



ZepHr™

Acquisition Tutorial



PN: S98-9528 Rev. 1.0



ZepHr™

Data Acquisition



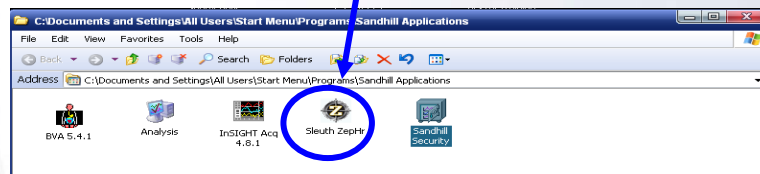
Insert Flashcard into card reader



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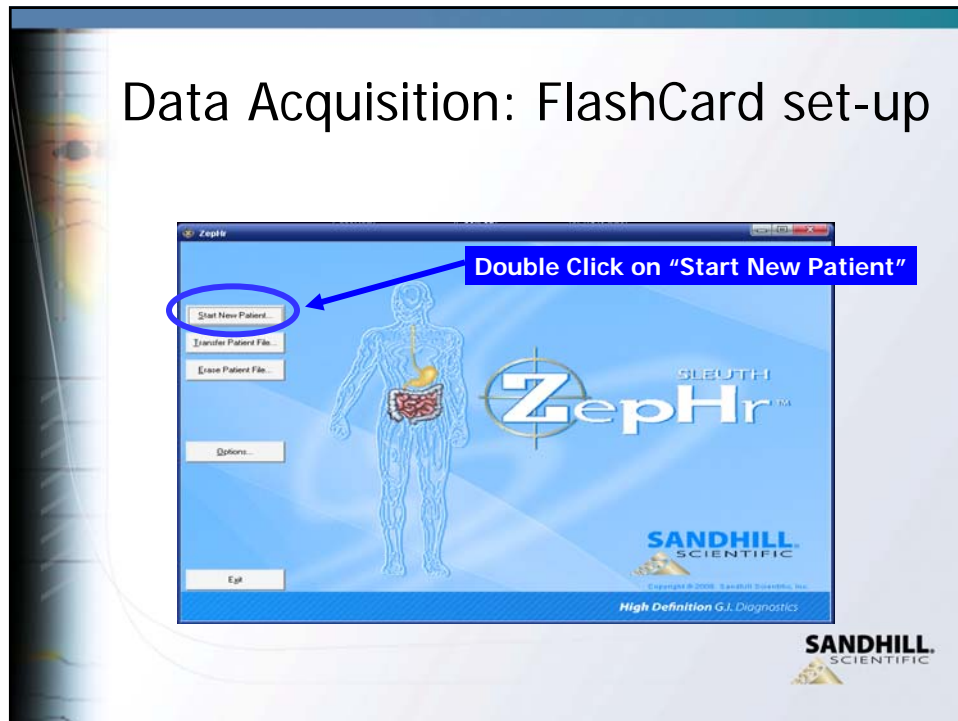
Data Acquisition: FlashCard set-up

- Turn on Computer work station
- Flash card reader should be connected to computer
- Insert CompactFlash card into the reader
- Double click on the "ZepHr" icon in the Sandhill application screen



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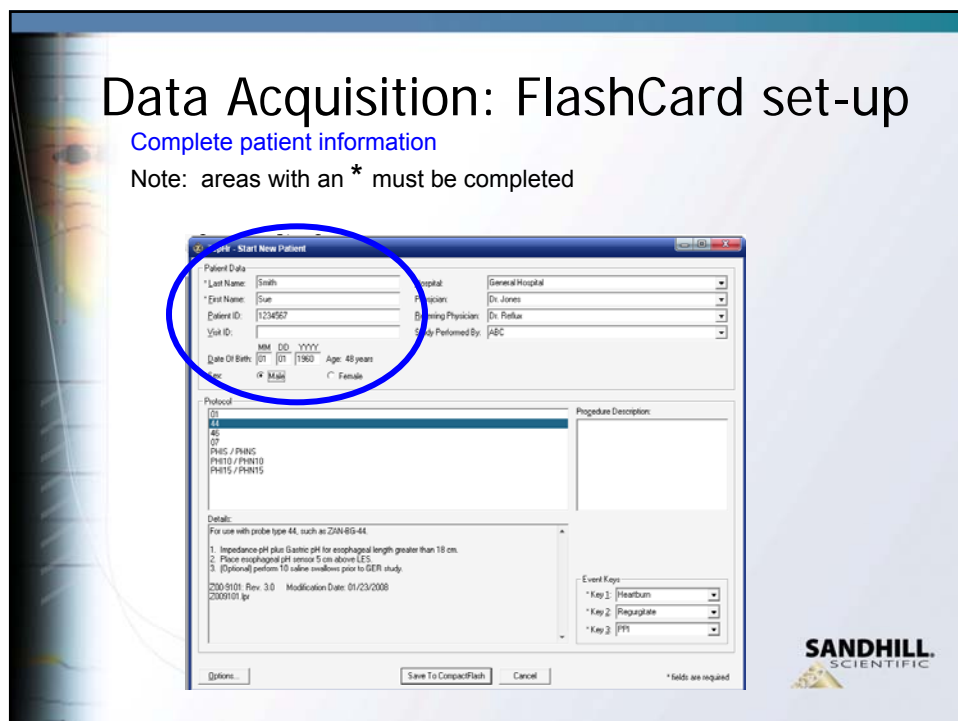
Data Acquisition: FlashCard set-up



