

The 3CPM Company Electrogastrogram

Broaden your scope of diagnoses in today's world of gastrointestinal disorders

Central Data Depot Reader and EGGSAS Reader Programs

Version 1.01

INSTALLATION MANUAL

THE ELECTROGASTROGRAM CDDR AND READER

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Broaden Your Scope of diagnoses in today's world of gastrointestinal disorders

3CPM CENTRAL DATA DEPOT READER & READER [©] Users Manual

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1 Introduction and Overview

The 3CPM Company's Electrogastrogram (EGG) Central Data Depot Reader (CDDR), and The 3CPM Company's Electrogastrogram (EGG) Reader are designed to import, view, and evaluate/re-evaluate patient studies that have been exported by using the 3CPM Export Program. The 3CPM export program is designed to be installed on any of The 3CPM Company's Electrogastrogram (EGG) versions. The CDDR allows you to collect multiple patient files that have been exported from multiple locations into a single patient database for review and analysis. The Reader version has the same features, and operates under the same instructions as the full research version with the only limitation being the inability to record a study. Its purpose is to allow you full access to studies recorded from the full version. The CDDR version restricts the ability to edit the data contained in the exported study in order to preserve the analysis done at various locations or on different machines. This version acts as it is named. It is a tool to create a Central Data Depot for the accumulation of data into one readable database for analysis. In addition, the CDDR gives the users the ability to create instances of the study called "What If" scenarios, which allow re-analyses of the data under different parameters without modifying the original study.

NOTE: The CDDR and the Reader program cannot be installed in a machine which already has the 3CPM EGGSAS program installed.

1.1 Overview of the Electrogastrogram

The 3CPM Company's Electrogastrogram (EGG) Machine is an EGG analysis system that records, stores, displays and prints the myoelectric signals from the stomach as an aid to diagnosis of various gastric motility disorders.

The filter characteristics of the amplifier allow those biological signals with approximate frequency ranges from 1 to 15 cycles per minute (cpm) to pass through for recording and digitization. Two channels of data are recorded during the session. One of these is the EGG signal itself; the other channel records respiratory rates. This respiratory recording channel is used to help identify artifact in the EGG signal caused by movement, deep breathing, etc.

The analog signals recorded from the EGG skin electrodes and the respiratory belt are amplified, filtered and fed into four cables. The cables are connected to a Human Interface Device, which is a small box that contains an analog to digital (A/D) converter for digitization of the EGG signal. The signal is then passed digitally via a USB cable to the actual 3CPM Electrogastrogram computer.

The data file that is created during the A/D conversion of the EGG signal undergoes Fourier transform (FT), an analysis of the frequencies contained in the EGG signal and a running spectral analysis (RSA). A plot of the RSA and calculation of the percentage of power in selected frequency bands are reports produced by the EGG analysis system.

These EGG data are presented in four major frequency ranges:

- normal (2.5 to 3.75 cpm)
- bradygastria (1.0 2.5 cpm)
- tachygastria (3.75 10.0 cpm)
- duodenal-respiratory (10.0 15 cpm)

The data in these ranges are described in four ways:

- 1. the raw power (log μV^2)
- 2. the percentage distribution of the power in the specific ranges described above
- 3. the ratio of power based on postprandial to preprandial power
- 4. the RSA of the EGG recording presented in a pseudo-3-D format

2 Program Operation

The **3CPM EGGSAS CDDR and the READER**[©] program both allow you to perform the following operations:

- Import a study or group of studies from the files created by the **3CPM EGGSAS EXPORT** program that integrates into any version of The **3CPM EGGSAS Program**.
- View the study data in raw form as well as the report generated in the original study.
- Read and present the Analysis the study.
- Print reports for a study.
- Create your own "What if" scenario and thereby reanalyze the study with different parameters while retaining the original studies and reports.

The **3CPM EGGSAS READER**[©] program also allows complete editing of all data to include the parameters set for analysis of the data.

2.1 Handling the exported study files that are sent to you

The exported patient files should arrive to you as a folder with the patient files and a database containing the data for those exported patients. Should you be sent this export and all the files exist but are not in a folder, you will have to create a folder on the computer and copy them into it. It is recommended that you create a folder on the desktop called "Imported Studies", then place each exported study folder within this folder. It is also possible that you will get exported studies in folders with generic names like "exported files", etc. It is also recommended that you rename these folders to better define exactly where they came from and when.

