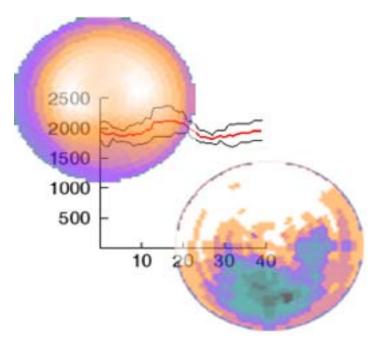


# **ENDG** *The Emory Normal Database Generator*

Version 1.0

# **Operating Instructions**



# Operating Instructions The Emory Normal Database Generator

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# **Introduction to the Emory Normal Database Generator (ENDG)**

## **Before You Begin**

Emory Normal Database Generator (ENDG) is a software application which enables you to create your own normal database for use with the Emory Cardiac Toolbox. A normal database, sometimes called a "normal file", is used inside Emory Cardiac Toolbox to compare to a clinical patient study. Areas of the patient study which are significantly reduced in counts compared to the corresponding area of the normal file, are considered abnormal, and appear as blackened areas on a Defect Extent polar map.

This document contains important information you need to know before using the Emory Normal Database Generator application, including warnings, errors, and limitations, as well as information on how to use this manual.

In this user manual, the program will often be referred to by its acronym, ENDG.

It is assumed that you have a working knowledge of nuclear medicine and are familiar with the operation of your Computer System.

## **About this Manual**

#### Conventions

Throughout this manual, the Emory Normal Database Generator application will also be referred to as ENDG. the following conventions are used to distinguish elements of text:

**Caution:** This is an example of the way cautions will appear in the manual. Cautions are used to alert you to situations that could result in damage to the system hardware or software.

**Note:** This is an example of the way notes will appear in the manual. Notes provide additional information about the current process or procedure, as well as parenthetic information regarding operation procedures.

<u>Underlined text</u> is used to introduce a numbered sequence of steps that the user is to follow.

**Bold Text** is used for section and sub-section headings. In addition, buttons and menu items that appear in ENDG are discussed using their labels--the exact text the user sees--and these are bolded within the text of this manual.

#### **Computer Interaction**

In the text of the manual, we will describe how the user should interact with the computer, as follows:

- "Left-click" means press the left-most mouse button while the cursor is on the indicated button or other part of the screen.
- "Right-click" means press the right-most mouse button while the cursor is on the indicated button or other part of the screen.

#### **Chapter Contents**

The chapters in this manual are organized as follows:

- Chapter 1, *Introduction*, provides information about the manual, as well as important information you need to know, before using the ENDG application.
- Chapter 2, Using the ENDG Application, describes all of the processing options and features.
- Appendix A, References
- Appendix B, Recommended Protocol Parameters

## **About Figures**

All illustrations in this manual are representative samples only. While your results will be similar in appearance, the data presented will reflect the study you are processing.

Throughout the manual, figures are used to illustrate the appearance of review screens and user interface elements such as buttons and lists. The screens that you see in ENDG may have blue, gray or tan backgrounds, depending on the Windows settings of the computer on which the software is running. Consequently, the figure background color may not match your particular machine.

# The Emory Normal Database Generator (ENDG)

#### Introduction

Creation of a normal file requires certain data to be specifically extracted from each patient study that is to be part of the file. This step is accomplished in ECToolbox, therefore each patient who is to be part of the normal group must first be processed in ECToolbox.

Briefly, the major steps to create a new normal file are as follows:

- Create a new database, or open an existing one.
- Add normal patients to the database.
- Calculate and display the normal distribution of all patients.
- Decide on the threshold for abnormality, to be used when a patient is compared to the normal file.
- Export the file for use with Emory Cardiac Toolbox.

# Saving Data for ENDG

To save a file which ENDG can use for building a normal file, follow these steps in ECToolbox:

- Select the button NFile PMaps, which is one of the permanent buttons on the left side of the screen. This will display the current patient's raw polar maps, and the composite polar maps for the currently-selected normal file.
- On the lower left of the screen, under Normal File Options, there are two buttons. One, Export To Normal Database, will export the file the ENDG needs. The other button, Launch Normal Database Generator, will start the ENDG application. The appearance of the buttons is shown in Figure 2-1.

