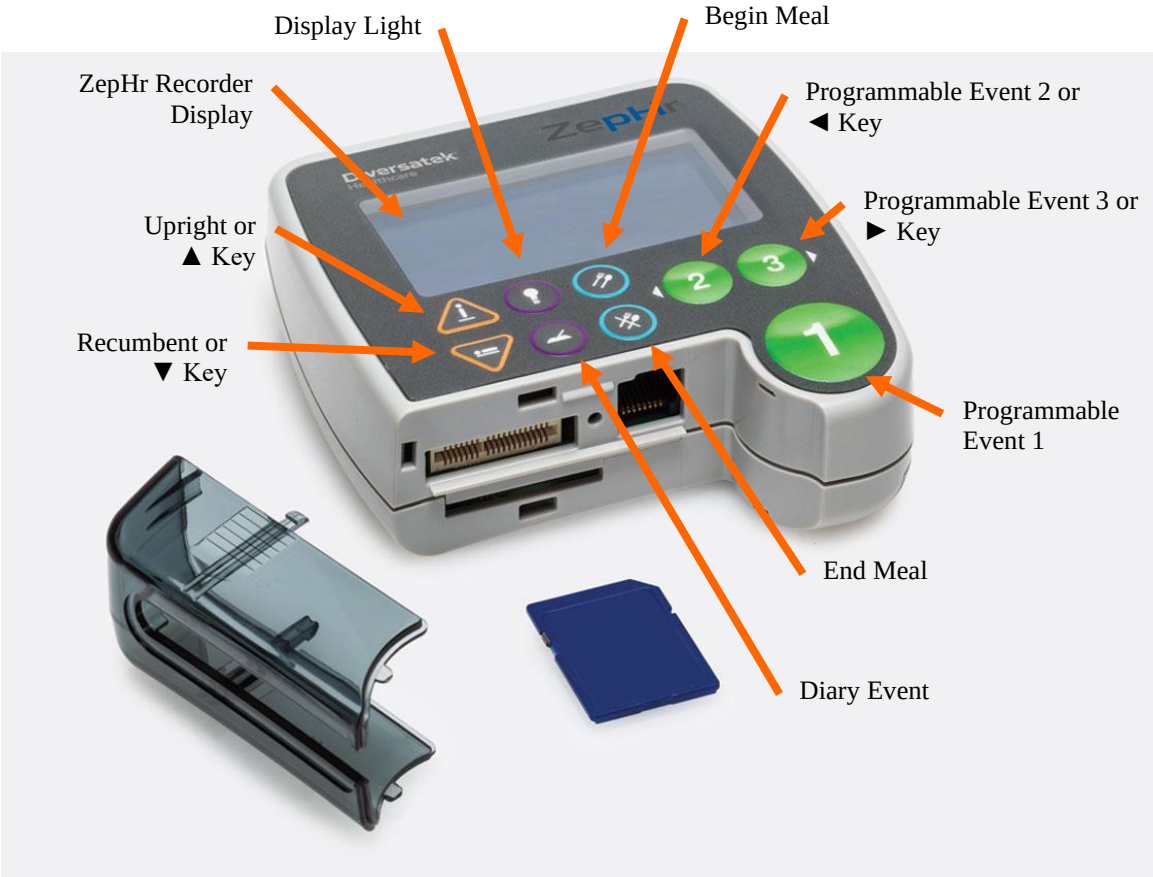


Figure 1: ZepHr Recorder - Front View

ZepHr Recorder Features:

- Small and light-weight.
- Verifies that the probe and selected protocol correspond.
- Supports calibration of Z/pH and pH-only probes.
- Supports pressure location techniques for probe positioning properly with respect to the lower or upper esophageal sphincter.
- Records and stores reflux data during ambulatory Z/pH or pH-only studies.
- Stores body position data as entered by Recumbent and Upright keys.
- Stores meal period data as entered by Begin Meal and End Meal keys.
- Stores symptom events as entered by programmable symptom Event 1, Event 2, and Event 3 keys.
- Stores diary event markers that may be referenced to a written diary.

See the Symbols Marked on Devices section at the beginning of this User's Guide for descriptions of Recorder keys.

1.3.7 Probe and Memory Card Connection Points

Figure 2: ZepHr Recorder - Top View with Cover Removed

ZepHr Connection Point Functions:

- Memory card connector supports insertion of a memory card for data storage. To insert, push the card in fully. To remove, push the card in and release, then pull the card out completely.
- For pH-only probes, the RJ-45 connector supports both input of signal from AirFlo Sphincter Locator and connection of pH-only probes.
- Z/pH probe connector supports both input of signal from the AirFlo Sphincter Locator and connection of Z/pH probes.
- A cover secures both memory card and probe connection during study to prevent disconnection during a procedure.

1.3.8 Battery Compartment

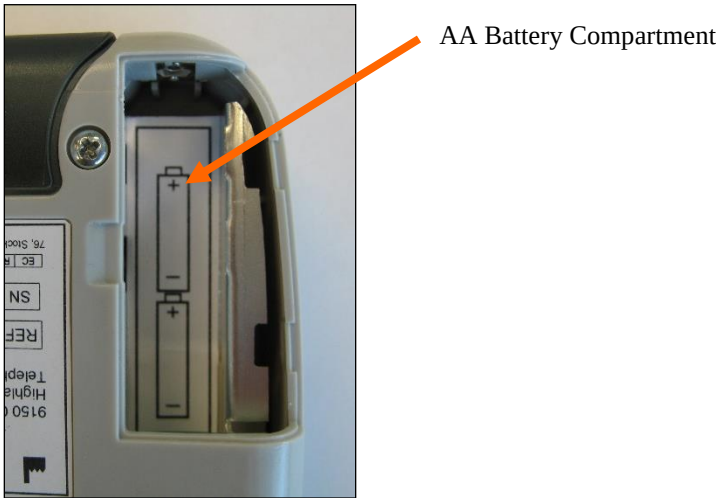


Figure 3: ZepHr Recorder – Back View with Battery Compartment Cover Opened

Battery Compartment Functions:

- Supports connection of AA alkaline batteries to power the Recorder.
- Recorder powers on when last battery is inserted.
- Removal of one battery powers down the Recorder.

NOTE: Incorrect installation of a battery causes no harm, but the device will not run. Refer to the battery orientation graphic inside the battery compartment (see image above).

NOTE: Use only alkaline (LR6) batteries. Good quality batteries such as Energizer and Duracell brand batteries are recommended. Other batteries may not fit properly and could cause interrupted studies and shortened battery life.

1.3.9 pH Calibration Kit

Figure 4: pH Calibration Kit

Calibration Kit Components:

- pH 4 and pH 7 calibration buffer solutions.
- Calibration tubes for calibration buffer solutions.
- Tube for rinse water.
- Calibration tube stand.

The ZepHr System Starter Kits and pH calibration kits (including pH buffer solutions and calibration tubes) are not covered by CE 2460 (not covered under the scope of notified body certification under EU medical device regulation).

⚠ CAUTION: Do not combine buffer bottles to consolidate multiple containers as this may change the concentration of the solution.

⚠ CAUTION: Do not fill the same calibration tube from more than one supply bottle as this may change the concentration of the solution.