2.2 Starting the Program

The program may be started in one of 2 ways:

- Double click on the desktop icon for the **3CPM EGGSAS CDDR**[©] program, Or the Reader icon on the desktop.
- Select the *Start* button, then *All Programs*, select *3CPM Company*, and then *3CPM EGGSAS CDDR.exe*, or *Start* button, then *All Programs*, select *3CPM Company*, and then *3CPM EGGSAS Reader.exe*

EGG PAS 3CPM EGGSAS Central Data Depot Reader Once the program is started, the main screen is displayed:



THE CDDR SNAPSHOTS MATCH THE READER PROGRAM

3 Importing a Study

In the "File" menu, select "Import Studies". This will open the following screen:

| • | | gs\administrator.GASTF | (O-DOC)Desktop | export\3CPM [| Database I import |
|---|--------------|------------------------|----------------|---------------|----------------------|
| | Patient name | | | Date of study | |
| | 110 | | | 06/04/2008 | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | | | | | |
| | • | | | | 11 |
| | a] | Select A | II Studies | | II |
| | . | Select A | II Studies | | 11 |

Import Database Screen

- When you open this screen the first time, the import database from field will be your present database. Do not select this. Each time you select a location for the imported database the program will remember that location and will start there the next time you try to import a database. Therefore you should **ALWAYS** check the "*Select Database to Import*" button.
- An "**Open**" screen will appear when you click the select button. It is a standard window like all programs use to let you navigate and find files. (example below)

| 0pen | | | | | ? |
|---|----------------|---------------------------|---|---------|------------|
| Look in: | exp | | • | + 🖻 💣 🖩 | I - |
| My Recent Documents Desktop My Documents | 2 3CPM EGGS/ | AS EXP | | | |
| | File name: | 3CPM EGGSAS EXP | | | Open |
| My Network | Files of type: | Patient databases (*.mdb) | | • | Cancel |
| Places | | C Open as read-only | | | |

Open Database Window

- Use the "**Desktop**" image on the left to navigate to your desktop. Double click the main folder you created to store the exported studies, find the study folder you want and double click it. The result will look like the image above.
- Select "Open".

This will take you back to the **"Import Remote Database"** screen with the correct database now listed. Click the **"Import"** button.

You will see a warning box appear over the import screen. This is to give you a moment to make sure you are importing the right files so you don't overwrite files already imported

This is what it looks like:



If you select **"NO"** it will take you back to the Import remote database screen to allow you to reselect, following the above steps.

Selecting "YES" will begin the import.

Once the data has been imported, the Import screen will look like this:

| <u> </u> |
|------------------------|
| Select All Studies |
| Import Import Complete |
| |
| Close Help |

You can now select "Close" and it will take you back to the main screen.

3.1 Duplicate Records and Files

Should you import a patient that already resides in your database, you will first get this warning:

| ase, overwrite? |
|-----------------|
| Cancel |
| |

If you select "Yes" it will overwrite all the data for that name in the database with the data you are importing.

As soon as you make a selection, another warning for the duplicate patient file will appear:

| Warning | | × |
|--|----------------|-----------|
| The study for patient 110 study date 06/04/3 | 2008 | |
| already exists, do yo | u want to over | write it? |
| Ves | No | |

If you select "Yes" it will overwrite the whole patient file.

NOTE: You must make the same selection for both each time, unless directed by **3CPM** technical support!

4 Opening a Study

To select a prior study, first display a list of patients and their studies by using one of the following 2 methods.

- Select the icon to open an existing file, $\mathbf{\mathbf{i}}$.
- Select *File* from the top menu and then select *Open Prior Study*.

The list of patients and the studies performed on them is displayed in the following screen.

| Patient name ffff, ttt - NE version2 - testt2 110 - test | Date of study 06/13/2008 06/13/2008 08/02/2008 06/04/2008 06/09/2008 | |
|---|---|-----------------------|
| - test change - ted - old | 07/30/2008 07/30/2008 08/02/2008 | Select patient databa |

Figure: Select Patient – Open Prior Study

If there is currently a study open, and you attempt to open another existing study, and have made changes to the current patient information or study and have not saved them, the following warning screen is displayed.



Figure: Warning – Save Patient

You have the following choices:

• Yes

Save the changes to the patient and/or the study and then display the list of patients and studies.

• *No*

The changes to the patient and/or the study are discarded and then the list of patients and studies are displayed.

• Cancel

The changes to the patient and/or the study are not saved and the list of patients and studies is not displayed. The program keeps the current patient and study.

