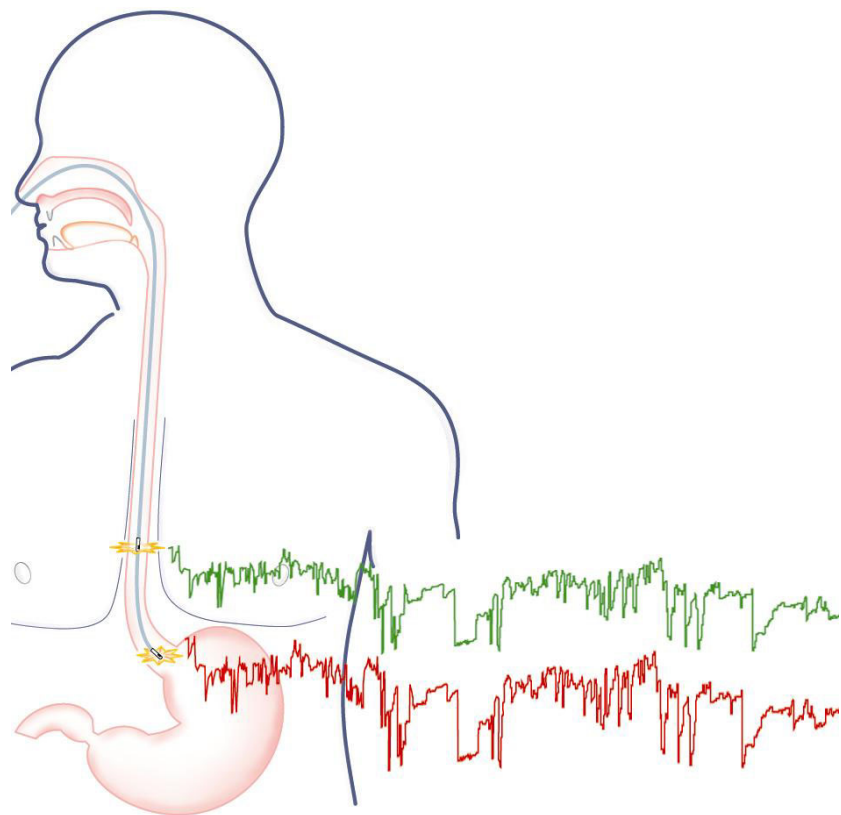




Medtronic

POLYGRAM NET™

pH Testing Application



User Guide



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At the time of printing/transfer to the CD-ROM, this manual correctly described the device and its functions. However, as modifications may have been carried out since the production of this manual, the system package may contain one or more addenda to the manual. This manual including any such addenda must be thoroughly read, before using the device.

The following situations void any guarantee(s) and obligations for Medtronic A/S:

- The device is not used according to the enclosed manuals and other accompanying documentation
- The device is installed or modified by persons other than Medtronic A/S service technicians

POLYGRAM NET™ is a trademark of Medtronic A/S.

Microsoft® is a registered trademark of Microsoft Corporation.

This system is CE marked in conformity with the requirements in the Medical Device Directive 93/42/EEC.

WARNING The device is not compatible for use in an MRI magnetic field.

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Introduction

Basic Information

The POLYGRAM NET™ pH Testing System is used to help diagnose and assess gastroesophageal reflux disorders (GERD). pH data are captured in the stomach and / or esophagus by means of a catheter, or a capsule, and a recording device. The data are then uploaded to the POLYGRAM NET™ pH Testing Application software for analysis.

CAUTION US law restricts this device to sale by or on the order of a physician.

Intended Use

The pH Testing System is intended to record, store, view, and analyze esophageal and gastric pH data to diagnose reflux disorders. The pH Testing System can also be used to locate the position of the proximal Lower Esophageal Sphincter (LES) manometrically to assist in the accurate positioning of the pH catheter.

CAUTION Physicians should exercise diligence in their interpretation of results from this system. It is always advisable to check analysis results against the signal tracings when a major consequence such as surgery occurs as a result of an investigation.

System Checklist

The following items are included in the POLYGRAM NET™ Application package.