⚠ CAUTION: Use fresh calibration buffer solution that is within its expiration date for each calibration. Use only Diversatek Healthcare buffer solutions for calibrating.

NOTE: Replace buffer solutions in the calibration tubes with fresh buffer and rinse water on a daily basis.

NOTE: Tightly cap the buffer solution bottles when not dispensing. Prolonged exposure to air may change the pH of the solution.

1.4 Software Installation

Your ZepHr System is delivered with all required software 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.

1.4.1 System Requirements

For ZepHr Systems with ZVU Software, 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.

1.4.2 Connecting the System to a Data Network

The PC utilized by the ZepHr 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 PC conforms to the conventional Ethernet standard IEEE 802.3. There are no required characteristics or configuration of the IT network.

If the PC is connected to a data network, please be aware of the following:

⚠ CAUTION: Connection of the PC 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.

1.4.3 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 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.

1.4.4 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.

1.4.5 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 1.4 Software Installation.

1.5 Security and Authentication

The ZVU 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.

2 Getting Started

This section provides important information to help you get started with the ZepHr recorder.

2.1 Selecting a Location for the Procedure

Selecting a proper location is critical for conducting successful reflux procedures. In most cases, the typical medical office procedure room will work successfully for reflux procedures. Consider the following items when selecting a location to use:

- Privacy: medical information and other protected personal information is usually discussed with the patient while setting up for a reflux procedure.
- Free of distractions: the area selected should be a quiet space with minimal distractions from other patients or medical personnel.

2.2 First-time Setup of a Recorder

With new systems, all required software has been installed on the Host Computer.

- Set the clock on the Recorder if it is the first time the Recorder is to be used. See section 3 Setup and Maintenance.
- Follow the directions in section 2.3 Overview: Run a ZepHr Study.

2.3 Overview: Run a ZepHr Study

- Put the memory card into the memory card reader attached to the computer.
- Set up the memory card for the upcoming patient study using ZVU. See section 4 Record the Patient Study .
- Remove the memory card from the computer's memory card reader and insert into the Recorder.
- Setup the Recorder for the patient. See section 4.2 Setup the Recorder for the Patient.
- Calibrate the probe. See section 4.3 Calibrate Probe.
- Position the probe in the patient. See section 4.4 Position the Probe.
- Instruct the patient in recording events. See section 4.7 Record Events and Body Positions.
- Start recording patient data. See section 4.5 Record the Study.
- (Optional) Perform 10 saline swallows prior to reflux study. See section 4.6 Record Esophageal Function Evaluation.
- After recording data for a sufficient amount of time, usually 24 hours, stop the recording. See section 4.8 Stop the Patient Study.
- Remove the memory card from the Recorder and replace in the computer's memory card reader.
- Transfer the patient data from the memory card using ZVU.
- (Optional) Once the data is successfully transferred off the memory card, the card can be erased to make way for the next patient study.

2.4 Training the Patient

The accuracy and success of the study is directly related to how well the patient understands how to properly operate the ZepHr Recorder. In addition, since the need to wear the recorder and probe is sometimes viewed as an inconvenience to the patient, a thorough understanding of the recorder may help to make the experience as stress-free as possible. Extra care should be taken to instruct the patient concerning at least the following items. It is helpful to provide a simple instruction/reminder sheet for these items and others you may determine through experience. Refer to the later sections of this manual for detailed explanations and instructions.

- Meaning and function of each button.
- How to properly press a button once for an event, and not repeatedly press the button for the same event.
- Point out the audible feedback (beep).
- How to recognize when the batteries are depleted and need to be replaced.
- How to replace the batteries and restart the recording.

- Remind the patient not to remove the probe or SD card from the recorder at any time.
- Remind the patient not to remove the recorder from the carrying case.
- Review with the patient precautions on wearing the recorder under clothing.
- Remind the patient to keep the recorder dry (i.e. do not take it into the shower or bath).
- Provide the patient with your facility's contact number to call if they have issues.

2.5 Patients with Special Needs

The ZepHr recorder has been designed to be simple to configure and operate. For patients with special needs such as visual or cognitive disabilities, it is recommended the patient be assisted by a guardian or caregiver to help with operating the recorder. In some cases, the recorder unit may be placed in a backpack or worn under the patient's clothing to minimize unintended operation of the recorder.

3 Setup and Maintenance

3.1 Setup Options

The recorder's *Setup* screen permits setting the language, setting the date, setting the time and setting the date format. It also can display information about the recorder such as the recorder type, the serial number, etc.

3.1.1 Access the Setup Screen

- Remove the memory card from the Recorder if it is plugged in. See Figure 2, page 8.
- Place AA alkaline batteries into the Recorder's battery compartment. Assure the batteries are correctly oriented as per the symbols in the battery compartment. See Figure 3, page 9.
- When the startup screen appears, press the **Diary** key. See Figure 1, page 7.
- Note: If desired, the *Setup* screen can also be accessed by following menu prompts:
  - Remove the memory card from the Recorder if it is plugged in. See Figure 2, page 8.
  - Place AA batteries into the Recorder's battery compartment. Assure the batteries are correctly oriented as per the symbols in the battery compartment. See Figure 3, page 9.
  - When the startup screen appears, press the **Event 1** or **Enter** key (**Enter**).
  - When the *No Flash Card* screen appears, press the ◄ key to highlight *NEXT* on the screen and press **Enter**.
  - When the task selection screen appears, use the ▼ key to scroll to the *Setup* option and press **Enter**.

3.1.2 Set Recorder Time and Date

Before beginning the initial study, the Recorder must be set with the current time and date for your location. Once these Recorder settings are accomplished, you will not need to perform this action again unless you wish to change the time to accommodate a change such as daylight savings time. The Recorder will maintain these settings during time periods when batteries are removed.

To setup the Recorder time and date:

- Go to the setup screen as described in section 3.1.1 Access the Setup Screen.
- When the *Setup* screen appears, use the ▼ key to scroll to the *Set Date* option by pressing **Event 1** or **Enter** key (**Enter**).
- Use the ▼ key and/or ▲ key to set the month.
- Use the ► key to scroll right or **Enter** to select the day field.
- Use the ▼ key and/or ▲ key to set the day.
- Use the ► key to scroll right or **Enter** to select the year field.
- Use the ▼ key and/or ▲ key to set the year.

- Press **Enter** to set the date and return to the main *Settings* screen.
- Use the ▼ key to select the *Set Time* option and press **Enter**.
- Use the ▼ key and/or ▲ key to set the hour.
- Use the ► key to scroll right or **Enter** to select the minute field.
- Use the ▼ key and/or ▲ key to set the minute.

NOTE: Set the minute field and the upcoming second field to the time when you will press **Enter** to start the clock.

- Use the ► key to scroll right or **Enter** to select the second.
- Press **Enter** when the time arrives matching your above settings.

The time and date settings are now complete.

- Highlight **Done** and press **Enter** to return to the *Setup* screen.
- Highlight **Done** and press **Enter** to exit the *Setup* screen and put the Recorder into the *Standby* mode.

3.1.3 Changing the Language

- Go to the setup screen as described at the start of the setup section.
- When the *Setup* screen appears, use the ▼ key and/or ▲ key, if necessary, to scroll to the *Language* option. Press **Event 1** or **Enter** key (**Enter**).