If the current study which you are working on is a What If scenario, and you attempt to open another existing study, and have made changes to the current What If scenario (see <u>What If</u>) and have not saved them, the following warning screen is displayed.

| Warning | | | × |
|--------------------------------------|------------------|---------------|------------------------|
| You have made changes to What If sce | nario and didn't | save them. Do | you want to save them? |
| (<u>Y</u> es | No | Cancel | |

Figure: Warning – Save What If

You have the following choices:

• Yes

Save the changes to the What If scenario and then display the list of patients and studies.

• *No*

The changes to the What If scenario are discarded and then the list of patients and studies are displayed.

• Cancel

The changes to the What If scenario are not saved and the list of patients and studies is not displayed. The program keeps the current patient and study.

You will notice that the Select Patient Screen now contains both the prior studies and any what if scenarios which are those studies under the main study that are indented and preceded by a dash (-).

If research reference numbers are being used, the reference number replaces the patient name.

Select a patient and a study in one of the following 2 methods.

- Double click on the patient name (not the date of study).
- Single click on the patient name and then click *OK*.

4.1 Viewing the Study – NOTE: With the CDDR Version You can not modify these screens!

These screens contain the data provided by the various EGG systems after they were analyzed. Changing them has been disabled. Use the "*What if*" option if you need to actually re-analyze the data

NOTE: If you have the 3CPM EGGSAS Reader program and wish to edit studies, refer to the manual for the full version of the program that was used to export the files. Or just skip to section 5.4.1 in this manual.

4.2 Navigating the Baseline and Post Stimulation Periods

Navigating between the baseline period and the post stimulation periods can be accomplished in several ways:

- Use the *View* menu at the top of the screen. Select from the first section of menu items to go to the specified period.
- Use the *Goto* menu at the top of the screen. Select from the menu items to go to the start of the study (baseline), the previous period, the current period, the next period or the end of the study (last period).
- Use the *Analyze* menu at the top of the screen. Select from the first section of menu items to go to the specified period.

Also note that if the period has been analyzed there is a check mark next to the menu item. This is an easy way of telling if a period has been analyzed.

- Use the dropdown list next to the patient name and date of study. Select the dropdown list and then select the period to go to that period.
- Use the *Goto* icons at the top of the screen just below the menu items. Uses the icons as follows:

K

This displays the baseline period.

◄

This displays the previous period. This has no effect if the baseline period is being displayed.

This displays the current period. This is useful if viewing the report or RSA and you wish to go back and look at the period you were previously viewing.

►

This displays the next period. This has no effect if the last post stimulation period is being displayed.

M

This displays the last post stimulation period.

4.2.1 The Baseline

The first screen displayed, after selecting a patient and study, is the raw signals in the baseline period.



4.2.2 Post Stimulation Period

A post stimulation period is displayed as shown in the following screen.



Notice that the period length and good minutes are already selected. These are the period length and minutes that were selected when the study was previously analyzed.

4.2.3 Events

The events for the current period may be viewed using the *Events* area in the lower right corner of the screen.

4.3 Viewing the Demographics

Patient demographics can be edited by selecting *View* from the top menu and then selecting *Patient demographics*. The patient demographics screen below is displayed.

| Patient Demographic | s | × |
|-------------------------------|-------------|---|
| Patient name First Name | Last Name M | |
| Date of Birth (mm/dd/yyyy) | | |
| Social Security Number | | |
| Address | | _ |
| Address | | - |
| City | | |
| State | Zip Code | |
| Phone number | | |
| Hospital number | | |
| 🔲 Research reference n | lumber | |
| | OK Cancel | |
| | Нер | |

Figure: View Patient Demographics

4.4 Viewing the Diagnostic History

Diagnostic history can be edited by selecting *View* from the top menu and then selecting *Patient diagnostic History*. The patient diagnostic history screen below is displayed.

| Diagnostic History | | × |
|--------------------|---|---|
| | | _ |
| Date of study | Diagnosis | - |
| 02/13/2004 | Post-prandial EGG is suggestive of Probable Tachygastria. | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| < | | |
| Date | | |
| Date | | |
| Diagnosis | | |
| | | |
| | | |
| | | |
| | | |
| , | | |
| | Go to study | |
| | OK Cancel Help | |
| | | |

Figure: Diagnostic History

4.5 Viewing the Patient Medications

Patient medications can be edited by selecting *View* from the top menu and then selecting *Patient Medications*. The patient medications screen below is displayed.

| Medications | | × |
|-----------------------------|---------------------------------------|---|
| Date of study 02/13/2004 | Medication | _ |
| < | | |
| Date | | |
| Medication | | |
| | Update Medication Go to study OK Help | |