# **Normal File Options** Export To Emory Normal Database Builder Launch Emory Normal Database Builder

Figure 2-1. Normal File Option buttons in ECToolbox.

Selecting the **Export**... button saves a file to the computer's hard disk, to a location inside the ECToolbox (a folder named ENDGData). As the file is about to be saved, a dialog is displayed showing the filename that will be used. The name can be edited if necessary.

### **Buttons and Controls in ENDG**

There are several parts to the ENDG window, which are always displayed. These basic elements are shown in Figure 2-2, and include menu items, buttons, an area for display of images and curve plots, and a status bar.

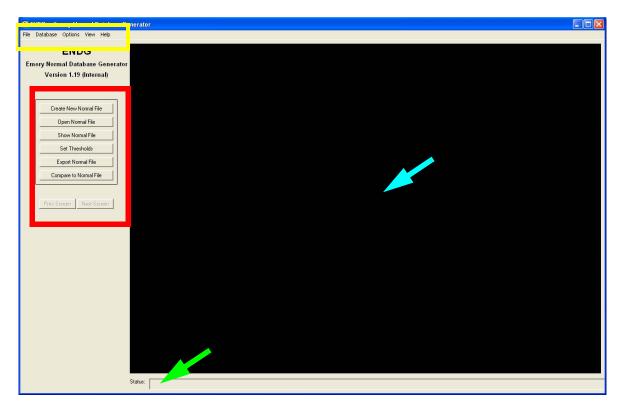


Figure 2-2. The parts of the ENDG window are highlighted. There is a main menu (yellow box), a set of buttons to access the main functions (red box), an image display area (blue arrow) and a status bar for text messages (green arrow).

Most of the user interaction that is necessary in ENDG takes place via the main buttons, which activate functions that represent the major steps that would be followed in creating and using a normal file.

#### main buttons

The menu and main buttons are shown in Figure 2-3. The buttons are shown from top to bottom in the approximate sequence in which the steps would be performed--opening a normal file, showing its contents, etc. The choices in the menu are additional functions, some of which are related to the button functions, but providing more details, or giving finer control over what the program is doing.

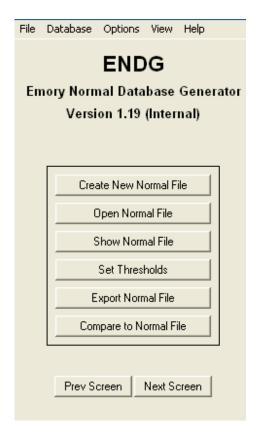


Figure 2-3. The main menu and main buttons for interacting with ENDG.

The buttons have tooltips, meaning that if the mouse cursor hovers over the button, a small text box appears, giving a brief hint of the button's function (Figure 2-4).

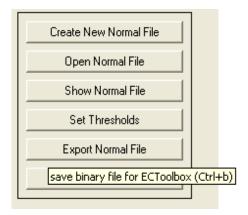


Figure 2-4. The tooltip hint for button **Export Normal File**.

The status bar is an area at the bottom of the window where a single line of text is occasionally displayed by the program. This is a message to the user, usually reporting the results of some action, as when a file has been saved to disk. See Figure 2-5 for an example.



Figure 2-5. The status bar. In this example, the program is reporting that a file was saved as intended. If the File Save operation had failed, the message would be different.

## **Managing Normal Files**

#### Selecting a File to **Work With**

The first step after ENDG starts is to select a normal file to work with. If the file already exists and you want to modify it in some way, then the file just has to be selected from a list. If you are just starting to work with the file, then it will have to be created.

To create a new normal file in ENDG, select the New Normal File button. The form shown in Figure 2-6 will be displayed. The form is in three sections, and asks the user to make several choices.

- The name of the new normal file. This can be any name desired, but typically would be descriptive of the type of scan data involved, such as thallium or sestamibi, and perhaps the acquisition protocol or some other element that distinguishes this file from any other. The name entered is the name the file will have when it is selected later for use inside ECToolbox.
- How to handle genders. There are two buttons here: Separate will indicate that you intend to create a normal file for females and another file for males. Combined indicates the intention to combine males and females into a single file. A combined file would be created, for example, if there was accurate attenuation correction or some other factor that would cause gender-related image differences to be minimal.
- Which gender group to work with initially. You must select to work with male data or female data. If the normal file is of the gendercombined type, it doesn't matter which group you select to work with.

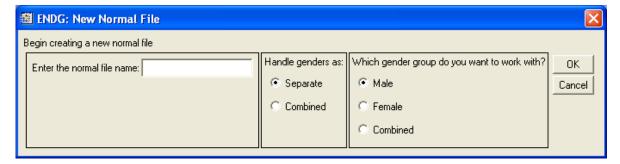


Figure 2-6. The form for describing the new normal file that is about to be created.

To select an existing file, use the **Open Normal File** button. The dialog shown in Figure 2-8 will be displayed. All of the existing normal files that you have previously created will be in the folder "userNormalFiles". Each subfolder has a name corresponding to the normal file name, which was entered when the file was initially created--using the form shown in Figure 2-6. Highlight the folder corresponding to the file you want and select **OK**.

**Note:** The Make New Folder button appears on this dialog form, as it always does when Windows is waiting for a user's file selection. Although this function can be used, it serves no particular purpose at this point in ENDG.

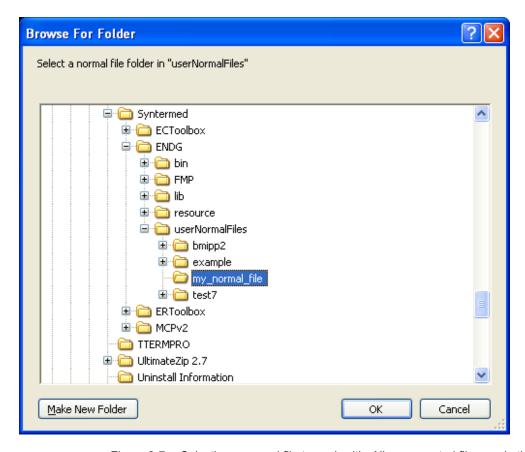


Figure 2-7. Selecting a normal file to work with. All user-created files are in the folder "userNormalFiles".

Once the desired folder has been selected, you will be asked which gender group is to be used first, via the dialog form shown in Figure 2-8. The default choice is male. Once this choice is made, the previously-saved data for the selected normal file is loaded by ENDG, and the normal file is available for examination. If a normal mean was saved, the results will be immediately displayed in curve and polar plot formats.

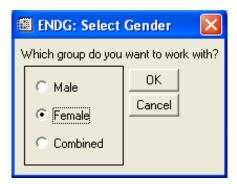


Figure 2-8. The form for selecting which gender group of data to look at. This setting can be changed at any time while working in ENDG.

If you have a separate-gender normal file, and you select to work initially with male data, for example, you can switch to female data at any time by using the menu choice **Options/Select Working Group**, which is explained below.

The next section discusses all of the menu options in ENDG. Most of these have keyboard shortcuts.

#### The File Menu

The File menu (Figure 2-9) has five options.

- Open XML in Internet Explorer. Use this option to open any XMLformat file for viewing.
- Save Normal File. This option saves the current "state" of the normal file that is open. This includes the number of patients, the ENDG version in use, the creation date and the mean arrays
- Save Screen. Saves a snapshot of the current screen as a graphic file on disk.
- Save and Exit. Saves the current "state" of the normal file and then exits the program.

Quit--Don't Save. Exits the program without saving anything.

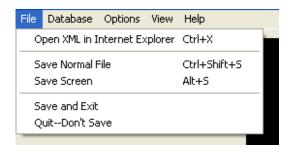


Figure 2-9. The File menu.

#### The Database Menu

The Database menu (Figure 2-10) has four options. All of these relate in some way to the list of patients that comprise the database for the current normal file.

- Add Patient(s). Allows a user to add one or more patients to the current normal file.
- Delete One Patient. Allows one patient to be deleted from the current normal file. See also the later section of this manual: "Comparison Screen Options" on page 34.
- Undelete One Patient. Allows one patient that was previously deleted to be restored to the current normal file.
- View Patient List. Allows the current patient database to be displayed.

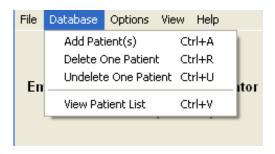


Figure 2-10. The Database menu.

#### The Options Menu

The Options menu (Figure 2-11) has two options.

- **Select Working Group**. Allows a user to select which gender group to work with. This can be different from the group selected when the normal file was first opened or created.
- Save Means as Textfile. Saves a textfile to disk, which summarizes
  the mean values for each sampled pixel in the normal file. For
  details, see "Comparison Screen Options" on page 34.



Figure 2-11. The Options menu.

#### The View Menu

The View menu (Figure 2-12) has three options.

- Mean Profiles.... Displays mean profile curves for stress, rest or reversibility. The three choices are accessed through a submenu that appears when **Mean Profiles...** is selected.
- Mean Polar Maps. displays a new window showing the mean and standard deviation maps for the current normal file.
- Patient Polar Maps. shows polar maps for all patients in the current working group, and their defect extent as compared to the normal mean and thresholds.

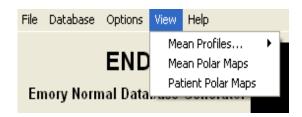


Figure 2-12. The View menu.

#### The Help Menu

The Help menu (Figure 2-13) has two options.

- Quick Help. This options displays a web page that gives brief instructions on using ENDG, including the steps for creating a normal file. This web page is found on the local computer, so you don't have to have an active internet connection to view it.
- About ENDG. displays the full name and version of the program.



Figure 2-13. The Help menu.

## **Managing the Patient Database**

Normal files are used to highlight perfusion deficits in a patient study by providing a normal range to compare against. The terms normal file and normal database are often used interchangeably. When we are developing a normal file, we have the concept of a *patient database*, which is the collection of patients whose data is used to generate the file. The patient database is one component of normal file development, but not the only one. We also have to set the thresholds for the normal file, and be aware of the mean and standard deviation for different segments of the left ventricle. This section of the manual deals with the various aspects of the database—the collection of patients—how to add to it, delete from it and review the contents of it.

#### **Adding Patients**

Patient studies can be added to the database by selecting **Add Patient(s)** from the **Database** menu, as shown in Figure 2-10. This menu selection causes the program to access a folder where patient data has been saved from ECToolbox, for the express purpose of being used in ENDG. See "Saving Data for ENDG" on page 11 to review how this works.

Selecting **Add Patient(s)** causes the patients available from ECToolbox to be displayed in a dialog. The dialog is shown in Figure 2-14.

When the dialog is displayed, use the mouse to highlight one or more files, and click the **Open** button. The selected files are immediately moved out of the displayed directory and into the **Patients** directory for the current normal file. Once this is completed, a message will be displayed in ENDG's status bar at the bottom of the screen, indicating how many patients were imported to the database.

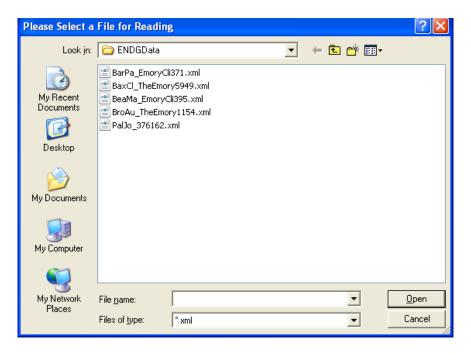


Figure 2-14. The dialog that is displayed when **Add Patients** was selected. The files listed, ending in ".xml" are available for import to the current database. Once imported, the files will disappear from this directory, and appear in the Patients folder of the current normal file.

#### **Deleting Patients**

There are two ways to delete a patient from the current normal file. In method one, you will identify a patient you want to delete, perhaps from a list of the patients in the file. Make a note of the ID of the patient to be deleted, and then select Delete One Patient from the Database menu. The dialog window shown in Figure 2-15 will then be displayed.

Enter the patient ID in the first textbox, and click the **Accept** button. This tells ENDG to find a patient with that ID.

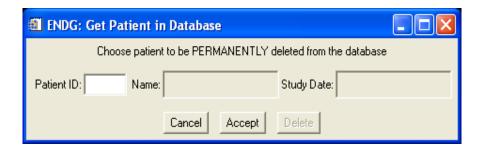


Figure 2-15. The dialog displayed in response to the menu choice **Database/ Delete One Patient**. You can only type into the **Patient ID** textbox.

If ENDG finds a patient with the indicated ID value, you will see the dialog window shown in . If the patient was not found, a message will be displayed.



Figure 2-16. The dialog displayed after ENDG has located the patient with selected for deletion. In this example, the patient has an ID of "120214", the name is "Rb-F20" and the study date is "6/3/2004". Note that the **Delete** button is now active.

To actually delete the patient, click the **Delete** button, which is now active.

You can also delete patients from the polar plot comparison page. See "Comparison Screen Options" on page 34.

#### Displaying the **Database**

To view the list of patients in the database of the current normal file, select View Patient List from the Database menu. In a few moments, a new window will open. This is an external application that displays the patient database, as shown in Figure 2-17.

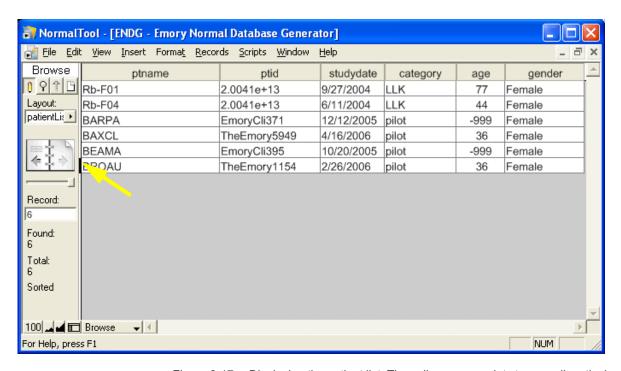


Figure 2-17. Displaying the patient list. The yellow arrow points to a small vertical line that is the current record indicator.

There are a number of tools included in this window. Briefly, some of the main options are:

 A column on the left side showing the number of patients in the database ("Total"), the number of patients shown in the window ("Found") and the record number that is current ("Record"). The current record is indicated by the small vertical line next to the patient name. See the figure above.

- small buttons for zooming the display, as shown in Figure 2-18.
- The patient information, displayed in columns. To sort the entire list by a particular descriptor such as name or gender, click the column header.

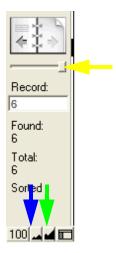


Figure 2-18. The database list window has controls for stepping from one patient to the next (yellow arrow), and zooming in (green arrow), or out blue arrow).

ptname	ptid	studydate
Rb-F01	2.0041e+13	9/27/2004
Rb-F04	2.0041e+13	6/11/2004
BARPA	EmoryCli371	12/12/2005
BAXCL	TheEmory5949	4/16/2006
BEAMA	EmoryCli395	10/20/2005
BROAU	TheEmory1154	2/26/2006

Figure 2-19. A portion of the database list window. Data can be sorted by any column. To sort by patient name, for example, click the column header labeled "ptname".

Note: Any time the database list window closes, whether automatically ENDG exits or because the user manually closed it, an informational window will display for about two seconds (Figure 2-20), and then disappear.

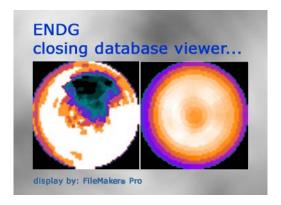


Figure 2-20. The information box displayed when ENDG's database list window closes.

## **Defining the Normal Mean**

#### **Calculating Means**

At any time when there are two or more patients in the database, the mean and standard deviation can be calculated by clicking the **Show Normal File** button. The mean +/- 1 standard deviation for each of the 12 profiles in the normal file will be displayed. Each profile represents 40 sampled pixels from one short axis slice from apex (profile 0) to base (profile 11). An example is shown in Figure 2-21.

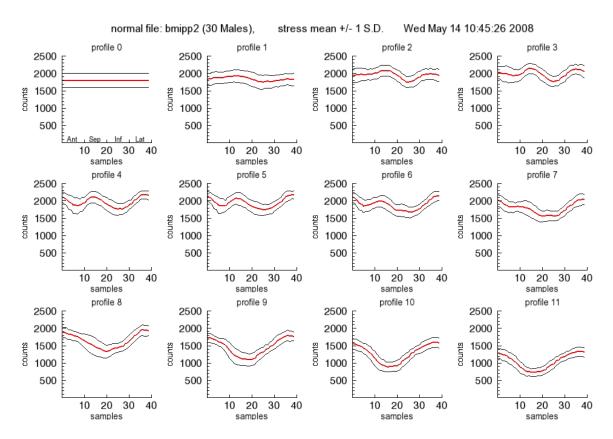


Figure 2-21. Red curves are mean values, black curves represent one standard deviation above and below the mean. Apex is profile 0.

The mean curve display characterizes the entire normal file. Sampled pixels are on the horizontal axis, and counts on the vertical axis. Sampling begins at 45 degrees in the antero-lateral direction when viewing the heart from the apex, so the myocardial sections are represented on the curves as shown in Figure 2-22, with the anterior quadrant being the first section of the curve, followed by septum, inferior wall and lateral wall.

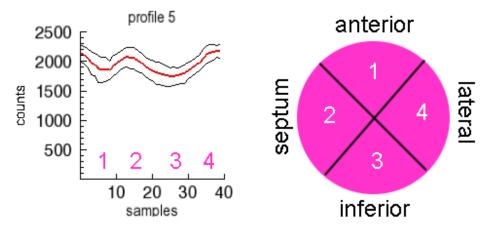


Figure 2-22. Myocardial walls as seen on each profile curve (left): 1=anterior, 2=septum, 3=inferior, 4=lateral. These correspond to the simple polar map style diagram on the right, which is the left ventricle in short axis as seen from the apex..

Be default, the stress mean curves are displayed first. To see the rest plots, either click the **Next Screen** button at the left, or use the **View** menu and select **Mean Profiles.../Rest**. To return to the stress curves from viewing rest or reversibility, use the **Prev Screen** button ("Previous Screen"), or use the View menu. The View menu can be used to recall the mean plots of your choice--stress, rest or reverse--at any time while ENDG has a valid normal file open. Once the curves are displayed, Next Screen and Prev Screen can be used to move between the three sets.

At the same time as the mean curves are displayed, ENDG will display a new window showing polar plots representing the mean for the current normal file. This display is shown in Figure 2-23. Stress, rest and

reversibility mean are shown across the top row, and stress, rest and reversibility standard deviation are across the bottom row.

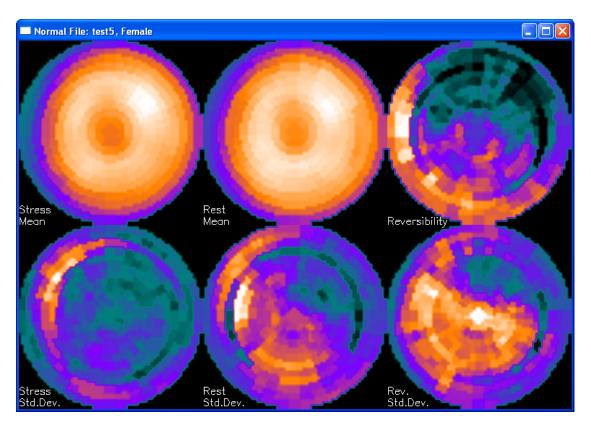


Figure 2-23. Mean and standard deviation polar maps representing the entire database of normal patients in the normal file.

The stress and rest maps represent the distribution against which a patient map is compared when the normal file is used in Emory Cardiac Toolbox.

#### **Setting Thresholds**

Normal files are used to determine the presence and size of perfusion defects in a patient study. Accurate definition of abnormal perfusion depends not only on the normal mean values that are present in the file, but on the thresholds for abnormality that have been set. Pixels in the patient myocardium that fall below the defined threshold are said to be abnormal. With a different threshold, that same pixel value may or may not be abnormal.

In ENDG, all thresholds are set to zero when a normal file is defined. To set thresholds for all regions of the myocardium, select the Set Thresholds button. The dialog shown in will be displayed.

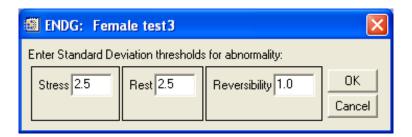


Figure 2-24. Dialog for setting abnormal thresholds

By default, thresholds are set to 2.5 standard deviations for the stress and rest polar maps, and reversibility is set to 1.0 std. dev. Any of these values can be changed. To save thresholds, click the OK button. The thresholds will be saved to a file on disk. To indicate that this operation was successful, ENDG displays a message in the status bar at the bottom of the screen.

An example of the contents of the threshold file is shown in Figure 2-25.

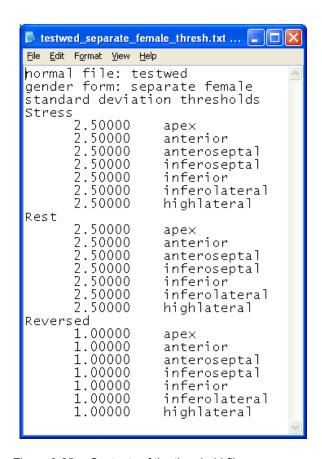


Figure 2-25. Contents of the threshold file.

## Comparing Patients to Normal

#### **Displaying Patient Polar Maps**

The current set of patients can be compared to the normal file you are developing, just as if they were clinical patients in ECToolbox. To do this, select the Compare to Normal File button. This produces a screen similar to the one shown in Figure 2-26, with each patient represented by a polar map. Areas of the map are blacked out if they differ significantly from the mean of all normal patients. Under each map is the ID and Name of that patient.

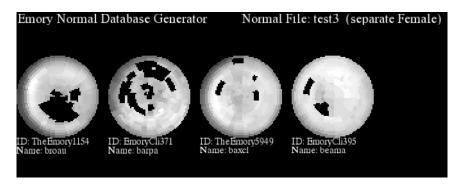


Figure 2-26. Four patients displayed with comparison to the current normal file.

#### Comparison Screen **Options**

There are several options that can be exercised on the normal comparison display.

A maximum of 3 rows of 7 polar maps are displayed at once. If there are more patients than this, you can see the next group by using the Next **Screen** button. Return to earlier patients using the **Prev Screen** button.

For any displayed polar map, a quantitative summary of the defects that are shown in black can be obtained by left-clicking the map. A small window will appear (Figure 2-27). Defect extent refers to the size of the abnormal black area within the polar map. Note that defect severity and reversibility values can only be seen by using the left-click method. To

dismiss the defect summary window, click either the **OK** or **Cancel** button, or the red "X" close widget in the corner.

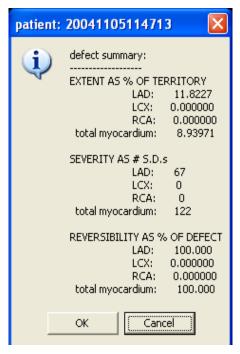


Figure 2-27. The defect summary window, which appears when a patient polar map is clicked with the left mouse button. Defect severity refers to the total number of standard deviations below the mean for every pixel within the blackout area.

As discussed in the section "Deleting Patients" on page 24, you can delete a patient from the database while on the Compare screen. You might want to do this if, for example, you see a patient with an unusually large defect. To delete the patient, click the polar map with the *right* mouse button. You will get a small question dialog. Selecting Yes will delete the patient, and draw an "X" through the map. This is a visual indicator that the patient was removed from the database, but still allows you to see the map, in case you decide to restore the patient. These displays are shown in Figure 2-28 and Figure 2-29.



Figure 2-28. This dialog is displayed when you right-click a polar map while on the Compare to Normal File screen. Selecting Yes removes the patient from the database.

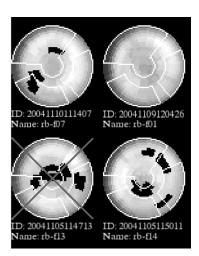


Figure 2-29. The patient comparison screen after one patient was deleted from the database, as indicated by the "X" on that polar map.

Deleting a patient has several effects: the polar map is marked on the display, the patient's record is removed from the current database, and the file saved by ECToolbox (from which the patient data was loaded) is removed from the normal file's Patients folder. However, the patient data has not disappeared entirely. It is still available to be restored to the

database in the future, at your discretion. This operation, which ENDG calls "Undelete", can be used immediately or at a later time when ENDG has been opened again. To restore a deleted patient, select Undelete from the Database menu. A window will be displayed, listing the patients in the Deleted Patients folder. Highlight one and select Open. The Compare screen will be re-drawn to include the restored patient's polar map, which no longer has an "X" on it. Note however that the restored polar map may not appear in the same place on the display, since the database is resorted when a patient is deleted.

# Saving Normal File Results

#### Saving the Database

When a normal file has just been created and named, several objects are saved into the userNormalFiles folder on disk. There is a Patients folder, which holds data for every patient added to the normal file, and a **Deleted Patients** folder, which holds patients that have been removed from the file. Two XML format files are also created, one which has the name of the normal file, such as "testfile.xml", which holds administrative details such as the number of patients in the file and the date it was created, and a database file with a similar name, such as "testfile db.xml", which holds the actual patient data, including the pixel arrays used to construct the mean.

If you add patients to the normal file using the **Database/Add Patient(s)** menu option, the database file is immediately updated with the data from those patients. However, the administrative file is *not* updated unless you select the Show Normal File button. This option calculates the means and standard deviations for the normal file and updates the administrative XML file. Show Normal File will also display the means, both as curves and as polar maps.

#### Saving the Means

Once the means have been calculated and displayed, the complete set of values can be saved to disk as a file. Use Save Means as Textfile from the Options menu. Afterward, the file can be opened in any text editor, and can also be opened using other applications such as a spreadsheet. See Figure 2-30 for an example.

	Α	В	С	D	Е
1	Patient	LAD % defect extent	LCX % defect extent	RCA % defect extent	total % defect extent
2	broau	17.5115	16.6667	18.1818	24.952
3	barpa	22.1675	7.93651	0	12.474
4	baxcl	23.5023	8.33333	0	14.0115
5	beama	0	3.7037	0	1.36054
6					
7					

Figure 2-30. A portion of the saved means file, as it appears when opened using a spreadsheet program such as (in this example) Microsoft Excel.

#### Saving the Thresholds

Thresholds for abnormality (explained in "Setting Thresholds" on page 32), are automatically saved to the administrative XML file as soon as they are set. The textfile listing the thresholds is also created automatically.

# Saving the Current Screen

Any display screen in ENDG can be saved as a JPEG format image to disk. Use the **Save Screen** function under the **File** menu. The image is saved to the directory folder under userNormalFiles that has the same name as the current normal file.

# Saving the Normal File for ECToolbox

Once your normal file is completed, it must be converted into a binary file in order to be used with Emory Cardiac Toolbox. There is only one step: select the button **Export Normal File**. The file will have the same base name as the normal file itself, with the extension ".nlg", and will be written to the appropriate directory inside the ECToolbox folder heirarachy.

# **User-Defined Normal Files in Emory Cardiac Toolbox**

Once you have created a normal file and exported it for use in ECToolbox, the last step to make the file usable is to set the preference in ECToolbox so that the file is recognized.

Using the dialog shown in , perform the following steps:

- Click the Edit button.
- The dialog shown in Figure 2-32 will appear.
- Use the Browse button, and choose the normal file you want to add from the list that is displayed. If there are male and female sections to the file, you must add them both.

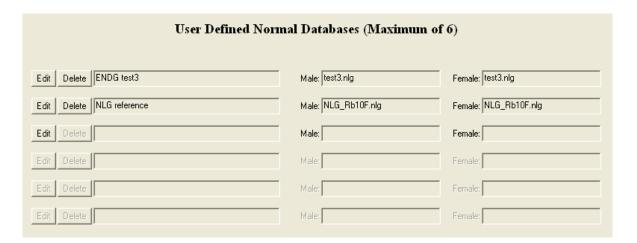


Figure 2-31. Setting up a user-defined normal database in ECToolbox.

A maximum of 6 user normal files can be handled by the current version of ECToolbox. If you have more than that, you will have to delete one in order to add a new one.

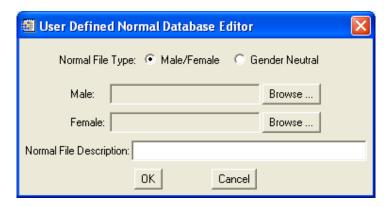


Figure 2-32. The dialog used for locating a user-defined normal file to be added to the ECToolbox list of available files.

Your normal file should now appear in the list of available files in ECToolbox's Study Verify window.