User Manual
for the
Digitrapper pH-Z
Ambulatory pH and Impedance Monitoring System

CAUTION: Federal law restricts this device for sale by or on the order of a physician.

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Contact Information

Sierra Scientific Instruments, A Given Imaging Company
5757 W. Century Blvd., Suite 660
Los Angeles, California 90045
866.641.8492
310.641.8492
www.sierrainst.com
Table of Contents

1. INTRODUCTION ...................................................................................................................................................... 3
   1.1 INTENDED AUDIENCE........................................................................................................................................ 3
   1.2 PURPOSE OF THIS MANUAL .......................................................................................................................... 3
   1.3 ACRONYMS AND ABBREVIATIONS ............................................................................................................ 3
   1.4 INDICATIONS OF USE ..................................................................................................................................... 3
   1.5 CONTRAINDICATIONS OF USE .................................................................................................................... 4
   1.6 INTENDED USE .............................................................................................................................................. 4
   1.7 WARNINGS / CAUTIONS .............................................................................................................................. 4

2. RECORDER OVERVIEW ........................................................................................................................................ 6
   2.1 GENERAL ......................................................................................................................................................... 6
   2.2 BUTTONS .......................................................................................................................................................... 6
   2.3 CONNECTION PORTS ....................................................................................................................................... 8

3. RECORDER SETUP ................................................................................................................................................ 10
   3.1 START STUDY .................................................................................................................................................. 10
   3.2 SETTINGS ....................................................................................................................................................... 13

4. TROUBLESHOOTING ........................................................................................................................................... 16
   4.1 GENERAL ......................................................................................................................................................... 16
   4.2 ERRORS ............................................................................................................................................................ 16

5. MAINTENANCE ...................................................................................................................................................... 17
   5.1 CLEANING THE RECORDER ........................................................................................................................ 17

6. PRODUCT LABELING ........................................................................................................................................... 18
   6.1 DEFINITIONS .................................................................................................................................................. 18
1. Introduction

Welcome to the Digitrapper pH-Z User Manual!

The Digitrapper pH-Z recorder, hereafter referred as Digitrapper, is an ambulatory monitoring system that allows for accurate and efficient measurement of pH and Impedance. This user manual provides a description of the Digitrapper and its use.

1.1 Intended Audience

This document is intended for use by medical personnel in conjunction with the Digitrapper recorder.

1.2 Purpose of This Manual

The purpose of this manual is to provide instruction on using the Digitrapper recorder. Technician and patient user interfaces are also defined.

1.3 Acronyms and Abbreviations

Acronyms and abbreviations used in this document are identified below:

<table>
<thead>
<tr>
<th>Acronym</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA</td>
<td>AA battery</td>
</tr>
<tr>
<td>HRM</td>
<td>High Resolution Manometry</td>
</tr>
<tr>
<td>IBP</td>
<td>Intrabolus Pressure</td>
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<tr>
<td>ID</td>
<td>Identification</td>
</tr>
<tr>
<td>LES</td>
<td>Lower Esophageal Sphincter</td>
</tr>
<tr>
<td>Med</td>
<td>Medicine or Medication</td>
</tr>
<tr>
<td>pH</td>
<td>potential Hydrogen</td>
</tr>
<tr>
<td>PIP</td>
<td>Pressure Inversion Point</td>
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<tr>
<td>s</td>
<td>Second</td>
</tr>
<tr>
<td>UES</td>
<td>Upper Esophageal Sphincter</td>
</tr>
<tr>
<td>USB</td>
<td>Universal Serial Bus</td>
</tr>
<tr>
<td>Z</td>
<td>Impedance</td>
</tr>
</tbody>
</table>

1.4 Indications of Use

The Digitrapper recorder obtains measurement of pH levels (and optionally, impedance levels) within organs of the human gastrointestinal tract. These include the pharynx, upper esophageal sphincter (UES), esophagus, lower esophageal sphincter (LES), and stomach. It is used in either a clinical or outpatient setting to acquire pH and impedance levels and store the corresponding data. The data can be uploaded into the AccuView analysis software where the information can be viewed for diagnostic and analysis purposes. The device is intended for use by physicians, surgeons, and medically trained personnel.
1.5 Contraindications of Use

The use of the Digitrapper recorder for pH/Impedance testing is contraindicated for the following: a) patients with an inability to tolerate nasal intubation, b) patients with significant bleeding disorders for whom nasal intubation has been deemed contraindicated, and c) patients with a known esophageal obstruction preventing passage of the instrument.