Data Acquisition: FlashCard set-up

Complete patient information

Note: areas with an * must be completed



Data Acquisition: FlashCard set-up

Complete Institution/Staff information

ZepHr - Start New Patient

Patient Data

* Last Name: Smith Hospital: General Hospital
* First Name: Sue Physician: Dr. Jones
Patient ID: 1234567 Referring Physician: Dr. Reflux
Visit ID: Study Performed By: ABC

Date Of Birth: MM DD YYYY 01 01 1960 Age: 48 years
Sex: Male Female

Protocol

01
44
45
07
PH15 / PHN5
PH10 / PHN10
PH15 / PHN15

Procedure Description:

Details:

For use with probe type 44, such as ZAN-BG-44.

1. Impedance-pH plus Gastric pH for esophageal length greater than 18 cm.
2. Place esophageal pH sensor 5 cm above LES.
3. (Optional) perform 10 saline swallows prior to GER study.

Z00-9101, Rev. 3.0 Modification Date: 01/23/2008
Z009101.lpr

Event Keys:

* Key 1: Heartburn
* Key 2: Regurgitate
* Key 3: PPI

Options... Save To CompactFlash Cancel * fields are required



Data Acquisition: FlashCard set-up

Select protocol for the probe to be used

Note: see probe package for the REF number for the protocol number. The ZepHr Recorder will verify that the protocol number matches the probe type when probe is connected to the recorder.

ZepHr - Start New Patient

Patient Data

* Last Name: Smith Hospital: General Hospital
* First Name: Sue Physician: Dr. Jones
Patient ID: 1234567 Referring Physician: Dr. Reflux
Visit ID: Study Performed By: ABC

Date Of Birth: MM DD YYYY 01 01 1960 Age: 48 years
Sex: Male Female

Protocol

01
44
45
07
PH15 / PHN5
PH10 / PHN10
PH15 / PHN15

Procedure Description:

Details:

For use with probe type 44, such as ZAN-BG-44.

1. Impedance-pH plus Gastric pH for esophageal length greater than 18 cm.
2. Place esophageal pH sensor 5 cm above LES.
3. (Optional) perform 10 saline swallows prior to GER study.

Z00-9101, Rev. 3.0 Modification Date: 01/23/2008
Z009101.lpr

Event Keys:

* Key 1: Heartburn
* Key 2: Regurgitate
* Key 3: PPI

Options... Save To CompactFlash Cancel * fields are required

Options menu will allow selected protocol to be displayed.

Displayed protocols

Data Acquisition: FlashCard set-up

This box is for comments that may need to be made about the procedure.

Select desired symptoms. If Symptom is not in the pull down list, it can be added at this time.

Note: a symptom must be selected, if patient does not have 3 symptoms, type NA or None.



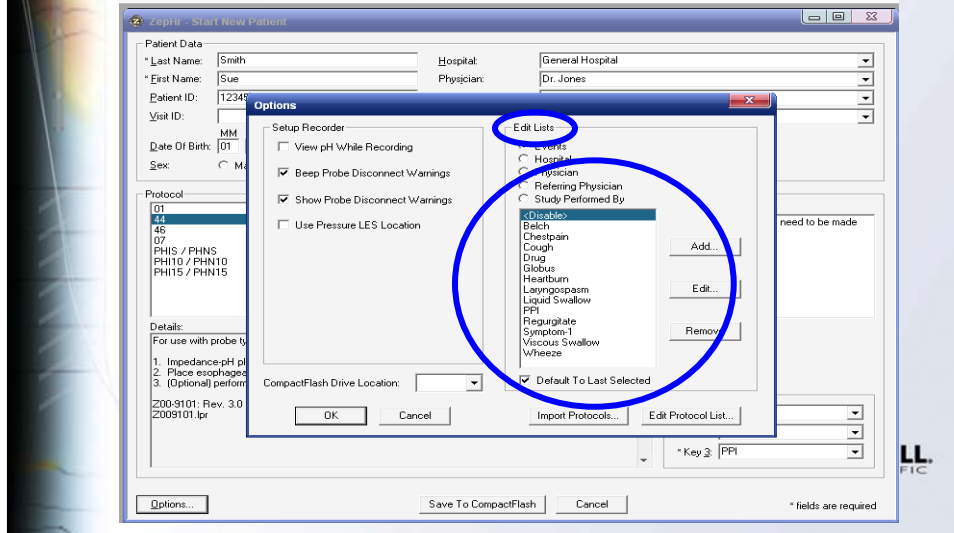
Data Acquisition: FlashCard set-up

Setting the **Options**, double click on the options icon

Data Acquisition: FlashCard set-up

Symptoms can be edited, added or deleted here by using the "add", "edit" or "delete" icons.

