Respiratory Technology Corporation

Dx–pH Measurement System™
Model Number XXXXX
Instructions for Use

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Dx–pH Measurement System™
User's Manual

Version X.X
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This publication is supplied for the purpose of using the Dx–pH Measurement System™ only. Respiratory Technology Corporation is responsible for the reliability and performance of the Dx–pH Measurement System™ only if the following conditions are met:

1. All repairs and modifications are carried out by Respiratory Technology Corporation or its assigned agents.

2. Caution: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

3. This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and, (2) This device must accept any interference received including interference that may cause undesired operation.

4. The transmitter's end location will have a label on the outside compartment stating: "Contains FCC ID: TLUDX-SYSTEM"

CAUTION: Federal Law (USA) restricts these devices to sale by or on the order of a physician.

Contraindications: Deviated Septum, nasal congestion or infection.

Table of Contents

Introduction

The Restech Dx–pH Measurement System™ is a 24/48-hour, ambulatory, pH monitoring system consisting of a single use pH probe and reusable transmitter and recorder system. The Dx–pH Probe™ and Dx–Transmitter™ simultaneously measure pH and transmit the data to a recorder. The Dx–Recorder™ processes the data and saves the information to a removable secure digital data card. The patient is able to interact with the receiver during the 24/48 hour pH study to record clinically relevant information such as meals and symptoms. After completion of the pH study, the pH data and patient information is downloaded from the data card to a PC using a card reader. The data and information can be viewed using a Windows based software program.

The Dx–pH Probe™ is provided non-sterile to the end user. It is disposable, with a usable life of one procedure. All other components are reusable.

Intended Use

The Restech Dx–pH Measurement System™ is intended to measure and monitor supraesophageal pH changes due to gastric reflux.

Symbols

The following symbols are used on the Dx–pH Probe™ and/or in the accompanying documentation.

SYMBOL	MEANING
	Lot Number.
	Non-Sterile.
	Date of Manufacture.
	Each device is for one (1) use only.
	Expires.
	Attention. Read instructions prior to use.

Dx–Recorder™ Event Markers and Control Keys

Event Marker Buttons

Heartburn Button 

Cough Button 

Meals Button 

Supine/Sleep Button 

Control Keys

Up Arrow Key 

Down Arrow Key 

Escape Key 

System Description

Components

The Dx–pH Measurement System™ includes the following:

Dx–pH Probe™
Dx–Transmitter™

Probe

NEED PICTURE

Transmitter

The Restech Dx–pH Measurement System™ contains a pH probe (Dx–pH Probe™) in a short, trans-nasal catheter that the patient wears for the duration of the study. The Dx–pH Probe™ measures pH and the transmitter sends the data to the Dx Recorder.

Dx–Recorder™
REPLACE PICTURE

The Dx–Recorder™ is a portable unit that receives pH data from the Dx–pH Probe™ and Transmitter. It saves this information to a removable data card. The patient is able to interact with the recorder during the pH study to record clinically relevant information and symptoms.

Data Card
REPLACE PICTURE

The Data Card is inserted into the Dx–Recorder™ after the physician enters the appropriate patient information on it.

After the study, the physician removes the card from the Dx–Recorder™ and inserts it into a Data Card Reader to review the pH Study using the Dx–pH Data View™ Software on a personal computer.

PC Flash Memory Card Reader

REPLACE PICTURE

Interfaces with the computer to download the data from the SD data card for display in the Dx–pH DataView™ software.

Dx–pH DataView™ Software
(CD Rom) REPLACE PICTURE

The Dx–pH DataView™ Software displays pH data that is stored on the Data Card by the Dx–Recorder™.

Dx–Calibration Vials™ and Dx–Calibration Stand™

REPLACE PICTURE

The Dx–pH Probe™ is calibrated with pH 4 and pH 7 standard buffer solutions prior to use in a study. Water is also included in the calibration kit to rinse the probe between calibrations.

Special Tool

The “special tool” is provided by Restech to ensure proper handling of the transmitter when changing the coin cell battery. It is to be used to remove the cover on the transmitter to allow battery access. It is also recommended

that this is used in removing the data card out of the back of the recorder.
NEED PICTURE

Batteries

Two AA alkaline batteries are required to power the Dx–Recorder™.
REPLACE PICTURE