1.6 Intended Use

The Digitrapper recorder is intended to be used as a tool for accurate acquisition of data acquired during pH/Impedance procedures. The tool is intended for use by trained medical personnel on inpatients or outpatients when performing pH/Impedance data acquisition.

1.7 Warnings / Cautions

The Digitrapper recorder is intended to be used only by trained medical personnel in performing pH/Impedance data acquisition. The quantitative estimates of physiological parameters acquired using the Digitrapper assists in the diagnostic process when uploaded into the AccuView analysis software but clinical conclusions should not be made without proper medical training and consideration of the patient history.

The Digitrapper recorder is classified as internally powered equipment, Type BF Equipment (portable, with a patient applied part, designed for continuous operation). The Digitrapper recorder is rated IP20 and as such is not protected from the ingress of water. The Digitrapper recorder also provides floating patient isolation, in the strictest sense, by a physical inability to connect both the patient and the USB port of a mains powered personal computer to the recorder simultaneously, under normal use.

**Permissible Storage and Transport Conditions:**

The Digitrapper pH-Z must be stored within the following environmental conditions:
Temperature: 0°C to 40°C
Relative humidity: 30% to 75%

**General EMC Statement:**

Although the Digitrapper pH-Z recorder is deemed to comply with EN 60601-1-2: 2002 this still cannot provide a total guarantee that other equipment in the immediate vicinity of the Digitrapper will not be affected by its inherent electromagnetic emission. Similarly, this other equipment may in turn affect the operation of the Digitrapper recorder. Refer to Section 6, “Product Compliance Declaration” for information on the use of the Digitrapper pH-Z and medical equipment.
Note that use of non-approved catheters may degrade the EMC performance of the Digitrapper recorder.

Additionally, the following guidelines and warnings should be obeyed:

- Remove all connections from the Digitrapper before changing batteries.
- Never operate the device or touch the patient with the AA battery cover removed.
- Do not attempt to recharge AA or cell batteries.
- Do not use any type of rechargeable batteries.
- Ensure the AA batteries are inserted using correct polarity.
- Dispose of all batteries according to local regulations.
- Do not place AA batteries near high heat or fire.
- Observe AA battery manufacturers’ instructions.
- Remove AA batteries if the recorder will not be used for an extended duration.
- The Digitrapper recorder is not suitable for use in the presence of a flammable anesthetic mixture with air or oxygen or nitrous oxide.
- Use only Antimony catheters recommended by Sierra Scientific Instruments.
- Recorder is intended for ambulatory use by patients while recorder is placed in protective carrying case. The use of this carrying case blocks access to I/O ports when patients are connected to active device (catheter).
2. Recorder Overview

This section provides a short walkthrough of the basic features and buttons of the Digitrapper recorder.

2.1 General

The Digitrapper recorder should be used in its provided carrying case at all times. The Digitrapper is powered by two Alkaline AA batteries and an internal lithium cell battery which holds the clock and settings.

2.2 Buttons

There are four buttons on the Digitrapper recorder which function differently in the Setup and Recording Modes.

2.2.1 Setup Mode

In Setup Mode, the medical personnel or technician configures the Digitrapper prior to conducting pH or pH/Z procedures. The arrows above the buttons correspond to the soft button choices on the display.
• **Select (Symptom):** The largest button on the far right is the “Select” button which allows the user to select whatever option they are currently highlighting. It will also save any changes made on the current screen.

• **Up (Supine):** The button second to the right is the “Up” button which allows the user to navigate to the menu choice above or to increase a value on a settings screen.

• **Down (Meal):** The button second to the left is the “Down” button which allows the user to navigate to the menu choice below or to decrease a value on a settings screen.

• **Back (Med):** The button on the far left is the “Back” button which allows the user to navigate to the previous menu. Pressing “Back” will not save any changes made on the current screen.

### 2.2.2 Recording Mode

In Recording Mode, the patient uses the buttons on the Digitrapper recorder to enter “events” that occur during the pH or pH/Z procedure.

![Digitrapper pH-Z Recorder Buttons](image)

• **Symptom:** The largest button on the far right is the “Symptom” button which allows the patient to indicate when he or she feels any kind of symptom (e.g. Heartburn, Chest Pain, Cough, etc.) This button is a single event (not durational). Note that after the study is uploaded, the AccuView Analysis software allows the medical personnel or technician to specify up to four unique symptoms during any particular study.

• **Supine:** The button second to the right is the “Supine” button which allows the patient to indicate when they are sleeping or reclining. This button is durational which means the patient should press the button at the onset of sleeping or reclining and press again after the sleeping or reclining period is over.