Figure: Patient Medications

4.6 Viewing the Pre-study Information

Select *Edit* from the top menu, and then select *Pre-Study Information*. This displays the prestudy information

| Pre-study information | × |
|--|---|
| Time of pre-test meal 7:29 AM | |
| Indication for procedure | |
| 🗖 Nausea 🔲 GERD 🦳 Post-prandial fullness | |
| Vomiting Eructus | |
| 🗖 Bloating 🗖 Early satiety | |
| Additional Indications | |
| | |
| | |
| Attending physician | |
| Referring physician | |
| Technician | |
| Begin Study Cancel Help | |

Figure: Pre-study Information

4.7 Viewing the Respiration Rate

Select View from the top menu and then select Respiration. Select the period you want to view..

| Respiration 🔀 |
|--|
| Post stimulation period 1: Post stimulation period 2: Post stimulation period 3: |
| Change Respiration Set Respiration |
| OK Cancel Help |

Figure: Respiration Rate

4.8 Viewing the Stimulation medium

Select *View* from the top menu, and then select *Stimulation medium and quantity*. This displays a window that allows you to see the stimulation medium used.

| timulation Medium Type of stimulati quan | ion medium and tity. |
|--|-------------------------|
| Description | |
| Quantity 8 | └ oz └ mi ☞ grams |
| O He | K elp |

4.9 Viewing the Suggested Diagnosis

Select *View* from the top menu, and then select *Suggested diagnosis*. The following screen is displayed.

| onghosis | | |
|----------------------|----|------|
| - Suggested diagnosi | | |
| | | |
| 1 | | |
| 1 | | |
| Diagnosis | | |
| | | |
| | | |
| | | 2 |
| | ОК | Help |
| | | |

4.10 Viewing the Recommendation

Select *View* from the top menu, and then select *Recommendations*. The following screen is displayed.

| Patient recommendations | × |
|-------------------------|---|
| | |
| | |
| | |
| | |
| | |
| | |
| | |
| Cancel Help | |
| | |

Figure: Patient Recommendations

4.11 Viewing the RSA

Select *View* from the top menu, and then select *RSA*. The RSA is a graph of the spectral estimates of the EGG signals in 4-minute epochs.



4.12 Viewing the Data Sheet

Select *View* from the top menu, and then select *Data Sheet* This will display the Data Sheet that is also included in the report.