X Volt Lithium Coin Cell Batteries
NEED PICTURE

To Be Supplied by User**:**

Computer

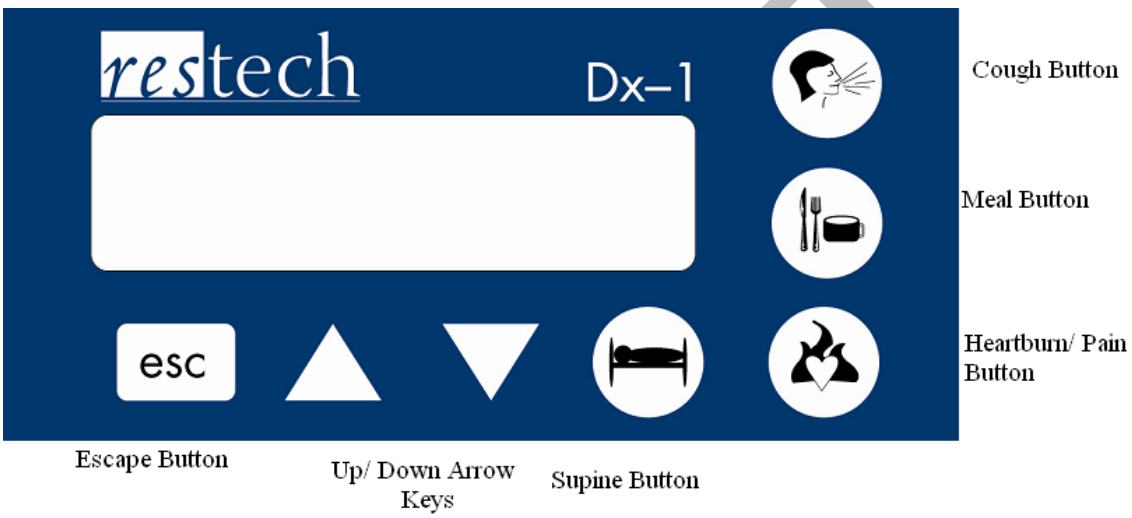
REPLACE PICTURE
A PC with CD ROM Drive and Windows based operating system runs the Dx–pH DataView™ Software program, generates reports to be printed and stores patient data on the hard drive.
(Recommended system requirements: 600 MHz Pentium III, Celeron or equivalent processor. Recommended disk space of 155 MB and18 MB RAM.)

Printer
REPLACE PICTURE
(Windows compatible) prints patients' pH reports for review by the prescribing physician.

Dx–Recorder™

The Restech Dx–Recorder™ is an external unit that receives and stores data sent by the Dx–Transmitter™. Upon completion of a study, trained personnel will remove the data card from the recorder and insert it into a PC flash memory card reader. The Dx–Recorder™ is designed to be lightweight, compact and easy for both the clinician and the patient to use.

The Recorder face:



Dx–pH DataView™ Software Program

Installing the Dx–pH DataView™ Software Program

1. Insert the Dx–pH DataView™ CD disk into your computer's CD drive
2. The installation window will either open automatically OR you can open the disk using Windows Explorer.
3. Open the Dx–pH DataView™ folder by double clicking the icon.
4. Open the Installation folder by double clicking the icon.
5. Double click the Install.msi icon.
6. Installation Wizard will begin.
7. After reading the Warning, click **NEXT** to continue.
8. The Wizard will inform you where the program will be installed, click NEXT to continue.
9. The Wizard will display the message "Ready to Install Application," click NEXT to continue.
10. When the program has been successfully installed, click NEXT to continue.

Setup of a New Study

To setup a new study, start the Dx–pH DataView™ program by double clicking the icon on your desktop or selecting it from the Start menu.
Insert a formatted SD data card (supplied by Restech) into the card reader of your computer.
A window titled "Removable Disk" should appear, close the window to continue.

In your Dx–pH DataView™ program, select "New Patient" from the File menu.
Enter the last name, first name, and study date in the appropriate fields. The patient name and study date are required fields; you will not be able to proceed if these fields are left blank.

Here you can also enter three user definable symptom events for your specific patient's study. Click the button that reads "Enter." A warning will appear that reads "you are about to overwrite all data on the card. Are you sure you want to do this?
If you have saved all studies in the Dx–pH DataView™ program, or printed the studies and saved them with the respective patient's files, choose **YES.**

> If you **did not save** the last study on the card and wish to do so, choose **NO.** Go back and save your previous study as instructed in the section entitled "Viewing and Altering Graphs." Exit the program and restart it, then verify that you have saved the data before deleting it from the card.

A window will appear prompting you to specify the location of your card reader. Select the appropriate drive and click **OK.**

The program will also ask you to confirm that all the information is correct, and if you are finished. Click **YES** or **NO**.

After entering the patient data on the memory card, remove it from the card reader and insert it into the Dx–Recorder™ unit.

Insert Picture of Side of recorder/Proper Insertion

Physician Setup of the Dx–Recorder™

> **Note**: It is important that you replace the batteries in both the transmitter and recorder prior to beginning each new study.

Replacing the Batteries

It is crucial that the batteries are replaced before each study, as the recorder will not allow a new study to be started unless new batteries are used.

Dx–Recorder™

Dx–Transmitter™

Insert Pictures of Proper Battery replacement

Setup

Setup allows you to adjust the system time, select the study duration, and set user interface options.

You will be prompted to either accept or change time and date information. If the time and date are correct, press any round shaped key to accept. If either is incorrect, you may reset it using the up/down arrow keys and then pressing any round key to accept.

Next, you will be asked to choose if the pH display is **ON** or **OFF**. If **OFF** is selected, the patient's display will only show the current time and patient name, it will not display the pH value during the study.

Finally, you will be prompted also to choose if an audible beep is **ON** or **OFF**. If **ON** is selected, a beep will sound when an event button is pressed. If **ON** is selected, no beep will sound when any event button is pressed.

The system will return to the main menu and apply the new settings once all choices have been entered.

Place a new coin cell battery into the transmitter (as shown above). When a new lithium coin cell battery is placed in the transmitter, it will power up and perform basic memory and function tests. If an error occurs, the transmitter will have the LED on the probe remain lit and send an error message to the recorder. If the tests are non-problematic, the transmitter will switch into normal operation mode and the LED will start flashing.