• **Meal:** The button second to the left is the “Meal” button which allows the patient to indicate when they are having a meal. This button is durational which means the patient should press the button at the onset of the meal and press again after the meal period is over.
• **Med**: The button on the far left is the “Med” button which allows the patient to indicate when he or she takes a medication or drug. This button is a single event (not durational). Note that after the study is uploaded, the AccuView Analysis software allows the medical personnel or technician to specify whether these events should be called “Med” or “Drug.

• **Stop a Recording**: There is a special button-press sequence which allows only trained medical personnel or technicians to stop a study while in Recording Mode. Pressing the “Meal” button along with the “Supine” button simultaneously and holding for 5 seconds will allow the study to be stopped. This functionality helps prevent a patient from accidentally stopping their own study.

Note: There is no Power button on the Digitrapper recorder as the device can only be used when AA batteries are installed. After installing the batteries, pressing any button will make the recorder power on. After a time of inactivity, the Digitrapper will go into standby mode, and the screen will turn off to save power. Pressing any button will bring the Digitrapper back from standby.

### 2.3 Connection Ports

There are four connection ports on the Digitrapper recorder:

- **8-pin RJ-45**: Use this connector to plug in pH-only catheters (and the pH portion of bifurcated 2 pH/Z catheters).

- **10-pin RJ-45**: Use this connector to plug in the Impedance portion of bifurcated 2 pH/Z catheters or single connector pH/Z catheters.
- **Mini-USB:** Use this connector to plug in a Mini-USB cable to upload the study (only use after catheter has been removed from patient and disconnected from recorder and recorder is removed from carrying case).

- **3.5mm Triple Contact Receptacle:** Use this connector to plug the recorder into an electrically isolated medical device, such as a sleep system, in order to receive a raw output of the pH signal.
  
  o The live pH values are output as a linear scaled value of the calibrated pH input seen by the recorder. The scale is set to 100 mV per pH, thus: when the recorder is reading 1pH, the output from the 3.5mm plug will be 100mV; at 2pH, the output will be 200 mV; 3pH will give 300 mV and etc.

  o The pH catheter channels are output as shown below:

  ![](image)

  - When using a 2 channel pH catheter, pH Channel 1 (tip) corresponds to the proximal sensor, while Channel 2 (ring) corresponds to the distal sensor. In order to receive separate pH outputs, use a triple contact plug, a dual contact plug will output only pH Channel 1.

  - A single channel pH catheter will only output through pH Channel 1.

  o **Note:** This port can only be used during procedures conducted in a medical facility under the supervision of trained medical personnel. This port must be connected to a Minimum Type BF Applied part port on an IEC 60601 certified medical device. This port is not intended for use during an ambulatory procedure.
3. Recorder Setup

This section contains details on how to start a study and configure the settings on the Digitrapper pH-Z recorder. There are two options in the Main Menu: Start Study and Settings.

3.1 Start Study

This selection will take the user through all the necessary steps in order to complete a pH or pH/Z study from start to finish. The “Start Study” option will navigate through the following actions:

3.1.1 Verification of Study Upload
Verify that the last study was uploaded before attempting to start a new study. Select “Next” to proceed.

3.1.2 Last Warning of Deletion of Previous Study
Check once more that the last study was uploaded before proceeding and erasing the previous study. Select “Yes” (Up button) to proceed.

3.1.3 Enter Patient ID Number (Optional)
To enter the Patient ID number, use the Up and Down (+/-) buttons to change each digit’s value and use the Right and Left buttons to navigate to the proper digit. Select “Done” to proceed to catheter calibration.

Note: If the user does not want to include the Patient ID number as part of the “Start Study” protocol, see Section 3.2.6.3 under Preferences for “Include Patient ID.”

3.1.4 pH Calibration (with Monitoring)
Before proceeding with calibration, ensure that all catheter manufacturers’ recommended practices have been followed (such as pre-soaking). Refer to catheter manufacturers’ Instructions for Use (IFU) documents for more detail.

Ensure that you have already installed a fresh set of AA size Alkaline Batteries.

Ensure the Recorder is secured in the carrying case by sliding the case from the bottom of the recorder to towards the buttons, the latch in the rear will become flush with the carry case surface when properly installed.
Connect the catheter to the appropriate ports on the recorder; check secure latching. It is recommended that the catheter be taped into the bottom channel of the carrying case to prevent accidental damage to the catheter during use.

Place catheter sensor region in the first pH buffer solution, or saline solution, and allow it to soak for the recommended 10 minutes. For best results, it is recommended that the buffer solutions be changed after every calibration.

Following the soak period, press “Start” to calibrate. Wait for the progress bar to indicate that the calibration is done then remove the catheter from the first buffer and rinse in water. Insert catheter into second buffer solution and press “Next” to calibrate.

After calibration is complete for both buffer solutions, intubate the patient. Use the real-time pH or Z (Impedance) readings to assist with catheter placement. After the catheter is intubated and positioned accordingly press “Next” to proceed.

Note: If calibration cannot be completed and the user receives either error or warning messages, refer to Section 4 “Troubleshooting.”
3.1.5 Start the Recording Mode

In order to begin the recording, press “Yes.” The display will then read “Recording” along with the current time (the real-time pH values can also be displayed optionally, see Section 3.2.6.5 “Show Recorded pH”).

During the recording mode, the patient can utilize the buttons for appropriate events such as symptoms, medications, supine periods, and meal periods. For more explanation on how to use these buttons, see Section 2.2 “Buttons.”

3.1.6 Completion of the Recording

When the study duration elapses, the recorder will display “Recording Complete.” In order to exit the recording mode in preparation for data upload, the below button sequence—known only by trained medical personnel or technicians—must be pressed.

To stop a study and/or go to upload screen: Press and hold the “Meal” and “Supine” buttons simultaneously for 5 seconds. This will allow the study to be stopped. This functionality helps prevent a patient from accidentally stopping their own study.

Note: If the trained medical personnel or technician chooses to end the study prior to the study duration elapsing, they must also use this special button sequence referenced above. In this event, a message reading “Are you sure you want to stop the study?” is displayed. In order to completely stop the study, the medical personnel or technician must select “Yes.” If no selection is made within five seconds, the recorder will go back into recording mode automatically.

3.1.7 Study Upload

After exiting the recording mode, disconnect the catheter from the unit, and remove the carrying case using the supplied tool to deflect the latching mechanism and slide the recorder out.
Connect the USB cable and initiate the study upload through the AccuView Analysis software on the PC. Wait for the progress bar to indicate that the upload is complete. After the data has been uploaded, disconnect the USB cable.

Note: If upload fails for any reason, refer to Section 4 “Troubleshooting.” Also refer to the AccuView Analysis User Manual for additional guidance on data upload if necessary.

3.1.8 New Study

In order to start a new study immediately after upload of the prior study, press Next to return to the Main Menu. Otherwise press “Turn Off” to enter Standby Mode.

3.2 Settings

3.2.1 Set Date/Time

This option allows the user to set the proper date and time for the recorder. Use the Up and Down (+/-) buttons to change each field’s value and use the Right button to change fields. Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.2 Catheter Type

This option allows the user to select the proper catheter type for the next study. Use the Up and Down buttons to select 1 pH, 2 pH, 1 pH/Z, or 2 pH/Z. Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.3 Study Duration

This option allows the user to select the proper duration for the next study. Use the Up and Down (+/-) buttons to select from 1-48 hours. Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.4 Language

This option allows the user to select the preferred language for the menus, information, and patient screens. Use the Up and Down buttons to select English, French, German, Italian, Spanish, or Swedish. Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.5 Display

This option allows the user to select several preferred display settings.

3.2.5.1 Backlight Duration

This option allows the user to select the preferred duration for the display backlight. Use the Up and Down (+/-) buttons to select from 0-50 seconds. Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.
3.2.5.2 Brightness
This option allows the user to select the preferred brightness level for the display. Use the Up and Down (+/-) buttons to select from levels 1-10. Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.5.3 Contrast
This option allows the user to select the preferred contrast level for the display. Use the Up and Down (+/-) buttons to select from levels 1-10. Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.6 Preferences
This option allows the user to select the preferred procedure and operation conventions for the Digitrapper.

3.2.6.1 Date Format
This option allows the user to select the preferred date format for the display. Use the Up and Down buttons to select between MM-DD-YYYY (Month, Day, Year) and DD-MM-YYYY (Day, Month, Year). Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.6.2 Time Format
This option allows the user to select the preferred time format for the display. Use the Up and Down buttons to select between 12 hour (HH:MM am/pm) and 24 hour (HH:MM). Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.6.3 Include Patient ID
This option allows the user to select whether the Patient ID should be included in the “Start Study” protocol. Use the Up and Down (+/-) buttons to select “Yes” or “No.” Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.6.4 Patient ID Length
This option allows the user to select how many digits are in the patient ID number at their facility. Use the Up and Down (+/-) buttons to select from 0-10 digits. Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.6.5 Show Recorded pH
This option allows the user to select whether the recorded pH value(s) should be visible during the patient recording. Use the Up and Down (+/-) buttons to select “Yes” or “No.” Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.6.6 pH Calibration Levels
This option allows the user to select the preferred pH calibration levels in buffer solutions. Use the Up and Down buttons to select from “4.0-7.0” (pH 4.0 first, then pH 7.0), “7.0-4.0” (pH 7.0 first, then pH 4.0), and
“7.0-1.0” (pH 7.0 first, then pH 1.0). Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.6.7 pH Sample Rate