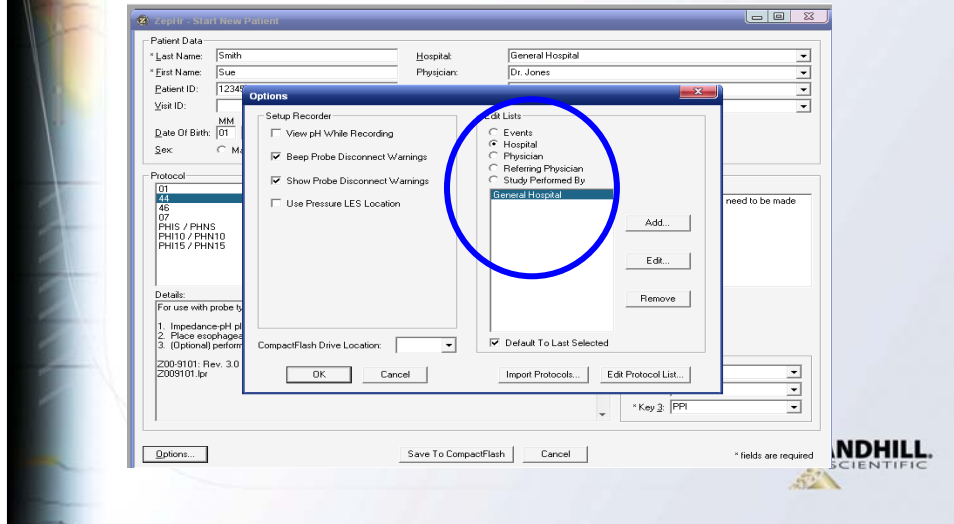
Note: The Events button must be selected when editing the events list,



Data Acquisition: FlashCard set-up

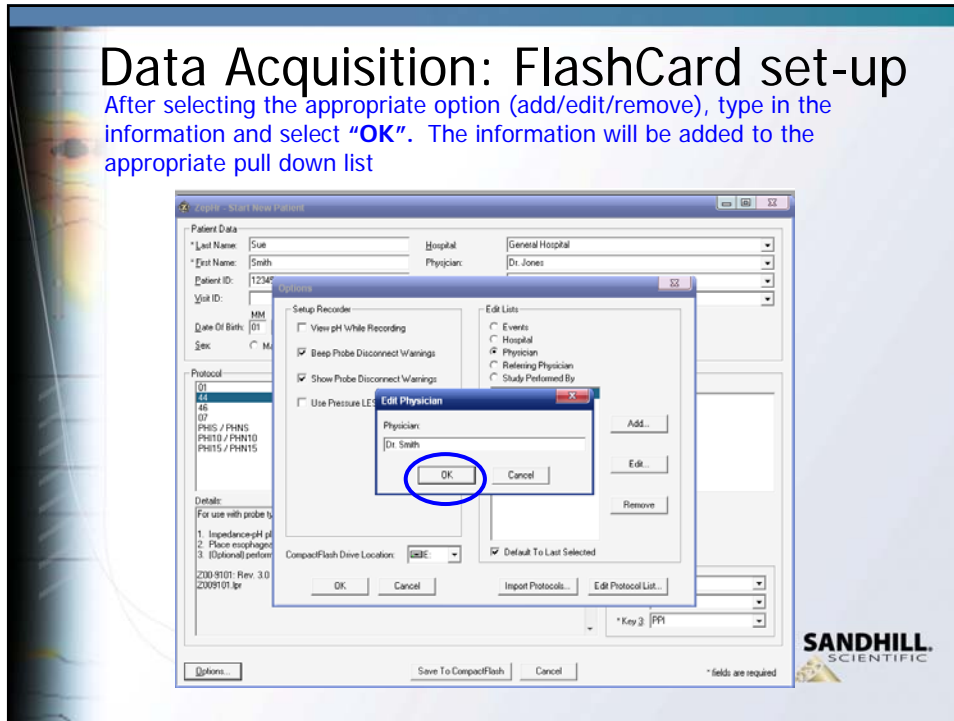
Hospital & Clinician Information can be customized

Note: To edit the information, select the appropriate button: "Hospital", "Physician", "Referring Physician" or "Study Performed By", then use the Add/Edit/Remove icons as needed.



Data Acquisition: FlashCard set-up

After selecting the appropriate option (add/edit/remove), type in the information and select "OK". The information will be added to the appropriate pull down list