  Note: The current language will be identified with an "*". Pressing **Enter** at this time keeps the current language.

- Use the ▼ key and/or ▲ key, if necessary, to scroll to the desired language. Press **Enter**.
- Remove and re-insert the batteries to power cycle the Recorder.

3.1.4 Changing the Date Format

The date format can be set to *mm/dd/yyyy* (month/day/year) format or to *dd/mm/yyyy* (day/month/year) format.

- Go to the setup screen as described at the start of the setup section.
- When the *Setup* screen appears, use the ▼ key and/or ▲ key, if necessary, to scroll to the *Date format* option. Press **Event 1** or **Enter** key (**Enter**).

  Note: The current date format will be identified with an "*". Pressing **Enter** at this time keeps the current date format.

- Use the ▼ key and/or ▲ key, if necessary, to scroll to the desired format. Press **Enter**.
- Remove and re-insert the batteries to power cycle the Recorder.

3.1.5 Enabling the Study Time Limit

The Study Time Limit is a configurable option that when enabled will stop the recording of a study 24 hours after it was started. Note this is 24 hours of clock time and not actual recording time. For example, if a study is stopped to change the batteries, the resulting recorded study time will be less than 24 hours.

- Go to the setup screen as described at the start of the setup section.
- When the *Setup* screen appears, use the ▼ key and/or ▲ key, if necessary, to scroll to the *Study Time Limit* option. Press **Event 1** or **Enter** key (**Enter**).
- Use the ► key or ◄ key to toggle the feature on or off. Press **Enter**.

3.1.6 About the Recorder

The following information about the ZepHr Recorder can be viewed by accessing the *About* screen:

- Type
- Serial number
- Configuration
- Revision number
- Firmware revision number
- Text revision number

- Go to the setup screen as described at the start of the setup section.
- When the *Setup* screen appears, use the ▼ key and/or ▲ key, if necessary, to scroll to the *About* option. Press **Event 1** or **Enter** key.

3.2 Cleaning Procedures

3.2.1 Recorder and AirFlo Sphincter Locator

Clean the outside of the Recorder and the AirFlo Sphincter Locator accessory as needed with disinfectant solutions or an approved hospital grade wipe defined by the appropriate rules of the using institution.

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

3.2.2 Calibration Tubes

Change the buffer solutions and rinse water in the calibration tubes with fresh solution on a daily basis. When using external reference probes, since these require the patient to place a finger in the buffer solution as part of the calibration process, replace the buffer solutions and rinse water after each use.

Clean the calibration tubes monthly or more frequently as required by the current hospital/clinic practices by following these steps:

1) Discard buffer solutions and rinse water that is in the calibration tubes.
2) Clean the tubes with mild soap and water, then rinse well with tap water and drain. For locations with hard water, do a final rinse with distilled water to help keep water deposits from forming.
3) Allow to air dry.

3.3 Preventative Maintenance

The ZepHr recorder should be periodically examined to ensure the device is in working order. This will help eliminate the chance for troubles when 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.

- Inspect the recorder enclosure for cracks and other damage.
- Check the retaining clips of the probe cover have not been broken off. If the retaining clips have broken off the probe cover should be replaced.
- Check the retaining clips of the battery cover have not been broken. If the retaining clips have broken off the battery cover should be replaced.
- Clean the positive battery contact using a cotton swab and alcohol to remove accumulated particles.

3.4 Service

There are no serviceable components in the Recorder. If necessary, the device should be returned to the manufacturer or manufacturer's representative for repair.

3.5 Decommissioning and Disposal

The ZepHr 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

4 Record the Patient Study

4.1 Setup the Patient in Zvu

The ZepHr recorder utilizes a memory card containing the information needed for the recorder to conduct the patient study. Set up the card using Zvu Software. For assistance on using Zvu for reflux studies, refer to the additional help guides and information accessible from within the software.

NOTE: Do not use the ZepHr memory cards for storing data files not related to the reflux study. The Zvu software will delete all files on the SD card prior to writing new files for a study.

- For a new patient, create the patient record using the Zvu Patient Management screen. For a patient that has already been the subject of a prior reflux or manometry study, locate the original patient record on the Patient Management screen.

- Add a new study to the patient record and select the workflow that is appropriate for the type of probe to be used for the study. (The workflow must match the probe type being used, otherwise the recorder may record incorrect data.) Add any additional study demographic information and save the patient record.

- Progress to the screen for setting up the memory card, set the following configurations and save the study files to the memory card.
    - Annotation (Symptom Event) Buttons 1, 2 and 3:
      These buttons provide a convenient way for the patient to indicate when a symptom has occurred. They can be customized depending on the patient's most common complaints. All three event keys must be assigned a symptom or be intentionally disabled using the <Disabled> event.

      It is suggested that the primary symptom or most frequent symptom be selected for Event Button 1.

      If desired, all event buttons can be set to the same symptom to simplify patient usage.

    - View pH While Recording:
      When this option is selected the pH value will be displayed on the screen of the Recorder.

    - Probe Disconnect Warnings
      Depending on which of these options are selected, the Recorder will either display a message on the screen informing the patient the probe has been disconnect, emit an audible warning beep, or both.

      NOTE: The probe disconnect warnings only apply to Z/pH probes. pH-only probes do not contain the probe disconnect circuitry and this setting is ignored by the Recorder.

    - Use Pressure LES Location
      Check this option if you are intending to use the AirFlo Sphincter Locator to position the probe in the patient.

4.2 Setup the Recorder for the Patient

NOTICE: Before starting the initial study, the Recorder must be set with the current time and date for your location. See section 3.1 Setup Options.

NOTE: Before starting each study, setup the new patient study on the memory card. See the section above for details.

- Insert the memory card into the Recorder. See Figure 2, page 8.

NOTICE: The icons on the memory card will help to insert the memory card into its slot on the Recorder with the proper orientation. Forcing the card in upside down will damage the Recorder.

- Insert new AA alkaline batteries into the battery compartment of the Recorder. The batteries must be inserted as per the graphic inside the battery door. See Figure 3, page 9. Secure the batteries with the battery cover.

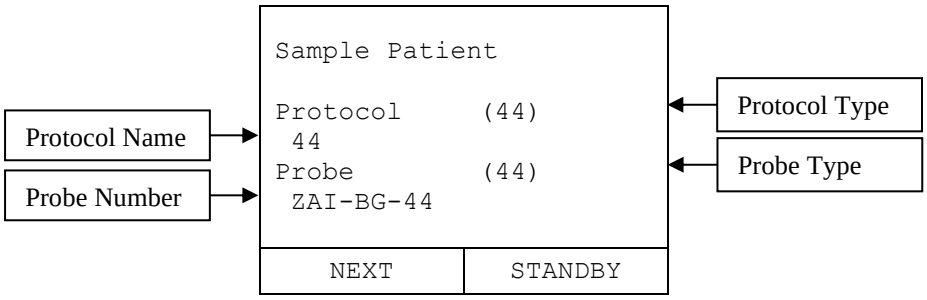
The Recorder will beep once when the last battery is inserted and battery power is available.

A "low power" alert will occur if the batteries are not new or have been partially exhausted.