- POLYGRAM NET™ Installation CD
- This User Guide
- Documentation CD
 - Reference Manual (Includes detailed description of POLYGRAM NET™ and Calculations used in the pH Testing Application)
 - User Guides (Language Versions)

The following items can also be supplied:

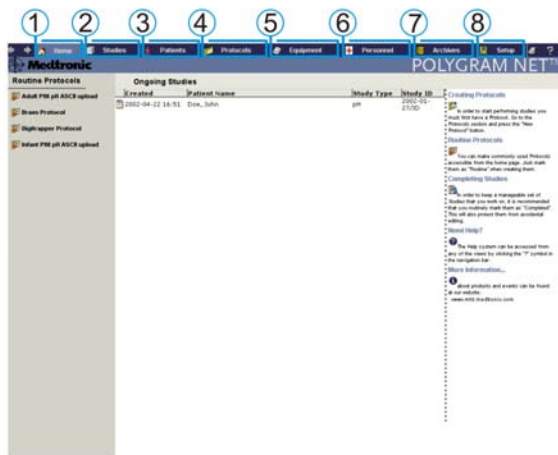
- pH Recording Devices
 - Digitrapper pH
 - Bravo pH Receiver
 - LES Identification Kit
- pH Sensors and Accessories
- PC (with trolley)
- Printer

Start pH Testing Application



Turn on the computer and start the POLYGRAM NET™ pH Testing Application by double-clicking the icon on your Windows® desktop.

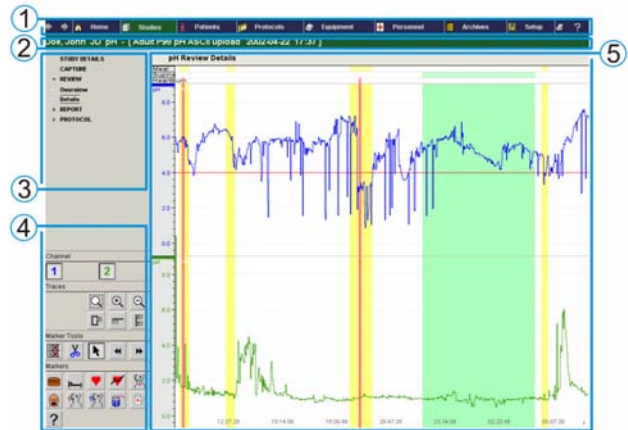
The program will start on the Home page from where you can have access to an ongoing study, or create a new one. From the Home page you can also navigate to all the other areas of the program.



1. Home
2. Studies
3. Patients
4. Protocols
5. Equipment
6. Personnel
7. Archives
8. Setup

Workspace

This illustration displays the main areas of the workspace in the application window to familiarize you with the terminology used in the manual.



1. Navigation Bar
2. Title Bar
3. View Selection Area
4. Tool Area
5. View Area

Create Study

To create a new Study, select a *Protocol* under *Routine Protocols* in the View Selection Area of the Home page, and fill out the *Study Details* page with the necessary information.

From the *List* of patients on the right, you can now choose an existing patient, or create a new one by clicking *Create New Patient* button in the Tool Area.

The screenshot shows the 'Study Details' form in the pH Testing Application. The form is titled 'Study Details' and includes a 'Study Completed' checkbox. The form is divided into several sections: 'CAPTURE', 'REVIEW', 'SIGNOFF', and 'PROTOCOL'. The 'PROTOCOL' section is currently active. The form includes the following fields and controls:

- Protocol: A14 P98 pH ASCII upload
- Date of Study: 2012-04-23 10:02
- Study ID: [Text input field]
- Physician: [Dropdown menu, value: None]
- Technician: [Dropdown menu, value: None]
- Referring Physician: [Dropdown menu, value: None]
- Reasons: [Text input field]
- Comments: [Text input field]
- Height: [Input field] cm [Input field] feet [Input field] inches
- Weight: [Input field] kg [Input field] pounds
- Calculated BMI: [Text input field]

On the right side of the form, there is a 'View All Patients' button and a table of patients:

Surname	Name	Patient ID	Last Examined
Doe	John	JD	2012-04-22 16:51

Study Details

- When ready, click *Capture*.

Capture

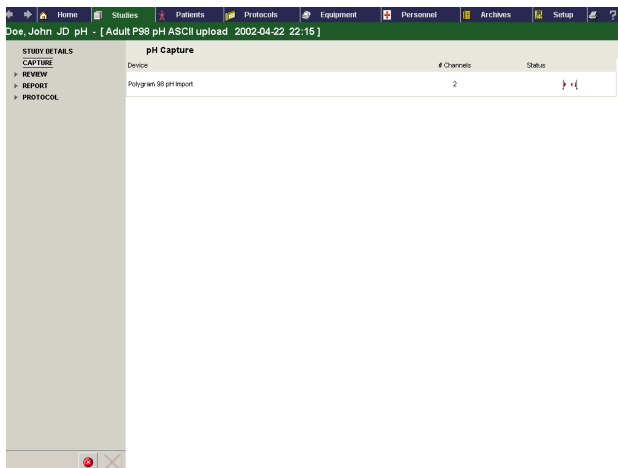
Data Upload

The first stage in Capture is to upload data. The devices you have chosen to upload the data from will be displayed on the screen.

The number of Symptom/Event buttons that will appear on the Data Upload view will depend on the number of symptom and event buttons available on the recording device.

Before starting the data upload, verify that each Symptom/Event button available from the drop-down list is assigned to the correct symptom.

To disable a Symptom/Event button, choose the *None* option from the drop-down list.



Capture – Data Upload

Uploading



When ready to start uploading, click the Upload button. Data from the recording device will be transferred to the POLYGRAM NET™ pH Testing Application.



Uploading data can be interrupted at any time during the upload by clicking the Cancel button.

NOTE The Cancel button is only available while data is being uploaded.



Click the Delete button to delete all the data currently uploaded from all the existing devices.

CAUTION When clicking the Delete button all the uploaded data from all the devices will be deleted, and the whole procedure should then be restarted from the upload stage.

NOTE The Delete button is only available after the first upload.

After a successful Upload, the system checks that the Catheter Type and the number of channels match the ones selected in Protocol. If the number of channels does not match, a caution statement followed by a dialog box will prompt you to accept the new settings. Once accepted, the protocol is automatically updated.

CAUTION If you do not accept the new settings by clicking Yes in the dialog box, the whole data upload will be invalid, and the whole upload procedure will have to be repeated.

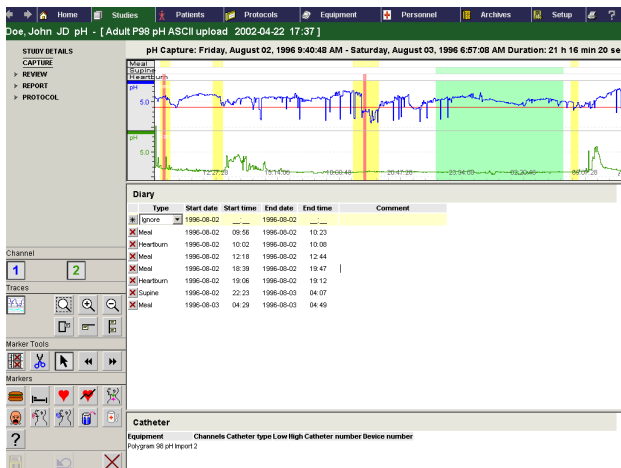
CAUTION The Catheter Type must always match the one used for the study. Please revise your protocol settings before uploading data.

- Once all data have been uploaded, and the information checked, you are automatically taken to the next stage in Capture.

Capture View

The Capture view displays the pH tracing with the Patient Diary and the Catheter settings below.

Examine the tracing to make sure that the recorded samples are valid.



Capture–Diary

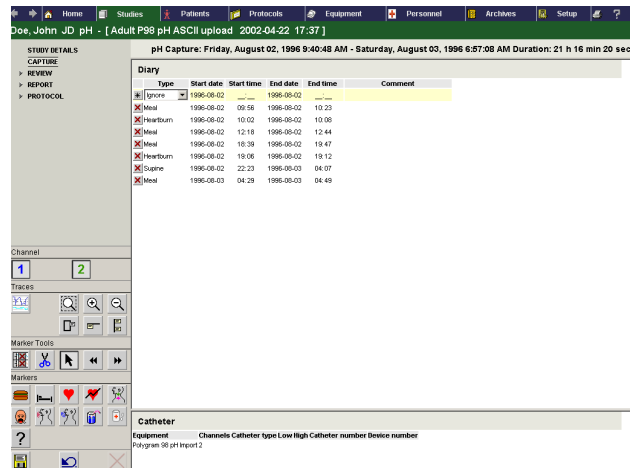
To work with the general tools, please refer to the [Working with Tools](#) section in this manual.

Diary

The Diary is visible in Capture view. The initial content and presentation depend on the Events and Symptoms entered by the patient during the study.



For a full view of the Diary, click the Show Full Diary button in the Tool Area.



Capture–Diary


Event / Symptom

During the recording, two categories of information are registered in the diary: Events and Symptoms.

All the Events and Symptoms that were written down instead of, or in addition to, the ones inserted into the system during the study can now be entered in the Diary manually, or by using the Symptom/Event buttons in the Tool Area, and then marking the corresponding trace area.

The Period will then be marked on the trace, and the new Symptom/Event with its corresponding information will appear in the Diary.

NOTE Each type of event and symptom included in the Diary adds a line to the bar graph portion above the pH traces.

 To Delete a Symptom/Event, click its corresponding Delete button inside the Diary.

Catheter Information

The following information is displayed in Capture view:

Catheter Type: Type of Catheter used for the study.

Low/High: The pH values that appear in High and Low are those measured by the system when calibrating a pH catheter. The obtained values might differ from the pH in the buffer

due to the Temperature Correction factor, which depends on the type of sensors used.

NOTE Low /High values can only be edited in Study Protocol after data has been uploaded

Catheter Lot/Batch Number: Enter the lot/batch number of the catheter used for the recording.

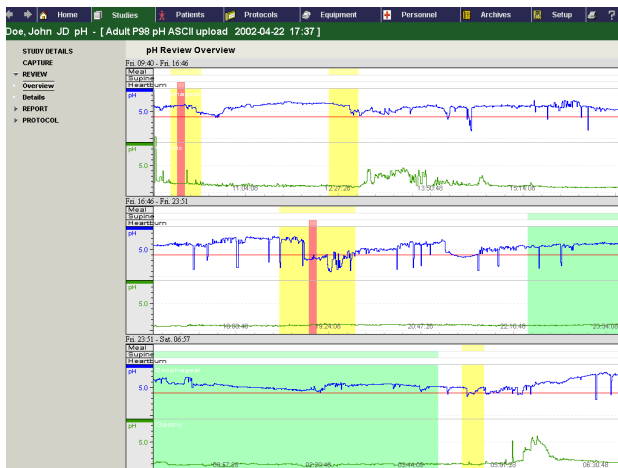
Device Serial Number: Enter the serial number of the device used for the recording.

Review

From Review you will have access to *Overview* and *Details* views, allowing you to review and analyze the recorded data, and interpret the results.

Overview

Click Overview to see the entire recording divided into 8-hour bands on the screen. This gives you a closer look at the trace information than what is available in Capture view. It is not possible to modify the view or the way in which you see the data.

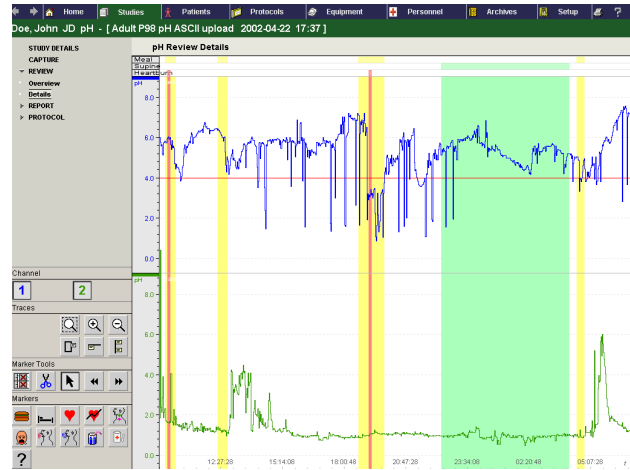


Overview

- To get a close look at the data, click *Details*.

Details

In Details, a full view of the tracing will be displayed. You will have the option to analyze the obtained data in more detail.



Details

Report Items

To access a report of a pH study, select *Report* in the View Selection Area.

A selection of the following information can be included in the report:

- Study Details
- Patient Details
- pH Traces and Diary Information
- Analysis Results
- Graphs and Clip Outs
- Normal Values

NOTE The content of the report depends on the protocol report settings.

Working with Tools

General Tools

The following General Tools are available in Capture and Review Views.

Channels



To view the tracings of a specific channel, click the channel's corresponding button in the Tool Area.

Selection Tool



Click the Selection tool to set a Marker to its normal position after marking artifacts.

Go to Function



Click to go to the Next or Previous Marker.

Zoom Area



Click the Zoom Area button to maximize the view of a specific area.

Zoom In /Out



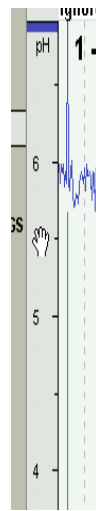
Click the Zoom In/Out button to maximize or minimize the graph view.

Artifacts



Click the Artifact button to mark unwanted portions of the tracing, which should be excluded from the analysis.

Raise/Lower or Compress/Expand Tracing



If the tracing goes outside the visible area on the screen, you can raise or lower the tracing for each channel separately. To do this, place the pointer over the scale bar. Click and drag the scale up or down.

To compress or expand the scale, you can right-click the scale bar in the desired channel and select Scale Up/Scale Down from the menu. Scale Up will expand the scale and increase the resolution making the trace larger. Scale Down does the opposite.

Measuring/Calculation Tools

Vertical Cursor



Switch On/Off by clicking the Vertical Cursor button in the Tool Area. When the line is selected, the values and time for that position will be displayed. To move the line to another position, select it, then holding down the left mouse key drag the line to the required position.

Horizontal Cursor



Switch On/Off by clicking the Horizontal Cursor button in the Tool Area. When the line is selected, the values for that position will be displayed. To move the line to another position, select it, then holding down the left mouse key drag the line to the required position.

Rectangular Selection Box



Switch On/Off by clicking the Rectangular Selection Box button in the Tool Area. When the rectangle is selected, the values for that portion will be displayed. To move the rectangle to another position, select it, then holding down the left mouse key, drag it to the required position. The size of the Rectangular Selection Box can be changed by dragging its left or right borders.

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