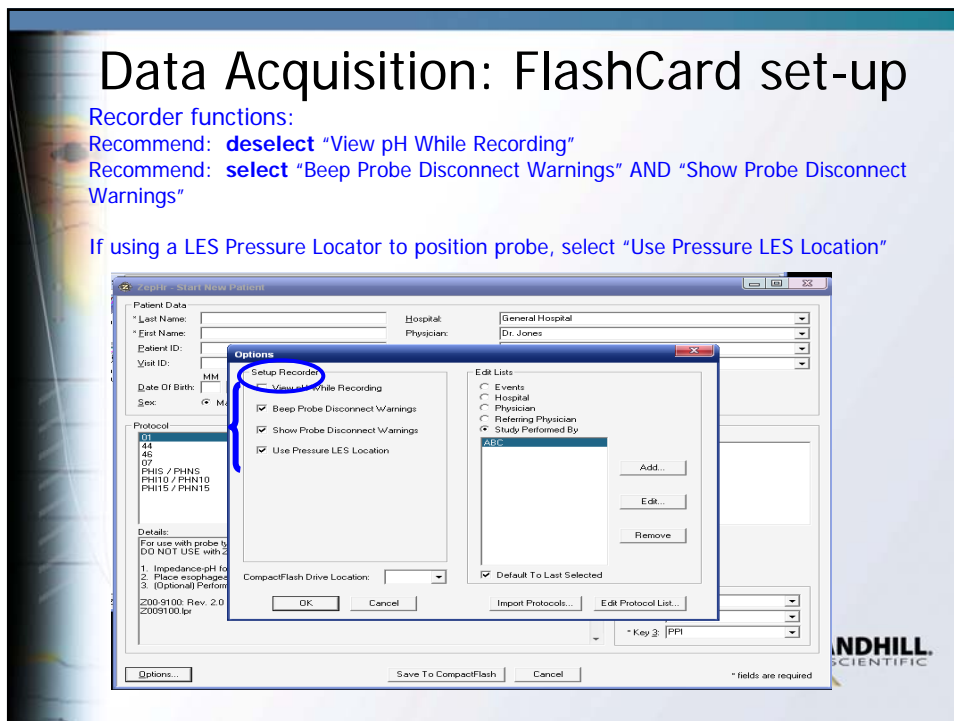
Data Acquisition: FlashCard set-up

Recorder functions:

Recommend: **deselect** "View pH While Recording"

Recommend: **select** "Beep Probe Disconnect Warnings" AND "Show Probe Disconnect Warnings"

If using a LES Pressure Locator to position probe, select "Use Pressure LES Location"

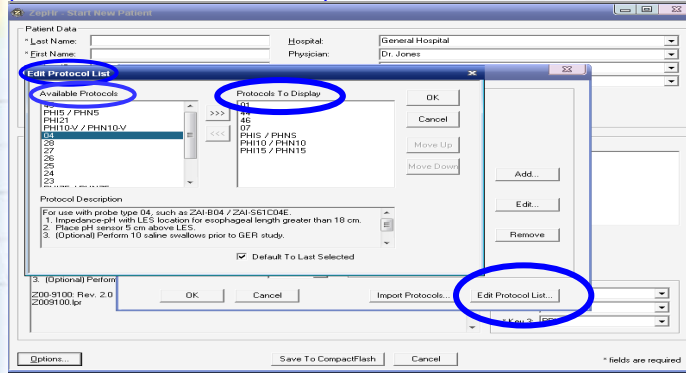


Data Acquisition: FlashCard set-up

To edit protocol list, select Edit Protocol List. This will show all the protocols available. Select only the Protocols needed to display in the "Protocols To Display" list.

Use the arrow (>>>) key to move the protocol to display.

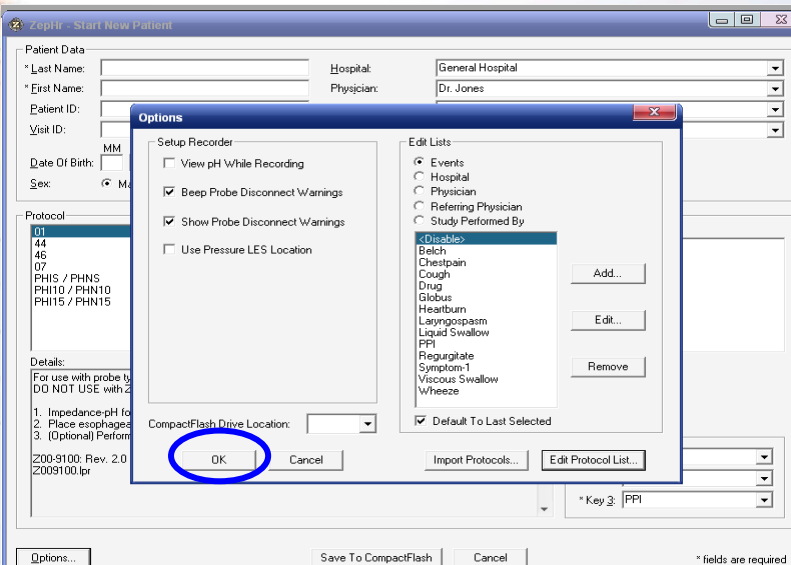
If the protocol is to be removed from the Protocol To Display, select the protocol and use the <<< key to move to the Available Protocols list.



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Data Acquisition: FlashCard set-up

When options are complete, select OK



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Data Acquisition: FlashCard set-up

Before saving to compact flash, review information to confirm that it is correct

Zephr - Start New Patient

Patient Data:

* Last Name: []
* First Name: Sue
Patient ID: 1234567
Visit ID: []
Date Of Birth: MM DD YYYY
Sex: Male Female

Hospital: []
Physician: Dr. Jones
Referring Physician: Dr. Reflux
Study Performed By: ABC

Protocol:

01
07
PHIS / PHNS
PH10 / PHN10
PH15 / PHN15

Procedure Description:

Details:

For use with probe type 01, such as ZAI-BS-01.
DO NOT USE with ZAN-S62C01E, ZIN-S61C01E, or ZPN-S61C01E!

1. Impedance-pH for esophageal length greater than 18 cm.
2. Place esophageal pH sensor 5 cm above LES.
3. (Optional) Perform 10 saline swallows prior to GER study.

Z00-9100 Rev. 2.0 Modification Date: 01/24/2008
Z009100.lpr

Event Keys:
* Key 1: []
* Key 2: []
* Key 3: FPI

Buttons: Options... Save To CompactFlash Cancel

Data Acquisition: FlashCard set-up

Click Save to Compact Flash icon

Zephr - Start New Patient

Patient Data:

* Last Name: Smith
* First Name: Sue
Patient ID: 1234567
Visit ID: []
Date Of Birth: MM DD YYYY
Age: 61 years
Sex: Male Female

Hospital: General Hospital
Physician: Dr. Jones
Referring Physician: Dr. Reflux
Study Performed By: ABC

Protocol:

01
44
46
07
PHIS / PHNS
PH10 / PHN10
PH15 / PHN15

Procedure Description:

Details:

For use with probe type 01, such as ZAI-BS-01.
DO NOT USE with ZAN-S62C01E, ZIN-S61C01E, or ZPN-S61C01E!

1. Impedance-pH for esophageal length greater than 18 cm.
2. Place esophageal pH sensor 5 cm above LES.
3. (Optional) Perform 10 saline swallows prior to GER study.

Z00-9100 Rev. 2.0 Modification Date: 01/24/2008
Z009100.lpr

Event Keys:
* Key 1: Heartburn
* Key 2: Regurgitate
* Key 3: FPI

Buttons: Options... Save To CompactFlash Cancel

* fields are required

Data Acquisition: FlashCard set-up

Click "OK" to Save Information to Compact Flash Card

Note: If there is a study on the card, it will be erased and the new patient data will be added.

The screenshot shows the Zephr software interface. At the top, there are fields for Patient Data: Last Name (Smith), First Name (Sue), Patient ID (12233456), Visit ID, Date Of Birth (01/01/1947), Age (61 years), and Sex (Female). Below these are fields for Hospital (General Hospital), Physician (Dr. Jones), Referring Physician (Dr. Smith), and Study Performed By (ABC). A central dialog box with a yellow warning icon and the text "The patient(Patient ABCD) on the CompactFlash card in drive E:\ will be erased. It has been transferred successfully at least once. The CompactFlash card must be reformatted before a new patient may be started." has "OK" and "Cancel" buttons. The "OK" button is circled in blue. Below the dialog box, there are fields for Protocol (01, 45, 07), PH15 / PHNS, PH10 / PHN10, and PH15 / PHN15. A "Details" section contains instructions for probe use and a list of steps. At the bottom, there are buttons for "Options...", "Save To CompactFlash", and "Cancel". The NDHILL SCIENTIFIC logo is in the bottom right corner.

Data Acquisition: FlashCard set-up

This message will appear on the computer screen.
To continue, Press Enter on the Computer Keyboard.

The screenshot shows a Windows command prompt window titled "C:\WINDOWS\System32\command.com". The text inside the window reads: "Insert new disk for drive F:
and press ENTER when ready...". The text "and press ENTER when ready..." is circled in blue.



Data Acquisition: FlashCard set-up

When this message appears, Press The Y KEY on the Keyboard and then press ENTER on the keyboard

```
C:\WINDOWS\System32\command.com
Insert new disk for drive F:
and press ENTER when ready...
The type of the file system is FAT.
Verifying 122M

Format cannot run because the volume is in use by another
process. Format may run if this volume is dismounted first.
ALL OPENED HANDLES TO THIS VOLUME WOULD THEN BE INVALID.
Would you like to force a dismount on this volume? (Y/N)
```



Data Acquisition: FlashCard set-up

This indicates progress in saving information to the Compact Flash card

```
C:\WINDOWS\System32\command.com
Insert new disk for drive E:
and press ENTER when ready...
The type of the file system is FAT.
Verifying 122M

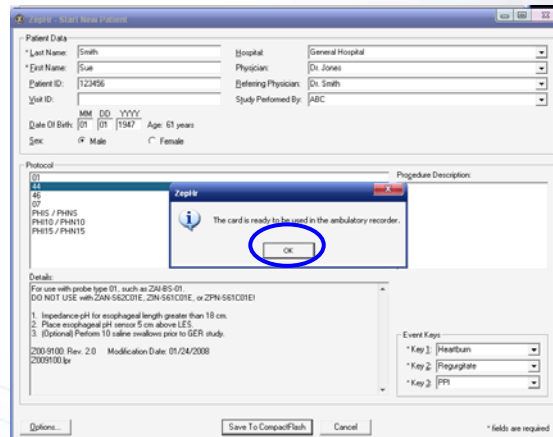
Format cannot run because the volume is in use by another
process. Format may run if this volume is dismounted first.
ALL OPENED HANDLES TO THIS VOLUME WOULD THEN BE INVALID.
Would you like to force a dismount on this volume? (Y/N) y
Volume dismounted. All opened handles to this volume are now invalid.
25 percent completed.
```



Data Acquisition: FlashCard set-up

When card formatting is complete :
Click "OK"

You may now remove the Compact Flash Card from the card reader.



Data Acquisition: FlashCard set-up



ZepHr™

Recorder Set-Up



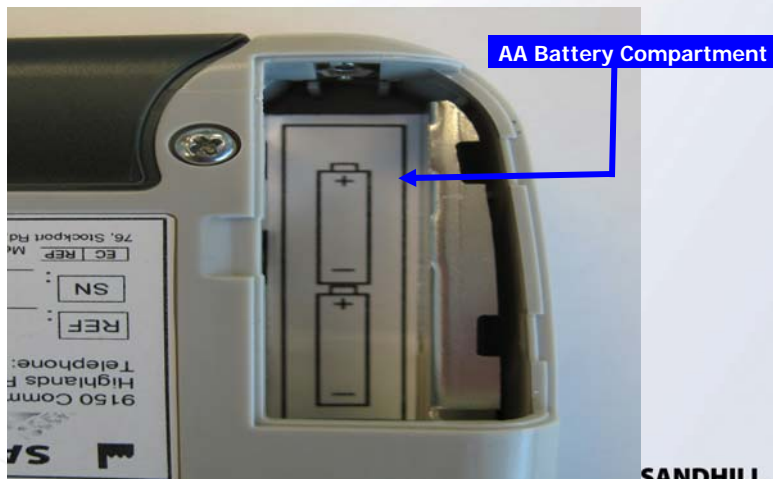
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Data Acquisition - ZepHr™ Recorder Set-Up

- Insert 2 NEW AA batteries into battery compartment of the ZepHr recorder.
 - Battery voltage will be displayed when batteries are inserted. If there is not enough voltage, a message on the screen will say that there is not enough voltage for a study.
- Insert CompactFlash card into ZepHr recorder
NOTE: The card must be aligned correctly when it is inserted into the recorder: top of the card must align with the top of the recorder
- Connect the probe to ZepHr recorder

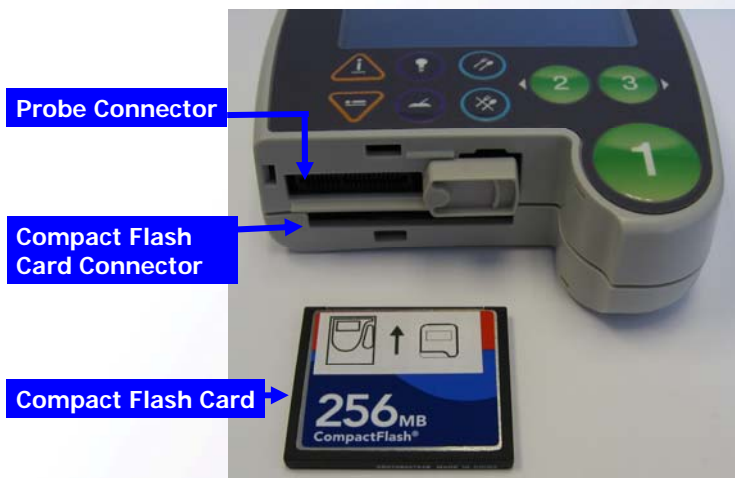
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Data Acquisition - ZepHr™ Recorder Set-Up



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Data Acquisition - ZepHr™ Recorder Set-Up



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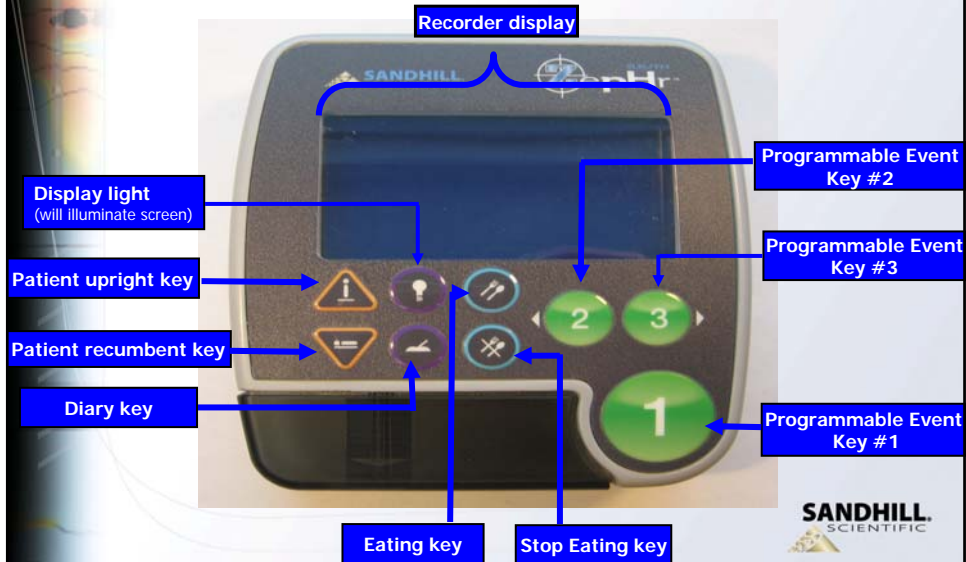
Data Acquisition - ZepHr™ Recorder Set-Up

Recorder Keys

- a. Programmable **Event 1** key – used for most prevalent symptom for the patient or the **"ENTER"** key for the user: 
- b. Programmable **Event 2** key - symptom for the patient and the move to the **LEFT** key for the user: 
- c. Programmable **Event 3** key – symptom for the patient and the move to the **RIGHT** key for the user: 
- d. **Start** and **Stop** of Eating keys: 
- e. **Upright** and **Recumbent** key for the patient and move **UP** and **Down** key for the user: 
- f. **Diary** key for the patient to record more symptoms or something notable for the procedure: 
- g. **Light bulb** key to illuminate the display of the recorder: 




Data Acquisition - ZepHr™ Recorder Set-Up



Data Acquisition - ZepHr™ Recorder Set-Up



1. When batteries are inserted, the voltage will be displayed along with the time and date.
2. To advance to the next step: push the  key.

NOTE: If the battery voltage is too low for a procedure, this will be displayed at this time.
Replace batteries.

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Data Acquisition - ZepHr™ Recorder Set-Up



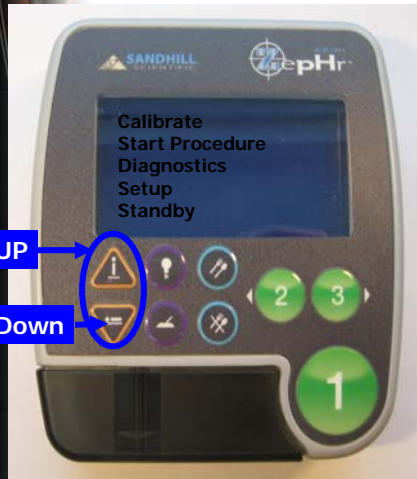
**The Display screen will read:
Card found/Reading Config File**

**Once this is complete the display
screen will show the patient
name and protocol selected**

**To advance to next step, use
the enter key.**

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Data Acquisition - ZepHr™ Recorder Set-Up

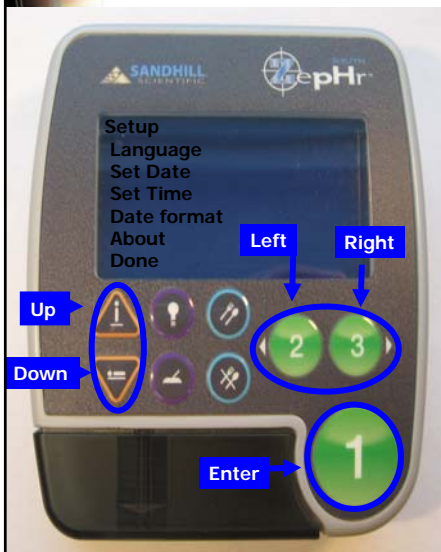


The screen will display:
Calibrate
Start Procedure
Diagnostics
Setup
Standby

- Use the up/down arrow to make selection:
- If date and time need to be changed, scroll to Setup.
- Instructions on changing date and time to follow.
- If no changes needed:
- Scroll to CALIBRATION – once selected, it will be highlighted



Data Acquisition - ZepHr™ Recorder Set-Up



The setup screen; use the up/down key to scroll to each line.

1. The language can be changed to:
 English/Deutsch/Italiano/Espanol.
2. The Date can be changed if needed.
 Scroll down to "Set Date".
 Push the "Enter key".
 The month will be highlighted.
 Use the Up/Down keys to select correct month, and the Left/Right key to move across the screen (Right key will go to the day).
 Use the Up/Down key to change the day.
 Left/Right key to move to the year.
 Up/Down key to change the year.
 When complete, select Enter.
3. To change the time, Scroll down to "Set Time".
 Push the Enter key.
 The hour will be highlighted.
 Use the Up/Down to select the correct hour, and the Left/Right key to move across the screen (Right key will go to the minutes).
 Use the Up/Down key to change the minutes.
 When complete, select Enter.



Data Acquisition - ZepHr™ Recorder Set-Up

Follow ZepHr Display Prompts to Calibrate pH Sensor/s



The pH electrode needs to soak in buffer for at least 10 minutes prior to calibration

For External Reference Probes:
See appendix



Data Acquisition - ZepHr™ Recorder Set-Up



Place the probe in pH buffer solution of 4.0 making sure that all of the impedance sensors are submersed.

Note: The probe will not calibrate if all the impedance sensors are not submersed in the buffer.

2. Push the  key to start sampling.



Data Acquisition - ZepHr™ Recorder Set-Up




There will be a 30 second countdown for electrode stabilization



Data Acquisition - ZepHr™ Recorder Set-Up



1. When the 30 second stabilization is complete, the count will be displayed and **pH 4.0 OK**
2. **"Next"** will be highlighted.
3. To continue, push the **"Enter"** key. 

Note: If calibration is not valid, the screen will say "low" and the recorder will go to a standby mode.

The calibration process should be started again. Use the same probe. If calibration fails a second time, use a new probe.




Data Acquisition - ZepHr™ Recorder Set-Up



Rinse the probe and wipe it off, insert it into the pH 7 buffer solution. "Next" will be highlighted.

Note: The impedance sensor must be submersed for the system to calibrate.

To continue, press the "Enter" key 



Data Acquisition - ZepHr™ Recorder Set-Up



There will be a 60 second countdown for electrode stabilization.



Data Acquisition - ZepHr™ Recorder Set-Up



When the 60 second stabilization is complete, the count will be displayed and **pH 7.0 OK**

"Next" will be highlighted. To continue, push the "Enter" key



Note: If calibration is not valid, the screen will say "low" and the recorder will go to a standby mode.

The calibration process should be started again using the same probe. If it fails a second time, use another probe.



Data Acquisition - ZepHr™ Recorder Set-Up



1. Pass the probe with the pH reading on the screen.
2. The probe is passed with the recorder displaying the pH. Unless selected in the set-up process, the pH will not be displayed once the recording is started.
3. Position the electrode 5 cm above proximal edge of LES determined either with manometry or pressure locator.

Start Recording!

Push the enter key to start recording

Data Acquisition - ZepHr™ Recorder Set-Up

Instruct Patient on use of the Recorder



Symptom keys: symptoms will be displayed on the recorder screen with corresponding symptom key.

“Key 1” is used for most prevalent symptom.

If patient has more than three symptoms, the “diary key” will need to be used for the other symptoms.

The use of acid suppressant medications should be recorded if the patient is on their acid suppressant medication for the procedure.



Data Acquisition - ZepHr™ Recorder Set-Up

Instruct Patient on use of the Recorder



Body position keys: the screen will display the body position selected.

When the patient is upright the upright key should be selected.

When the patient is recumbent the recumbent key should be selected.



Data Acquisition - ZepHr™ Recorder Set-Up

Instruct Patient on use of the Recorder



Start and Stop of Eating:

When **"Start Eating"** key is selected the eating event key will be displayed on the screen.

When eating is complete, select the **"Stop Eating"** key. This will remove the eating event from the screen.



Data Acquisition - ZepHr™ Recorder Set-Up

Instruct Patient on use of the Recorder



Back light key: will illuminate the screen when it is dark. (screen will go dark to save battery power)

Diary key: to be used for extra events or something notable that happened during the study



Data Acquisition – Patient Instruction

After review of use of the recorder, give the patient written instructions.

The instructions should include use of the recorder, instructions on the procedure- what the patient needs to do during the procedure, and a diary for the patient to report the diary events they documented during the procedure.



Data Acquisition - Stop Recording

Pt will return after the appropriate length of time



To Stop Recording requires a special key combination.

The key combination is: While pressing the “Light” key, press the “Event 1” key.

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

Use the “▼” key to select *Stop Recording*. Press “Event 1” key. The Recorder will switch to Standby mode.

It is advised to remove the batteries at this time.



Data Acquisition – Stop Recording

Once the recording is stopped, disconnect probe from the recorder

Extubate the patient

Remove CompactFlash card from the recorder

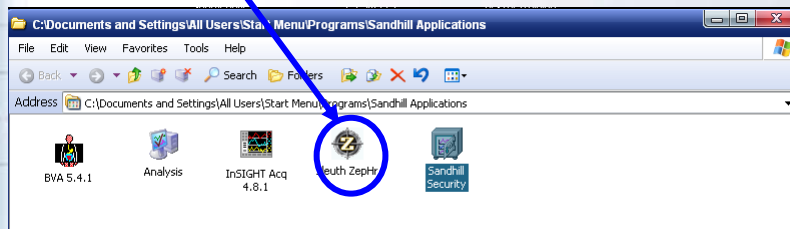


ZepHr™ - Downloading the Study

Turn on Computer work station

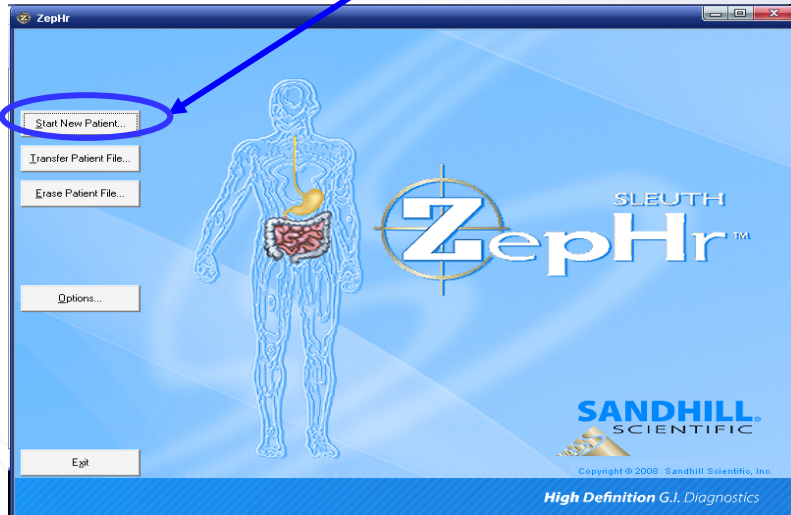
Insert Compact Flash Card into the card reader on the computer workstation

Click on the ZepHr icon in the Sandhill application screen



ZepHr™ - Downloading the Study

Select transfer Patient File



ZepHr™ - Downloading the Study

If needed, set pH sensor position.

Record probe depth.

Click on Transfer

The screenshot shows a patient data entry form. The "Patient Data" section includes fields for "First Name: Jane", "Last Name: Doe", and "ID: ABC-123 456". There are two circled input fields: "* pH Sensor Above LES (cm)" with the value "5" and "Probe Depth (cm)". The "Data Retrieval" section has a field for "Transfer GER Patient to:" with the path "C:\Sandhill\Patients\GER\" and a "Browse..." button. At the bottom, there is a "New Card Inserted" indicator, a circled "Transfer" button, and a "Cancel" button. A note at the bottom right says "* fields are required".



ZepHr™ - Downloading the Study

Patient Data

First Name: * pH Sensor Above LES (cm):

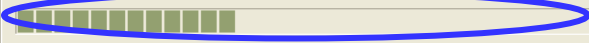
Last Name:

ID: Probe Depth (cm):

Progress Bar Indicates Transfer Status


Data Retrieval

Transfer GER Patient to:



Copying acquired data... Please wait.

* fields are required



ZepHr™ - Downloading the Study

Success

The patient data were successfully transferred! The data were saved in
C:\Sandhill\Patients\GER\GER Doe, Jane 02-28-2003 00.C01.

Would you like to:

Analyze this patient in BioVIEW Analysis,
Transfer another patient's data, or
Return to the main screen?

Click Analyze to
Open Study
in BioVIEW
Analysis Software



The Impedance-pH Study