| Bradygastria (1.0 - 2.5 cpm)Normal (2.5 - 3.75 cpm)Tachygastria (3.75 - 10.0 cpm)Duodenal (10.0 - 15.0 cpm)Entire Range (1 - 15 cpm)Perior (MinutDistribution of average power by in the 0 to 15 cpm range)42.21 50.7619.47 32.5126.17 14.5212.15 2.20100.00 100.002.5 to 1 0.0 to 3Ratios of average powers (POSTprandial / PREprandial) by frequency range1.65 1.2027e+0092.29 5.5460e+008 1.2709e+0090.76 5.6757e+0080.25 3.4618e+008 3.4618e+008 3.6172e+0073.9088e+009 3.9088e+0092.5 to 1 0.0 to 3Distribution of average power by frequency range1.2027e+009 1.9841e+009 1.2709e+0097.4564e+008 5.6757e+0083.4618e+008 3.6172e+0072.8491e+009 3.9088e+0092.5 to 1 0.0 to 3Average dominant frequency (+ trequency in the various requency ranges67 % 41 % 59 %22 % 0 % 0 %0 % 0 %0.8 to 3 8Standard Deviation Coca Cols 867 % 41 %22 % 59 %0 % 0 %0 % 0 %0.5 to 3 8 | | Bradygastria (1.0 - 2.5 com) | Normal | Tachynastria | Durada and | 310 (2011) 2010 2010 2010 2010 2010 2010 2010 | 12012030 |
|---|---|---------------------------------|----------------------------|----------------------------|----------------------------|--|----------------------------|
| Distribution of average power by frequency region (as % of power in the 0 to 15 cpm range) 42.21 50.76 19.47 32.51 26.17 14.52 12.15 2.20 100.00 2.5 to 1 0.0 to 3 Ratios of average powers (POSTprandial / PREprandial] by frequency range 1.65 2.29 0.76 0.25 1.37 0.0 to 3 Distribution of average powers (POSTprandial / PREprandial] by frequency range 1.2027e+003 5.5460e+008 7.4564e+008 3.4618e+008 2.8491e+009 2.5 to 1 Distribution of average power by frequency range 1.2027e+003 5.5460e+008 7.4564e+008 3.4618e+008 2.8491e+009 0.0 to 3 Average dominant frequency (+ Standard Deviation) 1.69 (0.82) 2.5 to 1 0.0 to 3 0.8 to 3 Percentage f% time with dominant frequency in the various requency ranges 67 % 22 % 0 % 0 % 0.8 to 3 Stimulation Medium Coca Cola 6 8 0 % 0 % 0.8 to 3 | | true are should | (2.5 - 3.75 cpm) | (3.75 - 10.0 cpm) | (10.0 - 15.0 cpm) | Entire Range (1 - 15 cpm) | Period (Minutes) |
| Ratios of average powers 1.65 2.29 0.76 0.25 1.37 0.0 to 3 POSTprandial / PREprandial) by frequency range 1.2027e+009 5.5460e+008 7.4564e+008 3.4618e+008 2.8491e+009 2.5 to 1 Distribution of average power by frequency range 1.2027e+009 5.5460e+008 7.4564e+008 3.4618e+008 2.8491e+009 2.5 to 1 Average dominant frequency (+- Standard Deviation) 1.69 (0.82) 2.5 to 1 0.0 to 3 Percentage (\$6) time with dominant requency in the various requency 67 % 22 % 0 % 0 % 2.5 to 1 Standard Deviation 41 % 59 % 0 % 0 % 0.0 to 3 Standard Deviation Medium Coca Cola 67 % 22 % 0 % 0 % 0.0 to 3 | listribution of average power by requency region (as % of power a the 0 to 15 cpm range) | 42.21 50.76 | 19.47 32.51 | 26.17 14.52 | 12.15 2.20 | 100.00 100.00 | 2.5 to 14.0 0.0 to 30.9 |
| Distribution of average power by irequency range 1.2027e+009 1.9841e+009 5.5460e+008 1.2709e+009 7.4564e+008 5.6757e+008 3.4618e+008 8.6172e+007 2.8491e+009 3.9088e+009 2.5 to 1 0.0 to 3 Average dominant frequency (+ Standard Deviation) 1.69 (0.82) 2.14 (0.96) 2.5 to 1 0.0 to 3 0.0 to 3 Percentage (\$6) time with dominant requency in the various requency angles 67 % 3.9 % 22 % 0.% 0 % 0.% 0.% 2.5 to 1 0.0 to 3 Stimulation Medium Coca Cola 8 Coca Cola 8 8 8 8 | latios of average powers POSTprandial / REprandial] by frequency range | 1.65 | 2.29 | 0.76 | 0.25 | 1.37 | 0.0 to 30.9 |
| Average dominant frequency (+- 1.69 (0.82) 2.5 to 1 Standard Deviation) 2.14 (0.96) 0.0 to 3 Percentage (%) time with dominant 67 % 22 % 0 % 0 % 0.% 2.5 to 1 requency in the various requency 41 % 59 % 0 % 0 % 0 % 0.0 to 3 standard Deviation 59 % 0 % 0 % 0.0 to 3 coca Cola 8 8 | listribution of average power by requency range | 1.2027e+009 1.9841e+009 | 5.5460e+008 1.2709e+009 | 7.4564c+008 5.6757c+008 | 3.4618e+008 8.6172e+007 | 2.8491e+009 3.9088e+009 | 2.5 to 14.0 0.0 to 30.9 |
| Percentage (%) time with dominant 67 % 22 % 0 % 0 % 2.5 to 1 requency in the various requency 41 % 59 % 0 % 0 % 0 % 0.0 to 3 anges Stimulation Medium Coca Cola 8 | verage dominant frequency (+- tandard Deviation) | 1.69 (0.82) 2.14 (0.96) | | | | | 2.5 to 14.0 0.0 to 30.9 |
| | ercentage (P4) time with dominant requency in the various requency anges timulation Medium Coca Cola 8 | 67 % 41 % | 22 % 59 % | 0 % 0 % | 0 % 0 % | | 2.5 to 14.0 0.0 to 30.5 |

4.13 Viewing Events

Select *View* from the top menu, and then select *Events*

| | Baseline | |
|------|---------------------------|--|
| | 0:28 - M | |
| | 2:26 - M | |
| | Post stimulation period 1 | |
| | 0:20 - MT | |
| | 4:14 - O 9:53 - MTO | |
| | 14:08 - 0 | |
| | 18:29 - ⊂ | |
| | 21:09 - 0 | |
| Desc | ription | |
| _ | | |
| | | |
| | | |
| | | |
| | | |
| | | |

5 Using the What If Scenario for Re-analyzing the Study

This option allows the user to perform reanalysis of a prior analyzed study, while keeping the original study data analysis intact. There is no limit to the number of What If analyses that can be performed based on an original study. You can also use the **F** symbol.