- At the Startup screen, press the **Event 1** or **Enter** key (**Enter**) to advance to the next screen.

NOTE: If there is an acquired study already on the memory card, you cannot proceed with calibration. If this warning occurs:
- Put the Recorder into Standby mode.
- Remove the memory card.
- Follow the directions in section 5 Transfer an Acquired Study for Analysis.

The Recorder will take a few seconds to read the memory card and then the patient's name or alternate patient identifier, protocol and probe information will be displayed.



NOTE: The protocol type field will be blank for:
- pH-only protocols
- Protocols that have not been assigned a two digit protocol type.

The probe type field will be blank for:
- pH-only probes
- Z/pH probes that do not have probe identifiers.

Studies can be performed if the probe type field is blank.

NOTE: Studies cannot be performed if the protocol type does not match the probe type. A "Probe incompatible with protocol" message will be displayed. The Recorder will not let the setup continue.

- Press the **Enter** key to advance to the Calibration screen. See section 4.3 Calibrate Probe for details.

4.3 Calibrate Probe

pH sensors must always be calibrated prior to acquiring a study. Internal reference probes can be calibrated without the patient present. However, external reference probes require the patient to be present during calibration.

The proper functioning of all impedance channels must be verified prior to initiating a new study. The impedance channels are verified during the pH channel calibration.

The pH calibration and impedance channel functional verification steps are achieved as follows:

NOTICE: Verify the probe is not expired. The expiration date is listed on the pouch label.

- Setup Equipment Figure 4 pH Calibration Kit.

NOTICE: Use fresh calibration buffer solution that is within its expiration date each time you calibrate. The solutions should be at room temperature during the calibration process. Use only Diversatek Healthcare buffer solutions for calibrating.

- Fill the center tube with tap water.
- Submerge all the probe sensors into the pH 4 calibration buffer solution or the tap water.
- Soak the probe for 10 minutes prior to calibration.

NOTICE: DO NOT soak pH probes in distilled/de-ionized water. Internal reference probes contain a specially formulated electrolyte gel. Prolonged soaking in ion-free water may change the concentration of the gel.

- Remove the bottom cover on the Recorder.
- Connect the probe to its proper port on the Recorder. See Figure 2.
- For external reference catheters, attach the electrode to the patient in proximity to the esophagus (e.g., on the chest of an adult) using the wet gel monitoring electrode provided with the probe. The electrode is gelled to improve signal quality. Before affixing the pad to the skin, clean the area with alcohol to de-fat the skin and shave the area if indicated to ensure good contact. Be sure the pad is well secured. If the patient has a skin condition that might interfere with the placement of the electrode, move the electrode patch to the nearest healthy spot of skin. Otherwise, switch to an internal reference probe with an equivalent sensor configuration.

Begin Calibration

- Using the ▼ key and/or ▲ key, highlight *Calibrate* on the Recorder display.
- Press the **Event 1 or Enter** key (**Enter**) to initiate the calibration process.
- Submerge all of the probe sensors into the pH 4 calibration buffer solution.
- Agitate the probe in the solution to remove any trapped air bubbles which may cling to the sensors.
- Press **Enter** to start the pH 4 calibration step.
- Wait 30 seconds to allow the pH channel values to stabilize. The Recorder will count down the seconds for you.

NOTICE: For external reference probes, the patient must submerse a finger into the buffer solution along with the probe. Do not drink buffer solutions.

If using a Z/pH probe, then the Recorder will check for any open impedance channels (impedance greater than 1000 ohms). If any channels are open, then an impedance error and the impedance values will be displayed on the Recorder screen.

- If an error occurs, verify that all impedance rings are submerged into the pH 4 calibration buffer solution.
- Once all of the impedance channels are below 1000, press **Enter** and then **Enter** again to continue with calibration. If all of the channels cannot be brought below 1000, the see section 6.3 Probe Fails to Calibrate for suggestions.

The Recorder will display the pH sensor A/D values as they stabilize. The display will then indicate that the pH 4 calibration is OK if the pH channel(s) are in the acceptable range. If the probe fails to calibrate, see section 6.3 Probe Fails to Calibrate for suggestions.

- Press **Enter** to select *Continue* and move to the next screen.

The Recorder will instruct you to place the pH sensor(s) in the pH 7 calibration buffer solution.

NOTICE: For external reference probes, the patient must submerse a finger into the buffer solution along with the probe.

- Rinse the probe (and the patient's finger if necessary) in the tap water.
- Gently dry the probe using tissue paper.
- Submerge all probe sensors into the pH 7 calibration buffer solution.
- Agitate the probe in the solution to remove any trapped air bubbles which may cling to the sensors.
- Press **Enter** to start the pH 7 calibration step.
- Wait 60 seconds to allow the pH channels to stabilize. The Recorder will count down the seconds for you.

The Recorder will display the pH sensor A/D values as they stabilize. The display will then indicate that the pH 7 calibration is OK if the pH channel(s) are in the acceptable range. If the probe fails to calibrate, see section 6.3 Probe Fails to Calibrate for suggestions.

Finish Calibration

- Press **Enter** to select *Continue* and move to the next screen.
- Rinse the probe (and the patient's finger if necessary) in the tap water.
- Gently dry the probe using tissue paper.

NOTICE: If an internal reference probe is calibrated before the patient arrives, keep the probe's pH channels submerged in the pH 4 tube after calibration to prevent the reference gel from drying out.

- To conserve power until the patient is ready for intubation, the Recorder can be put into Standby mode without losing calibration information.
  - To put the Recorder into Standby mode, highlight *Standby* and press **Enter**.
- When you are ready to proceed:
  - Press **Enter** to *Resume*.
  - Press **Enter** to read the memory card.
  - Press **Enter** once the card is read.
  - Press **Enter** to *Start Procedure*.
- Intubate the patient and position the probe. See section 4.4 Position the Probe for details.

CAUTION: Use of any harsh cleaning products may result in damage to the calibration tubes.

- Wash and rinse the empty calibration tubes using a mild soap and water.
  Do Not Use Alcohol or any wipes containing alcohol.
  Do Not Use Harsh detergents or any other cleaning agent.
  Do Not Use Hot Water.
- Leave the tube to air dry.
- When dry, put tubes away.

4.4 Position the Probe

After calibration is complete, the Recorder displays the "Position the Probe" screen.

In order to record accurate and useful study data, the distal esophageal pH sensor must be located 5 cm above the proximal LES (lower esophageal sphincter) in an adult sized esophagus (less for shorter esophagi). There are two common methods for accurately placing a probe in the patient's esophagus to ensure that the distal esophageal pH sensor is located at the correct position above the LES. These techniques are described in detail on the following pages.

4.4.1 Manometric Location of Probe

If the position of the LES is already known from previous manometric investigation, then the probe can be positioned in the patient based on the centimeter markings on the probe.

- Intubate the patient placing all sensors in the stomach. Normally a probe depth of 60 cm is sufficient to ensure all sensors are in the stomach.
- Position the patient in the left lateral position to increase the likelihood that the pH sensors contact gastric acid.
- Verify that the acid pH values are consistent for being in the stomach (below pH 4.4).

NOTICE: Verification of pH sensor position in the stomach using the displayed pH data is not advised if the patient is taking antireflux medications due to the suppression of gastric acid production.

The Recorder displays pH data in a non-temperature compensated format. For example, if not on acid suppression therapy a gastric acid value of pH 4.0 will appear as pH 4.4 on the Recorder display.

Off acid suppression therapy, gastric pH levels are distinctly lower than esophageal pH levels. Proper use of the pH data will verify that the probe is not curled in the esophagus and is indeed in the stomach.

- Withdraw the probe slowly to position the pH sensor the correct distance above the LES. The distal esophageal pH sensor is normally placed 1-5 cm above the LES as determined by the ZepHr protocol or the physician.
- Secure the probe to the patient using tape to prevent displacement during the study period.
- Put the bottom cover back onto the Recorder. Be careful to feed the probe through the provided slot in the cover so that the probe is not damaged.
- Start recording data. See section 4.5 Record the Study for details.

4.4.2 Pressure Sphincter Location of Probe

If the position of the LES is unknown, a pressure-sphincter-location technique can be used to identify the proximal border of the LES. This technique requires a sphincter infusion port equipped probe and a pressure infusor such as the AirFlo™ Sphincter Locator. Pressure measurement is accomplished through the infusion port located 5 or 6 cm from the distal esophageal pH sensor.

NOTE: Pay attention to the location of the infusion port in relation to the reference pH sensor on the probe. This infusion port length will be used later when positioning the probe above the proximal LES.

NOTE: In order for the Recorder to provide the pressure information when positioning the probe, the *Use Pressure LES Location* option must be checked before saving the patient file to the memory card.

Setup 1: Setup the ZepHr Equipment for pH-only studies

- Follow the infusor manufacturer's recommended procedure for the setup of the infusor.
- Connect the "Recorder" infusor cable to the connection point on the Recorder. See Figure 2. This connection will provide the uncalibrated pressure readings from the probe's infusion port to the Recorder's display.
- Connect the probe's infusion port to the infusor Luer fitting.
- Connect the probe to the infusor connector on the cable labeled "Probe".

Setup 2: Setup the ZepHr Equipment for Z/pH studies

- Follow the infusor manufacturer's recommended procedure for the setup of the infusor.
- Connect the adaptor "To ZepHr" cable to the ZepHr. This connection will provide the uncalibrated pressure readings from the probe's infusion port to the Recorder display.
- Connect the infusor "probe" cable to the ZepHr AirFlo Sphincter Locator adaptor's "From Locator" input.

CAUTION: Do NOT connect anything other than the infusor's "probe" cable to the ZepHr AirFlo Sphincter Locator adapter's "Locator input".

CAUTION: The infusion (air) port on the side of infused probes is for probe locating only and not for the infusion of any medications or other substances other than air from a Sphincter Locator accessory.

- Connect the impedance pH probe to the adaptor.
- Connect the probe's infusion port to the infusor Luer fitting.

Intubate the Patient

- Intubate the patient placing all sensors in the stomach. Normally a probe depth of 60 cm is sufficient to assure all sensors and the pressure port are in the stomach.
- Position the patient in the left lateral position to increase the likelihood that the pH sensors contact gastric acid.
- Verify that the acid pH values are consistent for being in the stomach (below pH 4.4).

NOTICE: Verification of pH sensor position in the stomach using the displayed pH data is not advised if the patient is taking antireflux medications due to suppression of gastric acid production.

The Recorder displays pH data in a non-temperature compensated format. For example, a gastric acid value of pH 4.0 will appear as pH 4.4 on the Recorder display.

- Increase the pressure in the infusor according to the manufacturer's instructions.
- Wait for pressure to stabilize on the display.
- Press the ▼ key to zero the gastric pressure.

Position the Probe

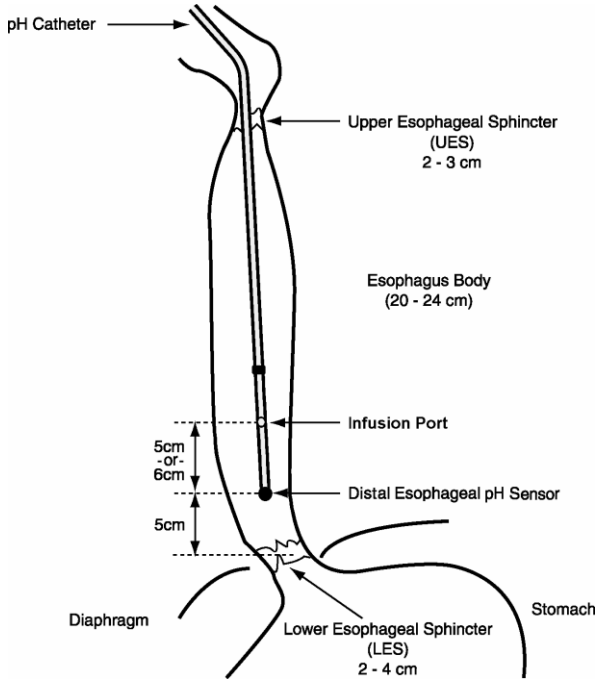


Figure 5: Pressure LES Probe Location

- Instruct the patient to not swallow until the probe is positioned. Swallows will generate contractions and relaxations in the LES and esophageal wall that will complicate the probe positioning procedure.
- Withdraw the probe in 1 cm increments, pausing five seconds between each movement.
- Observe the pressure readout after each probe movement. Watch for an increase in pressure indicating that the pressure port has entered the distal border of the LES.

NOTE: The infusor is not a calibrated system and therefore provides pressures relative to gastric pressure. The infusor pressures are not recorded and cannot be used to make diagnostic decisions regarding LES closure or relaxation pressure.

- When the pressure increases, withdraw the probe in 0.5 cm increments until the pressure goes negative indicating the pressure port has exited the proximal border of the LES.
- Once the proximal edge of the LES is known, position the probe at the appropriate distance above or below the LES as determined by the ZepHr protocol or by the physician.
- Secure the probe to the patient using tape to prevent displacement during the study period.

Disconnect the Infusor

- Disconnect the probe from the infusor.
- Replace the probe's infusion port cap to prevent reflux from escaping through the opening.
- Disconnect the infusor from the Recorder.
- If the probe is pH-only, then connect the probe to the Recorder.
- Put the bottom cover back onto the Recorder. Be careful to feed the probe through the provided slot in the cover so that the probe is not damaged.
- Start recording data. See section 4.5 Record the Study for details.

4.5 Record the Study

NOTE: If the *View pH While Recording* option was checked in ZVU when starting the patient, the pH data will be displayed in a temperature compensated format.

4.5.1 Start Recording after Calibration and Probe Positioning

- Press the **Event 1** or **Enter** key (**Enter**) to select *Record* and start the recording process.

4.5.2 Start Recording from Standby Mode

Standby does not record new patient data but does retain patient and calibration data by placing the Recorder in a sleep mode. The sleep mode does not require use of battery power. The Recorder can be activated from Standby once battery power is available and you are ready to initiate recording.

- Press the **Event 1** or **Enter** key (**Enter**) to select *Resume* and activate the Recorder display screen.
- Press **Enter** to select *Next* at the Start up screen.
- Wait for the memory card to be read.
- Press **Enter** to select *Next* at the Patient Information screen.
- Press **Enter** to select *Record* if patient data has already been acquired.

- or -

- Press **Enter** to select *Start Procedure* if no patient data has been acquired yet.
- Position the probe. See section 4.4 Position the Probe for details.
- Press **Enter** to select *Record* and start recording data.

NOTICE: Always put Recorder into Standby mode before removing the memory card or batteries. Failure to do so may corrupt the patient data files requiring the memory card be sent to Diversatek Healthcare for data recovery.

4.5.3 Start Recording after Battery Power Loss

If the batteries are removed or become depleted while the Recorder is in record mode, new batteries can be installed and recording resumed. During the time that the battery power is removed, the Recorder automatically enters Standby mode.

- To resume recording, follow the steps from section 4.5.2 Start Recording from Standby Mode.

4.6 Record Esophageal Function Evaluation

An esophageal function evaluation can be performed at the beginning or end of the data recording if the data recording is done with a Z/pH probe. The esophageal function evaluation (Z Swallow Challenge) consists of ten swallows of saline solution or some other substance with a high ionic content. This data can be analyzed in ZVU to assess the patient's capacity for bolus transit.

For each of the ten swallows:

- Prepare the ionic substance to be swallowed.
- Press the Swallow event key established when setting up the memory card, or press the Diary key and record the swallow.
- Instruct the patient to swallow the ionic substance.
- Wait 30 seconds between swallows.
- Once all ten swallows have been recorded, continue with the main study.

4.7 Record Events and Body Positions

4.7.1 Record Symptoms

The functions of the three symptom event keys are assigned while setting the patient specific instruction on the memory card (see section 4 Record the Patient Study). They can be tailored to the current patient's specific needs. Typically, the large round 1 key is set for the primary symptom. The symptom event keys will have their current symptom setting illustrated on the Recorder display screen.

Record a Symptom Event

- Instruct the patient to press the symptom event key corresponding to the symptom immediately after the symptom occurs.

When the key is pressed, a confirming beep will occur and the symptom key pressed will be highlighted on the Recorder display.

NOTE: If more than 3 symptom events need to be tracked, the diary key can be pressed and the specific type of symptom noted in the diary with the time of occurrence. These diary entries may be converted to specific entries for symptom index in the analysis software.

Disabled Event Keys

Pressing an event key which has been disabled will generate a confirming beep. However, an event will not be saved with the patient data.

Record a Diary Event

For patients who cannot comply with the symptom event recording procedure if more than 3 symptom events need to be tracked, the Diary key can be used by the patient. See Figure 1

- Instruct the patient to press the **Diary** key immediately after the symptom occurs.
- Instruct the patient to manually enter information in the patient's study diary immediately after pressing the **Diary** key.

When the key is pressed, a confirming beep will occur and the symptom key pressed will be highlighted on the Recorder display.

NOTE: The patient can press an Event key (1 – 3) or the Diary key to record the time of a symptom, but need not press both.

NOTE: When diary entries are made, it is important to also note the time the symptom occurred using the Recorder clock.

NOTE: Diary entries can be edited to reflect the actual symptom for symptom correlation in the analysis software in the post procedure phase.

4.7.2 Record Meal Periods

The meal periods of a ZepHr study must be annotated via the start meal and end meal keys. Once the start and end of meals are annotated, the meal period can be excluded from analysis.

Record the Start of a Meal

- Press the **Begin Meal** key. See Figure 1.

When the Begin Meal key is pressed, a confirming beep will occur and a *Meal* icon will appear on the Recorder's display as a visual confirmation that the Recorder is in meal annotation mode.

Record the End of a Meal

- Press the **End Meal** key. See Figure 1.

When the End Meal key is pressed, a confirming beep will occur and a *Meal* icon will disappear from the Recorder's display as a visual confirmation that the Recorder is no longer in the meal annotation mode.

- Instruct the patient to make a note in the patient's study diary if a mistake is made entering a meal period or prefers not to use the Meal keys.

NOTE: The times entered in the diary for the meal period should be taken from the Recorder's time display to assure proper synchronization to the recording. The meal's start and stop times can then be entered in the post-procedure editing process.

4.7.3 Record Body Position Changes

The periods of time the patient is in the upright or recumbent body position should be noted during the recording process. This data will then support analysis of the reflux patterns in the respective body positions.

The Recorder assumes the patient is in the upright body position at the initiation of recording.

The current body position annotation is illustrated on the Recorder's display.

CAUTION: Instruct the patient to not wear the strap around their neck while in bed or sleeping.

Record the Recumbent Body Position

- Press the **Recumbent** key to switch the Recorder from upright to recumbent mode. See Figure 1.

NOTE: When the Recumbent key is pressed, a confirming beep occurs and a *Recumbent Patient* icon appears on the Recorder's display as a visual confirmation that the Recorder is no longer in the upright mode.

Record the Upright Body Position

- Press the **Upright** key to switch the Recorder from recumbent to upright mode. See Figure 1.

NOTE: When the Upright key is pressed, a confirming beep occurs and an *Upright Patient* icon appears on the Recorder's display as a visual confirmation that the Recorder is no longer in the recumbent mode.

4.8 Stop the Patient Study

Once the time frame for the patient study has past (usually 24 hours), the data recording can be stopped and the memory card removed.

⚠ CAUTION: For patient safety, always extubate the patient *before* disconnecting the probe from the recorder.

- Extubate the patient.
- While pressing the **Light** key, press the **Event 1** or **Enter** key (**Enter**).

The screen will give the option to continue recording or stop recording.

- Use the ▼ key to select *Stop Recording*.
- Press **Enter**. The Recorder will switch to Standby mode.

NOTICE: Always put Recorder into Standby mode before removing the memory card or batteries. Failure to do so may corrupt the patient data files requiring the memory card to be sent to Technical Support for data recovery.

- Remove the bottom cover of the Recorder.
- Disconnect the probe from the Recorder and dispose of it in accordance with local biohazard requirements.
- Eject or pull the memory card out of the Recorder.
- Remove the batteries from the Recorder and discard.
- Transfer the acquired study. See section 5 Transfer an Acquired Study for Analysis for details.

5 Transfer an Acquired Study for Analysis

Once the completed study has been recorded the data needs to be uploaded from the memory card to the PC using ZVU Software. Remove the memory card from the recorder and insert it into the memory card reader on the PC. Launch ZVU and select the Download a Study link from the home page. For more information concerning using ZVU refer to the various help screens included with the software.

With the ZVU Software the clinician may:

- Display waveforms and contour as well as symptom events.
- Edit symptom events, body position and meal period data.
- Run AutoSCAN.
- Analyze waveforms to quantify reflux patterns.
- Generate study reports.

6 Troubleshooting

6.1 Recorder Setup Fails Because the Probe Does Not Match Protocol

The ZepHr Recorder reads the protocol on the memory card and compares the protocol's designated probe type to the actual type of probe plugged into the Recorder. If they do not match, the Recorder will show an error and not continue the setup.

- Put the Recorder into Standby mode.
- Remove the memory card.
- Plug the memory card into the memory card reader on the computer.
- Run ZVU.
- Select the appropriate workflow for the probe type to be used.
- Select the button to setup the memory card and confirm the optional settings and annotation (event) buttons are set as desired.
- Click the button to save the files to the memory card. Note that the memory card need not be formatted in this case.
- Remove the memory card from the reader.
- Put the memory card into the Recorder and restart the study.

If the Recorder continues to fail during startup, then contact the Technical Support. See section 7.1 Technical Support.

6.2 Battery Low or Exhausted

When recording a study, if the Recorder detects the battery level is too low it will automatically stop the recording and display a message. After a period of time, when the remaining battery power is fully depleted the screen will go blank and the recorder will be unresponsive. In either situation it is safe to replace the batteries with fresh ones and resume the recording.

From the Startup screen, resume the recording by the following key press sequence:

- Press **Enter** to activate the Recorder display screen.
- Press **Enter** at the Start up screen.
- Wait for Recorder to read the memory card.
- Press **Enter** at the Patient Information screen.
- Highlight *Record* and press **Enter**.

If the study is planned to be longer than 24 hours, it is recommended to stop the recording after the first 24 hours and replace the batteries. To stop the recording, do the following key press sequence:

- While pressing the **Light** key, press the **Event 1 or Enter** key (**Enter**). The screen will give the option to continue recording or stop recording.
- Use the ▼ key to select *Stop Recording*.
- Press **Enter**. The Recorder will switch to Standby mode.

NOTICE: Always put Recorder into Standby mode before removing the memory card or batteries. Failure to do so may corrupt the patient data files requiring the memory card be sent to Technical Support for data recovery.

- Remove all of the batteries from the Recorder and discard.
- Replace the batteries in the Recorder.
- Follow the key press sequence listed above to resume the recording after changing the batteries.

6.3 Probe Fails to Calibrate

6.3.1 Impedance Channel(s) Fail to Verify

If the Recorder displays a message informing you that there is an impedance error during the pH 4 calibration step, then try each of the following suggestions in turn until the channels verify.

- Confirm that the correct protocol has been selected.
- Confirm that the probe is connected securely to the Recorder.
- Confirm that all of the impedance sensor rings are submerged in the calibration buffer solution.
- Lightly agitate the probe in the calibration buffer solution and verify that there are no bubbles clinging to the probe.
- Disconnect the probe from the Recorder.
  - Make sure the electrical contacts on the probe as well as on the Recorder are clean and free of debris.
  - These contacts can be wiped with a clean cloth moistened with isopropyl alcohol.
    - NOTICE: DO NOT use water. DO NOT use Q-tips or cotton balls. DO NOT pour the alcohol onto the probe or Recorder directly.
  - Reconnect the probe to the Recorder verifying that a secure connection has been made.
- Try fresh buffer in the calibration tubes

If one or more impedance channel(s) continue to fail verification, then the probe may be damaged. Follow the instructions in section 4.3 Calibrate Probe again using a new probe.

If the impedance channels fail to calibrate in the new probe, then contact the Technical Support. See section 7.1 Technical Support.

6.3.2 pH Channel(s) Fail to Calibrate

If the Recorder displays a message informing you that one or more of the pH channels have failed, then try each of the following suggestions in turn until the channels calibrate.

- Confirm that the catheter has not expired.
- Confirm that the correct protocol has been selected.
- Confirm that the probe is connected securely to the Recorder.
- Confirm that the probe was soaked for at least 10 minutes in fresh, room-temperature calibration solution.
- Confirm that the calibration buffer solutions are fresh and within their expiration date. If they are not, dispose of the bad solutions and refill the tubes with fresh calibration buffer solutions.
- Confirm that all the pH and impedance sensors are in the buffer during calibration.
- Lightly agitate the probe in the buffer solution and verify that there are no bubbles clinging to the probe.
- If using an external reference probe, check if the electrode has become disconnected from the probe or patient.
- If using an external reference probe, verify that the patient's finger is in the same buffer solution as the probe.
- Disconnect the probe from the Recorder.
  - Make sure the electrical contacts on the probe as well as on the Recorder are clean and free of debris.
  - These contacts can be wiped with a clean cloth moistened with isopropyl alcohol.
    - NOTICE: DO NOT use water. DO NOT use Q-tips or cotton balls. DO NOT pour the alcohol onto the probe or Recorder directly.
  - On rare occasions, the pH sensor(s) might have an excess amount of oxidation on their surfaces. Gently wipe the pH sensor(s) with a clean cloth.
  - Reconnect the probe to the Recorder verifying that a secure connection has been made.

If the pH channel(s) continue to fail calibration, then the probe may be damaged. Follow the instructions in section 4.3 Calibrate Probe again using a new probe.

If the pH channels fail to calibrate in the new probe, then contact the Technical Support. See section 7.1 Technical Support.

6.4 Beep/Show Probe Disconnect Warnings

This audible/visible warning occurs when the connection is lost with the probe. Try each of the following suggestions in turn until the warning goes away.

- Verify that the probe is connected securely to the Recorder.
- If using an external reference probe, check to see if the electrode has become disconnected from the probe or patient.
- If using a pH-only probe, verify that the *Beep Probe Disconnect Warnings* option is unchecked before saving the patient file to the memory card.
- Disconnect the probe from the Recorder.
  - Make sure the electrical contacts on the probe as well as on the Recorder are clean and free of debris.
  - These contacts can be wiped with a clean cloth moistened with isopropyl alcohol.

    NOTICE: DO NOT use water. DO NOT use swabs or cotton balls. DO NOT pour the alcohol onto the probe or Recorder directly.

  - Reconnect the probe to the Recorder verifying that a secure connection has been made.
- Have the patient drink water. This action might reseat the probe to the wall of the esophagus.

If the warning still persists, then contact the Technical Support. See section 7.1 Technical Support.

6.5 Patient File Fails to Transfer

If the memory card or the batteries are removed before the Recorder is put into Standby mode, the patient files may not be able to be transferred. Removing the memory card or batteries may interrupt a write to the memory card that leaves the file format in an ambiguous state or the file allocation tables (FAT) out of sync.

Contact Technical Support. See section 7.1 Technical Support.

6.6 The Specified Memory Card Drive is Unavailable

Occasionally, Windows may lose connection with the memory card reader. In this case, ZVU will display an error message. Do the following:

- Verify that the USB cable is fully fitted into the memory card reader and the computer.
- Close any running programs.
- Shutdown the computer.
- Wait 30 seconds.
- Restart the computer.

When the computer is restarted, it should reconnect to the memory card reader. If it does not, then contact the Technical Support. See section 7.1 Technical Support.

6.7 Error When Erasing a Patient from the Memory Card

The Erase Patient feature attempts to identify the patient being erased and whether the files have been successfully transferred before it erases the patient files. If the patient file set is incomplete or has file format issues, then the software might error instead of erasing the patient files.

In this case, you can delete the patient files through Windows Explorer.

- Launch Windows Explorer and navigate to the memory card which will be named SANDHILLCF in the drive list.
- Select all of the files contained on the memory card.
- Press **Delete**. Click *OK*, if Windows Explorer asks for confirmation to delete the files.

The memory card should now be usable by ZVU. If it still does not work, contact the Technical Support. See section 7.1 Technical Support.

6.8 Error Messages Displayed by the ZepHr Recorder

The following table lists the possible errors the ZepHr Recorder may display and actions to resolve the situation.

Error Message	Description
Probe incompatible with protocol.	The probe installed in the recorder does not match the selected protocol. Either use the proper probe or reinitialize the SD card with the proper protocol.
Missing LOGGER.LCL file.	The calibration file is missing from the SD card. Transfer patient files to the PC using ZVU. Contact Technical Support if the data is corrupted.
pH Calibration Error.	The calibration of the pH sensors failed. Soak the probe in buffer for 10 minutes then retry the calibration procedure, try fresh buffers or use another probe.
Error writing: Logger.lev.	There was an error writing an event entry to the memory card. Transfer patient files to the PC using ZVU. Contact Technical Support if the data is corrupted.
Probe disconnected.	The probe has been disconnected from the recorder. Re-insert the probe connector into the recorder. The recording of the study will continue while this error is displayed.
ZepHr pH recorders do not support protocols that use impedance channels.	The ZepHr recorder is configured as a pH-only recorder and will not support protocols using impedance channels. Contact Technical Support for upgrade information.
No probe uses left.	The multi-use probe has been completely re-used and must be discarded.
Cannot record. Compact flash is full.	The memory card is full. Transfer data to the PC using the ZVU Software. Note: Do not use the memory card for other purposes than with the ZepHr Recorder, such as to save other unrelated files or as a back-up.
Waveform exists but errors were found in the patient protocol.	Recorded data exists on the SD card but the protocol on the card has an error and/or does not match the protocol that was used to record the data. Transfer patient files to the PC using ZVU. Contact Technical Support if the data is corrupted.
Incompatible SD card.	The SD card is not compatible with the ZepHr Recorder. Use only Diversatek Healthcare supplied SD cards. Contact Technical Support for replacements.
No SD card. No SD card detected.	The SD memory card was not detected or was not fully inserted into the Recorder. The connector is a push-in/push-out type. Push the card in until the card is seated in the most inserted position.
No probe detected. Connect probe.	The probe was not detected. Connect a probe to the recorder.
Patient data exists. Cannot calibrate.	Cannot recalibrate after recording has started because this could invalidate the recorded data. Download existing patient data if it exists. Note: It is not necessary to recalibrate if recording is temporarily stopped and restarted.
Bad or no protocol. No patient protocol found on compact flash.	The study protocol file on the SD card is corrupt or does not exist. Use ZVU Software on the PC to reformat the SD card.
Cannot record. Not calibrated.	The probe is not calibrated so the recording will not be started. Restart the recording procedure and calibrate the probe.

Impedance error: Channel(s) > 1000	The calibration procedure tests the impedance channels to ensure that they are working properly. An impedance channel reading >1000 can occur for a number of reasons: • One or more of the impedance rings is not submerged in the buffer. • There is an air bubble across one or more of the catheter's impedance rings. Agitate the catheter in the buffer and retry. • The buffer solution is contaminated. • The probe connector or the ZepHr connector is dirty. Clean with an isopropyl alcohol wipe. • The ZepHr connector has a bent or worn out pin. • The catheter is not functioning properly. • The ZepHr is not functioning properly.
Caution: Low battery voltage. Batteries may not last 24 hours.	The battery voltage level was below the recommended voltage for acquiring a 24 hour study. Insert fresh batteries. Note: the user may select Continue to begin the recording using the low voltage batteries. Although proceeding with low voltage batteries may be attempted for short, unofficial studies, do not attempt this when starting a 24 hour clinical study. If the battery level becomes too low during the recording of the study, a message will be displayed and the recording will be automatically stopped until the batteries are replaced.
Standby mode. Low battery voltage detected. Remove and replace batteries.	While a study was being recorded the battery level dropped too low. The recording has been stopped. The batteries should be replaced and the recording restarted.
Study ends at 24 hours after recording was started.	The Study Time Limit mode is enabled. See section 3.1.5 above for information to enable or disable this feature.

7 Appendix

7.1 Technical Support

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

NOTE: The ZepHr Recorder contains no user serviceable parts. The device must be sent to Diversatek Healthcare for servicing.

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) : Std hrs 7am – 5pm MST On-Call hrs 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.

7.2 Declaration of Conformity

The ZepHr Recorder complies with the following standards

Safety

- IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007)
- EN 60601-1 (3rd Edition)
- ABNT NBR IEC 60601-1:2010
- IEC 60601-1-11:2015 (2nd Edition)

EMC

- IEC 60601-1-2: 2014 (4th Edition)
- CISPR 11/EN 55011 – Group 1, Class A

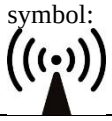
7.3 EMC Information

7.3.1 Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The ZepHr Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the ZepHr Recorder should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11/EN 55011	Group 1	ZepHr Recorder 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/EN 55011	Class A	The ZepHr Recorder 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	Not applicable (battery operated device)	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	Not applicable (battery operated device)	

7.3.2 Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The ZepHr Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the ZepHr Recorder 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	± 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 100 kHz PRR	Not applicable (battery operated device)	
Surge IEC 61000-4-5	± 2 kV line(s) to earth (common mode)	Not applicable (battery operated device)	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	U_T = 0%, 0,5 cycle (0, 45, 90, 135, 180, 225, 270 and 315°) U_T = 0%, 1 cycle U_T = 70%, 25/30 cycles (at 0°) U_T = 0%, 250/300 cycle	Not applicable (battery operated device)	
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 ZepHr Recorder is intended for use in the electromagnetic environment specified below. The customer or the user of the ZepHr Recorder 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	3 Vrms (150 kHz to 80 MHz) 6 V (ISM bands)	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the ZepHr Recorder, 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 2.7 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: 
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	
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 ZepHr Recorder is used exceeds the applicable RF compliance level above, the ZepHr Recorder should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the ZepHr Recorder. b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

7.3.3 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment the ZepHr Recorder			
The ZepHr Recorder is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ZepHr Recorder can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ZepHr Recorder 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 2.7 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.			

7.4 Specifications

Dimensions:		
Height:	4.5 in	(11.5 cm)
Width:	3.9 in	(10.0 cm)
Depth:	1.4 in	(3.5 cm)
Weight (no batteries):	7.4 oz	(210 gm)

Casing: Polycarbonate

Power Source: 2 - 1.5 VDC AA Alkaline (LR6) Batteries. Energizer and Duracell brand batteries are recommended. Other batteries may not fit properly and could cause interrupted studies and shortened battery life.

Memory Card: SD card. Contact Technical Support for replacement cards.

Channels

ZepHr pH
- Up to 3 pH channels.
- LES locator pressure channel

ZepHr Z/pH
- Up to 6 impedance channels
- Up to 3 pH channels.
- LES locator pressure channel
- Sync channel (requires adaptor cable)
- 2 non-calibrated pressure channels for recording (One is the LES locator channel.)

Impedance Measuring Range: 50 – 10,000 ohms

pH Measuring Range: 1.0 – 8.0 pH

Recording Time: 24 hours standard. Capable of 48 hours via mid-recording battery change.

Measurement Accuracy: pH +/-6% at pH 4 and pH 7
Impedance +/-15% at 1,000 ohms

Probe Type: Disposable (Contact Technical Support for suitability listing)

Operating Environment:	Temperature:	16°C - 40°C (60°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)