After identifying the appropriate transmitter, attach USB plug on the back of the transmitter to the jack on the end of the catheter; the connection should be secure without forcing it.

INSERT PICTURE HERE

Calibrate the Dx–pH Probe™

The clinician operating the transmitter and recorder during setup should have sufficient training prior to using the system. Only authorized clinicians should be authorized to operate the configuration and calibration controls. The patient will not be able to access this interface at any time during their study.

When calibrating a sensor, be sure to use only the fresh pH buffer solutions supplied by Restech for the most accurate calibration values. For convenience and safety, Restech provides the color coded Dx–Calibration Stand™ and the Dx–Calibration Vials™ which are pre-filled with pH buffer solution.

Select "Cal" from the main menu.
The recorder will display the Transmitter ID number that was used. You will be prompted to accept this ID. Pressing the up or down keys allows you to change the ID #. Press any round key to accept when the appropriate transmitter ID is displayed.

A series of calibration displays will guide you through the process; you will first need to pre-soak the probe tip in pH 7 for at least ten minutes. If this has already been accomplished, you may select to bypass the presoak. After calibration in pH 7, you will be instructed to place the probe in the water, also supplied in the Restech Dx–Calibration Vials™ and then in pH 4. After calibration in pH 4, you will be instructed to rinse the probe with water. After rinsing the probe, the calibration routine is complete.

The system will display the current pH reading of the probe. If you are not satisfied with the calibration results, press Esc, and then select the "Cal" option from the main menu to perform the calibration process again.

The system will not allow a new study to be performed unless the calibration has been performed successfully. If there is data on the card from a previous study, the recorder will alert the user and return to the main menu. A previous study can only be removed using the Dx–pH DataView™ Software. If no previous study exists, the patient's name will be displayed on the screen.

You will also be prompted to select either a 24 or 48 hour study. Use the Up / Down keys to select the appropriate time duration and then press any round key to accept

Determine Proper Positioning of the Catheter

Ask the patient which side of their nose is clearer and easier to breathe through. Numb this side with Xylocaine gel, 2% on A Q-tip, but **do not numb the patient's throat**. Insert the probe through the patient's nose. The round tip will help it curve around into the oropharynx. It may be helpful to saturate the catheter of the probe in a lubricant to ease the insertion.

Use the markings on the side of the catheter to determine when it has been inserted to 12 cm. Have the patient open their mouth, and with a tongue depressor, push the patient's tongue down. The LED will blink after starting the study on the recorder. Use this light to help determine when the probe is in the appropriate position in the patient's oropharyngeal region.
Note: Have the patient swallow sips of water to see if they can feel the probe in their throat; if they can, pull it back slightly until it is comfortable for the patient.

After the proper position has been determined, attach the catheter to the patient's face using surgical tape, securing the catheter as closely to the nares as possible to ensure that it does not move during the study.

The patient may prefer to have the transmitter either taped to the skin or attached to their clothing with the provided clip on the transmitter case. If it is attached to their clothing, be sure to tell them to use caution when changing clothes so they do not rip the tape off their skin or pull the probe out.

Retrieving and Reviewing a Study

After completing the prescribed study duration, the patient will return the unit to the physician's office. Here, a nurse or the physician will remove the Dx–pH Probe™ and collect the equipment.

After the patient has returned the device, use the special tool provided with the transmitter to remove the data card from the recorder by gently pressing the card in slightly further, then allowing it to retract out from the slot.

Download pH Data

Start the Dx–pH DataView™ program by clicking on the icon or selecting it from the start menu.

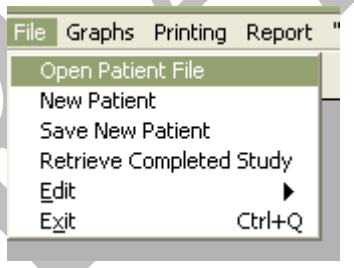
After removing the data card from the side of the recorder, insert it into the provided card reader. If a window for the card automatically opens, simply close it and proceed with the following instructions.

In the "File" menu of the Dx–pH DataView™ program, select the option to "**Retrieve Completed Study**"

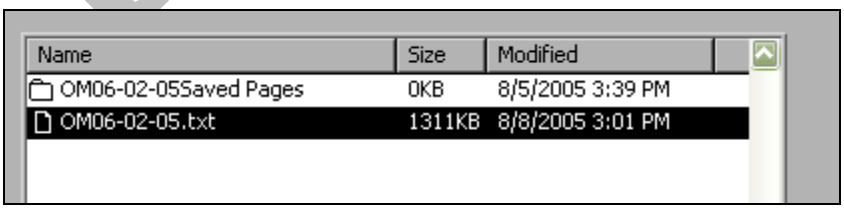
Opening a Past Study

Start the Dx–pH DataView™ program by selecting it from the start menu or double clicking your desktop icon.

From the "File" menu, select "Open Patient File"

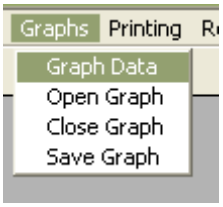


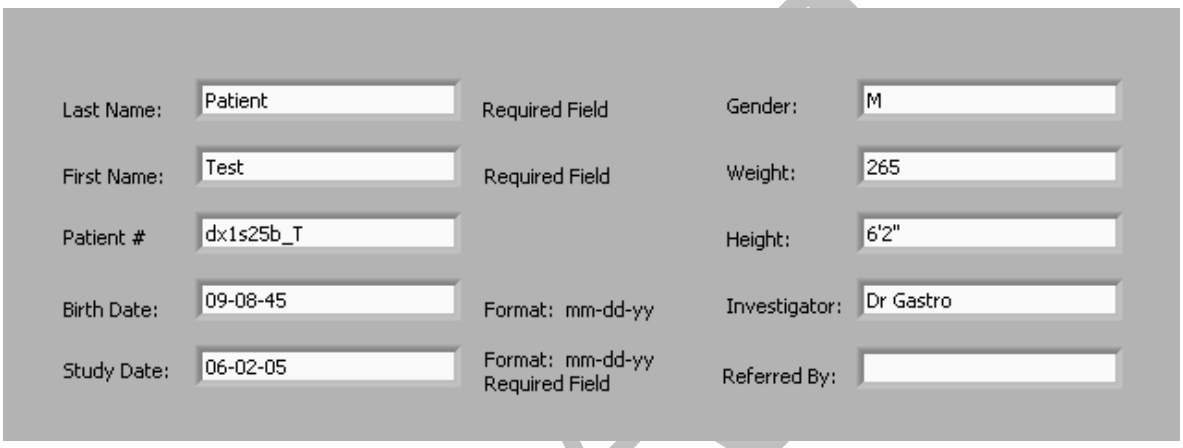
Select the appropriate patient from the list and double click it.



Viewing and Altering Graphs

To view a graph of the patient's study, select "Graph Data" from the "Graph" Menu while their information is on the screen.

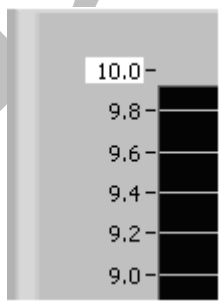


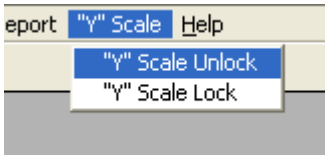


Changing the pH Scale

The pH scale is set at a default of 0-10. To change this scale, select "Y" Scale Unlock from the ""Y" Scale" Menu. Now you can enter the desired values for the study in review.

When the appropriate range has been entered, select "Y" Scale Lock from the "Y" Scale Menu. These values will become the "default" values for the study.





Altering Graph Views

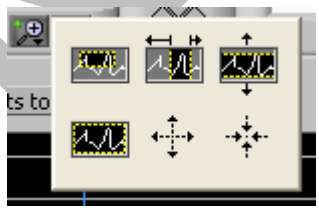
1. You may also enter the number of minutes to average and the percent drop below baseline.

The program averages the values over the specified number of minutes (baseline) and detects drops of the specified percentage below baseline.

2. When viewing the pH graph, you can manipulate it in various ways to control which information you view. The three buttons in the top right corner of the screen perform various functions to allow this manipulation.

a. The button on the left allows you to move the cursors along the X axis. When the cursor rests on a point, it will display the time and date, as well as the pH value of that point.

b. The middle button provides six different functions:



These functions are the following:

Select one rectangular section of the graph to enlarge; 

Select an area to stretch and enlarge along the X axis; 

Select an area to stretch and enlarge along the Y axis; 

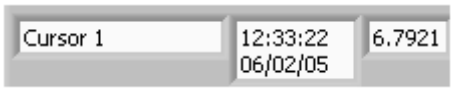
Auto scale–Return to graph to its original configuration 

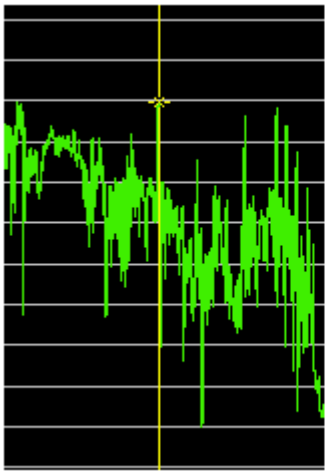
Enlarge a portion of the graph with respect to a chosen point. 

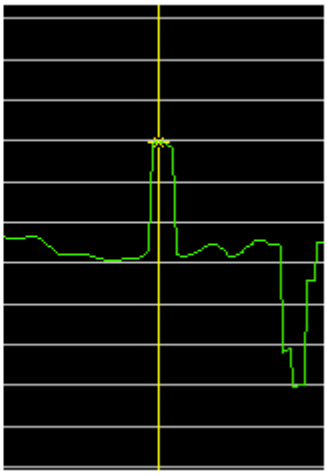
Reduce the size of the graph with respect to a chosen point. 

c. The button on the right to grab the graph at any point and drag it up, down, to the left or the right.

3. The  button is for scrolling in fine increments to view pH changes with precision along the X or Y axis. Note that to use it along the Y axis, the "Y" Scale must be unlocked.
   The two graphs below illustrate this function. The graph on the right is an expanded version of the graph on the left; the cursor is on the same point in each graph. The information that is displayed is the same.

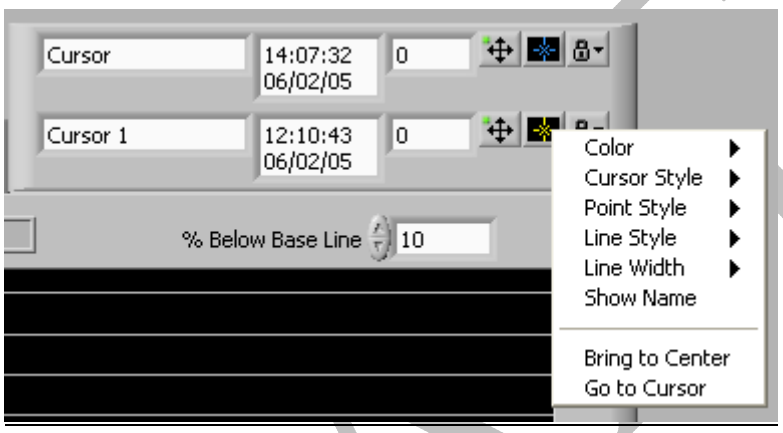






4. The horizontal scroll bar allows you to move the entire tracing itself along the X axis or to scroll along the pH tracing while viewing the pH values and time in the fields on the right hand side. To do the latter, the cursor must be engaged.

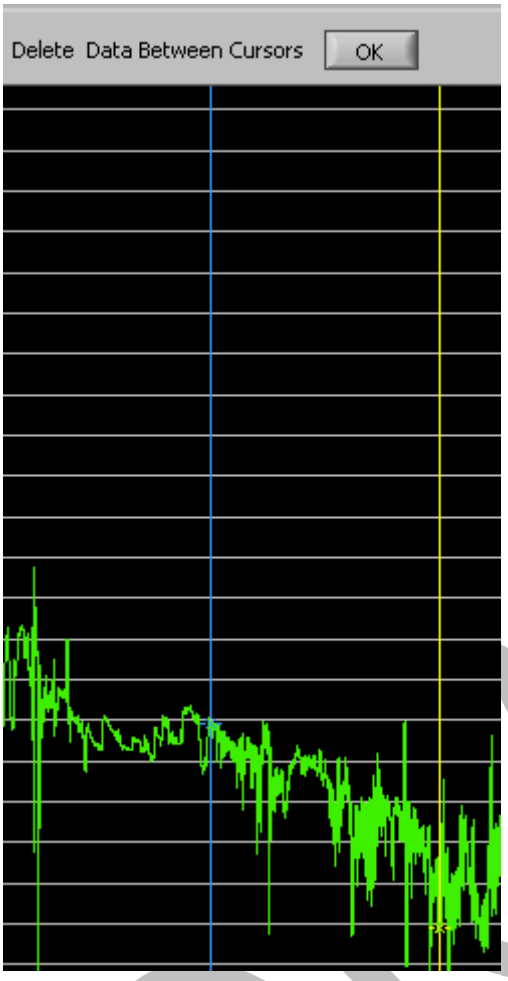
5. The cursors can be used to examine values at certain points, as well as to delete certain data from the analysis (Artefacts).



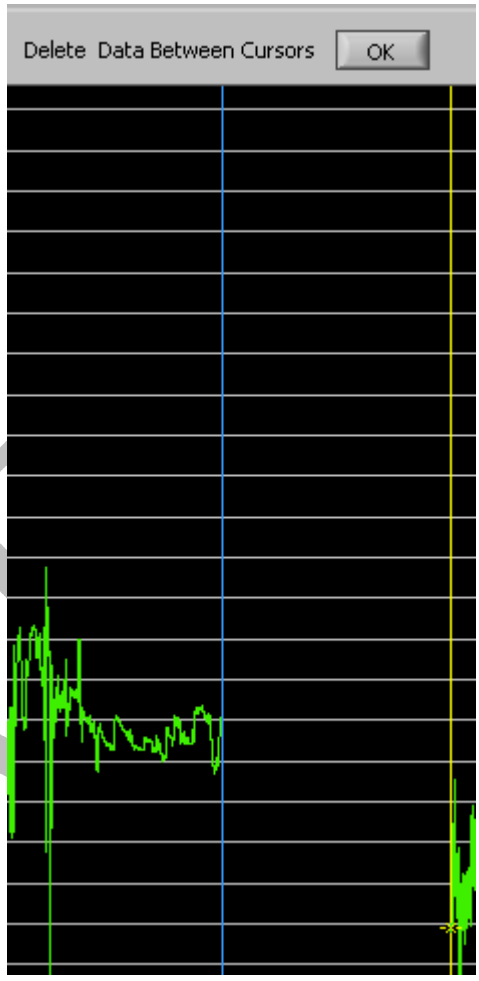
The button in the center allows you to change the color and style of the cursor, the point style, the line style and width, display the name of the cursor, bring it to the center of the page, and go to it. The lock button secures the specific cursor characteristics you have set.

When trying to remove data, move the cursors to either side of the data set you want to remove. Ensure that the points are correct by looking at the values displayed. When you are certain that the points should be removed, click the button that says remove data between the cursors (the Artefact).

Before:



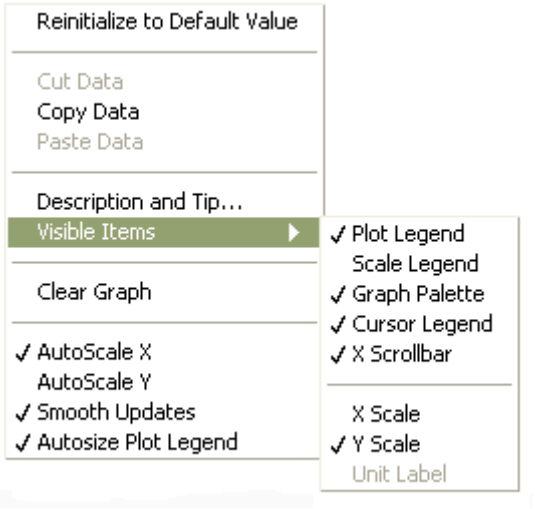
After:



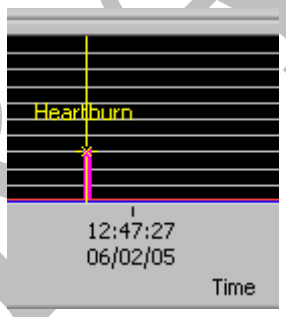
If you think you may have made an error, or you would like to perform the edit again, click the button that says **Undo Delete.**

After deleting the specified data sets, it will not be included in the analysis and will not be printed. To replace this data, you will have to download the study again from the data card.

You can right click on any point on the graph to display the following menu:

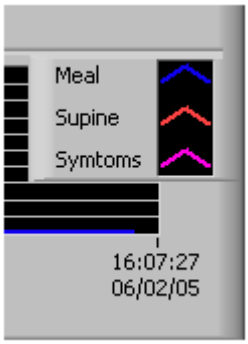


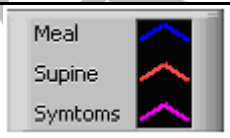
An event marker appears on the lower graph as follows:



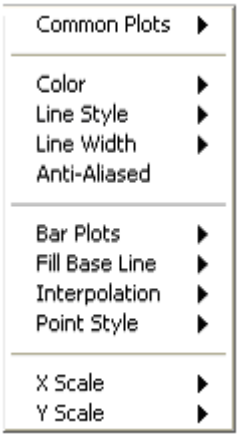
Changing the Style of Graphical Elements (Lower Graph)

Placing your cursor over any of the three lines (Meal, Supine, or Symptoms) and right clicking your mouse will allow you to change the appearance of the lower graph.

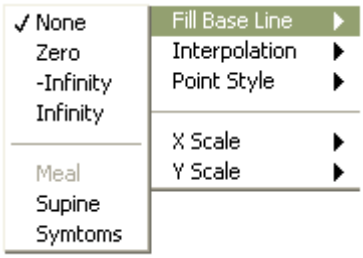




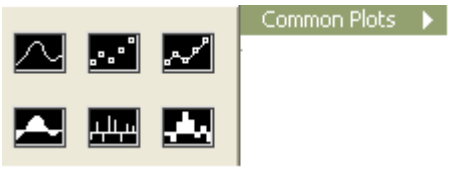
The following menu will appear:



"Fill Base Line" will

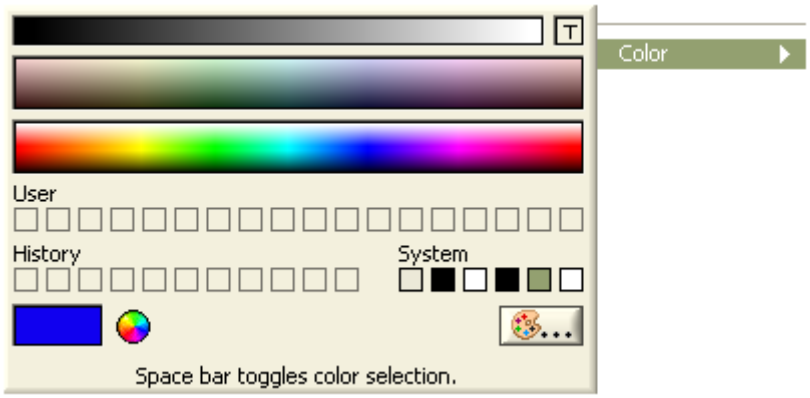


Selecting "Common Plots" will allow you to change the type of graph you use to view the study data

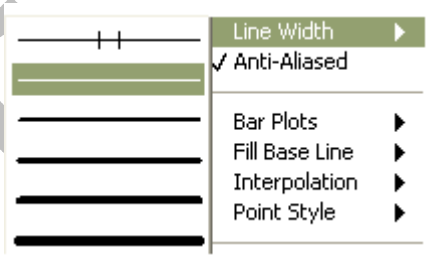


Changing the Style of Graph Elements (Lower Graph - Continued)

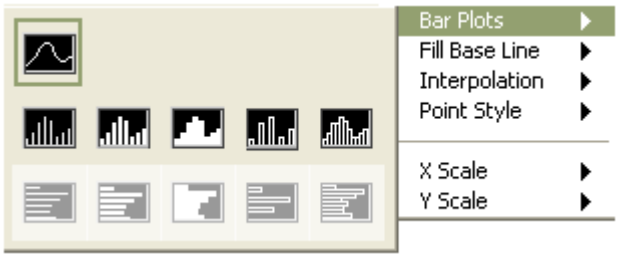
Choosing "Color" will allow you to change the color of each line. You must place the cursor over each line individually to change the colors.



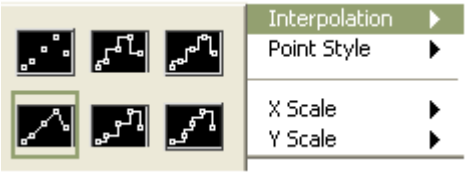
"Line Width" allows you to adjust the width of the graph lines



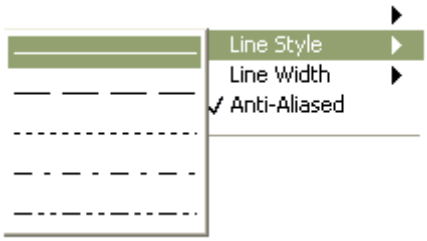
"Bar Plots"



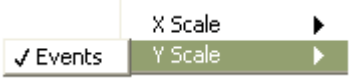
The "Interpolation" function allows you to connect the points using various methods of interpolation illustrated in the six different option boxes.



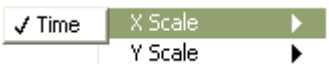
"Line Style" allows you to choose the style of line you want to view: solid, dashed, dotted, etc.



"Y Scale" shows you what is displayed on the Y axis.



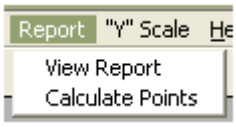
"X Scale" shows you what is displayed on the X axis.



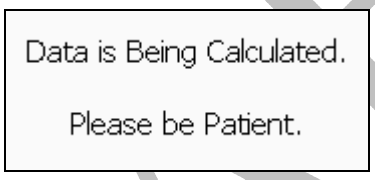
Note:
After altering the graph, be sure to recalculate the points in the "Report" menu and select "Save Graph" from the "Graphs" menu.

Viewing the Report and Diary

To view the report, select "View Report" from the Report menu.



A warning will appear to remind you to recalculate the points if you have made changes to the graph or other data. The following message will appear if you choose to recalculate the data:



Wait until the message disappears before clicking anything: doing so before appropriate will only increase your wait time.

The report contains fields for the following information:
Patient name (first and last), patient number, birth date, study date, gender, height, weight, Investigator, and referring doctor. The patient name (first and last) and study date are required fields in specific formats.

The user defined events are displayed, and if none were entered, the words "Event 1, Event 2 and Event 3" will fill the space.

Also in the report are the arithmetic mean, standard deviation, variance, median, maximum, and minimum values.
The pH events are numbered alongside the lowest pH and the start time of the event.
In the patient diary, the "symptoms" are listed in chronological order with a start and stop time for each symptom. Supine and Meal periods are listed here as well.

You can alter the patient diary in the event that a button was inadvertently pressed or was not pressed when it should have been because the patient forgot to. If you must enter time based on the patient diary, such as a meal, try to verify the time given visually by looking at that point on the graph to check for coincidence.

Symptom Index

The symptom index correlations are performed by……

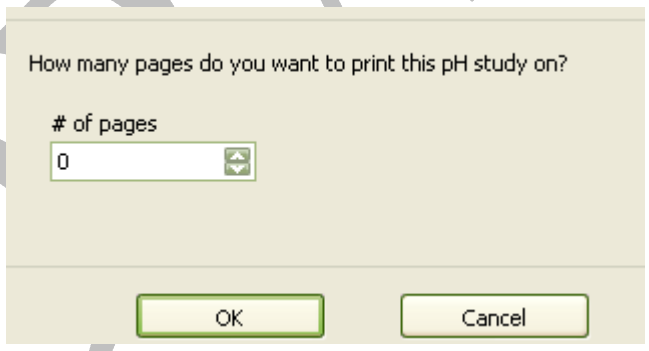
You may add notes that will be printed with the report as well in the field labeled “Notes:”

When finished with the study, you may initialize the card for a new patient. You should do this as soon as you know the information for the next planned study.
Note: If you choose to initialize the card all previous information will be removed from that card; make sure the patient data has been saved.

Printing Graphs and Reports

Selecting “Print Graph” from the Printing Menu prints the graph with no preview.

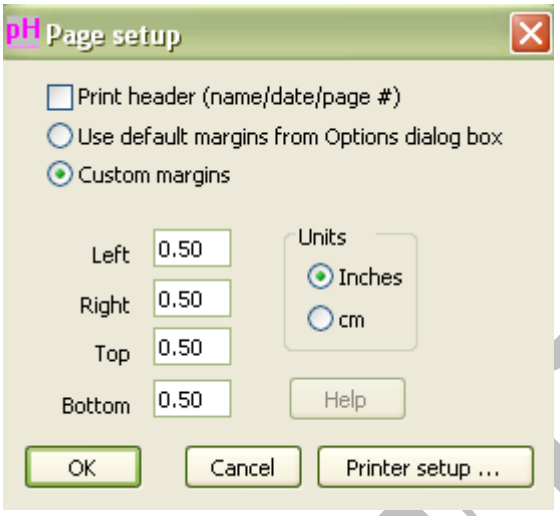
If you select “Print Study” from the Printing Menu, you will be asked how many pages you want the study to occupy.



Select desired number and click “ok” or cancel to nullify your request.

Selecting “Print Report” from the Printing Menu prints the Study Report with no preview.

To change the settings for the printer and the page setup, choose “Page Setup” from the Printing Menu.



Click **OK** when the desired settings have been selected.

Patient Operation of the Dx–pH Measurement System™

The Dx–pH Measurement System ™ was designed with patient convenience and ease of use as two of its foremost concerns. The patient is responsible for pressing event buttons, keeping a diary, and following the physician's instructions.
Before the patient is sent home, the following instructions must be emphasized along with the regular patient instructions (attachment B):

- How to keep a written diary. For analysis, information about episodes of pain and episodes of cough, supine periods, and meal periods is needed and is very important. (See attachment B)
- How and when to use the event keys. Take care to emphasize the importance of pressing the **Heartburn** key immediately when chest pain is felt, as well as the other symptom buttons to ensure an accurate analysis.
- Not to bathe/shower with the Dx–Recorder™ or Dx–Transmitter™ or expose them to water; they are not waterproof, only water resistant.
- To keep the Recorder within a reasonable distance to avoid data loss.

Troubleshooting

Symptom	Possible Cause	Try
Initial Start Up		
Status display indicates low batteries.	AA Batteries are low.	Replace AA Alkaline batteries.
Calibration		
Status display indicates a failed calibration.	Incorrect Calibration Fluids or sequence used.	Press Esc and repeat calibration in proper sequence or try another probe
	Inoperable sensor.	Try another probe
Status display indicates that transmitter is out of range. No readings.	Transmitter out of range. Inoperable transmitter.	Move recorder closer. Select new device. Return to manufacturer for evaluation.
Recorder will not accept the data card	Data is still saved from previous study	Download data into Dx–ph DataView™ and reinitialize card
Start pH Study		
Transmitter identified does not match the one identified for study.	Unit was not calibrated using this transmitter.	Recalibrate.
No pH reading displayed in study mode.	Medical provider has configured unit to have readings turned off.	
Data Transfer		
PC indicates no card.	SD card reader not plugged into USB port.	Verify connection.
Patient Interface		
Unit does not beep when an "event" button is pressed.	Medical provider has configured unit to have beep turned off.	
Unit does not beep when an "event" button is pressed.	Button is not functioning	Notify medical personnel
		Record events in patient diary.

Cleaning

The exterior surface of the Dx–Recorder™ may be wiped down with a soft cloth lightly moistened with 70-90% isopropyl alcohol. The recorder should be turned off when cleaned. Care must be taken not to allow any liquid to pass into the front cover of the Recorder. Let the surfaces evaporate thoroughly before use.

Service

The Dx–Recorder™ does not require routine calibration or servicing of internal components, unless the recorder becomes damaged. For general service of the unit, please contact your sales representative or Respiratory Technology Corporation Customer Service at (800) XXX-XXXX.

See your warranty information for contact information and eligibility requirements.

Attachment A - Patient Instructions

Dx–pH Measurement System™

PATIENT INSTRUCTIONS FOR USE

While you are having a pH study performed with the Restech Dx–pH Measurement System, it is important to go about your daily functions as usual to best reflect the lifestyle and symptoms you experience. This will ensure that your condition may be properly studied and diagnosed.

When you experience any symptoms, write them down in your patient diary as soon as possible. Record the time **from your Dx–Recorder™; do not use another clock, as this may provide inaccurate data.** Also, press the correct button firmly on your recorder one time.

If it is a symptom such as cough or heartburn, press the button firmly once.
If it is an event such as a meal or a supine period, press the button both when you begin the event and when you finish. (i.e., when you lie down and again when you get up)

It is extremely important for the correct analysis of your study that you record these occurrences precisely and in some detail. It will be helpful for your physician's accurate diagnosis of your disease. For example, if you have an episode of heartburn that is accompanied by regurgitation, describe it in your patient diary. This subjective diary is one of the most crucial components of your study.

Stay within a close range to the recorder. Though the range of transmission is up to 25 ft., if you exceed this range you may not hear the alert from the Dx–Recorder™ in time to correct the transmission deficiency, or worse, you may leave the house without it.

Do not try to power the Dx–Recorder™ unit off. Pressing extra buttons or removing the batteries will corrupt your study data and require the test to be re-done.

Do not Shower or bathe with the Dx-pH Measurement System. Do not get the recorder and transmitter wet or expose them to excessive moisture; they are not waterproof. Doing so may damage the equipment as well as provide incorrect or inaccurate data.

Most importantly, follow any instructions your doctor gives you closely.

If you have any questions regarding the study, call your physician's office or the provided contact (if available).

Attachment B - Patient Diary

Shown below is an example of a patient diary for patients to fill out during their individual pH studies. Explain the importance of the proper use of the patient diary. Let the patient know that (s) he can go about his or her daily routine as usual. Instruct your patient to fill in the diary for meals and sleep periods using the time from the clock displayed on the Dx–Recorder™. This will ensure that the diary times entered in the Dx–DataView™ software are correct when the patient's pH study is analyzed.

Patient Diary
Restech Dx–pH Measurement System™ Study

Patient Code		Investigation Date	

All Meals	Begin Time	End Time	What I Ate
Breakfast			
Snack			
Lunch			
Snack			
Dinner			
Snack			
Snack			

Lying Down	Begin Time	End Time	Remarks
Time			
Time			
Time			
Time			

Significant Symptom	Begin Time	End Time	Description
1			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			