The data in a What If scenario is as follows:

- Period start minutes
- Period lengths
- Selected good minutes
- Respiration rates

5.1 No Prior What If Scenarios

The What If window is displayed as follows if there are no prior What If scenarios.

| What If Scenario | | × |
|------------------|--------------------|---|
| Date/Time | Description | - |
| 2008/02/08 14:42 | NEW | |
| 2007/07/13 | Original study | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| Description | | |
| NEW | | _ |
| 1 | | |
| | Save Recall Delete | |
| | Jave Netali Delete | |
| | Close Help | |
| | | |

The "NEW" item is automatically selected. Enter a description in the *Description* field. The choice: "NEW" or "Original study" is not allowed as What If descriptions.

After the description is entered, select the *Save* button to save it. After saving the What If scenario, the *Recall* button becomes enabled. Then select either *Close* or *Recall* button to go back to the main display. The description is displayed above the graphs and to the right of the period dropdown list.

5.2 What If Scenarios

The What If window is displayed as follows if there are What If scenarios for a study.

| Wh | at If Scenario | | X |
|-----|------------------|--------------------|---|
| | Data/Time | Description | - |
| | 2008/02/08 14:59 | NEW | - |
| | 2007/07/13 | Original study | |
| | 2008/02/08 14:56 | 5 periods | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| | | | |
| Des | scription | | |
| 5 p | periods | | |
| Ľ | | | |
| | | Save Recall Delete | |
| | | Close Help | |

Figure: What If Scenario with What If scenarios

The list is ordered by descending date and time (i.e. the most recent date and time is at the top of the list). The "NEW" and "Original study" listings are always displayed first in the list.

The What If scenario that is currently being viewed on the main display is automatically selected.

Now the *Recall* and *Delete* buttons are enabled.

A What If scenario is loaded by either double clicking on the scenario in the list or selecting it and then selecting the *Recall* button.

A What If scenario is deleted by selecting the item in the list and then selecting the *Delete* button. If the currently viewed scenario is deleted and the user just selects the *Close* button to go back to the main display, the original study is displayed (the What If description is no longer displayed).

5.3 Saving What If Scenarios and Studies

The data for a What If scenario and the study data are treated differently when saved.

If a What If scenario is loaded, the *Save* toolbar button, will save only the data items in the What If data (see the list above). Any other items that have been changed will not be saved at this time.

Example:

If a user changes the good minutes in a given period in the currently loaded What If scenario and also changes the diagnosis and selects the *Save* toolbar button, only the data for the What If scenario will be saved. The diagnosis will not be saved. Then the user opens the What If window and will be prompted to save the patient data (i.e. the diagnosis).

Each time the What If window is opened, the program checks for any unsaved data in both the What If scenario and the study. If either or both have unsaved data, the user will be prompted to save the data.

5.4 Re-analyzing the Study in the What If instance created

5.4.1 Changing the Baseline

The first screen displayed, after selecting a patient and study, is the raw signals in the baseline period.



Notice that the good minutes are already selected. These are the minutes that were selected when the study was previously analyzed.

You may change the selected minutes by changing either the *Start minute* or *End minute*. Notice that the *Set Good Minutes* becomes unchecked. You must check it again to accept the new good minutes.

WARNING – Changing the baseline minutes will erase all selected minutes or subsequent post stimulation periods. The What If scenario option should be used to perform reanalysis if you would like to preserve the original analysis.

5.4.2 Change a Post Stimulation Period

A post stimulation period is displayed as shown in the following screen.



Figure: Main Screen – Re-Analyze Post Stimulation Period

Notice that the period length and good minutes are already selected. These are the period length and minutes that were selected when the study was previously analyzed.

You may change the period length by changing either the *Start minute* or *End minute*. Notice that the *Set Period Length* becomes unchecked. You must check it again to accept the new period length. Also notice that the *Set Good Minutes* has become unchecked.

You may change the selected minutes by changing either the *Start minute* or *End minute*. Notice that the *Set Good Minutes* becomes unchecked. You must check it again to accept the new good minutes.

WARNING - Changing the post stimulation periods or minutes will erase all prior selected minutes or subsequent post stimulation periods, if the newly selected periods or minutes are saved. The What If scenario option should be used to perform reanalysis if you would like to preserve the original analysis information. Use the **Reset Periods** Button and then set the proper periods you wanted

5.4.3 Changing Events

The events for the current period may be changed using the *Events* area in the lower right corner of the screen.