This option allows the user to select the preferred pH sample rate. Use the Up and Down (+/-) buttons to select from 1 - 1/10 Hertz (1 sample every second to 1 sample every 10 seconds). Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.

3.2.6.8 Button LEDs

This option allows the user to select whether they want the LEDs on the buttons to light up when pressed during recording mode. Use the Up and Down (+/-) buttons to select On or Off. Select “Done” to save changes and return to Main Menu or “Back” to return to Main Menu without saving changes.
4. Troubleshooting

4.1 General

- Ensure the catheter is connected into the corresponding connector in the recorder and pushed in until it snaps.
- Ensure the catheter has soaked for at least 10 minutes in buffer prior to calibration. Ensure the catheter type connected is the catheter type selected within the recorder settings.
- Replace buffer solutions if necessary and ensure the buffers being used are the buffers selected within the recorder Preferences.
- Ensure all pH sensors are submerged in the buffer during calibration.

4.2 Errors

**Error Code 1:** Potential Hardware Issue (Check Manual) - This error indicates that the pH Signal is out of the acceptable range for the recorder. This could indicate a potential issue with the Catheter or possibly the Digitrapper hardware. Heed above tips, if problem persists, contact Manufacturer for further troubleshooting.

**Error Code 2:** Potential Probe or Hardware Issue (Check Manual) - This error indicates that there is an unstable pH signal on the catheter or recorder. Try calibrating a new catheter. If error persists, contact Manufacturer for further troubleshooting.

**Error Code 3:** Potential Probe or Buffer Issue (Check Manual) - This error indicates that the pH Signal is out of the acceptable range for the catheter or buffer solution. Try replacing buffer solution or calibrating a new catheter. If error persists, contact Manufacturer for further troubleshooting.

**Error Code 4:** Bad Blocks in Flash (Check Manual) - This error indicates that there may be bad blocks in the Flash Memory on the recorder. Contact Manufacturer for further troubleshooting.

**Error Code 5:** Upload Failed (Check USB cable) - This error indicates that the USB cable may have been removed during upload. Check USB cable connections on computer and recorder and try to upload again. If error persists, contact Manufacturer for further troubleshooting.

**Error Code 6:** Upload Error, Possibly no Data in Recorder - This error indicates that there may be no data on the recorder to upload. Check USB cable connections on computer and recorder and try to upload again. If error persists, contact Manufacturer for further troubleshooting.

**Error Code 7:** Insufficient AA battery power, Replace before proceeding - This warning indicates that the current AA batteries installed do not have sufficient power to run the recorder during a study. Replace the AA batteries before conducting a new study. If warning persists, contact Manufacturer for further troubleshooting.
**Error Code 8:** Internal cell battery low, Replace before proceeding - This warning indicates that the internal cell (Lithium) battery installed does not have sufficient power to run the recorder during a study. The internal cell battery is not user replaceable, contact Manufacturer for further instructions.

### 5. Maintenance

The Digitrapper pH-Z System requires no routine maintenance, other than the cleaning as described in Section 5.1.

If use models result in excessive drain of the internal lithium battery, the battery may need to be replaced by the manufacturer.

#### 5.1 Cleaning the Recorder

The recorder may be cleaned with a slightly damp cloth.

**Do Not Clean with Acetone.**

**The Recorder Must Never be Immersed in Any Liquid.**
# 6. Product Labeling

## 6.1 Definitions

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Definition/Meaning</th>
</tr>
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<tbody>
<tr>
<td>![Symbol]</td>
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<tr>
<td>![Symbol]</td>
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<tr>
<td>![Symbol]</td>
<td>Manufacturer</td>
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<td>pH Catheter Port</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>pH + Impedance Catheter Port</td>
</tr>
<tr>
<td>![Symbol]</td>
<td>Mini B USB Port</td>
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<tr>
<td>![Symbol]</td>
<td>3.5mm 2 channel Analog pH output</td>
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</table>

<table>
<thead>
<tr>
<th>Button Symbol</th>
<th>Definition/Meaning</th>
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<td>![Symbol]</td>
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