Select an event from the list. The description is displayed below it.

Select *Edit* to change the event. You cannot change the time of the event.

Select *Delete* to delete the event. The following warning is displayed.

| Warning | \mathbf{X} |
|-----------------------------------|--------------------------|
| Are you sure you wan 44:35 - O | It to delete this Event? |
| Yes | No |

Select Yes to delete the event and No to if you don't want to delete the event.

5.5 Changing the Diagnosis

Select *Edit* from the top menu, and then select *Suggested diagnosis*.

If you have previously entered a diagnosis, you may also change it by selecting *Edit* from the top menu and then selecting *Suggested diagnosis*.

5.6 Changing the Recommendation

Select *Edit* from the top menu, and then select *Recommendations*. This displays a window that allows you to change the recommendations.

5.7 Changing the Pre-study Information

Select *Edit* from the top menu, and then select *Pre-Study Information*. This displays a window that allows you to change the pre-study information.

5.8 Stimulation medium

Select *Edit* from the top menu, and then select *Stimulation medium and quantity*. This displays a window that allows you to change the stimulation medium.

5.9 Change number of minutes per graph

The number of minutes, *as they are viewed*, per graph is initially set to 4 minutes. This may be changed by selecting *View* from the top menu and then selecting *Change number of minutes per graph*. The following window is displayed.



Figure: Change number of minutes per graph

Enter the number of minutes you want to see displayed on each graph and then select **OK** to save the number of minutes per graph. The graphs will change according to the number of minute entered.

6 Reports

The default or standard report consists of 2+ pages organized as follows:

- Page 1
 - Facility information at top of page
 - Patient information
 - Patient name
 - Date of study
 - o Attending physician
 - Referring physician
 - o Technician
 - o Indications
 - o Stimulation medium
 - o Diagnosis
 - o Recommendations
 - Signature and date
- Page 2
 - RSA
- Page 3 plus required additional pages
 - Raw data graphs of the selected minutes. One graph per period.

6.1 Configuring Reports

Reports can be configured to include/exclude the following items.

- Patient information
- RSA
- Data Sheet
- Raw data graphs of the selected minutes. One graph per period.
- Graphs of the entire raw signal starting on the next available page until all graphs are printed.
- Event log

Configure the graphs by selecting *Report* from the top menu and then selecting *Configure Report*. The following screen is displayed.

| Configure report |
|--|
| Core report only |
| If the core report is de-selected, you can then select the items to be in the report. |
| Patient Information |
| Diagnosis/Recommendations |
| RSA 🔽 |
| 🔲 Data sheet |
| 🗖 Summary Graphs |
| Raw Signal of Selected Minutes |
| 🔲 Entire raw signal |
| 🖂 Event log |
| OK Cancel Help |
| Configure Report |

Select the items you want included in the report or de-select the items that you want removed from the report. Select *OK* to put the items in the report.

Select *Cancel* to leave the report unchanged.

6.2 Facility Information

Facility information can be entered at any time. Select *Report* from the top menu and then select *Facility/practice information*. The following screen is displayed.

| Facility Information |
|----------------------------|
| Facility/Practice name |
| Address |
| Address |
| City |
| State Zip Code |
| Phone number |
| Save and close Cancel Help |

Figure: Facility Information

Enter the information and select Save and close to save the information in the database.

Cancel discards any newly entered information and leaves the facility information unchanged in the database.

The information initially entered will appear at the top of all reports, unless edited.

6.3 View/Printing

Once the study has been analyzed, the report can be viewed by selecting *Report* from the top menu and then selecting *View report*. While the report is being viewed, it can be printed.

Print the report using one of the two following methods.

- Select the print icon, from the top menu.
- Select *Report* from the top menu and then select *Print report*.

Either of these methods displays a standard Windows Print screen.

| i inter | | |
|---------|------------------------|--------------|
| Name: | hp deskjet 5550 series | Properties |
| Status: | Ready | |
| Туре: | hp deskjet 5550 series | |
| Where: | USB001 | |
| Comment | | |
| Paper | | Orientation |
| Size: | Letter (8.5 x 11 in.) | Portrait |
| | Auto | A Clandscape |
| Source | JAdio | |
| Source: | | |

Select Printer

Backing Up and Restoring Data 7

You can backup or restore your data by selecting *File* from the top menu and then selecting Backup or Restore. The following screen is displayed.

| Backup/Rest | ore Data | | | × |
|-------------|----------|-------|---------|---|
| | Backup | | Restore | |
| | | | | |
| | | Start | | |
| | | | | |
| | Close | | Help | |

Figure: Backup/Restore Data

7.1 Backup

Select *Backup*. A standard Microsoft Windows "Save as" screen is displayed. The *File name* is "3CPM EGGSAS.MDB". The file name must not change. Navigate to the directory (including Network directories) or drive where you want to backup the data to and select *Save*.

For example, your data is on the C: drive and you select D: drive (the CD drive) to backup up your data to. Once you select *Save* from the standard Microsoft Windows "Save as" screen, the above screen is changed to:

| Backup/Restore Data |
|---------------------------------|
| Backup Backup Backup to: |
| D: |
| , Start File being copied |
| Paralue |
| раскир |
| Help |

Figure: Backup Data

Select *Start* to start the backup. During the backup, the file being copied is displayed under *File being copied*. Also the field next to the text "Backup" displays the progress of the backup.

If the backup has completed successfully, the following screen is displayed.

| EGGSAS |
|------------------------------------|
| The backup completed successfully. |
| ОК |

Figure: Backup Complete

Select *OK*. Then select *Close* from the above screen.

If the backup fails, an appropriate error message is displayed indicating what may be wrong. The following is a list of possible errors.

- There is no destination disk in the selected drive.
- The destination disk is full.
- The file already exists. This message is only displayed once. If you elect to overwrite the first file, then all additional files are overwritten.
- There is an error writing to the directory/disk. This may occur for a number of reasons.
 If you are writing to a CD, try another CD, the CD may be damaged.

- If you are writing to a directory (either on the local PC or on the network) make sure you have permission to write.

7.2 Restore

To restore data from a backup, exit the program, restart the program and select *File* from the top menu and then select *Backup or Restore*.

IMPORTANT NOTE: Restoring data will only work if it is the first action performed after starting the program.

The initial Backup/Restore data screen is displayed (Figure: Backup/Restore Data).

Select *Restore*. A standard Microsoft Windows "Open" screen is displayed. The *File name* is "3CPM EGGSAS.MDB". The file name must not change. Navigate to the directory (including Network directories) or drive where you have the backup data you want to restore and select *Open*.

For example, your backup data is on the D: drive in the directory "EGGSAS data 13-14 Feb 04". Once you select *Open* from the standard Microsoft Windows "Open" screen, the screen shown in Figure **Backup/Restore Data** is changed to:

| Backup/Restore Data | × |
|--|---|
| Backup Restore Restore from: D:\Database 13-FEB-04 | |
| Start File being copied | |
| Restore | |
| <u>Close</u> Help | |

Figure: Restore Data

Select *Start* to start the restore. During the restore, the file being copied is displayed under *File being copied*. Also the field next to the text "Restore" displays the progress of the restore.

If you are restoring over an existing database, you will get the following message.



Figure: Overwrite

If you want to overwrite the existing database and data files, select *Yes* and the restore operation will continue. If you don't want to overwrite the existing database and data files, select *No* and the restore will stop.

If the restore completes successfully, the following screen is displayed.

| EGGSAS |
|-------------------------------------|
| The restore completed successfully. |
| ОК |

Figure: Restore Complete

Select *OK*. Then select *Close* from the above screen (Figure: **Restore Data**).

If the restore fails, an appropriate error message is displayed indicating what may be wrong. The following is a list of possible errors.

- There is no source disk in the selected drive.
- The destination disk is full.
- The file already exists. This message is only displayed once. If you elect to overwrite the first file, then all additional files are overwritten.
- There is an error writing to the directory/disk. This may occur for a number of reasons.
 - If you are writing to a directory (either on the local PC or on the network) make sure you have permission to write.
 - If you have performed any other action with the program, close the program and restart it.

8 Closing the Program

The program can be closed in the following ways:

- Click on the X in the upper right corner of the main program screen.
- Select *File* from the top menu and then select *Exit*.

If you made changes to the current patient information or study and have not saved them, the warning screen shown in figure <u>Warning – Save Patient</u> is displayed.

If you made changes to the current patient What If scenario and have not saved them, the warning screen shown in figure <u>Warning – Save What If</u> is displayed.

You have the following choices:

• Yes

Save the changes to the patient and/or the study or the What If scenario and then close the program.

• *No*

The changes to the patient and/or the study or the What If scenario are discarded and then the program is closed.

• Cancel

The changes are not saved and the program is not closed.

NOTES: