CARDIOSCAN 12 CONFIGURATIONS

Notebook or Desktop Computers:

a. SANDISK ImageMate Compact Flash Card External Reader: connects to computer's USB port

b. Rainbow Security Key: connects to computer's USB port or to computer's parallel port

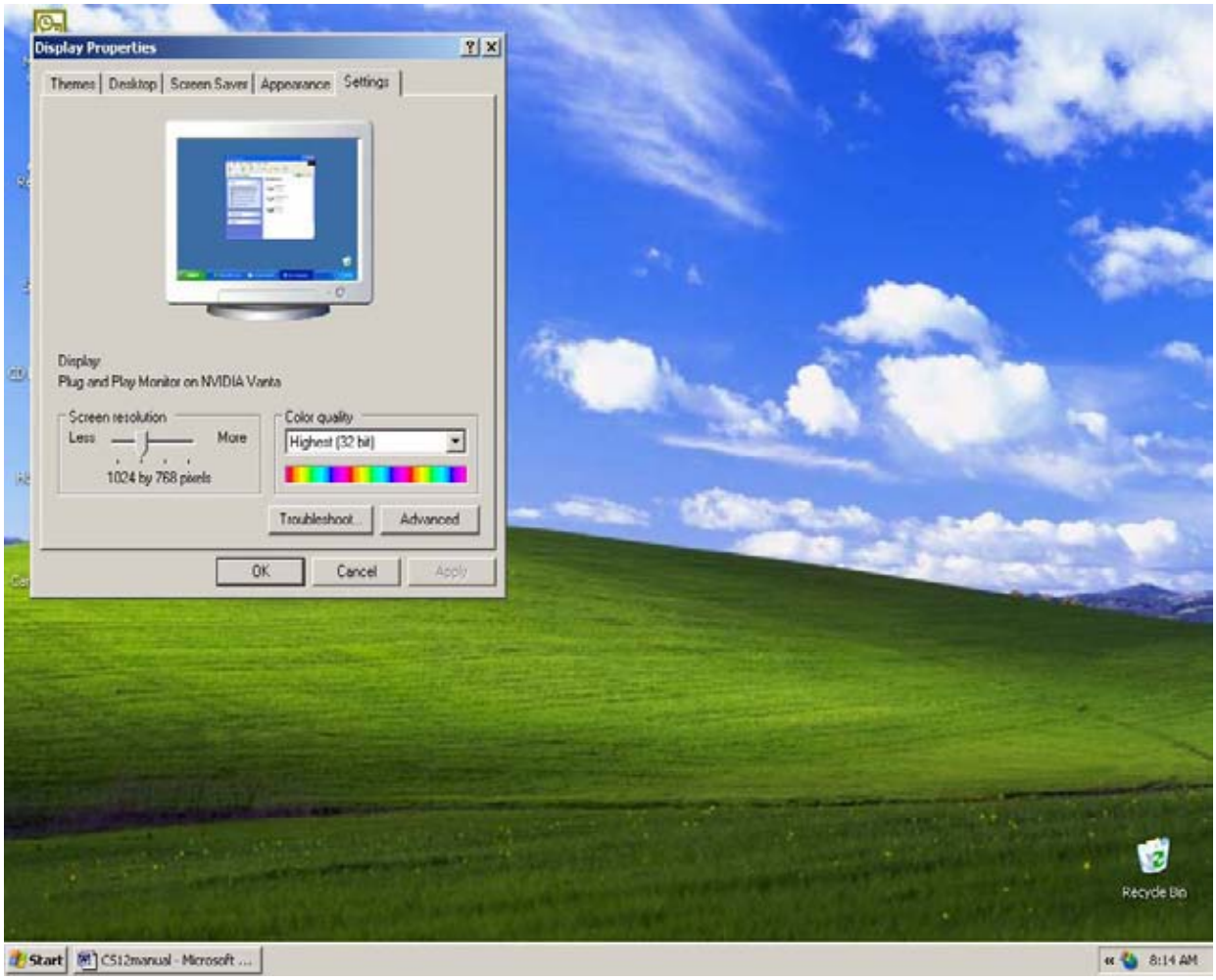
c. Installation Software

d. Miniature Digital Holter recorder with SANDISK 40MB, SANDISK 48MB, SANDISK 64MB or SANDISK 128MB Compact Flash Card

e. Operation Manual

f. Technical Manual

LOADING CARDIOSCAN 12 SOFTWARE INTO WINDOWS XP



1. To setup the screen display, right click your mouse anywhere in the Windows XP desktop. Click on Properties. Click on the Settings tab. Go to Screen resolution and slide the bar to 1024 x 768 pixels. Click on APPLY. Click on OKAY. Go to Control Panel. Click on "Taskbar and Start Menu." The only item that should be checked under Taskbar is "Group similar taskbar buttons." If other items are checked, click on the checkmark to deselect. The check mark will disappear. Click on Apply. Click on OK.

2. To set up the printer, please see the accompanying technical manual. NOTE: Use only the software driver supplied by the printer manufacturer.

3. Shut down the computer and turn off its power.

4. Connect the ImageMate to the computer's USB port and power up the computer. Windows XP has the drivers for this device already installed. Note on the bottom right of the computer screen that the computer will load the driver automatically. This will take about 1 minute.

5. Place the CardioScan 12 program disk in the computer.

6. To load the security key driver, double click on the Sentinel 7.0 zip file in the Security Key Drivers file. Unzip this file and follow the prompts to load the Security Key Driver software.

   NOTE: Make sure the security key is not installed in the computer when you are downloading the Security Key software!

7. Shut down the computer and turn off its power.

8. Power up the computer and follow the prompts to Add New Hardware (this is the Rainbow Security Device – the USB security key).

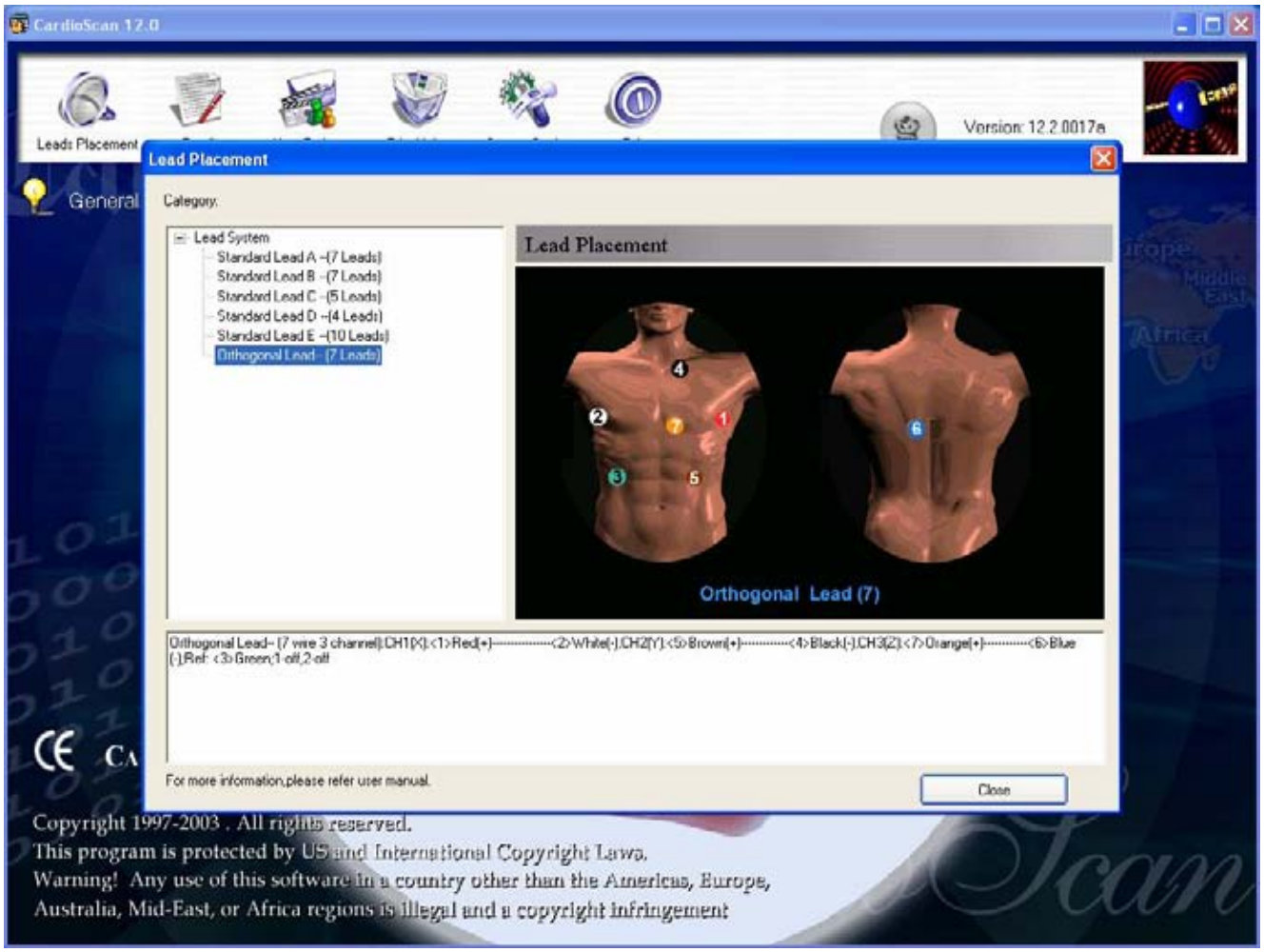
9. To load the CardioScan 12 software do the following:

   a) Double click on MY COMPUTER.
   b) Double click on the drive where your CardioScan 12 program disk is located.
   c) Double click on the CardioScan 12 file folder.
   d) Double click on the PUBLIC folder.
   e) Click on the SETUP icon. The program files will start to load.
   f) At the Welcome screen, click on Next.
   g) Type in your name, business and the serial number. The serial number you need to use is DMSH80 000005 7894567545. You must fill in all fields on this screen. Failure to do so will result in the program aborting.
   h) Click on Next. Click on Next.
   i) Click on Finish.
   j) Double click on MY COMPUTER.
   k) Double click on the drive where your CardioScan 12 program disk is located.
   l) Double click on the CardioScan 12 file folder.
   m) Double click on the CardioScan 12 zip file.
   n) Click on UNZIP.
   o) Click on OK.
   p) After the file is loaded, restart your computer.

   LOADING THE LANGUAGE FILE

   a) Go to My Computer.
   b) Click on the CD drive with the Holter disk in it.
   c) Click on the CS12 file.
   d) Click on the Language File so it is highlighted blue.
   e) Click on Copy This File on the left side of the screen.
   f) Click on Local Disk C:
   g) Scroll down to Carsc12 and click.
   h) Click on Copy

   EASY TRANSLATION CHANGES
   a) Go to My Computer
   b) Click on Local Disk C:
   c) Click on CarSc12
   d) Click on Eng (for English or if you have a language file, click on the language file)
   e) Click on Edit
   f) Click on Find
   g) Type in SAECGVCG
   h) Click on Find Next
   i) Type in SAECG/VCG
   j) Click on File
   k) Click on Save
   l) Click on Exit.
   m) To see your change, go to the Data Access Choices of the Holter program and you will see the change. Each time you get a new software package, we advise you to copy the new language file into your Holter program and translate all of the English words. All new updates in the language file are in English only.



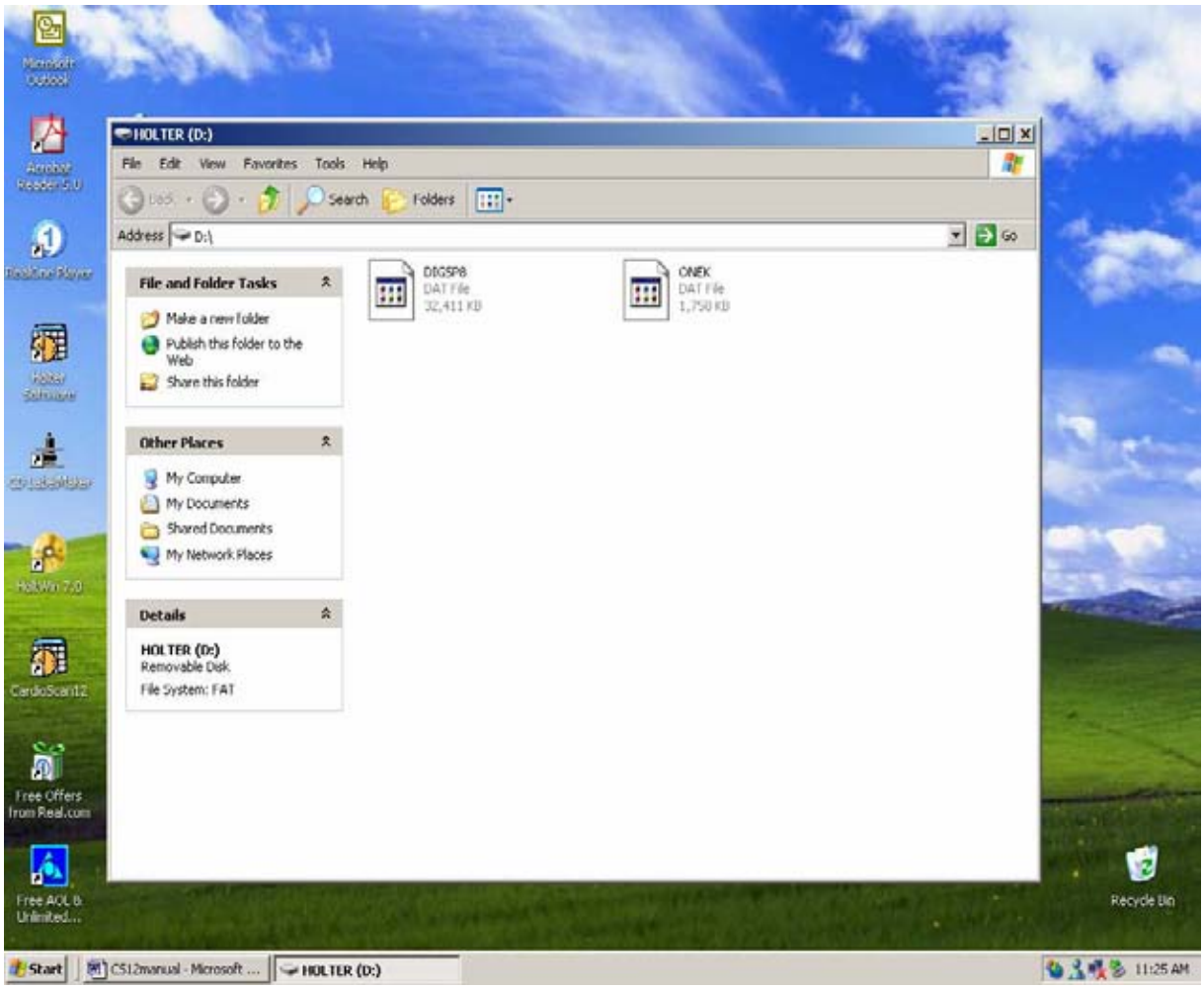
HOLTER PREPARATION NOTES

Prior to hooking up the patient make sure the following steps are done.

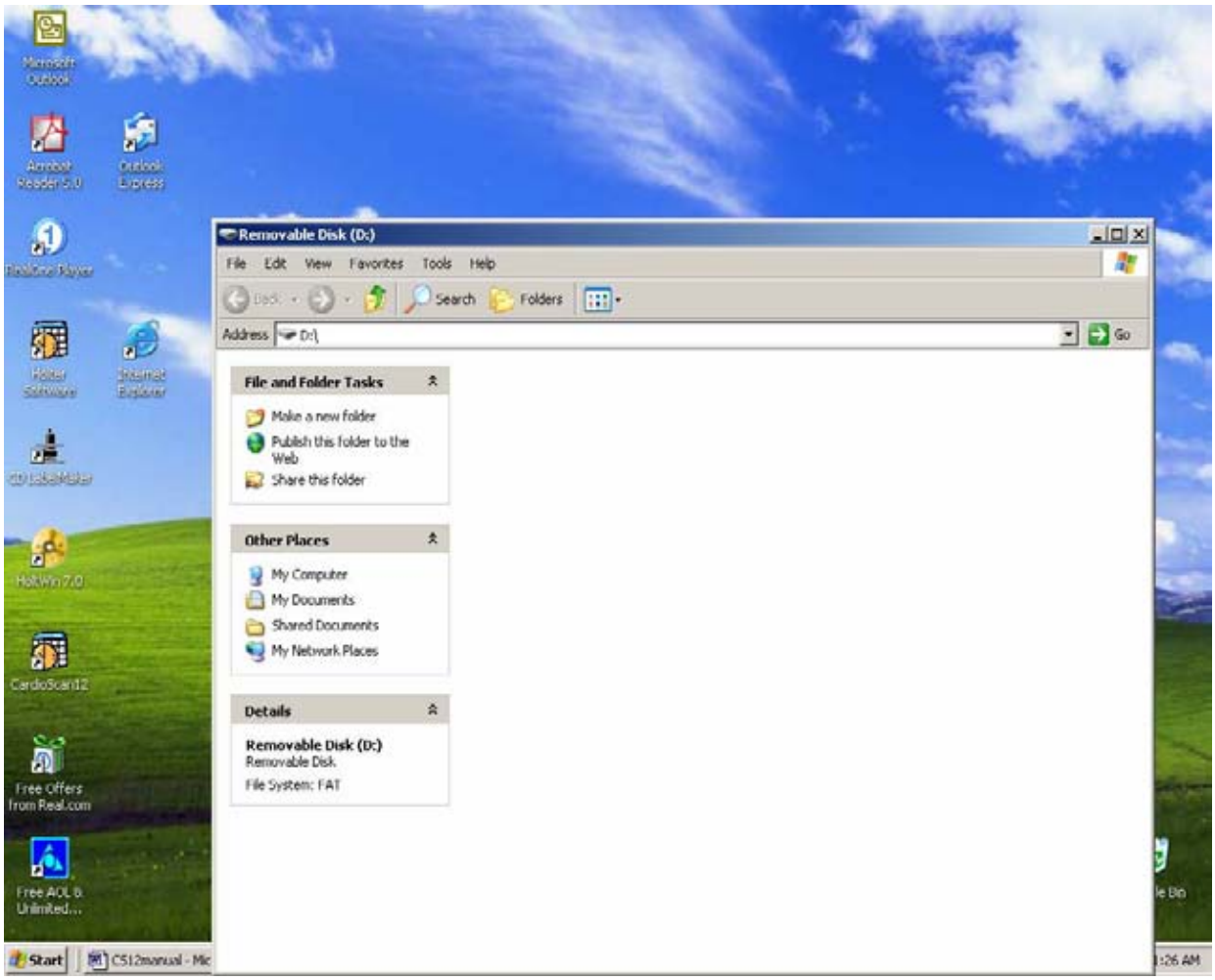
Flash Card Preparation:

Place the SANDISK compact flash card into the ImageMate Reader. Click on My Computer. Right click the mouse on the ImageMate Reader drive. Right click on the file on the screen. Click on Delete. Click on Yes. If you have SAECG data recorded on the flash card, there will be two files on the compact flash card. Make sure to delete both files. Click on Close. To make sure the files have been completely erased on the compact flash card, double click on the ImageMate Reader drive. If the flash card has been properly erased, there will be no files listed on the screen.

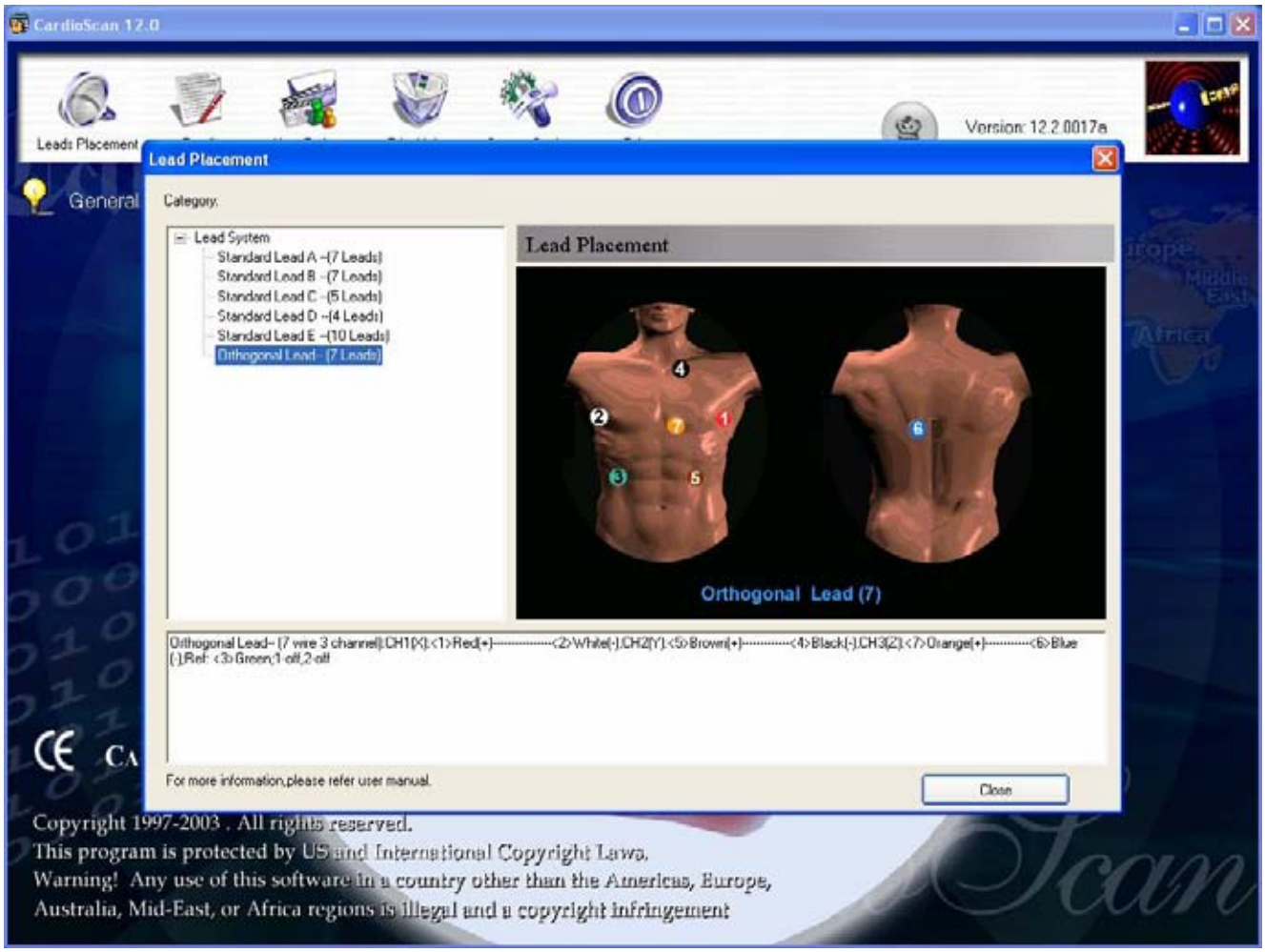
NOTE: Even though this process is duplicated in the recorder, it is your responsibility to have a blank compact flash card.



The above screen shows that there are two files on the compact flash card. This indicates that the compact flash card has not been erased.



The above screen shows a compact flash card that the files have been erased. There are no files on the screen.



Patient Preparation:

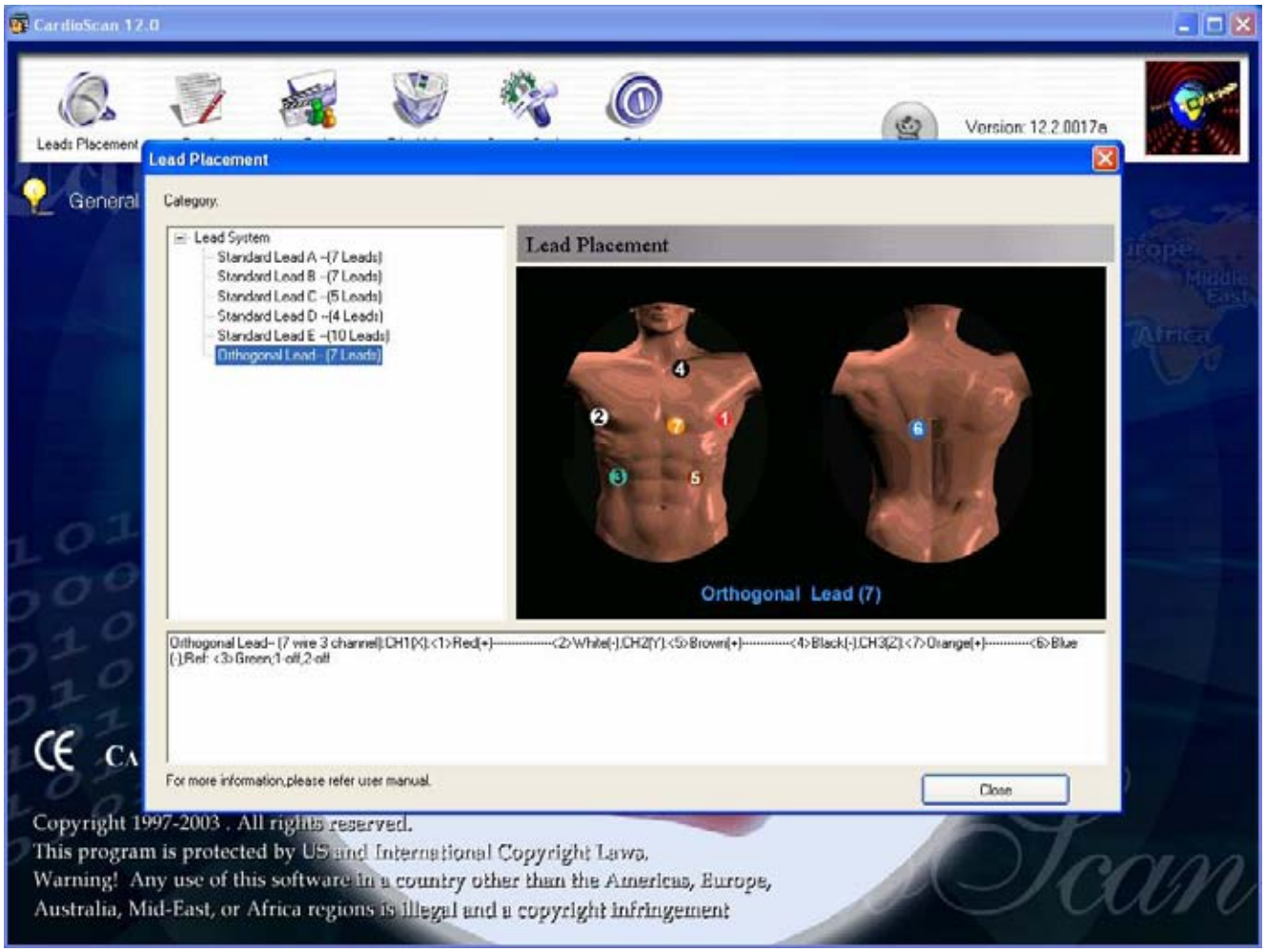
1. Abrade and clean the patient's skin for each electrode site.
2. Make sure to use stress loops when hooking up the lead wires to the patient.

NOTE: Remember that you are using Digital Holter recorders which record at a much higher frequency than cassettes. It is imperative that you spend the time to do good patient preparation!

This is the CardioScan 12 Main Screen Display.

Move the mouse to “LEADS PLACEMENT” and click.

NOTE: If you click on EXIT, you will return to the Windows XP desktop.



LEADS

There is no established standard for electrode lead placements for Holter ECG monitoring. On this screen you will find different hookups located under Lead Systems. They are as follows:

Standard Lead A (7 Leads)
Standard Lead B (7 Leads)
Standard Lead C (5 Leads)
Standard Lead D (4 Leads) Note: Use only for the 300-8 recorder.
Standard Lead E (10 Leads)
Orthogonal Lead (7 Leads)

Place your mouse over the hookup you desire and click. The picture to the right will automatically change the hookup you have selected. There is a written description of each hookup that will be found on the lower left of the screen.

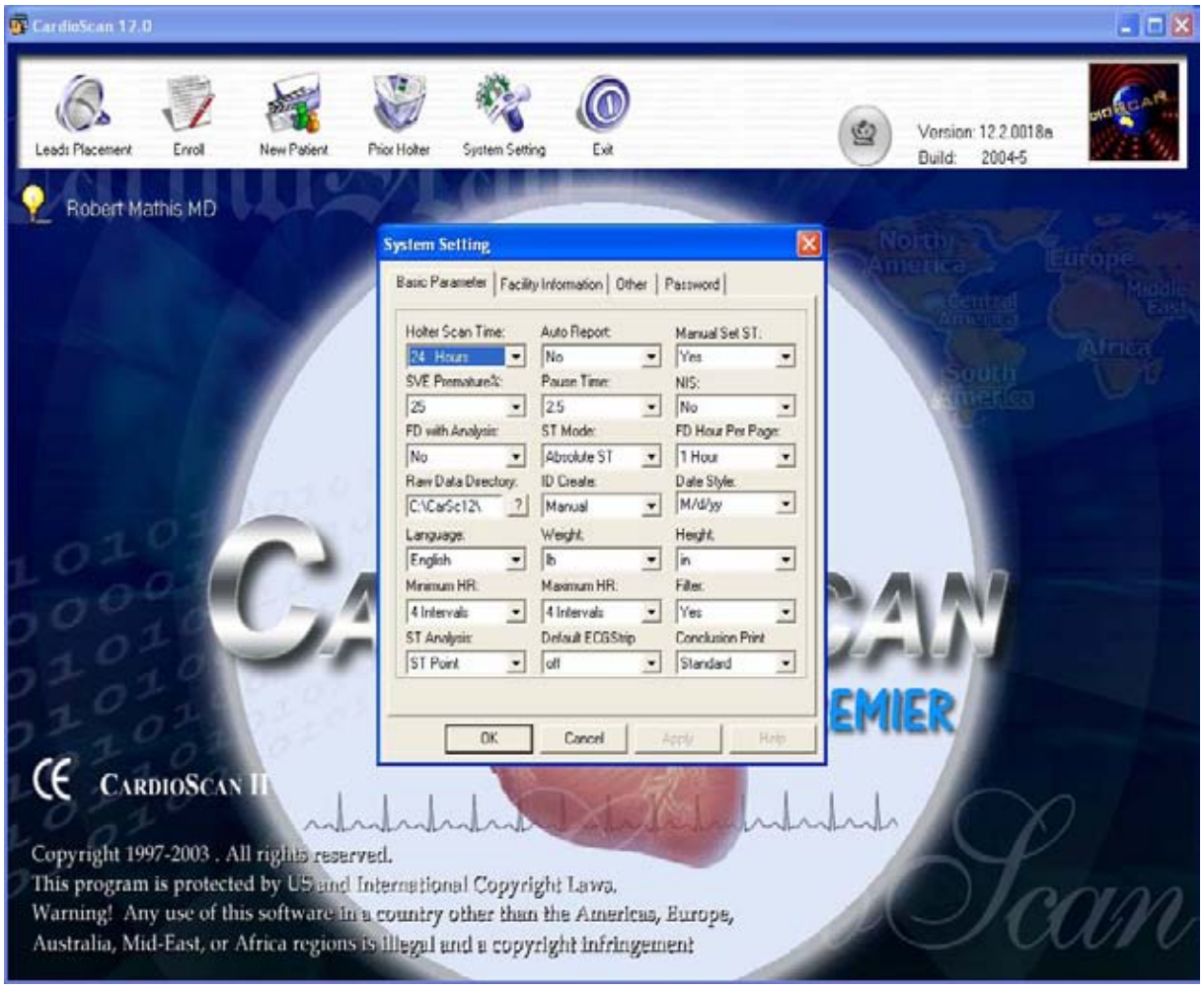
The most important factor in electrode application is good skin preparation. Most users clean the electrode sights vigorously and slightly abrade the skin at only the small area where the electrode gel makes contact with the skin. Only the physician can decide on the methodology for electrode skin preparations for his or her patients.

To exit this screen, click on the CLOSE button at the bottom of the screen.

SYSTEM SETTINGS

To view and edit the default settings and enter the facility information, move the mouse arrow to SETTING and click.

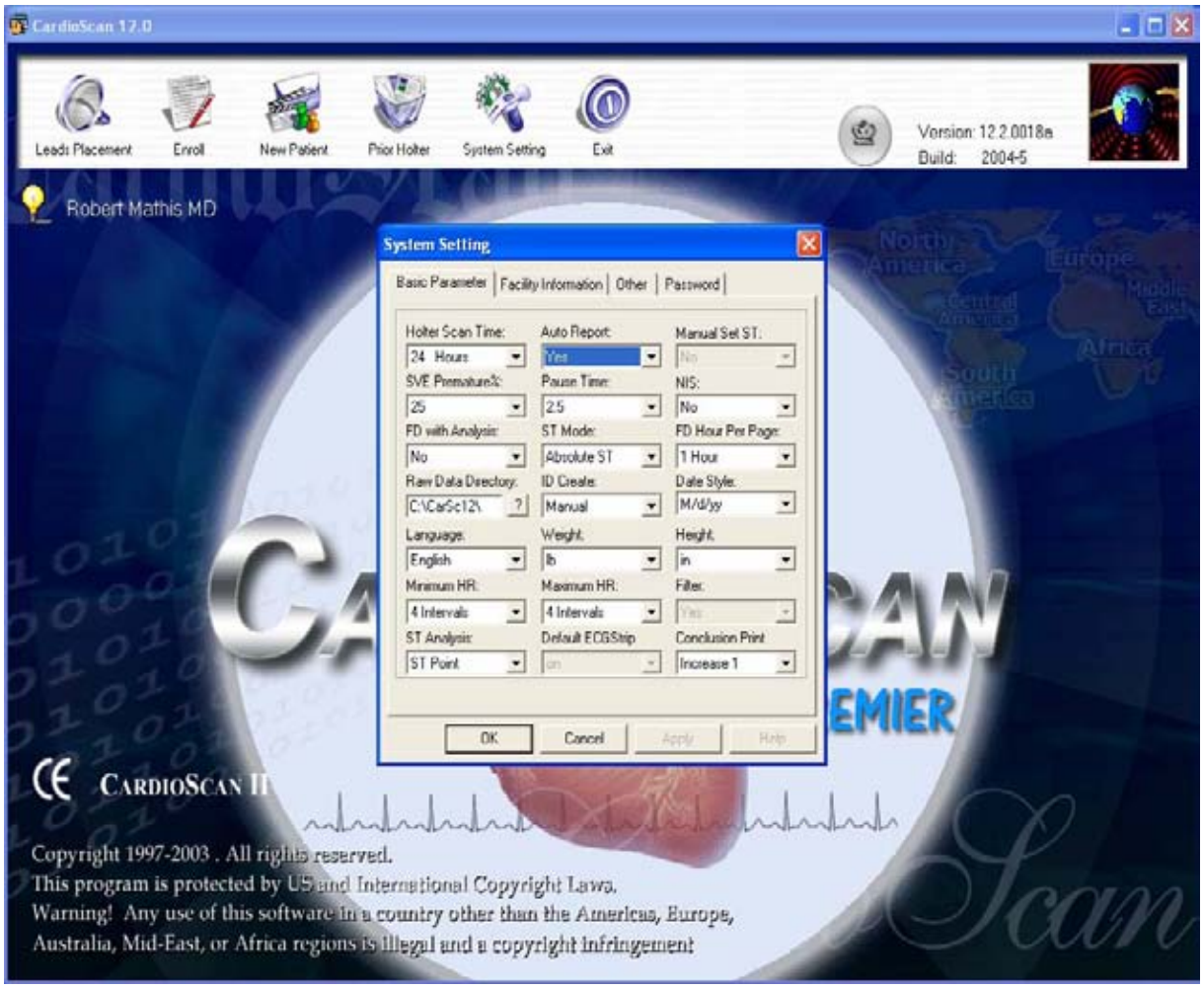
NOTE: If you click on EXIT, you will be returned to the Windows XP desktop.



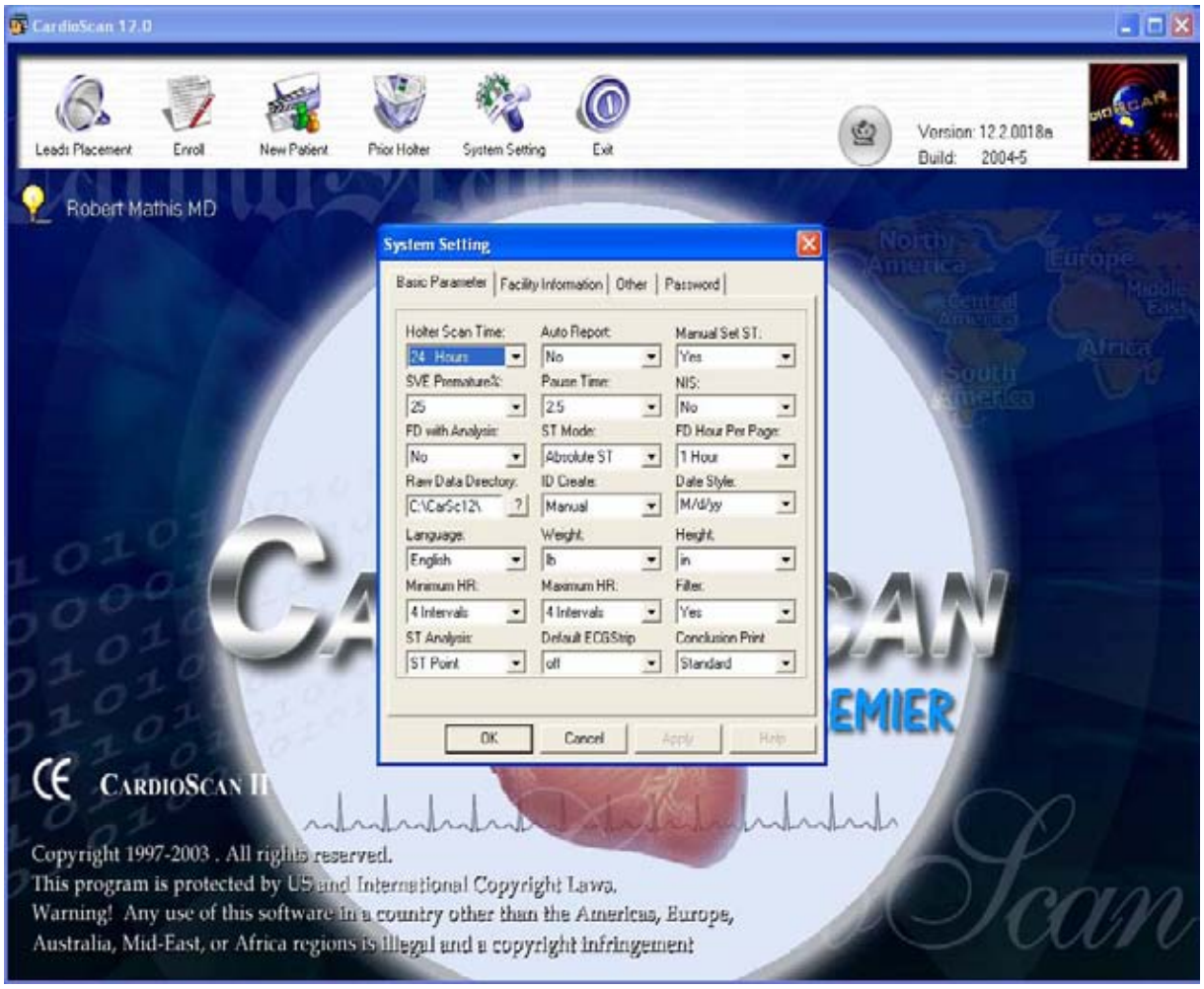
BASIC PARAMETER TAB

Move the mouse arrow to any default setting and activate with a click. Selecting the desired setting with the mouse arrow and performing a click will change each setting.

HOLTER SCAN TIME: Allows you to input the amount of hours recorded.



AUTO REPORT: The normal mode is NO. For a user who does not want to do any editing prior to printing the report, you can use the YES mode. This is the key to the SUPER SIMPLE HOLTER REPORT. Scroll down to Yes. Notice the Manual Set ST, Filter and Default ECG Strip are faded out. These options have become preset. The only choice you need to make is if you want a Full Disclosure printed out with the report. If you do, make sure to select Yes under FD with Analysis. With the Auto Report set in Yes, a Holter report and ECG strips will automatically print out after the patient data has been downloaded.



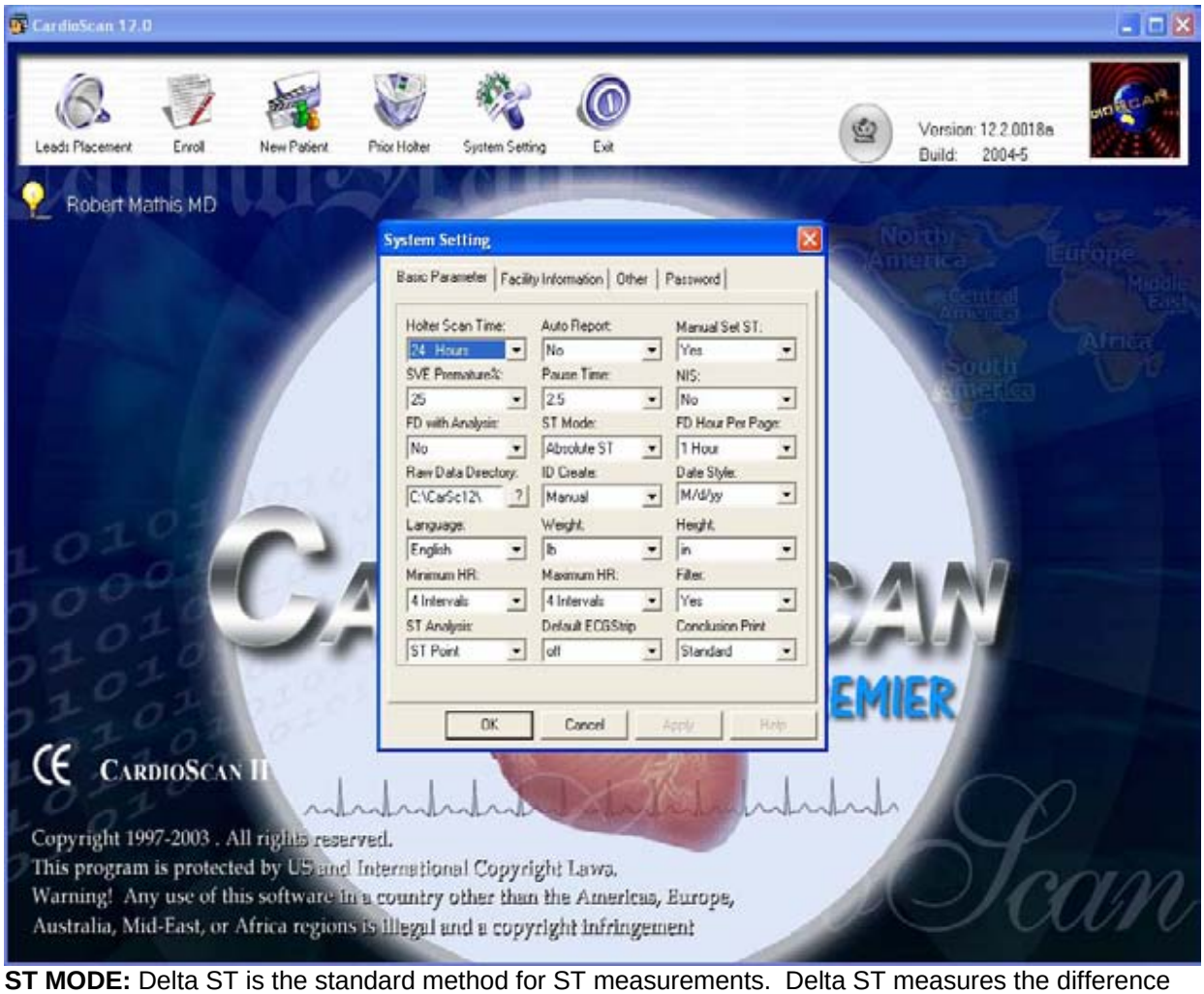
MANUAL SET ST: Selecting YES allows you to manually set the Baseline Reference, J-Point and ST-Point for each channel of recorded data. The NO selection has the program automatically make these selections. YES selection is recommended.

SVE PREMATURE %: Allows you to select the prematurity rate (from 15 – 50) for an SVE. The OFF selection disables this part of the analysis.

PAUSE TIME: Allows you to select the length of a pause from 1.5 – 3.0 seconds.

NIS: This option is for those that are connected to the NIS database program.

FD WITH ANALYSIS: Tells the program to automatically print out a full disclosure after the program has completed an analysis.



ST MODE: Delta ST is the standard method for ST measurements. Delta ST measures the difference in ST changes. Absolute ST always measures from the 0-reference baseline, and does not consider the patient's normal ST level for each individual ECG lead.

FD HOUR PER PAGE: Select 1 Hour, 2 Hour or 4 Hour of ECG data to be printed on each page.

RAW DATA DIRECTORY: Allows you to store and retrieve originally recorded ECG files onto CD-R disks.

ID CREATE: Manual allows you to enter any ID# for the cover sheet of your Holter report. Auto commands the computer to enter an ID number.

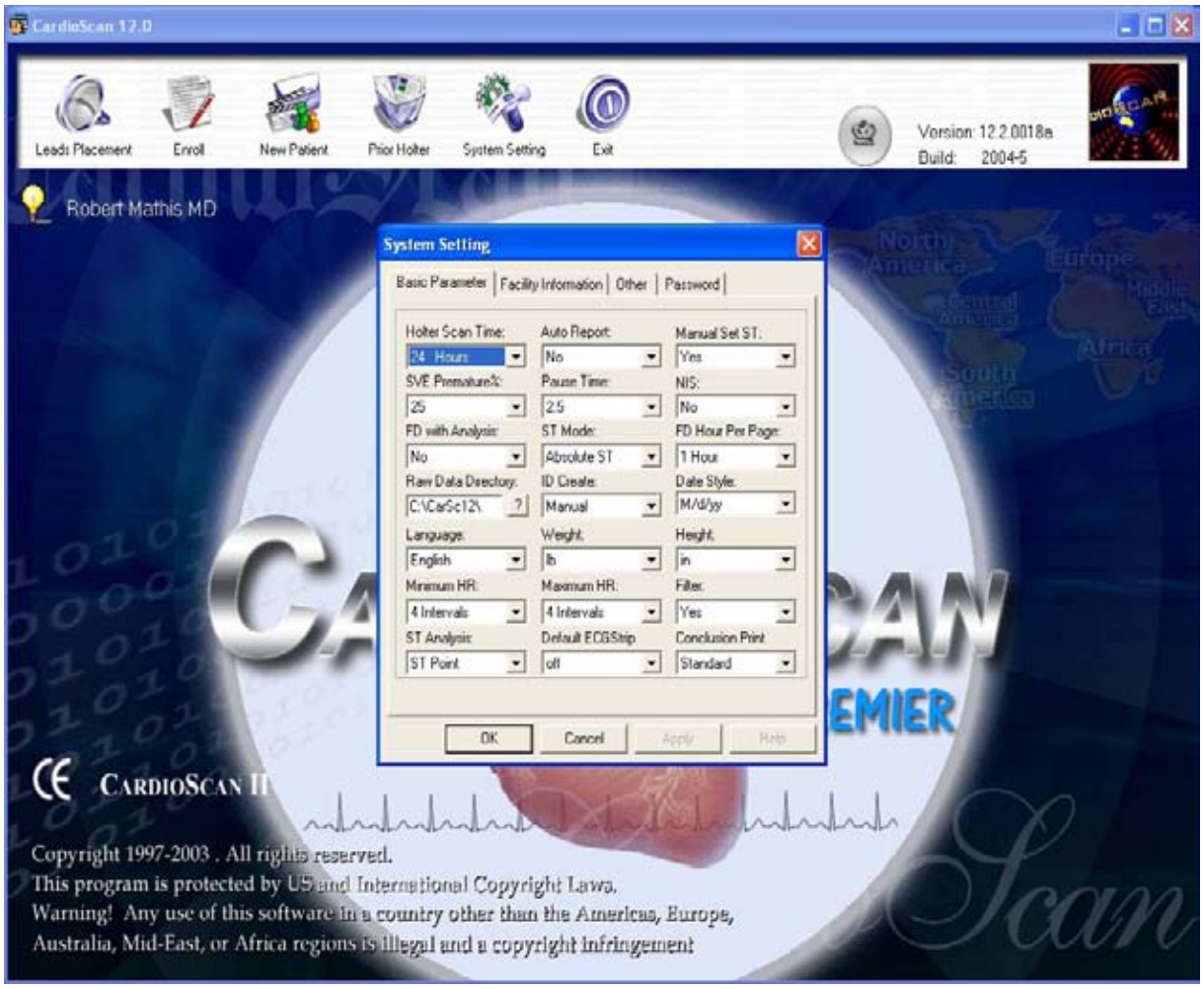
DATE STYLE: Lets you select your date format, either month-day-year for day-month-year.

LANGUAGE: Gives you the option of running the program in one of the listed languages. NOTE: Passwords are required for all languages except English.

WEIGHT: Lets you select between pounds and kilograms.

HEIGHT: Lets you select between inches and centimeters.

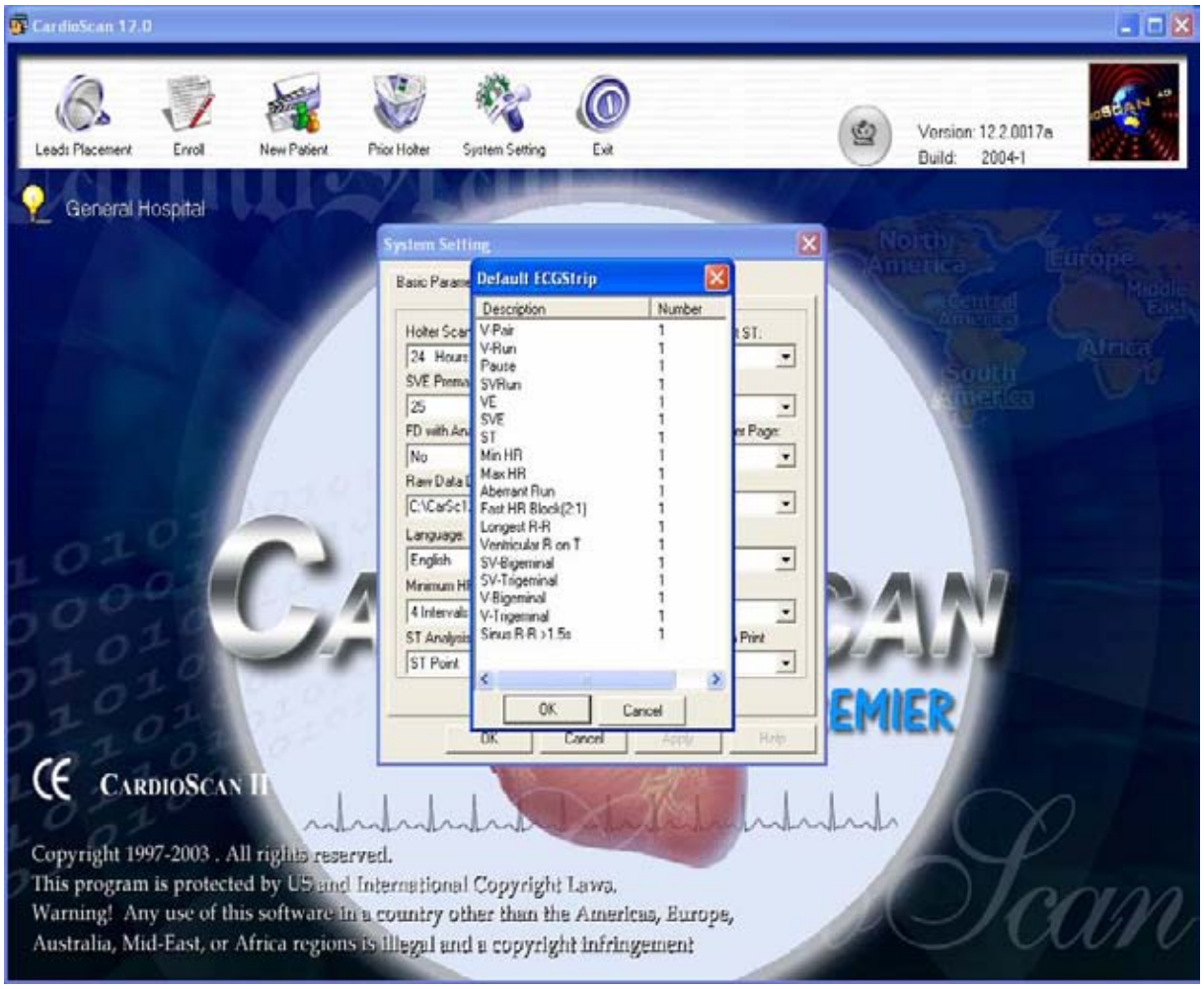
MINIMUM HEART RATE: Allows you to select the amount of beats used to average the minimum heart rate. You may select from 1 interval, 2 intervals, 3 intervals, 4 intervals or 5 intervals.



MAXIMUM HEART RATE: Allows you to select the number of beats used to average the maximum heart rate. You may select from 1 interval, 2 intervals, 3 intervals, 4 intervals or 5 intervals.

FILTER: A yes will turn on a filter to help clean up recordings with a lot of artifact. A no will leave the recording as is.

ST ANALYSIS: For ST analysis, some physicians prefer to measure the ST level from the J-point and other physicians prefer the ST point. You can select either choice from ST Analysis.



DEFAULT ECG STRIPS SAVE: This feature allows you to select the amount of ECG Strips to automatically print out from each Abnormal ECG Events category. Scroll down and select on. The following screen will appear.

Click on the number under the name of the strip under the Description column. A blue highlight bar will appear. Click three times on the number associated with the strip description. A cursor will appear. Type in the total number of this type of strip you wish to have printed out automatically with each report. Press the ENTER key on the keyboard.

Repeat the above for each type of strip. When you have finished click on the OK bar.

CONCLUSION PRINT: This feature lets you select from 3 different report cover sheet options. They are Standard, Increase1 and Increase 2. Samples of these cover sheets follow.

Standard Conclusion Print

General Hospital
12, Maple Street, Los Angeles. CA 90714
Phone: 800 222-5555 Fax: 800 222-5556

Recording Start Date 2/18/2002

HOLTER ECG REPORT SUMMARY

Recording Start Time 10:00

Patient Name:	g g	ID#:	
Address:		Age: DOB:	Sex:
Pacemaker:	None	Weight:	Height:
Supervising Physician:	Doctor A	Referring Physician:	Doctor B
Indications:			
Medications:			

HEART RATE

Minimum HR-4 Intervals:	47 bpm at 10:51
Maximum HR-4 Intervals:	107 bpm at 11:20
Average HR-24 Hours:	65 bpm
Minimum HR-Hourly:	56 bpm at 10:00
Maximum HR-Hourly:	74 bpm at 11:00
Analyzed Beats:	7524
Analyzed Minutes:	117

VENTRICULAR ECTOPY

VE Total	1331
V-Pair Total:	11
V-Run Total:	14
Longest V-Run:	9 beats at 11:53
Maximum HR V-Run:	130 bpm at 11:27
Minimum HR V-Run:	102 bpm at 10:13
VE's per 1000/per Hour:	167/666
Ventricular R on T:	4

HEART RATE VARIABILITY

SDNN-24 Hour:	161
SDANN:	151
SDNN Index:	53
rMSSD:	29
pNN50:	7
Spectral Power-24 Hour:	3340.5
Min Spectral Power Hour:	3340.5
Max Spectral Power Hour:	3340.5

ST SEGMENT ANALYSIS

Total ST Minutes Ch. 1:	13
Total ST Minutes Ch. 2:	8
Total ST Minutes Ch. 3:	21
Max Delta ST Depression:	-5.7 at 11:20
Max Delta ST Elevation:	+0.2 at 11:45
Max ST Episode:	17 Minutes at 11:11
Max HR In ST Episode:	105

SUPRAVENTRICULAR ECTOPY

SVE Total:	21
SV-Run Total:	1
Longest SV-Run:	6 beats at 10:37
Maximum HR SV-Run:	93 bpm at 10:37
SVE's per 1000/per hour:	3/11
Total Aberrant Beats:	0
Atrial Fib/Flutter:	N/A

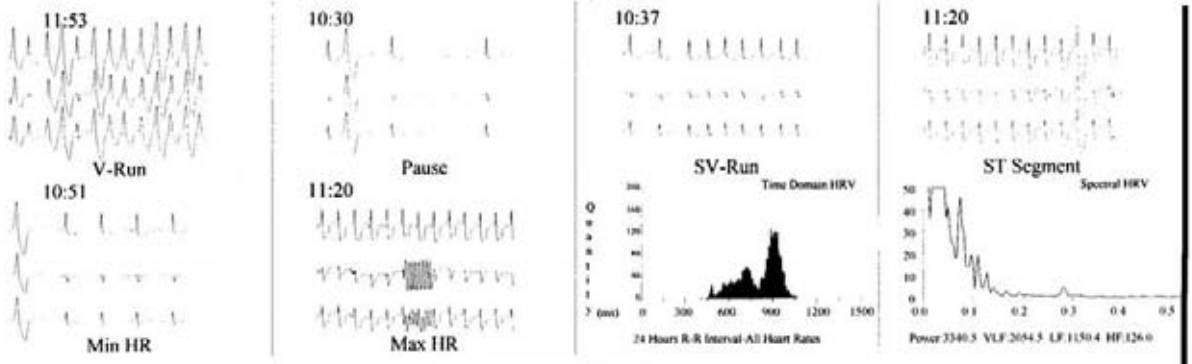
BRADYCARDIA

Pauses in Excess of 2.5 sec:	2
Max Pause:	3.4 sec at 10:30

QT

Max QT:	496 ms (Ch. 1)
Max QTc:	549 ms
Time of Max QT/QTc:	at 11:05. HR 72 bpm.
Bundle Branch Block:	N/A

SIGNIFICANT ECG EVENTS



CONCLUSIONS

The average heart rate was 65. The minimum heart rate was 47 at 10:51. The maximum heart rate was 107 at 11:20. Pauses greater than 2.5 seconds were 2. Ventricular ectopy was 1331, with 14 V-Runs and 11 V-Pairs. Ventricular Bigeminy events were 0 and Ventricular Trigeminy events were 63 . Supraventricular ectopy was 21, with 1 SV-Runs, Supraventricular Bigeminy events were 0 and Supraventricular Trigeminy events were 0 . Total A-Fib(Flu) minutes were 0. ST episode minutes totaled 21. The maximum Delta ST change was -5.7 and occurred at 11:20.

Physician Signature:

Physician Must Review Data
Printed: 2/19/2002 11:01:51 2002

Increase 1 Conclusion Print

General Hospital
12, Maple Street, Los Angeles. CA 90714
Phone: 800 222-5555 Fax: 800 222-5556

Recording Start Date 2/18/2002

HOLTER ECG REPORT SUMMARY

Recording Start Time 10:00

Patient Name:	h h		ID#:		
Address:			Age:	DOB:	Sex:
Pacemaker:	None		Weight:	Height:	
Supervising Physician:	Doctor A		Referring Physician:	Doctor B	
Indications:					
Medications:					

HEART RATE		VENTRICULAR ECTOPY		HEART RATE VARIABILITY	
Minimum HR-4 Intervals:	47 bpm at 10:51	VE Total	1331	SDNN-24 Hour:	161
Maximum HR-4 Intervals:	107 bpm at 11:20	V-Pair Total:	11	SDANN:	151
Average HR-24 Hours:	65 bpm	V-Run Total:	14	SDNN Index:	53
Minimum HR-Hourly:	56 bpm at 10:00	Longest V-Run:	9 beats at 11:53	rMSSD:	29
Maximum HR-Hourly:	74 bpm at 11:00	Maximum HR V-Run:	130 bpm at 11:27	pNN50:	7
		Minimum HR V-Run:	102 bpm at 10:13	Spectral Power-24 Hour:	3340.5
Analyzed Beats:	7524	VE's per 1000/per Hour:	167/666	Min Spectral Power Hour:	3340.5
Analyzed Minutes:	117	Ventricular R on T:	4	Max Spectral Power Hour:	3340.5
ST SEGMENT ANALYSIS		**SUPRAVENTRICULAR ECTOPY**		**BRADYCARDIA**	
Total ST Minutes Ch. 1:	13	SVE Total:	21	Pauses in Excess of 2.5 sec:	2
Total ST Minutes Ch. 2:	8	SV-Run Total:	1	Max Pause:	3.4 sec at 10:30
Total ST Minutes Ch. 3:	21	Longest SV-Run:	6 beats at 10:37	**QT**	
Max Delta ST Depression:	-5.7 at 11:20	Maximum HR SV-Run:	93 bpm at 10:37	Max QT:	496 ms (Ch. 1)
Max Delta ST Elevation:	+0.2 at 11:45	SVE's per 1000/per hour:	3/11	Max QTc:	549 ms
Max ST Episode:	17 Minutes at 11:11	Total Aberrant Beats:	0	Time of Max QT/QTc:	at 11:05. HR 72 bpm.
Max HR In ST Episode:	105	Atrial Fib/Flutter:	N/A	Bundle Branch Block:	N/A

CONCLUSIONS

The average heart rate was 65. The minimum heart rate was 47 at 10:51. The maximum heart rate was 107 at 11:20. Pauses greater than 2.5 seconds were 2. Ventricular ectopy was 1331, with 14 V-Runs and 11 V-Pairs, Ventricular Bigeminy events were 0 and Ventricular Trigeminy events were 63 . Supraventricular ectopy was 21, with 1 SV-Runs, Supraventricular Bigeminy events were 0 and Supraventricular Trigeminy events were 0 . Total A-Fib(Flu) minutes were 0. ST episode minutes totaled 21. The maximum Delta ST change was -5.7 and occurred at 11:20.

Physician Signature:

Physician Must Review Data Printed: 2/19/2002 10:54:33 2002

Increase 2 Conclusion Report

General Hospital
12, Maple Street, Los Angeles. CA 90714
Phone: 800 222-5555 Fax: 800 222-5556

Recording Start Date	HOLTER ECG REPORT SUMMARY	Recording Start Time
2/18/2002		10:00

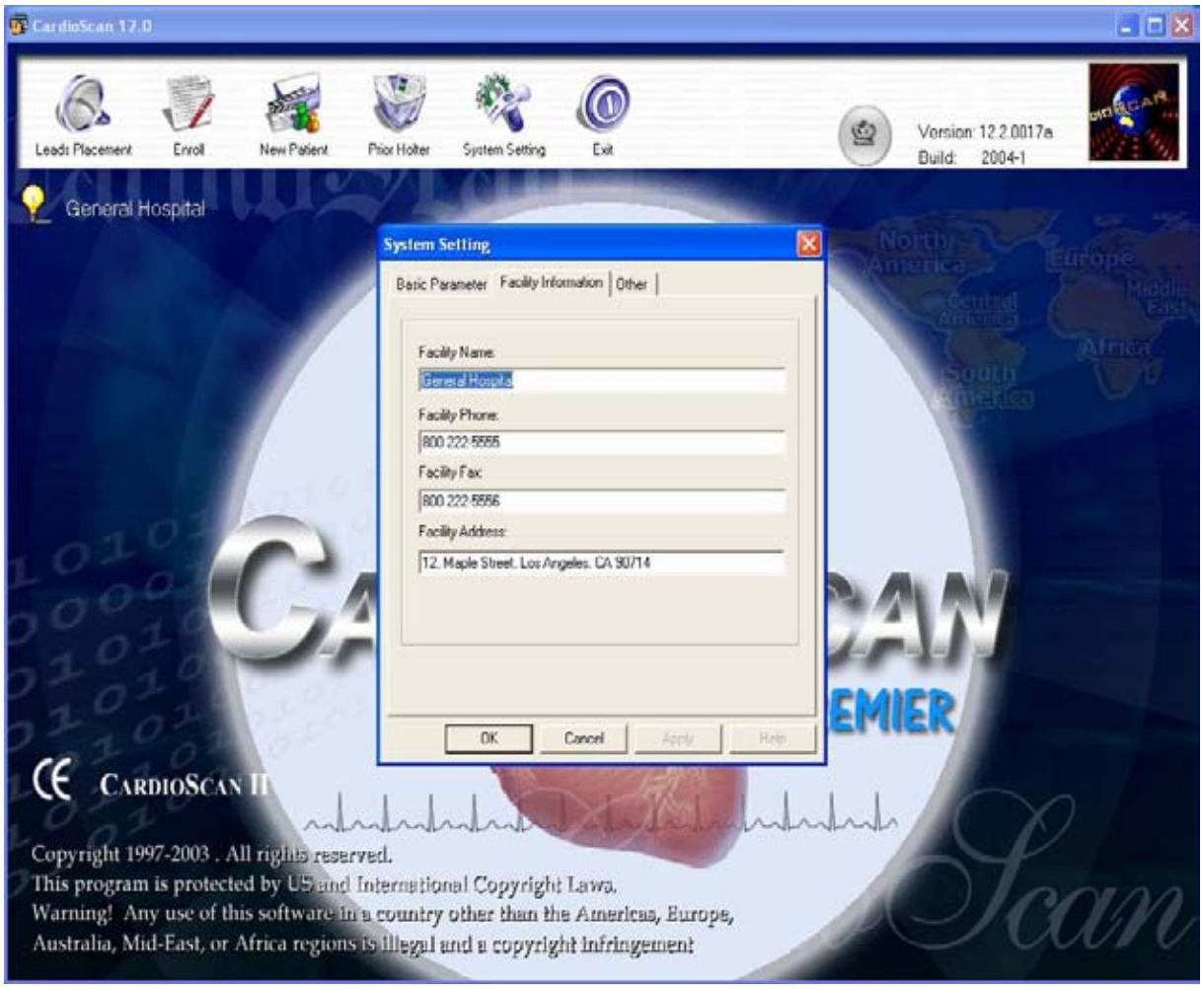
Patient Name:	h h	ID#:			
Address:		Age:	DOB:		Sex:
Pacemaker:	None	Weight:		Height:	
Supervising Physician:	Doctor A	Referring Physician:	Doctor B		
Indications:					
Medications:					

CONCLUSIONS

The average heart rate was 65. The minimum heart rate was 47 at 10:51. The maximum heart rate was 107 at 11:20. Pauses greater than 2.5 seconds were 2. Ventricular ectopy was 1331, with 14 V-Runs and 11 V-Pairs, Ventricular Bigeminy events were 0 and Ventricular Trigeminy events were 63 . Supraventricular ectopy was 21, with 1 SV-Runs, Supraventricular Bigeminy events were 0 and Supraventricular Trigeminy events were 0 . Total A-Fib(Flu) minutes were 0. ST episode minutes totaled 21. The maximum Delta ST change was -5.7 and occurred at 11:20.

Physician Signature:

 Physician Must Review Data Printed: 2/19/2002 10:58:22 2002



FACILITY INFORMATION TAB

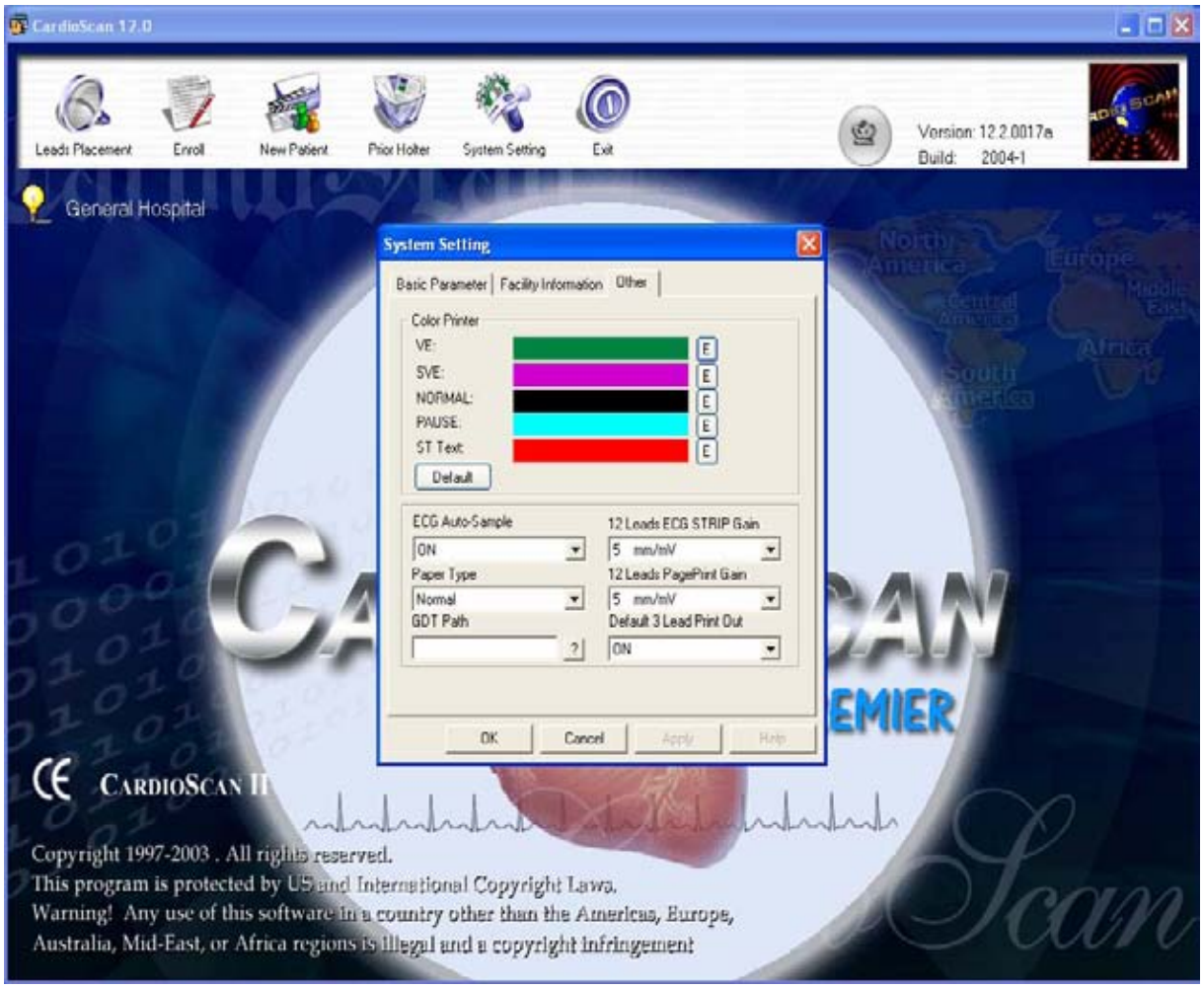
FACILITY NAME: Enter the facility's name, as you want it to appear on the heading of the report.

FACILITY PHONE: Enter the phone number of the facility.

FACILITY FAX: Enter the facility's fax number.

FACILITY ADDRESS: Enter the address of the facility.

When all of the data is entered, click on OK.

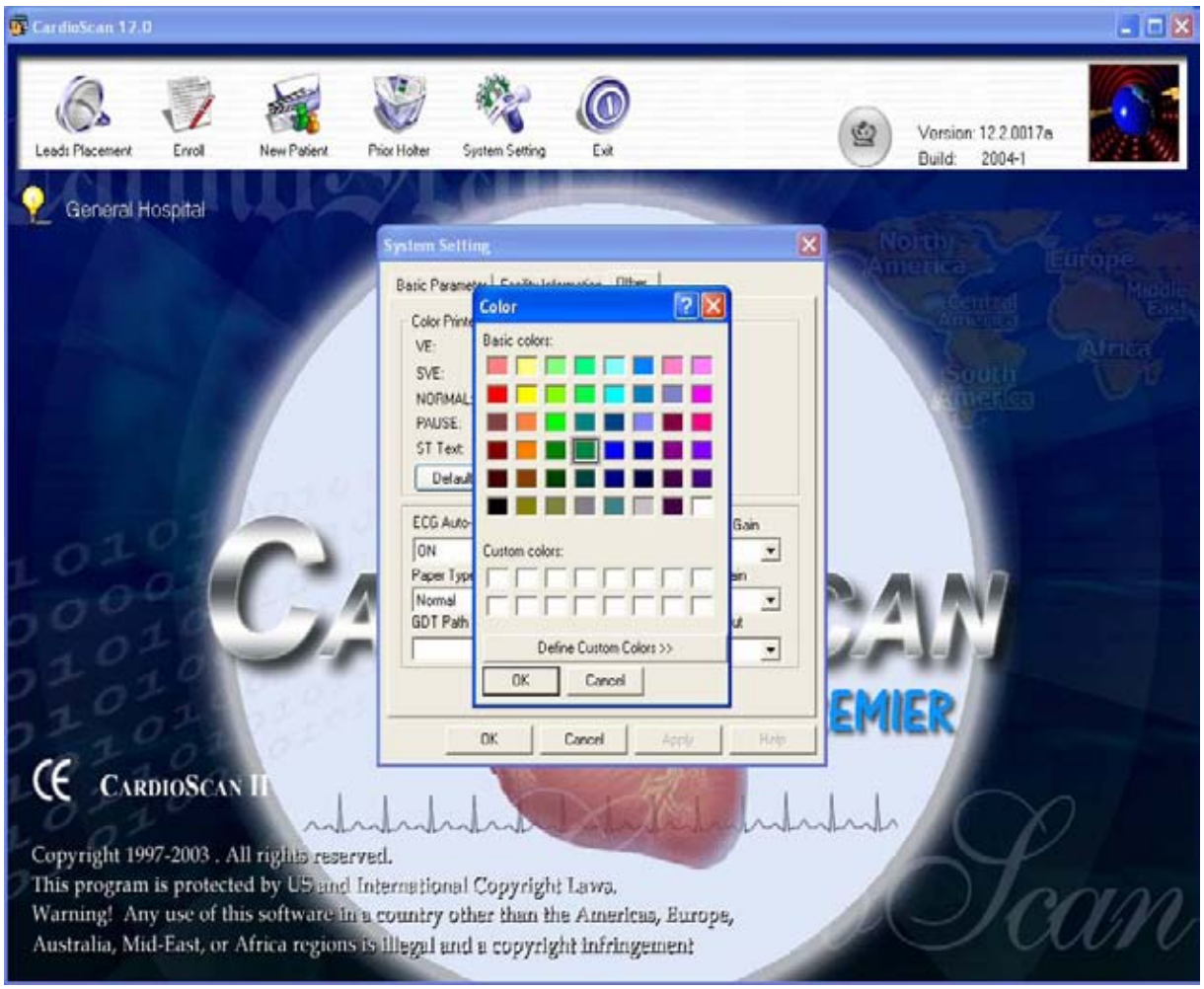


OTHER TAB

The Color Printer field allows you to select the colors you prefer for the following ECGS:
VE, SVE, Normal, Pause and ST Text

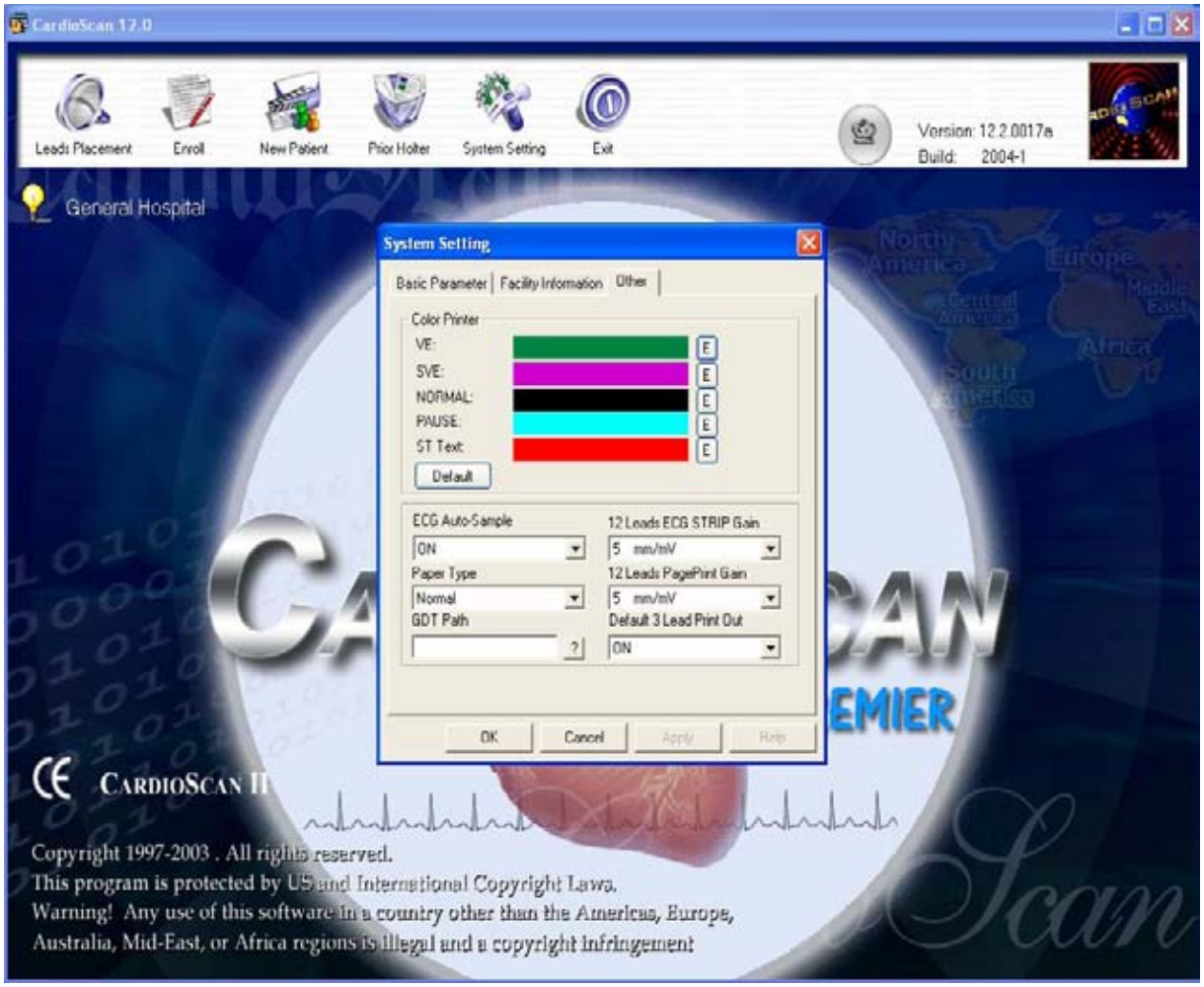
The default colors are green for a VE, magenta for an SVE, black for a normal beat, blue for a Pause and red for ST.

To change the color, click on the E to the right of the current color. The following screen will appear.



Click on your color selection and then click on OK.

The color you selected will now be the color for the ECG.



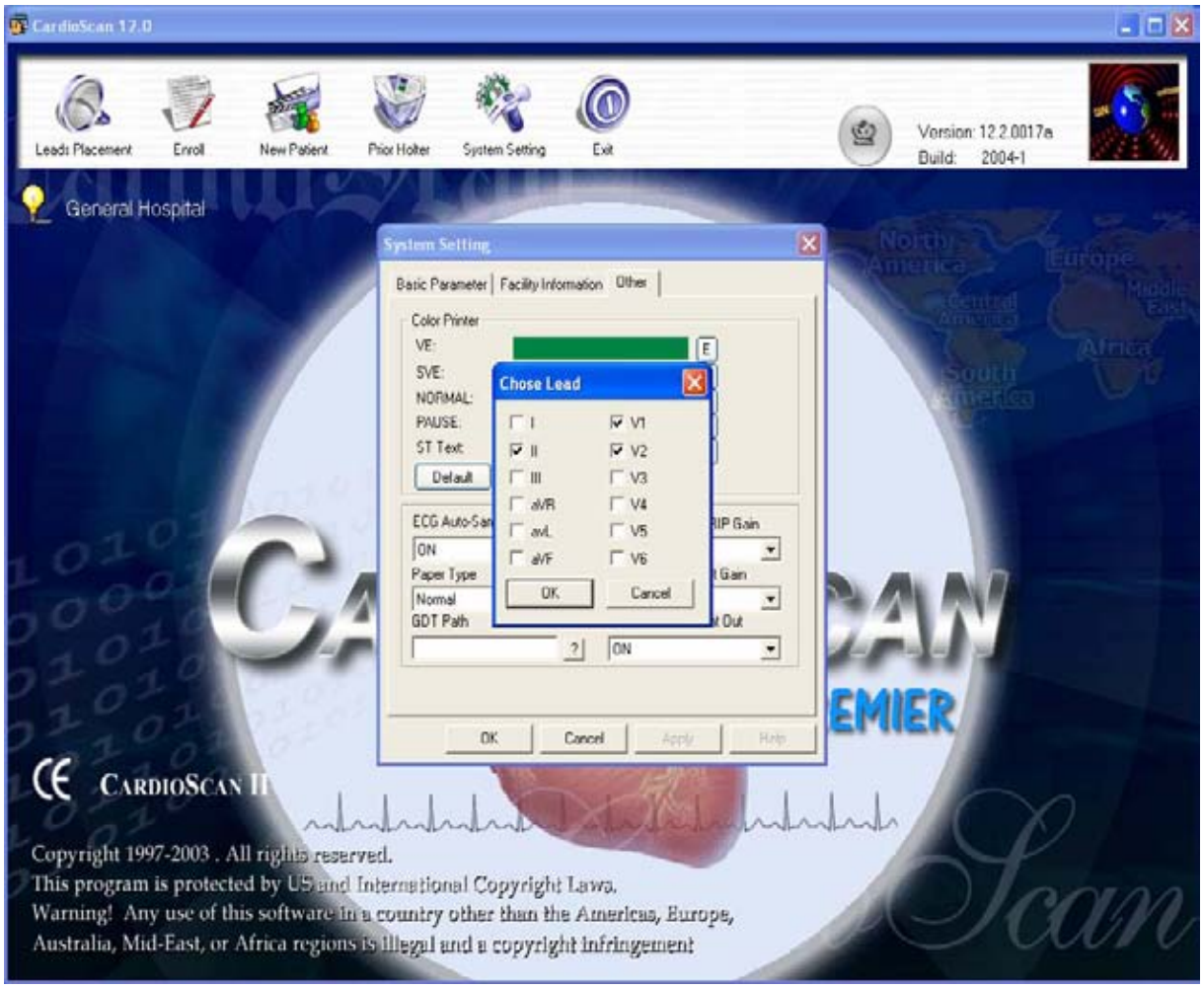
ECG-Auto Sample: Keep this option on ON for a better ECG screen resolution .

Paper Type: Allows you to select between normal (plain paper) or color paper. Most cases you would select Normal. In the event the operator desires to use a preprinted color, gridded paper, then select the Color mode

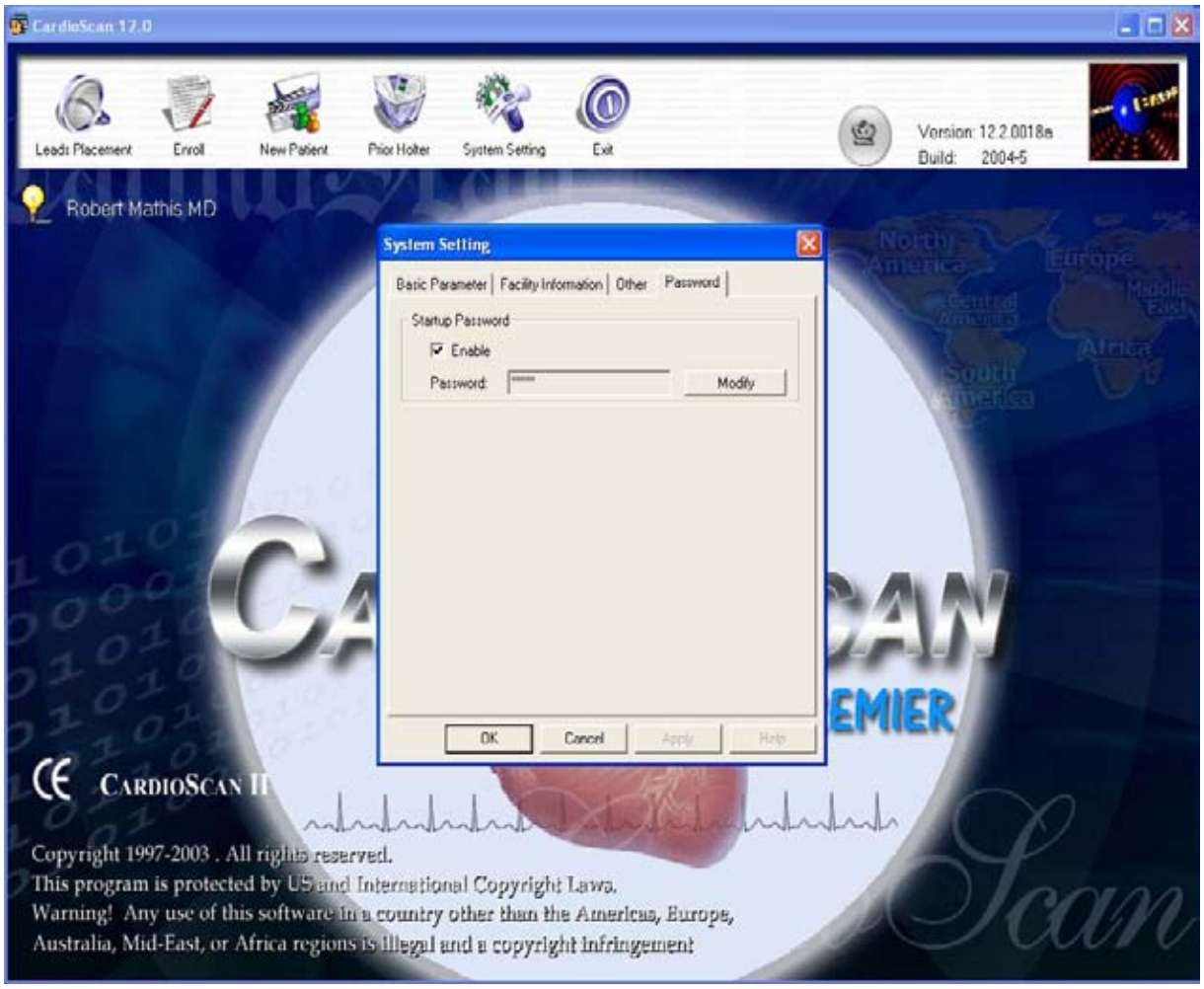
GDT Path: For German reimbursement software.

12 Leads ECG STRIP Gain: Allows you to select between 2.5mm/mV, 5mm/mV or 10mm/mV for the gain selection for the ECG screen displays.

12 Leads Page Print Gain: You can set the gain on the 12 Lead ECG print out to 5mm/mV or 10mm/mV.



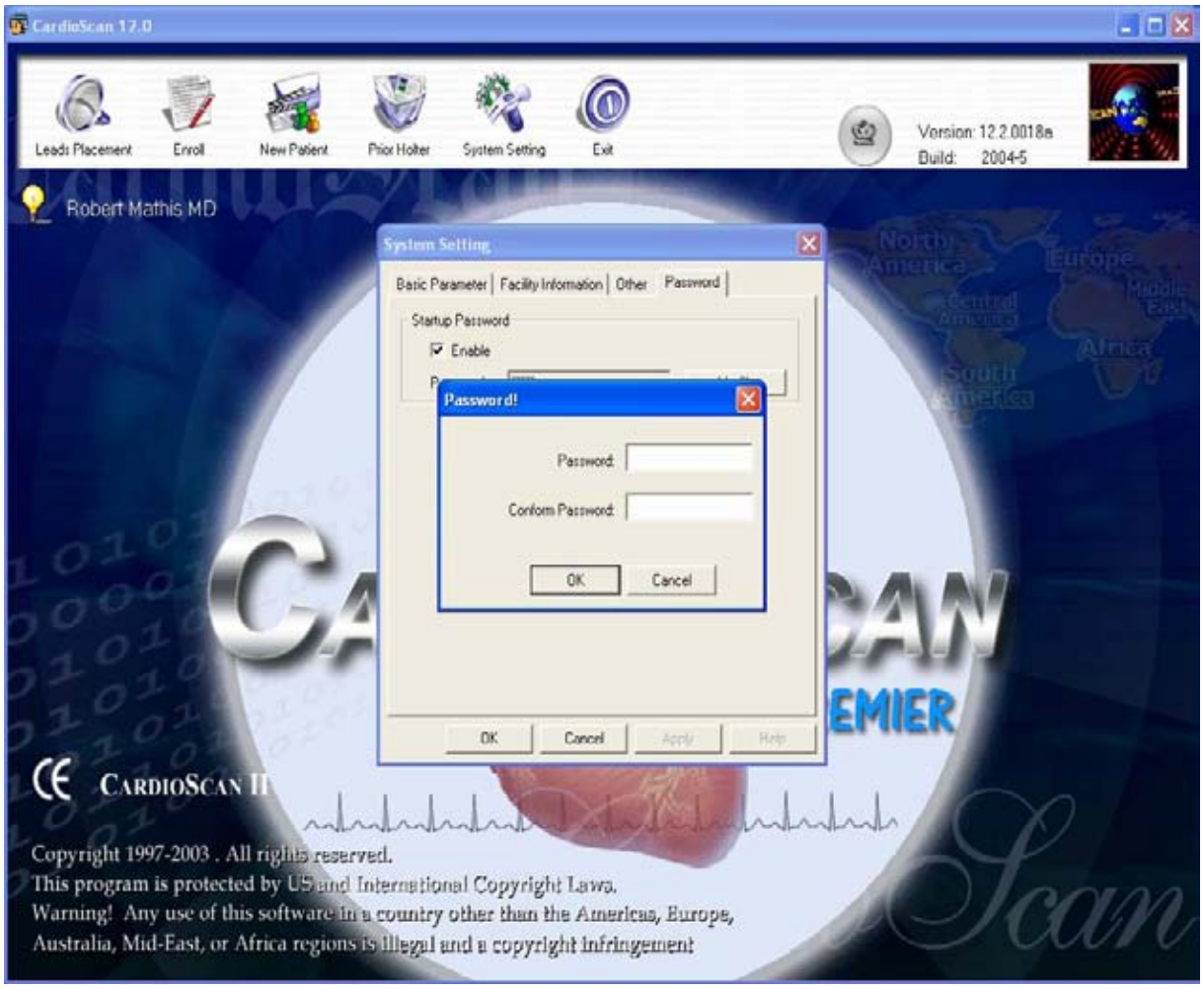
Default 3 Lead Print Out: The ON setting allows you select the 3 leads you choose to print out from a 12 lead recording. After you have selected the leads, click on OK to set your options.



PASSWORD TAB

To set a password for the Holter software, click on the Password tab. The above screen will appear.

Click on the box next to Enable. The following screen will appear.



Enter your password in the Password field and then enter the same password in the Confirm Password field. Click on OK.

Once you have set the password, every time you click on the Holter icon from the Windows desktop you will be required to enter the password.

If you forget your password, the default password is dmsdms.

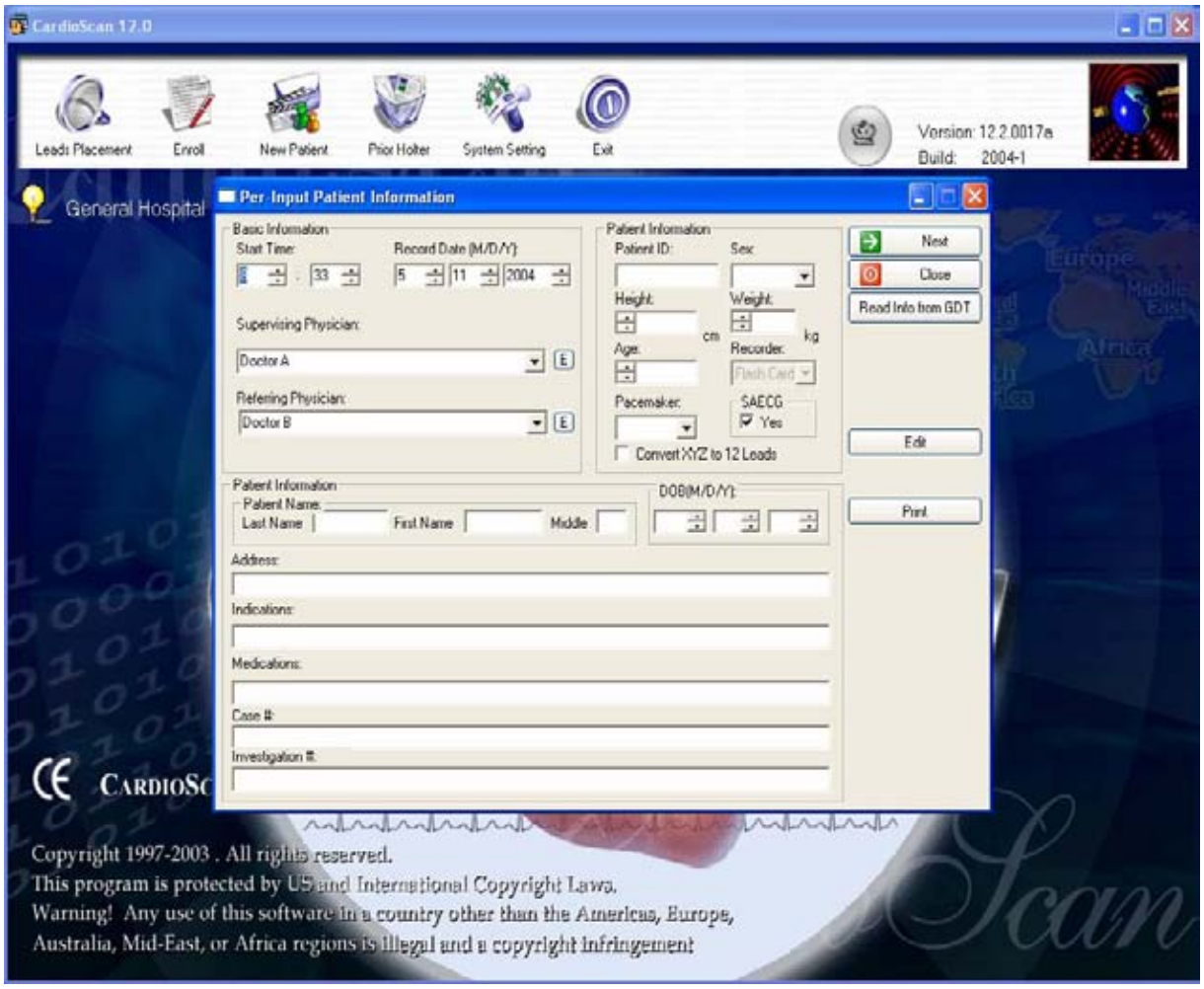
Click on OK to exit System Settings.

ENROLL A PATIENT

The purpose of the Enroll setting is to label the flash card with the patient's data. Once the patient returns with the flash card, the data will be automatically entered into the New Patient Information.

Prior to recording the patient's 24-hour Holter ECG, you want to enter the patient information onto the SANDISK compact flash card. To "Enroll" the patient information, follow these steps:

1. Insert the SANDISK compact flash card into the ImageMate reader.
2. From the CardioScan 12 main menu, click on the ENROLL icon at the top of the screen.



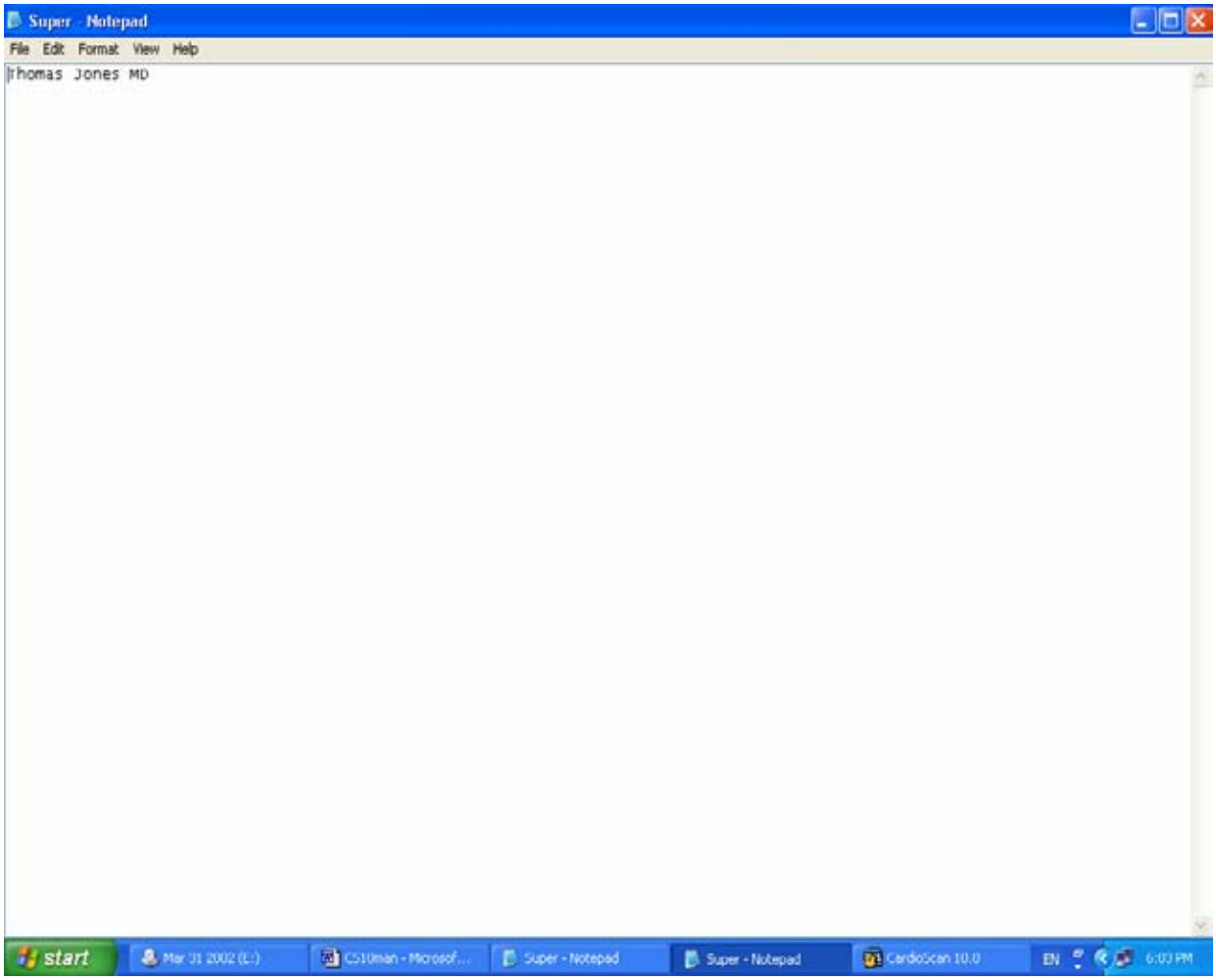
Using your keyboard, enter all the patient information. To move between the fields, you may either press the TAB key or click on a field with your mouse.

NOTE: There are a minimum of six fields that **must** be filled with data in order to process the patient's data. They are Start Time, Record Date, Pacemaker, Supervising Physician, Recorder and Patient Name.

A check mark in the Convert XYZ to 12 leads will allow you to edit and analyze 12 Channels of ECG data.

A check mark in the SAECG box will allow you to edit SAECG data and create a report. Without editing the SAECG data, you will be unable to create a report.

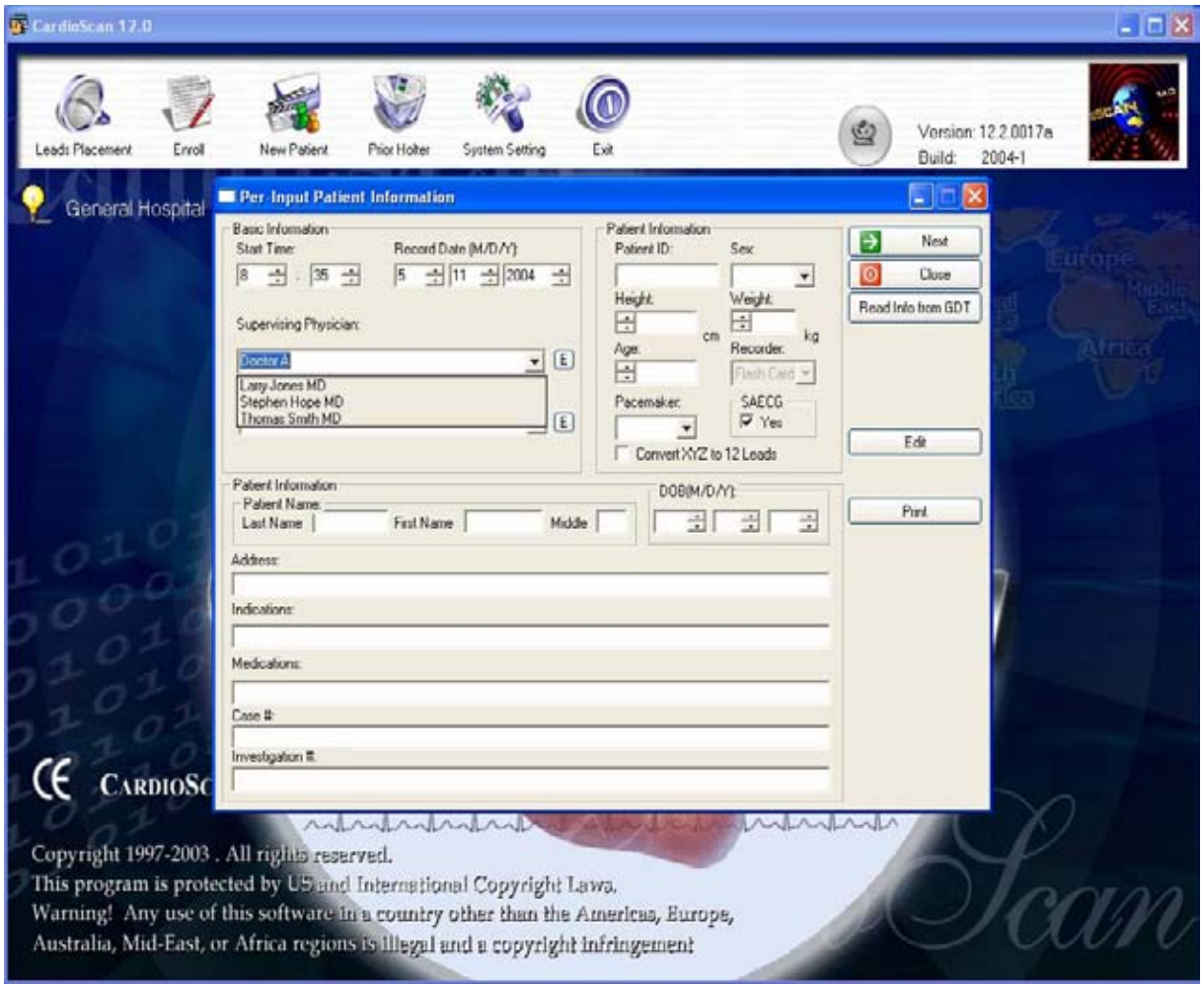
Pacemaker processing requires a YES in the "Pacemaker" field.



To make a database of Supervising Physicians, click on the E next to the Supervising Physician field. You will see the above screen.

Enter all of the doctor's names. After you enter the last name make sure to press the ENTER key. If you do not do this, the doctor's full name will not be displayed when you access that physician. Click on File and click on Save. Click on File again and then click on Exit.

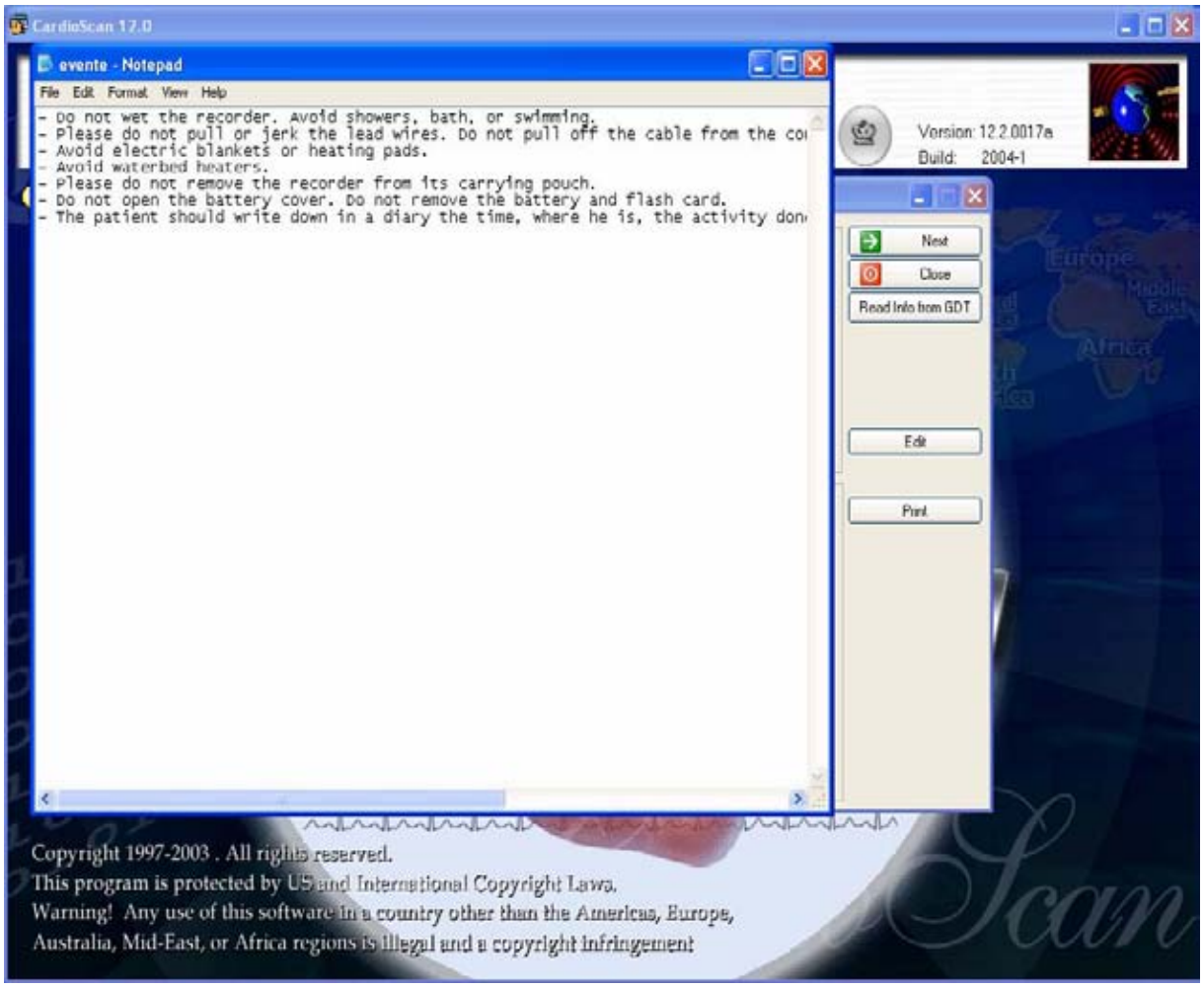
Repeat the above process for storing Referring Physician names.



You will be returned to the Patient Data screen. Click on the down arrow next to the Supervising Physician field and you will see a list of the names you have entered.

To select a doctor, simply double click on the doctor's name. His name will now appear in the Supervising Physician field. After you have selected the Supervising Physician, continue entering all of the patient's data.

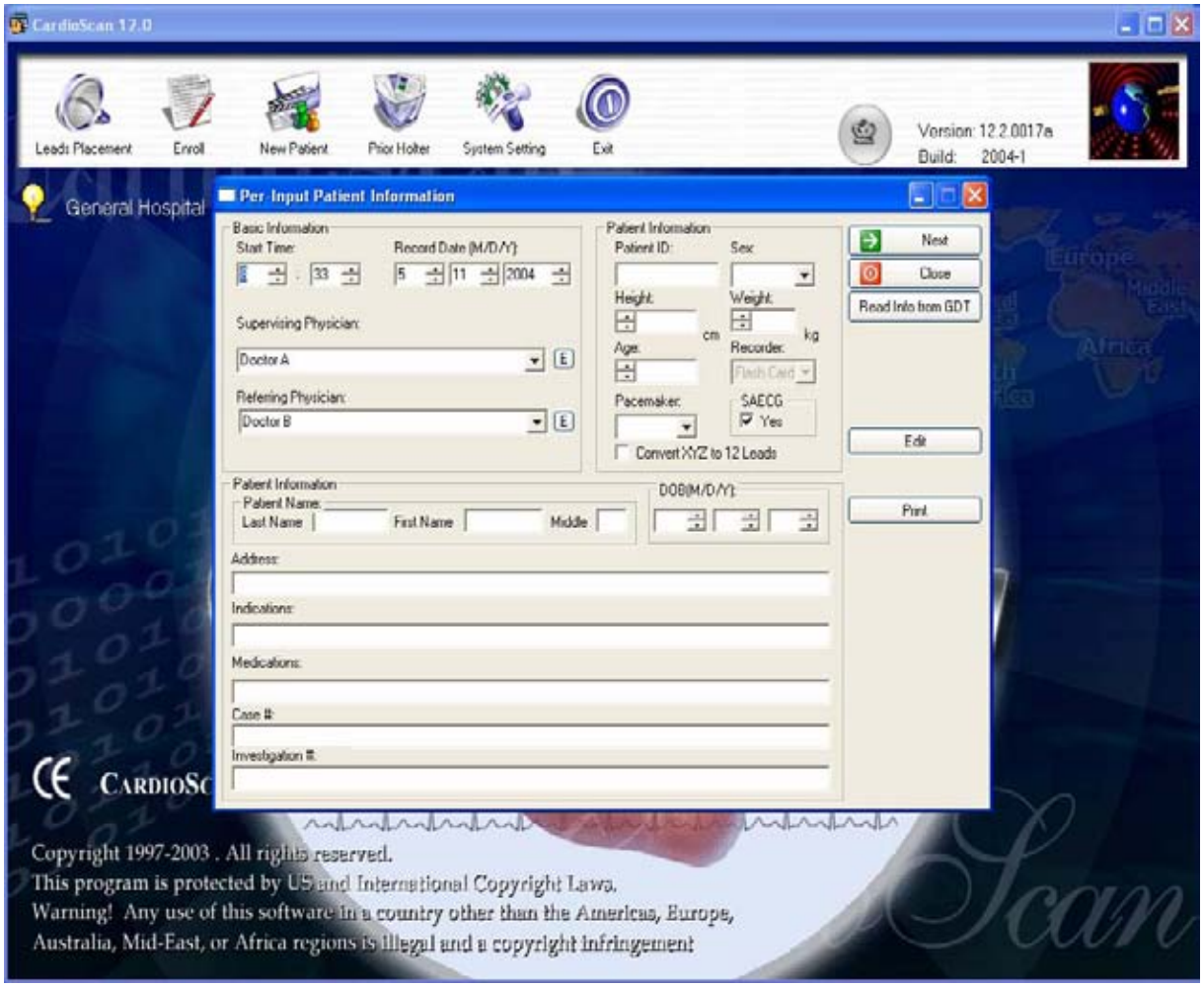
After entering all the information click on the EDIT bar. This will take you to the patient diary screen.



This screen allows you to enter individualized patient instructions in your Patient Diary.

To erase the patient instructions that are already entered, simply highlight the instructions with the mouse by right clicking the mouse and dragging the mouse over the instructions. This will leave a black highlight bar over all of the instructions. Press the backspace key on the keyboard. This will erase all of the patient instructions on the screen.

To enter new instructions, simply begin typing. Make sure to type in good, clear instructions so it is easy for the patient to follow them. After you have entered all of the instructions, click on File and then click on Save. This will save the instructions you have just entered. These new instructions will now be the default patient instructions. To change the instructions you must repeat the above steps. Click on File again and then click on Close. You will be returned to the Patient Information screen.



Click on the PRINT bar to print out the Patient Diary.

Click on NEXT to load the patient information to the disk. You will be returned to the Main CardioScan 12 screen.

Remove the SANDISK compact flash card from the ImageMate reader.

Insert the SANDISK compact flash card into the patient's digital Holter recorder.

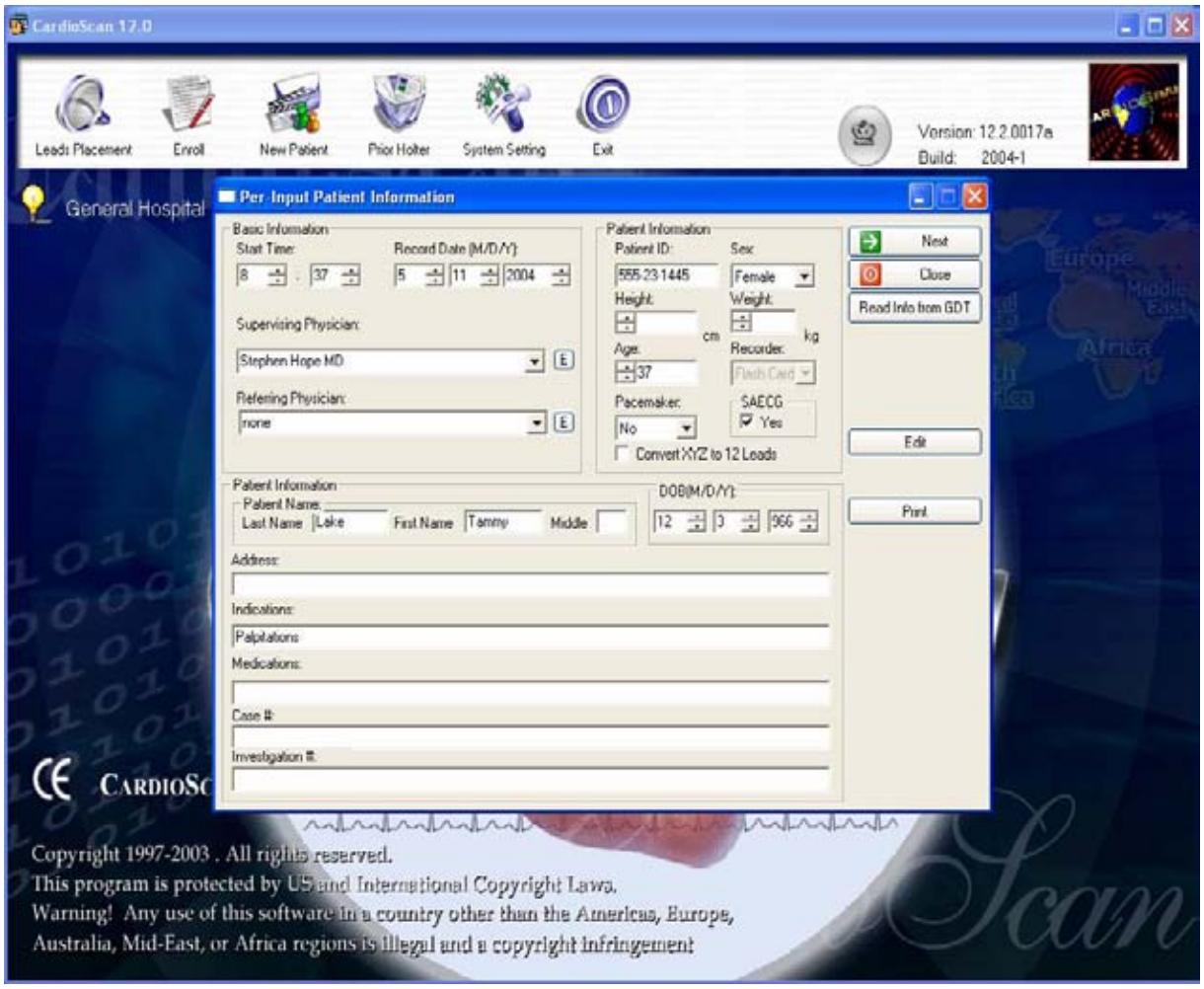
NOTE: The ENROLL feature will only work if the same computer is used for both the flash card patient data entry and the processing of the Holter ECG.

PROCESS A HOLTER RECORDING

If you have used the ENROLL feature, insert the SANDISK compact flash card into the ImageMate reader. Click on the NEW icon at the CardioScan 12 main screen. Any patient data that was entered during the ENROLL process on this compact flash card will come up in the new patient information screen.

NOTE: If you click on the NEW icon at the CardioScan 12 main screen and then insert the SANDISK compact flash card into the ImageMate reader, the data entered on this compact flash card using the ENROLL feature will not appear on the screen. You **must** insert the SANDISK compact flash card into the reader before clicking on the NEW icon.

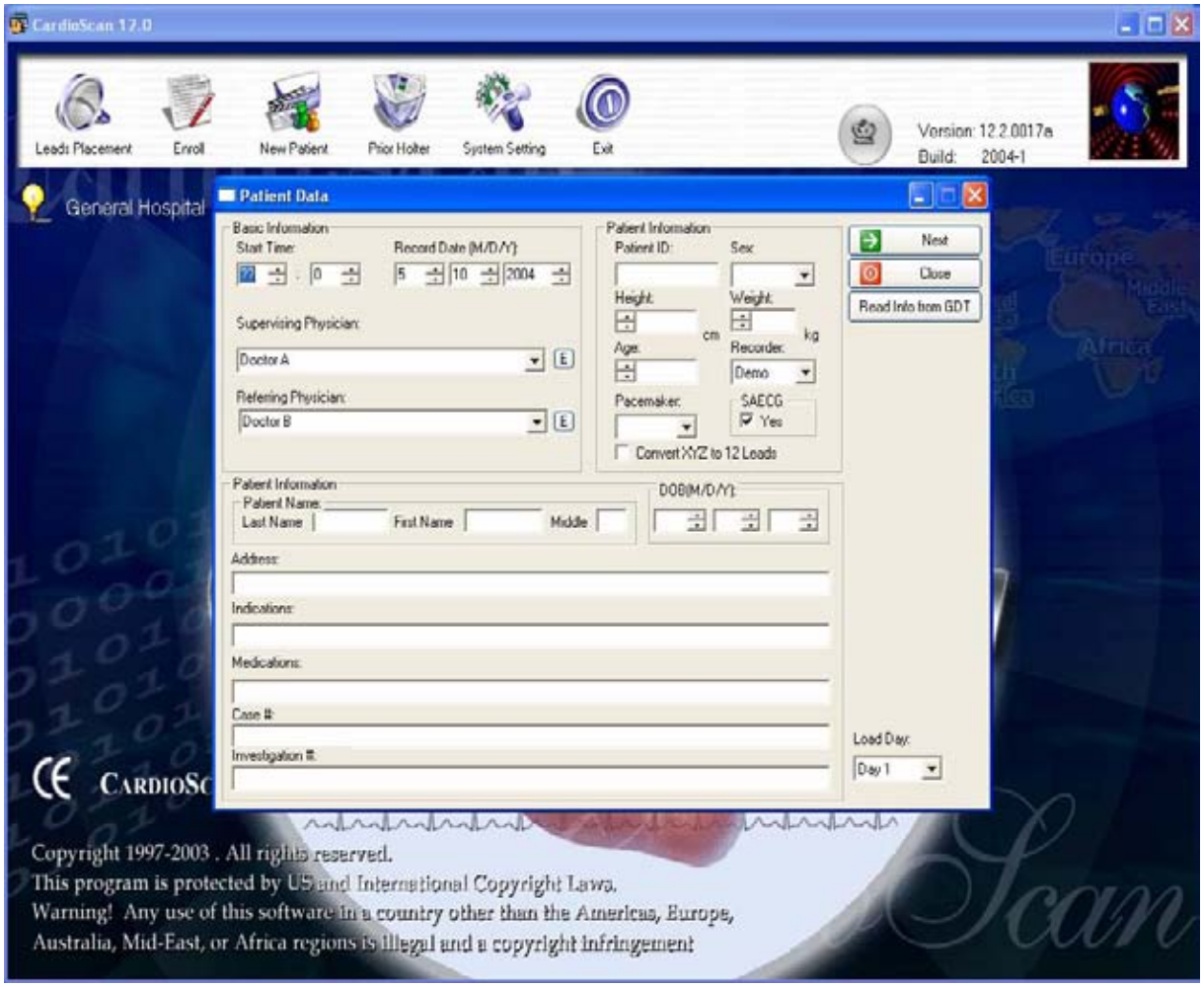
If you have not used the ENROLL feature, click on the NEW icon at the CardioScan 12 main screen. Turn to page 34 for the next step.



The patient information data you entered using the ENROLL feature is now on the screen. To continue with the processing of the Holter data, click on the NEXT.

If you did use the ENROLL function, go to page 36.

If you did not use the ENROLL function, go to the next page.



PATIENT DATA MENU

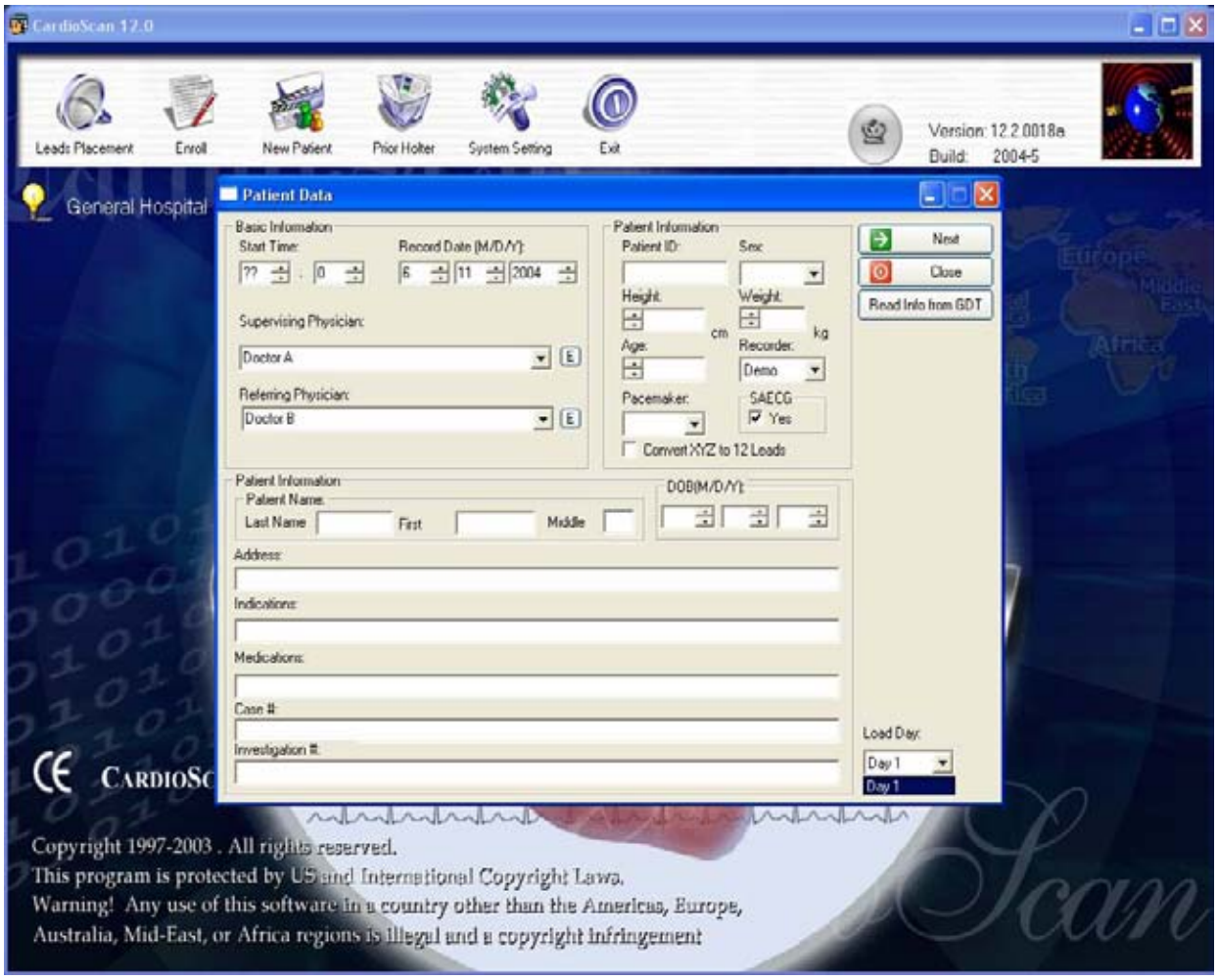
In this menu there are six (6) fields that **must** be filled with data in order to proceed. They are Start Time, Record Date, Pacemaker, Supervising Physician, Recorder and Patient Name. Enter the data in each field. To move to the next field, press the TAB key on the keyboard or point and click with the mouse.

The Recorder field allows you to select a Flash Card (Digital) Holter recording or a DEMO practice file. This setting will default to its last setting when the computer is powered up.

A check mark in the Convert XYZ to 12 Leads will allow you to edit and analyze 12 Channels of ECG data.

A check mark in the SAECG box will allow you to edit SAECG data and create a report.
NOTE: Without editing the data, you will be unable to create a report.

Pacemaker processing requires a YES in the “Pacemaker” field.

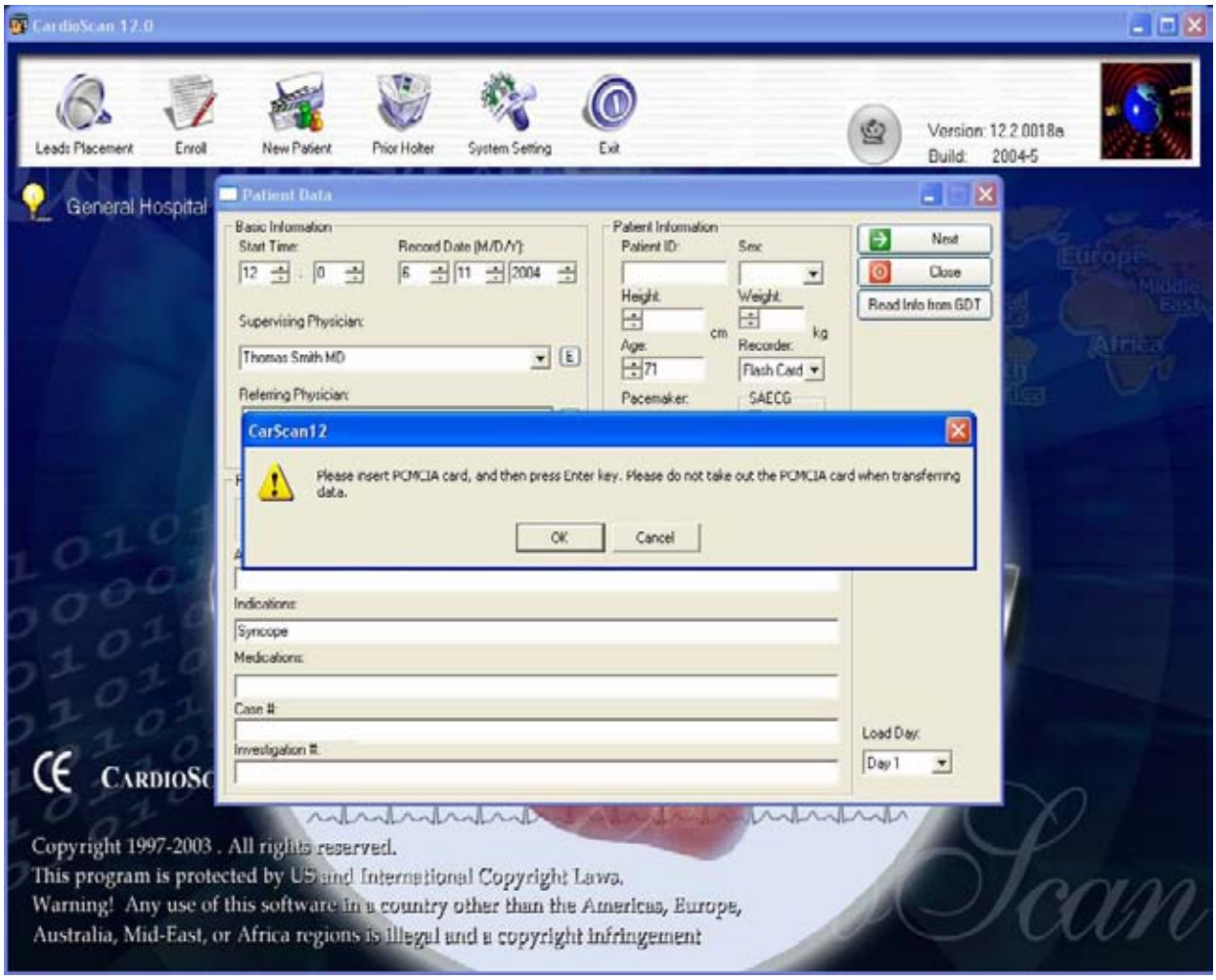


If you are doing a multi-day Holter using the DMS 300-8 or DMS 300-12 Digital Holter recorder, you will need to assign the Load Day. Day 1 would be from the initial Holter hookup until midnight of the same day. Day 2 would start at 00:00 and Day 3 would start at 00:00 of the following day. To identify these files in the Prior file, D1 will be marked after the patient's last name for Load Day 1. D2 will be marked after the patient's last name for Load Day 2 and D3 will be marked after the patient's last name for Load Day 3.

Clicking on CLOSE will return you to the main menu. After entering all of the data, click on NEXT.

NOTE: See pages 28 to create a database of Supervising Physicians.

NOTE: If you used the ENROLL program, click on NEXT.

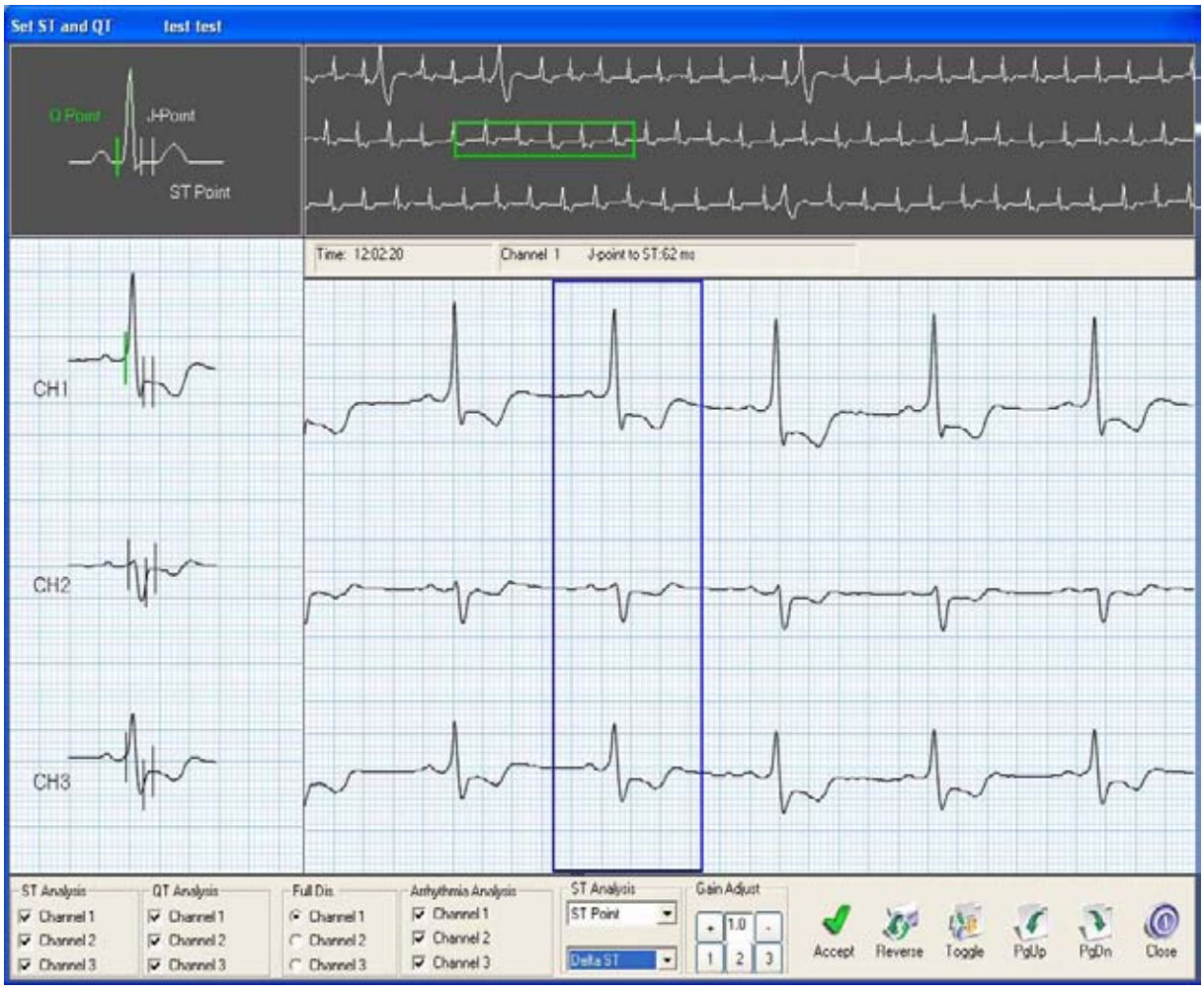


After clicking on NEXT, the above message will appear.

Insert the SANDISK compact flash card in the reader, arrow side up. Click on OK. Clicking on the CANCEL bar will return you to the Patient Data Menu.

The Data from the compact flash card will now be transferred to the hard disk of the computer. Depending on the speed of the computer, the transfer of the Holter ECG to the computer hard disk should be less than 60 seconds.

NOTE: If you used the ENROLL feature, your SANDISK compact flash card is already in the reader. Click on OK to proceed with the analysis. Clicking on the CANCEL bar will return you to the Patient Data Menu.



SET ST AND QT

If you have selected yes for Manual Set ST (as highly recommended), then the Set ST and QT display will appear after the Holter ECG data has been completely transferred to the computer's hard disk drive. Otherwise, the next display will be Analyse ECG Data.

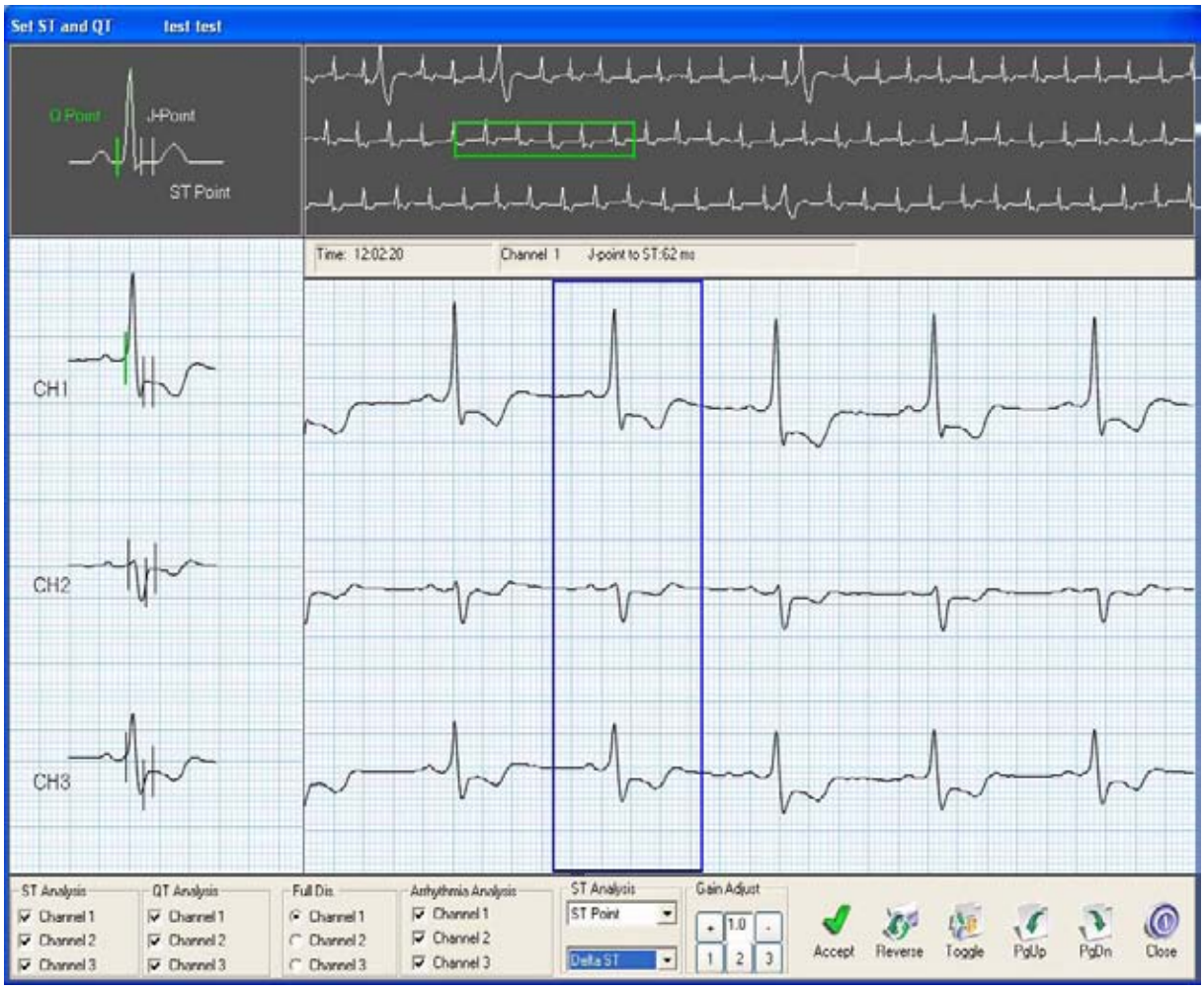
1. There is a rectangular box in the 1-minute ECG strip at the top of the display. You can move this box (thereby selecting a new beat) by placing your cursor on a different beat and clicking your mouse. To select a different minute, press the Page Up or Page Down button on your keyboard OR click on the Page Up or Page Down icons at the bottom of the screen.

2. To select a beat from the enlarged eight-second strip, simply click your mouse within the blue box on the enlarged eight-second strip. Drag and center the box to the beat you desire.

3. The ST Analysis box on the bottom left of the screen shows you which channels are being analyzed. To delete a channel, move your cursor to the desired box and click. A check mark next to a channel indicates that ST Analysis will be done for that channel. In many cases, physicians will not want to analyze the ST for a negative going QRS.

4. The QT Analysis box on the bottom left of the screen shows you which channels are being analyzed. To delete a channel, move your cursor to the desired box and click. A check mark next to a channel indicates that QT Analysis will be done for that channel. QT analysis requires an R-wave in excess of 5mm and a positive amplitude T-wave in excess of 2mm.

5. The Full Disclosure box at the bottom of the screen allows you to select the channel that will be printed out in the Full Disclosure. To select a different channel, move your cursor to the desired channel and click. The black dot indicates which channel will be printed.

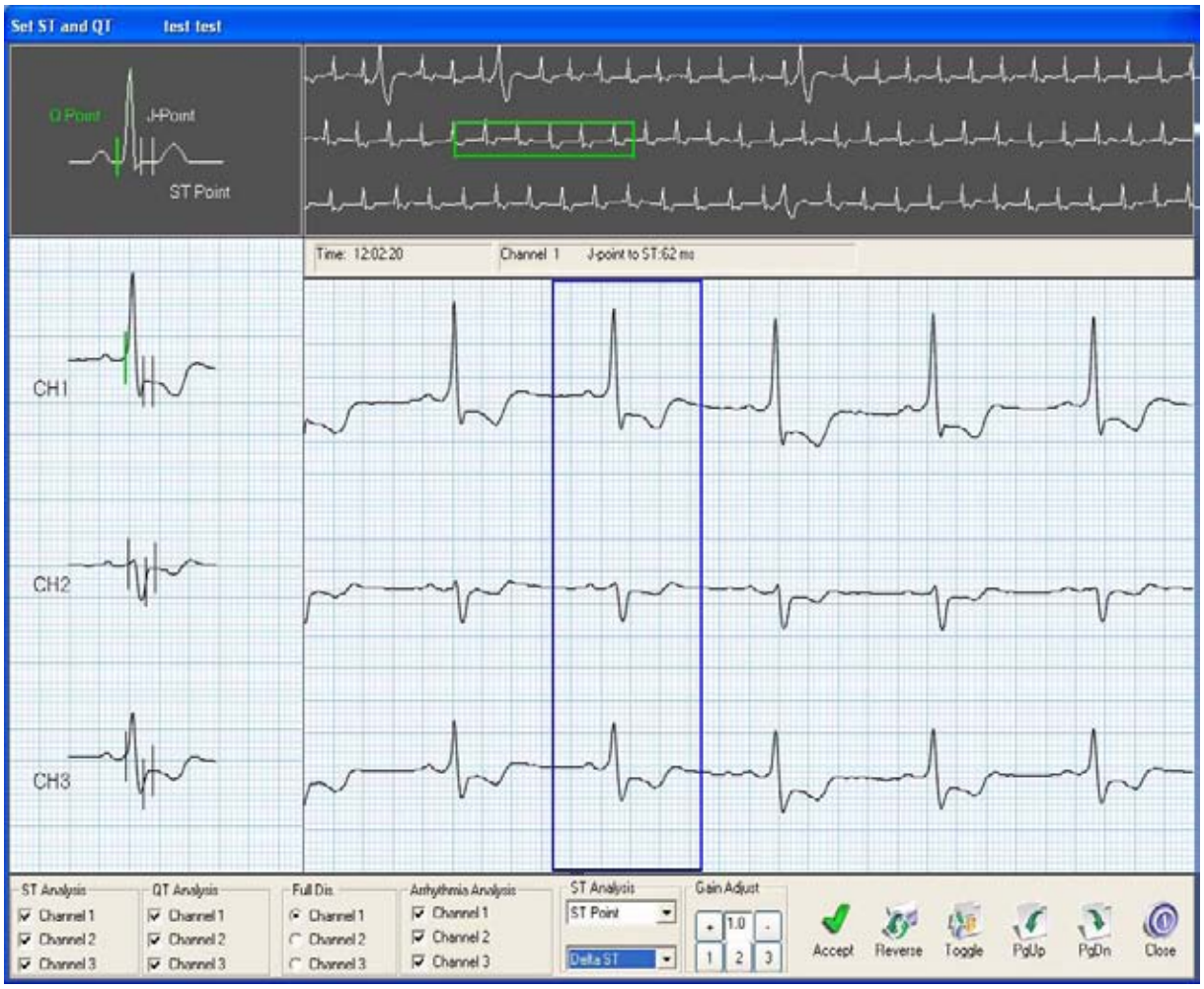


6. The Arrhythmia Analysis box at the bottom of the screen allows you to select which channels will be analyzed for arrhythmias. With a mouse click in the dialogue boxes, you can change the leads for arrhythmia analysis. The maximum number of leads for arrhythmia analysis is 3-leads. Always select 3-leads.

7. The ST Analysis allows you to select (1) either the J-Point or ST-Point for measuring the ST level and (2) either the Delta ST or Absolute ST method for basic ST analysis. The Delta ST is the standard method for ST measurements. Delta ST measures the difference in ST changes. Absolute ST always measures from the PR-reference baseline, and does not consider the patient's normal ST level for each individual ECG lead.

8. The Gain Adjust box at the bottom of the screen allows you to adjust the gain for each channel individually. Click on the number of the channel you wish to adjust. Then click on the + box if you want to increase the gain. Clicking on the – box decreases the gain. After you have adjusted the gain for one channel, you may adjust it for the other channels, if needed. As you increase the gain, you will notice the beats on the screen of the channel you are adjusting get larger. If you decrease the gain, the beats on the screen for the channel you are adjusting will become smaller.

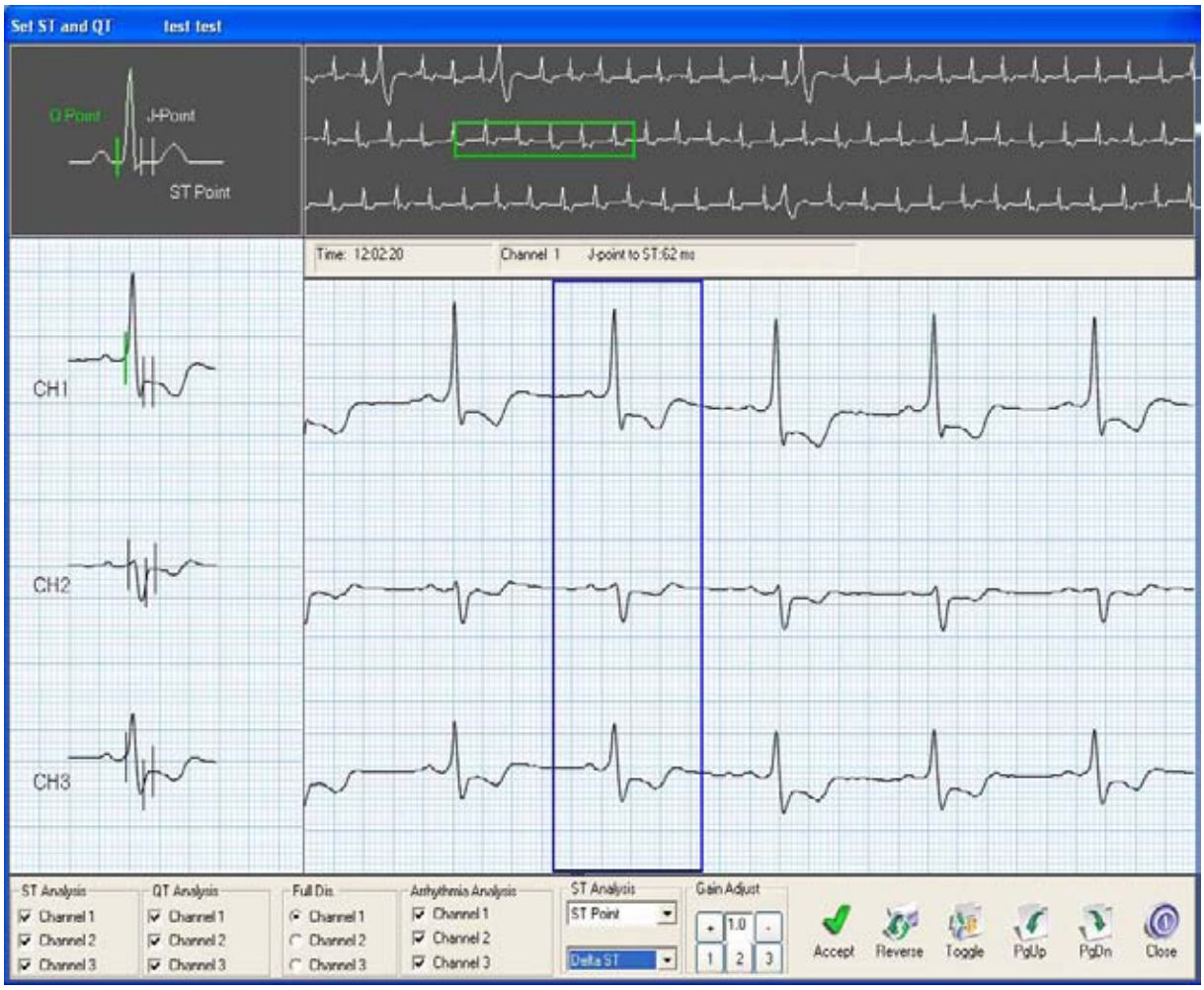
9. If any of the ECG channels has a reversed polarity because of improper electrode placement, click on the Reverse icon at the bottom of the screen before setting the markers on the beat. The polarity of the beat will be reversed.



EDIT ST-QT

1. Select the beat you wish to do your ST and QT measurements. To do this, point and click your mouse on the beat in the 1-minute strip at the top of your screen. The enlarged eight-second strip appears on the screen. If you desire another beat within this strip, point and click your mouse within the blue box on the enlarged eight-second strip. Drag and center the box over the beat you desire.

2. The green vertical marker is the active marker. The first vertical marker is for placement between the P-wave and R-wave. Use your right and left arrow keys on the keyboard to set this marker in place. Move the first vertical marker to the beginning of the Q-wave. Once in place, press the TAB key on your keyboard or mouse click on the Toggle icon at the bottom of the screen. The computer program uses the first marker at the beginning of the Q-wave to search prior to the first marker for a baseline PR location for the ST measurements.



3. The second vertical marker is for setting the J-Point. Find a spot where the QRS ends and then press the right arrow key once. Then press the TAB key on your keyboard or mouse click on the Toggle icon at the bottom of the screen to display the third vertical marker.

4. The third vertical marker is for setting the ST Point. Using your right and left arrow keys on your keyboard, move the marker to the right to set the sample point. Do not allow this marker to be at the beginning or the upslope of the T-wave. If necessary, keep moving left to avoid the T-wave, especially on the negative going QRS complexes. The ms distance from the J-Point to ST is displayed in the middle of the screen above the enlarged 8-second ECG strip. 62ms to 78ms is recommended.

After all the markers are placed in their desired locations, click on the Accept icon at the bottom of the screen OR press the F10 key on the keyboard. This will take you to Channel 2. Repeat the above process and do the same for Channel 3. After pressing the F10 key on Channel 3 or clicking on the Accept icon on Channel 3, this display will disappear and analysis will begin. If you have selected the Convert XYZ to 12 Leads option in the patient information setup screen, you will have 12 channels for your ST and QT to setup instead of the standard 3 channels.

NOTE: If you make an error on your ST setup and would like to go back and reset the markers, simply click on the 1, 2, or 3 in the Gain Adjust box. This will move the cursor to the appropriate channel (such as clicking on the 1 will give you the active cursors on Channel 1).

This screen is for visual information only. There are no operator functions to be performed with this screen display. Analysis of the Holter recording is now being performed. Depending on the speed of the computer, complete analysis for the 24-hour Holter ECG should be 10 to 30 seconds.

Once analysis is completed, you will be prompted to remove the SANDISK compact flash card from the ImageMate reader. The following screen will appear.

DATA ACCESS CHOICES (12-Lead Recordings)

This menu allows you to review, edit and process your Holter reports. The functions available are as follows:

Edit
Page Scan
Mega Scan
QT Validation
A-Fib/Flutter
HRV/HRT
ST Scan
FCG
ECG Strip
Hourly
Report
Re Analysis

To access one of these choices, point and click your mouse on the icon of the desired function.

At this time, point and click your mouse on the “Edit” icon.

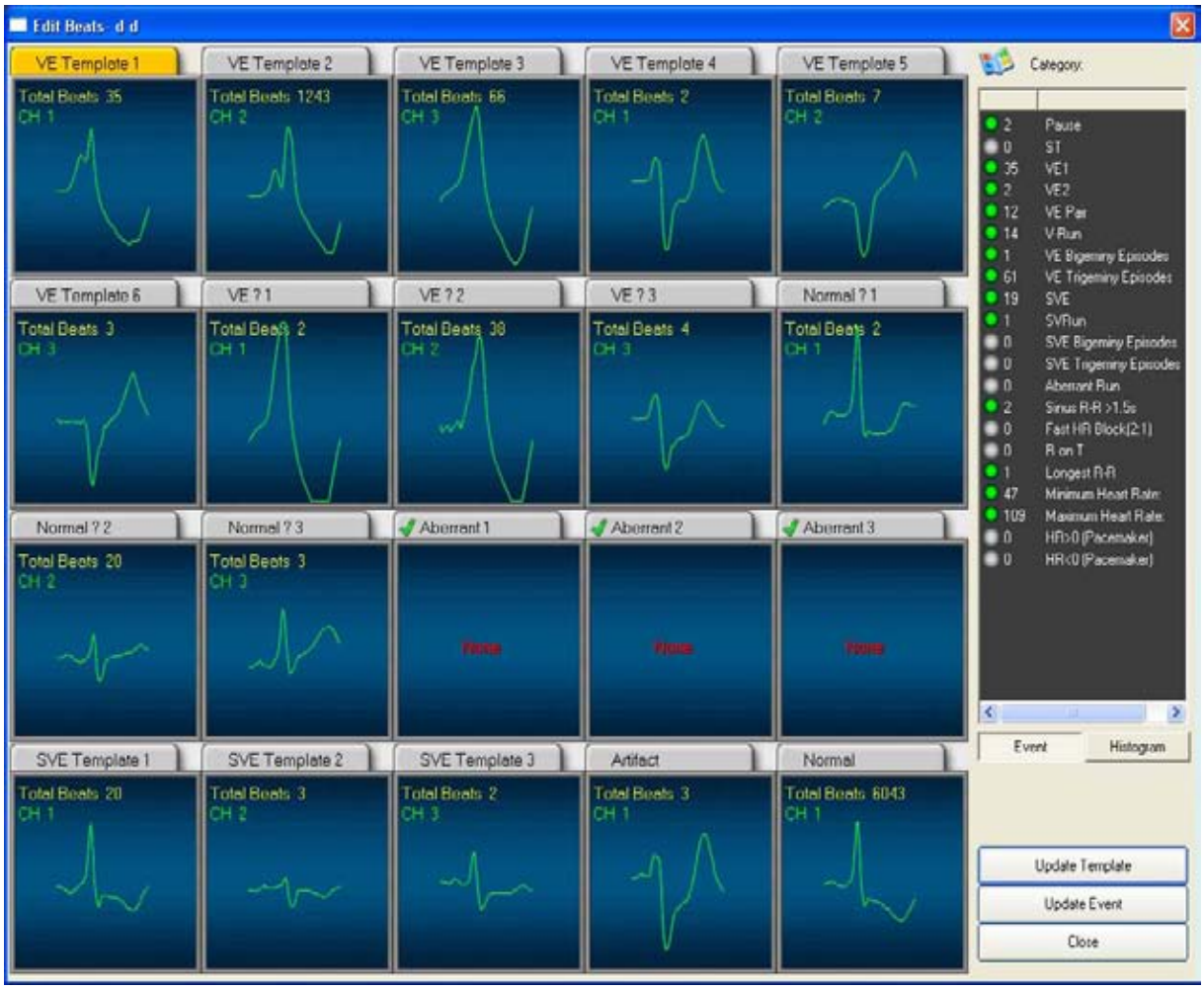
DATA ACCESS CHOICES (3-Lead Recordings)

This menu allows you to review, edit and process your Holter reports. The functions available are as follows:

Edit
Page Scan
Mega Scan
QT Validation
A-Fib/Flutter
HRV/HRT
ST Scan
ECG Strip
Hourly
SAECG&VCG
Report
Re Analysis

NOTE: You can do both the 3-Lead Analysis and the 12-Lead Analysis with the XYZ (Orthogonal) Hookup. On the first analysis pass you may do the 3-Lead Analysis to access the SAECG & VCG data access choices. On the second analysis pass you may do the conversion for the 12-Lead Analysis.

To access one of these choices, point and click your mouse on the icon of the desired function.



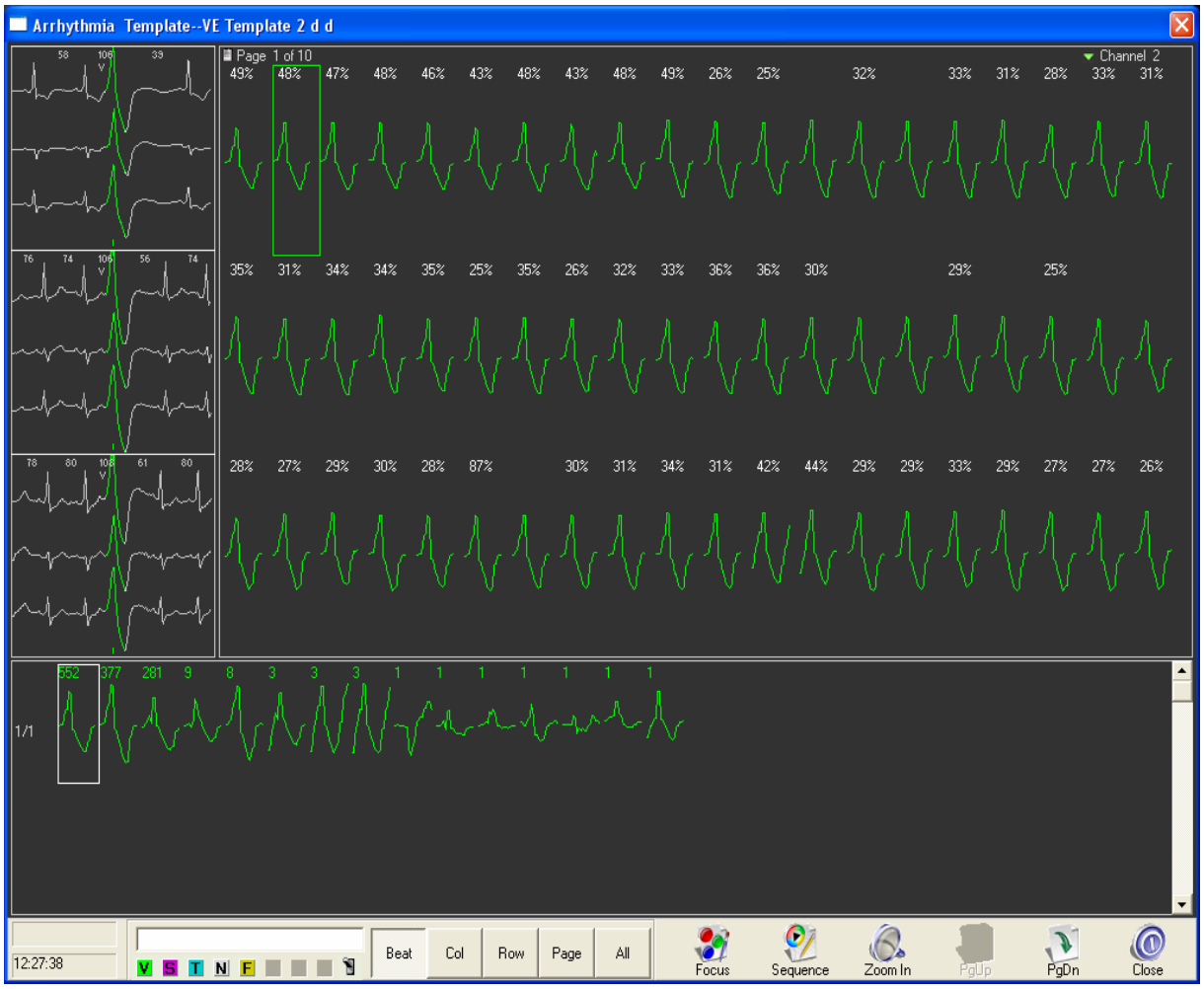
EDIT BEATS

The purpose of the Edit Beats display is for you to review and edit the various arrhythmia templates for VE, Aberrant, SVE and Normal beats. After you have completed the editing process, you can then review 8-second strips of a broad range of Abnormal ECG Events.

Twenty templates have been programmed for your review. VE 1 template looks for ventricular ectopic beats with a positive QRS in channel 1. VE 2 template looks for ventricular ectopic beats with a positive QRS in channel 2. VE 3 template looks for ventricular ectopic beats with a positive QRS in channel 3. VE 4 template looks for ventricular ectopic beats with a negative QRS in channel 1. VE 5 template looks for ventricular ectopic beats with a negative QRS in channel 2. VE 6 template looks for ventricular ectopic beats with a negative QRS in channel 3. VE?1 template looks for borderline ventricular ectopic beats with a negative or a positive QRS in channel 1. VE?2 template looks for borderline ventricular ectopic beats with a negative or a positive QRS in channel 2. VE?3 template looks for borderline ectopic beats with a negative or a positive QRS in channel 3. Normal?1 template looks for beats that are not quite borderline nor are they normal in channel 1. Normal?2 template looks for beats that are not quite borderline nor are they normal in channel 2. Normal ?3 template looks for beats that are not quite borderline nor are they normal in channel3. Aberrant 1 template looks for aberrant beats in channel 1. Aberrant 2 template looks for aberrant beats in channel 2. Aberrant 3 template looks for aberrant beats in channel 3.

Point and click your mouse to the first template with ECG data in its box OR press the ENTER key on the keyboard. This will be the template with the yellow box around it. In the above example, it would be VE Template 2. This will prompt a new screen display that shows all the beats assigned to that particular template.

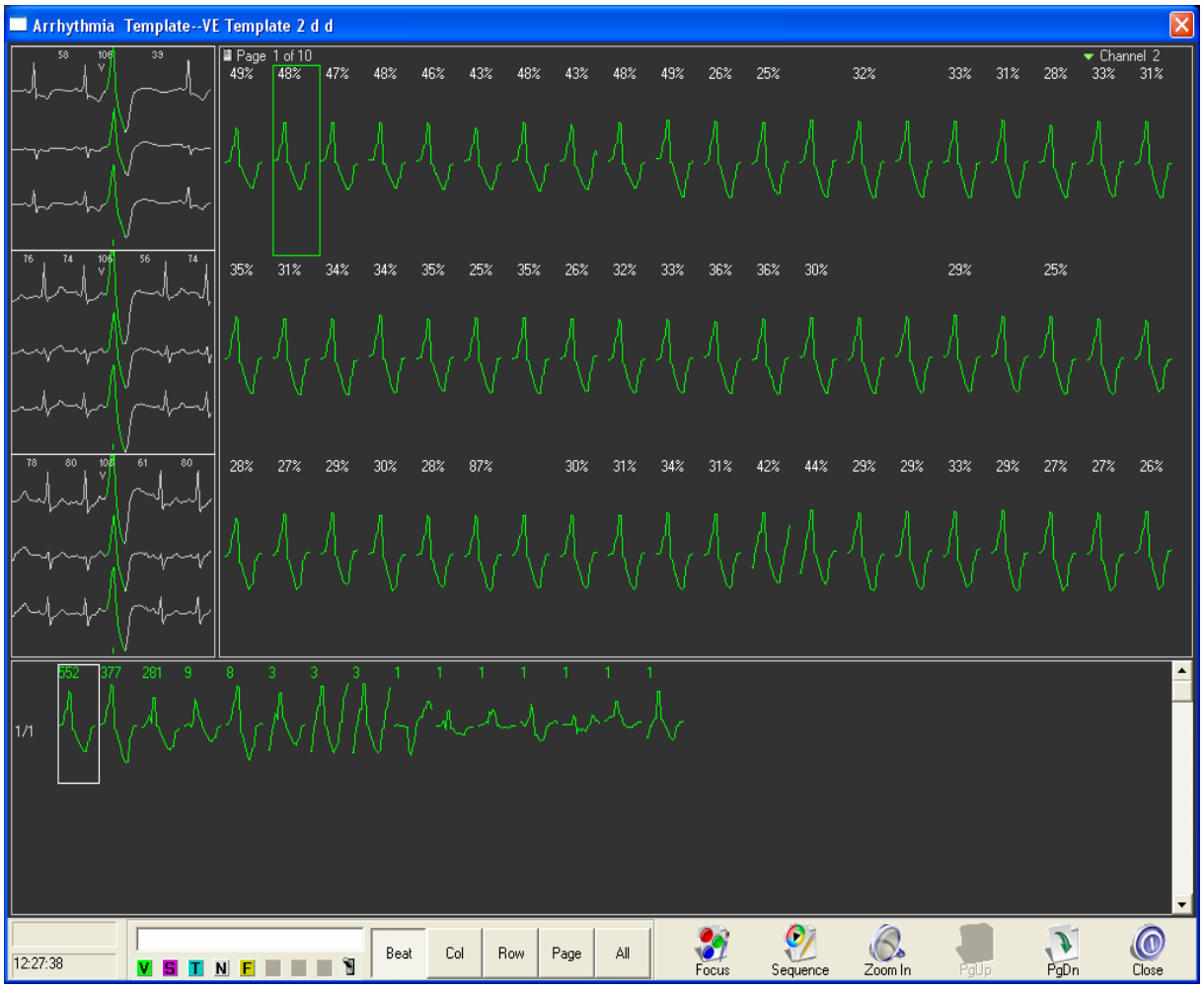
NOTE: Pressing the F1 key at any place in the program will automatically print out a page screen.



On the left side of the screen, you see a column of ECG strips. These strips correlate to the column of beats where the rectangular beat box is located. The beat in the column is the colored beat in the strip. As you move the beat box (either by mouse or by arrow key) across the different columns of beats, the strips will change accordingly.

Each beat is color coded per the “Color Panel” description at the bottom of the screen. The Label Code and Color Code for the beats are as follows:

LABEL CODE	**COLOR CODE**	**DESCRIPTION**
V	Green	Ventricular Ectopy
S	Magenta	Supra-Ventricular Ectopy
T	Blue	Aberrant
N	White	Normal
F	Yellow	Artifact



This screen shows the “Double Morphology” templates. The “Double Morphology” helps you edit entire morphologies in a quick and concise method.

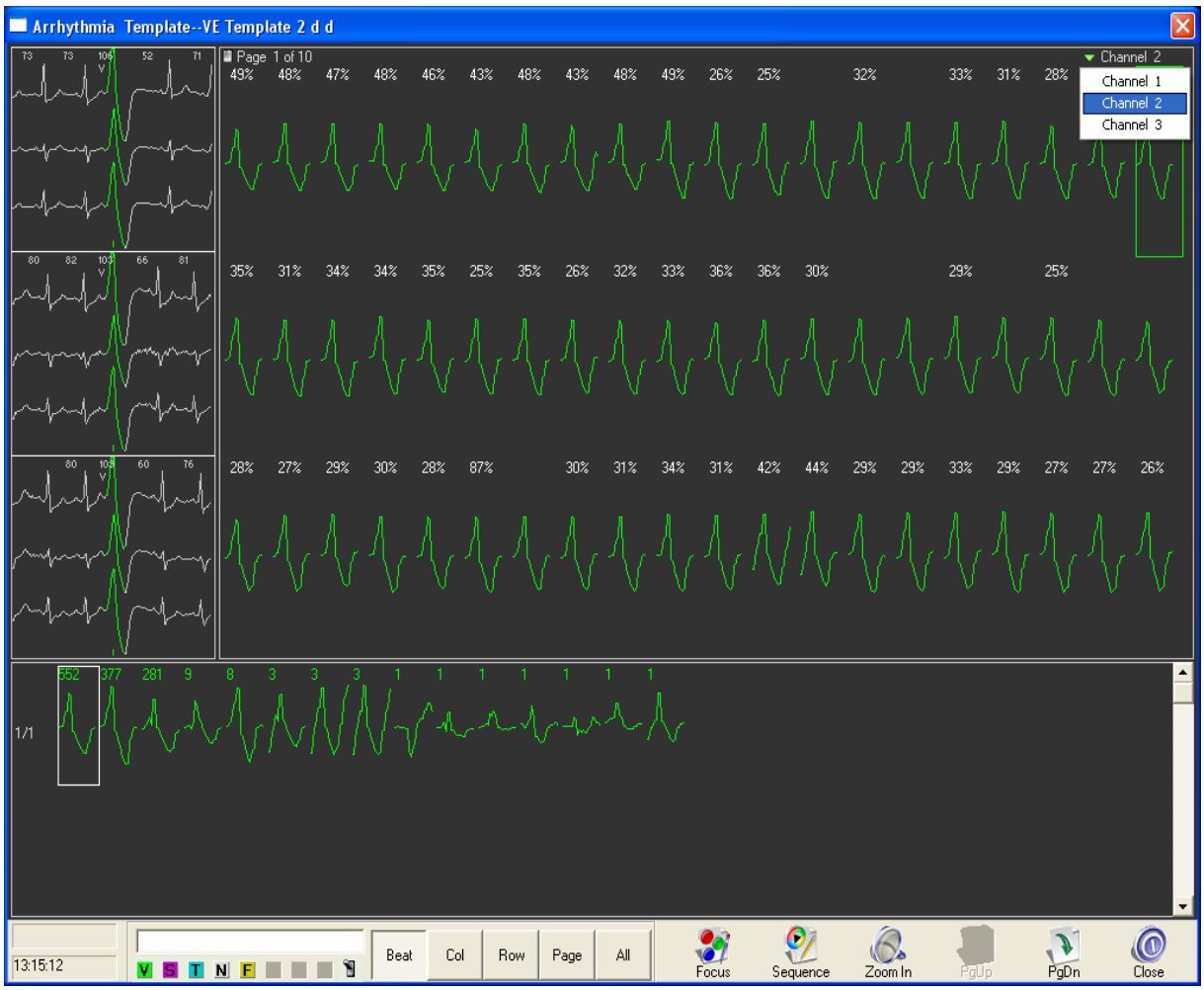
The first beat in the bottom half of the screen shows that there are 552 of this particular morphology in the template. There is no need to go through the viewing of all 552 beats, though if you choose to do so, you may look at the upper half of the screen and see the first 60 beats.

If you have more than 60 beats in a morphology template you may click on the PgDn icon at the bottom of the screen to move to a new page of beats. The top of the screen will show you which page you are viewing out of the total number of pages for this morphology.

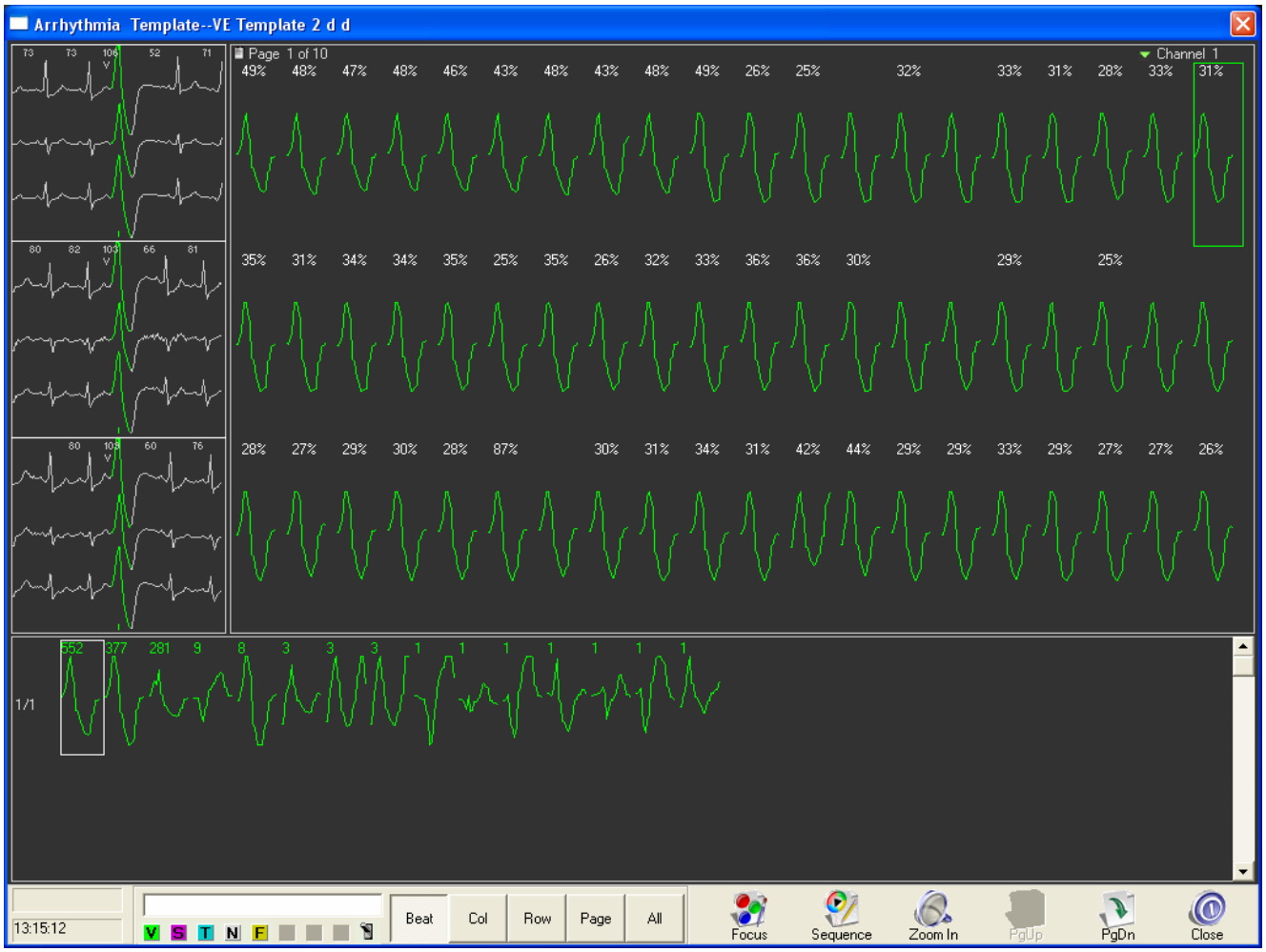
The number above each beat in the morphology indicates the pre-maturity level of the beat.

If you have more than two rows of morphology templates on the bottom of the screen, point and drag the mouse on the slide bar at the bottom right of the screen to see the remaining morphology templates.

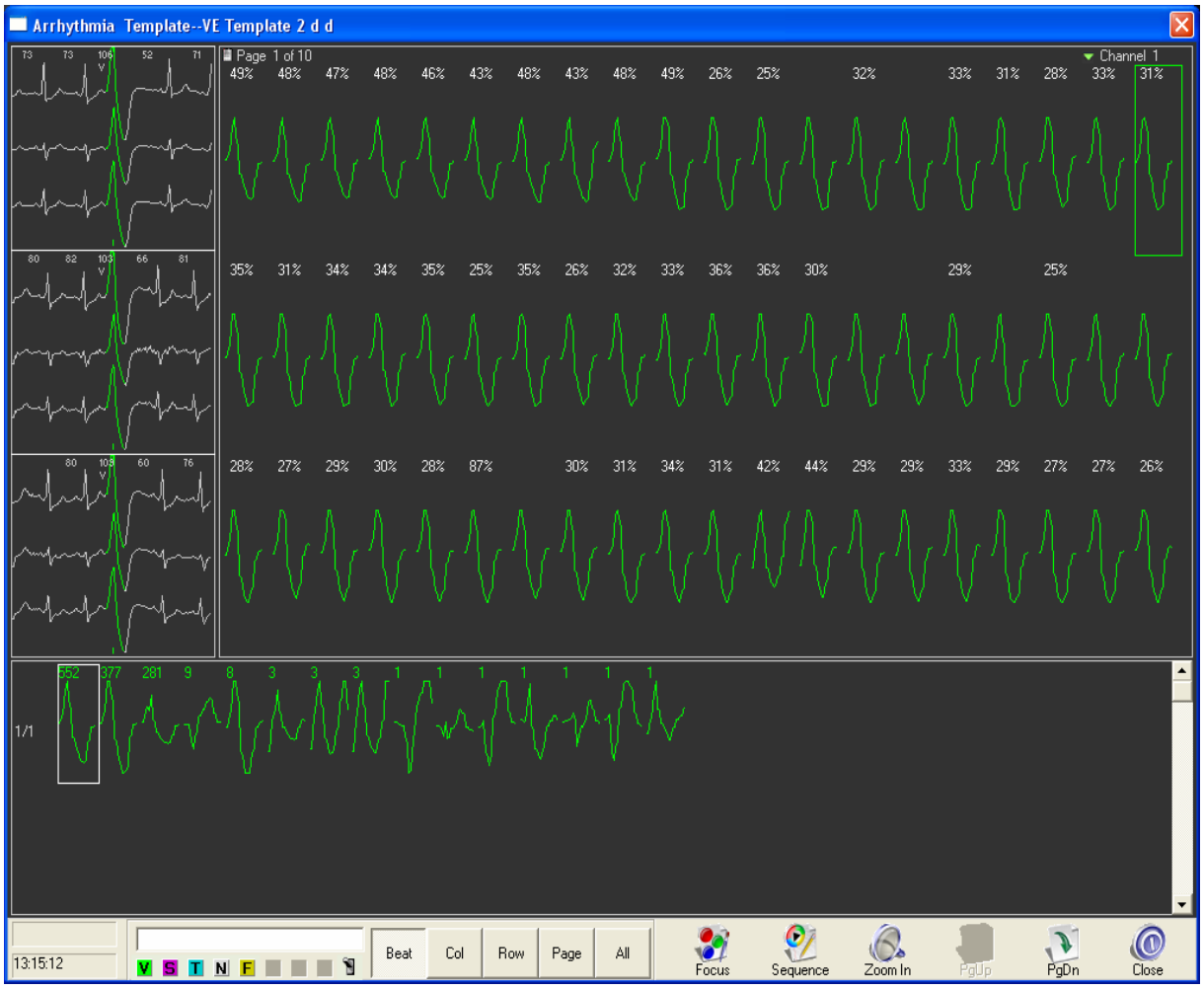
In the above example you are viewing beats from Channel 2. If you choose to view beats from another Channel, click on the Channel notation in the upper right hand corner of the screen.



A pop up box will appear. Scroll down and click on the channel you wish to view.



You will now view the beats in the channel you have selected. In our above example, we have selected Channel 1.



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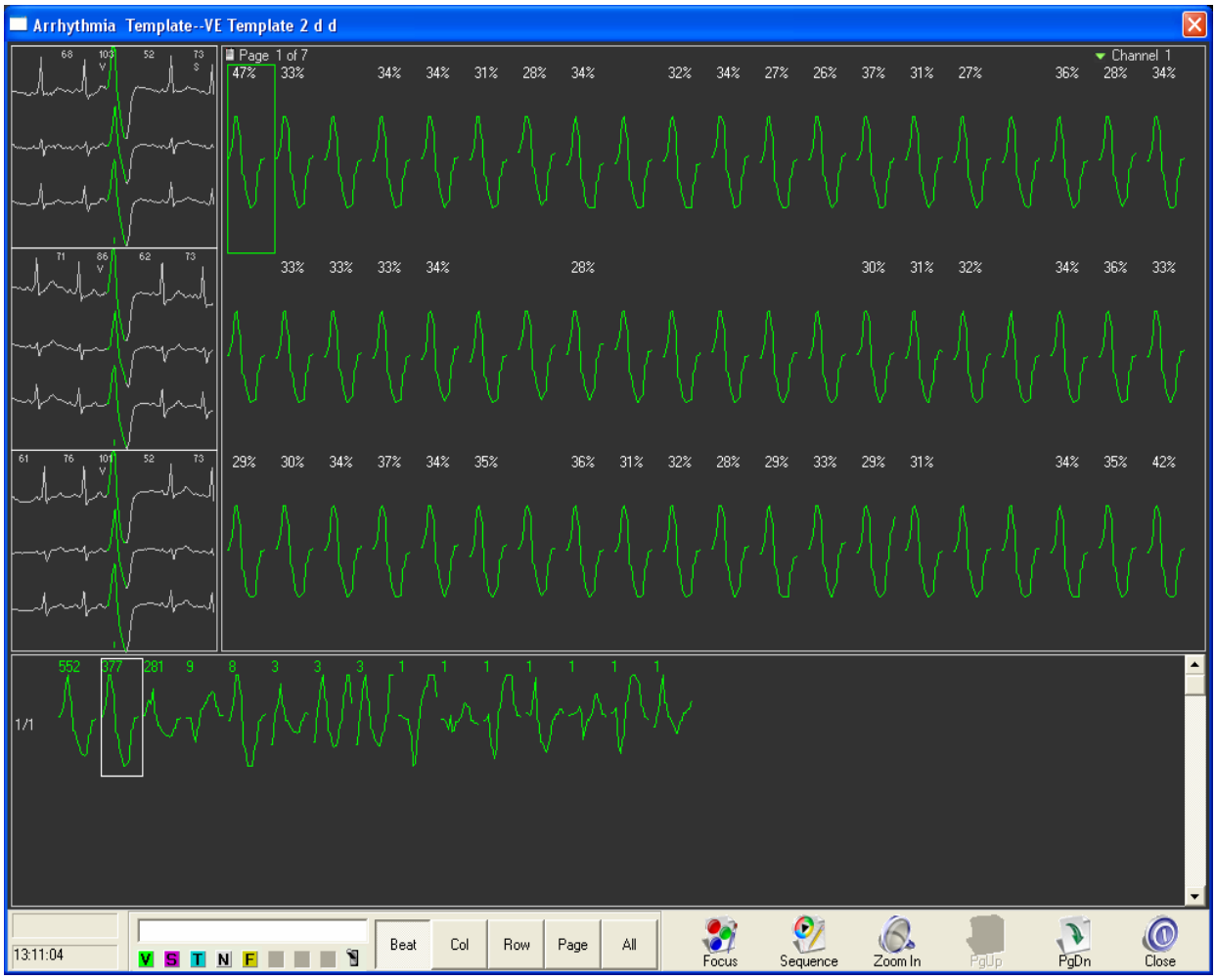
A total of 1243 VE beats were detected in this template. The bottom of the display shows the beats placed into 15 wave shapes (morphologies). 552 beats were placed in Template 1, 377 beats were placed in Template 2, 281 beats in Templates 3 etc.

The white rectangular box at the bottom shows the VE Template for the 552 VE beats above. To view the 377 beats Template 2, press the X key on the keyboard or point the mouse arrow and left click. To go back to the first 552 VE beats you may press the Z key on the keyboard or point the mouse arrow and left click.

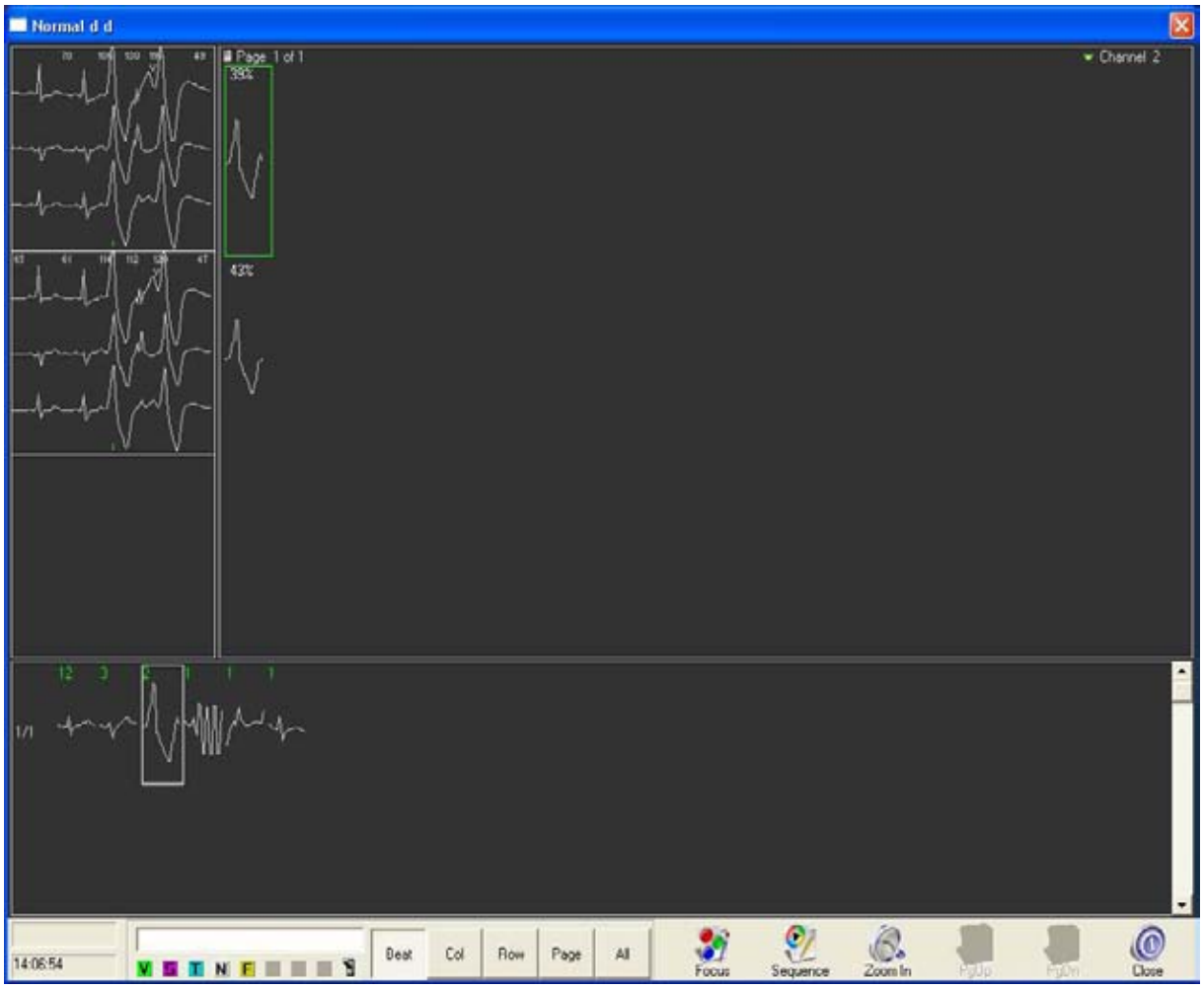


The white rectangular box has moved to Template 2 and the first 60 beats in the template are displayed on the screen.

The green box at the top of the display can be moved from beat-to-beat by the arrow keys on the keyboard or by pointing the mouse arrow on the beat and clicking.

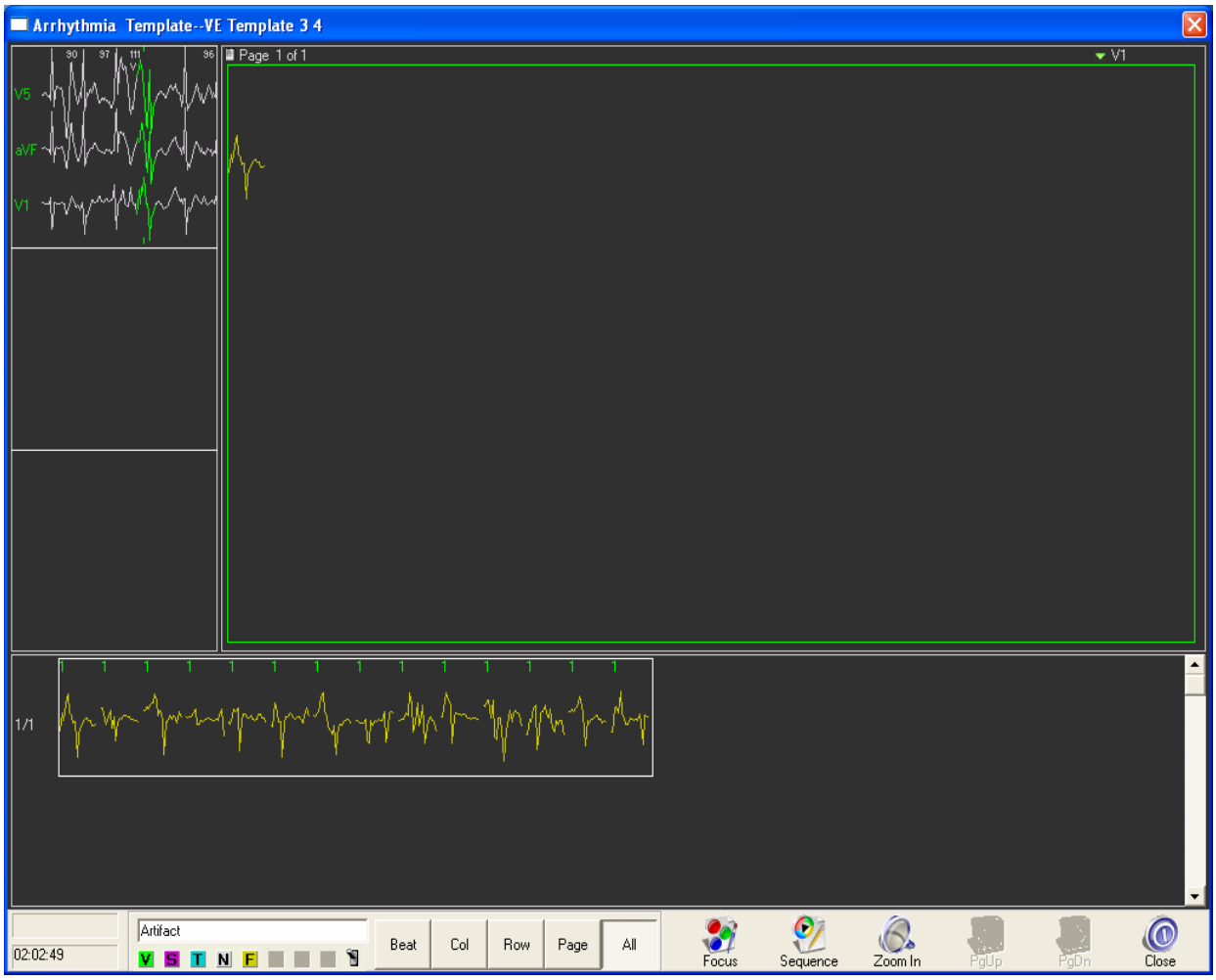
For quicker editing, you can look at the beats in the morphology templates on the lower half of the screen. You see that all the beats are highlighted green, so they are being counted as VEs. If you agree that these are all VEs, simply click on the CLOSE icon at the bottom of the screen or press the ESC key on the keyboard and move on to the next template to edit.

If you see a wave shape that is different, such as the 10th beat from the far right, point the mouse arrow on the wave shape and click. You can examine the beat in the template, but you will not need to use valuable time looking at the other templates.

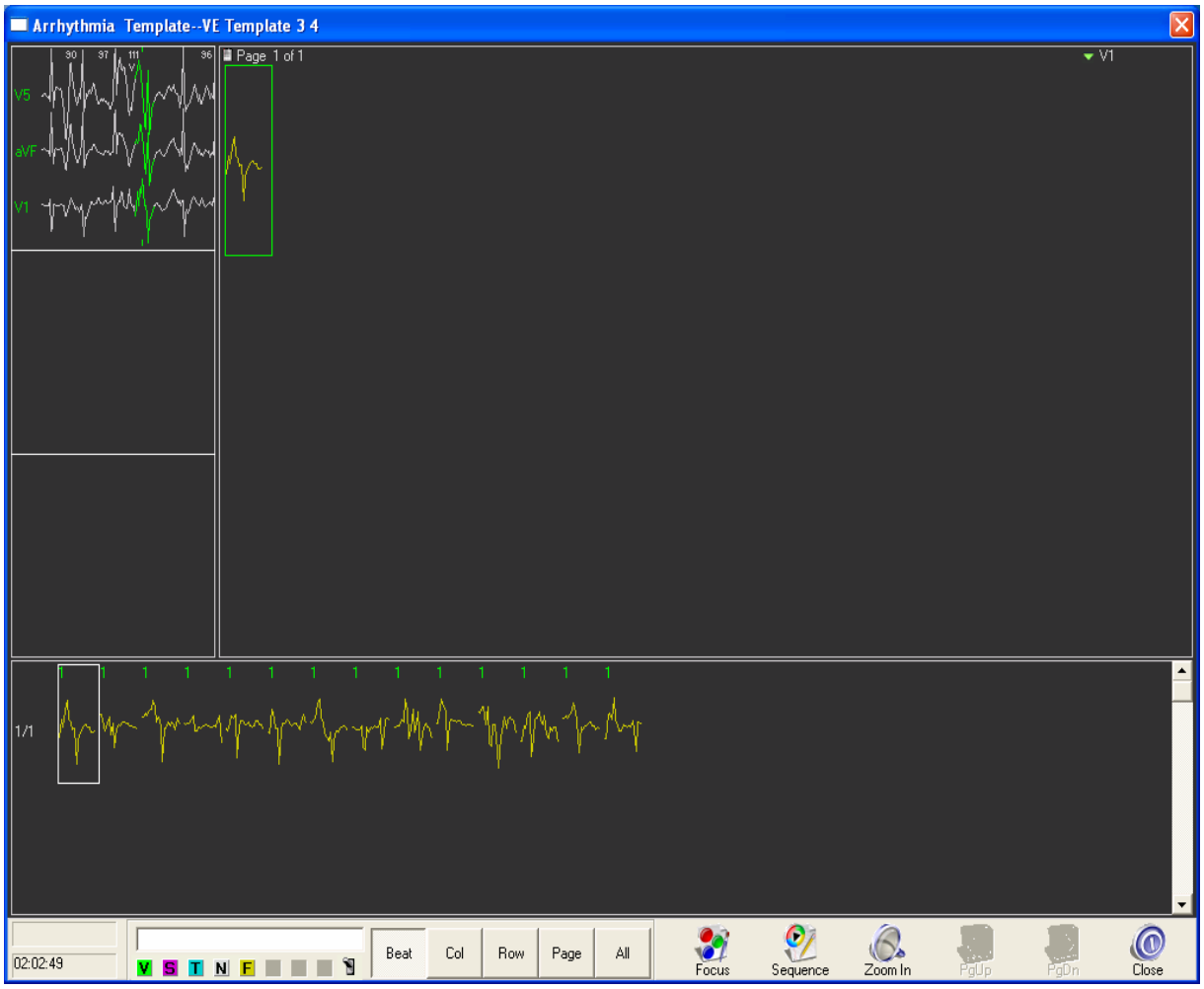


Above is an example of the Normal ?2 template. Visually you can see the third beat (going from left to right) have a strong possibility of being a VE. In our example we have clicked on the third beat and indeed it is a VE. You can easily change the beats in these two morphology templates without having to go through all the other beats in the template.

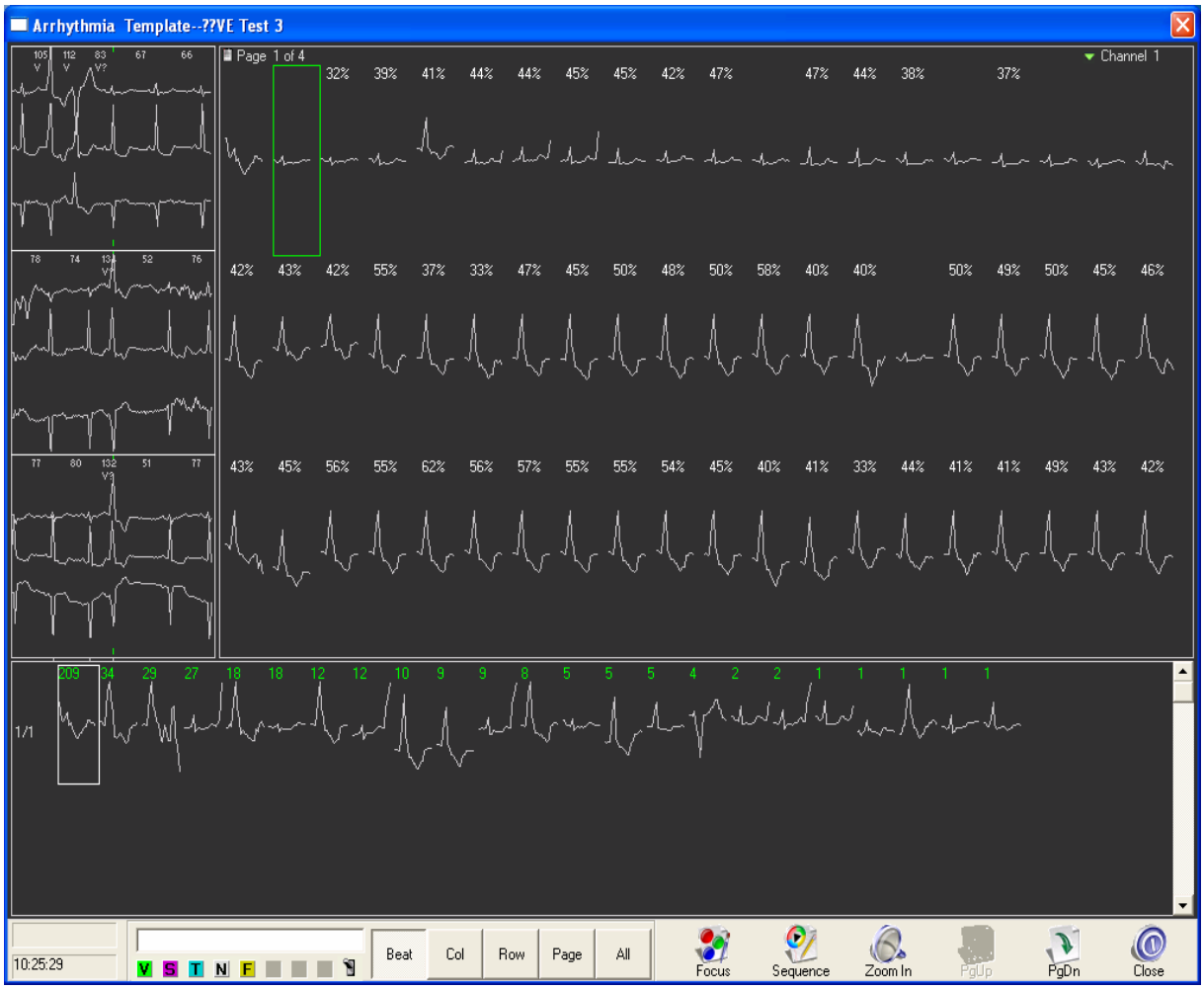
Above is an example of a VE template that is full of artifact. At first glance you can see that all the beats are obviously artifact. Instead of going through each beat in the template you may simply point the mouse arrow on the first wave shape in the lower half of the screen and drag the mouse to the end of the morphologies.



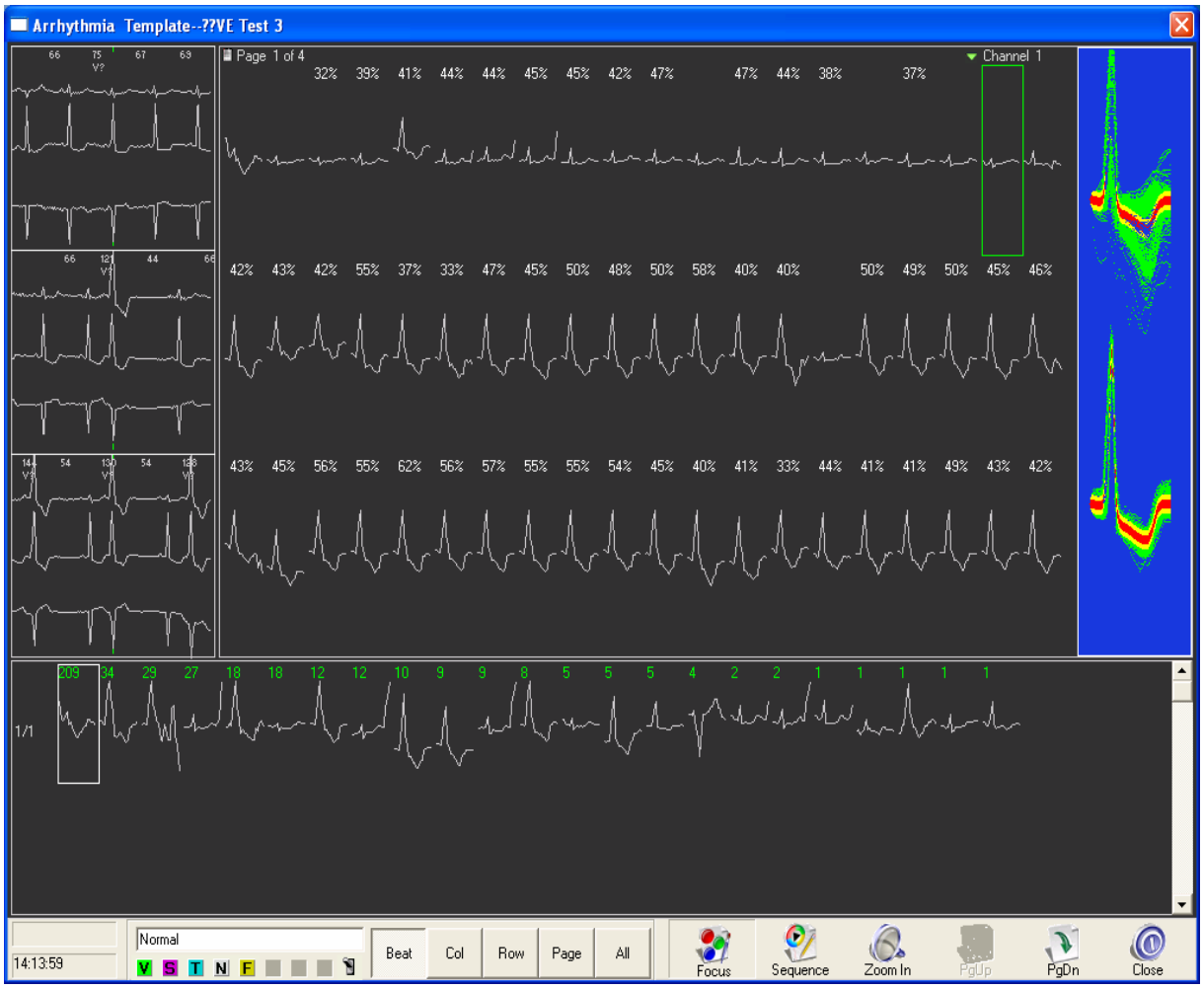
Click on the All box at the bottom of the screen and then the yellow F box and all the morphologies in the row will be noted as artifact (or you can press the A key and then the F key on the keyboard). Using this technique you can change all the morphologies in the templates without having to look at each individual beat.



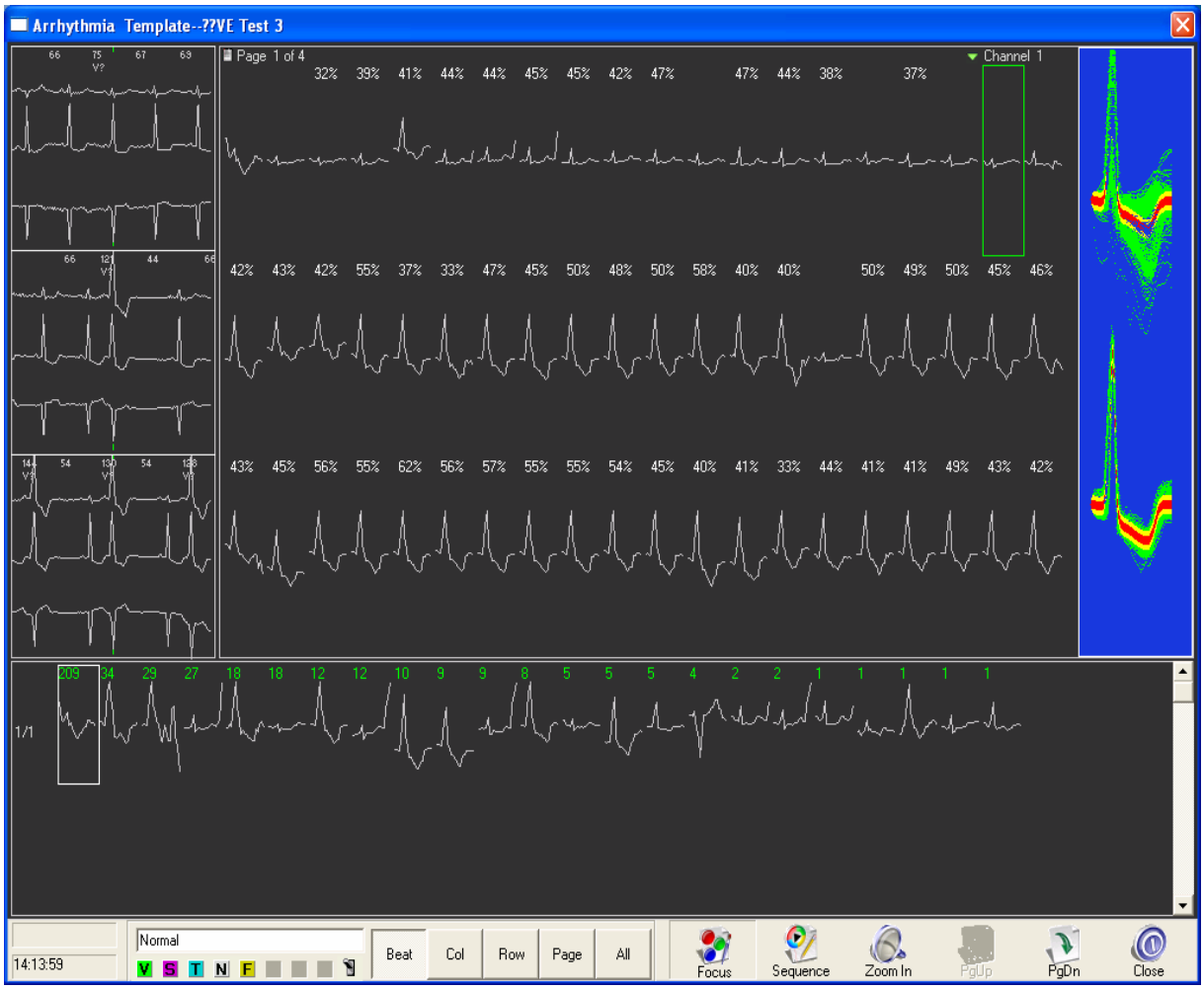
To change all of the morphologies in the entire template to artifact, simple click on the Toggle Switch Icon next to the beat box at the bottom of the screen. Click on the All icon box and click on the yellow F at the bottom of the screen (or you can press the A key followed by the F key on the keyboard).



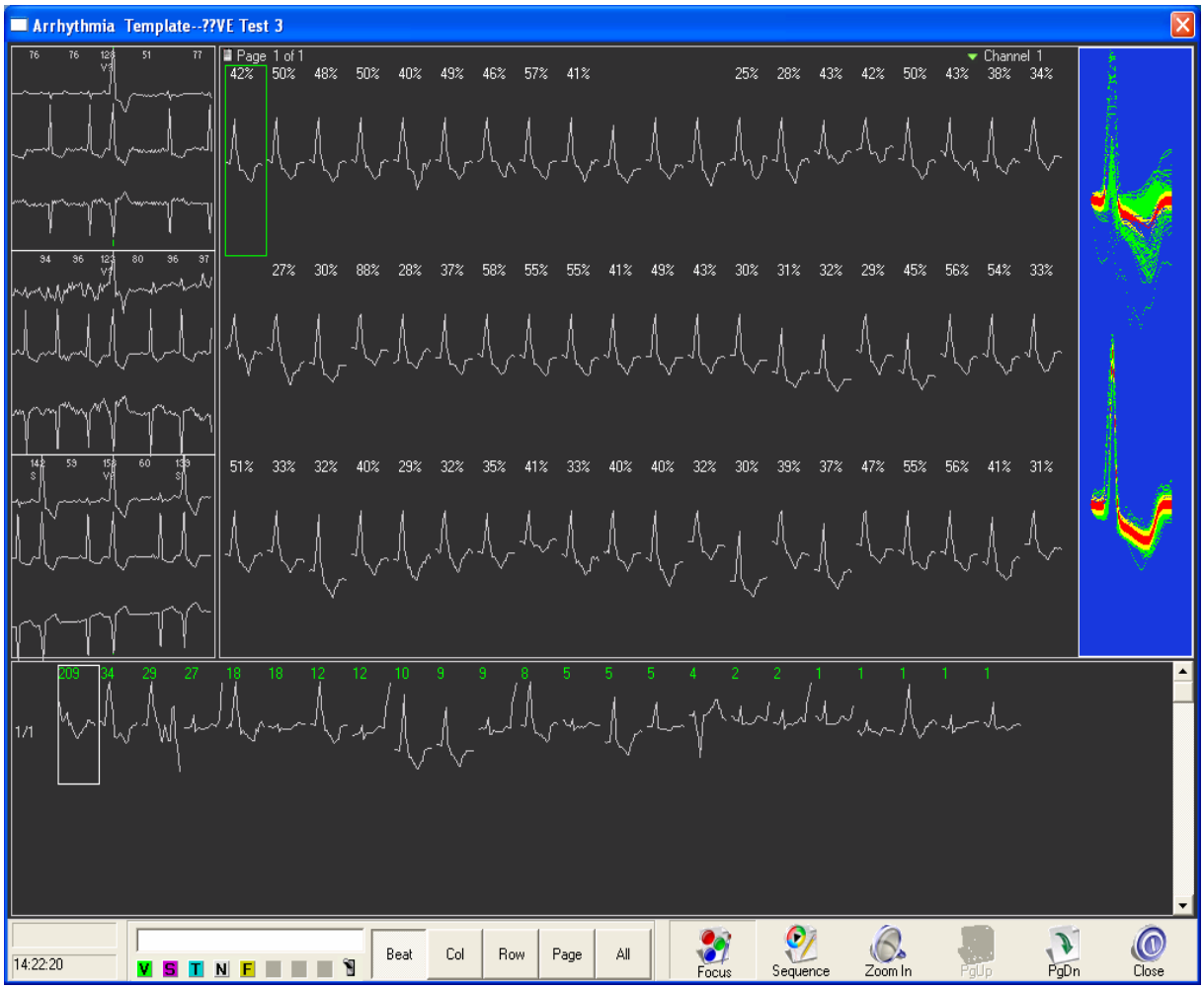
The Focus tool allows you to trace an outline of an abnormal beat and leave only beats in the sub-template that match it exactly as drawn. This is especially useful when you have a subtemplate of mixed morphologies, as above.



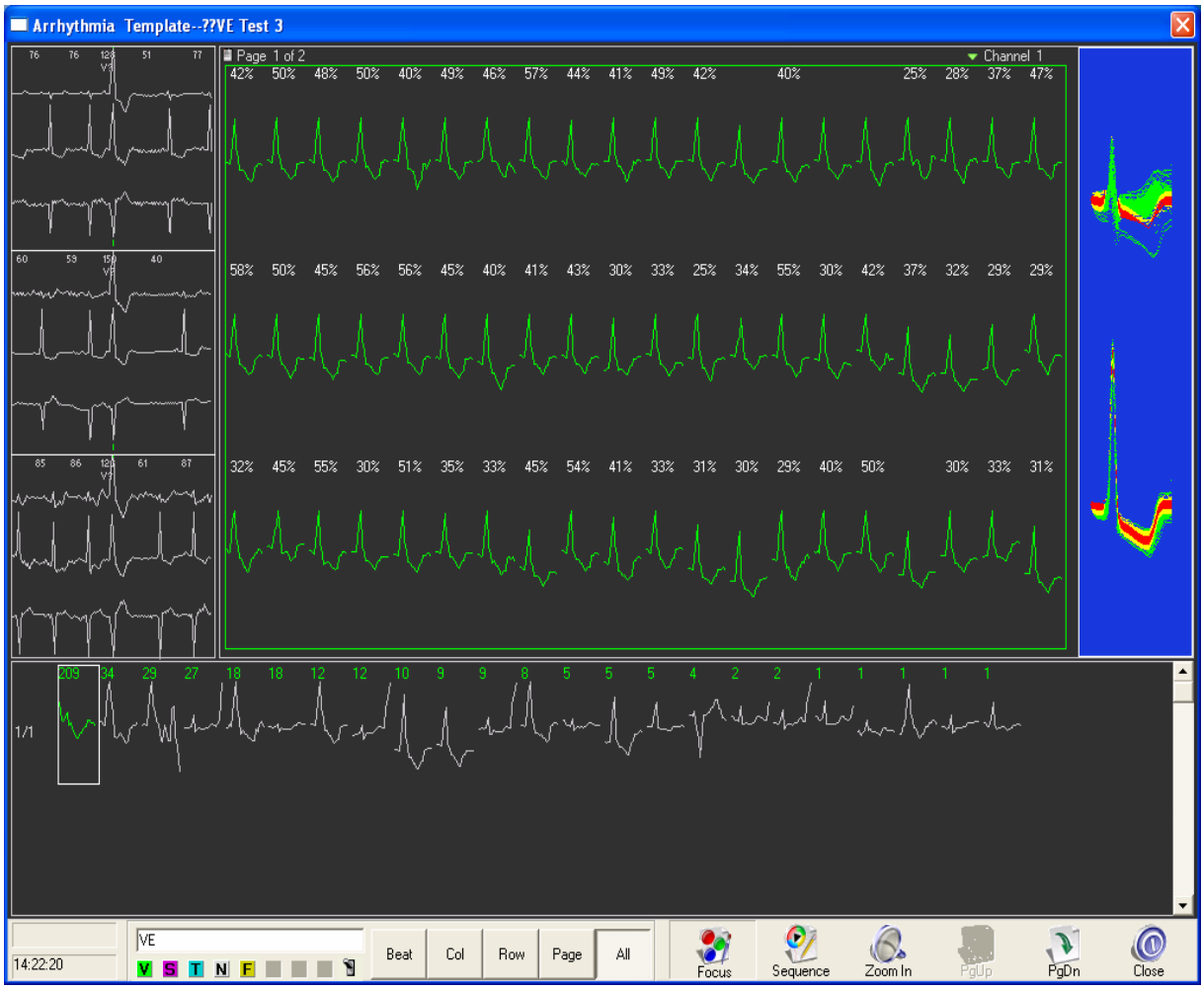
Click on the Focus icon. A blue screen will appear on the upper right side of the screen. Notice the two beats. As we are looking at beats in Channel 1, the top beat is Channel 1 and the lower beat is Channel 2. If you wish to change the beats in the blue screen, point the mouse to the line next to the blue screen (in our example, it says Channel 1). Click on the down arrow and select the channel you want to view. If you select Channel 3, the beats in the blue screen will be Channel 3 and Channel 1, if you select Channel 2, the beats in the blue screen will be Channel 2 and Channel 3.



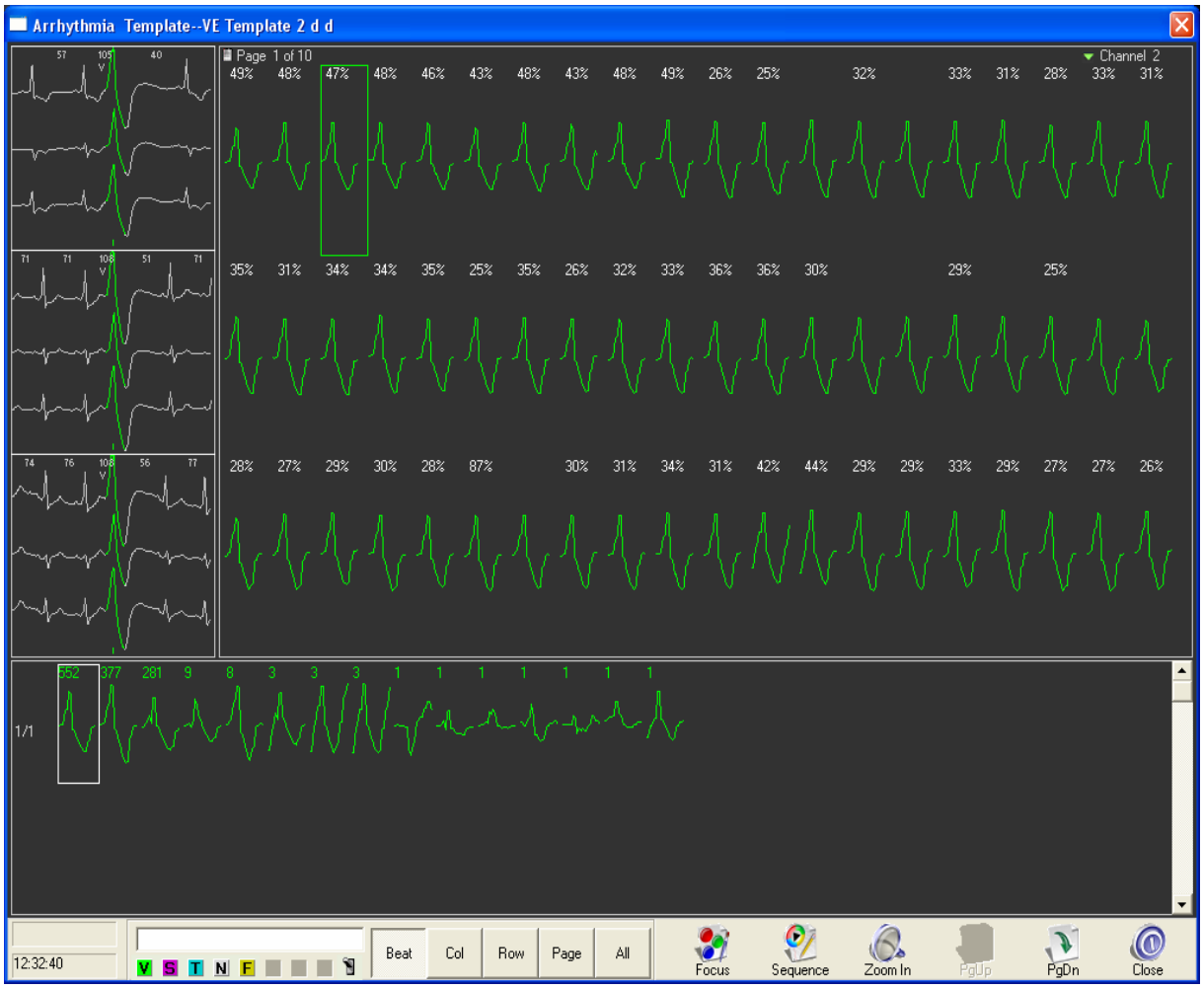
To use the Focus tool, point and click on the outline of the shape of an abnormal beat. In our example, you would want to trace the outline of the large beat, as these are the VE beats. As you click on the outline you will see beats added and removed in the sub-template.



The beats left in the sub-template are meets that match exactly the outline you have traced by your clicking. In our example above, you can see that only VE beats are in the sub-template.



Once you have completed the outline, you can label all of the beats in the sub-template. In the above example we have labeled them all as VEs.

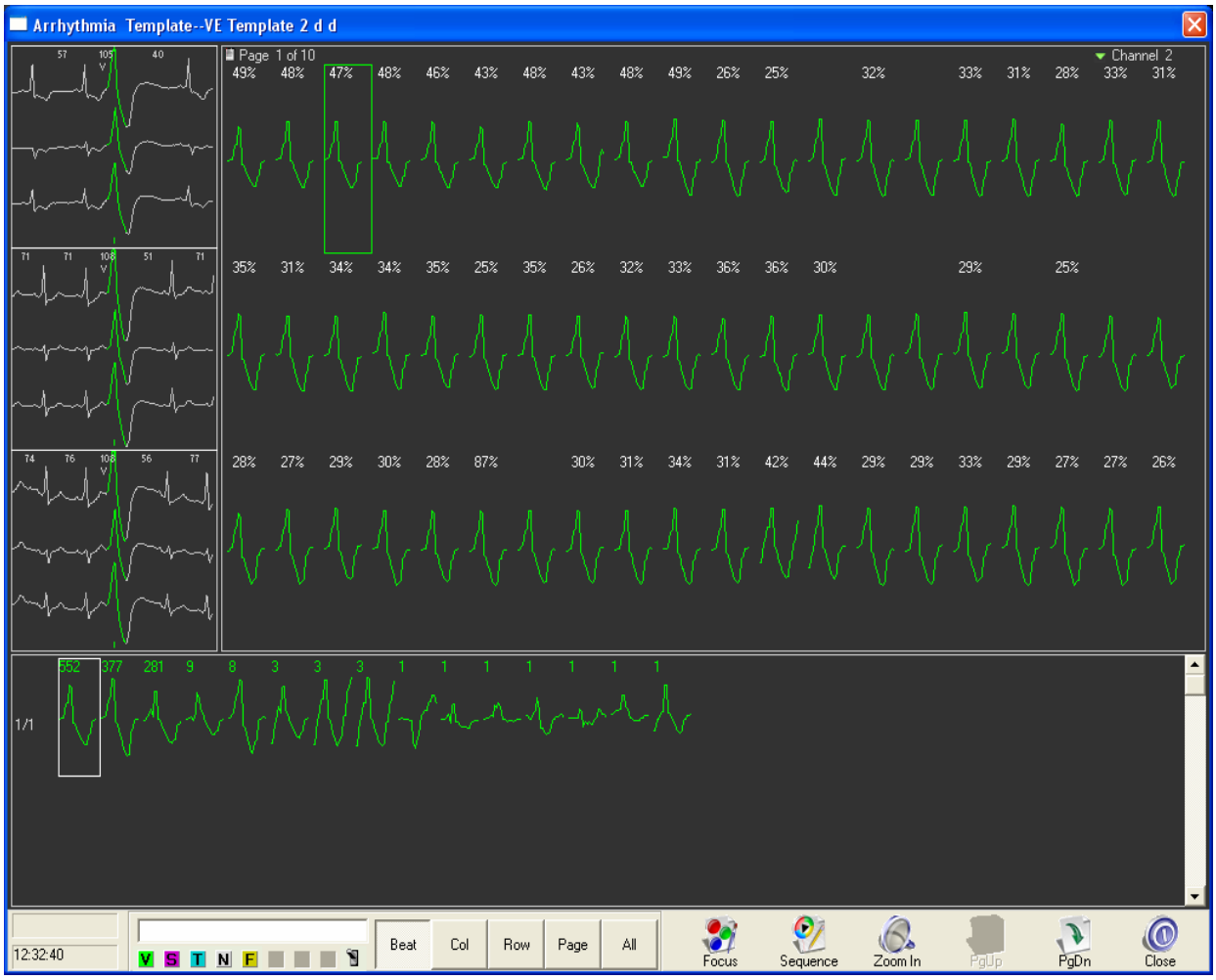


To edit a beat individually, move the beat box to the beat, using the mouse or arrow key. If you use the arrow key, move the cursor to the beat box. Using the mouse, point and click on the beat desired. Click on the appropriate label code (V, S, T, N, or F) at the bottom of the screen for the beat OR you may press the corresponding letter from the label code on your keyboard.

To edit a column of beats at one time, click on the COL button at the bottom of the screen or press the ALT key and the letter C key on the keyboard. A rectangular box going the length of the column will appear. You may move the column cursor using the right and left arrow keys on the keyboard. Click on the appropriate label code (V, S, T, N, or F) at the bottom of the screen for the column of beats OR you may press the corresponding letter from the label code on your keyboard.

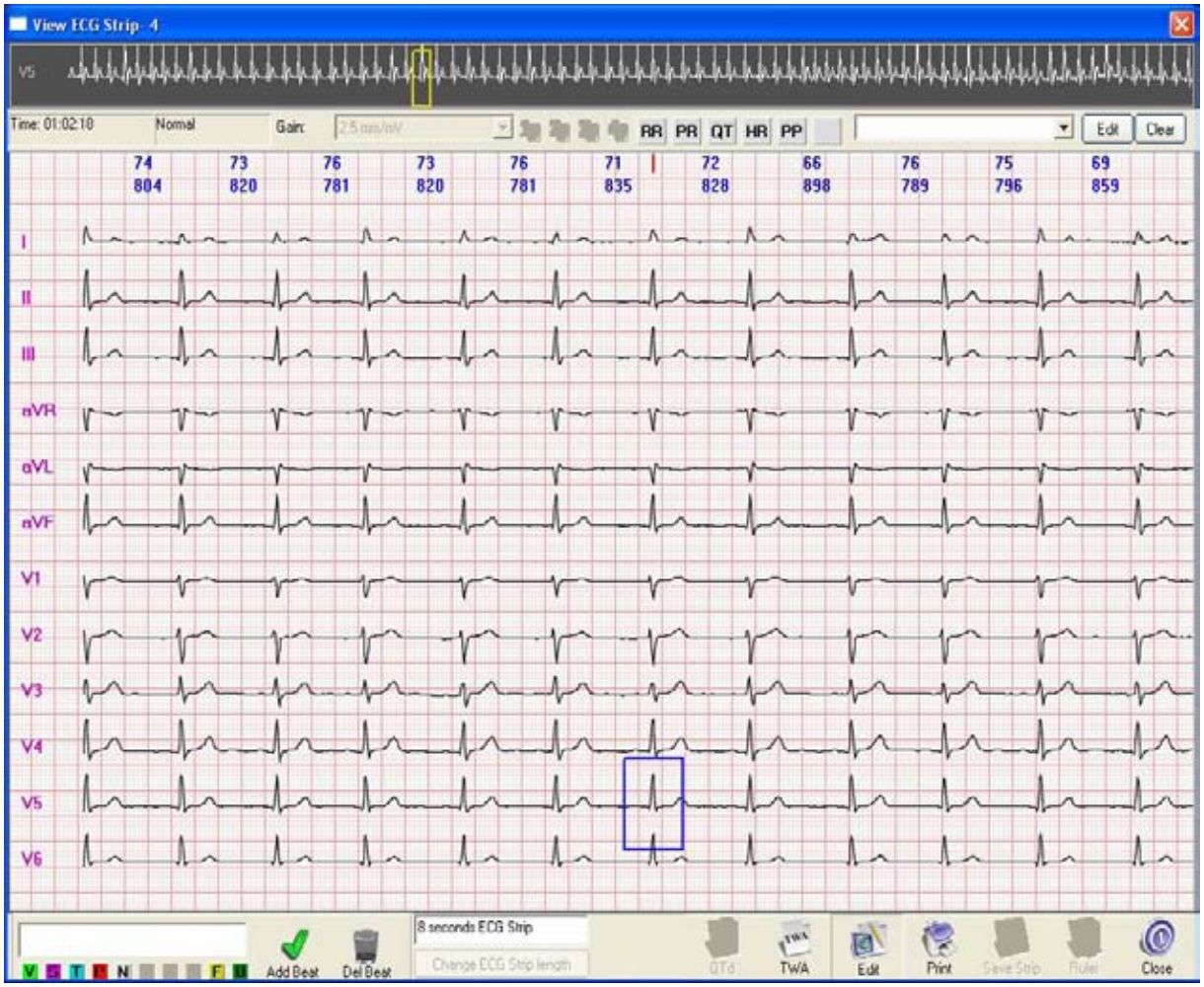
To edit a row of beats at one time, click on the ROW button at the bottom of the screen or press the ALT key and the letter R key on the keyboard. A rectangular box going the length of the row will appear. You may move the column cursor using the right and left arrow keys on the keyboard. Click on the appropriate label code (V, S, T, N or F) at the bottom of the screen for the row of beats OR you may press the corresponding letter from the label code on your keyboard.

To edit a page of beats at one time, click on the PAGE button at the bottom of the screen or the ALT key and the letter P key on the keyboard. A rectangular box will surround all of the beats on the screen. Click on the appropriate label code (V, S, T, N or F) at the bottom of the screen for the row of beats OR you may press the corresponding letter from the label code on your keyboard.



To edit all of the beats in a template at one time, click on the ALL button on the bottom of the screen or press the ALT key and the letter A key on the keyboard. Then click on the appropriate label code (V, S, T, N, or F) at the bottom of the screen OR you may press the corresponding letter from the label code on your keyboard.

To sequence through each beat in a template, point and click on the SEQUENCE icon at the bottom of the screen or press the Q key on the keyboard. The following screen will appear.



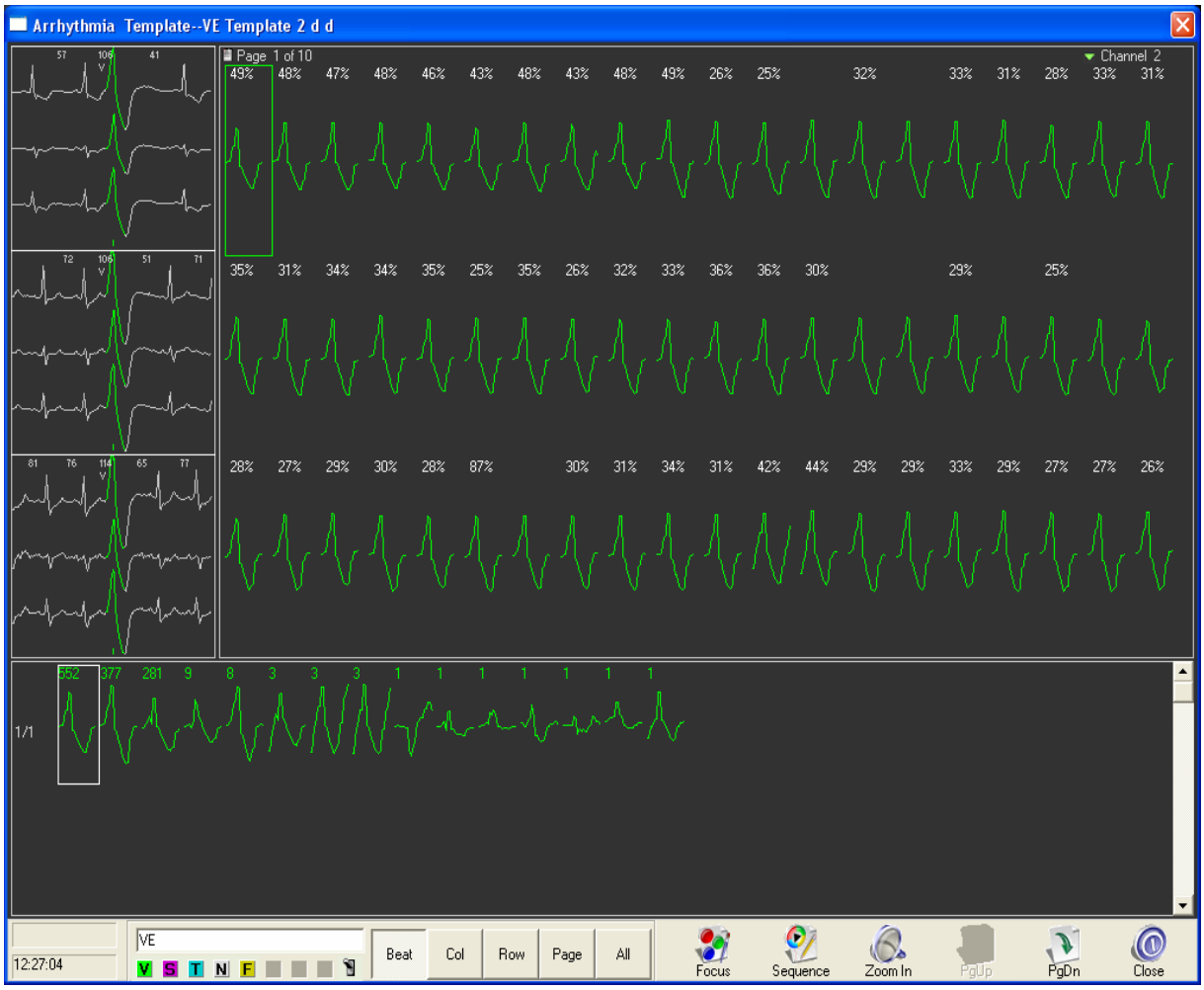
The first beat in the template will be shown to you in an enlarged eight-second strip (the above example is a 12-Lead ECG display). The beat with the blue box around it is the beat in the template.

NOTE:

1. If you use the Sequence function, a blue box will appear around a beat. The beat the box is around is the beat from the template.
2. If you double clicked the mouse on the beat in the template, ore pressed the ENTER key or clicked on the ZOOM icon, you will be taken to the enlarged 8-second strip. Once at the strip, you must right click the mouse. Then a blue box will appear around the beat that is the beat from the template.

Point and click your mouse on the appropriate label code for the beat in the blue box OR type the corresponding letter on your keyboard for the appropriate label code. After labeling the beat, the system will take you to the next beat in the template and it will be shown to you in the enlarged eight-second format. Continue labeling the beats until you have sequenced through all of the beats in the template. When you have finished sequencing through the beats, you will be returned to the following screen.

If you are processing the patient's ECG data in a 3-channel mode, the strip you will see will be a three channel strip like the one above.

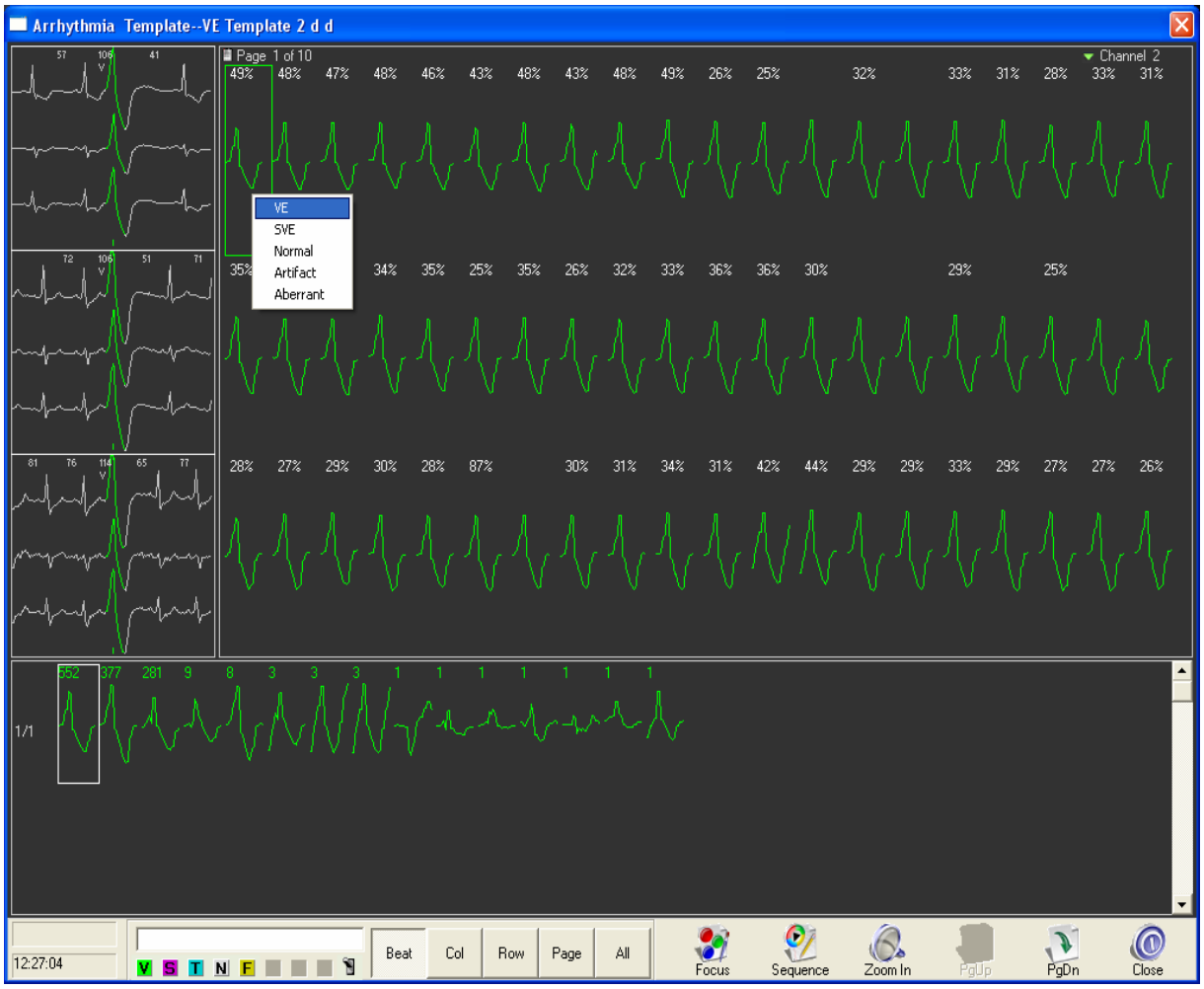


To view a beat in an enlarged eight-second strip, point and double click on the beat with your mouse or press the ENTER key. Also, you may click on the ZOOM IN icon at the bottom of the screen OR press the enter key. The eight-second strip with the beat you are viewing will appear on the screen.

If you have numerous pages of beats in your template, you may click on the Page Up or Page Down icons at the bottom of the screen OR press the Page Up or Page Down keys on your keyboard. If you look at the bottom left of the screen, you will see how many pages of beats are in the template.

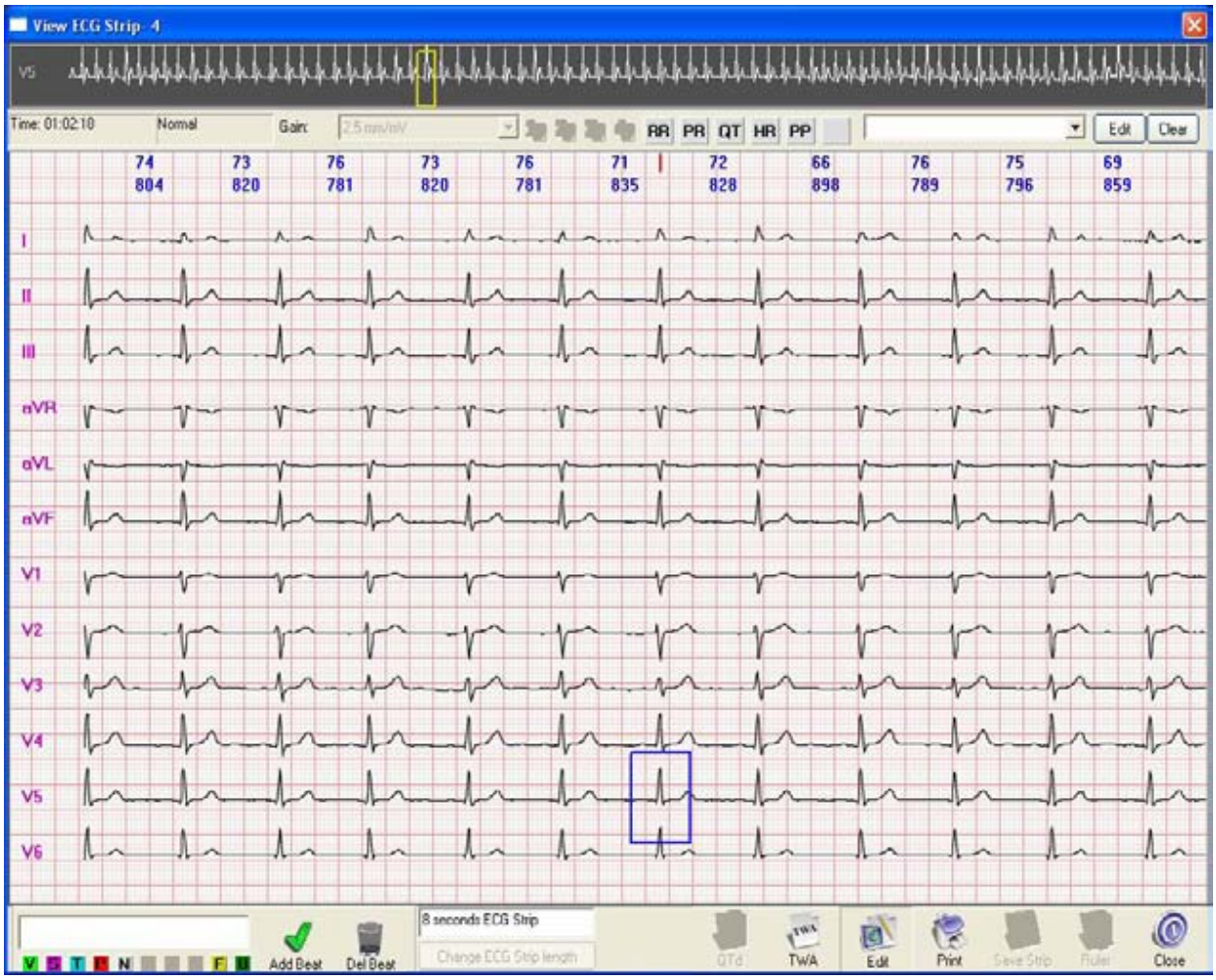
If you have a large number of pages (such as 34), you can get to the last page quickly by pressing and holding down the Page Down key on the keyboard. Most editing is done at the beginning and ending beats in a template.

When you have completed editing all of the beats in the template, click on the CLOSE icon at the bottom of the screen.



An additional aid to editing an individual beat is to point and click your mouse on the desired beat. This will move the rectangular box around the desired beat.

Right click with your mouse and a pull down menu will appear with various beat labels. Move the mouse arrow to the desired label and click. The beat has been labeled and edited.



There are 3 different ways to enlarge an individual beat.

1. Double click on the beat.
2. Move the beat box to the desired beat with the arrow key and press the ENTER key on your keyboard.
3. Point and click with your mouse on the desired beat. Click on the ZOOM IN icon at the bottom of your screen.

The beat with the red mark above it indicates the beat that is being edited in this template.

To immediately print the strip, click on the PRINT icon at the bottom of the screen.

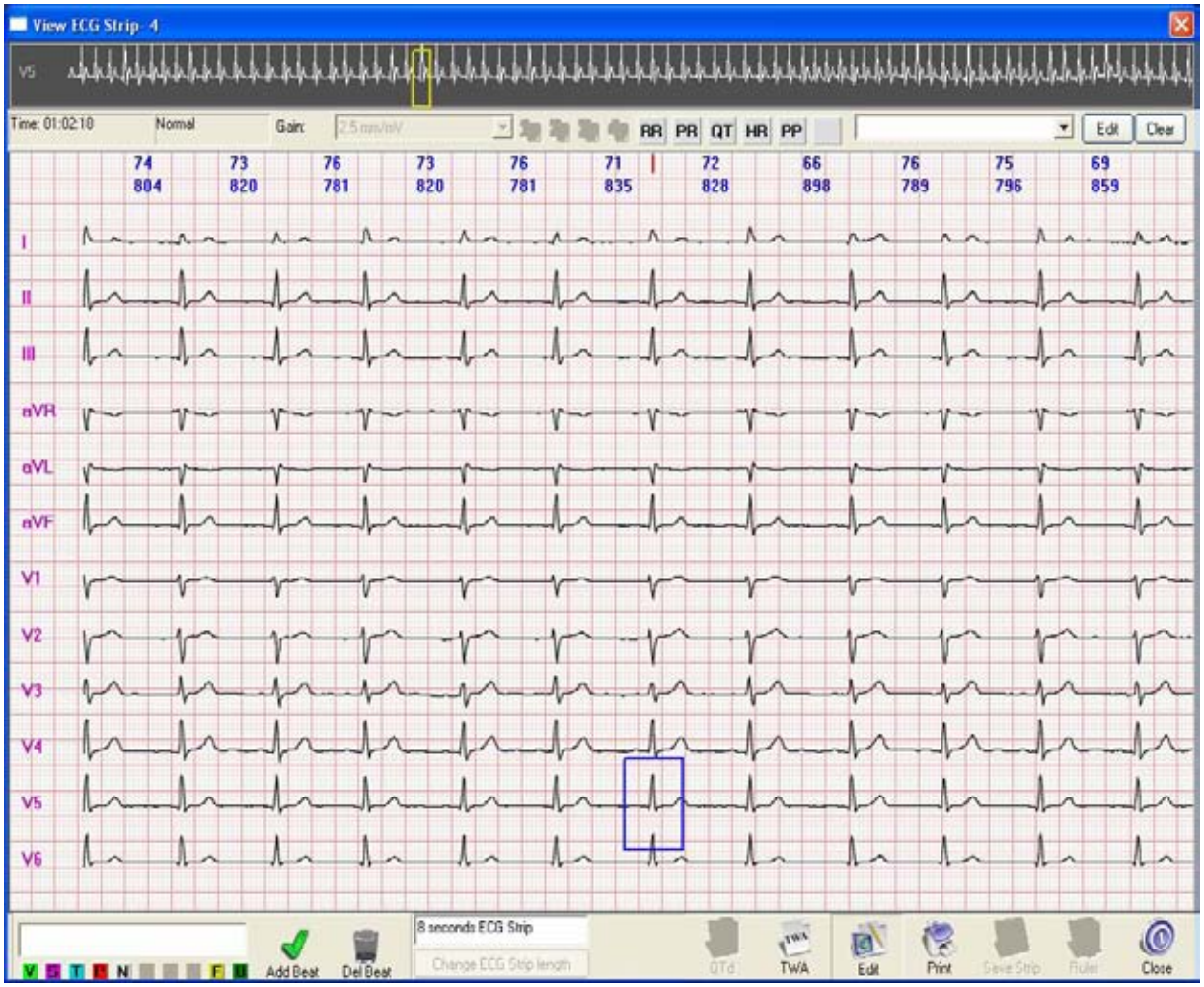
NOTE: If you are using the 3 channel analysis, a pop up window will appear and ask you if you want a 3 lead or a 12 lead strip. Click on the option you desire. If you select 3 lead, a 24-second ECG will be printed, with the desired 8-second strip in the middle of the page print. If you select 12 lead, an 8 second strip will print.

NOTE: If you are using the 12 channel analysis an 8 second strip will print.

To save the strip to print out later with the report, click on the SAVE STRIP icon at the bottom of the screen.

To edit a beat in the eight-second strip, please refer to the next page for instructions.

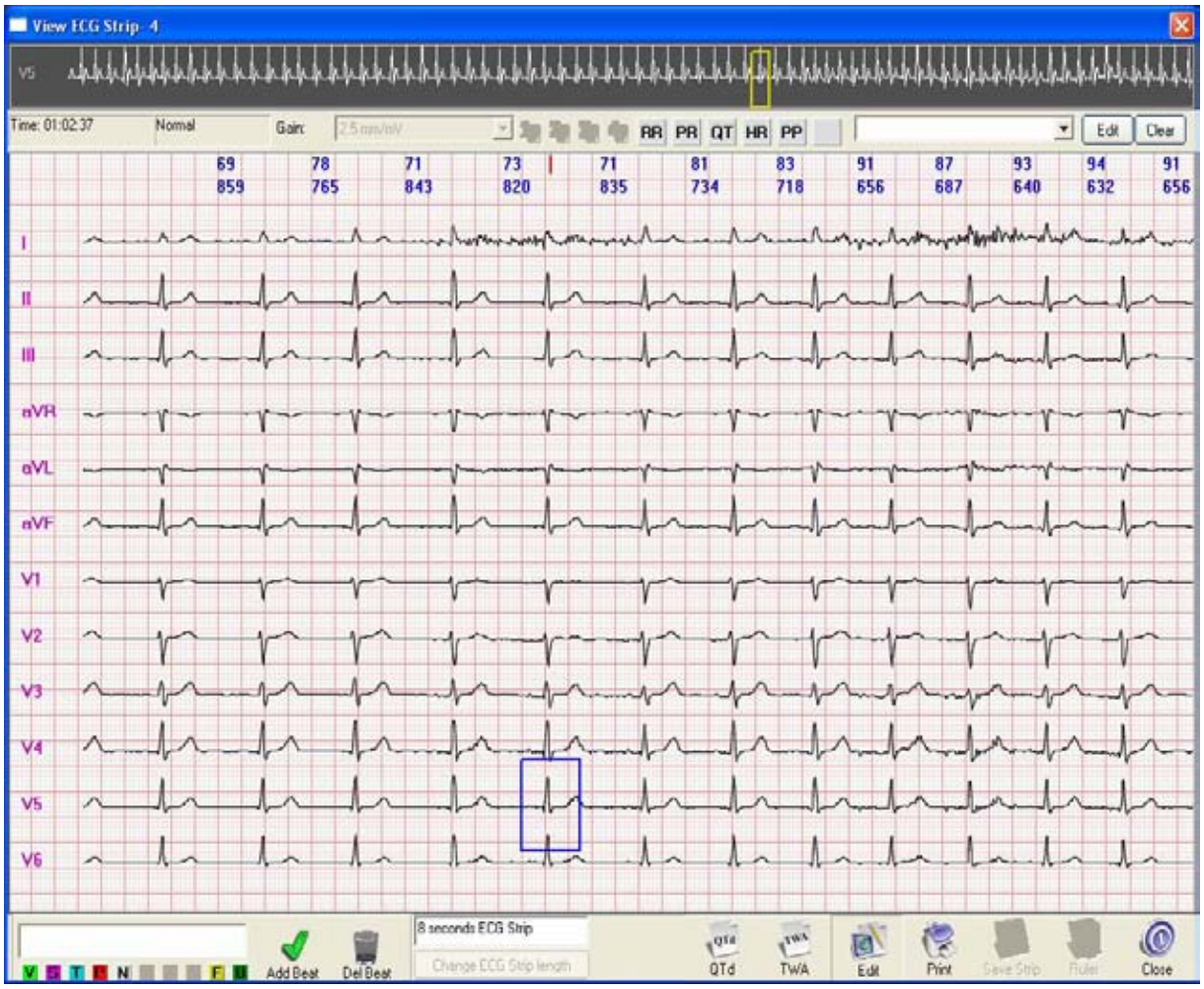
To return to the Template screen display, click on the CLOSE icon at the bottom of the screen.



EDIT VE, SVE AND PAUSE IN AN ENLARGED STRIP

If you notice a beat on the strip is mislabeled, you may edit it at this time.

The rectangular box on the strip indicates that you are in the edit mode. Click on the label code on the bottom of the screen to re-label the beat OR you may press the appropriate letter from the label code on the keyboard. You can use the right mouse click or arrow keys on the keyboard to move this edit box.

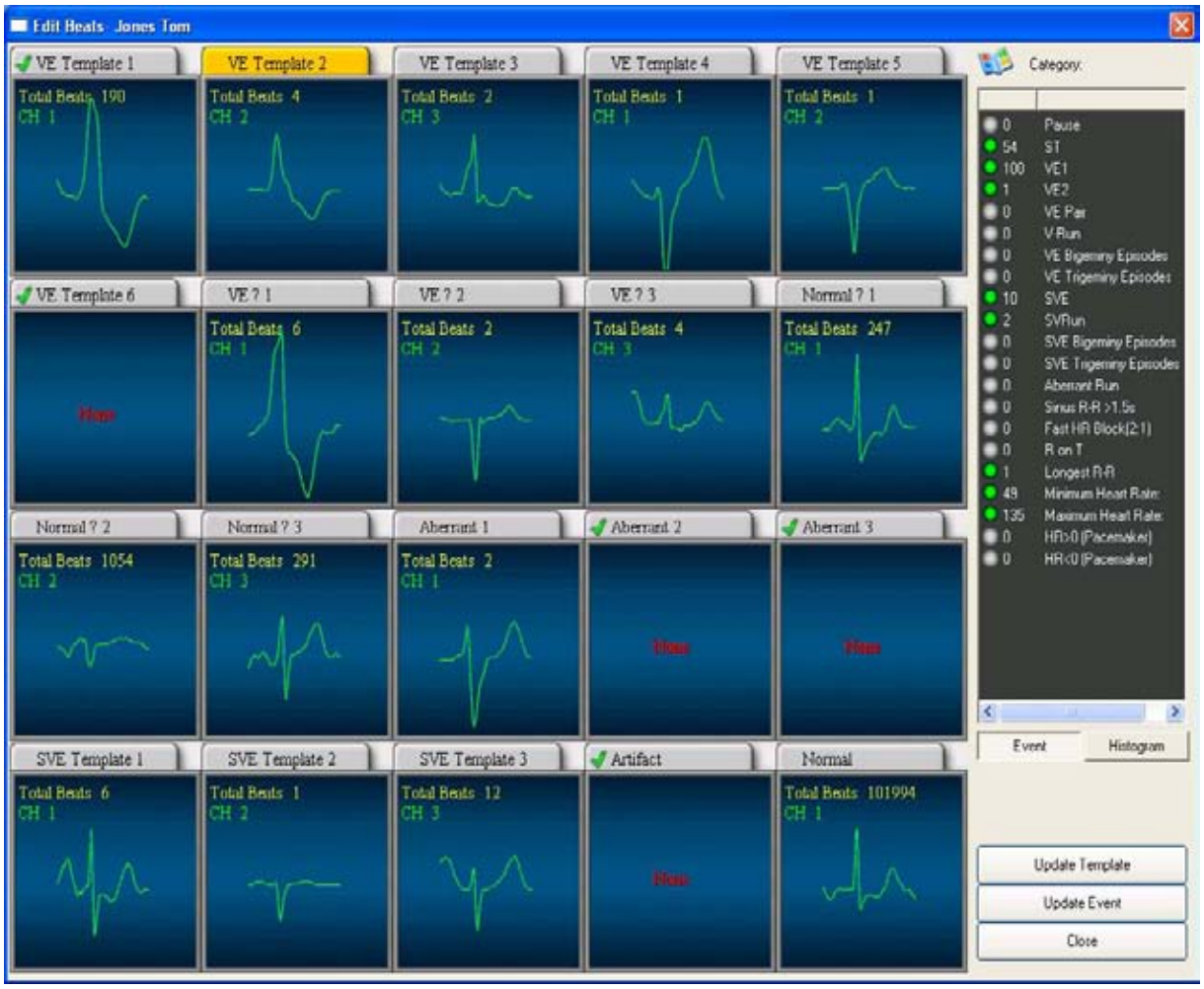


If the rectangular box skips over the desired beat, it is because the beat was rejected by the analysis. There are 3 ways to edit that beat into the analysis.

1. Right click the mouse. A rectangular box will appear on the strip. Place the mouse arrow on the R-wave of the desired beat and double click the mouse. A line will appear on the beat. Click on the label code on the bottom of the screen to label the beat OR press the appropriate letter from the label code on the keyboard.
2. Right click the mouse. A rectangular box will appear on the strip. Press the INSERT key on the keyboard. A vertical marker will appear on the strip. Using the right or left arrow key on the keyboard, move the vertical marker to the R-wave of the desired beat. Click on the label code on the bottom of the screen to label the beat OR press the appropriate letter from the label code on the keyboard.
3. Right click the mouse. A rectangular box will appear on the strip. Click on the ADD BEAT icon at the bottom of the screen. Use the arrow keys on the keyboard to move the marker to the R-wave of the beat. With your mouse, click on the appropriate label from the label code at the bottom of the screen OR press the appropriate letter from the label code on the keyboard.

To delete a beat from the Holter file, move the rectangular beat box to the beat and click on the DEL BEAT icon at the bottom of the screen.

When you have completed your tasks on this display, click on the CLOSE icon on the bottom of the screen OR press the ESC key on the keyboard. You will be returned to the Arrhythmia Template screen. Click on the CLOSE icon on the bottom of the screen or press the ESC key on the keyboard to return to the Edit Beats Screen.



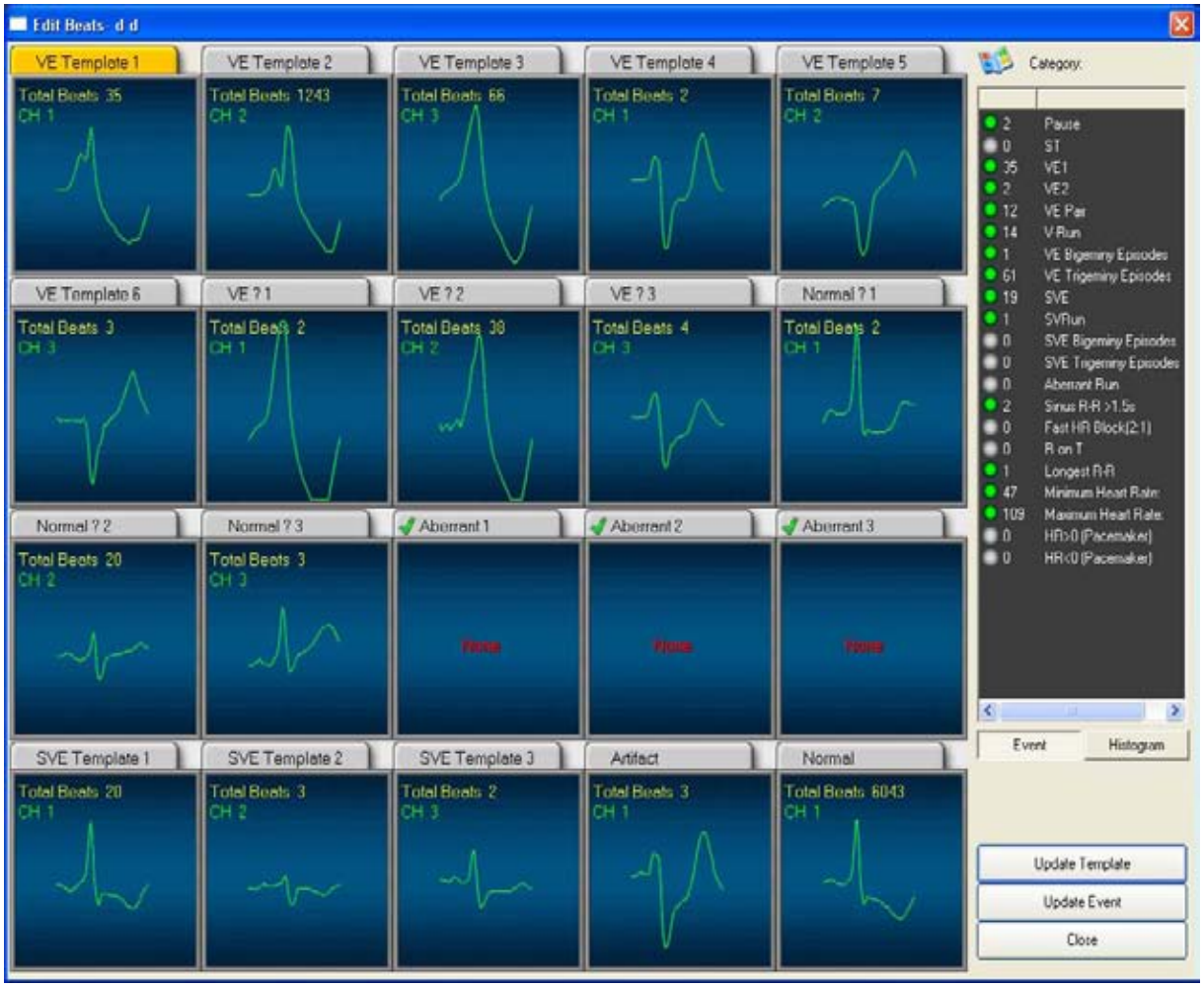
When you are finished editing a Template (pages 46-70), press the ESC key on the keyboard or click on the Close bar at the bottom of the screen. You will automatically be brought to the above screen display and will be taken to the next Template that has beats in it.

After editing the first template you will notice the template you have just edited has a green check mark will appear next to the template name. The green check mark indicates the template has been edited. The next template to be edited will have a yellow highlight to it. To access the data in the template, mouse click on the template OR press the ENTER key on the keyboard and follow the previous procedures until all of the templates are edited.

After you have edited the last beat in the last template, Normal, press the ESC key on the keyboard or click on the CLOSE icon. You will be returned to the above display. An Update Template icon is at the lower right of the screen. You must click on the Update Template icon to complete the arrhythmia analysis process.

NOTE: If you do not edit the Normal template you must still click on the UPDATE TEMPLATE button on the lower right side of the screen. This will save all of the changes you have made while editing.

EDITING NOTE: Some technicians prefer to use the keyboard only during editing, some prefer to use the mouse and still some prefer to use both the mouse and the keyboard. Any of these three techniques will work.

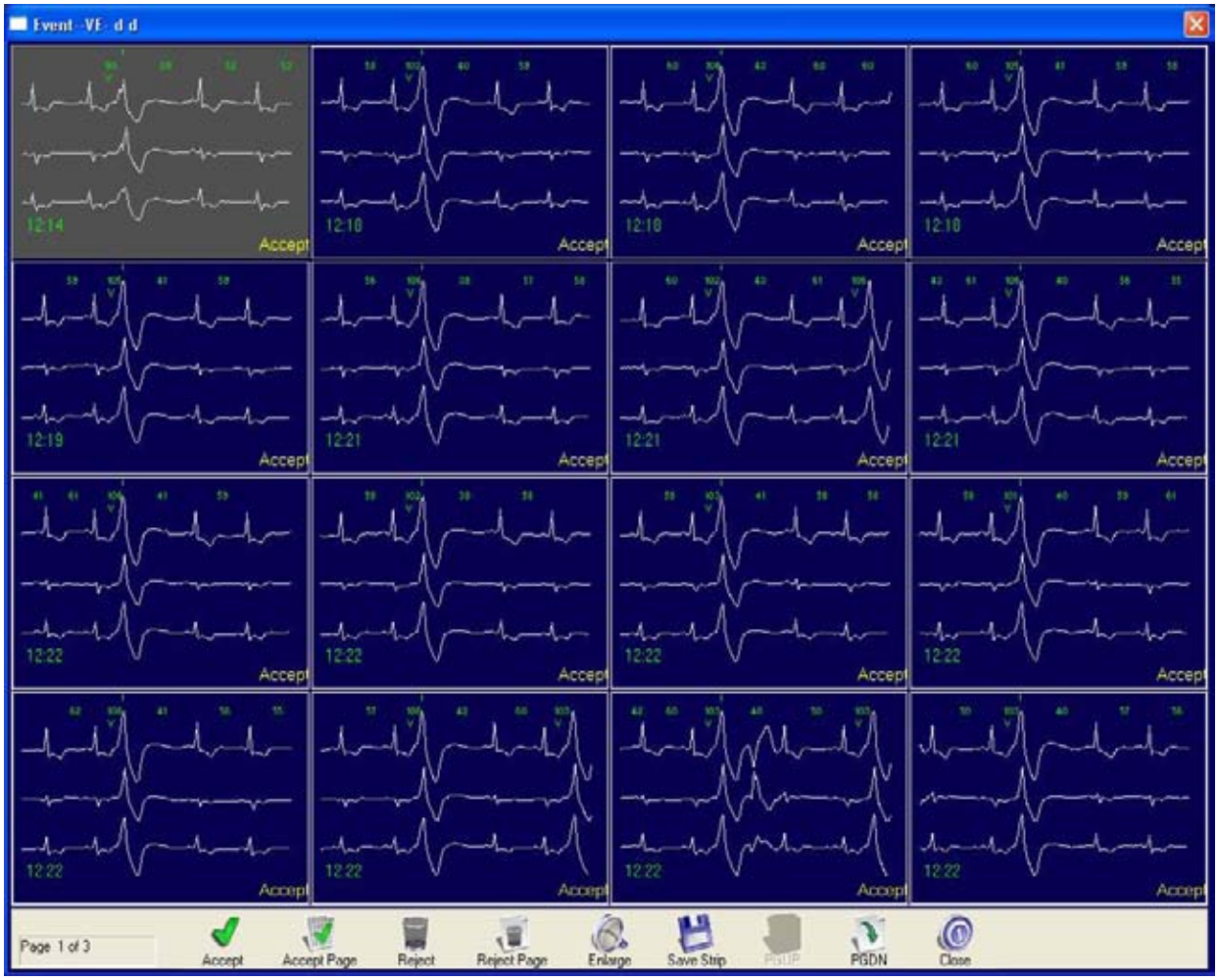


REVIEW OF ABNORMAL ECG EVENTS

The categories for Abnormal ECG Events are Pause, ST, VE1, VE2, VE Pair, VE Run, VE Bigeminy Episodes, VE Trigeminy Episodes, SVE, SV Run, SVE Bigeminy Episodes, VE Trigeminy Episodes, Aberrant Run, Sinus R-R >1.5 seconds, Fast HR Block (2:1), R on T and Longest R-R. Other events that you can edit on this screen include Minimum Heart Rate and Maximum Heart Rate.

The VE1 Category will show you up to 100 VE beats from the VE1 Template. These are positive going VEs. The VE 2 Category will show you up to 100 VEs from the VE4 Template. This template has negative going VEs. The purpose of this is to show multifocal VEs. If you use the Auto Save ECG Strip Mode in the ECG Strip Category, VEs from both VE1 and VE 2 will print out so the physician can see the multifocal VEs.

To edit an Abnormal ECG Event, click on the category bar or press the ENTER key on the keyboard. The following screen will appear.



This screen will show you up to 16 ECG Events. There may be several pages of events, as indicated by the page count on the lower left of the screen. In this example, there are three pages.

The green marker at the top of the strip indicates the Abnormal Event. All of the events displayed have been accepted. To reject an ECG event, move the mouse to the appropriate ECG event strip and click OR use the arrow keys on the keyboard to the appropriate ECG event strip. The strip will lighten to gray. Click on the REJECT icon at the bottom of the screen or press the letter R key on the keyboard.

To view this strip in an enlarged eight-second strip, click on the ENLARGE icon at the bottom of the screen or press the ENTER key on the keyboard.

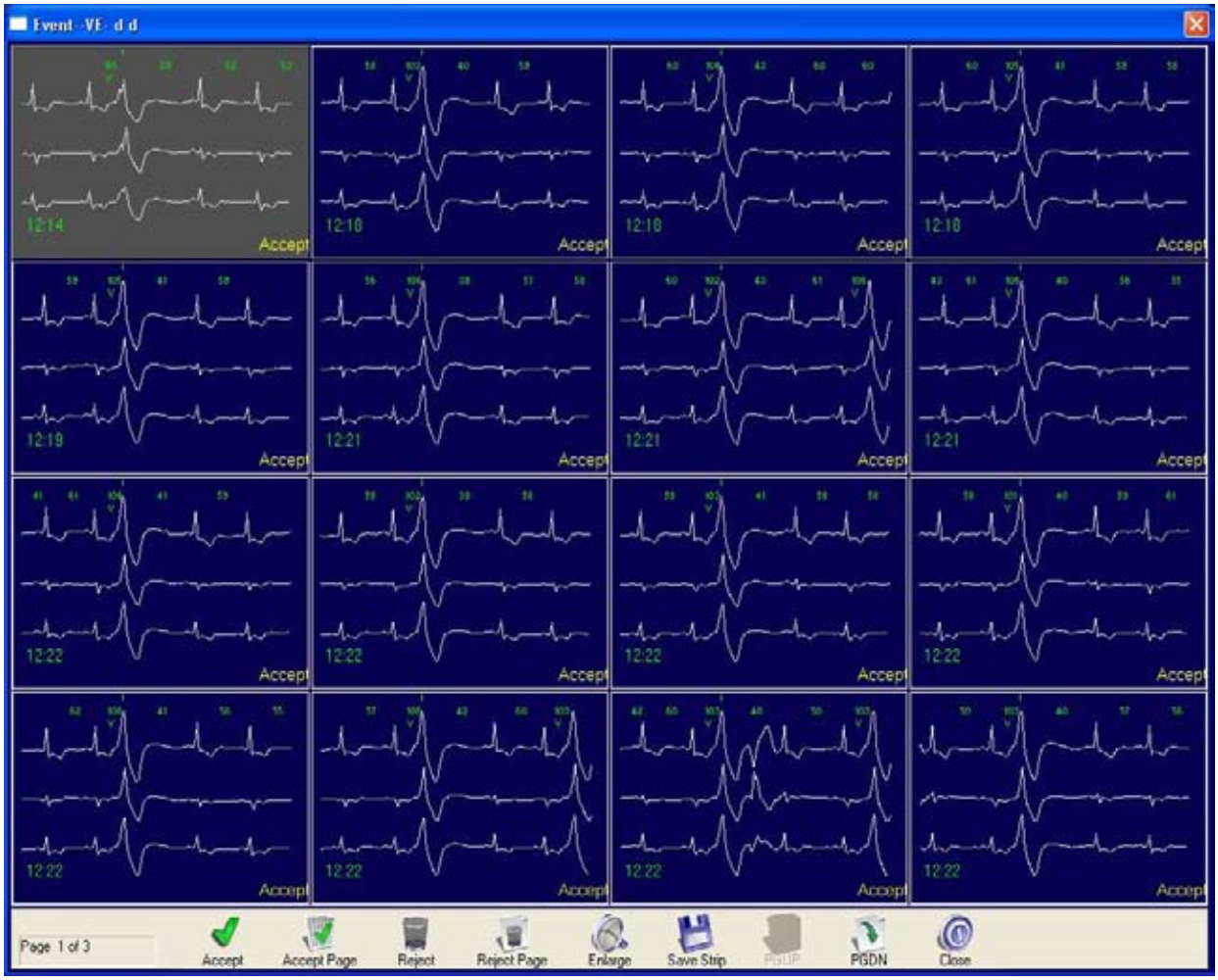
To save this strip to be printed with the report, click on the SAVE STRIP icon at the bottom of the screen.

To reject an entire page of events, click on the REJECT PAGE icon at the bottom of the screen.

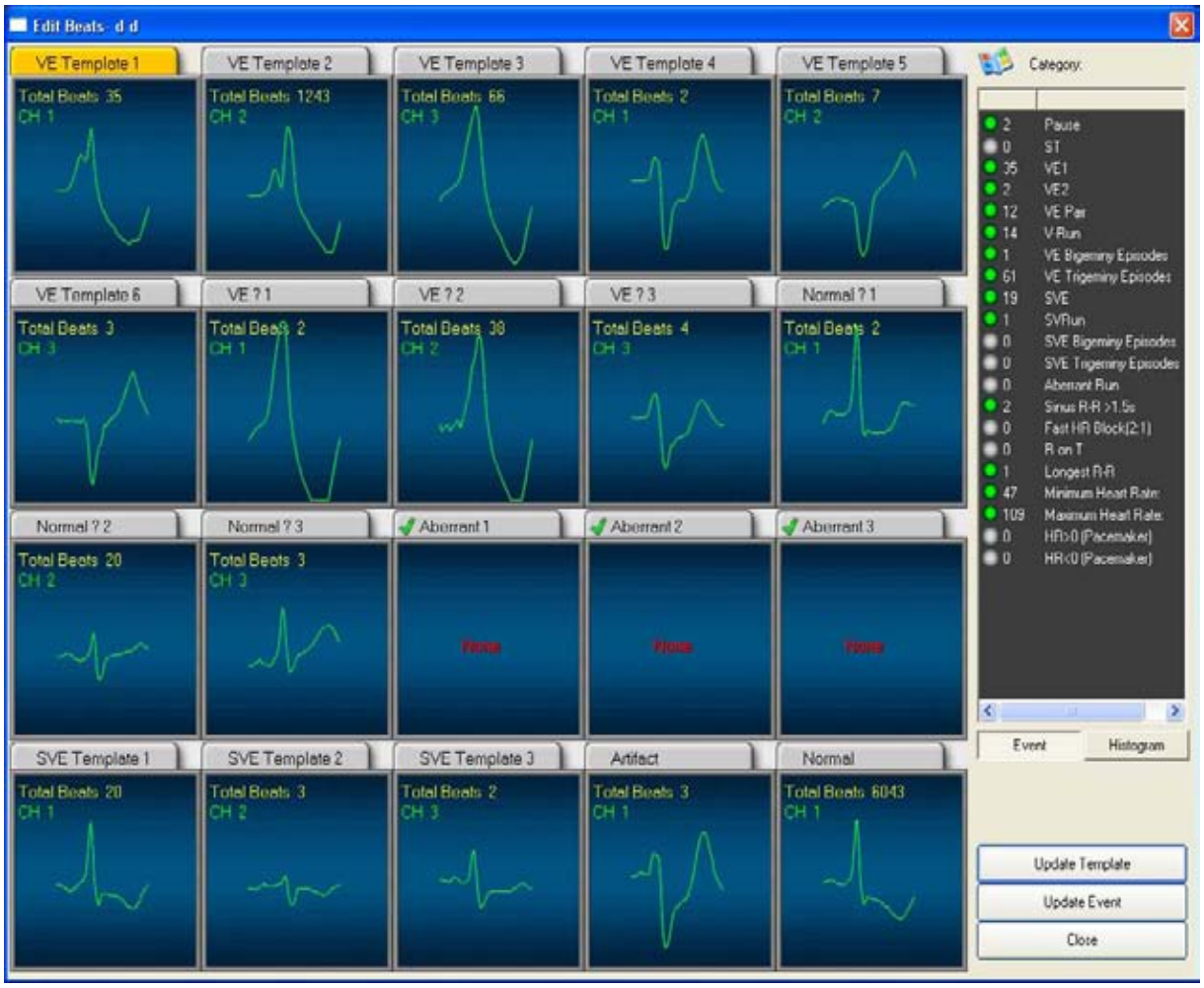
To accept an entire page of events, click on the ACCEPT PAGE icon at the bottom of the screen.

To reject the entire category, click on the REJECT ALL icon at the bottom of the screen.

To view other pages of events in this category, click on the PGUP or PGDN icon on the bottom of the screen OR you may press the Page Up or Page Down key on the keyboard..



To go to the next Abnormal ECG Event category, click on the CLOSE icon at the bottom of the screen OR press the ESC key on the keyboard.

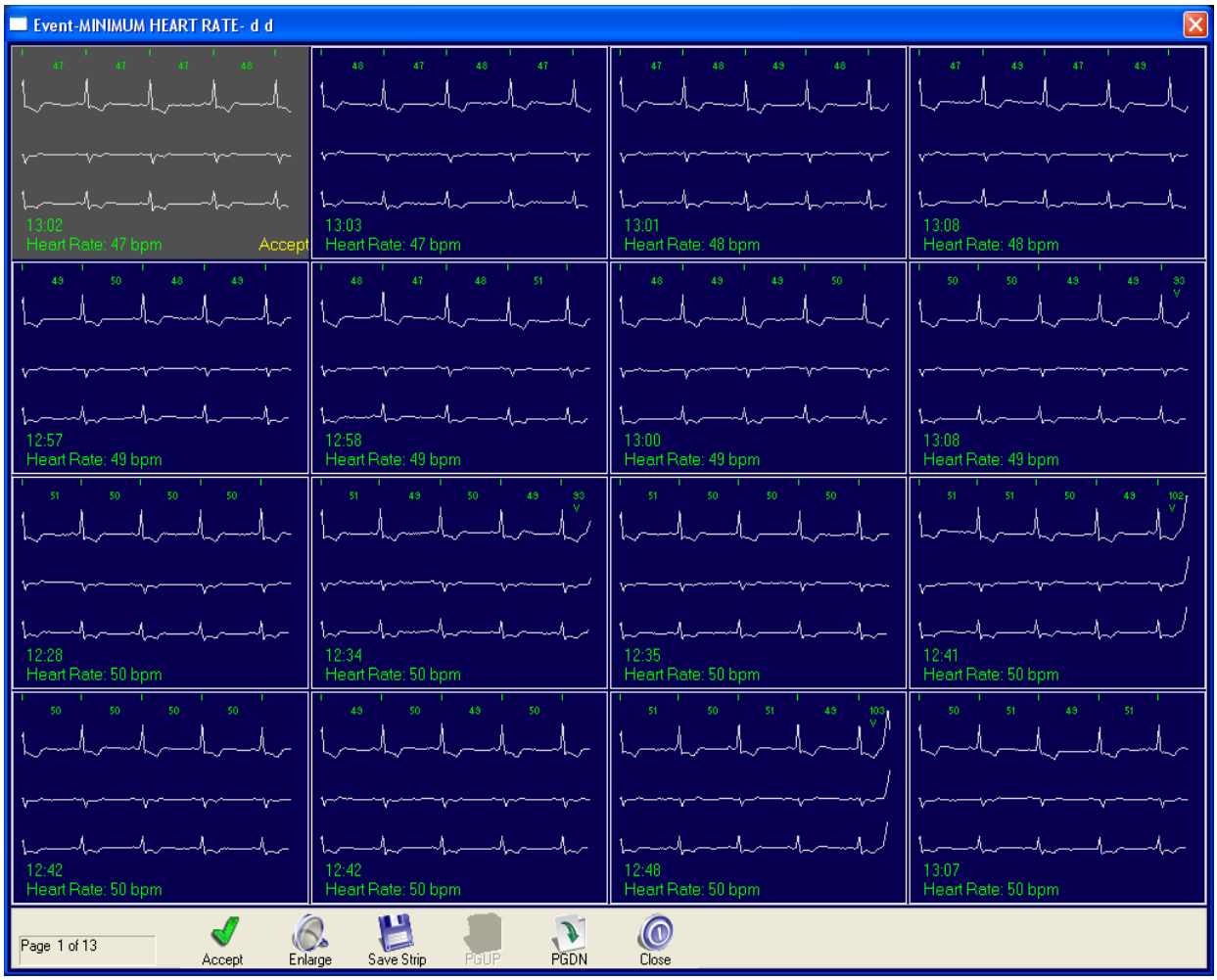


Select the next Abnormal ECG Event category you choose to edit and click on the category bar OR press the ENTER key on the keyboard. Repeat the aforementioned editing techniques for the remaining categories.

NOTE: If there is a zero in a category, the category name will be in gray and you will not be able to edit this category. That is because the category had no events.

NOTE: After you have edited the category, the button next to the category will turn red.

The editing for the Minimum Heart Rate and Maximum Heart Rate categories is different.



EDITING MINIMUM AND MAXIMUM HEART RATE

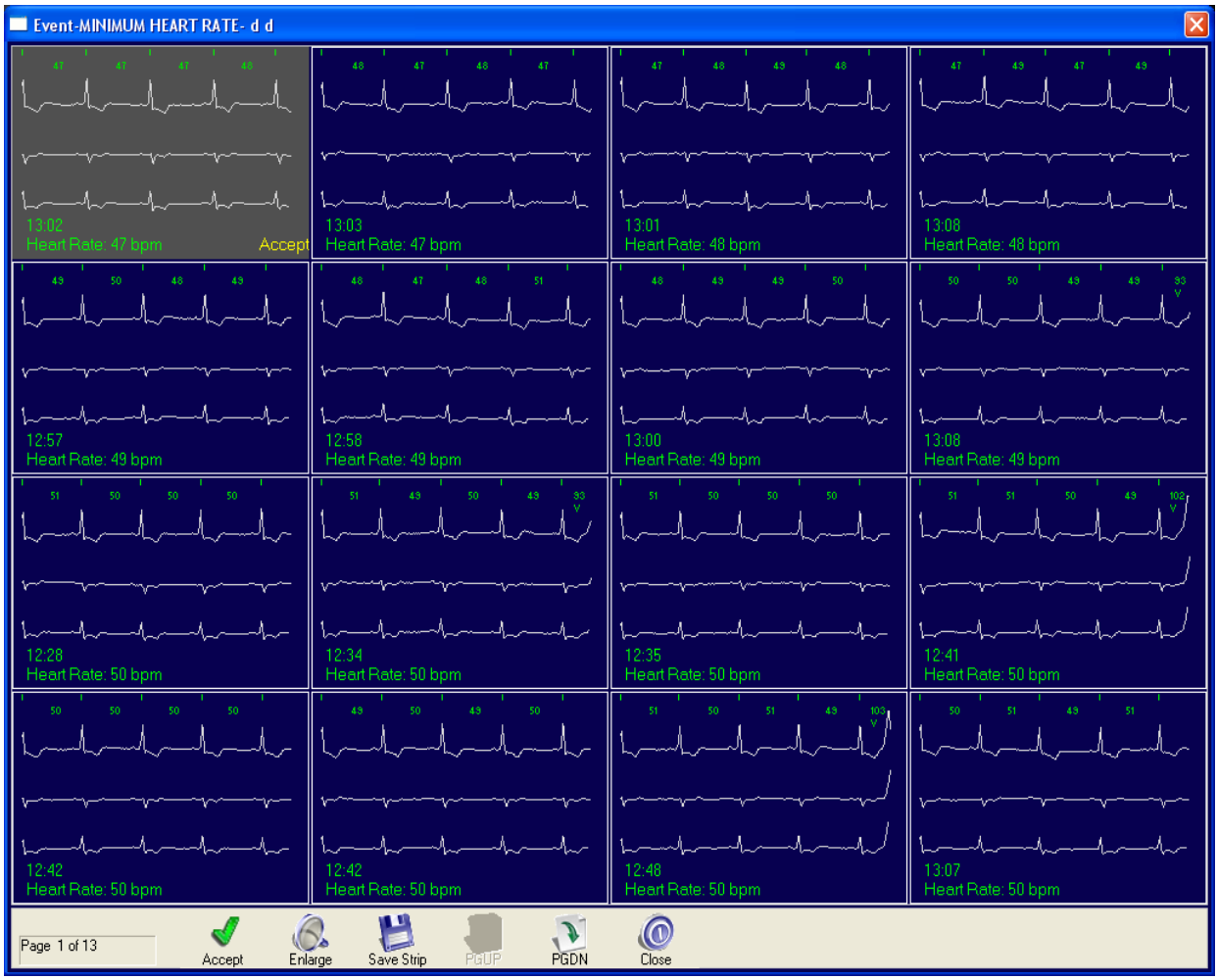
Only one event is accepted as the Minimum Heart Rate and Maximum Heart Rate.

The green vertical markers at the top of each strip should be located above successive R-waves. If this is the case for the first selected event, click on the CLOSE icon at the bottom of the screen OR press the ESC key on the keyboard. You will be taken to the Edit Beats screen.

NOTE: In the Settings Menu, you chose how many intervals would be counted to determine your minimum and maximum heart rate, either 1 interval, 2 intervals, 3 intervals, 4 intervals or 5 intervals. The interval count determines how many consecutive R-waves should be counted.

If the green markers are not located above successive R-waves, click on the first heart rate strip that has successive R-waves marked and click on the ACCEPT icon OR use the arrow keys on the keyboard to move to the desired strip and press the letter A on the keyboard. The word Accept will appear in the lower right corner of the selected ECG Event strip.

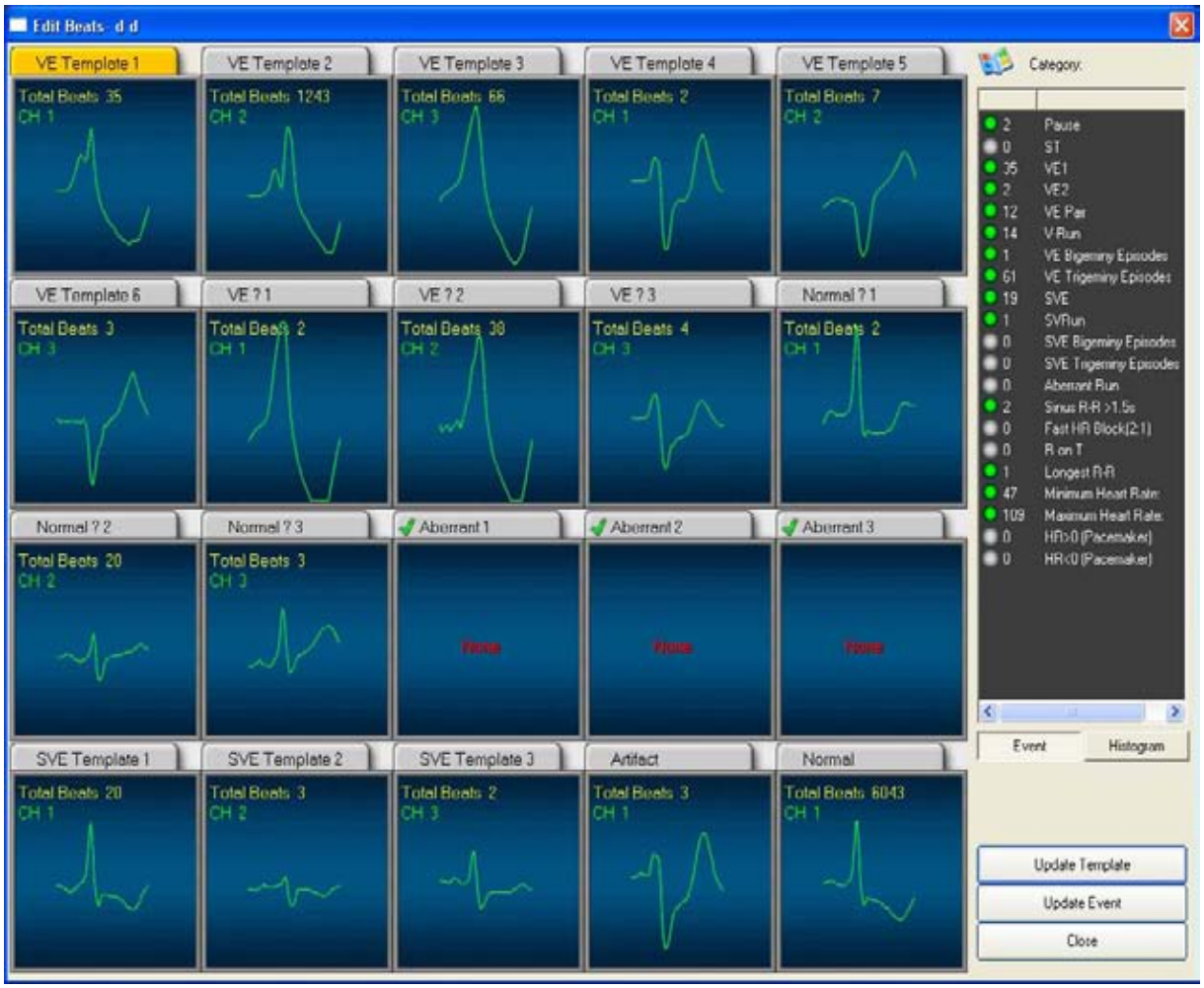
NOTE: There may be more than one ECG Event strip with the same Heart Rate with the intervals being counted correctly. In an instance like this, it is always preferable to choose the ECG Event strip with the least amount of artifact.



If there are no Minimum Heart Rates with green markers above successive R-waves, click on the PGDN icon at the bottom of the screen OR press the Page Down button on the keyboard. This will bring you a new page of 16 events. Keep paging down until you locate and accept the desired event.

After completing the Minimum Heart Rate category, click on the CLOSE icon at the bottom of the screen OR press the ESC key on the keyboard. You will be returned to the Edit Beats screen.

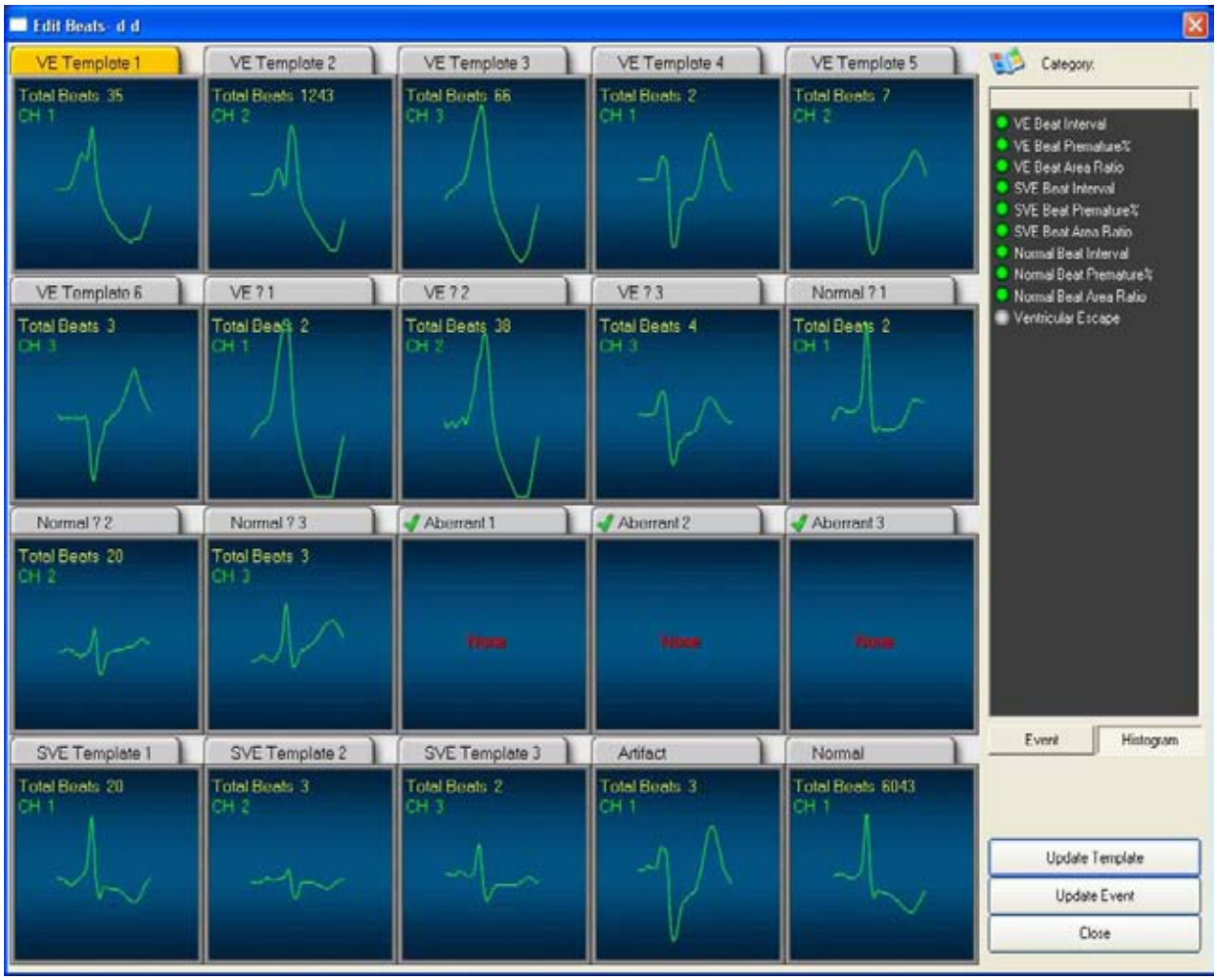
To edit the Maximum Heart Rate category, follow the above instructions to locate the Maximum Heart Rate.



After you have completed the Maximum Heart Rate edit, click on the UPDATE EVENT bar OR press the ENTER key on the keyboard.

An updated status screen will appear as the program accepts the changes.

Click on the CLOSE bar OR press the ESC key on the keyboard and you will be returned to the Data Access Choices menu.



Once you have completed editing the Events, click on Histogram. The display on the next page will appear. The purpose of the Histogram features is to check the beats that are out of the normal range of VEs, SVEs and normal beats.

VE beats have three histogram choices. They are histograms by Interval, Prematurity % and Area of QRS. The SVE beats and Normal beats have the same histogram choices.

The histograms should be used after you have completed the Template editing.

Quite often you will see very unique and interesting abnormalities at the far left and right sides of the histograms. The Normal Beat Interval histogram will sometimes find some very interesting ECG events.

In our example, we have clicked on the green mark that is to the far right of the VE Beat Interval Histogram.

Once the mark is clicked on, you will see directly below the graph mini 8-second strips of all the VEs that have occurred at this range. In our example, there is one.

At the bottom of the screen is an enlarged 8-second strip of the VE. The red mark at the top and bottom of the strip indicates which beat we are looking at.

To create a classification for this beat that we want to reclassify as something other than a VE, SVE, Aberrant, Pause, Normal or Artifact, right click on the green button across from the U under Beat Classification at the lower right hand side of the screen. The following screen will appear.

Enter the type of beat you want this called, such as Bundle Branch Block in the empty field next to Label. At the empty field next to Beat Type Char, enter the strip label you would like to have this classification noted as, such as BBB.

After you have entered the classifications click on the OK button.

Note that the BBB label you had assigned as the strip name is noted on the strip prior to the beat. Under the classification categories on the lower right side of the screen, there is now a Bundle Branch Block category. Under Category at the upper right of the screen the Bundle Branch Block is now listed.

This beat has now been classified as Bundle Branch Block.

Next, press the left arrow key on the keyboard to move to the next beat on the graph. The following beat appears.

To label this beat as a Bundle Branch Block, simply press the U on the keyboard or the Bundle Branch Block label under the Beat Classification on the lower right of the screen.

The beat is now classified as Bundle Branch Block.

If you have 3 or 4 histogram levels at the far right of the VE histogram, it is more efficient to do a mouse point and drag over the quantity of beats.

Review each histogram and, if they are the same abnormality, left click and hold the mouse on the abnormality furthest to the left and drag the mouse to the abnormality furthest to the right. Release the mouse. A beige highlight screen will cover the span of the beats you wish to change.

Press the U key on the keyboard to change the labels to Bundle Branch Block.

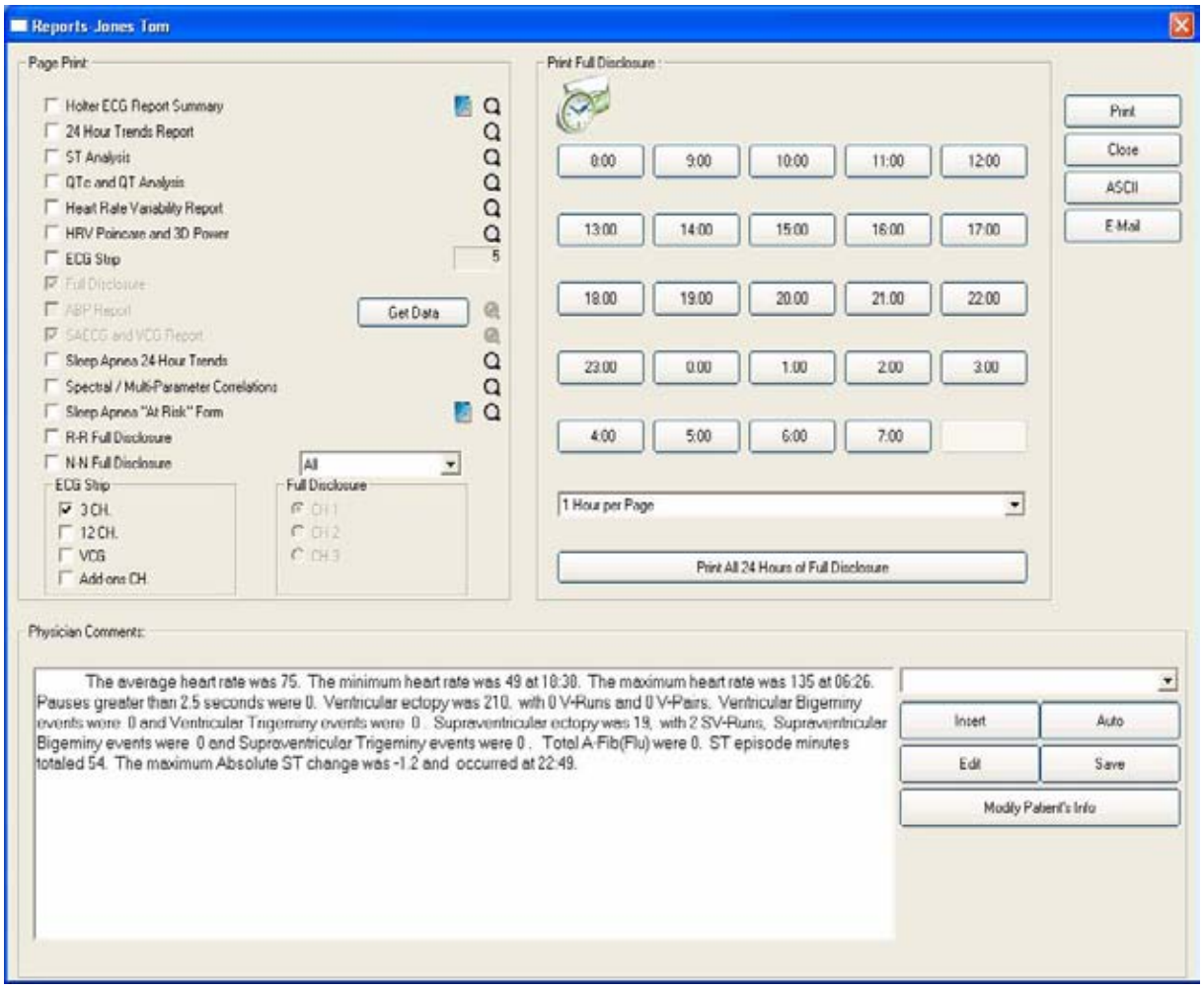
The beats have now been relabeled as Bundle Branch Block.

You may continue to edit using the same technique as mentioned in pages 75 -81. Once you have completed the editing press the ESC key on the keyboard or click on the X in the upper right side of the screen to close the screen.

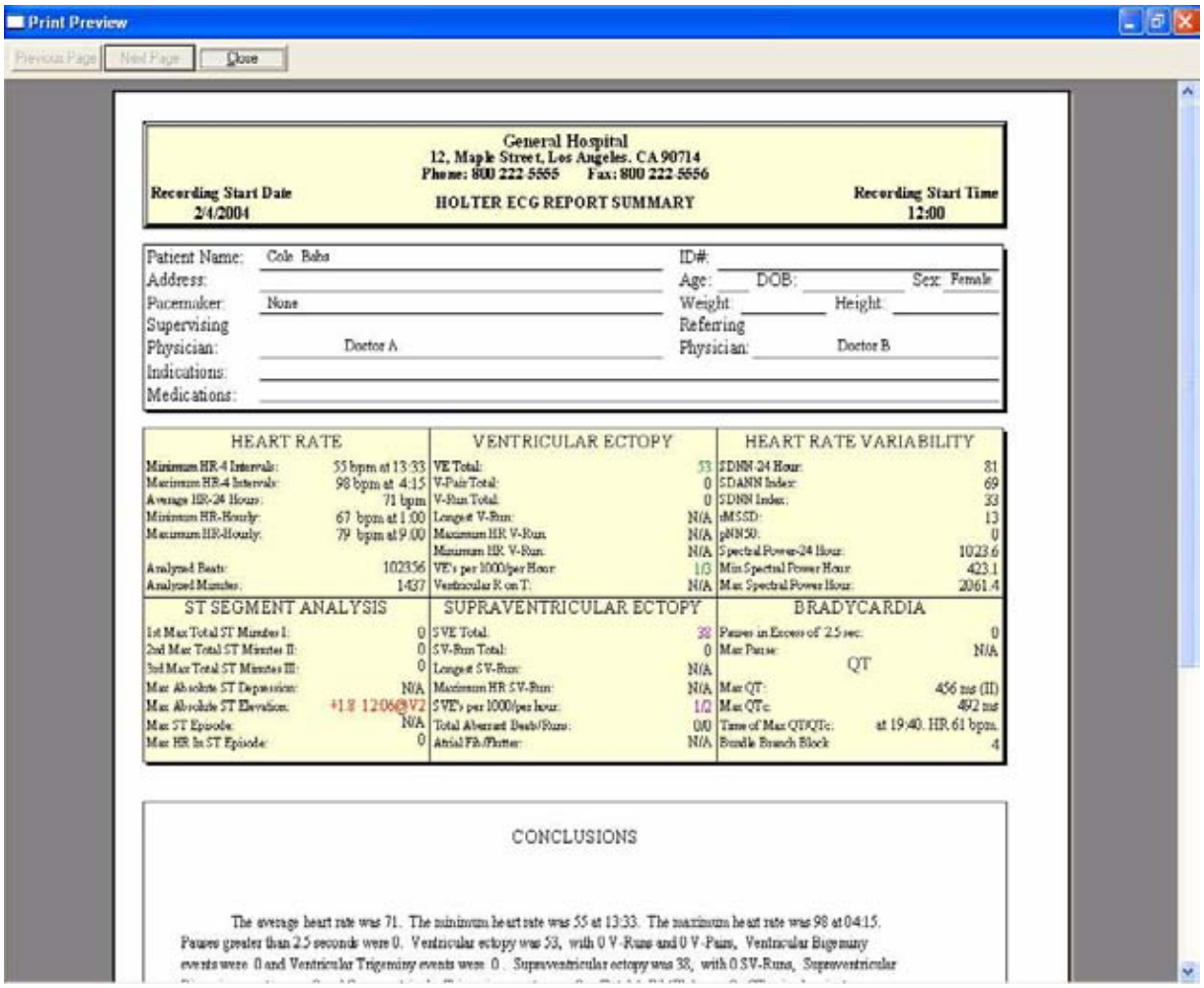
Click on the Update Event bar on the lower right side of the screen.

Once the events have been updated you will see the Bundle Branch Block category listed with a green button under the Category screen. This information has now been added to the report.

To verify this has been added to the report, click on the Close bar at the bottom right side of the screen. At the Data Access Choices click on the Report icon. The following screen will appear.



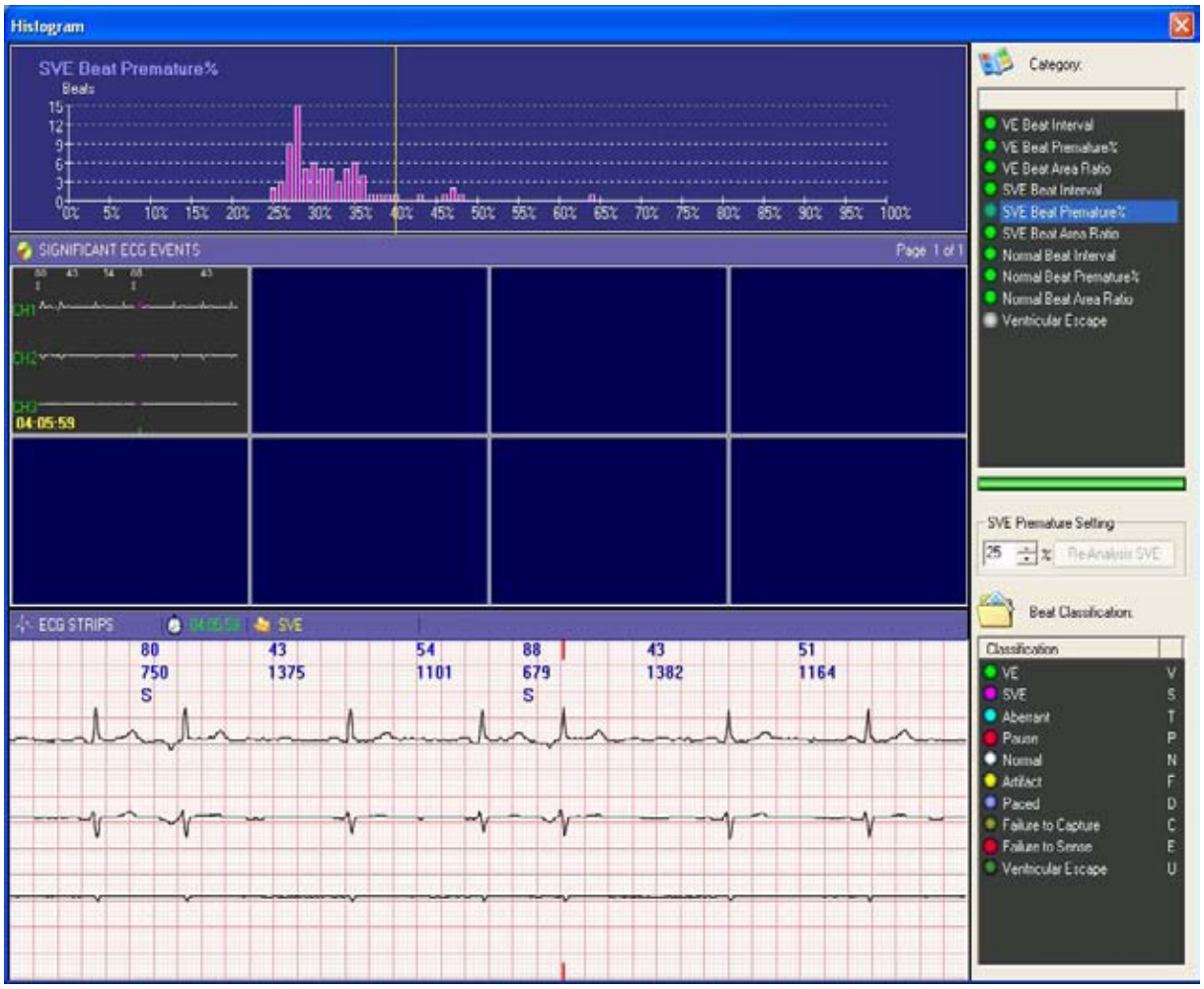
Click on the magnifying glass icon to the right of the Holter ECG Report Summary.



The report will appear. Click the magnifying glass icon twice to enlarge the report. You will see the Bundle Branch Block has been added underneath the QT field on the right side of the report above the Significant ECG Events category.

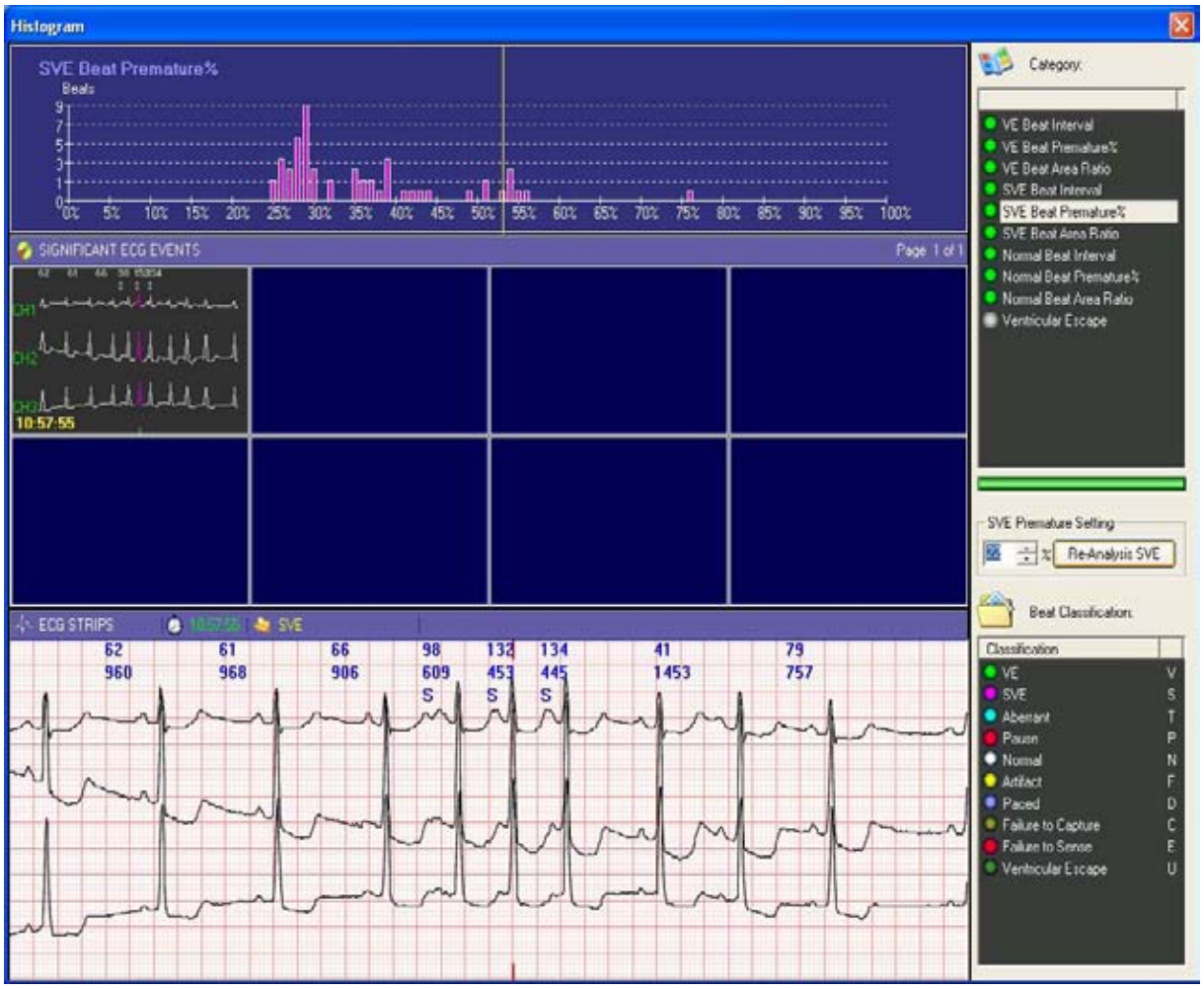
Click on the Close bar at the upper left of the screen to exit this screen.

Press the ESC key on the keyboard or click on the X of the top right of the screen to exit the Report section and return to the Data Access Choices.



You can reanalyze the SVE's at a different percentage prematurity without changing any of the other analyzed and edited analysis data.

The middle of the right screen shows you an SVE Premature Setting. Click on the up or down arrow to set the prematurity level you desire.



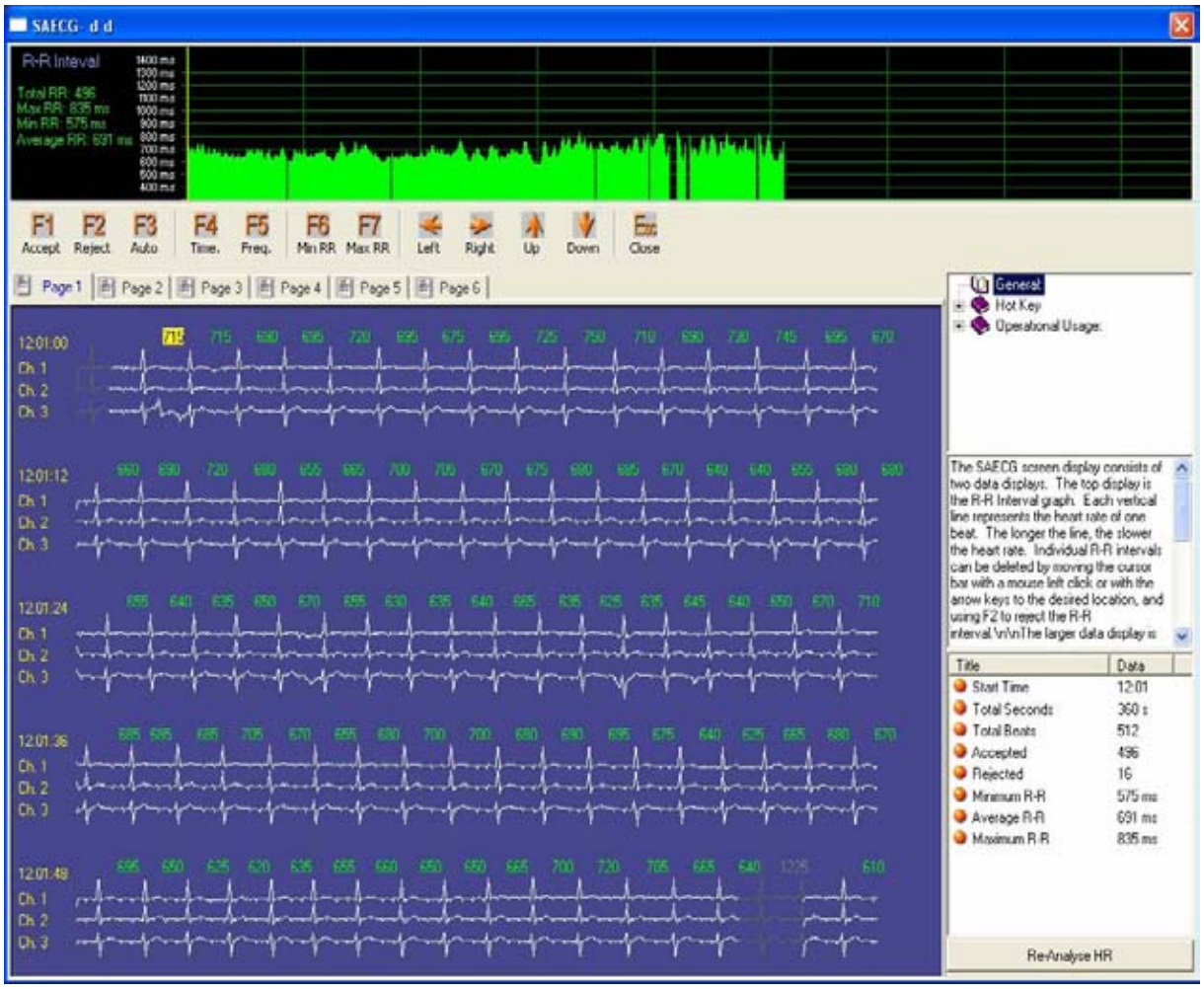
Once you have set the prematurity level, the ReAnalysis SVE bar becomes active. Click on the bar and the SVE analysis will be performed without changing any of the other analyzed data.

You may continue to edit using the same technique as mentioned in pages 75 -81. Once you have completed the editing press the ESC key on the keyboard or click on the X in the upper right side of the screen to close the screen.

SAECG/VCG

If you are editing a 3 channel Holter, you may generate a SAECG and VCG report. Click on the SAECG/VCG icon at the Data Access Choices Menu.

Click on SAECG. The following screen will appear.



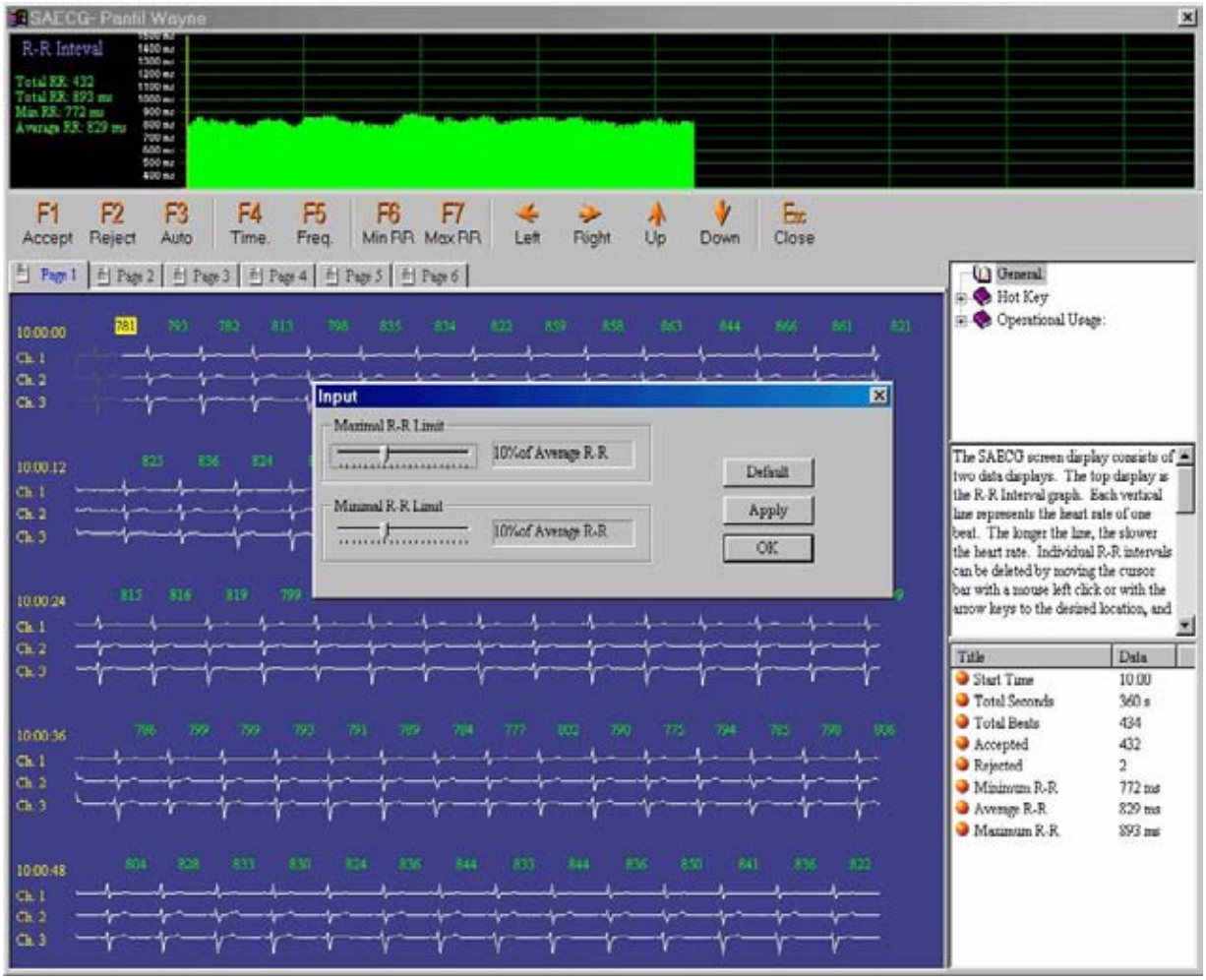
The SAECG screen display consists of two data displays. The top display is the R-R Interval graph. Each vertical line represents the heart rate of one beat. The longer the line the slower the heart rate is. Moving the cursor bar with a mouse click or with the arrow keys to the desired location, and using F2 to reject the R-R interval can delete individual R-R intervals.

The large data display is one minute of ECG data. Each horizontal sweep represents 12 seconds of ECG data. Placing the mouse cursor on the desired location and clicking can eliminate undesired ECG beats. Reversing this process will cause rejected bats to be accepted. It is desirable to remove beats with artifact from the SAECG Late Potential file. You can access minutes 1 through 6 by pointing and clicking the mouse on the Page 1, Page 2, Page 3, Page 4, Page 5 or Page 6 tabs or you can change the minutes by pressing the PGUP and PGDN keys on the keyboard.

Below the R-R Interval graph are function keys. These function keys are described below:

F1 Accept Key – Move the cursor to a blank location on the R-R Interval graph, point and click on F1 or press the F1 key on the keyboard. The deleted interval will be restored.

F2 Reject Key – Move the cursor to the desired vertical line on the R-R Interval graph, point and click on F2 or press the F2 key on the keyboard. The R-R Interval will be deleted from the SAECG file.



F3 Auto Key – Click on the F3 or press the F3 key on the keyboard and the above screen will appear. The percentage shown represents all R-R deviations exceeding the percentage of the average heart rate that will automatically be deleted. The percentage default is 10%. If desired, place the cursor on the slide bar, click and drag to the desired percentage.

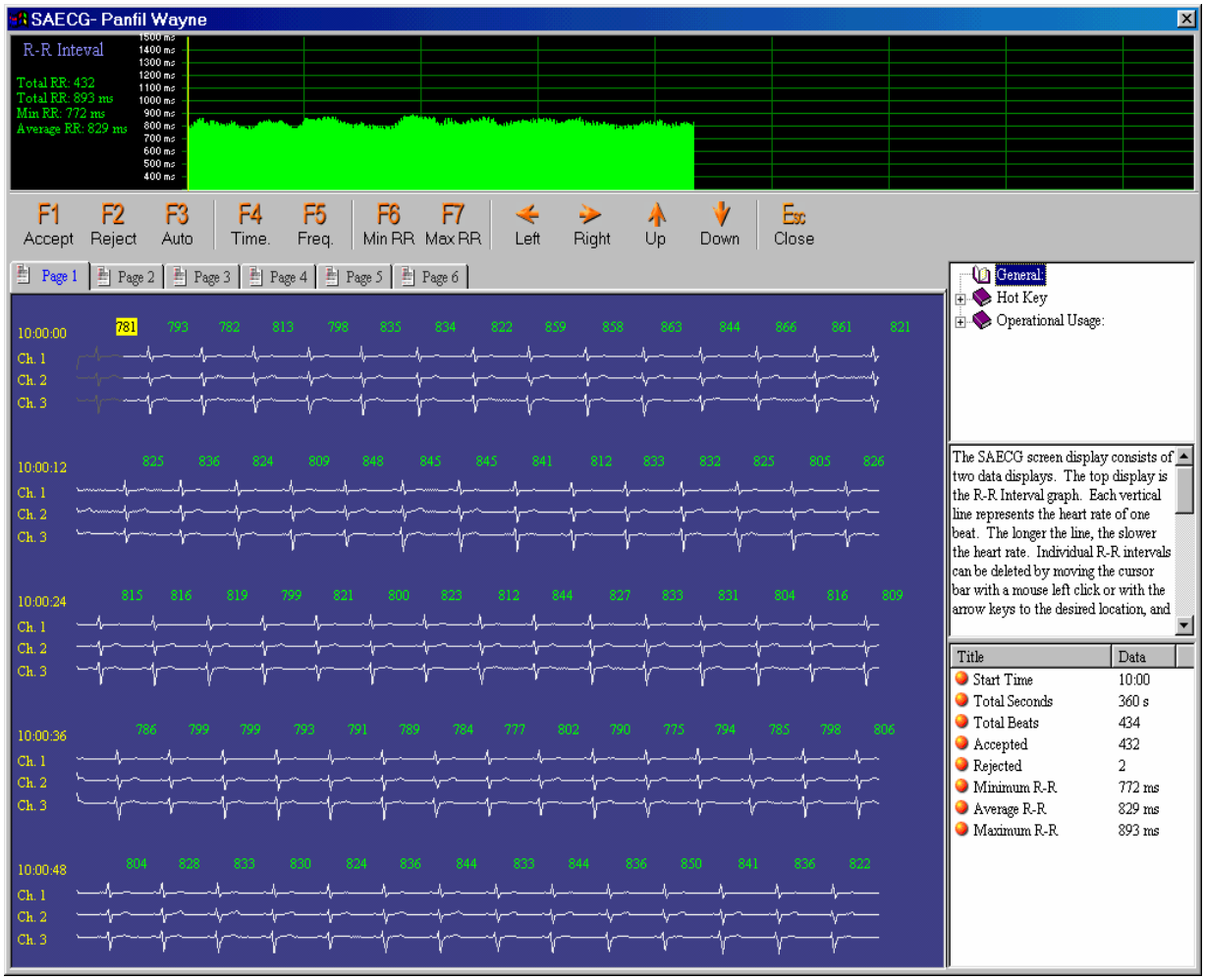
F4 Time – Click on the F4 or press the F4 key on the keyboard to activate the Time Domain screen display.

F5 Freq. – Click on the F5 or press the F5 key on the keyboard to activate the Spectral Frequency display.

F6 Min R-R – Click on the F6 or press the F6 key on the keyboard and the screen cursor will be moved to the minimum R-R interval in both displays.

F7 Max R-R – Click on the F7 or press the F7 on the keyboard and the screen cursor will be moved to the maximum R-R interval in both displays.

Left, Right, Up and Down Arrows – Click or press the ARROW keys on the keyboard to move the screen cursor. The Up and Down arrows move in larger increments than do the side to side arrows.



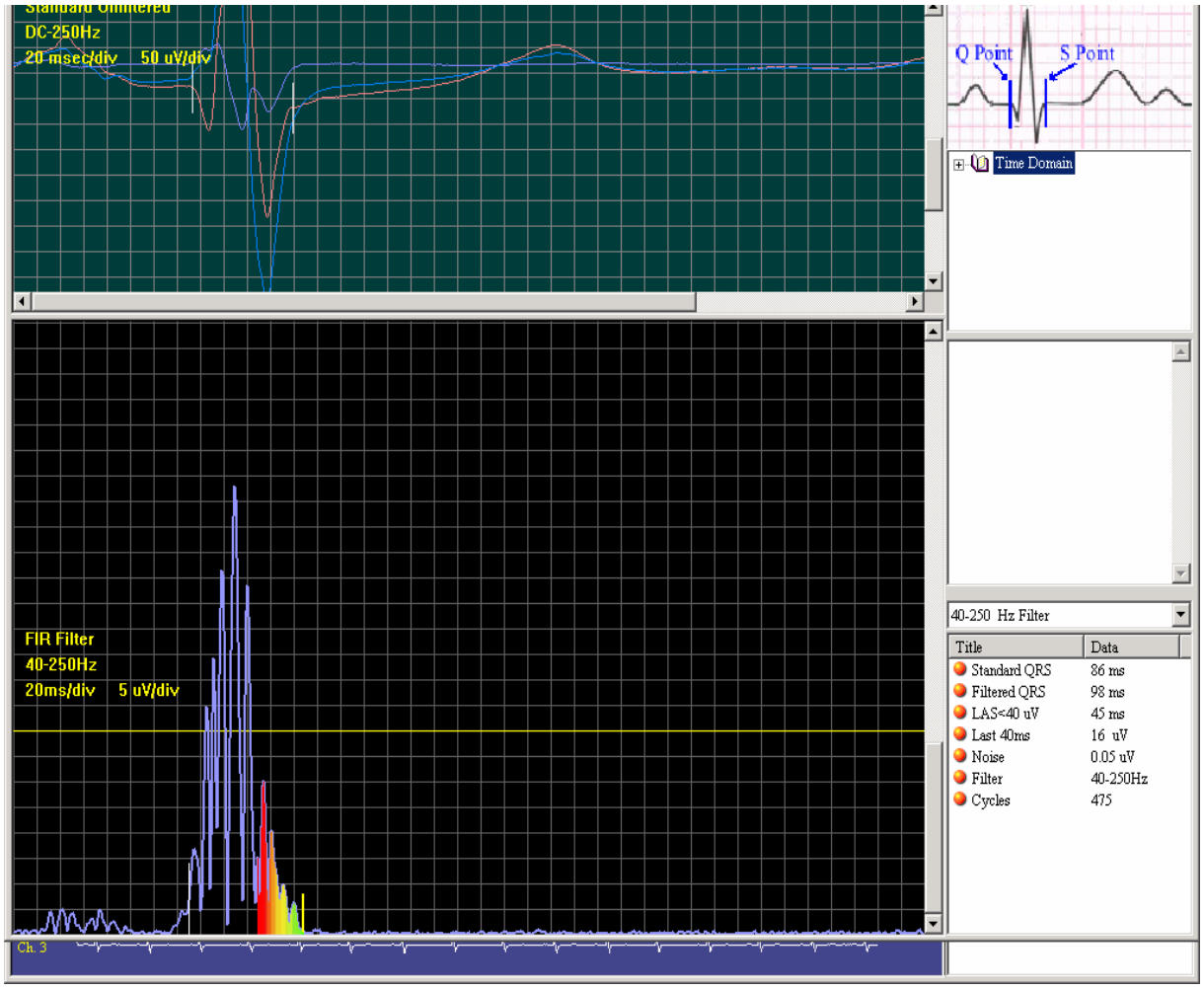
Operational Usage:

1. Click on F3 to set the desired percentage of rejected beats from the heart rate average. 10% is routinely used.

2. Click on Page 1. Delete all beats that have artifact in any of the 3-channel ECG. To delete beats, point and click on artifact. The beat will be colored gray. If you make a mistake, just click on the artifact again. The color will change back to white and it will be added to the beat file. Repeat this procedure for pages 2, 3, 4, 5 and 6.

3. It is recommended to have a total of 200 or more qualified beats for good SAECG analysis. The data box at the lower right of the screen show you the count of the Accepted Beats.

4. Click on F4 time to proceed to the Time Domain Analysis set-up.



Time Domain Analysis Set-Up

There are four (4) vertical cursors and one (1) horizontal fixed measurement on this screen. The active screen cursor will be highlighted in bright yellow. Use the Tab key on the keyboard to change the active screen cursor. The arrow keys on the keyboard will move the screen cursor.

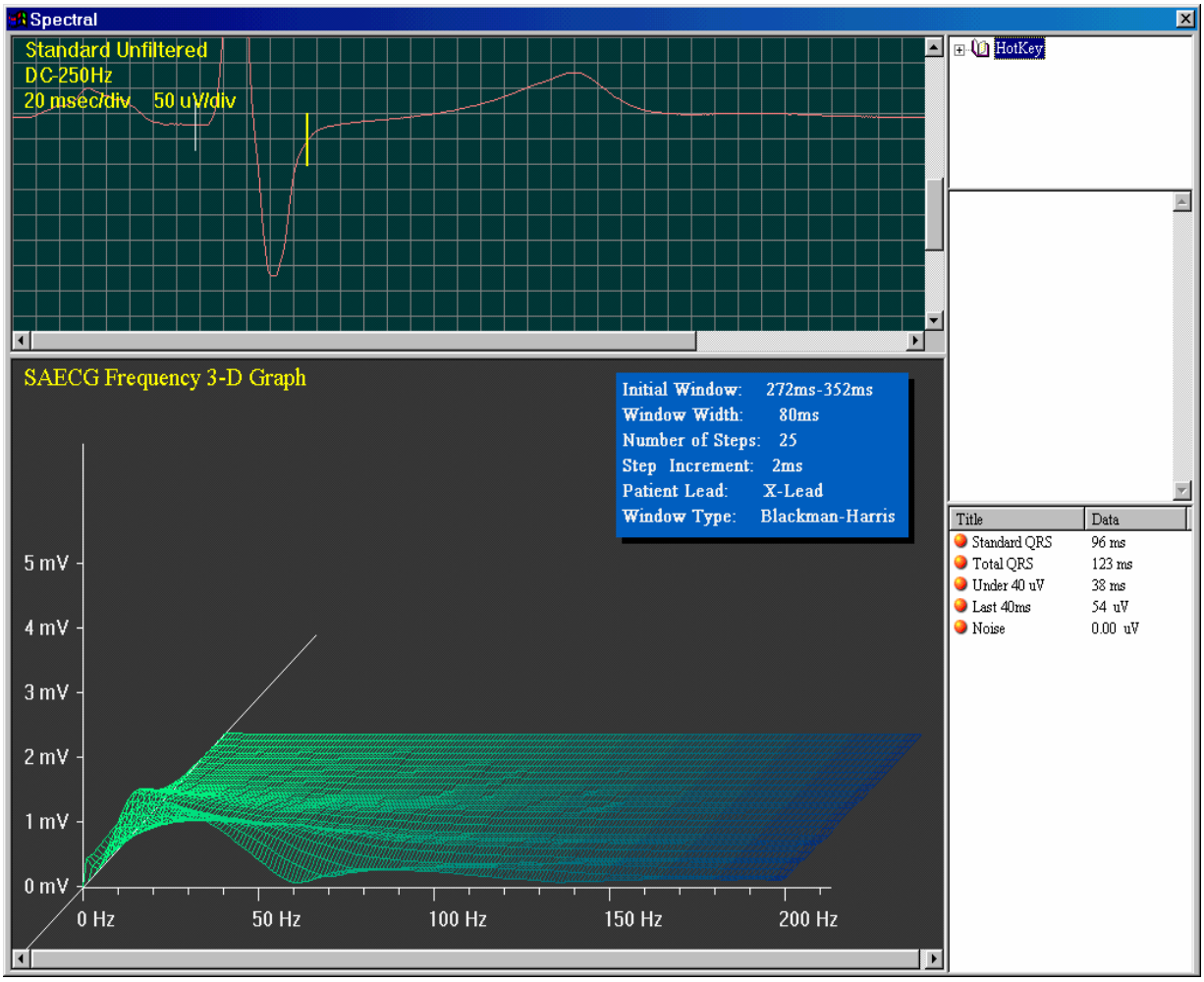
The top of the screen has 3 channels of a superimposed Standard QRS. The first cursor should be at the Q Point. If the cursor is not in this position, you must adjust it by using the arrow keys on the keyboard. A computer algorithm auto-selects the beginning of the Standard and Filtered QRS and the end of the Filtered QRS.

The second cursor should be at the end of the QRS (J Point). If it is not, press the Tab key on the keyboard to activate the second cursor. Use the arrow keys on the keyboard to place the cursor at the end of the QRS.

The bottom half of the screen shows the Filtered QRS. A computer algorithm locates the cursor to the right of the Filtered QRS. If you disagree with the location, press the Tab key on the keyboard to activate the third cursor. Use the arrow keys on the keyboard for moving to the end of the Filtered QRS.

The cursor at the beginning of the Filtered QRS moves simultaneously with the cursor for the beginning of the Standard QRS. Note that the Filtered QRS is usually a wider measurement than the Standard QRS.

To exit, click on the Close “X” at the top of the screen.



Spectral Frequency Analysis Set-Up

Click on F5 Freq. and the SAECG Frequency 3-D Graph will come up on your screen.

View the Frequency Graph for Channel 1. You can move the active yellow screen cursor at the end of the QRS with the ARROW keys on your keyboard. Note that the Initial Window Width numbers will change in the data box directly above the 3D graph as well as the 3D graph. The information in the Data Box at the lower right of the screen will also change.

Right mouse click. Scroll down to Show Ch. 2 and click. The SAECG Frequency Graph will change with each channel. You will be able to view the changes in spectral power. Right mouse click. Scroll down to the Show Ch. 3 and click.

When you are finished with this screen, click on the Close icon “X” at the top right corner of the screen display. You will be returned to the SAECG main screen display. Click on the Close icon “X” at the right corner of the screen display. You will be returned to the Data Access Choices screen.

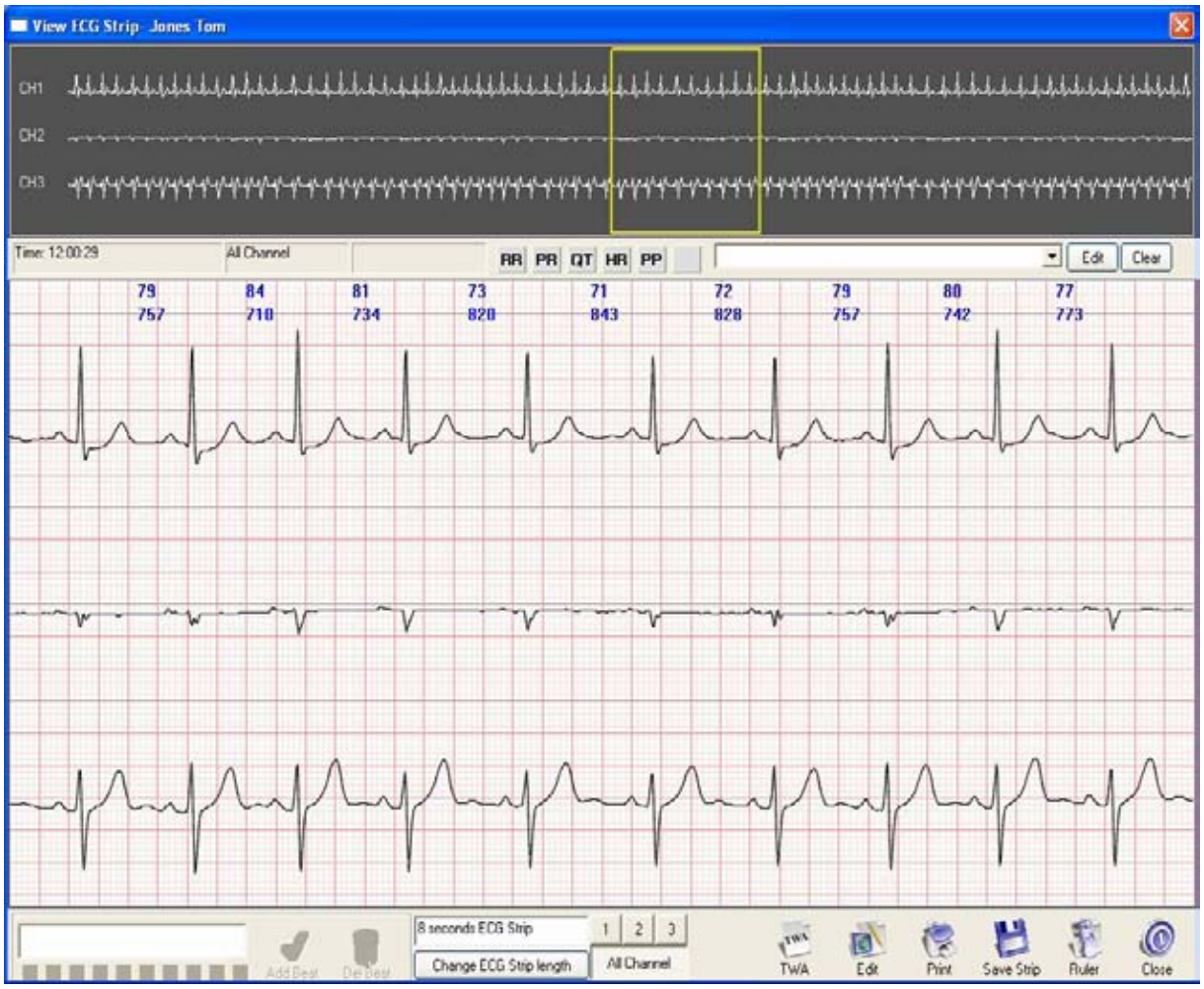
The VCG Program is not functional at this time.

T-WAVE ALTERNANS ***NOTE: THIS PROGRAM IS NOT TO BE USED IN THE USA!***

T-Wave Alternans is the difference it T-Wave amplitude from beat-to-beat. The measurement difference can be either a positive or negative difference from the prior beats. Large changes in T-wave amplitudes are believed to be a good predictor of a future V-Tach.

To access the T-Wave Alternans function, click on the ECG Strip icon from the Data Access Choices menu.

Enter the time in the upper left corner and click on View or press the Enter key on the keyboard.



Click on the TWA icon at the bottom of the screen. The following screen will appear.

The top left corner ECG superimposition shows all the selected beats in the group of 128 beats. When you see a tight superimposition, you know all the selected beats were a clean ECG with a small amount of baseline wander.

The Histogram Bar Graph next to the ECG superimposition shows the simple distribution of T-Wave height in micro-volt levels. The wider the bar graphs, the more the T-Wave Alternans.

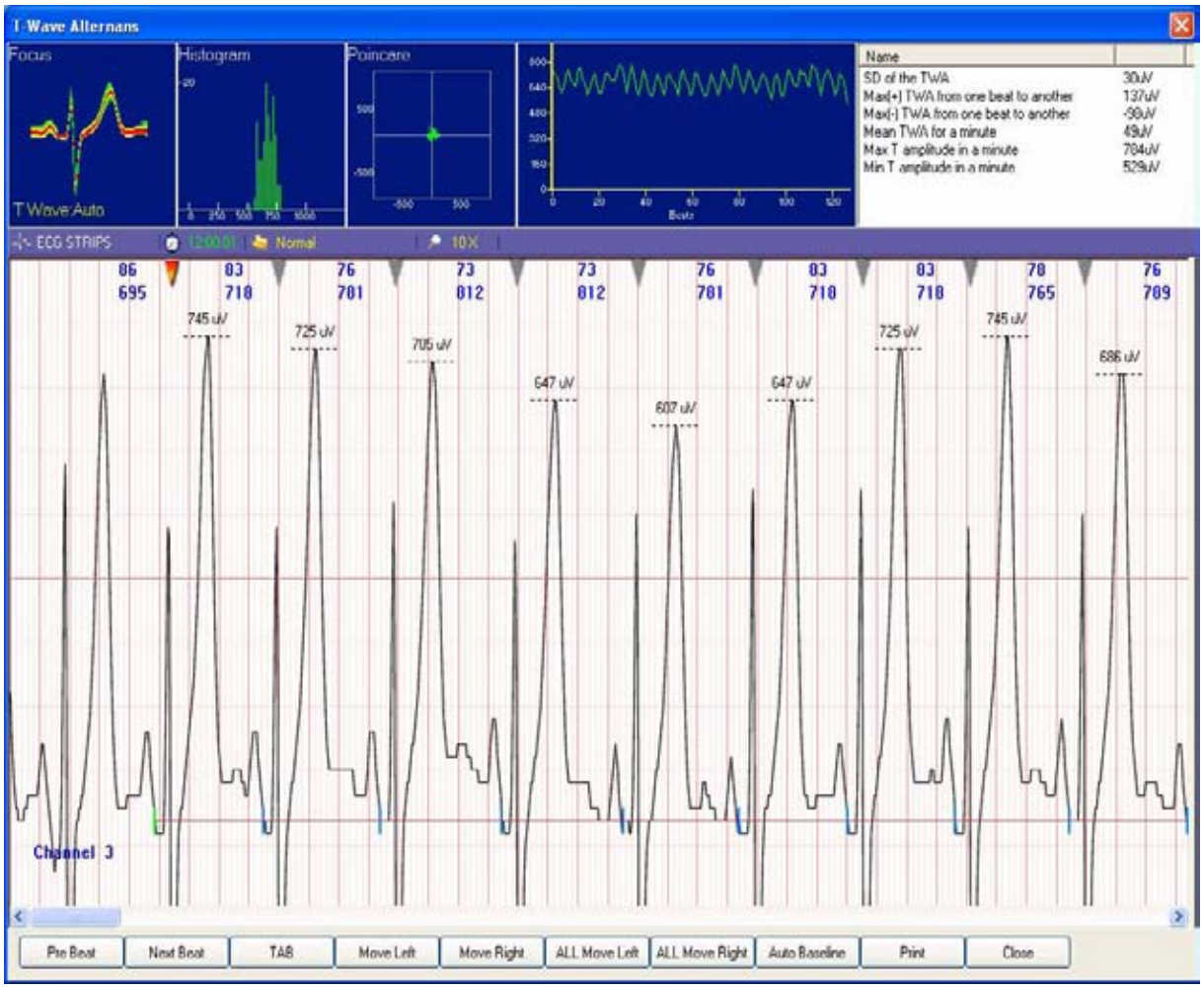
The Poincare Plot next to the Histogram Bar Graph is a chaos plot showing the difference in T-Wave height. The more the dots are scattered, the more the T-Wave Alternans.

The Beat-to-Beat Graph next to the Poincare Plot shows the T-Wave height of each successive T-Wave. The more jagged the graph, the more the T-Wave Alternans.

The Numerical data at the upper far right of the screen shows the measurements of T-Wave Alternans. There is not yet a consensus of how much T-Wave Alternans equals a positive or negative test.

Select one channel of clean ECG data and click on the TWA icon. Use the right mouse click on 8-second ECG strip to select the channel with the largest and cleanest T-Wave.

To expand the size of the T-wave, press on the + key on the numberpad of the keyboard.



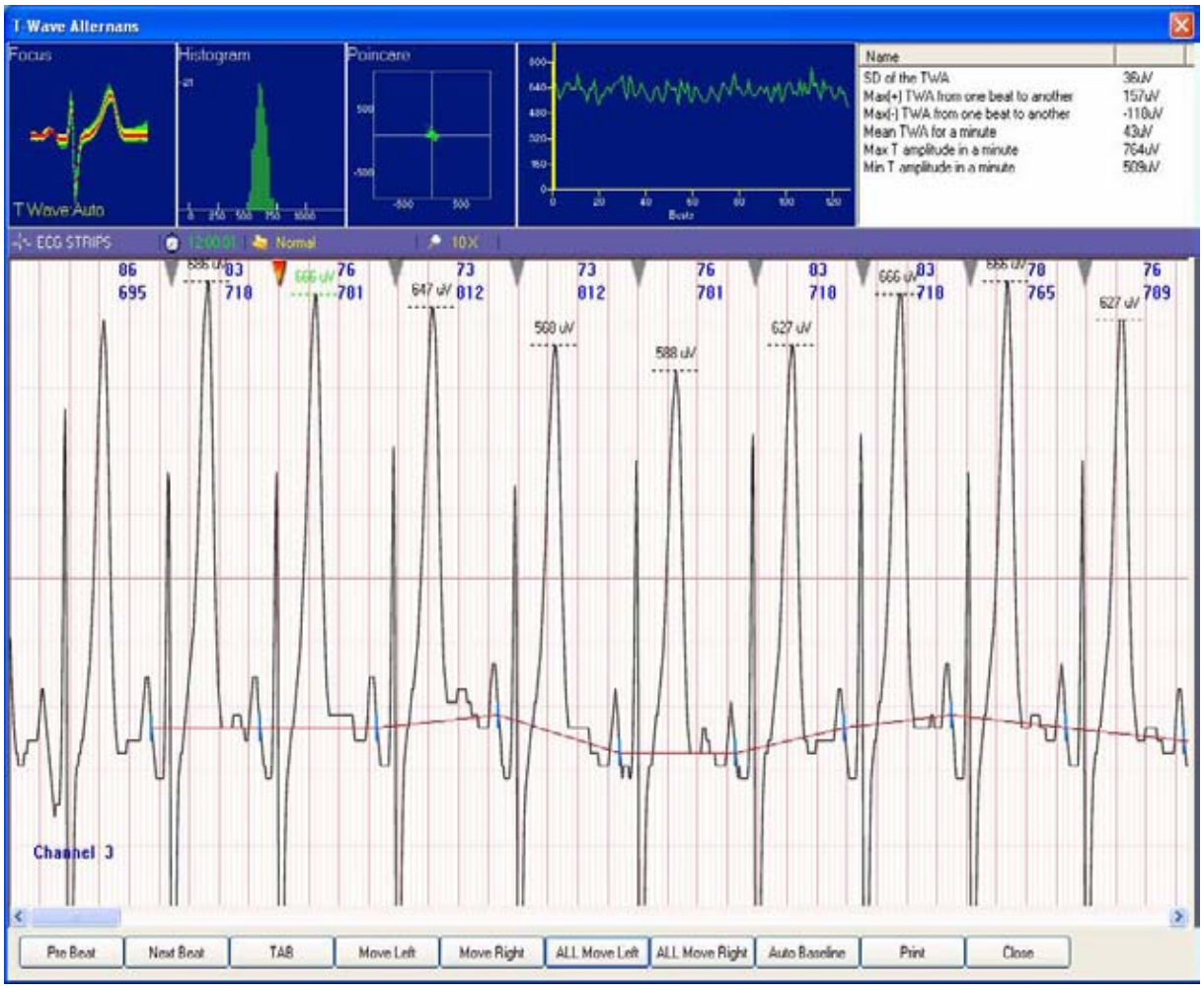
The above screen shows a x10 expansion. The expansion number is noted on the purple bar above the strip in the middle of the screen.

NOTE: As you expand the screen you may find you want to lower the ECG beats so you have a better view. You will notice that the mouse cursor is a hand on the screen. Just point, left click and drag the hand down the screen to lower the ECG.

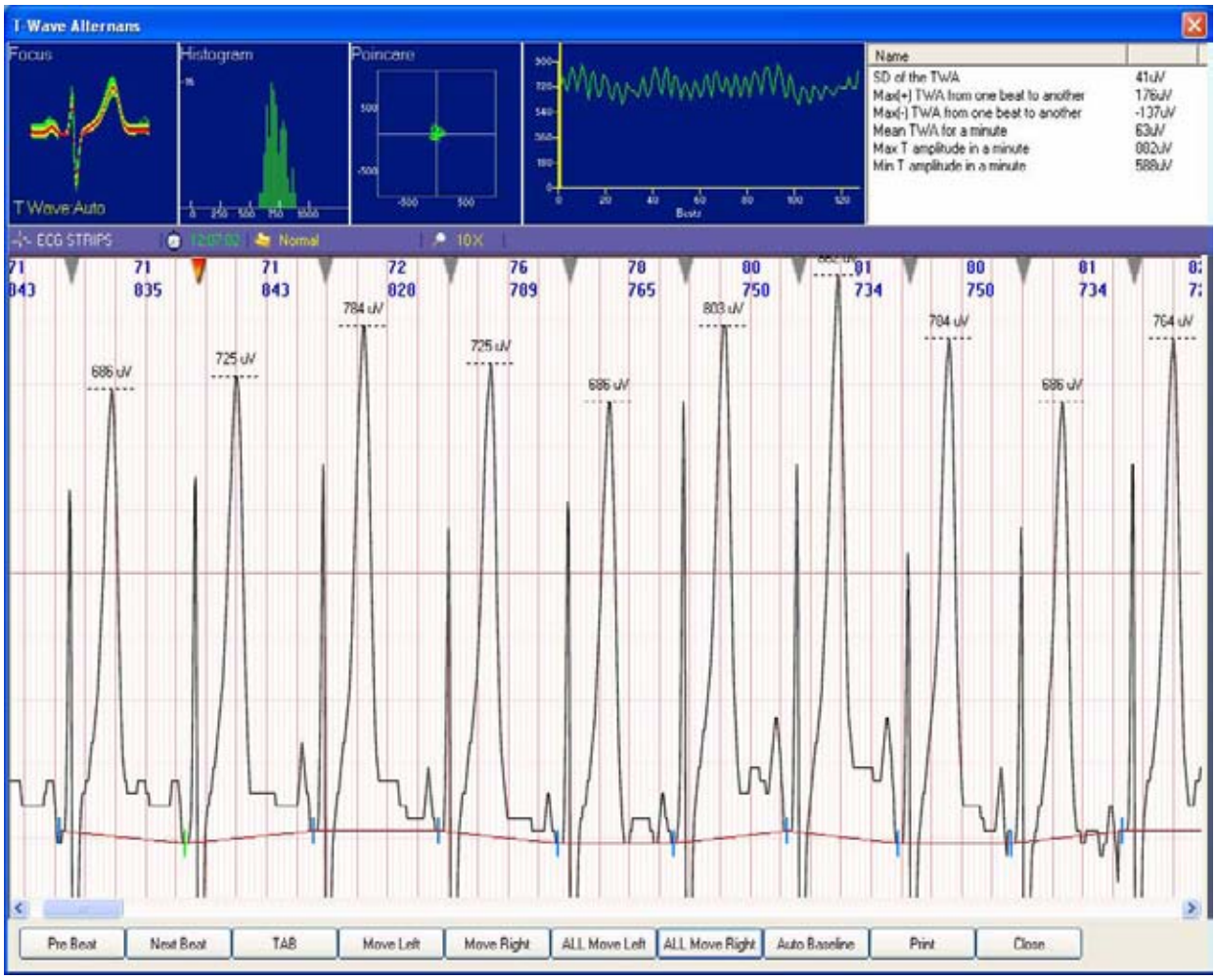
To change the channel you are viewing, right click anywhere in the screen and a drop down menu will appear. Click on the channel you desire.

The expansion helps us to visually see changes in the T-Wave peaks.

Each group of selected beats has 128 beats.

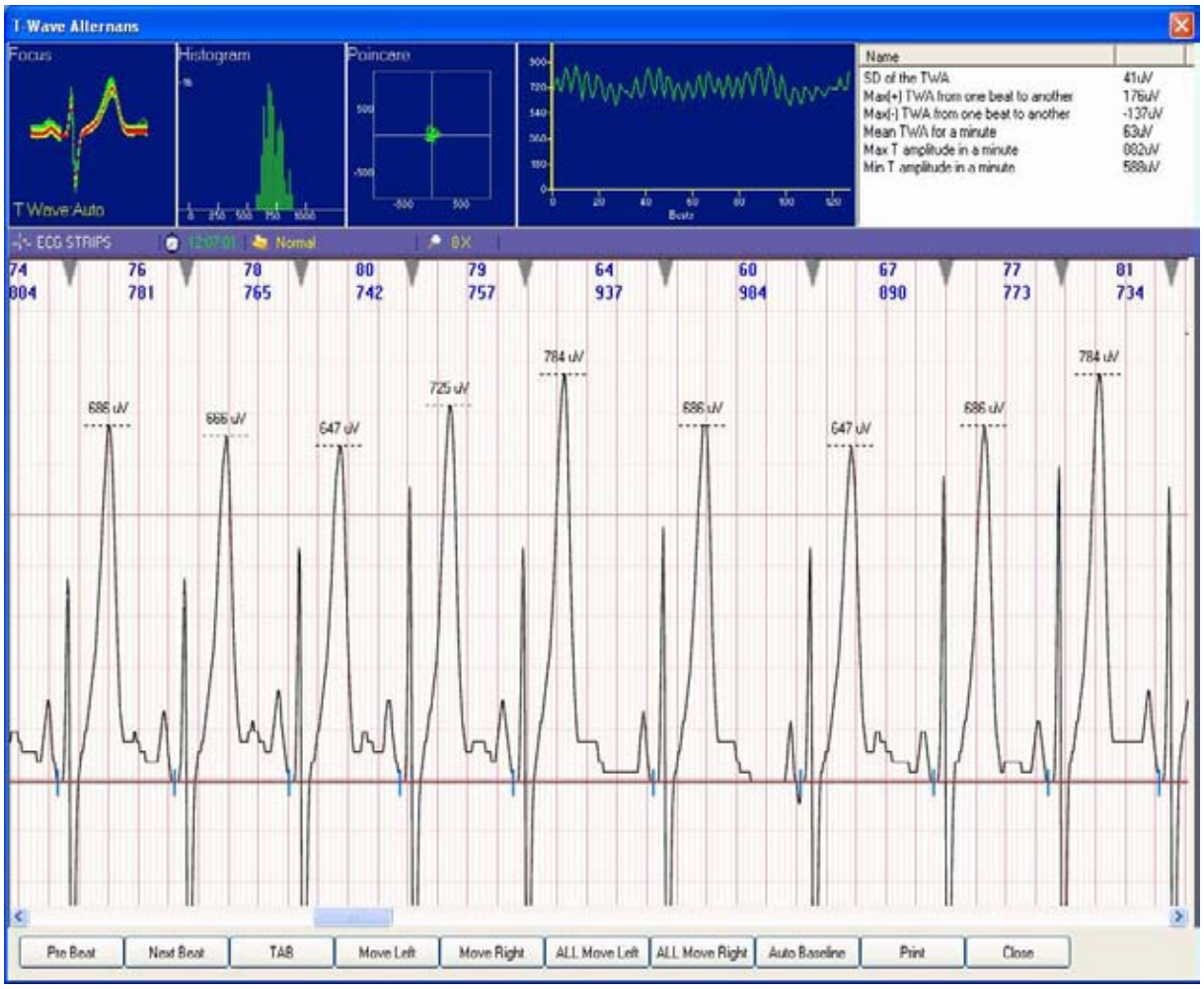


Set the blue cursor on the beats at either the P-R Baseline, J-Point or end of the T-Wave. To do this, click on the ALL Move Left bar or ALL Move Right Bar. You will notice as you click on either of these bars the blue cursor will move along the beats.



In the above example, we have set the blue cursor at the P-R Baseline.

The next step is to straighten the baseline. Click on the AutoBaseline bar.

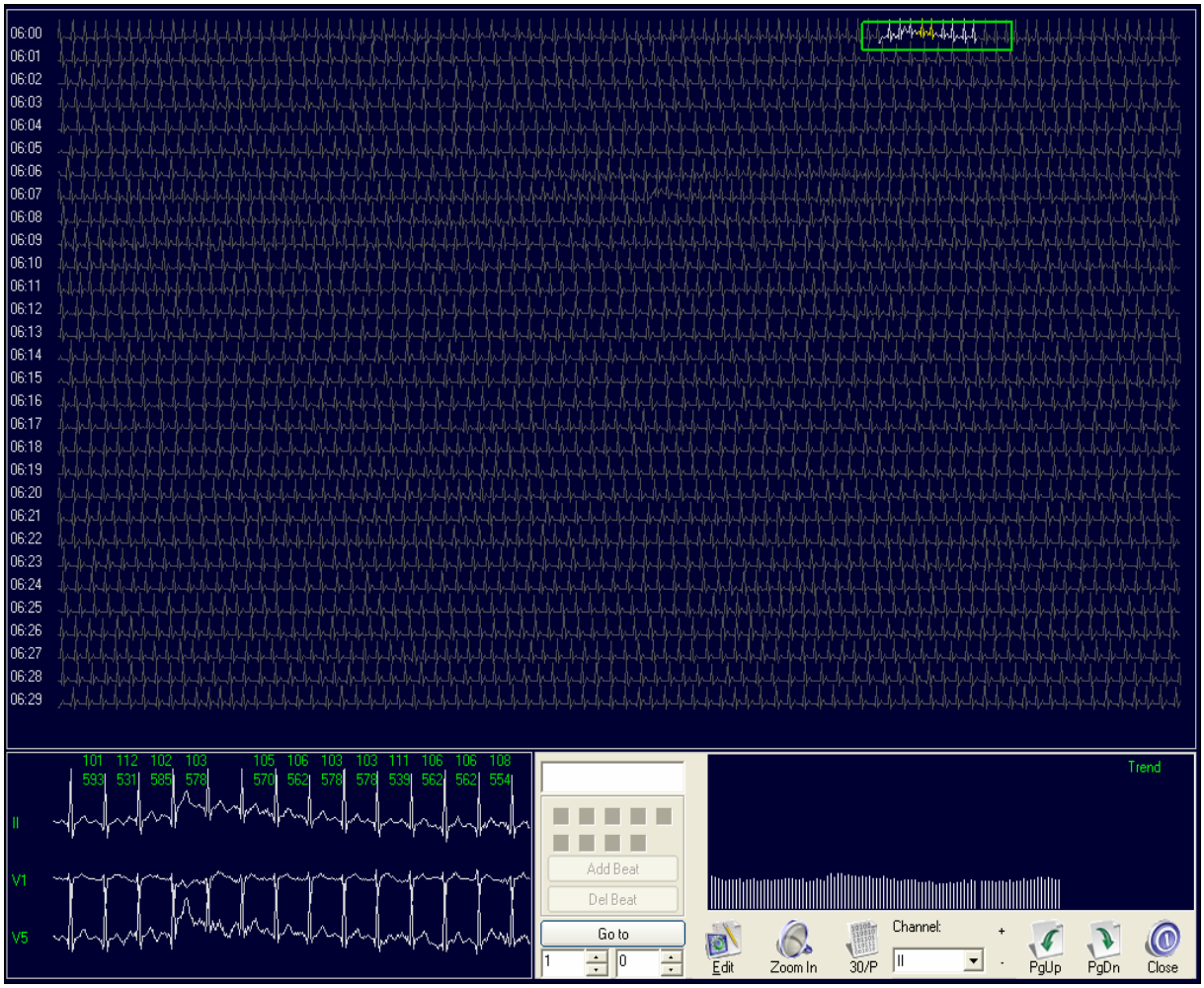


Press the “Print” bar to print the report.

PAGE SCAN MODE

To see the Full Disclosure ECG on the screen display, click on the PAGE SCAN icon on the Data Access Choices screen.

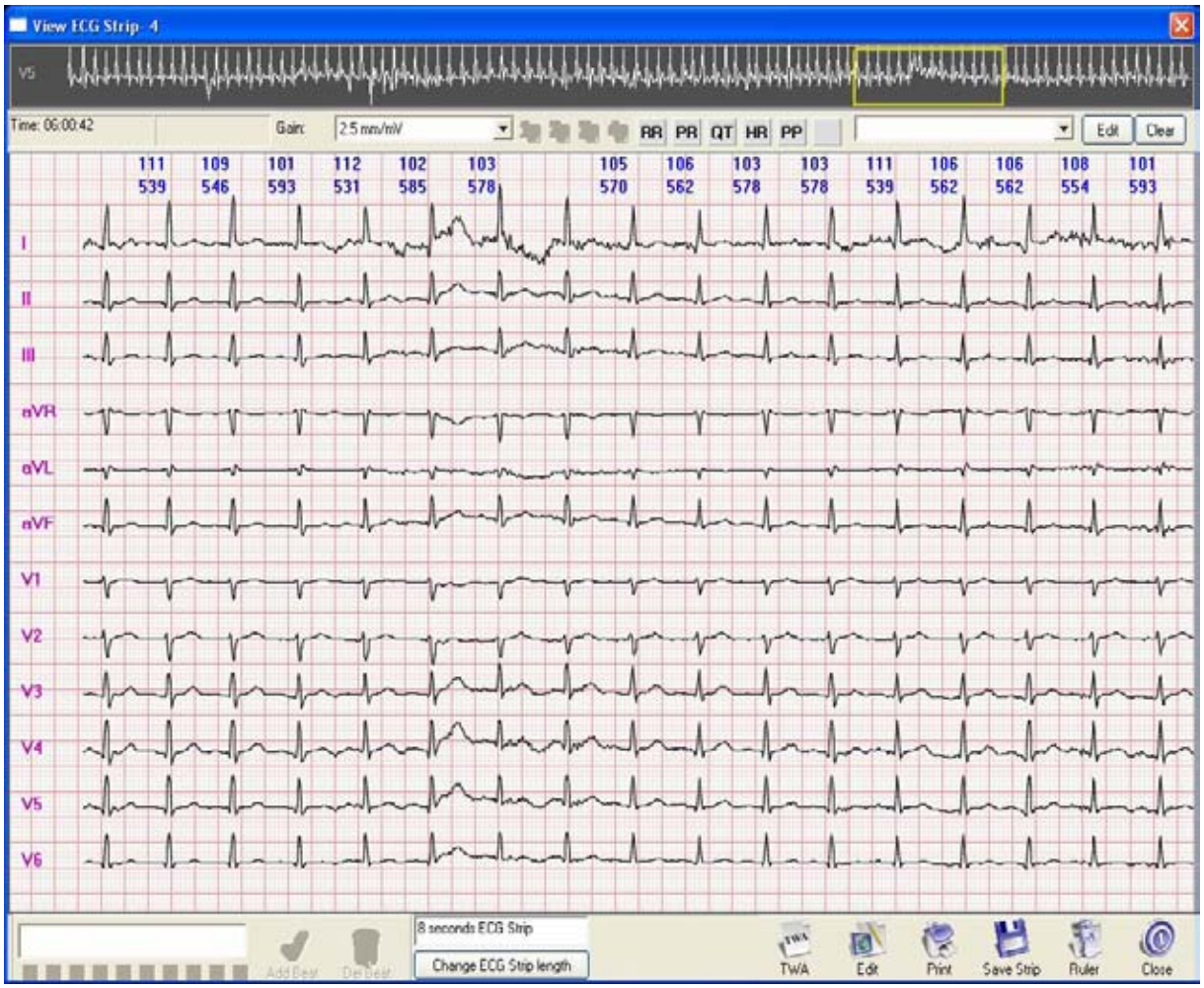
There are three editing modes in Page Scan, Page Scan Normal, Page Scan Artifact and Page Scan Sleep Apnea.



Page Scan Artifact shows only the beats that the analysis algorithm has rejected, along with the beats before and after the rejected beats. The rejected beats, as well as the before and after beats, are colored yellow.

When the beats are rejected they are not available for arrhythmia or pause analysis. If a V-Tach or Pause were rejected because of too much noise, then you would have to rely on the Full Disclosure or Page Scan to see the un-analyzed event. The Page Scan Artifact editing mode is a very quick method to see all the beats that were rejected, and lets you add them back into the arrhythmia or pause analysis, if desired.

In the above example we have used the mouse arrow and did a left click to place the green rectangular box over the third set of rejected beats on the screen Page Scan display. On the lower left side of the screen an enlarged 8-second 3 channel view of the rejected beats is displayed. Double click on the green rectangular box or press the ENTER key.



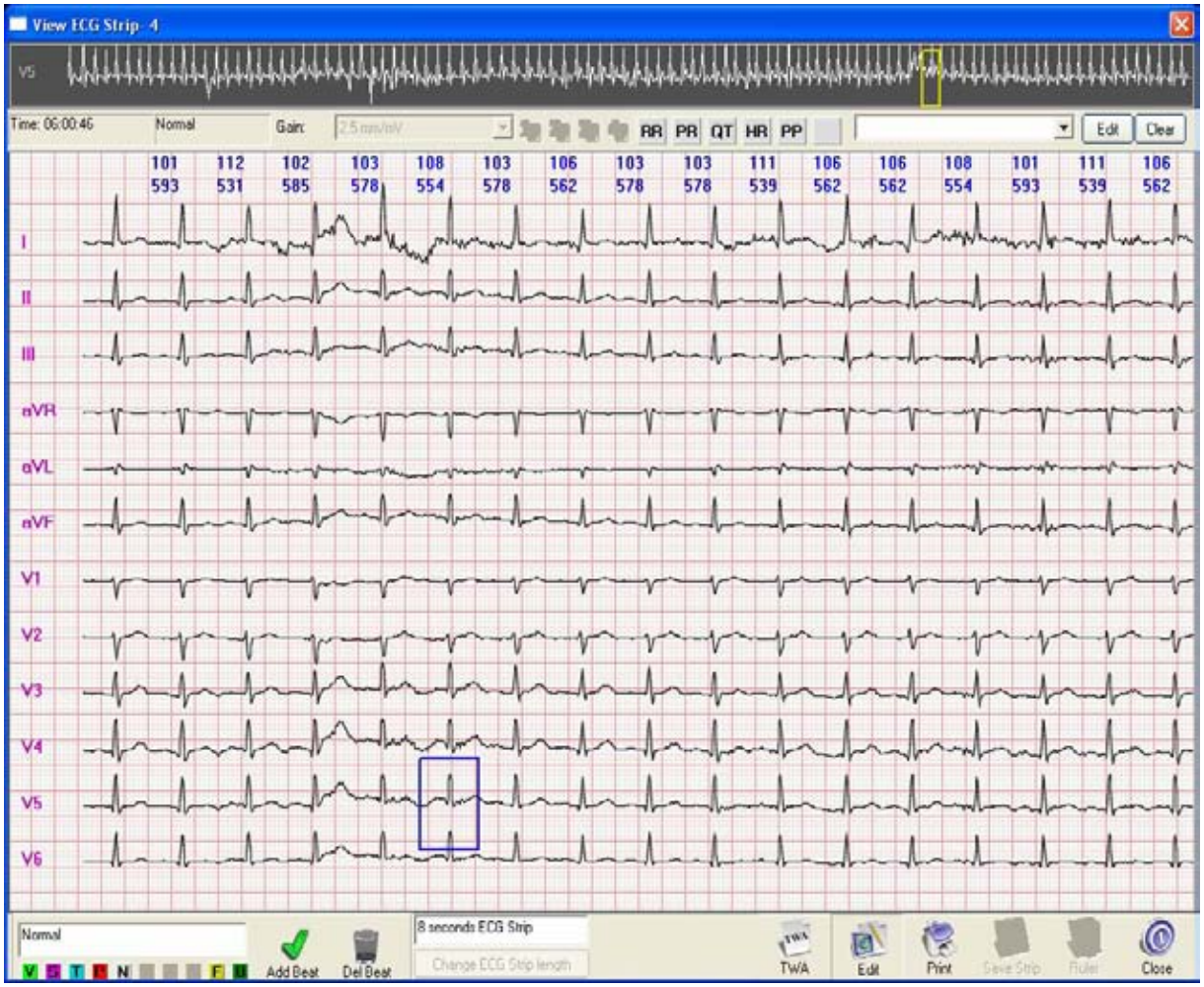
An enlarged 8-second strip will appear on the screen.

There are 3 ways to edit the beat into the analysis.

1. Double left click the mouse arrow on the R-wave of the beat that needs to be entered into the analysis. A blue vertical marker will appear. Click on the label code on the bottom of the screen to label the beat OR press the appropriate letter from the label code on the keyboard.

2. Right click the mouse. A rectangular box will appear on the strip. Press the INSERT key on the keyboard. A blue vertical marker will appear on the strip. Using the right or left arrow key on the keyboard, move the vertical marker to the R-wave of the desired beat. Click on the label code on the bottom of the screen to label the beat OR press the appropriate letter from the label code on the keyboard.

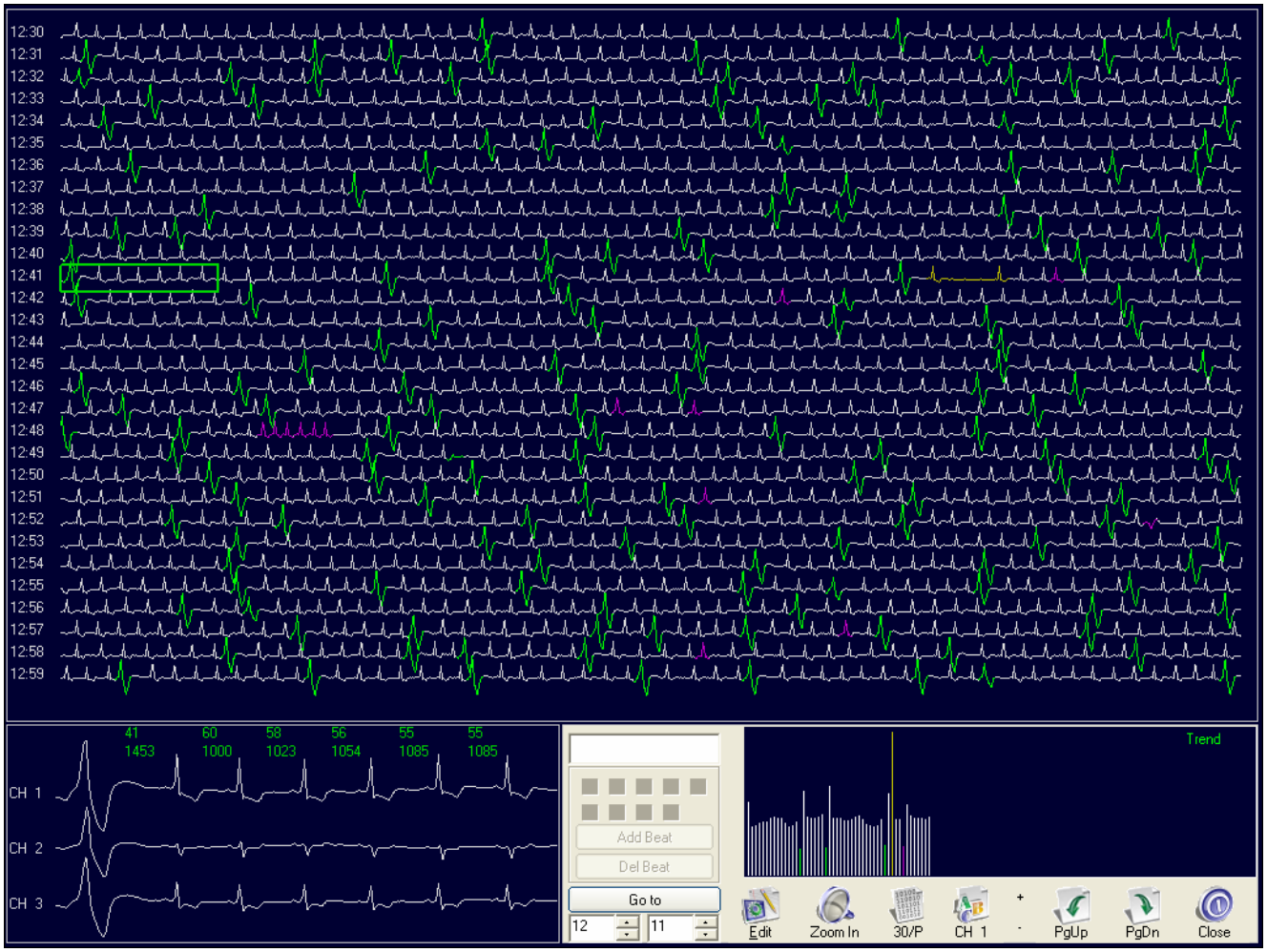
3. Right click the mouse. A rectangular box will appear on the strip. Click on the ADD BEAT icon at the bottom of the screen. Use the arrow keys on the keyboard to move the marker to the R-wave of the beat. With your mouse, click on the appropriate label from the label code at the bottom of the screen OR press the appropriate letter from the label code on the keyboard.



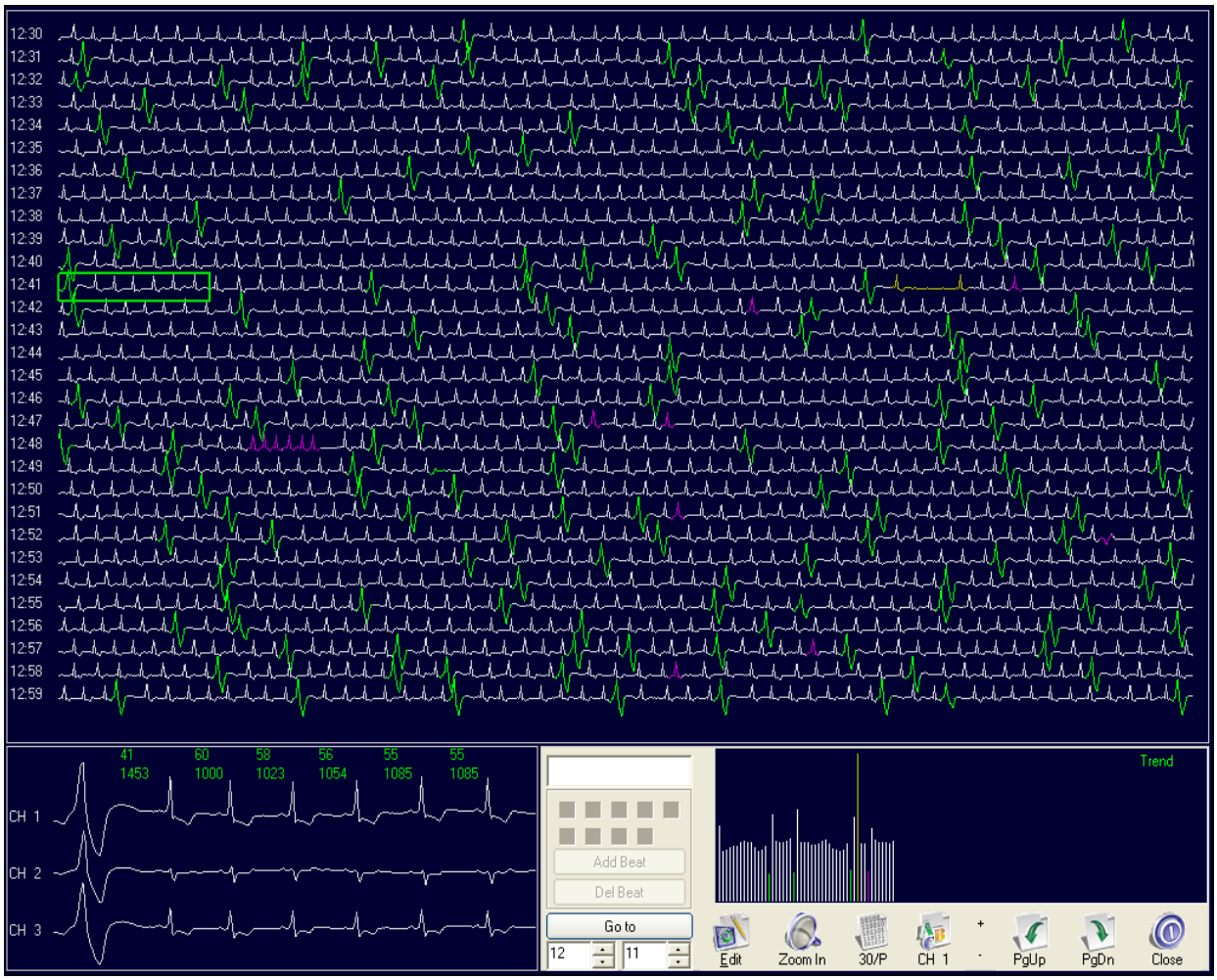
In our example, you can see that we have labeled the beat a normal as it is notated on the strip.

Click on the CLOSE icon at the bottom of the screen. You will be returned to the Page Scan Artifact screen.

To add more beats into the analysis, repeat the above steps.



To activate the Page Scan mode, click on the Page Scan icon on the Data Access Choices screen and then click on Page Scan Normal.



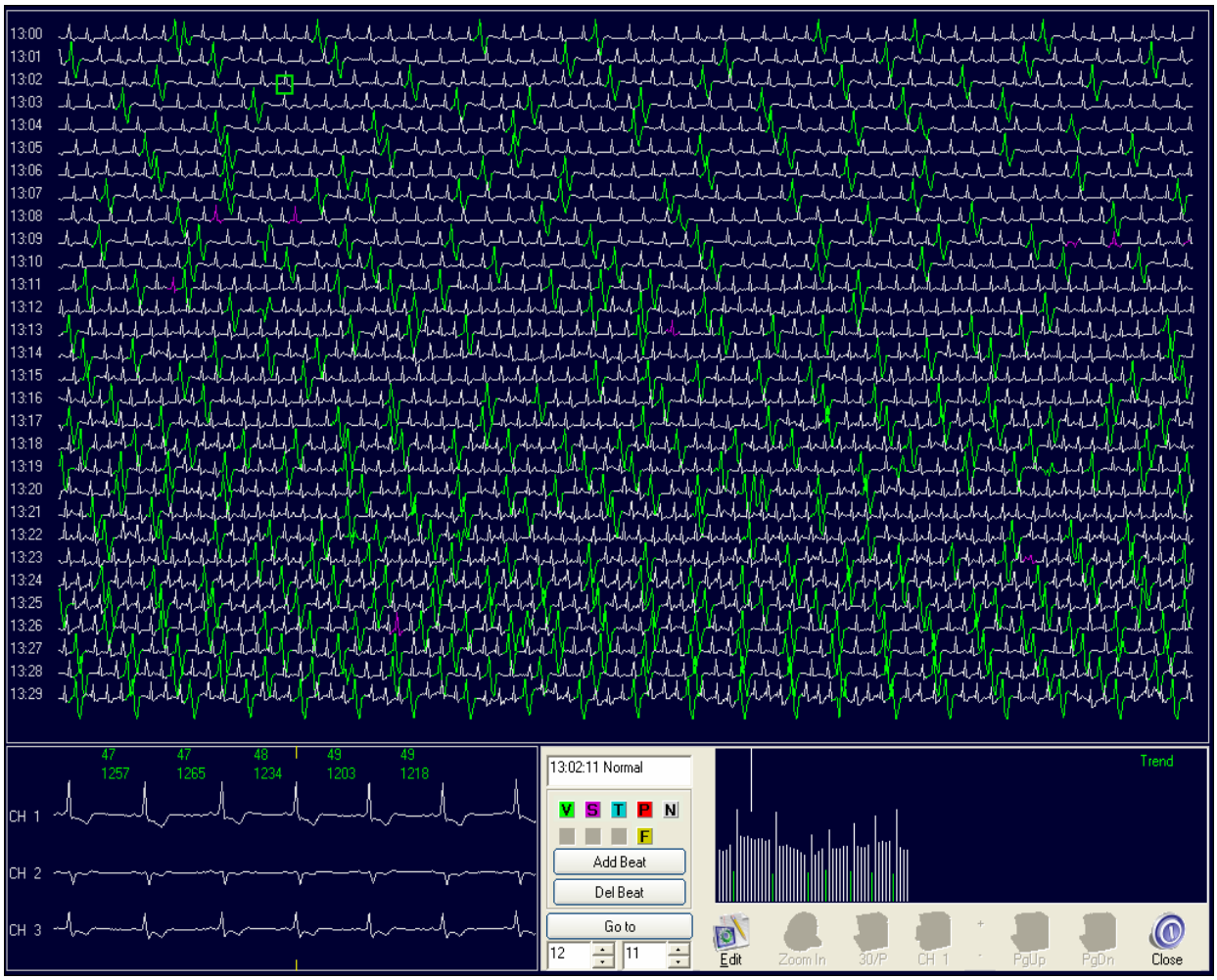
The above screen shows 30 minutes of ECG data. To change the display to 20 minutes of ECG data per page, click on the 30/P icon on the bottom of the screen until you see 20 minutes of ECG data on the screen. The icon will change to 20/P. To change the display to show 10 minutes of ECG data on the screen, click on the 30/P icon at the bottom of the screen until you see 10 minutes of ECG data on the screen. The icon will change to 10/P.

Time is listed on the left side of the Full Disclosure ECG. Each horizontal sweep is one minute of time in the 20-minute per page mode and the 30-minute per page mode. Each horizontal sweep is 30-seconds in the 10-minute per page mode.

An eight-second rectangular box can be moved around the screen display with the arrows on the keyboard OR by pointing and clicking with your mouse. If you see an ECG of interest, you can move the rectangular box to the desired location OR simply point your mouse to the beat you desire and click. The eight-second rectangular box will be moved to that spot. A 3-channel enlargement of this box can be found on the lower left of the screen. To view this strip in an enlarged eight-second strip, click on the ZOOM IN icon on the bottom of the screen.

To change the channel of the ECG data on the page scan, click on the CH 1 icon at the bottom of the screen. You can select Channel 1, Channel 2 or Channel 3.

To view the next page of data, click on the PGDN icon on the bottom of the screen. To view the previous page of data, click on the PGUP icon on the bottom of the screen.



To view a specific minute, enter the time in the time field at the bottom center of the screen. The first field is for the hour and the second field is for the minutes. After you have entered the time, click on the GO TO bar.

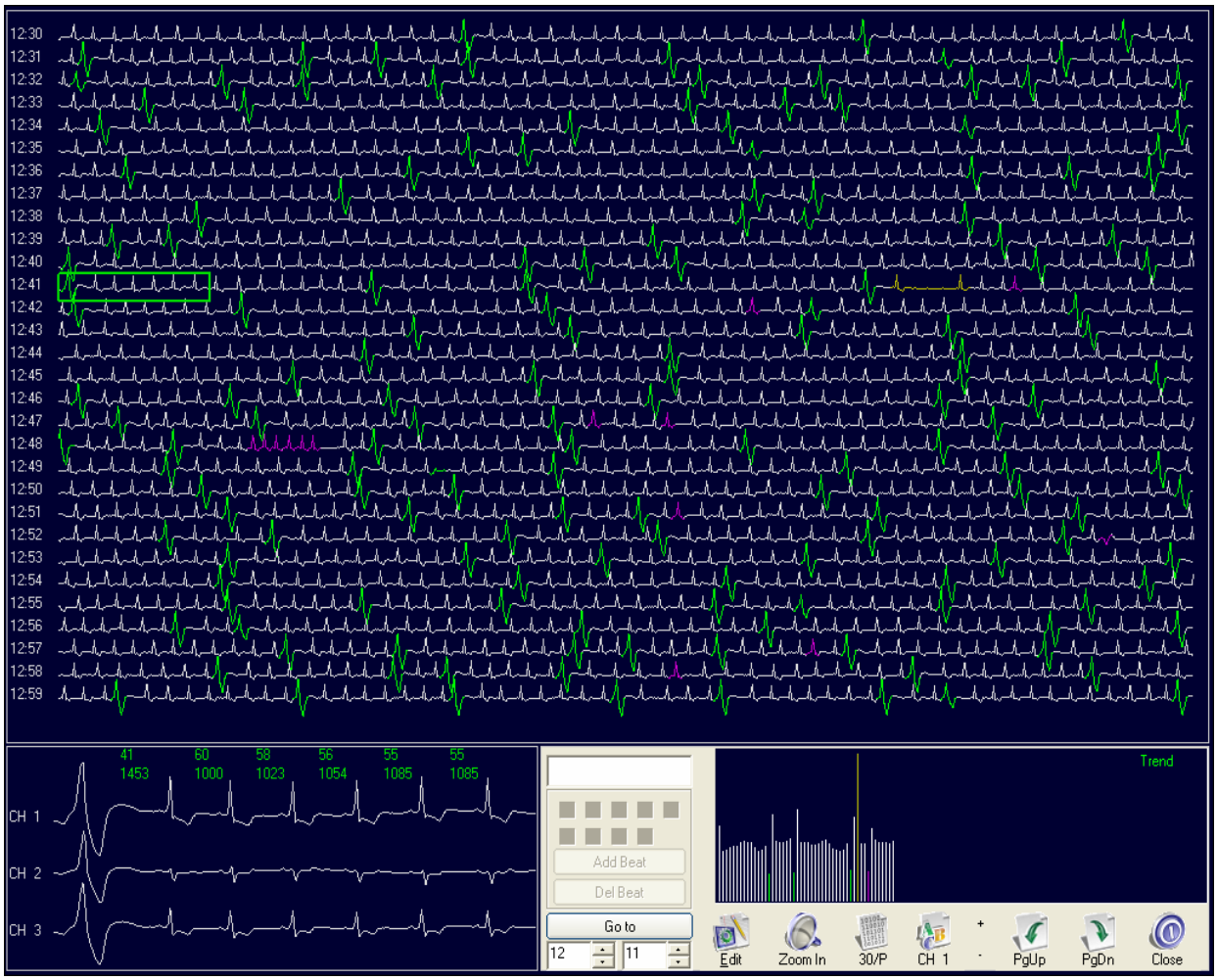
To Edit in the Page Scan mode, click on the EDIT icon at the bottom of the screen. The eight-second rectangular box will decrease in size to an individual beat box. This box can be moved with the arrow keys on the keyboard.

To begin the editing process, move the box to the beat you wish to edit. You may click on the appropriate letter from the label code in the middle bottom of the screen OR press the appropriate letter from the label code on your keyboard.

After you have edited and labeled the beat, press the ESC key on your keyboard. The eight-second rectangular box will reappear on the screen. To edit another beat, click on the EDIT icon on the bottom of the screen.

To add a beat, click on the EDIT icon at the bottom of the screen. With the arrow keys on your keyboard move the beat box to the beat prior to the beat you want to add. Click on the ADD BEAT bar on the lower part of the screen. Move the beat box until it is centered over the beat. Again, click on the ADD BEAT bar on your screen. Press the ESC key on your keyboard.

To delete a beat, click on the EDIT icon at the bottom of the screen. Move the beat box over the beat you choose to delete. Click on the DEL BEAT bar on the screen. Press the ESC key on your keyboard.



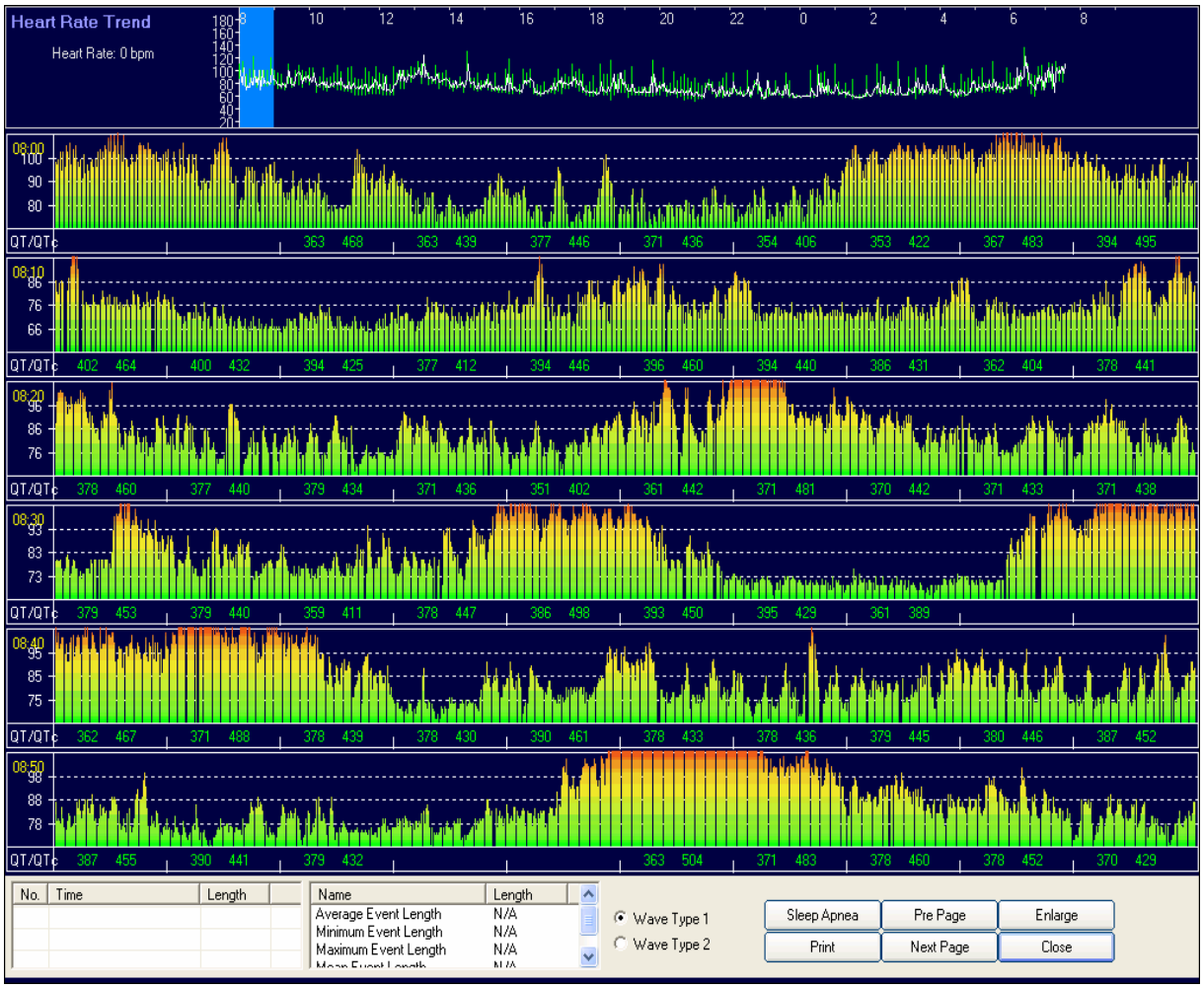
The R-R Variability Graph is located above the icons on the Page Scan screen. This graph shows you the changes in R-R during a one-minute period. In the example above, you will note the SVE on the 30-minute page scan screen. This SVE can also be seen on the R-R Variability Graph by the shorter line that is colored magenta.

Once you have finished editing in the Page Scan mode, click on the CLOSE icon at the bottom of the screen. An updating message will let you know the changes you have made to the Holter file are being calculated. You will be returned to the Data Access Choices screen.

SLEEP APNEA

To review the Sleep Apnea data, select he Page Scan Sleep Apnea from the Page Scan icon.

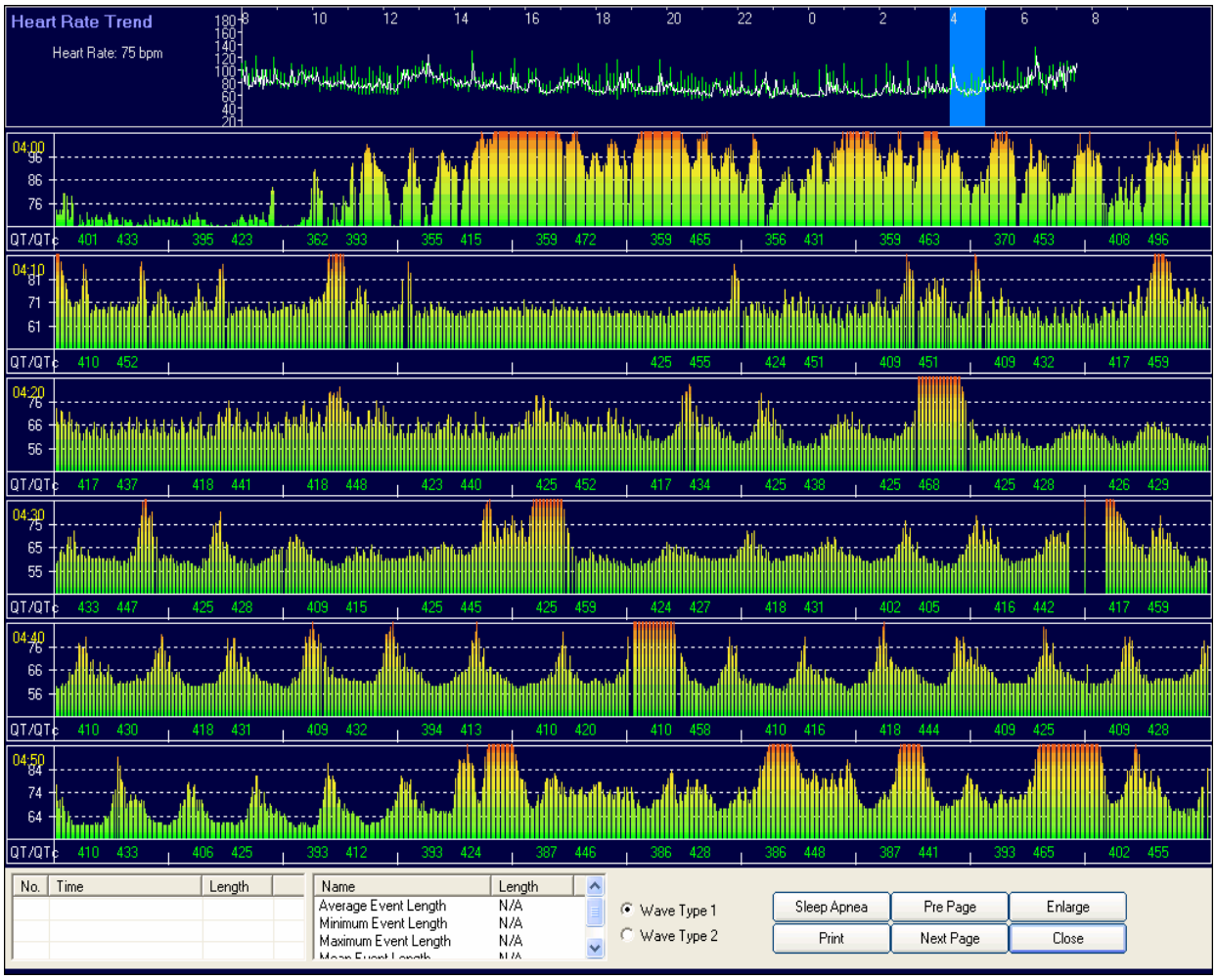
The following screen will appear.



The top of the screen is a 24-hour tachogram.

The vertical lines are N-N intervals for 1 hour. Each horizontal sweep is 10-minutes of N-N intervals. C

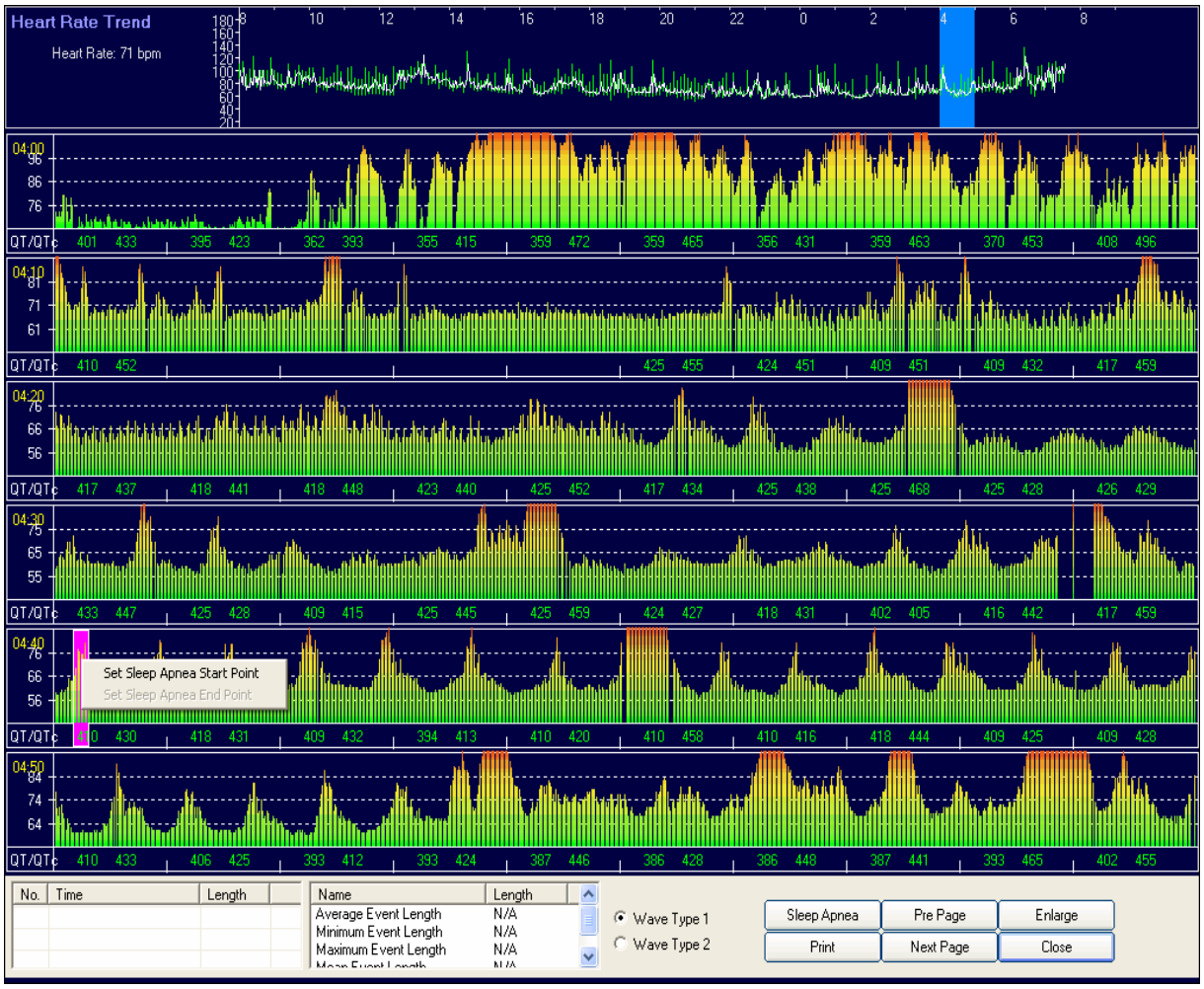
Click on the Sleep Apnea button at the bottom of the screen.



Click on the 4 AM hour in the 24 hour tachogram at the top of the screen.

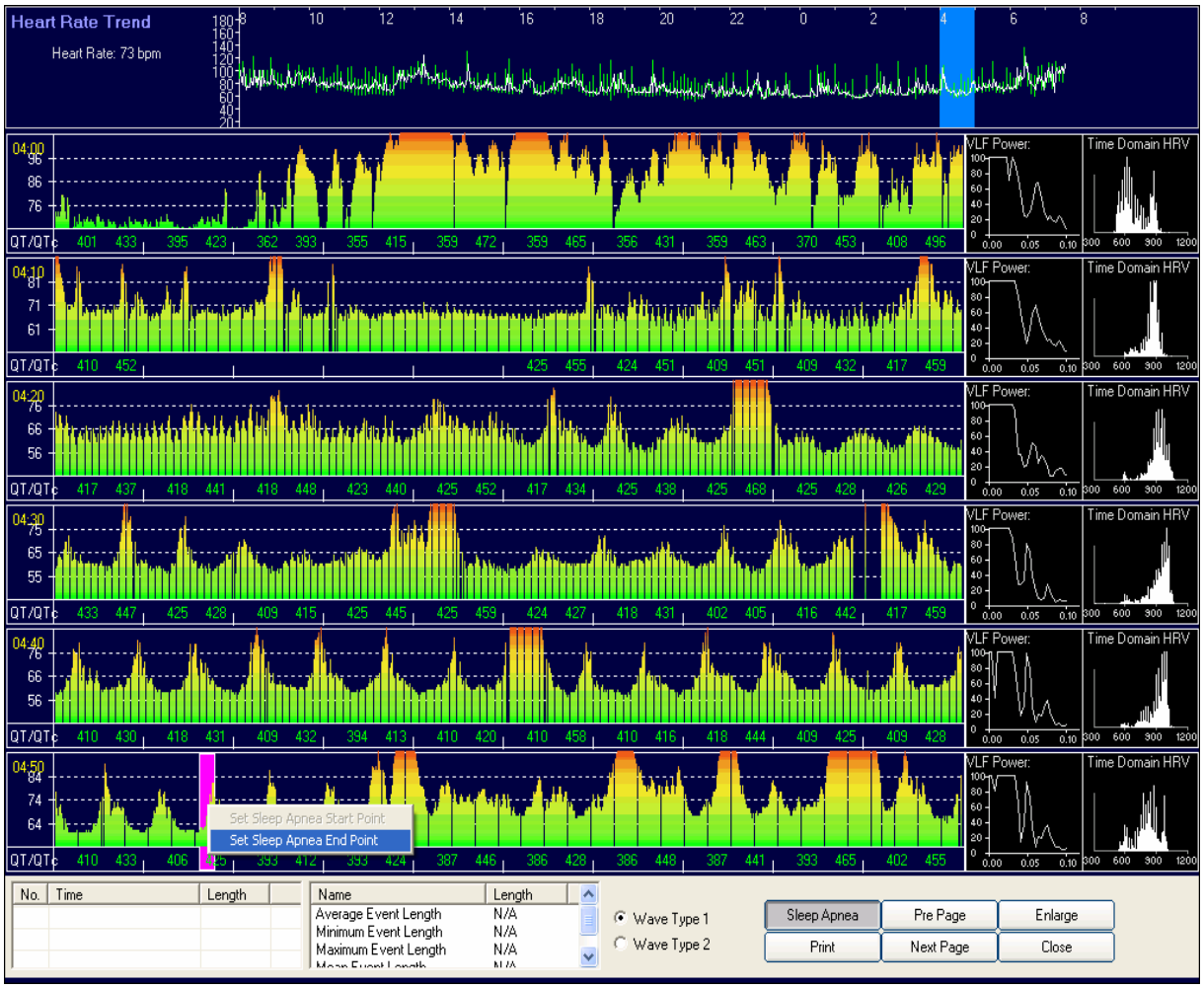
The heart wave shape seen at the 4:40 time is characteristic of Sleep Apnea.

To the right of each 10 minute N-N is a VLF power graph.

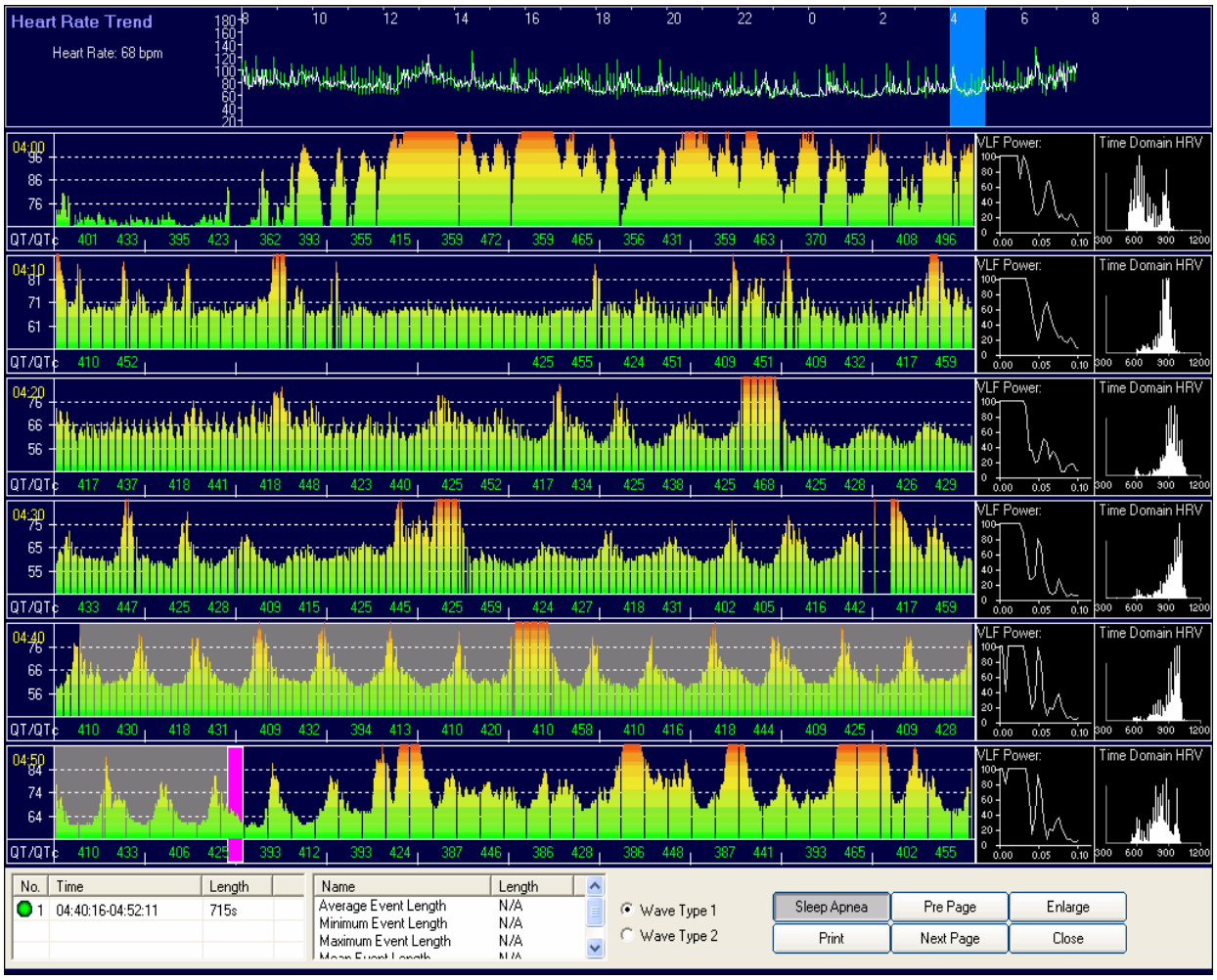


Click on the first peak at the 4:40 time. A pink highlight bar will appear.

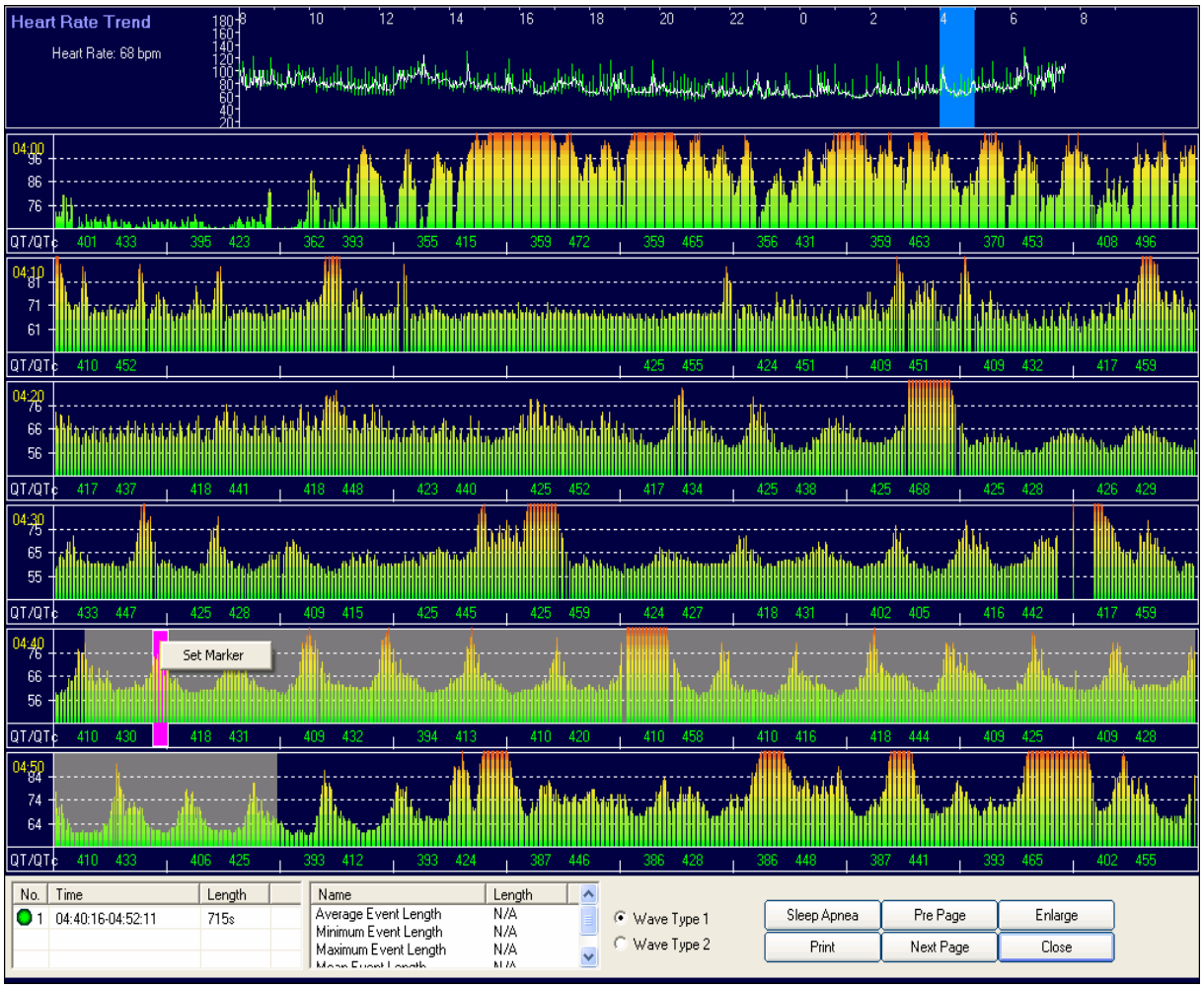
Right mouse click and the above popup screen will appear. Click on Set Sleep Apnea Start Point.



Click on 4:52 and then right click to get the above popup screen. Click on Set Sleep Apnea End Point.



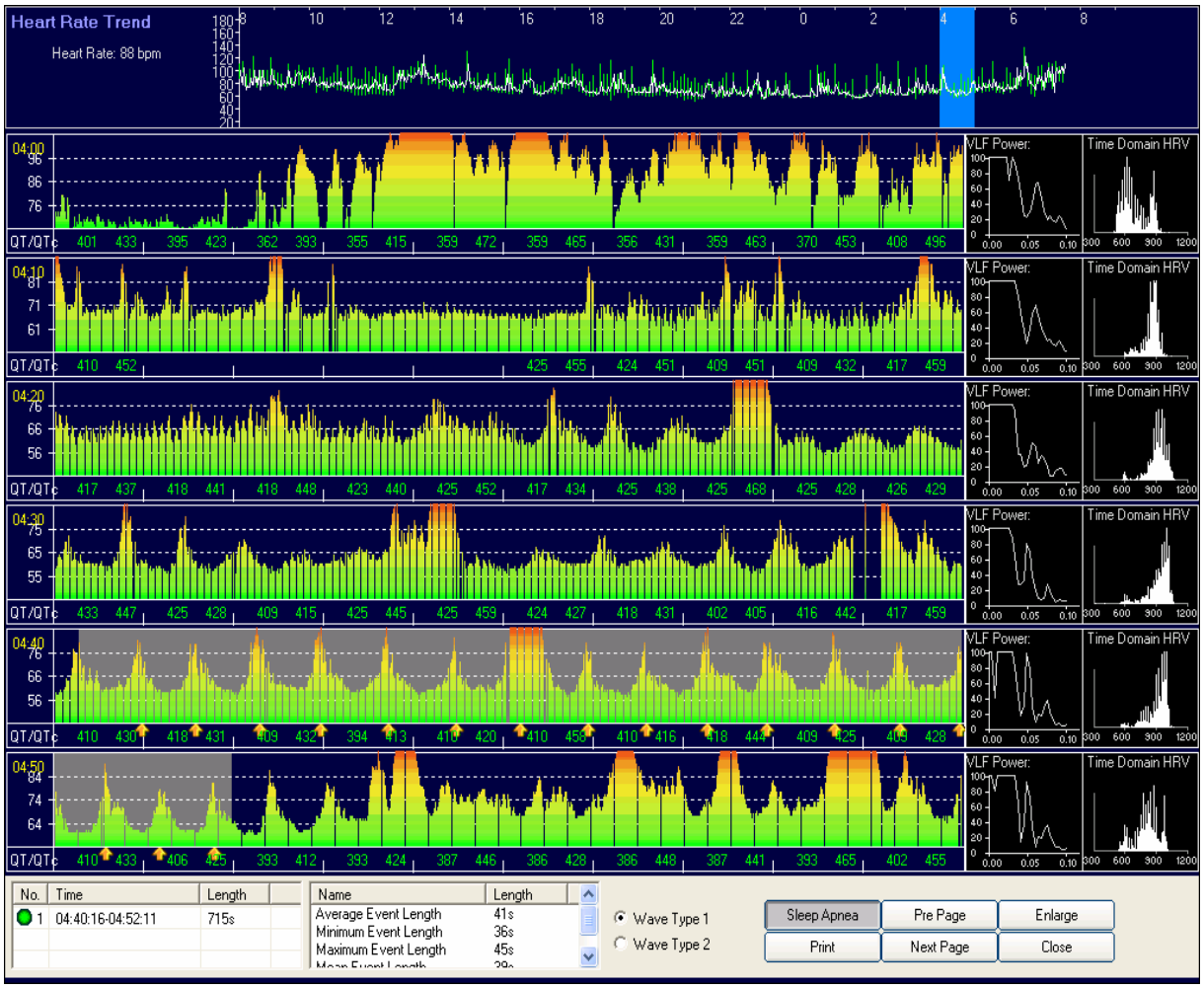
The entire time you have set as Sleep Apnea is now highlighted and noted in the bottom left of the screen.



Now we will set the individual events within the episode.

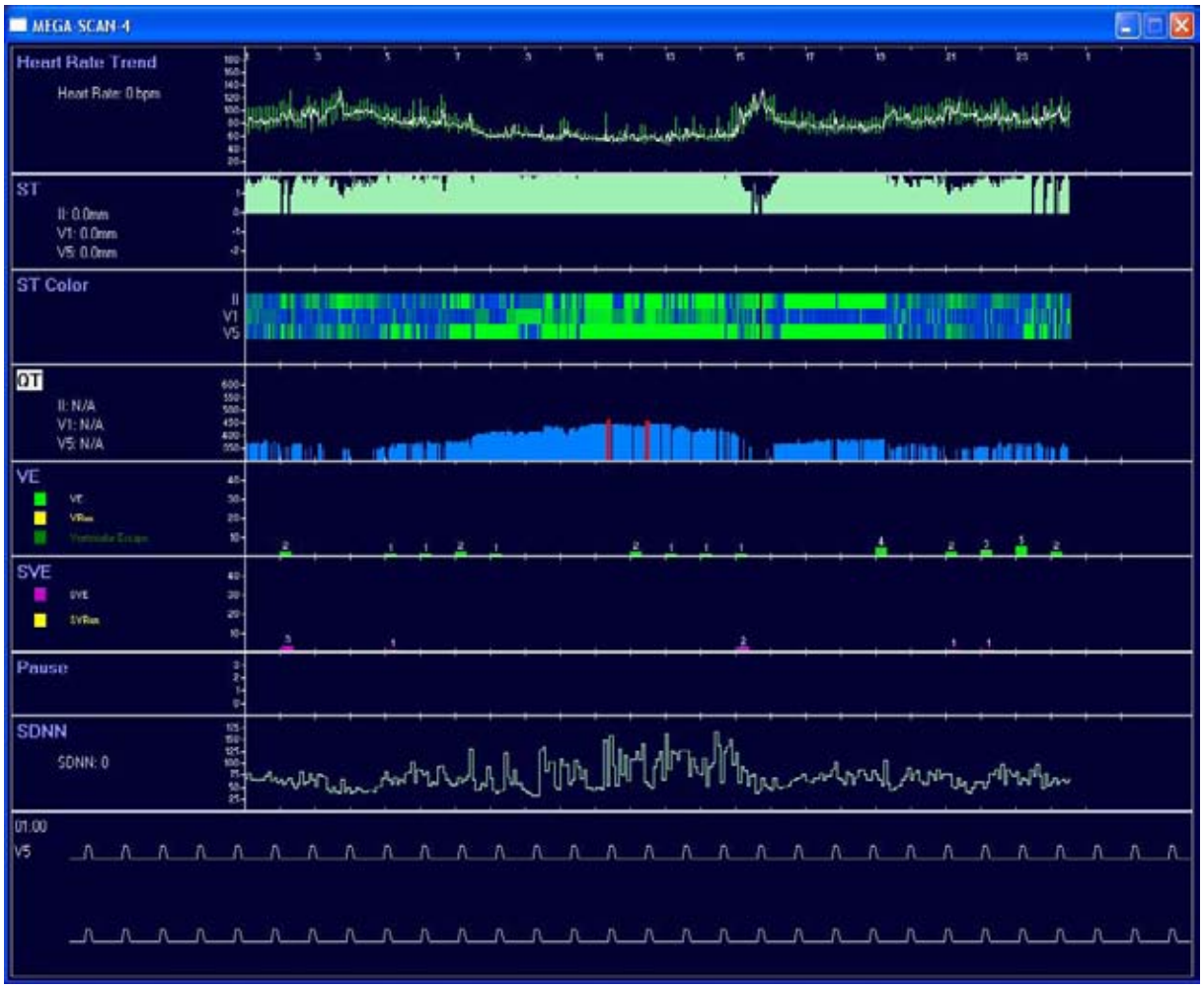
Point and click on the first high heart rate after the Set Start Point. Left click and a popup screen will appear. Click on the Set Marker popup screen.

Continue to click and set the marker on each high heart rate peak during the period (in the above example, there will be 17 settings).



At the bottom of the screen you will see an automatic calculation of the length of the Sleep Apnea episode and the lengths of the Sleep Apnea events. There appears to be a correlation that the shorter events are Obstructive Sleep Apnea.

To print a report, click on the Print bar at the bottom of the screen.

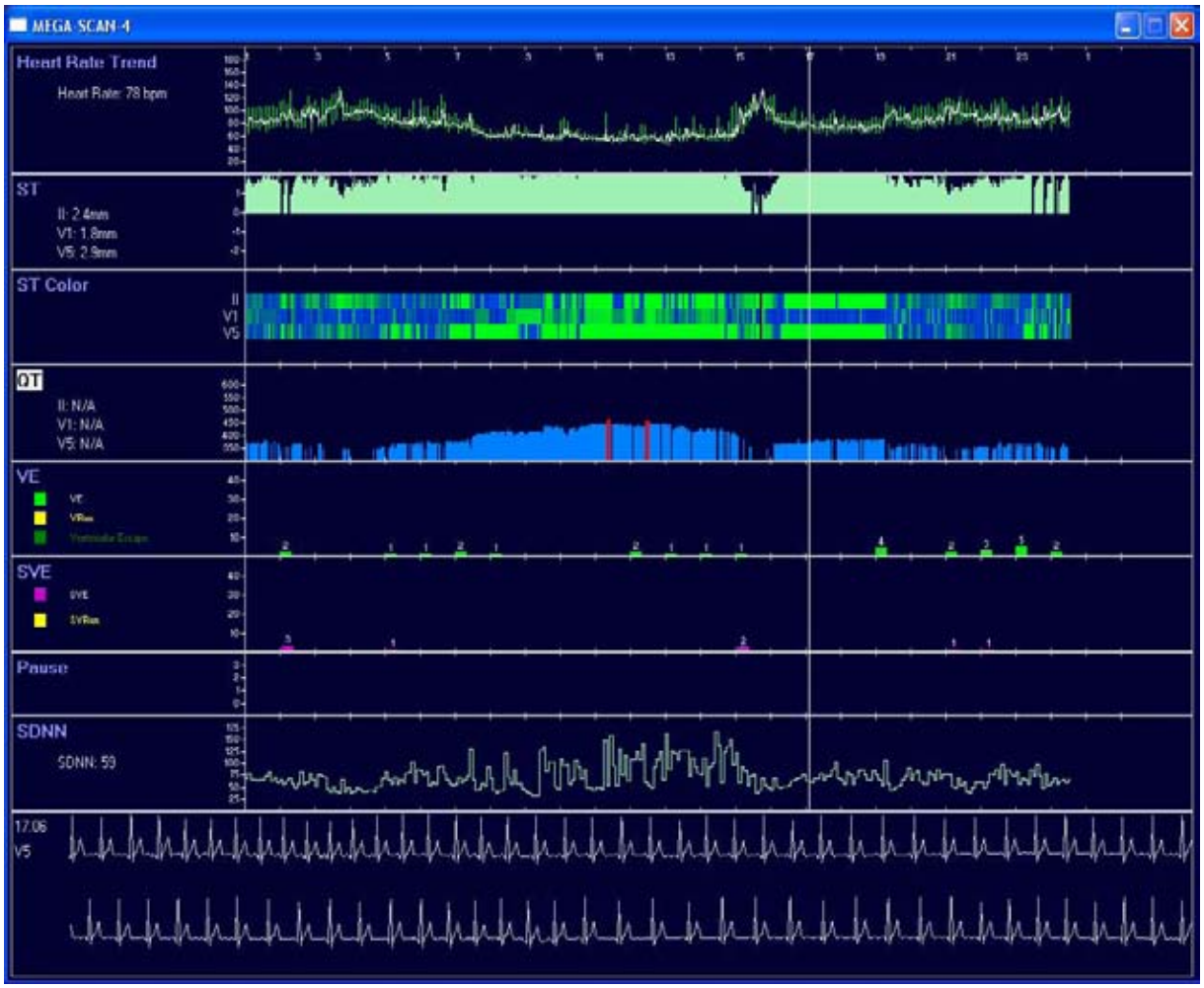


MEGA SCAN

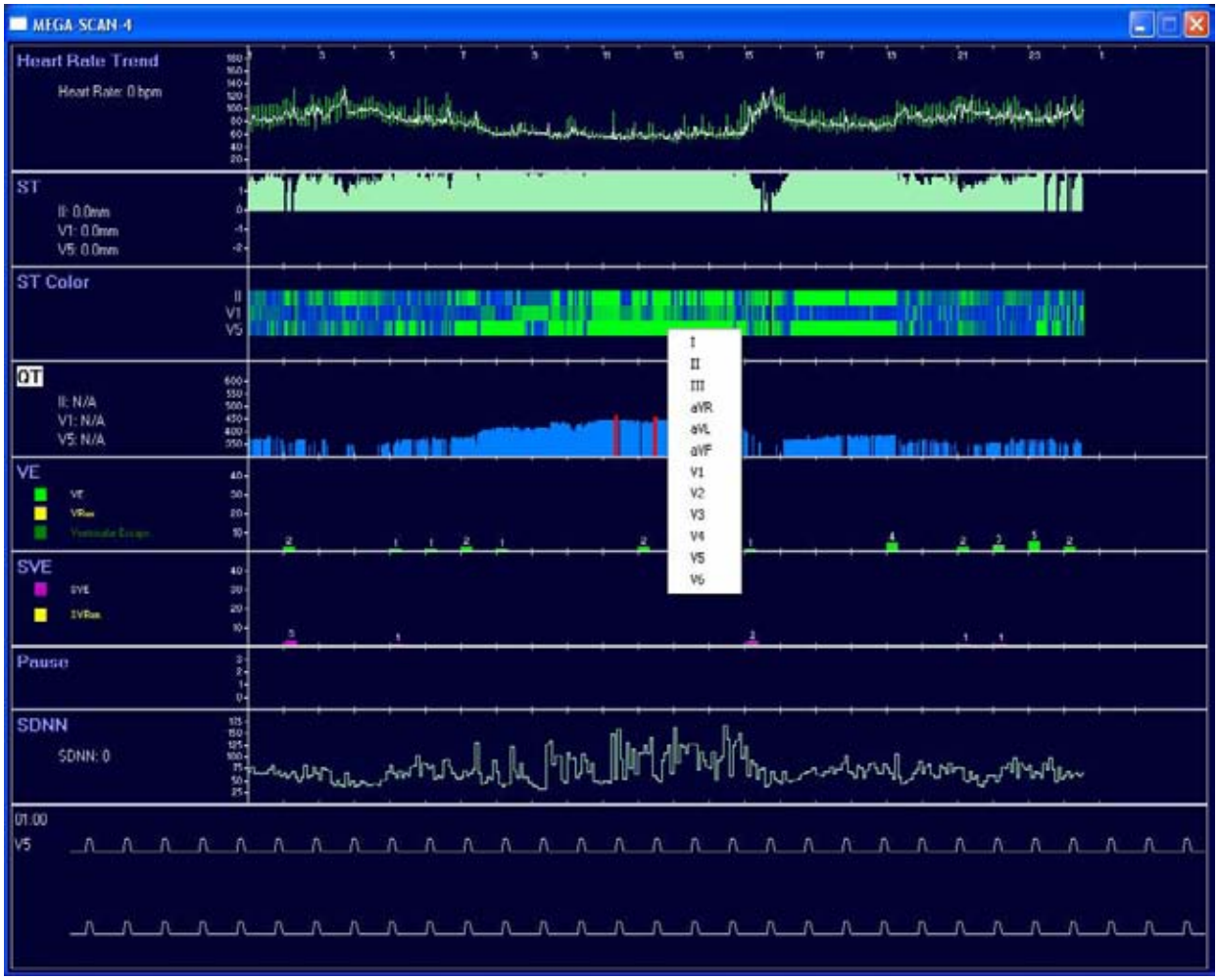
To access the Mega Scan graph, click on the MEGA SCAN icon on the Data Access Choices screen.

The purpose of the Mega Scan process is to allow you to slide a cursor through a 24-hour trend to view areas of interest. 24-hour trends of min-avg-max heart rate are displayed in a minute to minute basis. VE, V-Run, SVE, SV-Run and Pause trends are shown on an hourly basis. ST Segment trends for all 3 channels are shown on a minute to minute basis. You may toggle between QT and QTc trends that are shown on a one-minute basis. The SDNN of Heart Rate Variability is shown in 5-minute increments.

The Mega Scan process will also be useful in locating intermittent events of Atrial Fibrillation and Atrial Flutter. Sudden increases in the vertical range of the min-avg-max heart rate could be indications of Atrial Fibrillation or Flutter.



To activate the cursor, point and click your mouse anywhere within the 24-hour graph. This vertical cursor spans from top to bottom of all 24-hour trends. To move the cursor, you may use the arrow keys on the keyboard or point and click with the mouse on the location you desire to see. To move to a precise point, point and click with the mouse to the approximate location. Use the keyboard arrows to move the cursor to the exact spot.

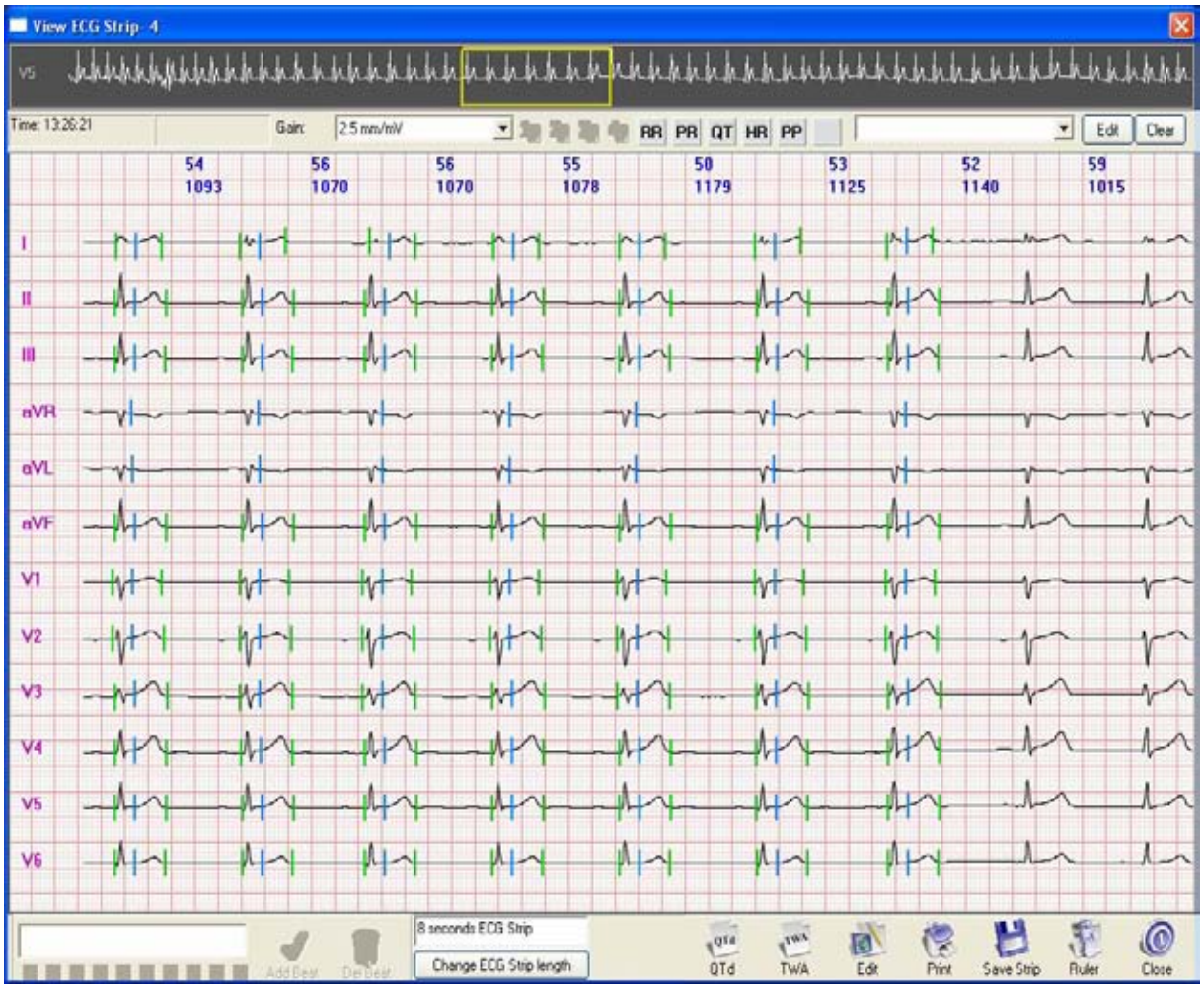


Right click your mouse and the above drop screen will appear.

If you select Show Ch. 1, the ST and QT graphs will be for Channel 1. If you select Show Ch. 2, the ST and QT graphs will be for Channel 2. If you select Show Ch. 3, the ST and QT graphs will be for Channel 3. If you have converted to the 12 lead analysis, you will have the options of leads I, II, III, aVR, aVL, aVF, V1, V2, V3, V4, V5 and V6.

You can move the cursor across trends for all of the simultaneously displayed data. As you do so, a one-minute, single channel associated ECG strip will be shown on the bottom of the screen. To activate an enlarged eight-second strip, press the ENTER key on the keyboard or double click with your mouse.

NOTE: To activate the QTc graph, click on the letters QT (with the white background) at the beginning of the QT graph. The QT graph will be replaced with the QTc graph.



The enlarged eight-second ECG strip allows you to validate the ST and QT measurements.

In the example above, ST validation is being done on Channel 2 and Channel 3. The blue marker indicates where the ST sample point should be set. If you see that it is incorrect, you need to re-analyze the patient data and reset the ST markers in the correct location.

In the example above, QT validation is being done on Channel 1. The first green marker indicates the beginning of the Q-wave; the blue marker indicates the ST sample point and the second green marker should be at the end of the P-wave. If you see these markers are incorrect, you need to reanalyze the patient data and reset the ST markers in their correct location.

To return to the Mega Scan screen, press the ESC key on the keyboard.

QT VALIDATION

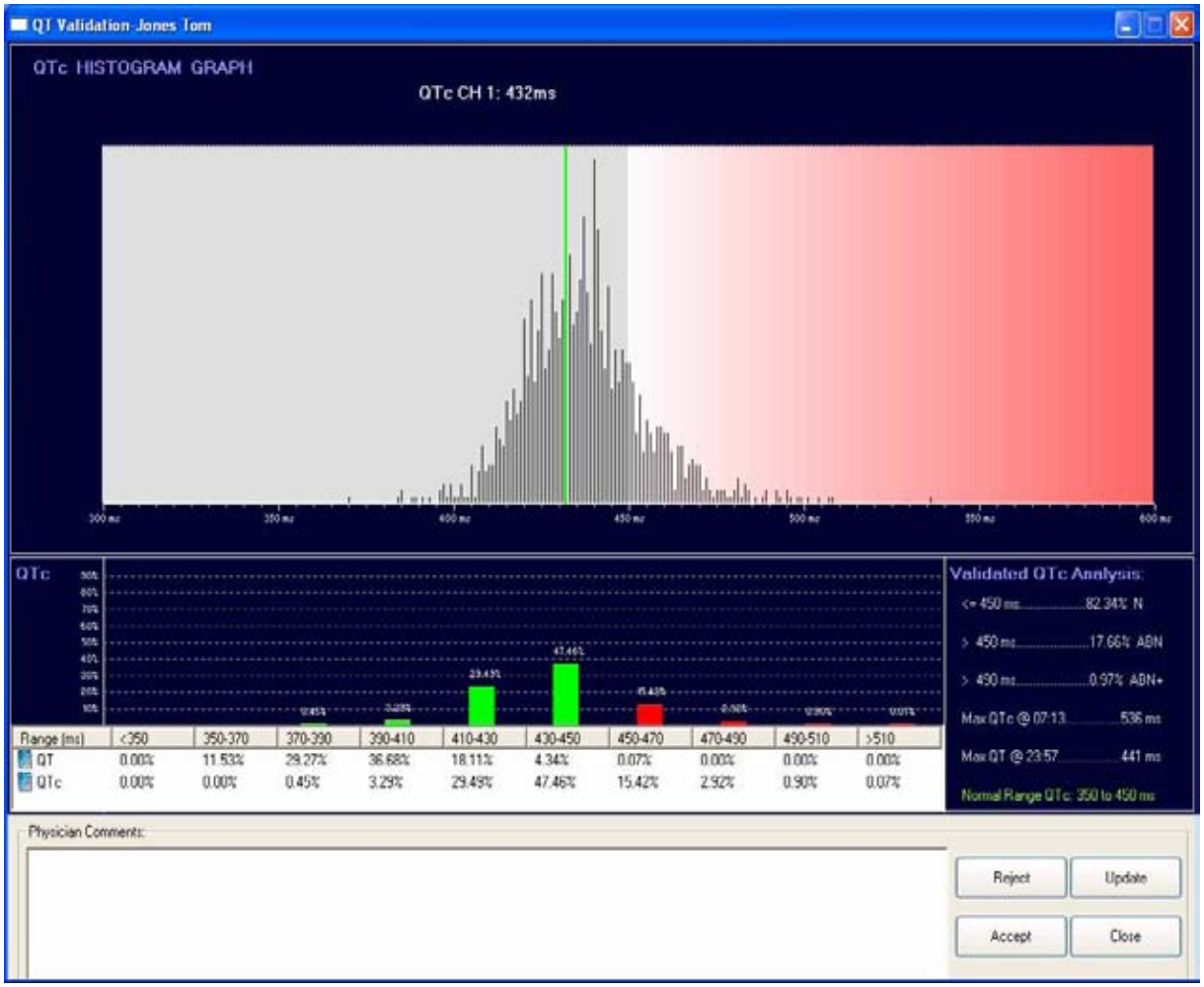
Most Holter companies do not attempt to perform QT analysis. However, elongated QT can have as serious, or more serious, consequences than V-Tach, Pauses and ST episodes. This QT validation program is the first time in Holter ECG that the Holter cardiologist or technician can validate the accuracy of its QT and QTc analysis.

QT is analyzed on a beat-to-beat basis. The heart rate is factored into the QT analysis so that QTc and QT measurements can be made from the same data. A QTc Histogram is then developed. Those QTc measurements at the far right side of the histogram that exceed a QTc of 450ms or more are generally recognized as the worrisome intervals.

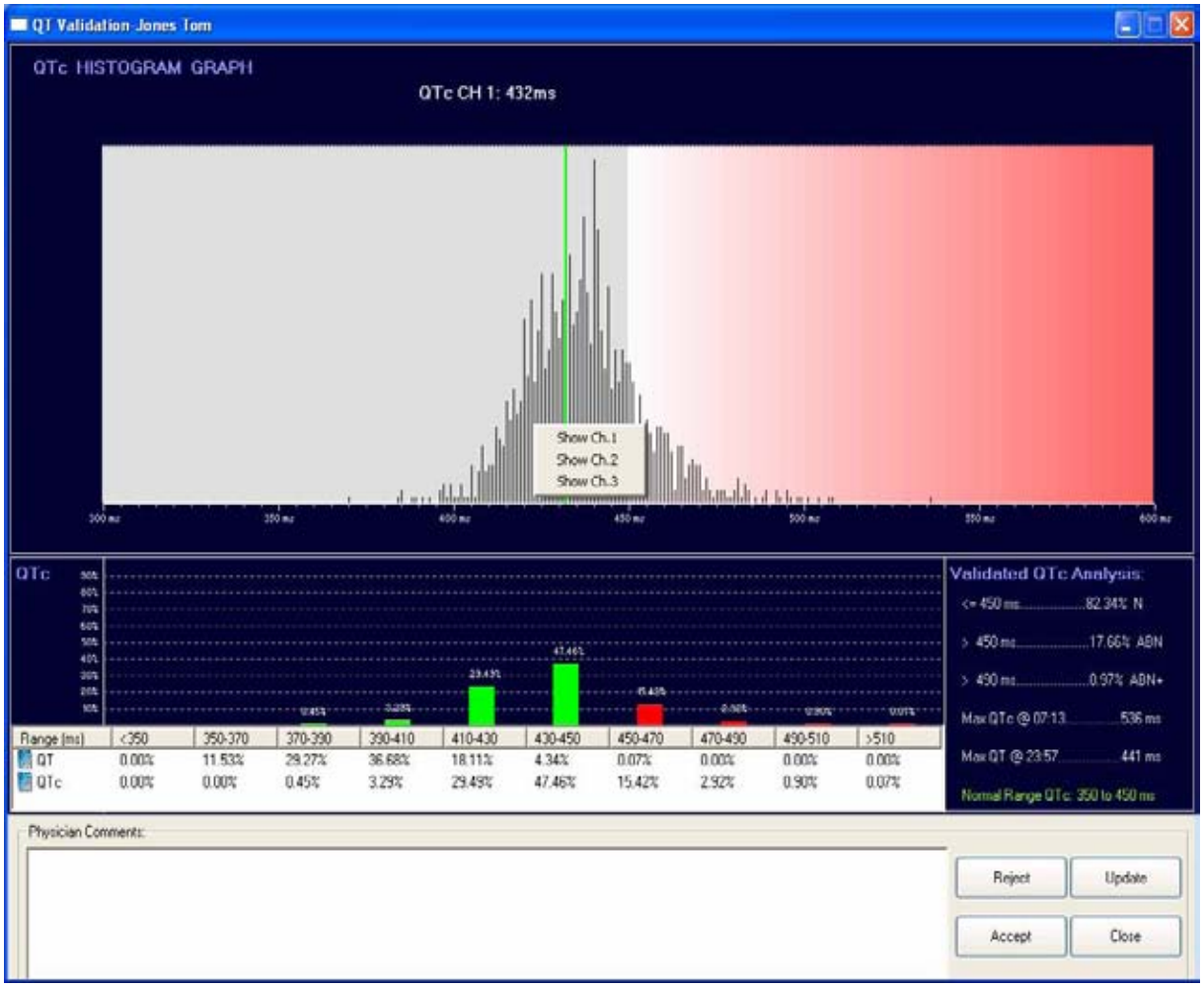
To enter the QT Validation program, point and click on the QT Validation icon.

NOTE: There is an increasing awareness that drugs used for non anti-arrhythmic and non-cardiovascular indications may have significant effects on re-polarization, and may cause serious ventricular tachyarrhythmias under specific circumstances. Clinicians should be aware of this risk of prolongation of re-polarization and take precautions to further minimize it.

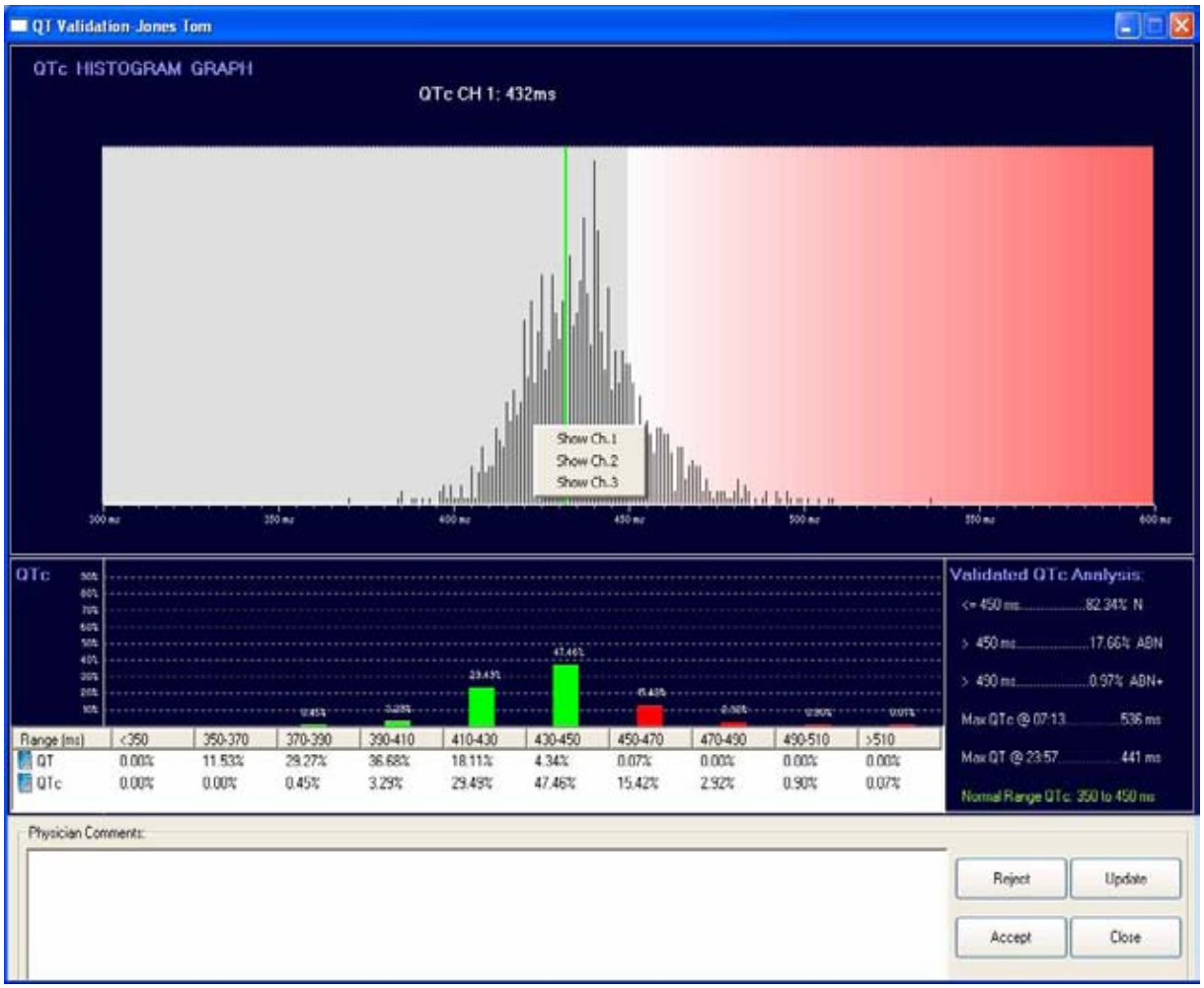
We recommend you visit the University of Arizona CERT website for more drug information at www.qtdrugs.org.



Carefully examine all the details in the displayed QTc Histogram. Generally, QTc intervals in excess of 450ms are very worrisome to the physician. All QTc intervals in excess of 450ms are shown at the right side of the QTc Histogram. The lead of the QTc Histogram Graph you are viewing is noted above the graph.



To change the lead that you are viewing, right click your mouse anywhere inside the QTc Histogram Graph. The above drop screen will appear. Move your cursor to the lead you wish to view and click. The graph will change to the lead you have selected.



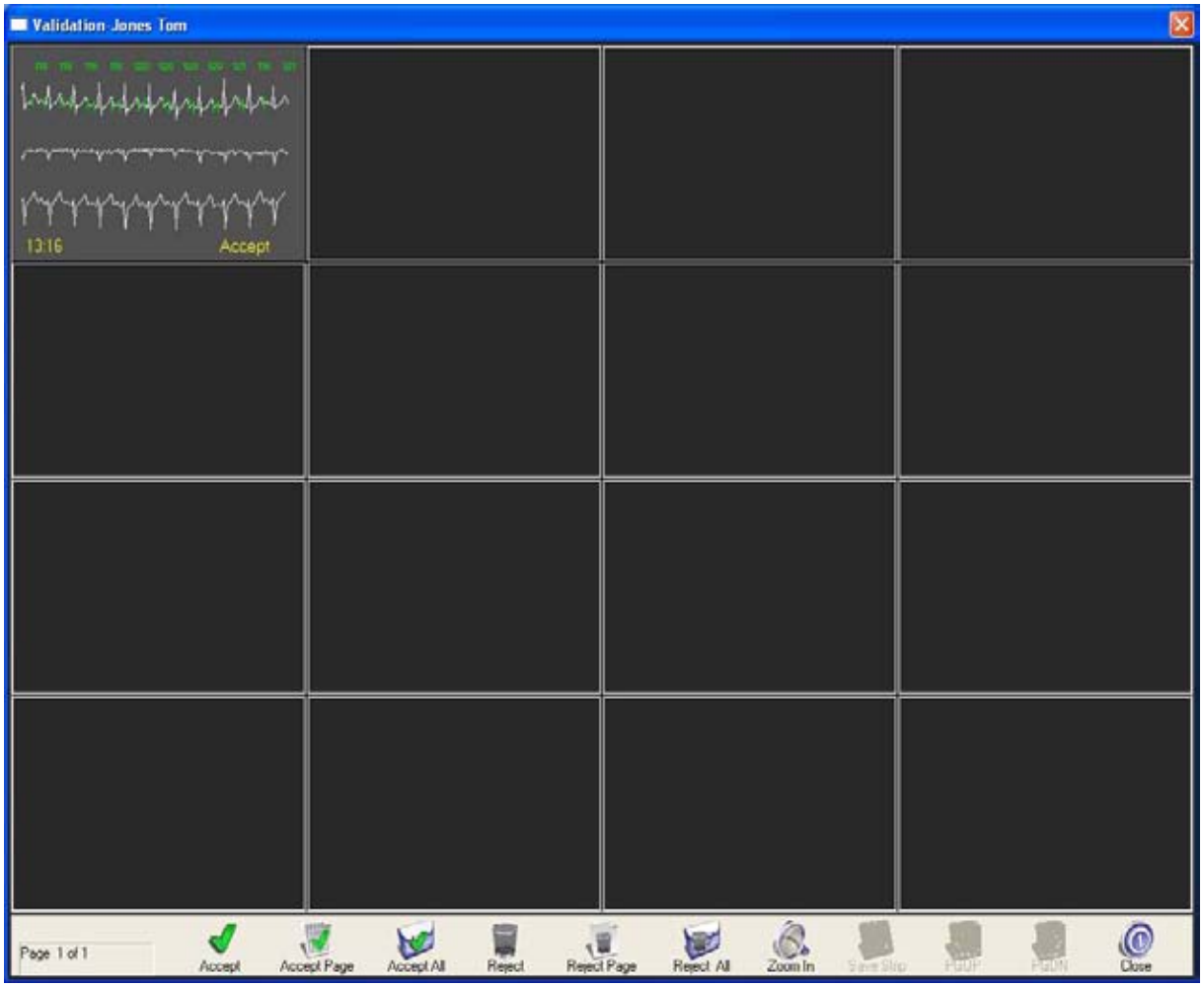
Point and click your mouse on the right side of the histogram. A large, green vertical cursor will appear. This cursor can also be moved with the arrow keys on the keyboard.

To view and validate the accuracy of these selected QTc's, press the ENTER key on the keyboard or mouse left click on the cursor. The following screen will appear.

NOTE: The ECG conditions that must be met in order to do QT analysis are as follows:

1. The R-wave must exceed 5mm in positive amplitude.
2. The T-wave must be positive and exceed 2mm in amplitude.

Both of these conditions must be met to do QT analysis.



On this screen up to 16 mini ECG strips appear. All of these strips correlate to the QTc ms reading from the histogram. In the lower left-hand side of the screen you can see how many pages of correlating strips you have.

Small vertical green lines mark the locations of the specific spots from where the QT was analyzed. The gray colored box is the strip you are working with. To enlarge this strip press the ENTER key on the keyboard or double left click with the mouse or point and click on the Zoom In icon at the bottom of the screen. An enlarged 8-second ECG strip will be displayed.

Note that the vertical QT markers are shown on the 8-second strip and that both the QT and QTc numbers are displayed on the lower left-hand corner of the ECG strip. The QTc number is the same QTc number that was shown on the previously shown QTc Histogram. The QT number is the length of the QT interval before it was corrected for heart rate (QTc). By seeing that the markers are set correctly and measuring an interval, you can validate the accuracy of the QTc.

To measure an interval, point and click on the RULER icon at the bottom of the page. A small ruler and red cross will appear on the screen. Place the red cross at the beginning of one of the Q waves being measured. Drag the cross horizontally to the end of the T wave. Release the left mouse button.

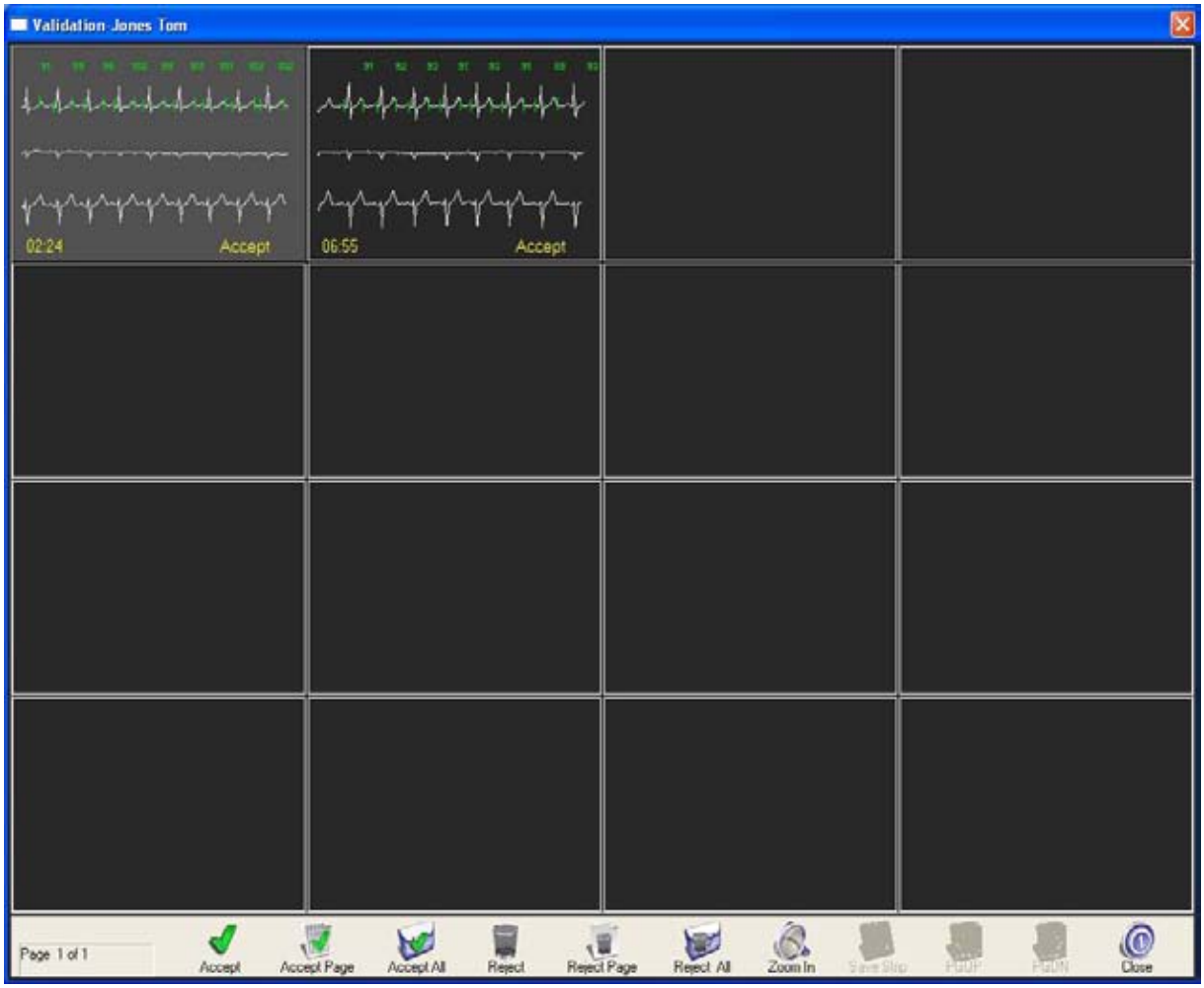
NOTE: If you are doing a 12 Lead Analysis, all 12 leads will appear on the 8 second graph.

A measurement will appear in the field above the strip (in this example, 409 msec). This number is the result of the measurement you have just made using the Ruler. The msec measurement should be similar to the QT measurement being shown on the bottom left of the screen. If the new display of QT interval is similar to the original QT measurement, then you have properly validated the accuracy of the QT analysis for the QTc selected from the QTc Histogram. As long as the QT measurement from the ruler is within plus or minus 16 msec, then you have an acceptable similar reading.

The arrow markers are at 50% of the R-R interval. The reason for the 50% arrow markers is that a general rule of thumb is that the QT interval should be less than 50% of the R-R interval. The 50% arrow markers give the physician a quick reference for QT analysis.

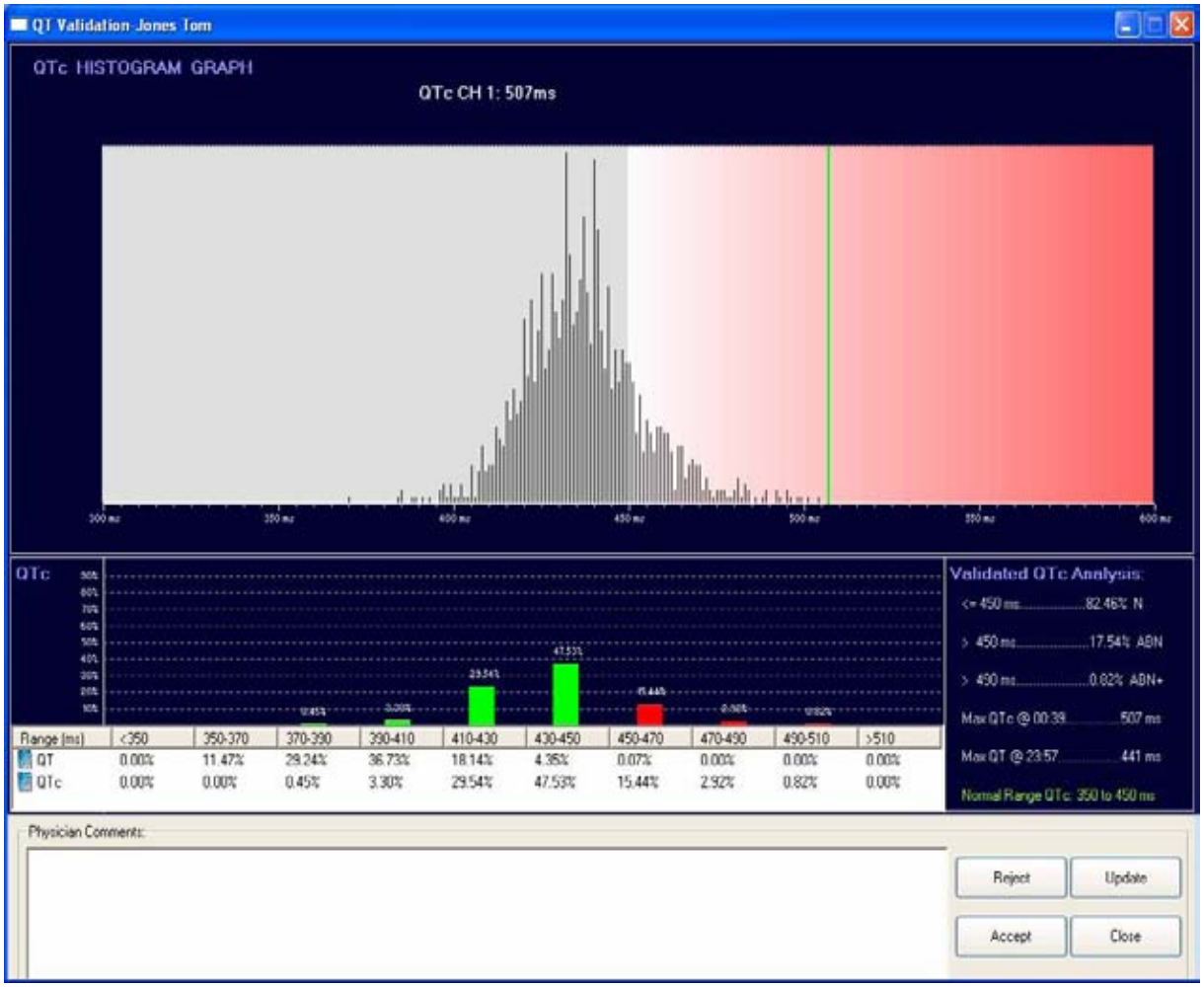
Also the Basset formula for QTc has been the standard for the past 90 years. However, it appears to be accurate in only a small range of heart rate (about 60-80BPM). When you get into the much faster and slower heart rates of the 24-hour Holter ECG, the formula breaks down. The 50% arrow markers them become very valuable for the diagnosing phyisican.

NOTE: If you notice that all the green cursors are set incorrectly, then you must exit the QT Validation program to the Data Access Choices screen and Re-Analyze the patient data. Make sure that you set the ST markers correctly per the directions in the ST QT Setup Screen.



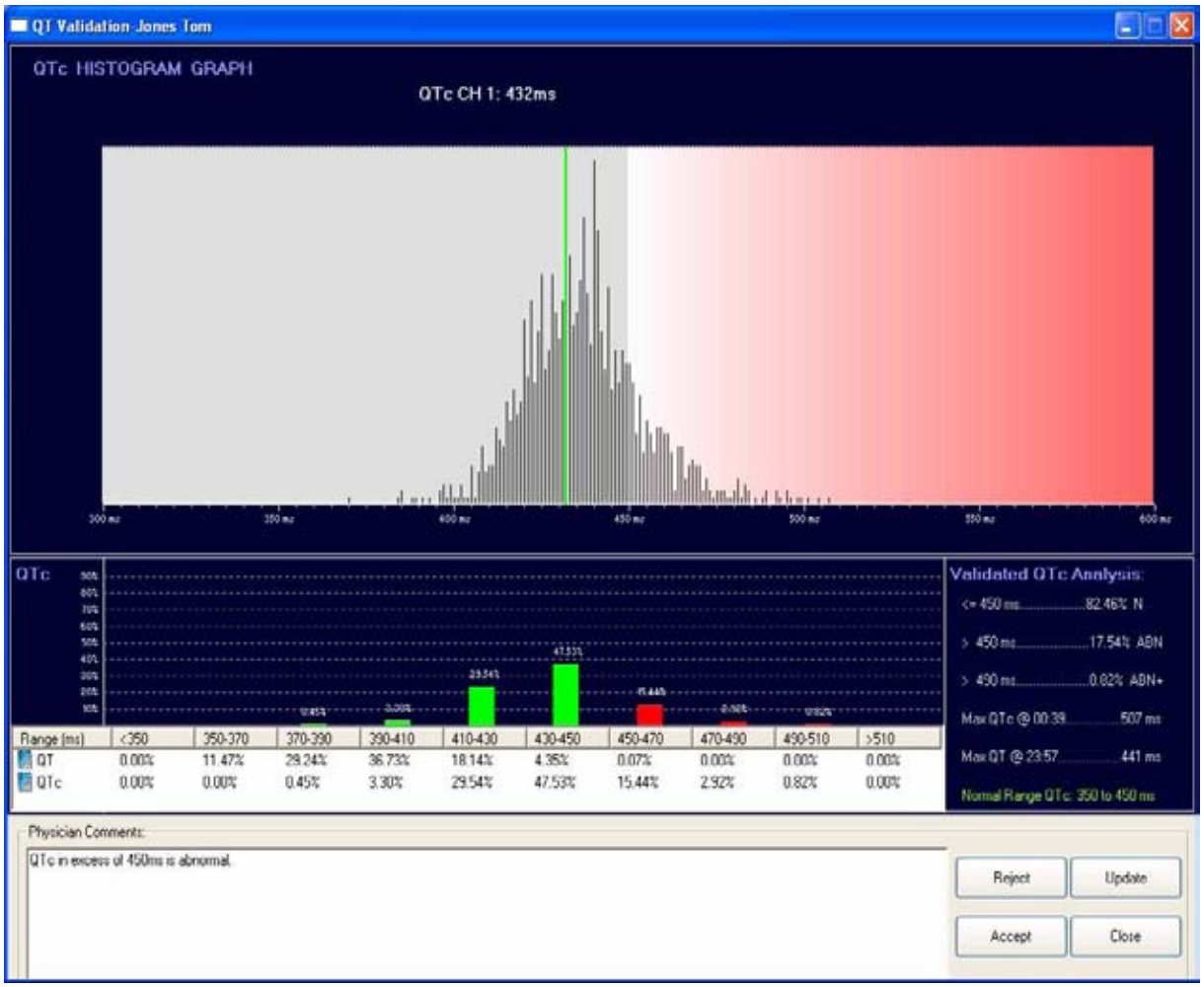
If you want to reject only a single QT from several QT's that were at the same QTc histogram location, point and click on the REJECT icon at the bottom of the screen. This will remove the single QT that is in the gray color. You can remove other selected QT's by pointing and clicking on the other ECG strip boxes and clicking on the REJECT icon.

When you have finished this process, point and click on the CLOSE icon at the bottom of the screen. This will return you to the QTc histogram.



To remove all QT's from a selected histogram location, point and click on the Reject box on the lower right side of the screen. A red line will appear on the QTc Histogram, indicating that these QT's and QTc's have been eliminated from the analysis of the QT and QTc.

Repeat the above steps as necessary. You only have to validate one or two of these elongated QTc's in order for the physician to know that the patient has a very serious abnormality. After finishing your validation checks, return to the QTc Histogram screen.



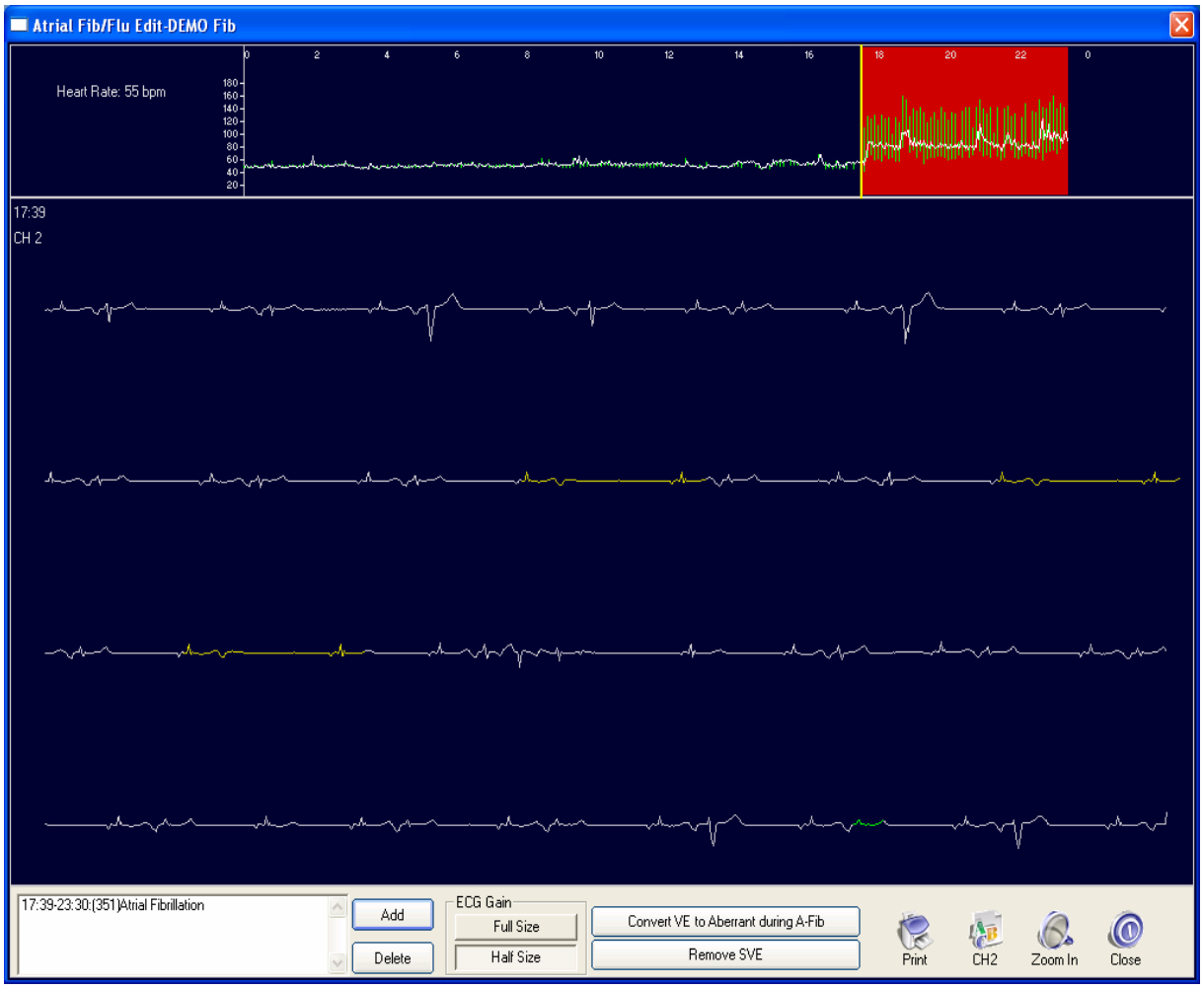
To add Physician Comments on the QTc report, simply point and click in the Physician Comments field and begin typing.

Once you have finished validating the QTc's and entering the Physician Comments, point and click on the Update box on the lower right-hand side of the screen. Then click on the Close box. You will be returned to the Data Access Choices screen.

A-FIB/FLUTTER

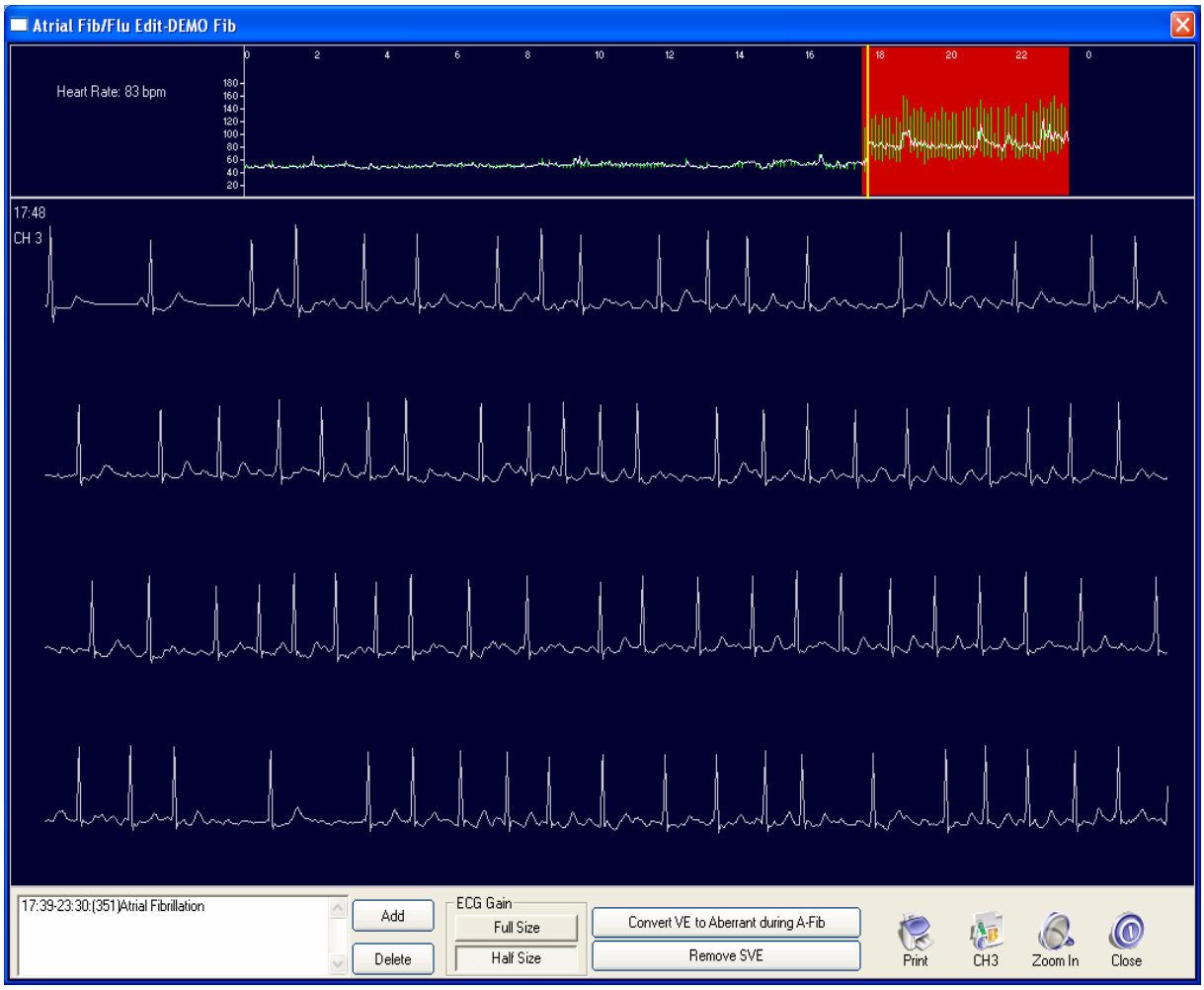
Generally, physicians do not wish to count any SVE beats during periods of Atrial Fibrillation. This program allows you to easily edit this data.

Point and mouse click on the A-Fib/Flu icon at the Data Access Choices screen to begin the editing.



This screen shows a 24-hour trend graph that shows the minimum, average and maximum heart rate for each minute. The last few hours of the trend shows a large variability for many minutes in the minimum and maximum heart rate. The time period analyzed as Atrial Fibrillation is boxed in and color-coded. The beginning and ending times of the Atrial Fibrillation are shown in the Comments section on the lower left side of the screen.

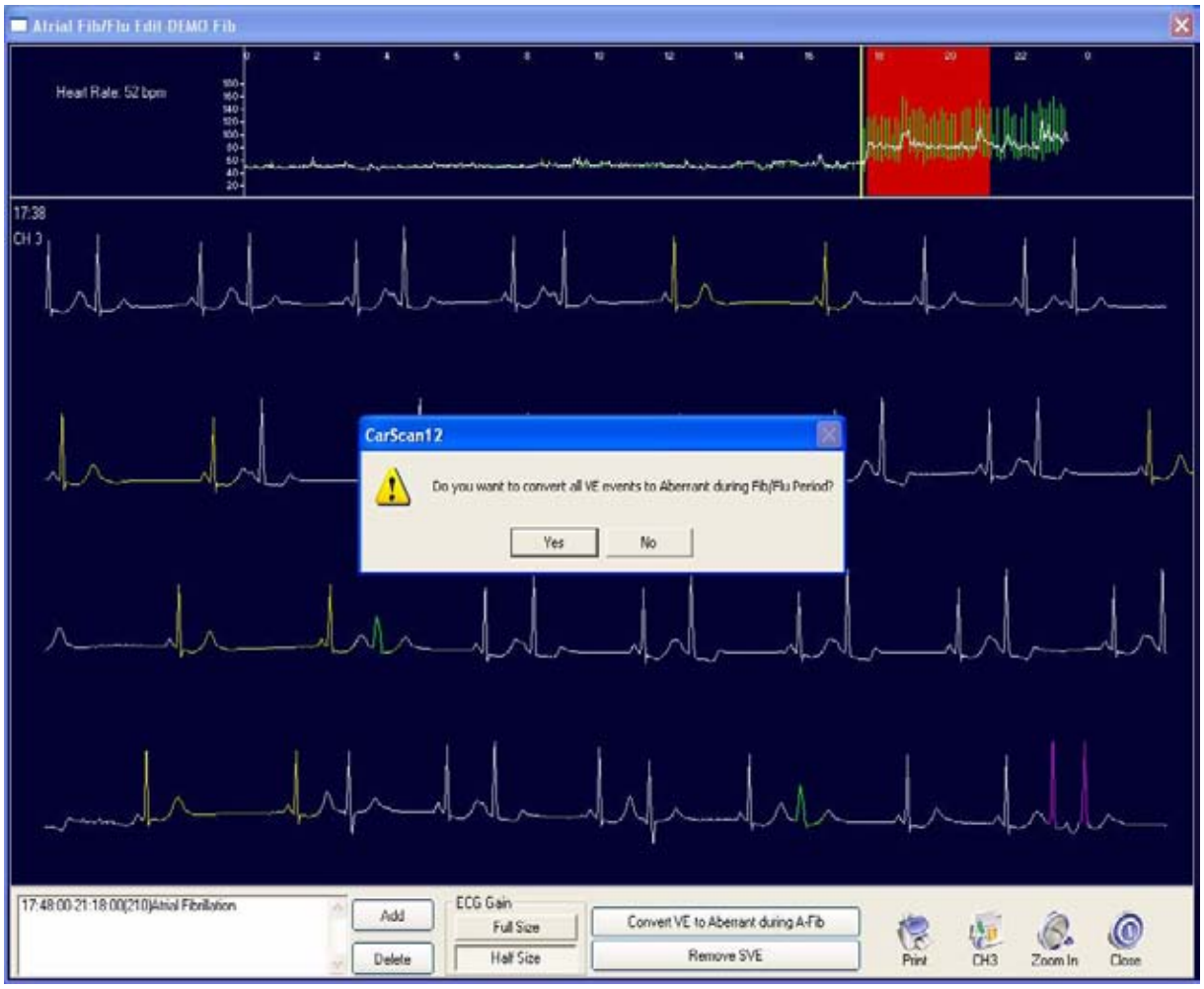
There is a large yellow cursor at the beginning of the boxed in A-Fib area. The minute this cursor is on is displayed below the 24-hour trend graph (This cursor can be moved anywhere on the 24-hour trend graph using the arrow keys on the keyboard or by pointing and clicking with the mouse). If the channel of the displayed minute is not of the best quality, you may point and click on the Channel icon at the bottom of the screen. This will change the channel of the minute you are viewing on the screen.



Check to see if there are any beats being called SVE's (they would be colored magenta on the enlarged minute in the middle of the screen).

All SVE counts need to be deleted from A-Fib minutes. You can verify that the minutes in red are A-Fib minutes by pointing the mouse arrow and doing a left click. You will see the 1-minue ECG and visually verify the A-Fib. Do this several times. Then, to remove the magenta SCE beats, left click on the "Remove SVE "icon, click on Yes, and all SVE labels will be removed from all A-Fib minutes.

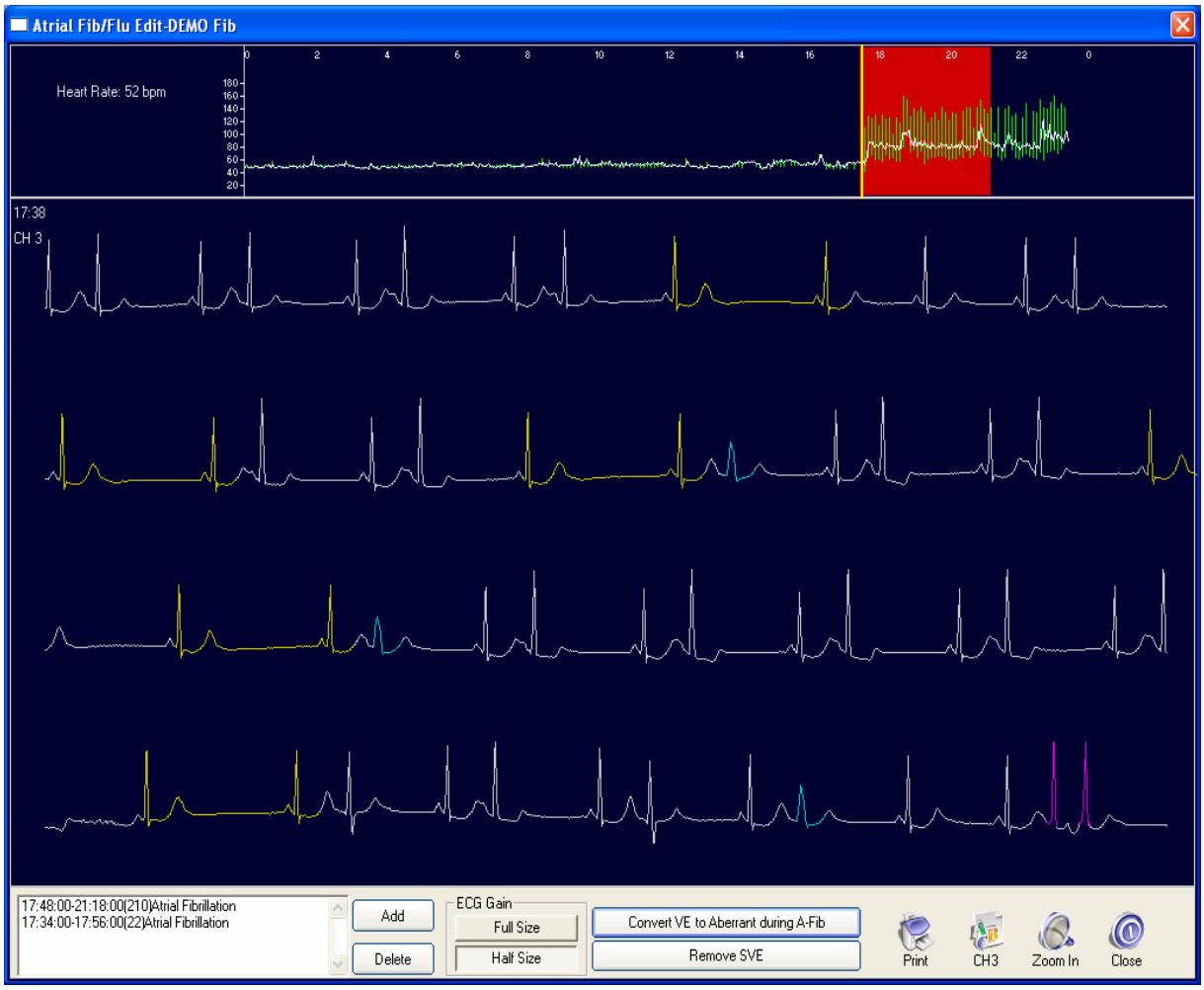
As you remove SVE's, you will see an updating screen. This lets you know all the SVE counts for all the Atrial Fibrillation minutes have been removed from the analysis, the template edit and all other sections of the Holter displays and reports.



You can also change all VEs to Aberrant beats during the A-Fib period.

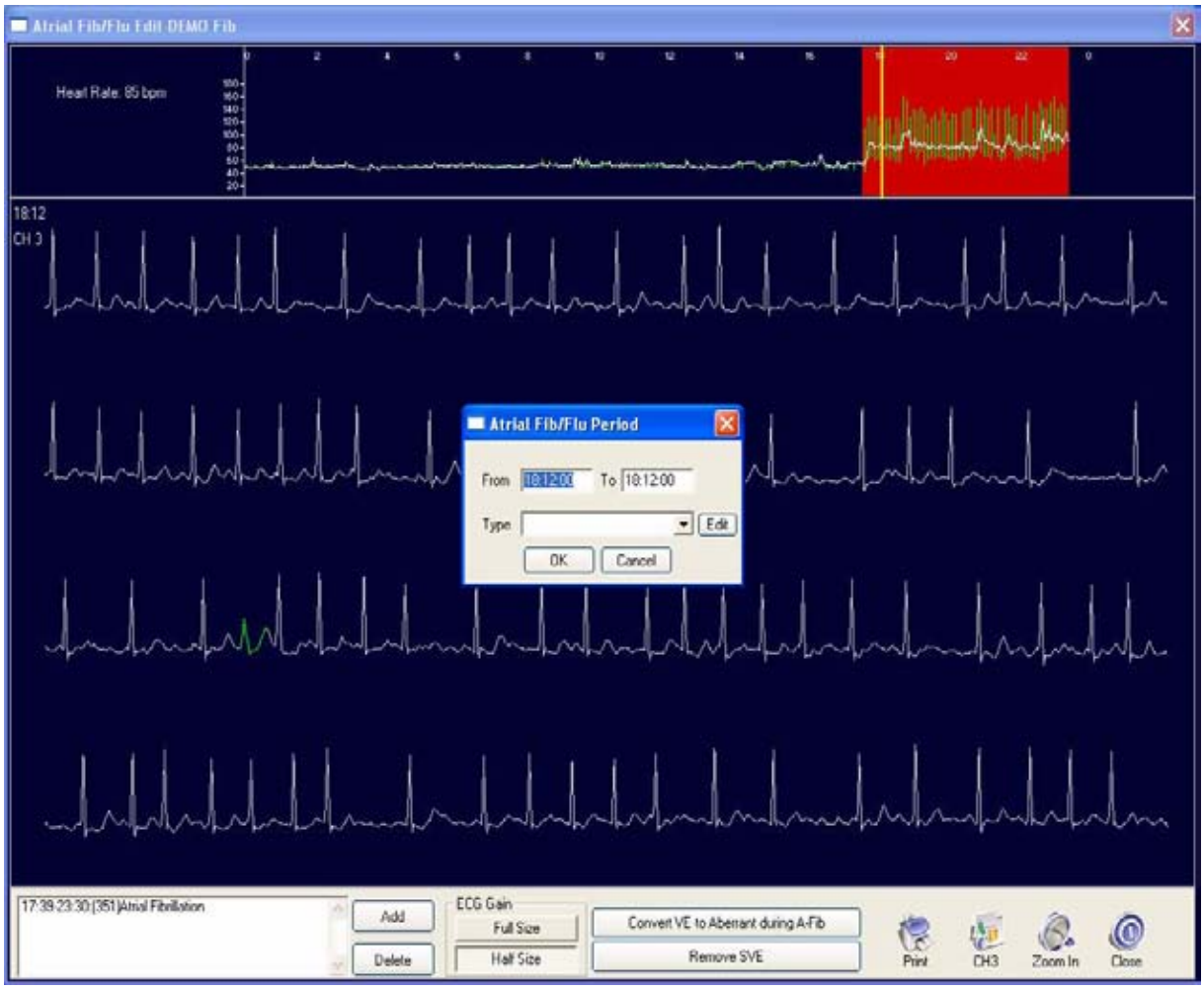
In the above screen the VEs are labeled in green. Click on the Convert VE to Aberrant during A-Fib bar at the lower middle fo the screen.

The above popup menu will appear. Click on Yes.



An updating bar will appear on the screen.

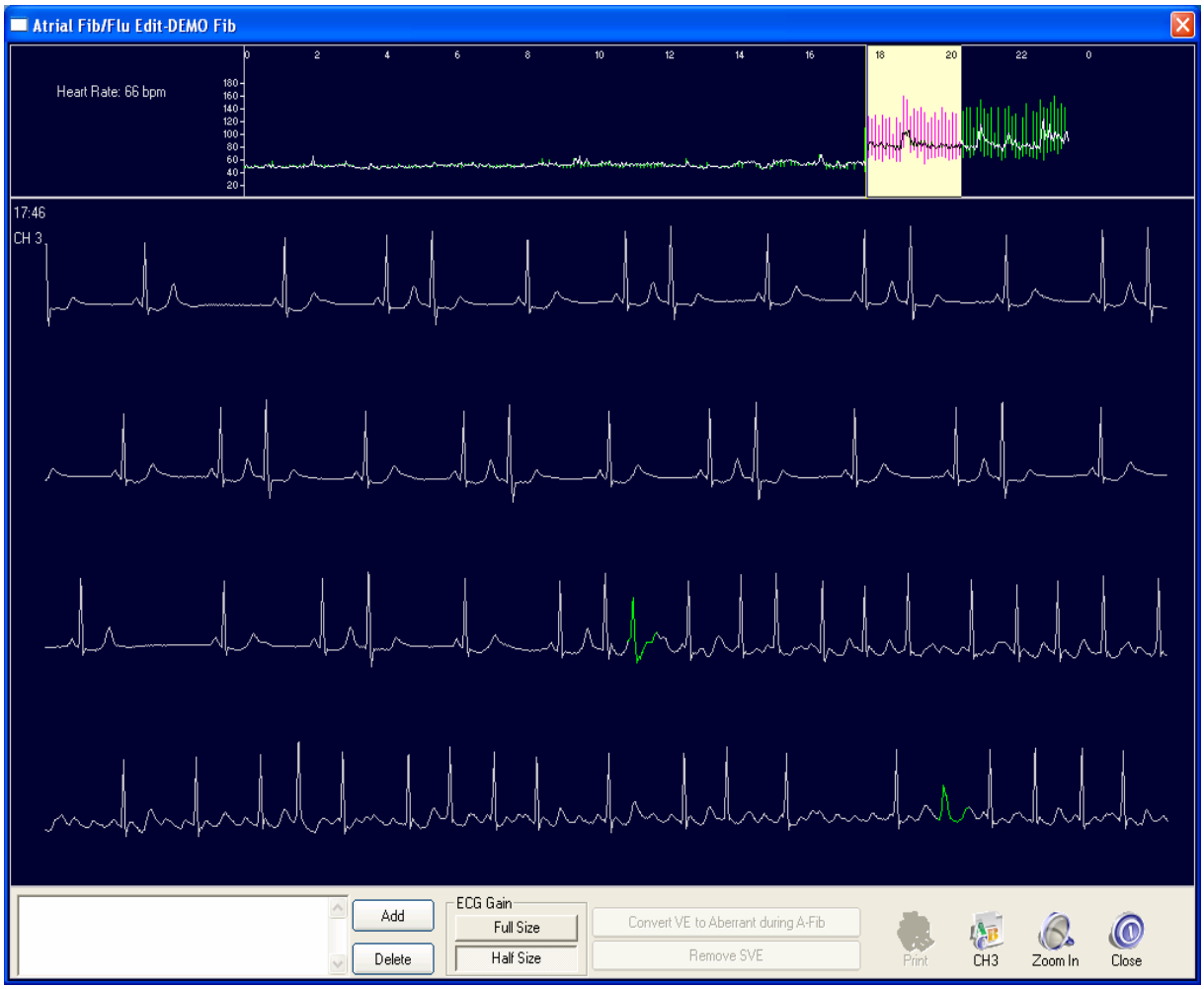
Once the update is complete, you will notice all of the green VE beats will have changed to blue Aberrant beats.



Click on the Add button and the above screen appears.

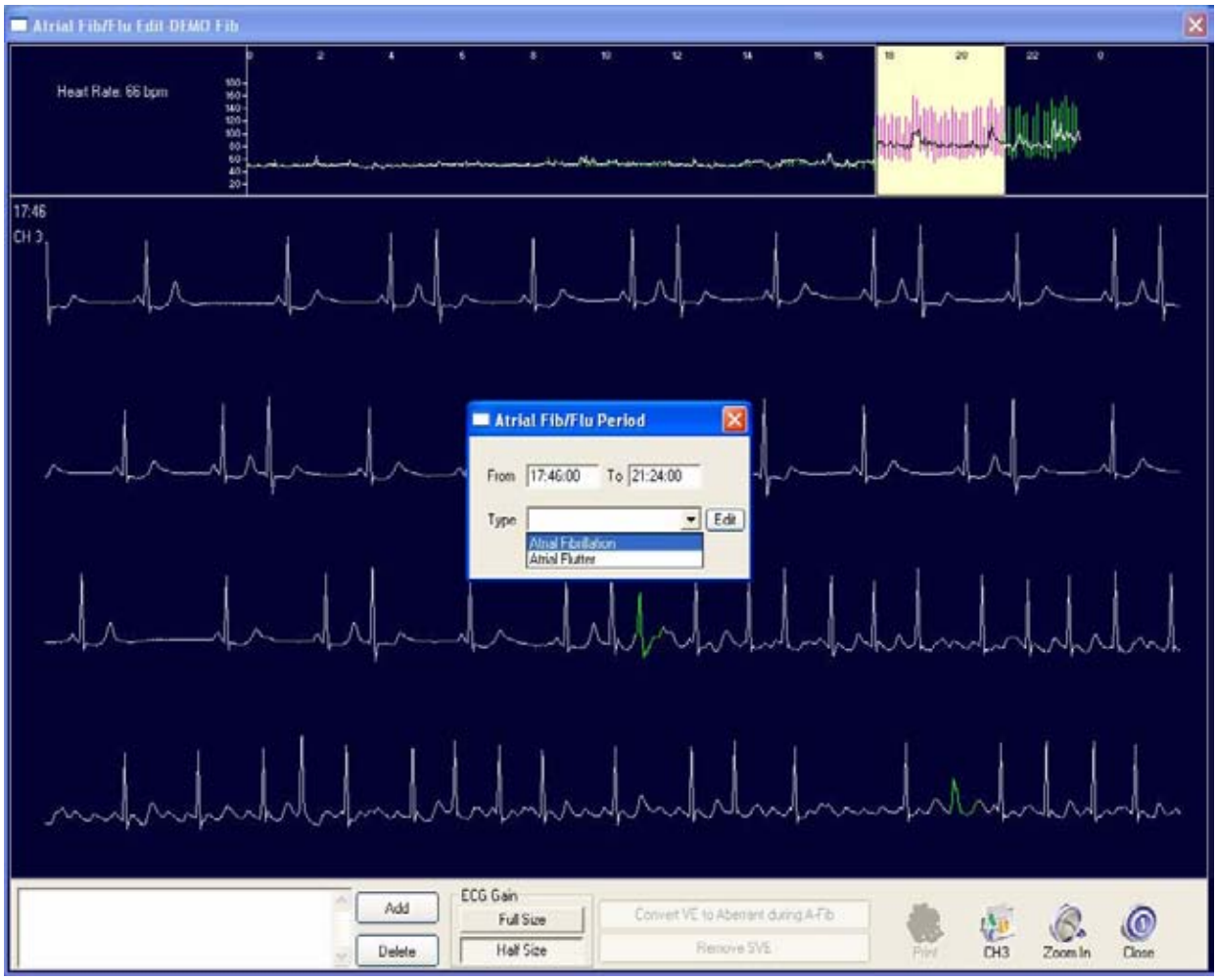
Enter the beginning of the time period of the Holter recording you wish to have listed as Atrial Fibrillation or Atrial Flutter. Press the TAB key on the keyboard. Enter the end time of the period of the Holter recording you with to have listed as Atrial Fibrillation or Atrial Flutter. Click on the down arrow next to the Type field and select Atrial Fibrillation or Atrial Flutter. Click on OK.

The time period you have added will now be noted in the Comments section and marked on the 24-hour trend graph.



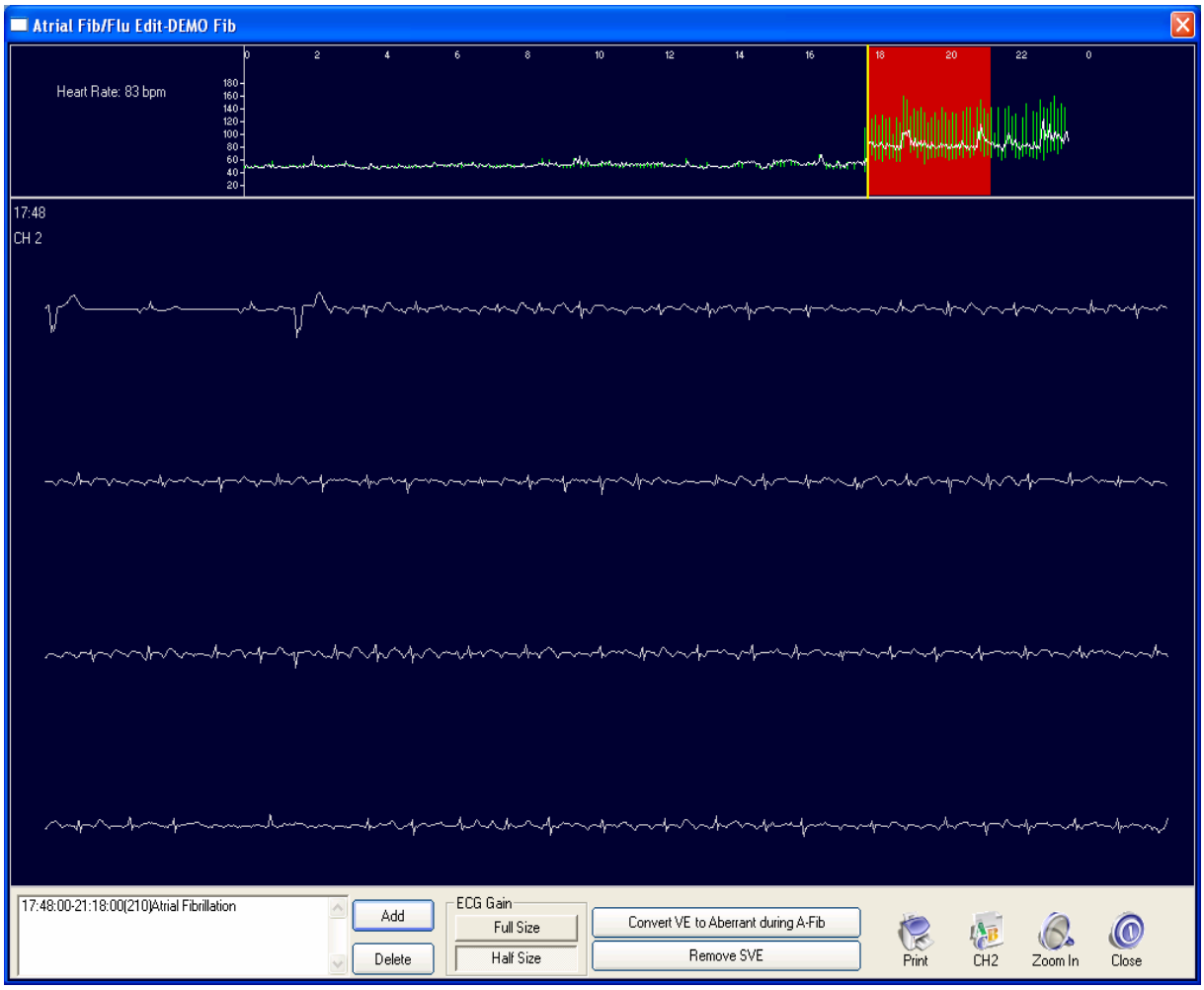
You can also add minutes to the A-Fib count using the point and drag method.

Left click and hold the mouse cursor at the beginning of the A-Fib in the 24 hour graph. Drag the cursor across the minutes you want to add to the A-Fib calculation. Release the mouse when you are at the end of the A-Fib period. A white highlight will be over the area of minutes you want to label A-Fib.



Click on the Add button at the bottom of the screen. The above popup menu will appear.

Select the label of Atrial Fibrillation or Atrial Flutter. Click on OK.



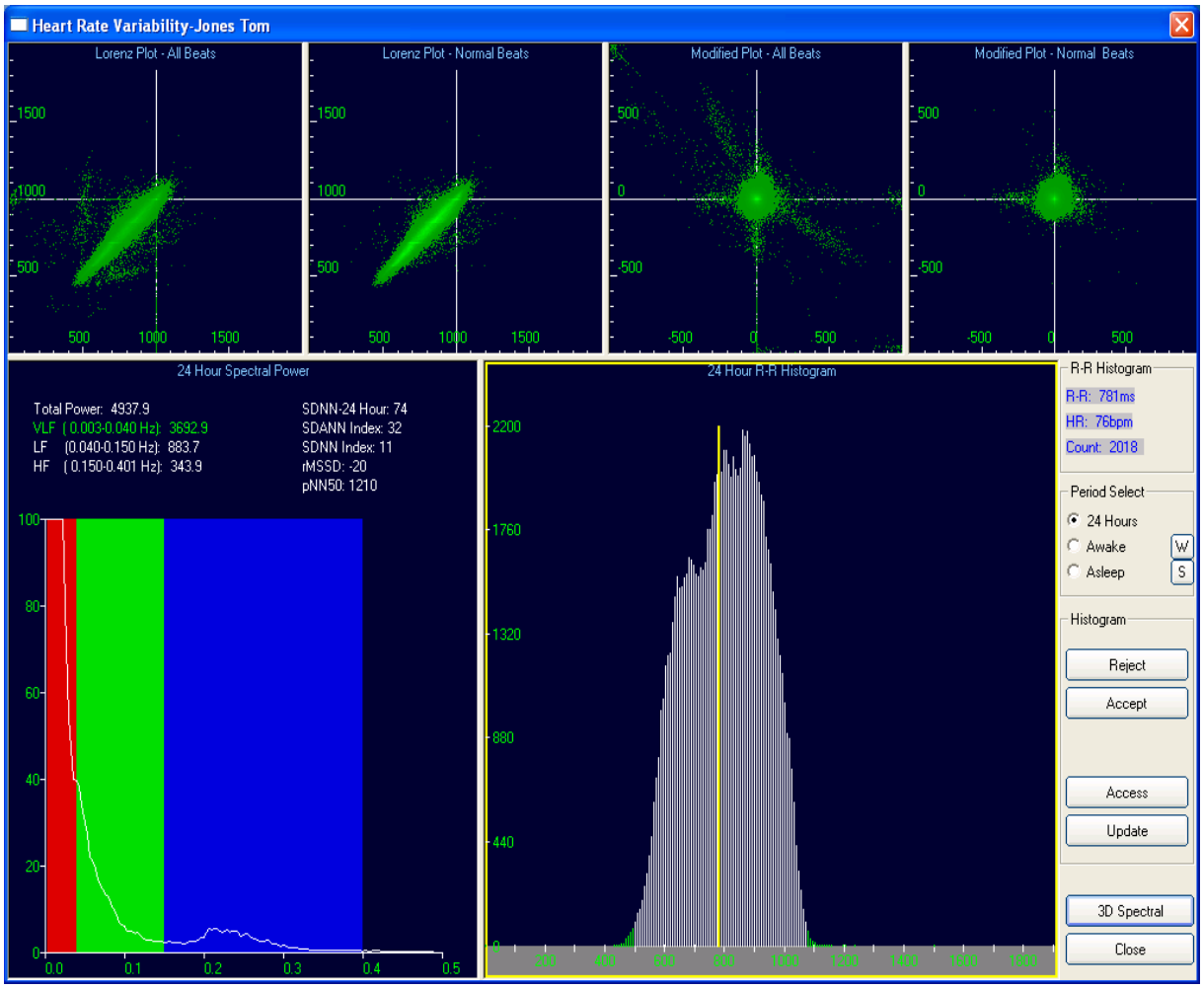
The Atrial Fibrillation time has been added to the comments section in the lower left side of the screen. Also, you will note the red highlight in the 24 hour graph at the top of the screen indicating the time period of which the patient is in Atrial Fibrillation.

Upon completion of editing the Atrial Fibrillation, point and click on the Close icon at the bottom left of the screen. You will be returned to the Data Access Choices screen.

HEART RATE VARIABILITY

To work with the Heart Rate Variability (HRV) graphs, point and click on the HRV/HRT icon at the Data Access Choices screen.

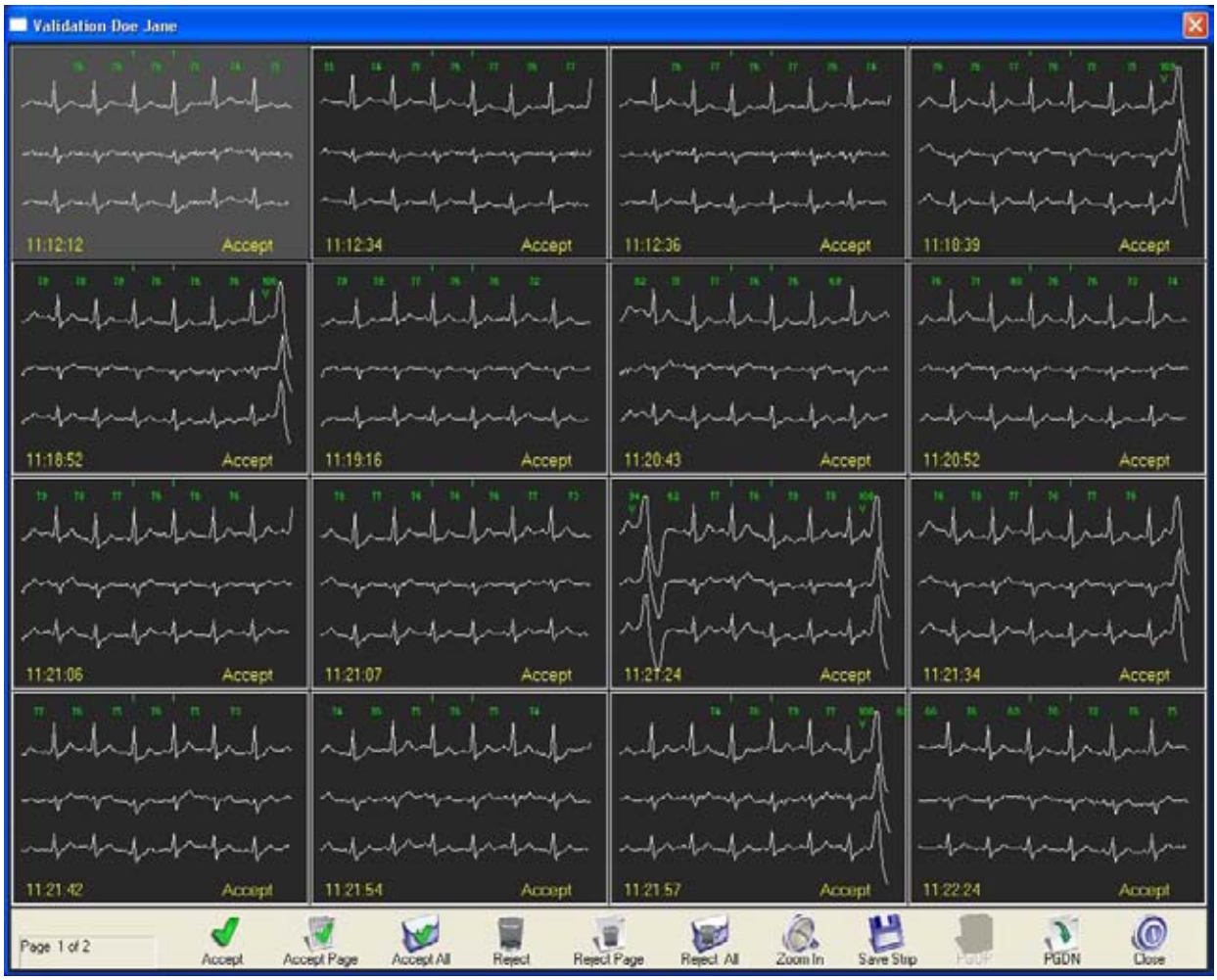
Select HRV and the following screen will appear.



This display shows the Poincare plots across the top of the display.

The left side is a Spectral Power Graph. Some physicians desire to create their own frequency range. To adjust the ranges of Very Low Frequency (VLF), Low Frequency (LF), and High Frequency (HF), point and click anywhere in the 24 Hour Spectral Power Graph. A yellow line will box around this third of the screen. Press on the TAB key of the keyboard until you get to the frequency you wish to change (the range description of the frequency you are changing will be highlighted in green above the graph). Use the ARROW keys on the keyboard to adjust the graph to the ranges that you believe to be correct for your testing purposes. Upon completing your adjustments, click on the Accept bar in the middle right of the screen.

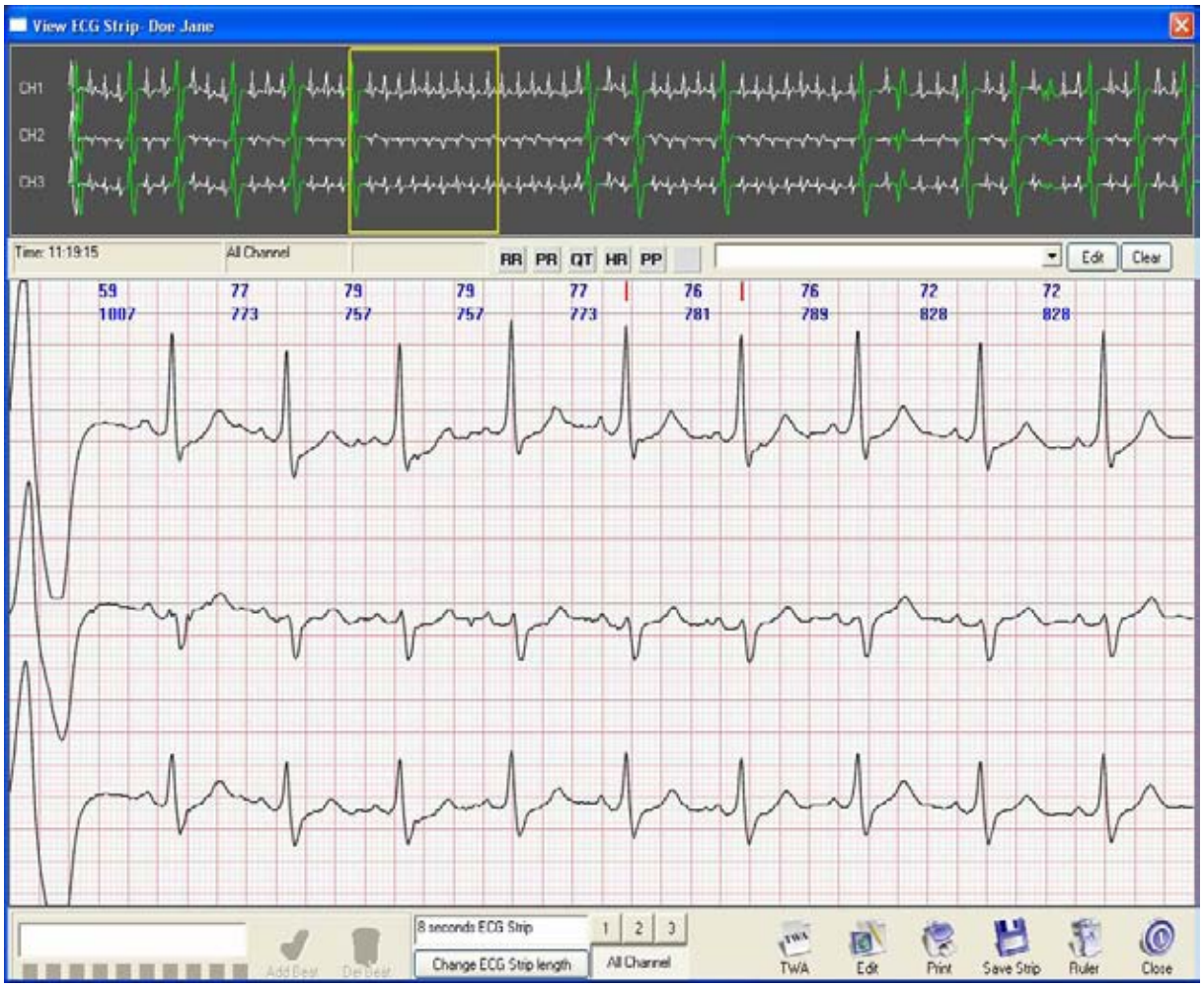
The right side of the screen is a Time Domain R-R Interval Graph. You may want to validate that all arrhythmia and artifact beats have been removed from the HRV file of only normal R-R intervals. To activate the editing of this screen, point and click your mouse anywhere in this section of the screen. A yellow line will box around this third of the screen. You can view the ECG data at either far end of the histogram (highlighted in green) to determine if any of these ECG's should be rejected from the HRV data file. To view the data, move the large yellow cursor to any of the minutes highlighted in green using your ARROW keys on the keyboard or your mouse. Double click with your mouse once the cursor is set. The following screen will appear.



Only normal beats should be included in the HRV counts. Any abnormal beats or artifact will cause the HRV data to be incorrect.

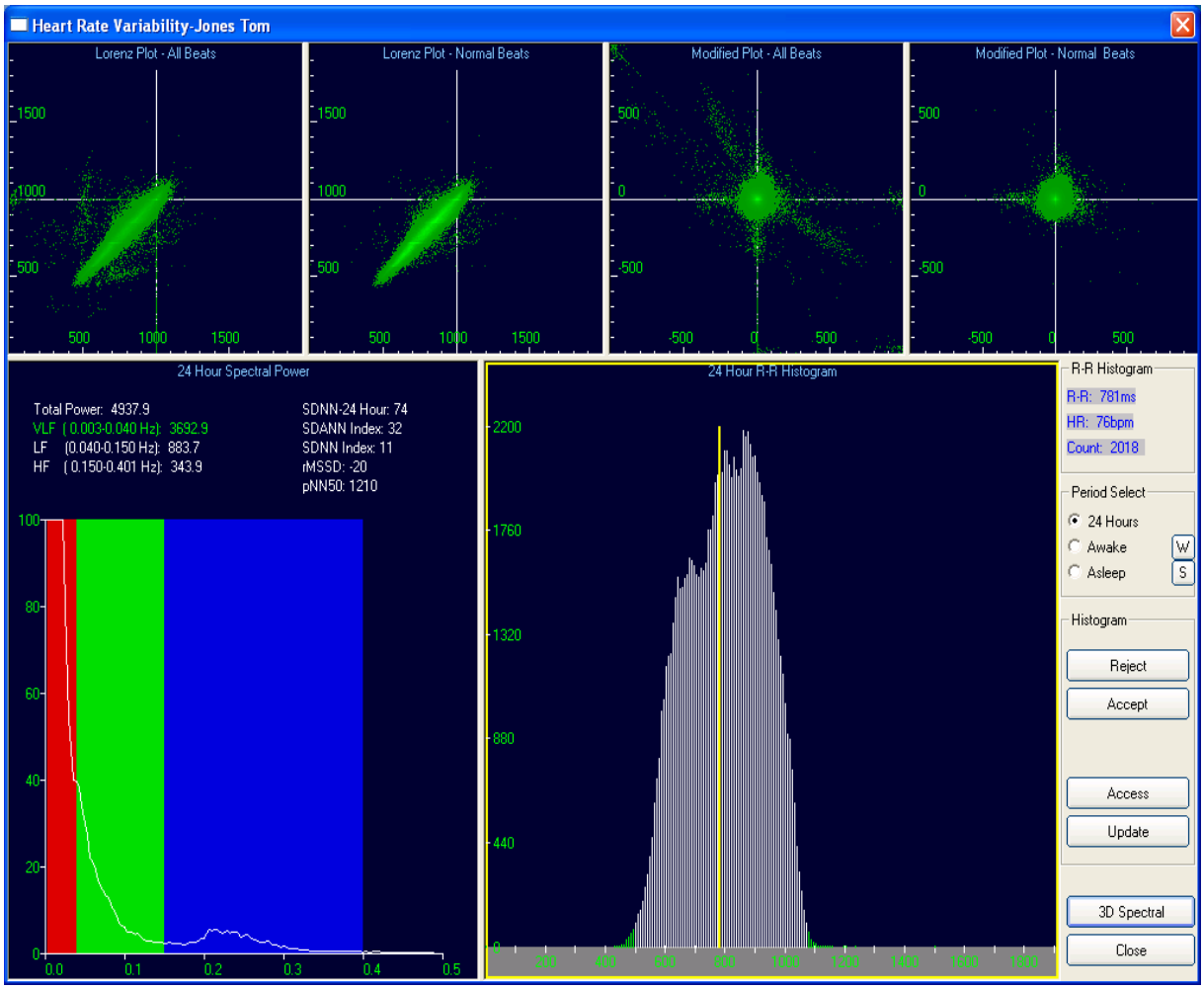
This screen shows up to 16 mini strips that have been included in this range of the HRV interval graph. The R-R (N-N) interval being counted has two green vertical markers set above it. The purpose is to show the R-point trigger location for each beat. If the green markers are not located at the expected R-point trigger, then this beat should be rejected from the HRV file, by a left click on the Reject icon, or pressing the R key.

To reject any data, move to the ECG strip with the R-R interval you wish to reject using the ARROW keys on the keyboard or by pointing and clicking with the mouse. The strip will turn light gray. Point and click on the Reject icon at the bottom of the screen. You will now see Reject at the bottom of the strip. To reject all the intervals being counted on the screen, point and click on the Reject Page icon at the bottom of the page. To reject all the intervals being counted in this area of the histogram, point and click on the Reject All icon at the bottom of the page.



To show the R-R interval in an enlarged 8-second strip, point and click on the Zoom In icon at the bottom of the screen or press the ENTER key on the keyboard. You need to see 2 red vertical markers. They need to be located at the peak of 2 successive R-waves, in order to visually validate an acceptable R-R interval for HRV analysis.

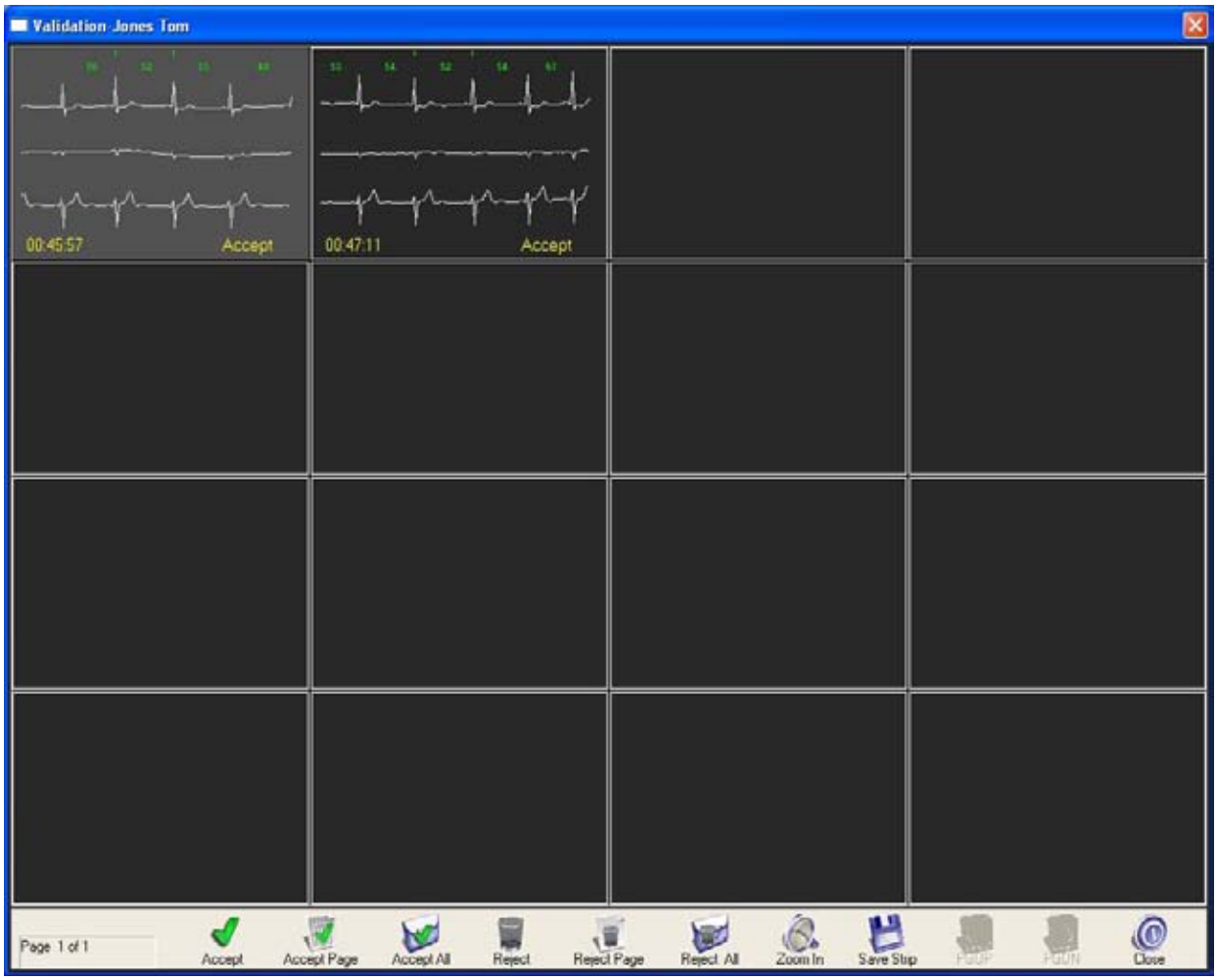
To return to the mini strips, point and click on the Close icon at the bottom of the screen.



There is a new feature in editing and verifying the correctness of the HRV file.

The histogram in the lower right has green data bars at the far left and the far right of the histogram. This is for the extreme low and high heart rates during the 24-hour Holter ECG. This is the most likely data that might have detection errors.

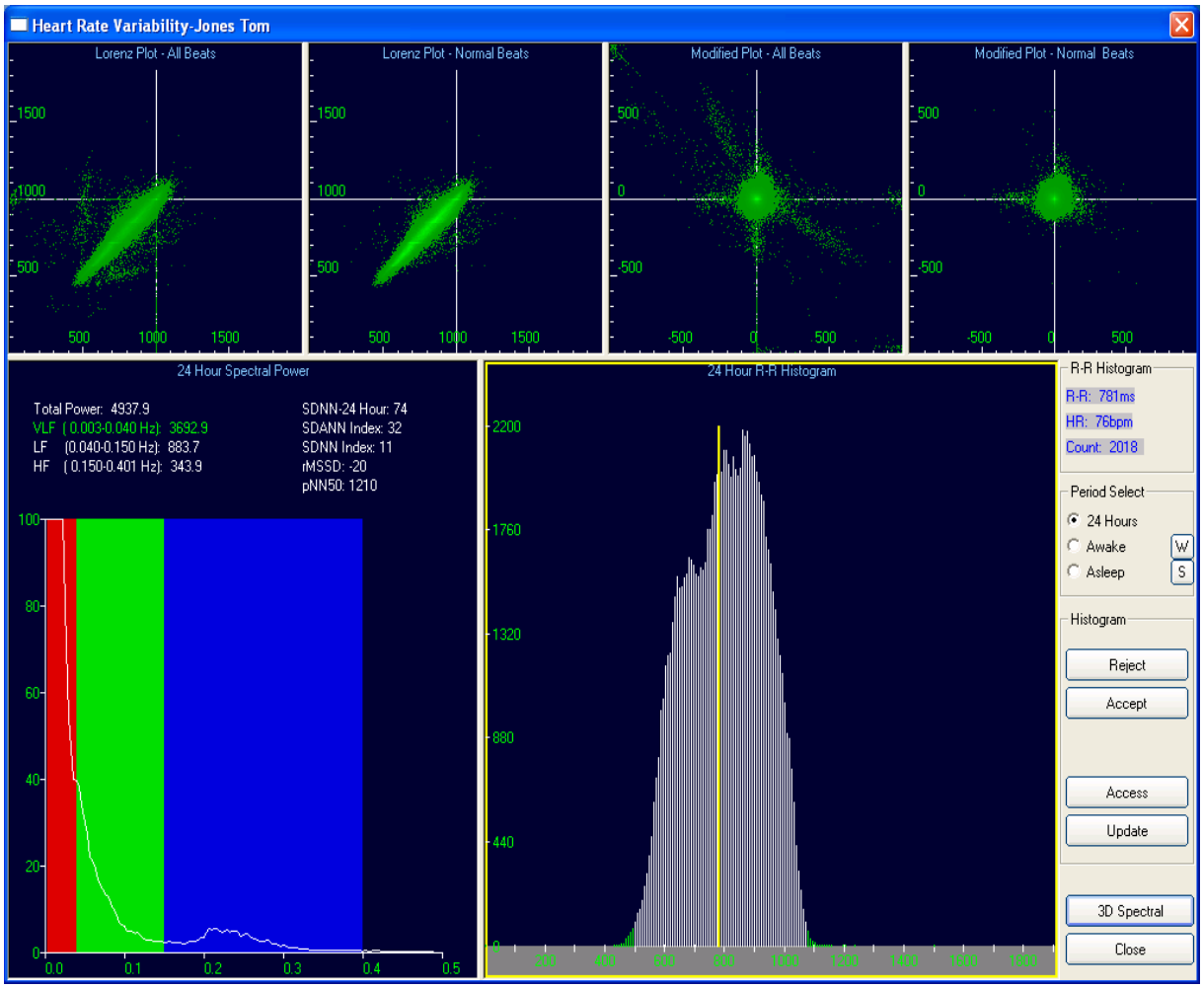
Click on a green bar and the following screen will appear.



This display shows there were two N-N intervals at a heart rate of 52.

The key item is that there are 2 green markers at the top of each R-R interval. Both of these markers need to be exactly on top of the peak of the R-wave. Otherwise, the data must be rejected in this menu from the N-N data analysis file. When you leave this file, there is auto re-analysis of the HRV data file.

After you have completed the editing of unwanted N-N intervals and after closing out the HRV menu, the software does an automatic re-analysis of HRV.

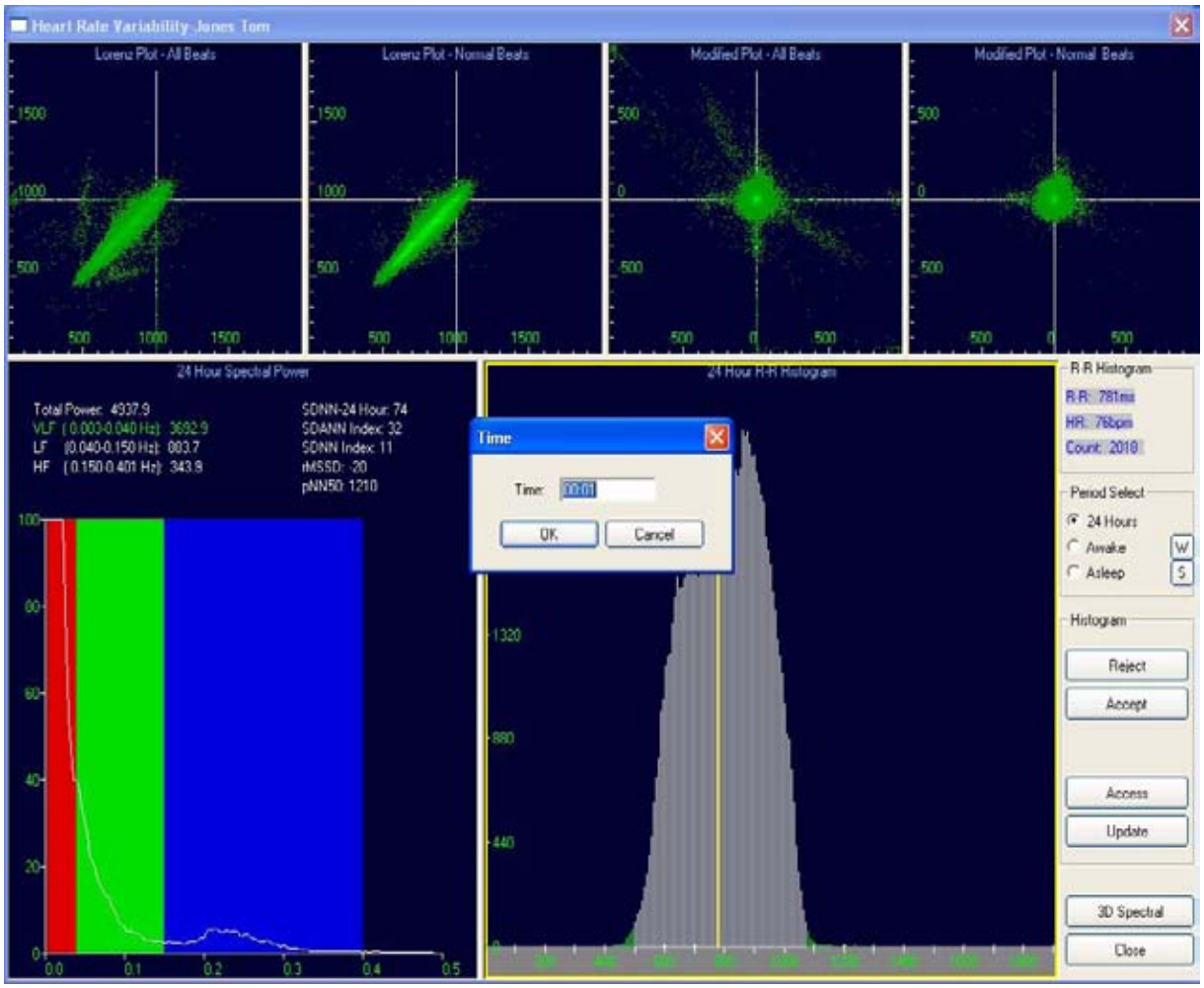


This screen shows the Spectral Power Graph and Time Domain R-R Interval Graphs for the patient's 24 hour ECG.

To show the Spectral Power Graph and Time Domain R-R Interval graphs for the time the patient was awake and asleep, click on the box to the right of Awake under the Period Select option on the right side of the screen (and do the same on the box to the right of Asleep). The following screen will appear.

This function is essential for Sleep Apnea Analysis. Follow the steps on the following pages for entering the time the patient wakes-up in the morning (Awake) and the time the patient goes to sleep in the evening (Asleep).

If the patient diary does not contain "awake and asleep" time, then go to the Mega Scan under Data Access Choices and look for the logical awake and asleep times, based on the slower heart rate that you expect during sleep hours.



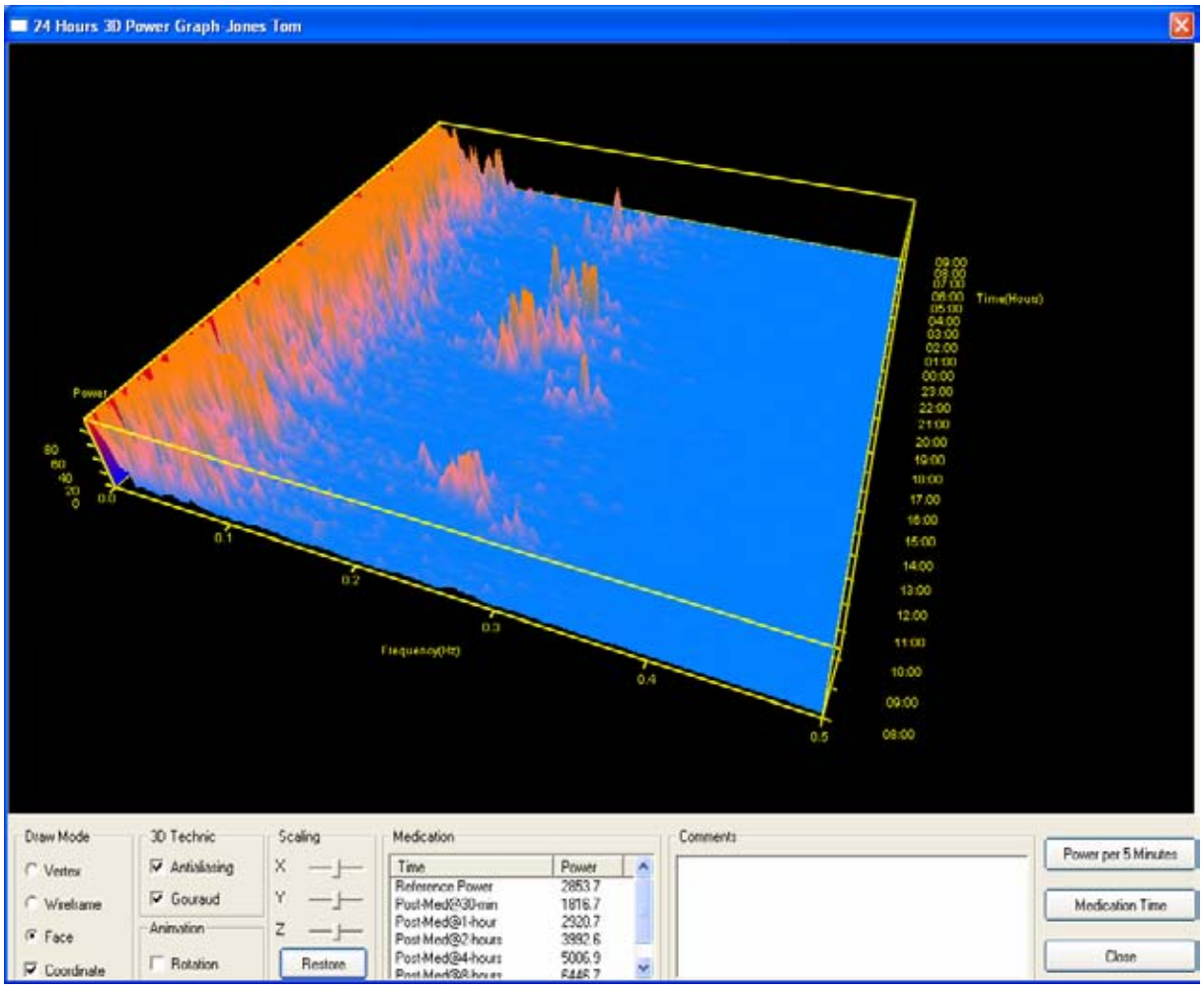
Enter the time from the patient diary when the patient woke up. Click on OK.

Click on the box next to Asleep under the Period Select option on the right side of the screen. The above screen will appear. Enter the time from the patient's diary when the patient went to sleep. Click on OK.

To view the graphs for the patient's awake or asleep period, click in the circle to the left of the Awake or Asleep option under the Period Select option on the right side of the screen. The data for the time period you have selected will appear on the screen.

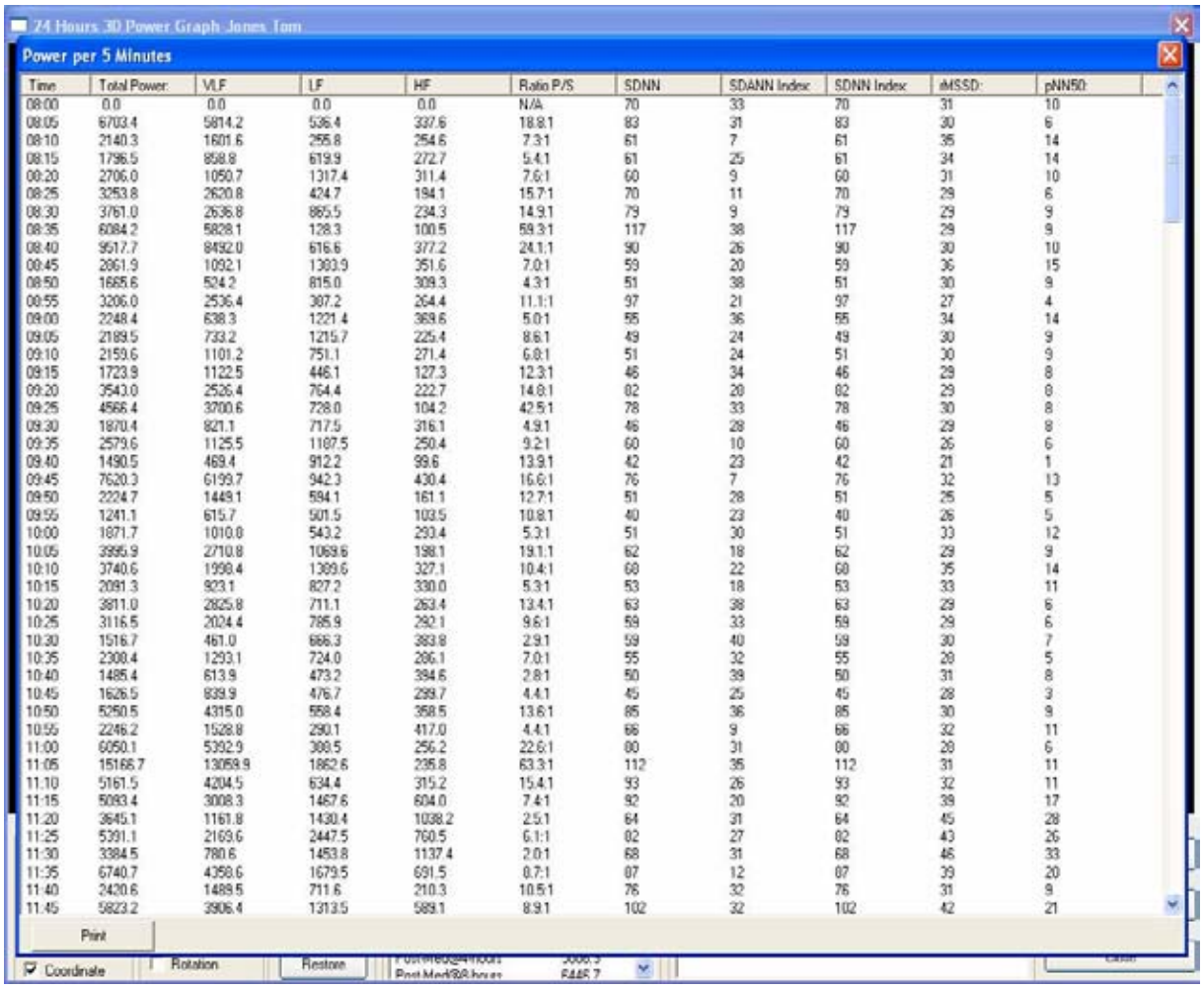
To access the 3D Spectral Power Graph, click on 3D Spectral at the lower right of the screen.

To see the results of Sleep Apnea analysis (after you have entered the awake and asleep times), go to the Report icon under the Data Access Choices and print the Sleep Apnea Analysis pages.



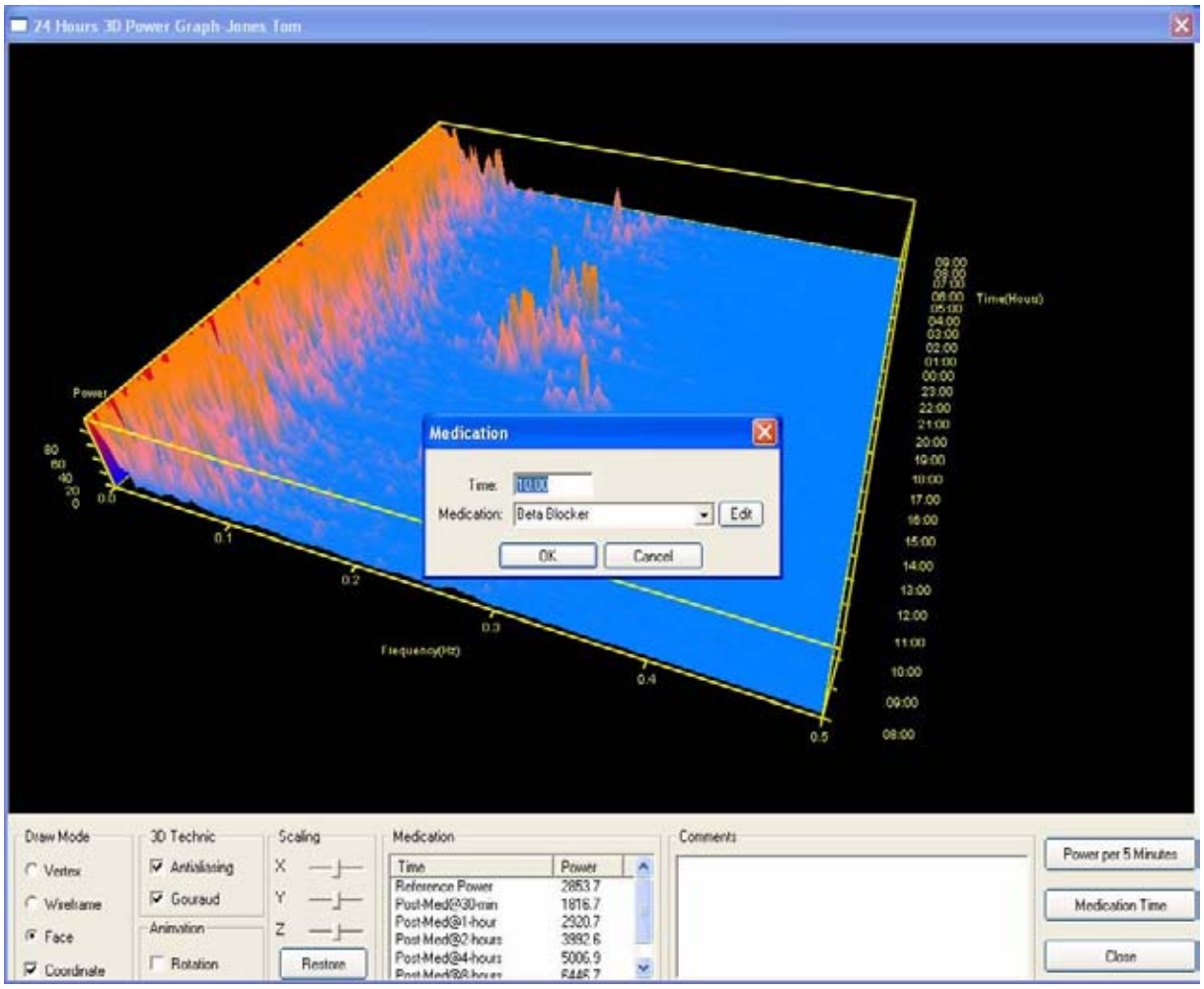
Each 5-minute data period is analyzed by the spectral frequency methodology. A power graph is drawn for each 5-minute period, and then overlaid on each other. The resulting 3-D power graph creates a 24-hour power graph that provides instant visual understanding of the patient's heart rate variability.

To view the totals for each 5-minute period, click on the Power per 5 minute on the lower right side of the screen.



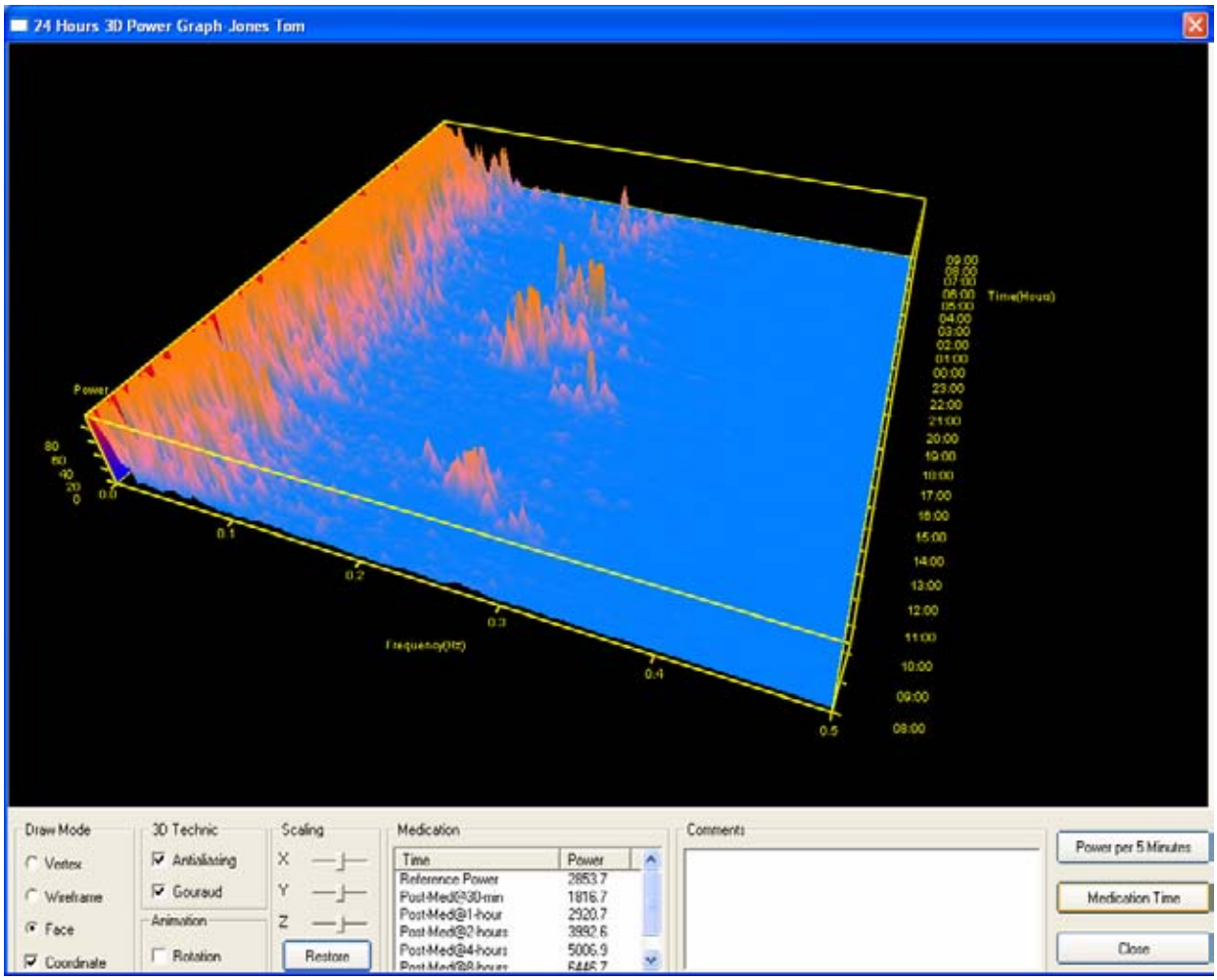
Spectral analysis of each 5-minute period is calculated. Power is calculated for Total Power, VLF Power, LF Power, HF Power, Ratio P/S, SDNN, SDANN Index, pNN50 and a formula for determining the ratio of parasympathetic to sympathetic activity. To view additional 5-minute periods point and click on the down arrow.

To exit this screen, click on the X at the top of the Power per 5-minute box.



This system includes a unique feature of measuring the drug efficacy in relation to HRV. Click on the Medication Time bar on the lower right of the screen. The above screen appears.

Enter the time the patient took medication and then enter the medication information. Click on OK.



An immediate analysis appears under the Medication box in the middle of the screen. You are shown the Reference Spectral Power compared to the first 30 minutes after taking the medication, the first hour, the first two hours, the first four hours and the first eight hours.

The Reference Spectral Power is the Total Power for the 2 hours immediately preceding the medication time.

After you have retrieved all the information from this screen, point and click on the Close bar at the bottom left of the screen. Point and click on the Close bar again and you will be returned to the Data Access Choices screen.

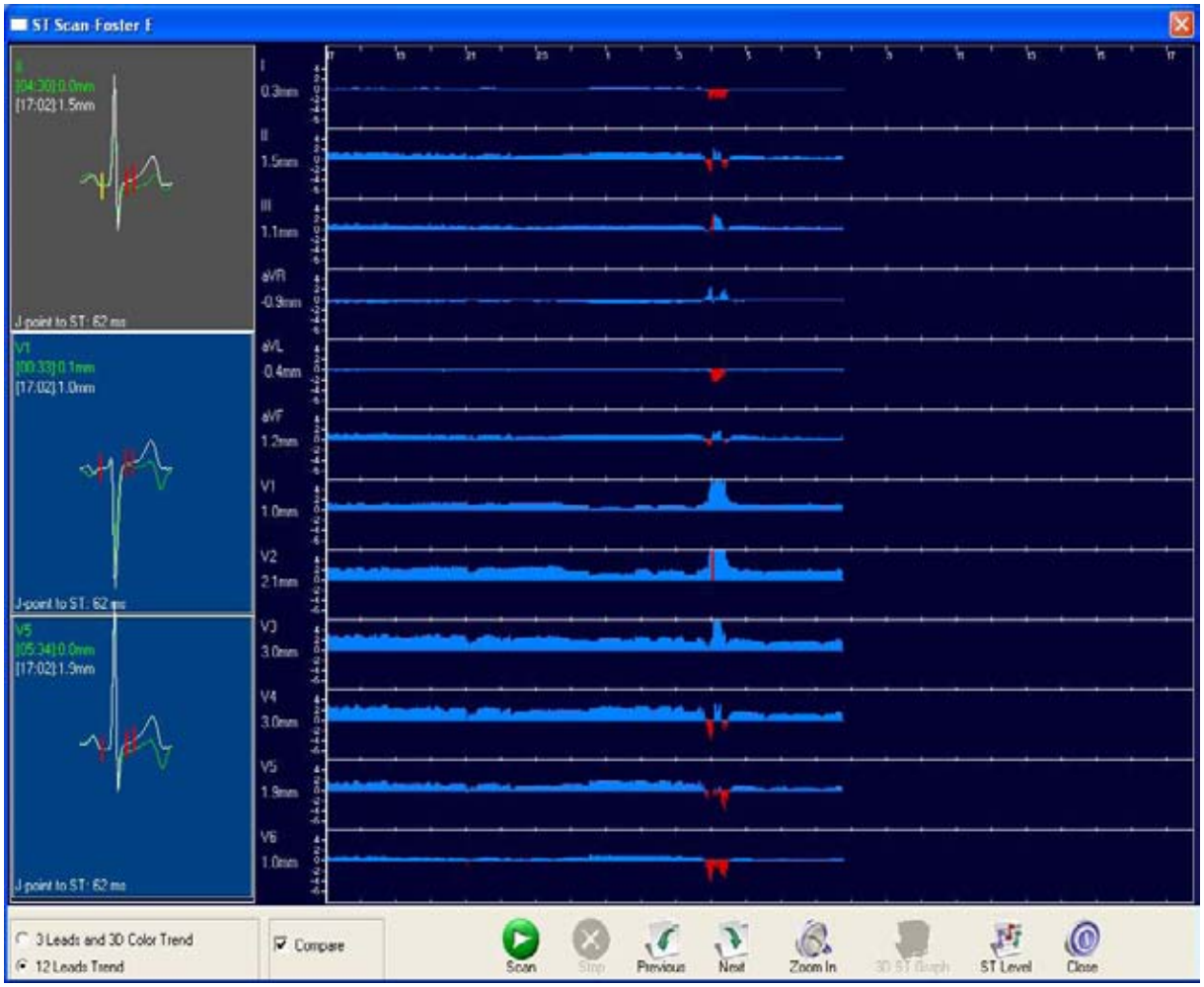
NOTE: For more detailed HRV power information, please refer to the 5-minute power numbers described earlier. You can view and/or print the total power numbers that were pre and post medication time.

To exit, click on the Close bar at the bottom right of the screen and then click on the Close bar at the bottom of the screen again. This will return you to the Data Access Choices Menu.

ST SCAN

12 Lead ECG's can be recorded with either a 300-12 digital Holter recorder with 10 electrodes or with a 300-7 digital Holter recorder with an XYZ (Orthogonal) hookup. The XYZ can produce a derived 12-lead and 18-lead ECG. The 300-12 digital Holter recorder can record a 24 our or a 48 hour ECG.

To view the ST Scan, click on the ST Scan icon in the Data Access Choices. The following screen will appear.



The ST is analyzed in all 12-Leads. This screen shows any 3 leads in a superimposition format and a color-coded ST trend of each minute.

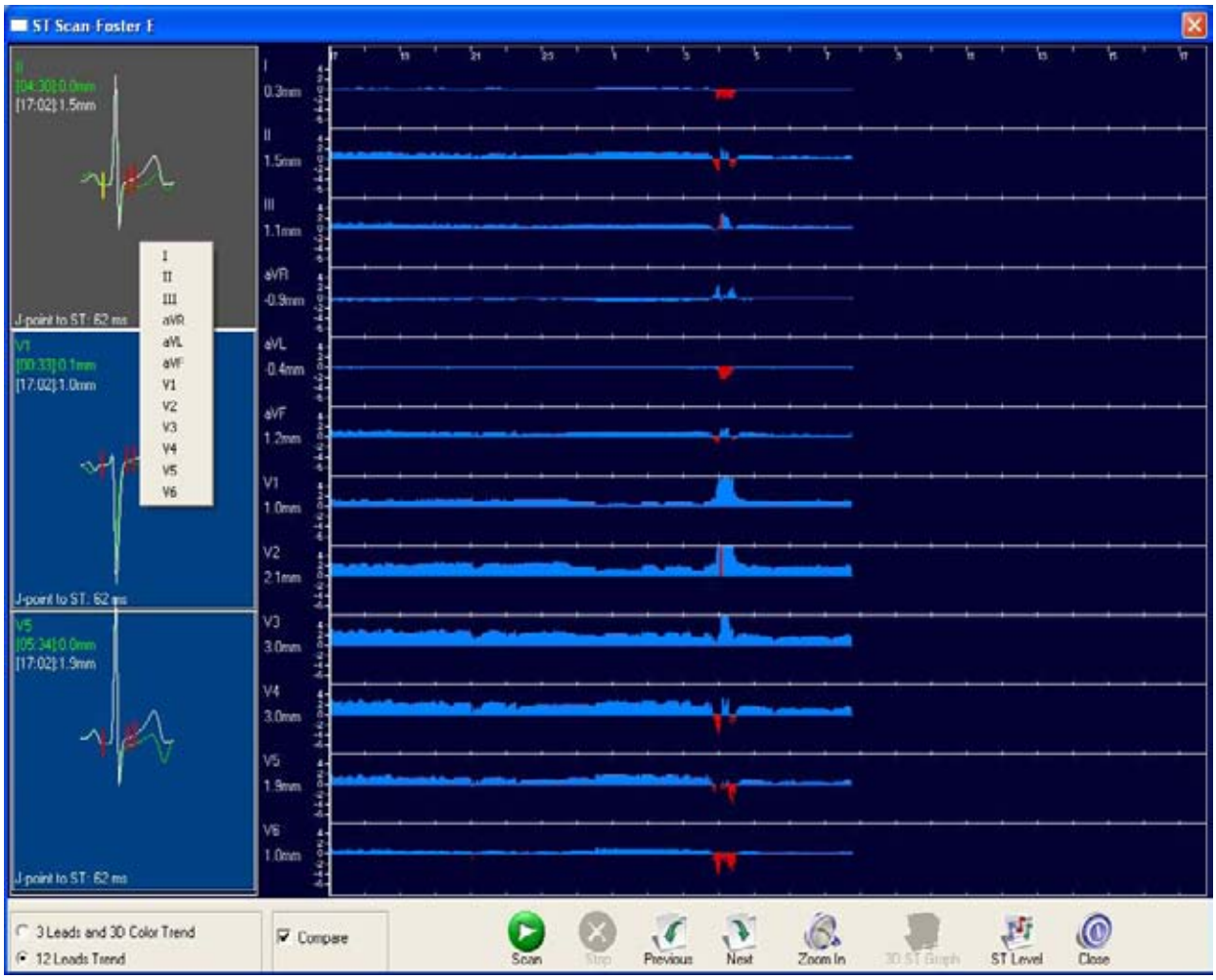
The 3-lead superimposition shows ST and P-wave changes in a very quick scan of the 24-hour ECG. To activate the scan mode, click on the Scan icon on the bottom of the screen.

The green ECG in the background in the 3-lead superimposition scan is the normal reference. The white ECG in the 3-lead superimposition scan is the current time ECG.

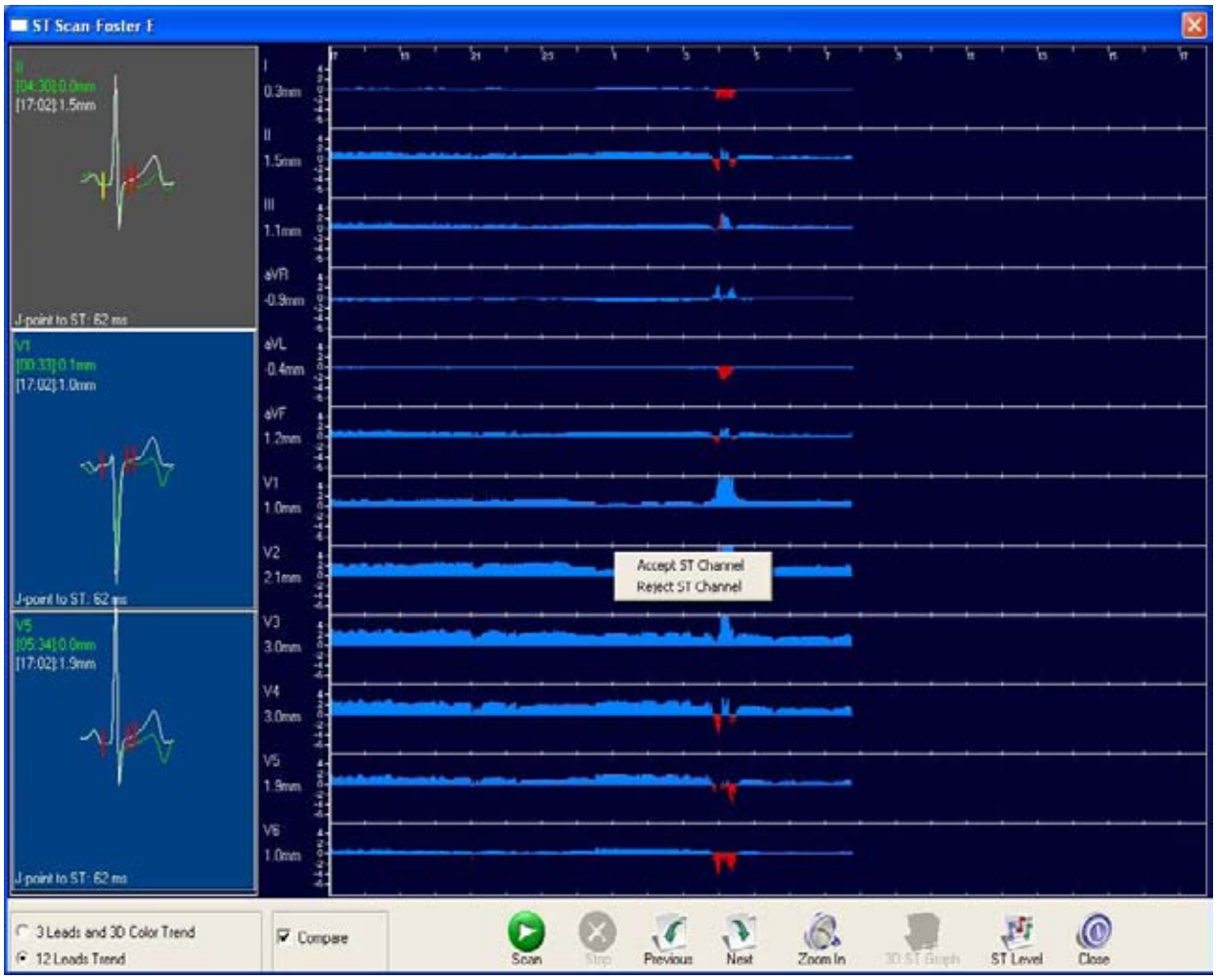
NOTE: If you choose to not have the normal reference beat in the background, click on the box next to Compare in the lower left section of the computer screen.

ST analysis numbers for the normal reference and the current ST are shown in the upper left corner of each superimposition box.

The vertical markers for PR baseline, J-point and ST are shown. The J-Point to ST measurements are shown at the bottom of each superimposition box.

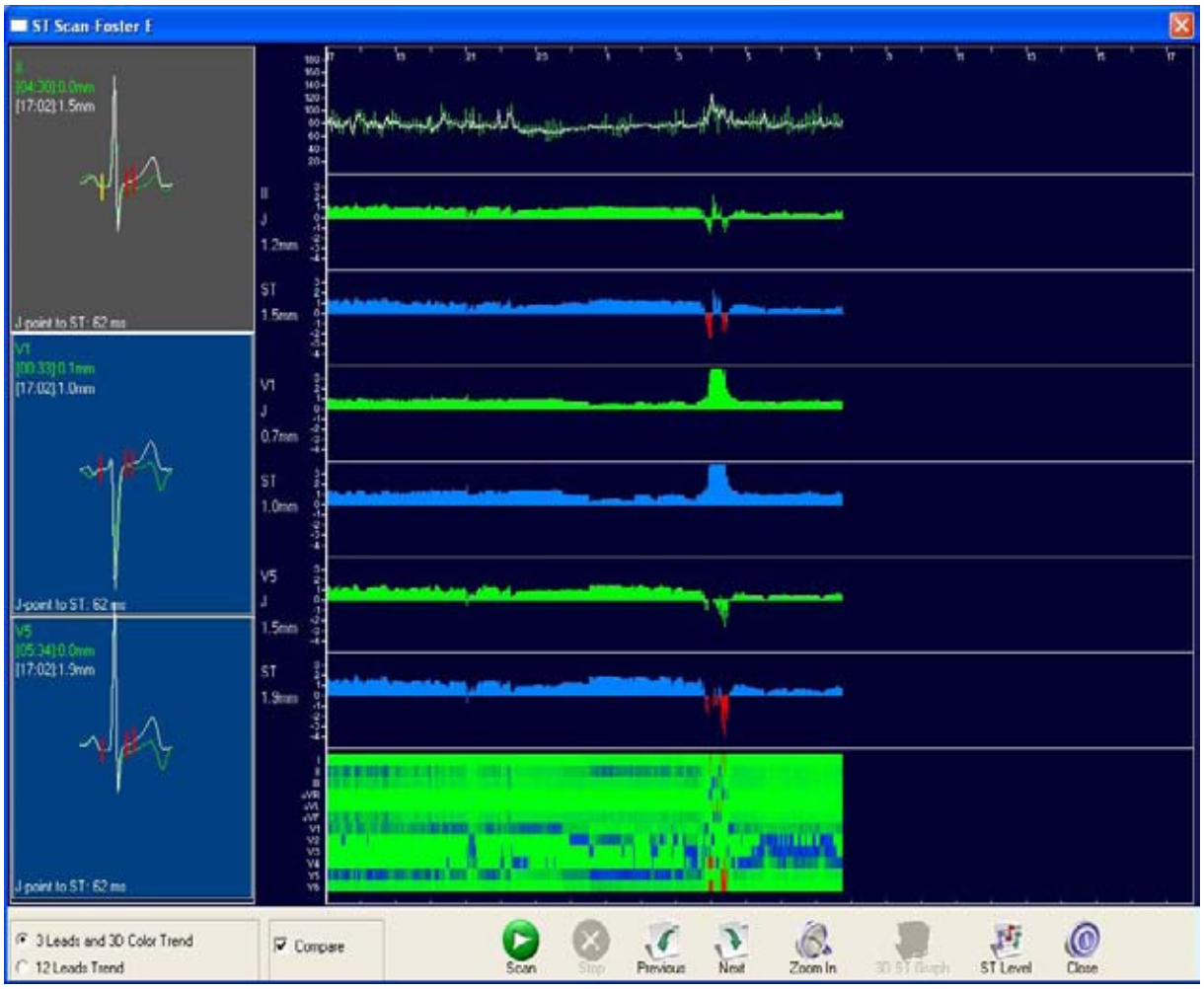


To change a lead for the superimposition ECG display, point the mouse arrow on the superimposition box you wish to change. Right click with the mouse. The above drop screen will appear. Click on the lead you wish to display. The lead you have selected will appear in the previously grayed box.



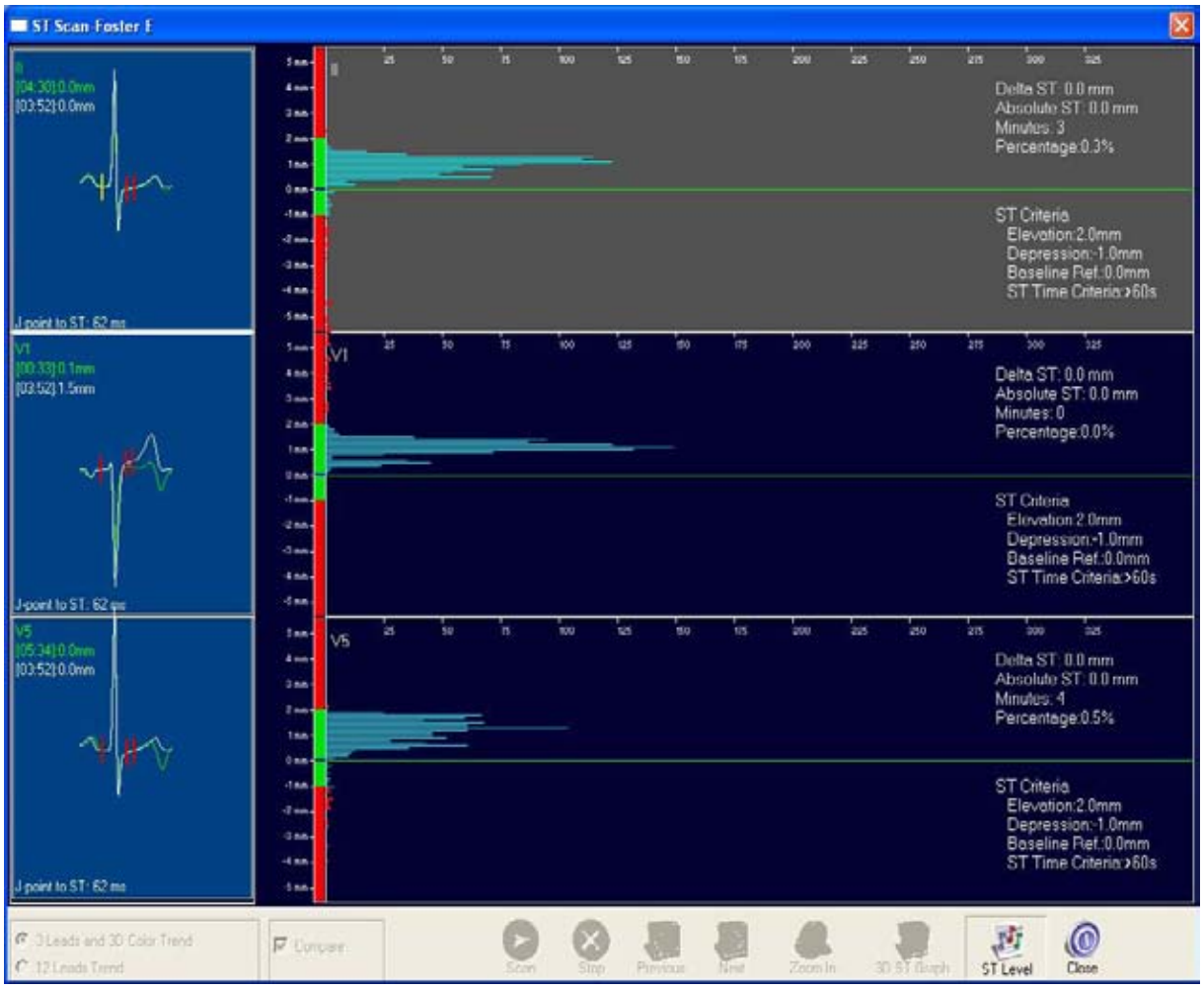
Any single or multiple leads of ECG can be rejected from the analysis by placing the arrow in the lead trend (in the example above lead V1 has been selected) and right clicking the mouse. Scroll down to Reject ST Channel and click. The lead will be removed from the graph and from the analysis process.

To include a previously rejected lead in the analysis, right click in the lead trend and the pop up menu will appear. Click on Accept ST Channel. The lead will appear on the graph and be included in the analysis process.



To view 3 leads and the 3D Color Trend, click on the circle next to the 3 Leads and 3D Color Trend option on the lower left of the screen.

This graph shows a 24-hour Heart Rate Trend Graph at the top of the screen. Below that are three channels with the J Point graph (in green) and an ST graph (in blue). Below these graphs is a color coded graph for all 12 leads.



Click on the ST Level icon at the bottom right of the screen and the above display will appear with independent histograms for each 12 lead.

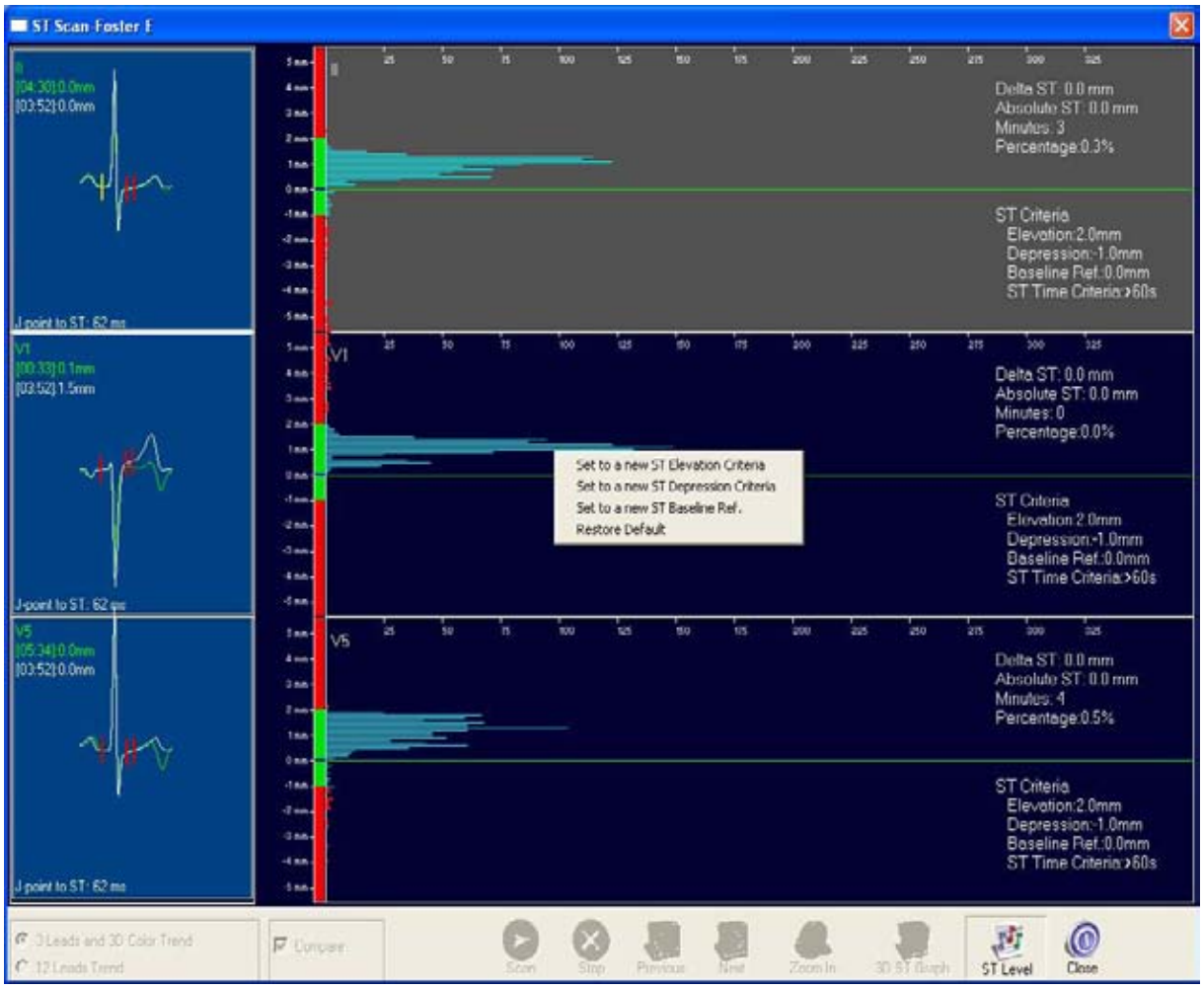
The horizontal blue lines show the number of minutes at each ST level that are in the normal ST range. The short red lines show the ST level and number of minutes for those minutes of ST depression.

To do a manual quick scan of each individual lead, click in the desired lead's histogram. The background of the histogram will turn gray. Press the down arrow key on the keyboard to scan through the lead. As you arrow down through the histogram, you will see the Delta ST, Absolute ST and how many minutes are at each level. The lower half of the histogram shows the ST criteria.

To verify the accuracy of an ST depression, arrow down to the depression and press the ENTER key on the keyboard.

The V1 lead from the previous histogram is highlighted in red and the ST measurement point is the blue marker. The rectangular box at the right side allows you to reject the lead from the ST analysis. To reject the lead from the analysis, click on the box at number one and then click the Update ST Edit bar. This removes this lead at this time from the ST Analysis. The accuracy of all leads of ST analysis can be validated with this ST verification procedure.

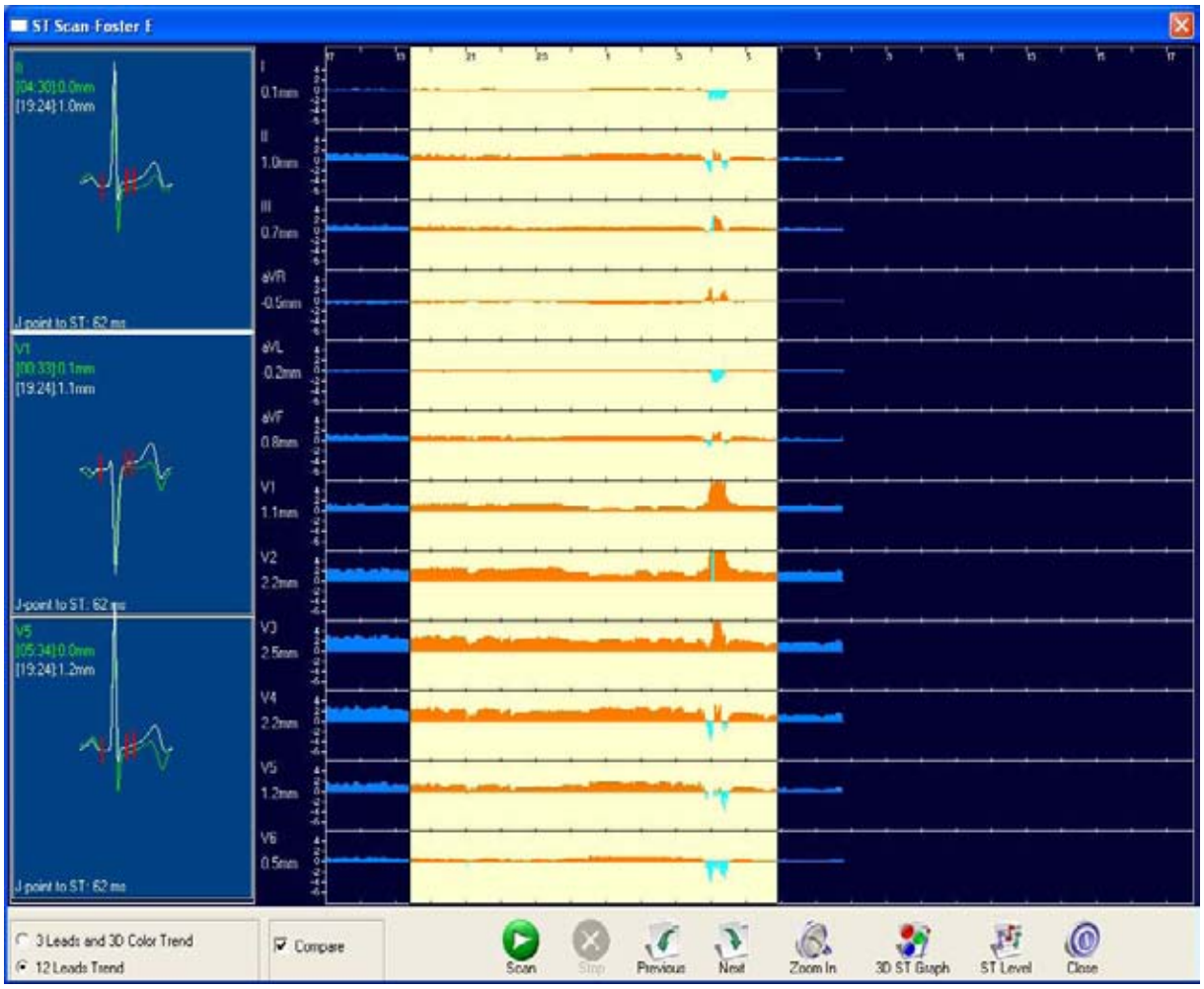
Click the Close icon at the bottom left of the screen and you will be returned to the previous histogram screen.



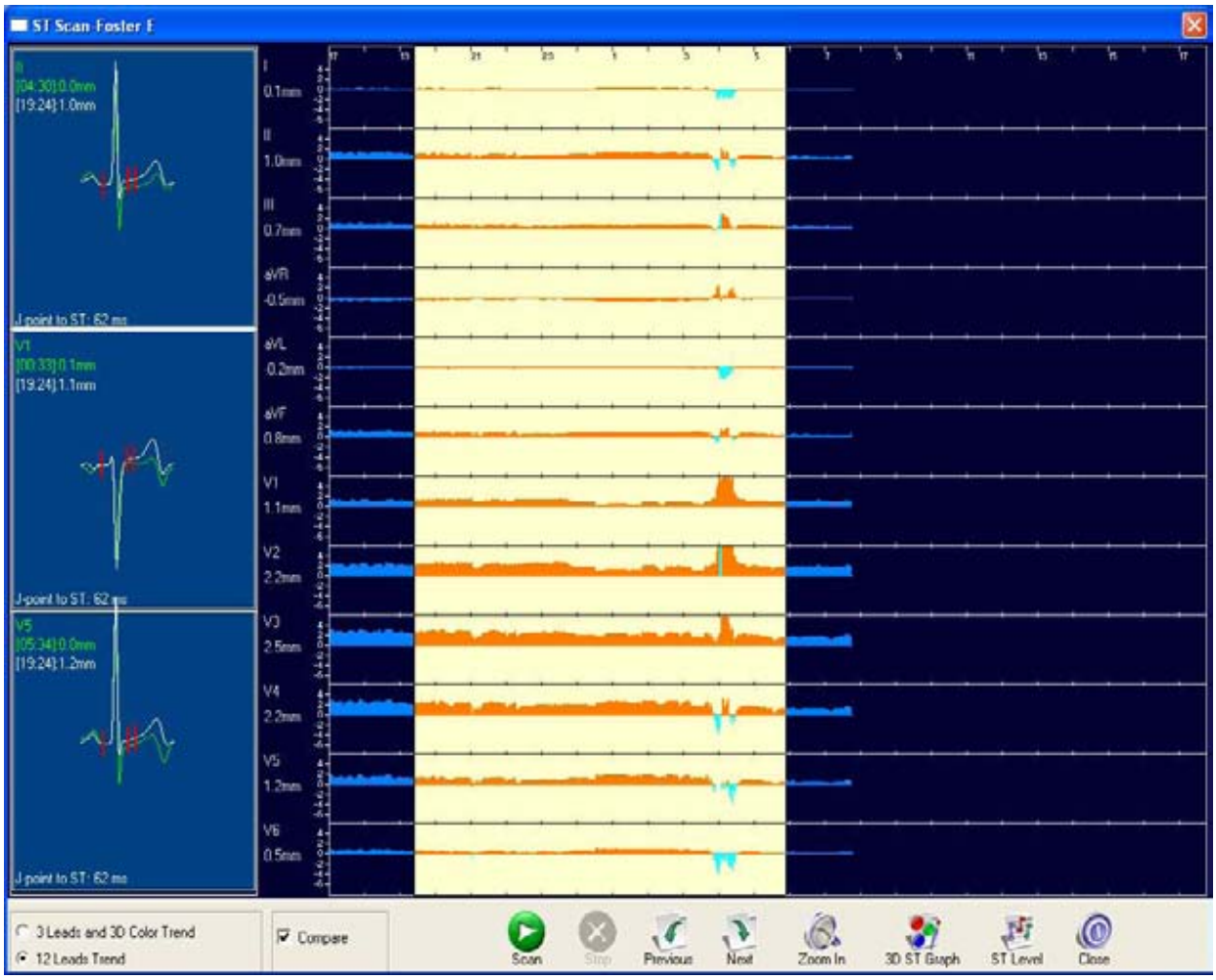
To change the ST Elevation and Depression Criteria and/or to set a new ST Baseline Reference level, click in the lead histogram you wish to change. The histogram will turn grey. Use the up or down arrow keys on the keyboard to move the green line cursor up and/or down the graph. Move the green line cursor to the position you wish to select as the ST Elevation Criteria. Right click the mouse. The above pop up screen will appear. Click on “Set to a new ST Elevation Criteria.” The graph will be readjusted to this new setting.

To set a new setting point for the ST Depression Criteria and/or a new ST Baseline Reference, repeat the above steps, selecting the appropriate setting criteria.

To restore the ST criteria to the original settings click in the lead histogram you wish to change. Right click the mouse. Click on Restore Default. The ST criteria settings will be reset to the default position.



Any ECG lead can be immediately reanalyzed. Point and drag the mouse for any desired time period. Click on the selected ECG on the left side of the display. In the above example we have chosen Lead II.



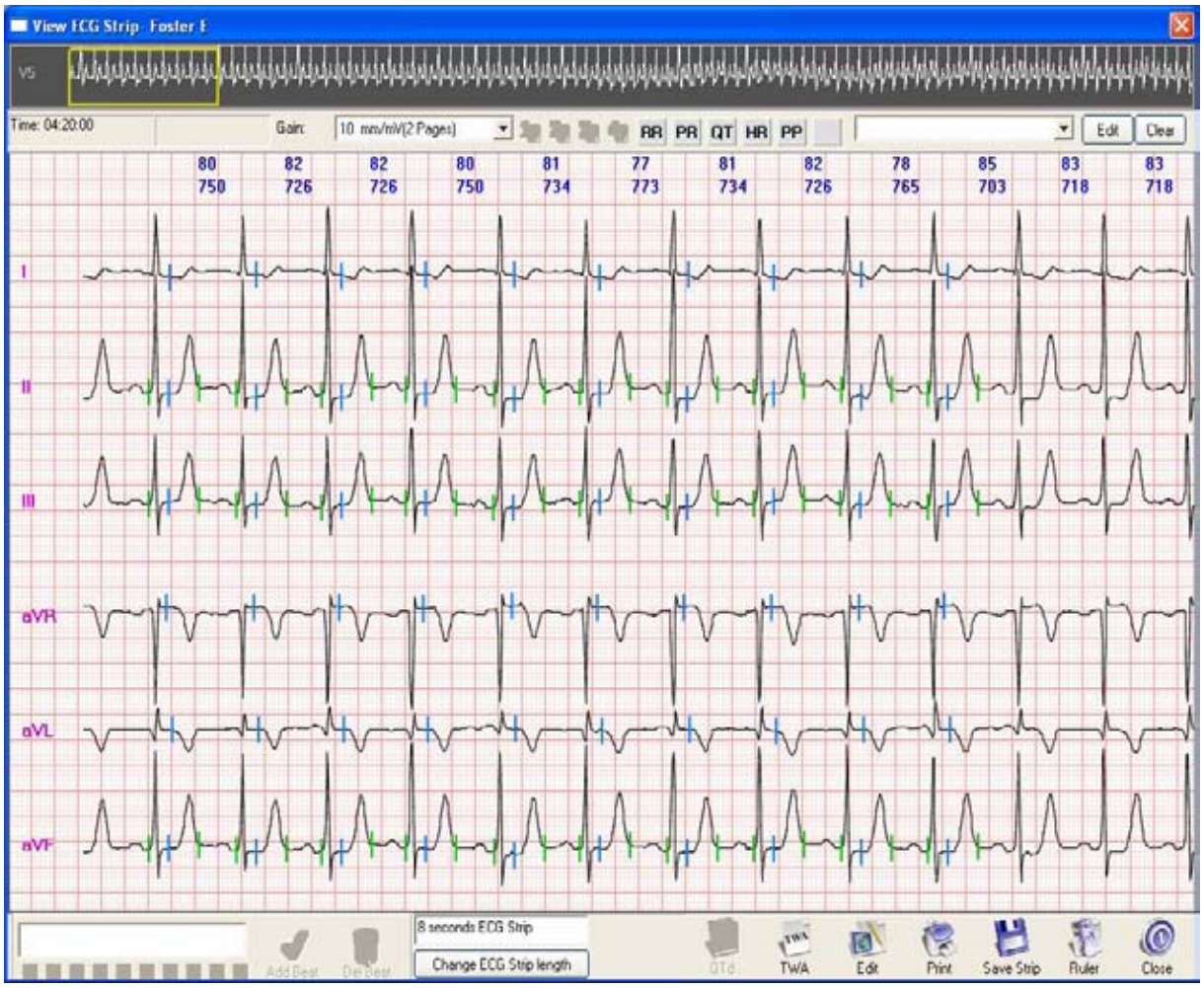
Reset the first vertical marker using the arrow keys on the keyboard. Press the TAB key on the computer and reset the J Point marker using the arrow keys on the keyboard. Press the TAB key and reset the ST Sample Point marker using the arrow keys on the keyboard. Press the ENTER key on the keyboard. The ST analysis process will now take place. When the 100% indicator appears in the lead box, then the lead has been completely reanalyzed.

You can view the 12-Lead ECG from anywhere in the 24-hour ST Trend Graph. To view the leads, double click the mouse or point the mouse and press the ENTER key on the keyboard on the time in the graph you wish to view.

The exact location of the ST sample point is shown with the blue vertical marker. This marker is viewed for the verification for all ST and other analysis functions.

You can select 12, 6 or 3 lead displays of the ST data by selecting different gain options at the top of the screen. Click on the down arrow and select the gain you wish to use for the strip display. The 2.5 mm/mV, 5 mm/mV and 10mm/mV displays show 12 leads of data on one page.

To see 6 lead displays, select the 10mm/mV (2 Pages option. The following screen will appear.



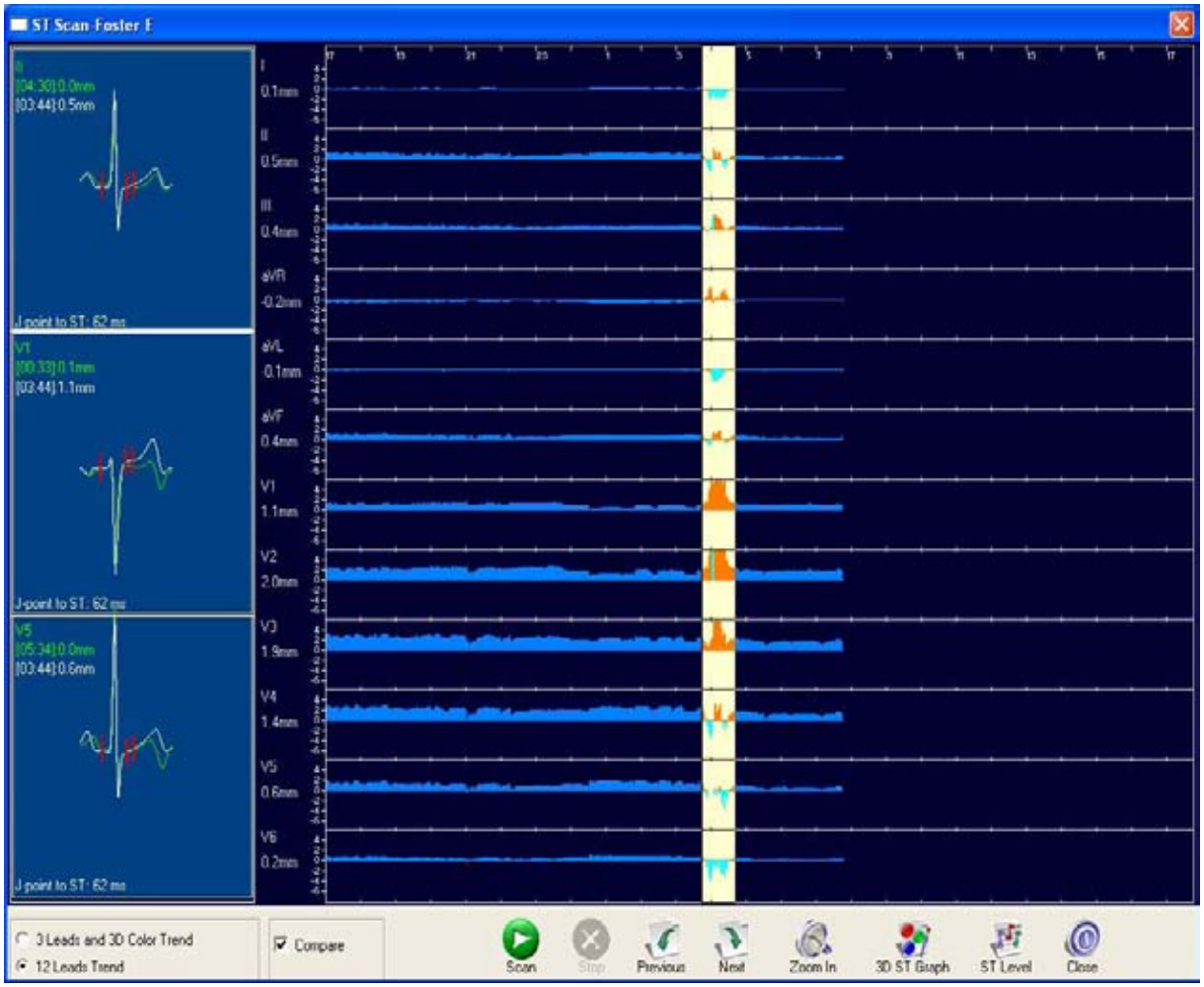
Note the 1 and 2 icons next to the Gain indicator field. Clicking on the 1 icon shows the first 6 leads of the strip. Clicking on the 2 icon shows the next 6 leads of the strip.

To see 3 leads of data on the select the 10mm/mv (4 Pages) option. The following screen will appear.

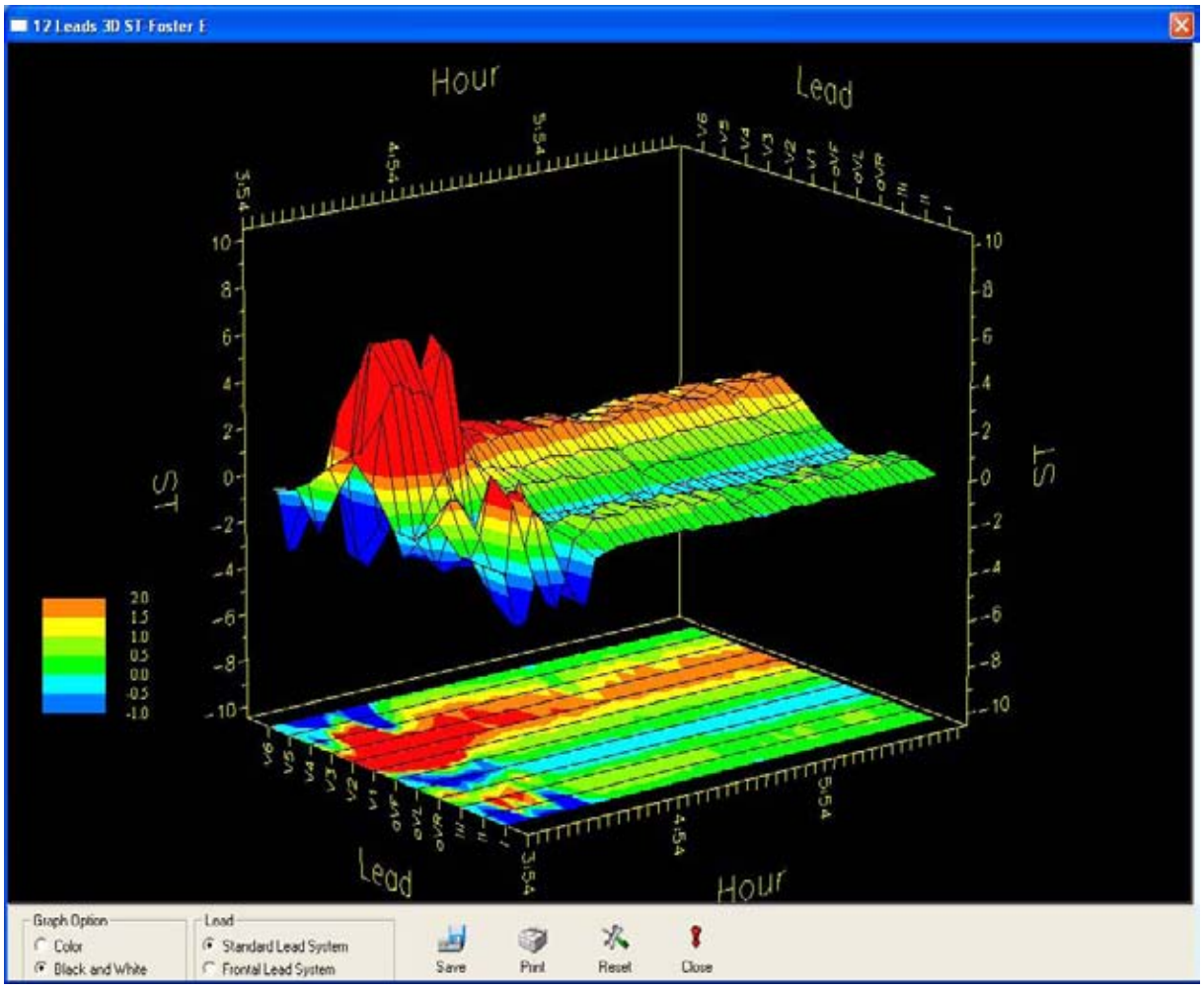
You will see the first 3 leads of the strip. Clicking on the 2 icon next to the Gain field will show you the next 3 leads of the strip. Clicking on the 3 icon next to the Gain field will show you the next 3 leads of the strip and clicking on the 4 icon next to the Gain field will show you the last 3 leads of the strip.

To use the ruler to verify any measurements, click on the Ruler icon at the bottom of the screen. A red cross icon will be at the tip of the mouse pointer. Point and drag the red cross across the area you wish to measure. Release the mouse button and a box will appear over the area you have measured with the measurements appearing in the field above the strip next to the Edit button.

Use the Page Up or Page Down buttons on the keyboard to move to show you pre and post ST data.

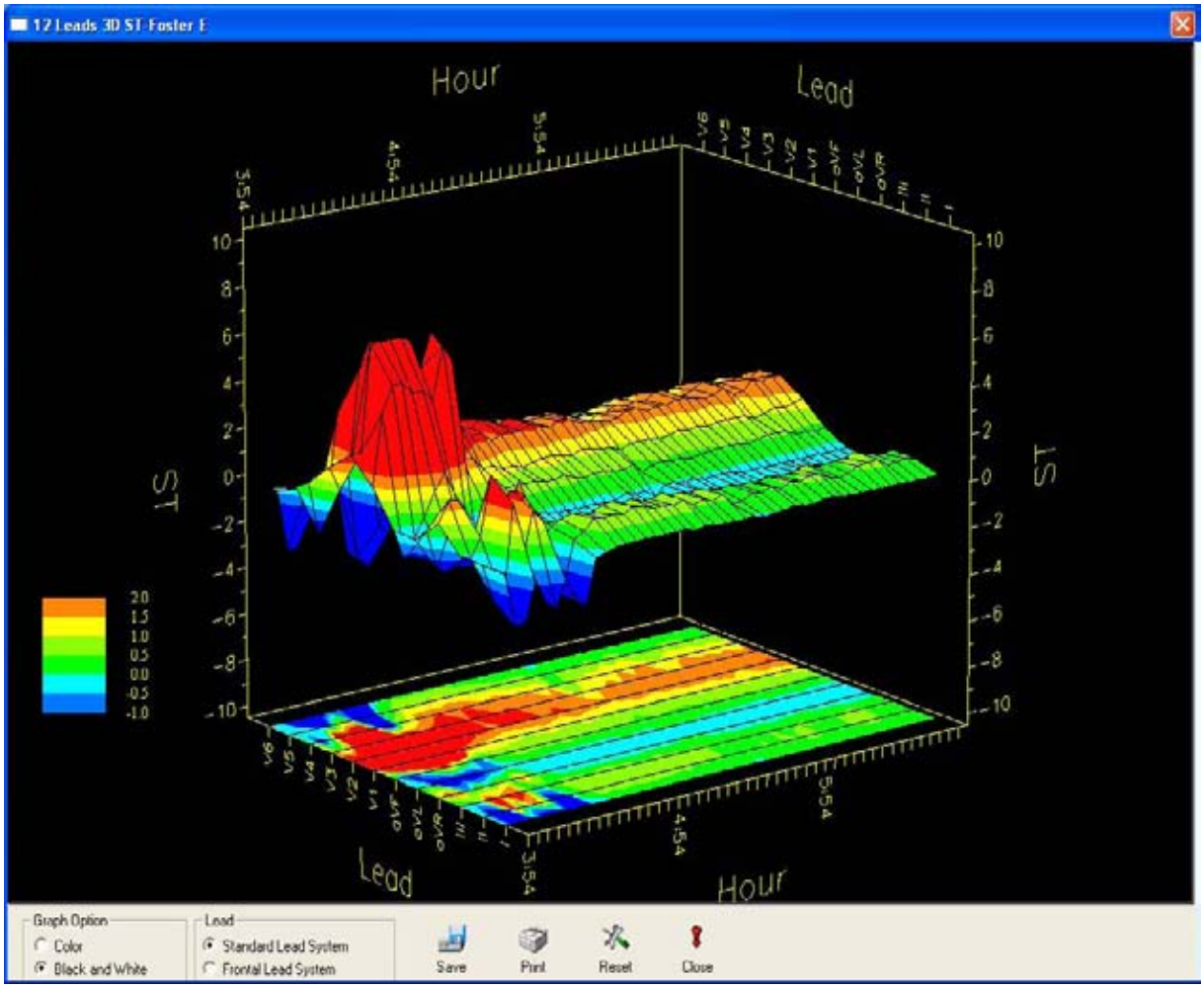


To view a 3D display of ST activity point and drag the mouse over a 3 hour period of major ST depression on the 24 hour ST Trend Graph. Click on the icon for 3D ST Graph at the bottom of the screen.



The color graph on the left of the screen shows the coloring for ST elevation and depression used in the graph.

In our example above the graph shows leads aVL, aVR and I were rejected. The deep blue color shows ST depression in leads V6, V5, V4, aVF, III and II.

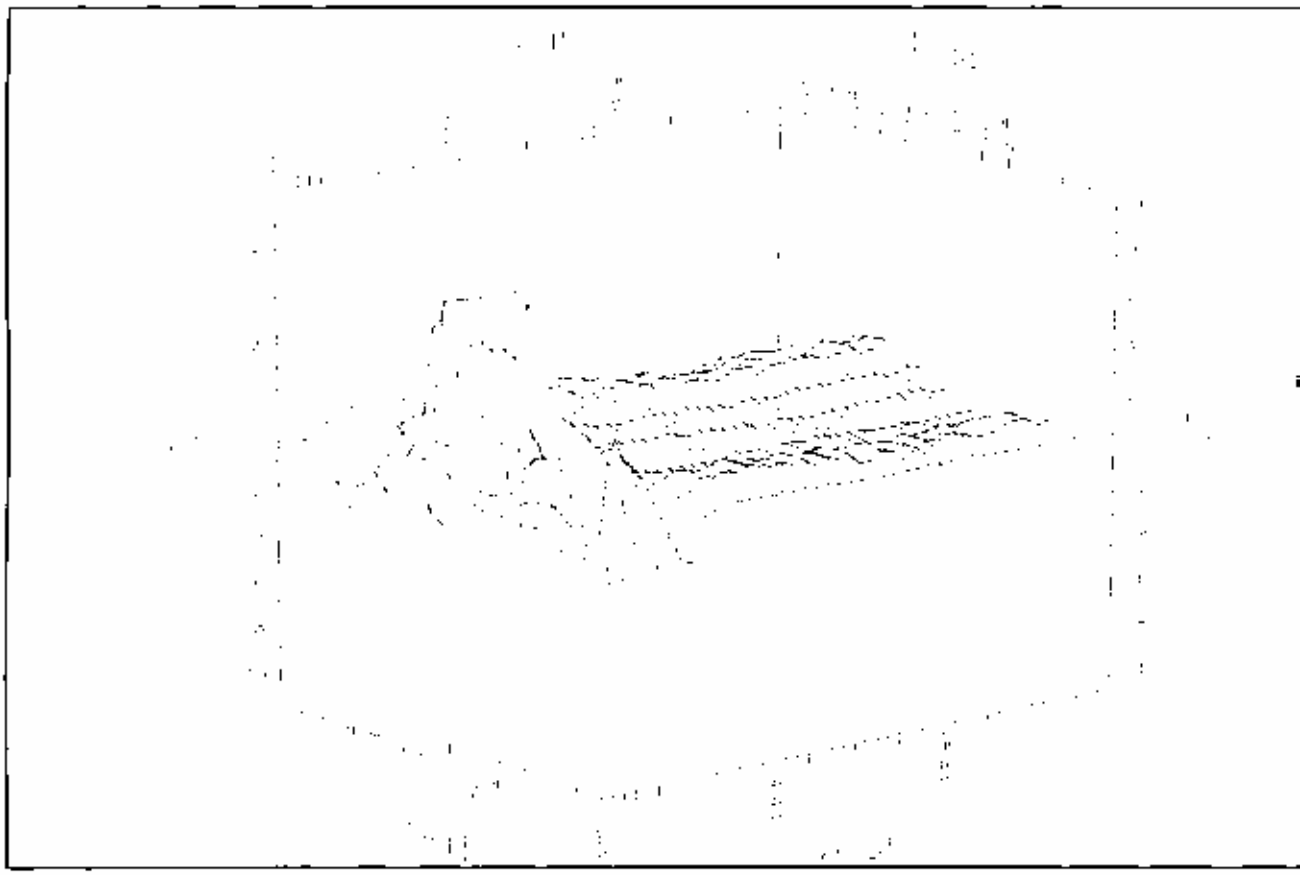


This graph can be rotated in any direction. Point the mouse to the graph, left click and drag the graph to the position you desire.

To reset the graph to its original position, click on the Reset icon at the bottom of the screen.

To print a report page of this graph with all hourly ST totals from all leads, click on Print. The following page will be printed out.

To print a report in black and white, click on Black and Wait under Graph Option and then click on the Print icon. To print a report in color, click on Color under Graph Option and then click on the Print icon.



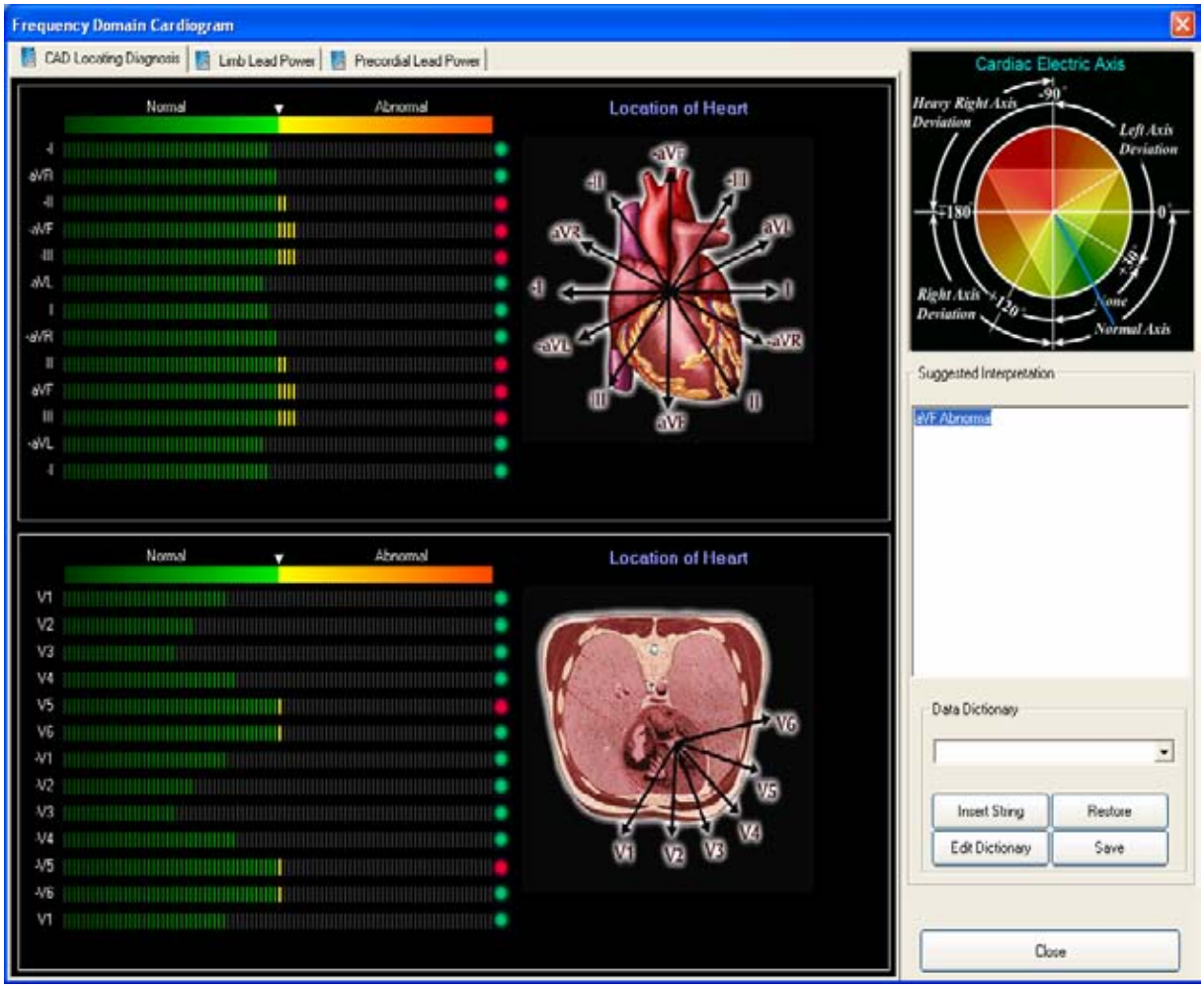
Time	Avg HR	Min HR	Max HR	ST I	ST II	ST III	ST aVR	ST aVL	ST aVF	ST V1	ST V2	ST V3	ST V4	ST V5	ST V6
17:00	80	65	96	0.0	+0.8	+0.5	-1.0	-0.5	+0.7	+0.9	+2.7	+3.5	-3.4	+2.1	+0.2
18:00	80	68	93	0.0	+0.9	+0.7	-0.9	-0.4	+0.7	+1.0	+3.0	+3.4	+3.1	+1.0	+0.3
19:00	77	72	91	+0.1	+0.9	+0.6	-0.9	-0.4	+0.7	+1.0	+2.6	+3.2	+2.9	+1.1	+0.4
20:00	79	67	97	0.0	+0.7	+0.5	-0.8	-0.6	+0.5	+1.1	+2.9	+3.3	+2.9	+0.8	+0.2
21:00	78	72	100	-0.5	-0.3	0.0	-0.7	-0.4	-0.1	+0.8	+3.0	+3.1	-2.8	-0.8	-1.0
22:00	74	66	98	-0.1	+0.4	+0.3	-0.7	-0.5	-0.3	+1.1	+2.8	+3.2	+2.7	+0.3	-0.1
23:00	68	63	72	0.0	+0.7	+0.4	-0.6	-0.3	+0.5	+1.0	+2.9	+2.9	+2.3	+0.8	+0.1
0:00	73	70	78	-0.1	+1.0	+0.6	-0.9	-0.3	+0.7	-0.1	+2.0	-2.4	-2.9	+1.2	-0.5
1:00	74	69	82	+0.3	+1.1	+0.6	-0.9	-0.3	+0.8	+0.3	+2.1	+2.8	+2.9	+1.4	+0.8
2:00	77	72	84	0.0	+0.4	+0.5	-0.9	-0.4	+0.4	+0.4	+2.1	+2.8	+3.0	+0.4	0.0
3:00	80	74	113	-2.3	-2.7	-1.1	+2.5	-0.9	-1.3	+4.5	+5.9	-2.8	-3.4	-1.9	-4.0
4:00	90	75	126	-2.2	-2.5	-3.2	+2.3	-2.6	+2.0	+6.8	+7.0	+6.6	-4.0	-4.0	-4.1
5:00	79	73	94	-0.1	+0.2	+0.3	-0.4	-0.5	+0.2	+0.8	-2.2	-2.2	+0.5	0.0	-0.1
6:00	77	73	83	0.0	+0.3	+0.3	-0.3	-0.3	+0.3	+0.9	+2.2	+2.0	+0.9	+0.3	0.0
7:00	80	76	89	-0.1	+0.2	+0.1	-0.5	-0.5	+0.1	+0.8	-2.3	+2.3	+0.6	+0.1	-0.1
8:00	N/A	N/A	N/A	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
9:00	N/A	N/A	N/A	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
10:00	N/A	N/A	N/A	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
11:00	N/A	N/A	N/A	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
12:00	N/A	N/A	N/A	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
13:00	N/A	N/A	N/A	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
14:00	N/A	N/A	N/A	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
15:00	N/A	N/A	N/A	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
16:00	N/A	N/A	N/A	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
17:00	N/A	N/A	N/A	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
Totals	77	63	126	-2.3	-2.7	-1.1	+1.0	-2.6	+1.3	+6.8	+7.0	+6.6	-4.0	-4.0	-4.1

FCG CADgram

The early detection of ischemia may be the #1 objective of a clinical cardiologist. There would be a very major advance in Holter ECG if a company could develop a technology for detecting CAD for the majority of patients who have unknown ischemia.

The CardioScan 12 solves this problem by combining quality ST analysis of 12-Lead ECG with the new and unique FCG CADgram.

To access the FCG CADgram, click on the FCG icon from the Data Access Choices screen.

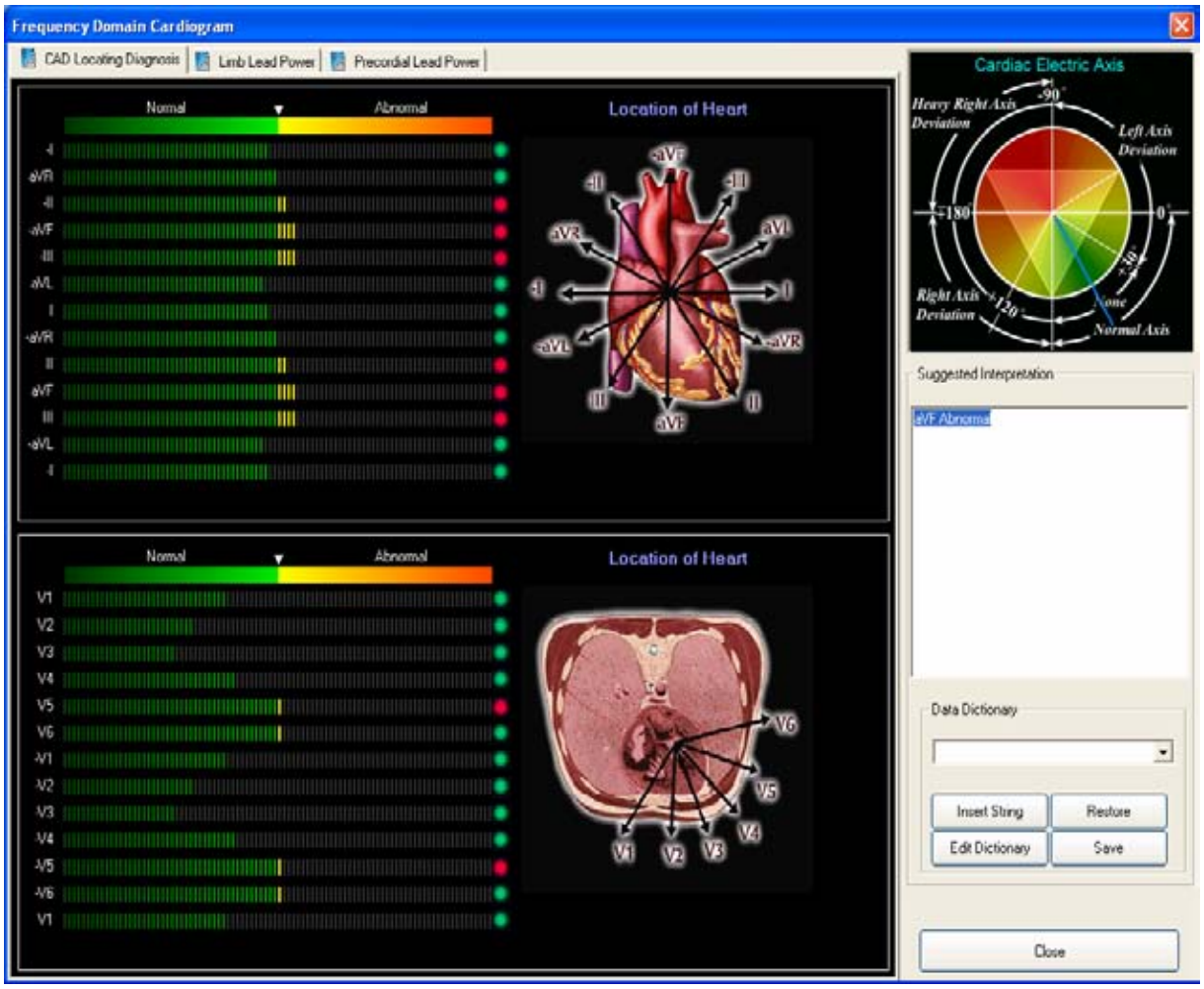


The FCG CADgram is a new test for the western countries. Its value has been proven with over 5 years of testing on over 2000 patients in China. Its purpose is to detect and locate blockages in the coronary arteries without the presence of any exercising component

An exercise stress test is of little value without the exercising component and the Holter is very limited in detecting CAD (coronary artery disease) in the absence of exercise during the Holter ECG recording. The FCG, combined with 12-lead ST analysis, significantly increases the detection of CAD in the Holter ECG recording environment.

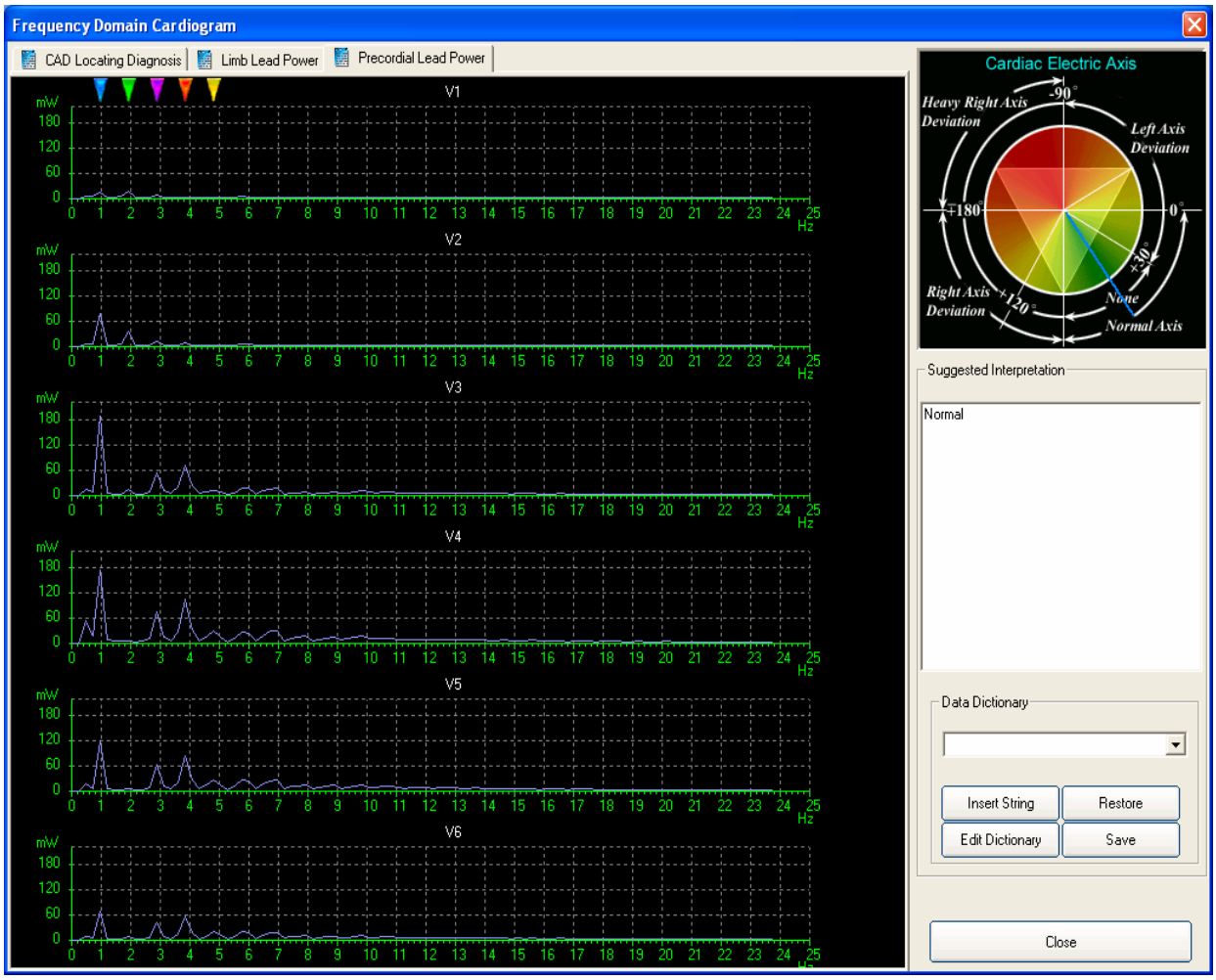
The FCG test must use only the 10-electrode, 12-Lead Holter digital recorder.

The above display shows an abnormal FCG from a patient that had a negative stress test.



You can see a series of green horizontal histogram bars for the adjacent ECG leads. The longer the green bars, the more likely you would find blockages with the angiogram. At the halfway mark you get into the abnormal positive tests.

A positive FCG CADgram is a strong indication for doing an Exercise Stress Test.



The above FCG CADgram is created from a non-exercise, low heart rate environment. The FCG selects a time period of only 90 seconds of slow and steady heart rate, usually when the patient is asleep. A frequency analysis is performed on all 12 leads. All the beats for each lead are made into one beat by a SAECG technique.

A frequency analysis is then performed on the PQRST morphology for each of the 12 leads. The resulting frequency power distributions are shown on the left side of the screen Leads V1, V2, V3, V4, V5 and V6 are shown.

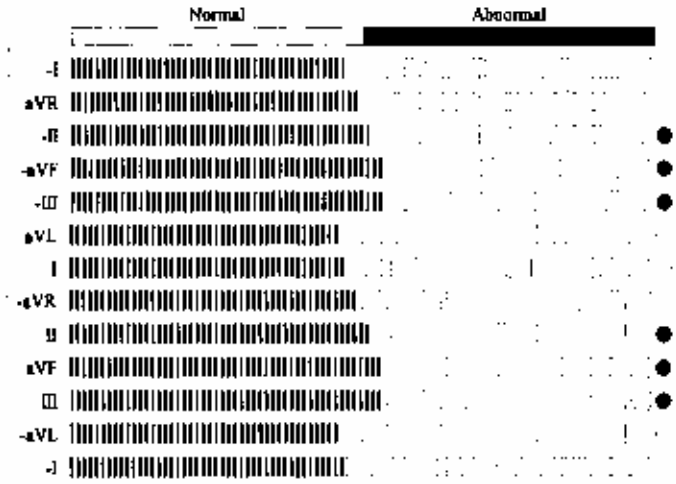
This is a normal distribution A normal FCG will show the most power (vertical axis) at the beginning (0 to 2 Hz) of the horizontal axis. The power will then decrease, with very little power after 10Hz. The power under the green arrow (about 2Hz) should be very little for a normal patient.

An abnormal FCG will start with small power, then enlarge from 2 to 5 Hz and then decrease. A patient with significant power under the green arrow can indicate an abnormal ischemia condition.

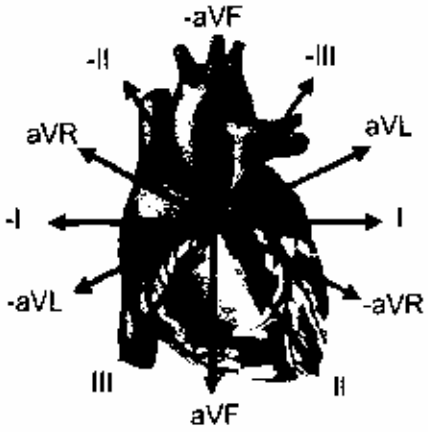
You receive a 2-page report for the FCG CADgram. Its purpose is to correlate with what you would expect to receive from an exercise stress test. It is recommended that a positive FCG CADgram is a strong indication for performing an exercise stress test. The stress test should be your traditional tool for going on to an angiogram.

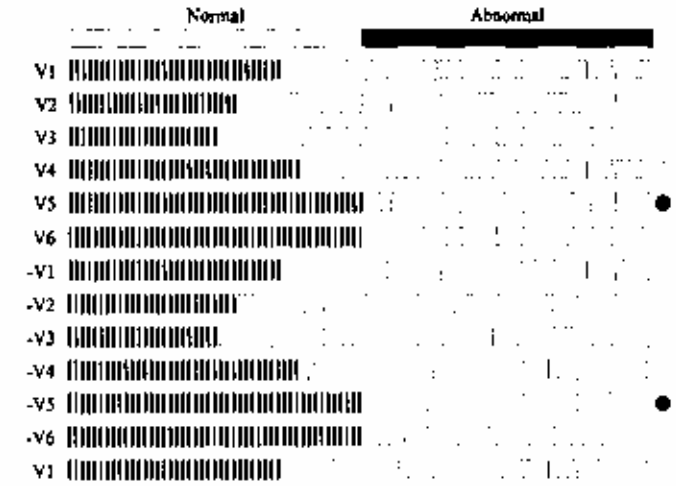
The FCG CADgram requires a clean, 12-lead ECG trace and the proper cleaning of the patient's skin at each electrode site is imperative.

The circular diagram in the lower left of the report page shows a very detailed depiction of the QRS axi

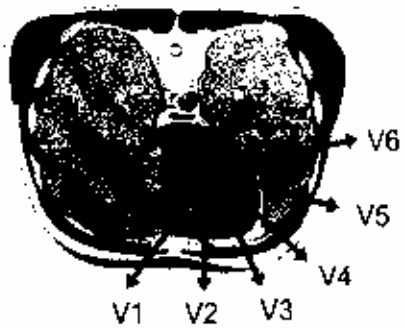


Location of Heart

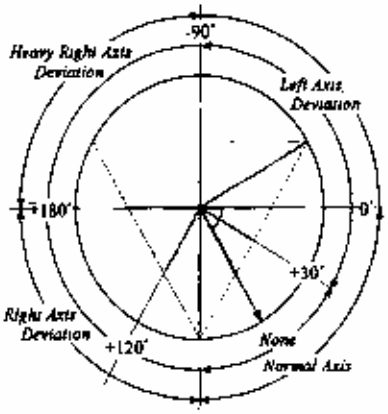




Location of Heart



CAD Locating Diagnosis



QRS Axis 60.0°

aVF Abnormal

CONCLUSIONS

ECG STRIP

From the ECG Strip menu, you will be able to select various ECG strips for printout. The ECG strip can be either in the 3-lead or 12-lead format.

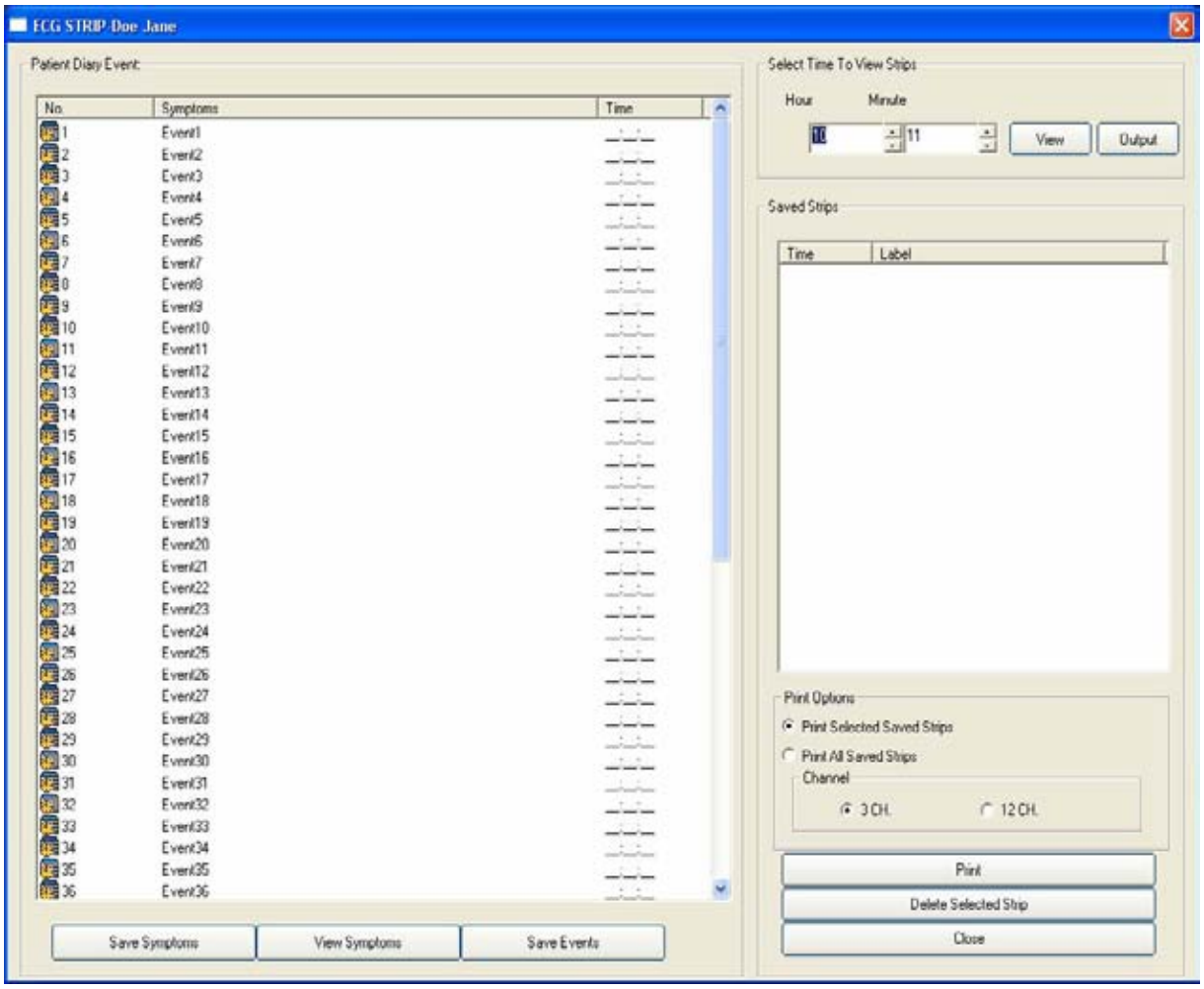
If the 12-lead format is selected, the ECG lead placement should have been the “Orthogonal 7-lead” hookup as described under the “Lead” menu of the program.

To access the viewing, saving and printing of ECG Strips, point and click on the ECG Strip icon from the Data Access Choices screen.

ECG Strips can be selected from other menu displays. They can also come from ECG Strip displays in Edit, Page Scan, Mega Scan, QT Validation, A-Fib/Flutter and HRV.

If the Auto Report feature is selected in the Setting default menu, the first event of each category in Abnormal ECG Events is saved for the Holter report printout.

Click on the ECG Strip icon and the following screen will appear.



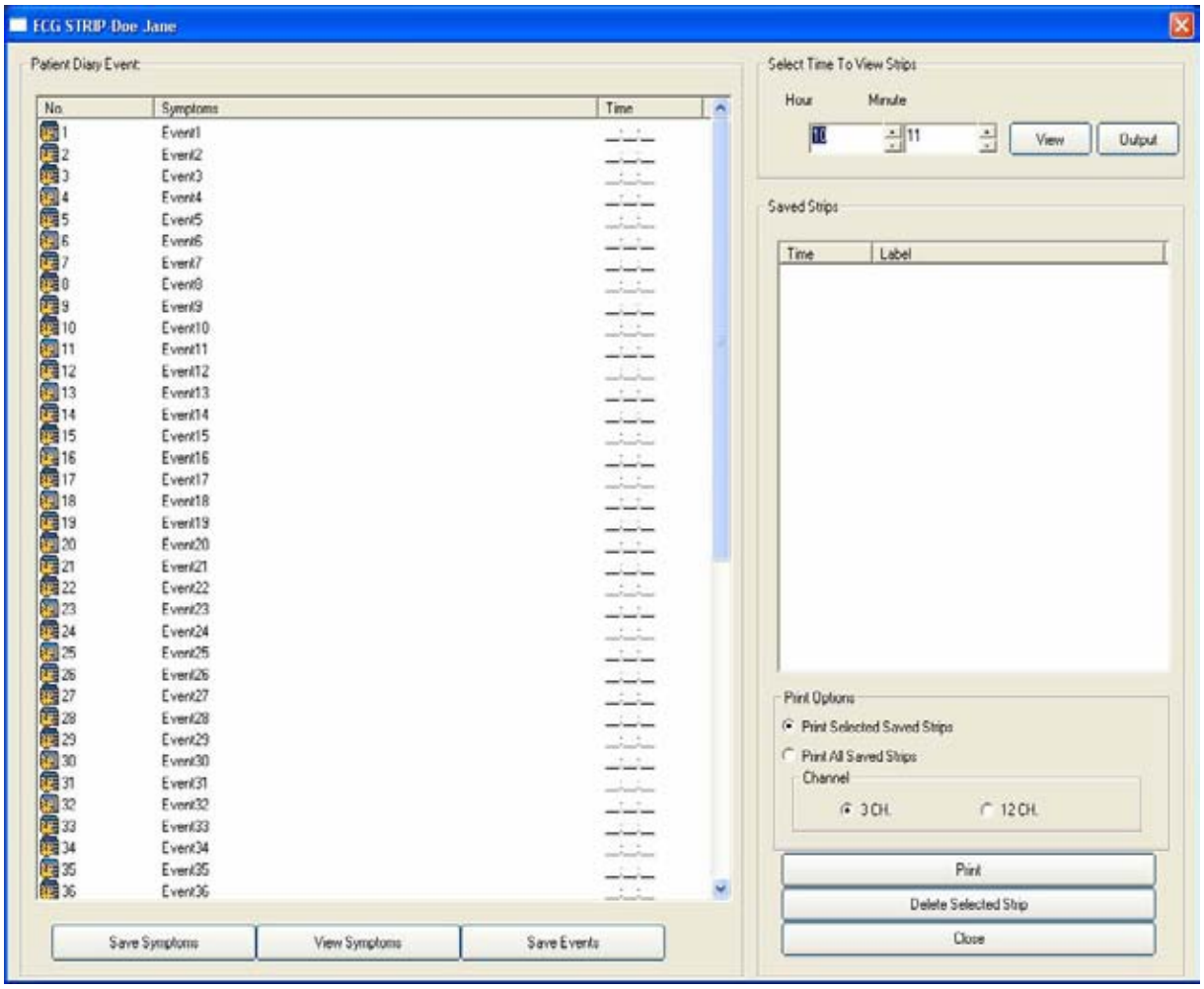
PATIENT DIARY EVENTS

Each time the patient depresses the event button on the recorder, an event time is logged on the flash card. All logged events will come up under the Patient Diary Event of the above screen.

If the patient has entered a symptom of the event in his/her patient diary, you may add the description to the strip by doing the following.

1. Click on the Event you wish to enter the symptom. Blue will highlight this event.

2. Click on the Event again. The following screen will appear.



3. Press the Back Space key on the keyboard to delete the Event Number.

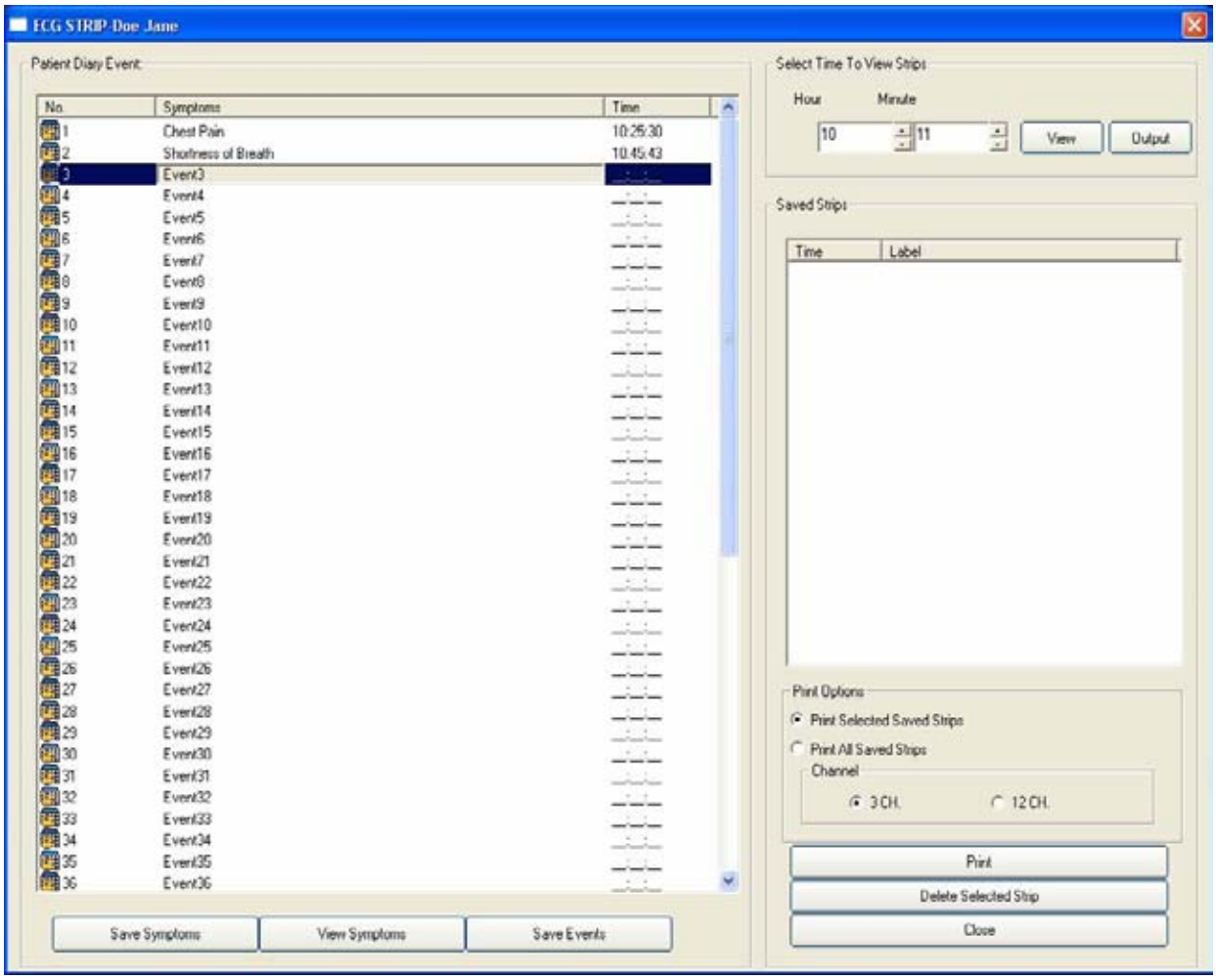
4. Type in the symptom as listed in the diary.

5. Press the ENTER key on the keyboard. The color gray will now highlight the symptom you have entered. Mouse click on the Save Symptoms bar at the bottom of the screen to save this strip to the final report.

NOTE: As you save strips, they will be entered into the Saved Strip column on the right side of the screen.

6. Use the ARROW keys on the keyboard to move to the next Event you wish to edit and repeat the above instructions until you are finished with your entries.

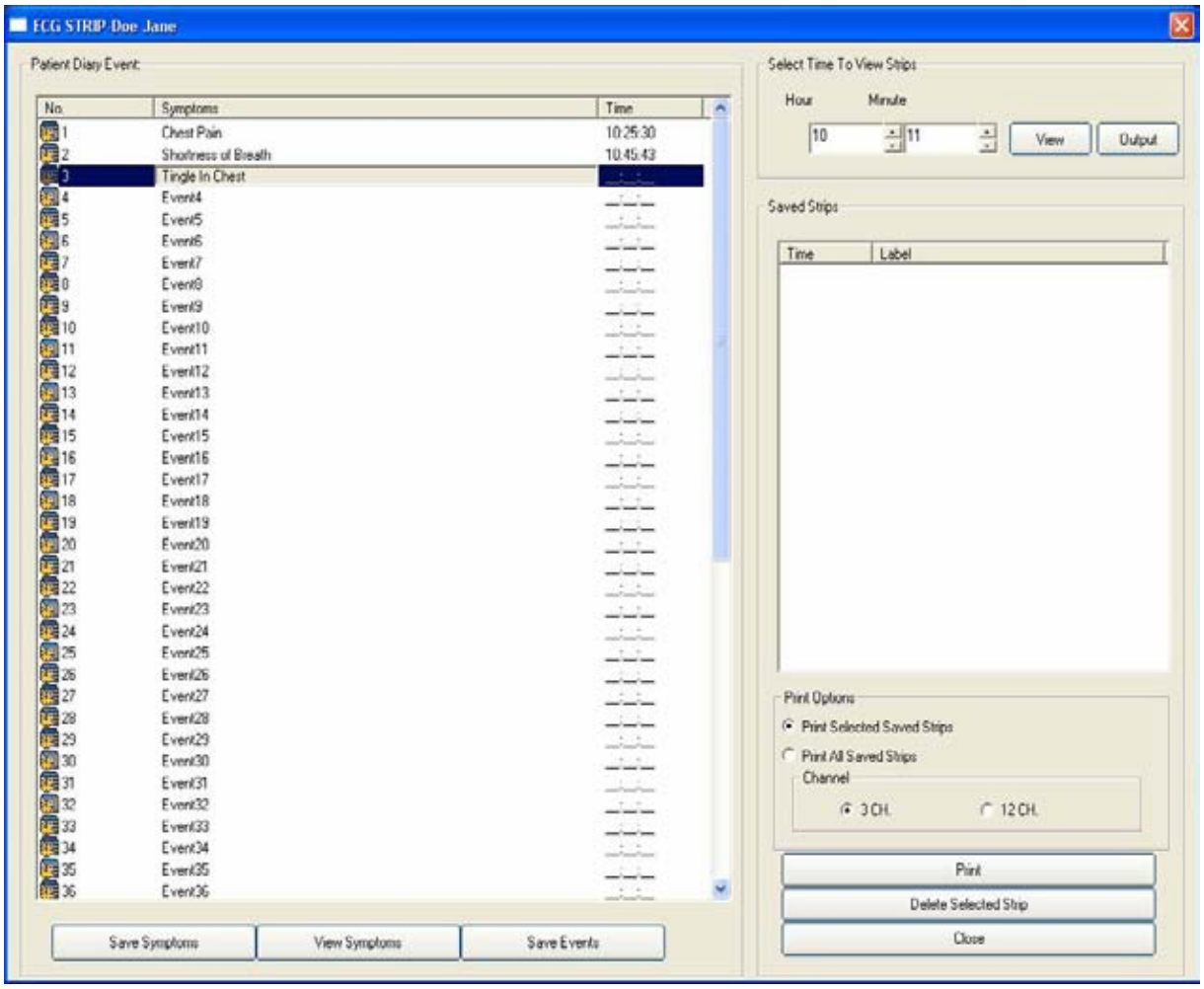
To view a patient event simply click on the event you wish to view and then click on the View Symptoms bar at the bottom of the screen. An enlarged 8-second ECG strip will appear on the screen.



At times, the patient may have forgotten to press the event marker on the recorder yet entered times and symptoms in the patient diary. To add these symptoms and times to the screen do the following:

1. Click on the next available Event entry with no time associated to it (in the above example it is Event 6). A gray highlight will appear.

2. Click on the line again and a cursor will appear in the field. Using your keyboard, enter in the symptom from the patient diary.



3. Click on the Time field next to the symptom you have just entered. The Symptom field will turn gray.

4. Click on the Time field again and you will get a cursor in the field.

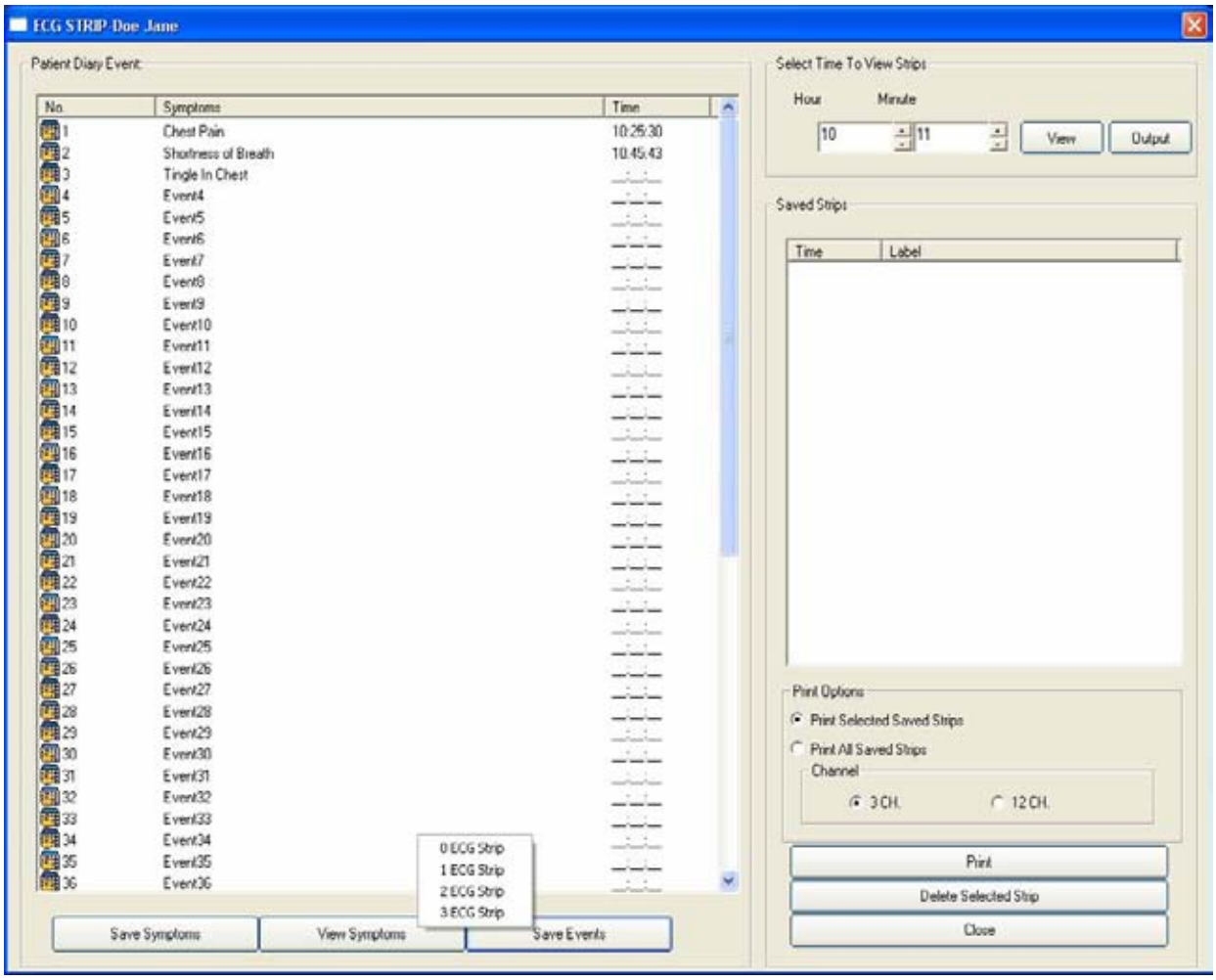
5. Enter the hour from the patient diary associated with the symptom. Remember to use military time.

6. Enter the minute from the patient diary associated with the symptom. Press the TAB key on the keyboard. The symptom and time are now entered into the patient diary.

7. To save these strips for the final report, click on the Symptom to be saved.

8. Click on the Save Symptoms bar at the bottom of the screen. You will see the time and symptom noted in the Saved Strips column on the right side of the screen.

9. Repeat this for all the strips you wish to save.



To save strips from the Events you have previously edited, click on the Save Events bar at the bottom of the screen.

If you do not want any ECG strips with the report, click on 0 ECG Strip.

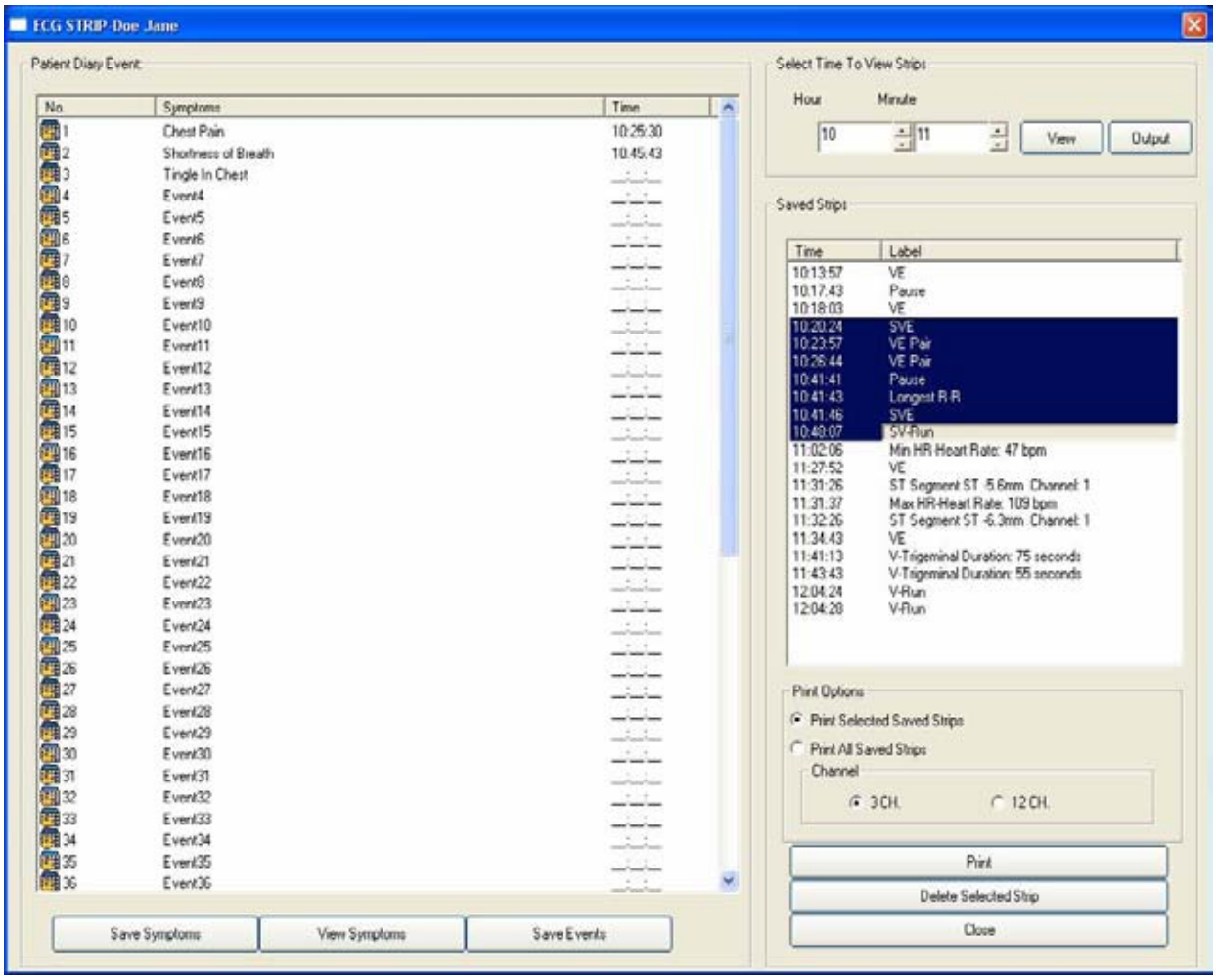
To save the first strip in each Event category, click on 1 ECG Strip.

To save the first two strips in each Event category, click on 2 ECG Strip.

To save the first three strips in each Event category, click on 3 ECG Strip.

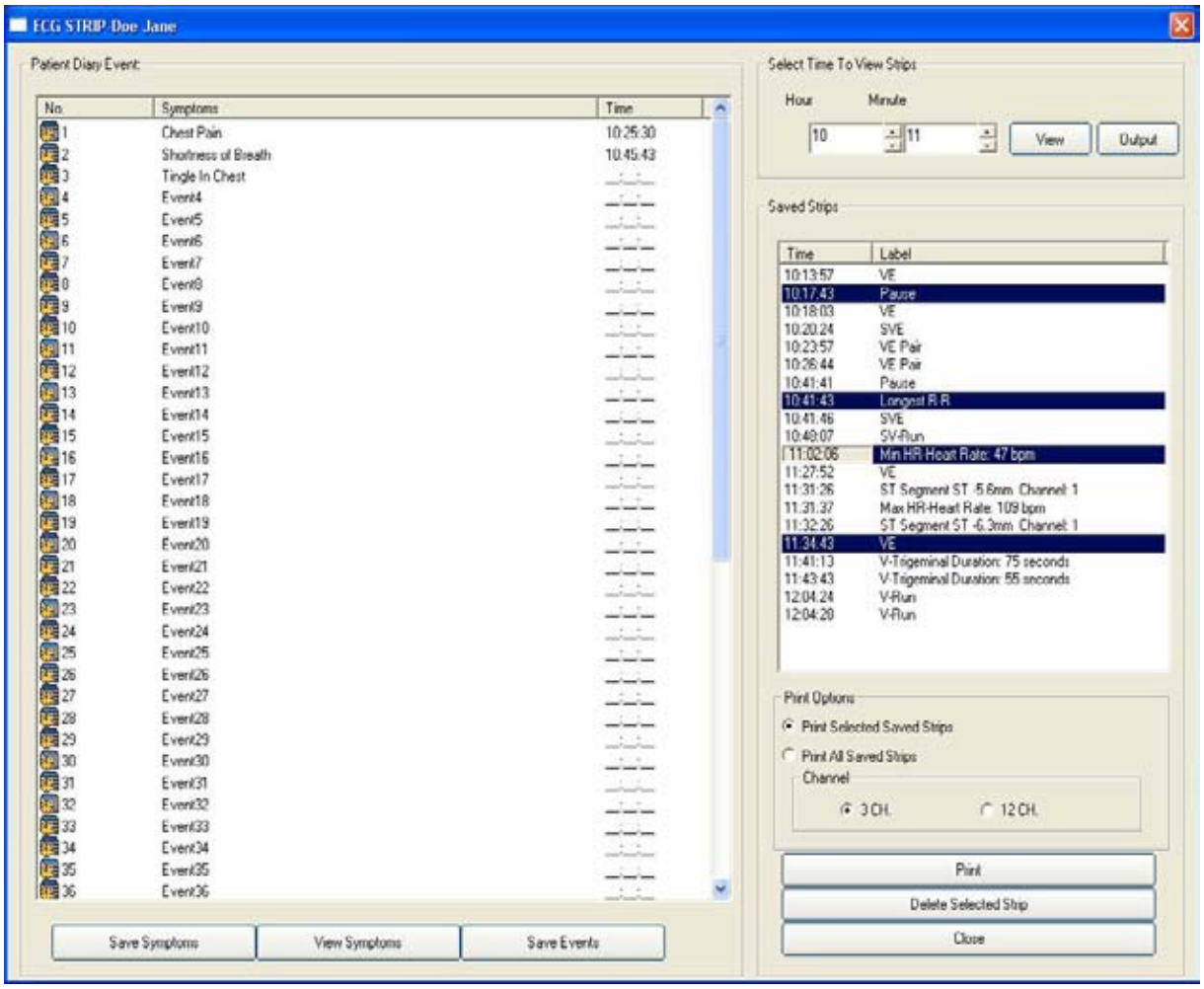
The strips will be added to the Saved Strips column on the right side of the screen. These strips will be printed out with the final report.

NOTE: The number of strips you have selected becomes the default number, until you decide to change the number. If you selected 2 strips, then the default will give you 2 strips for the report and 2 strips for future reports without accessing the “Save Event” icon.

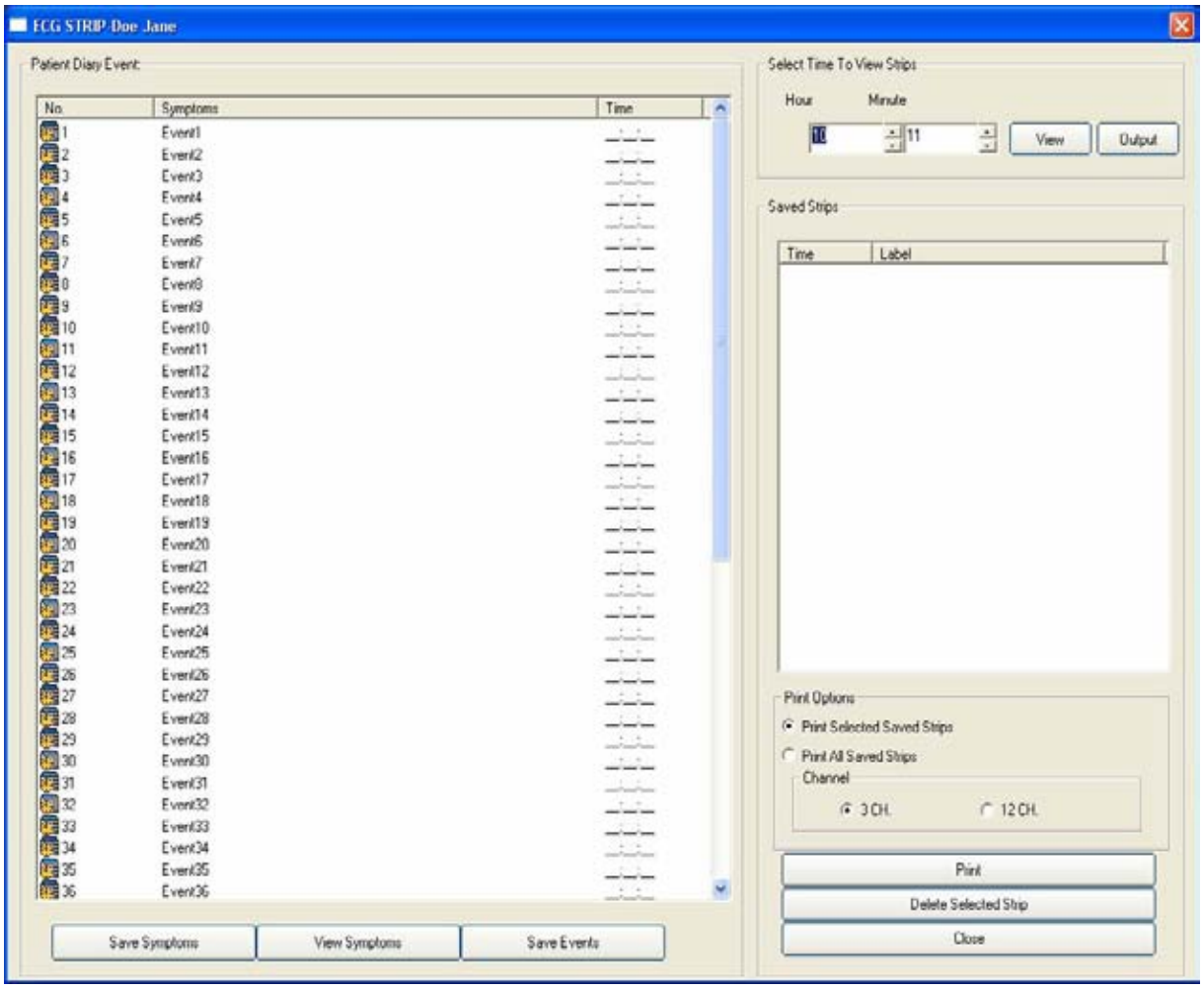


DELETE MULTIPLE ECG STRIPS

To delete multiple ECG strips at one time, click on the first strip you wish to delete. A blue highlight bar will appear. Hold down the SHIFT and CTRL key on the keyboard. Click on the last strip you wish to delete. Release the SHIFT and CTRL keys on the keyboard. A blue highlight bar will cover all the strips to be deleted. Click on the Delete Selected Strip bar. All the blue highlighted strips will be deleted.



To delete multiple individual strips, click on the strip you wish to delete. A blue highlight bar will appear over the selected strip. Hold down the CTRL and ALT keys on the keyboard. Click on all the other strips you wish to delete. A blue highlight bar will appear over the selected strips. Once you have selected all the strips you wish to delete, release the CTRL and ALT keys on the keyboard. Click on the Delete Selected Strip bar.



ENLARGED 8-SECOND STRIPS

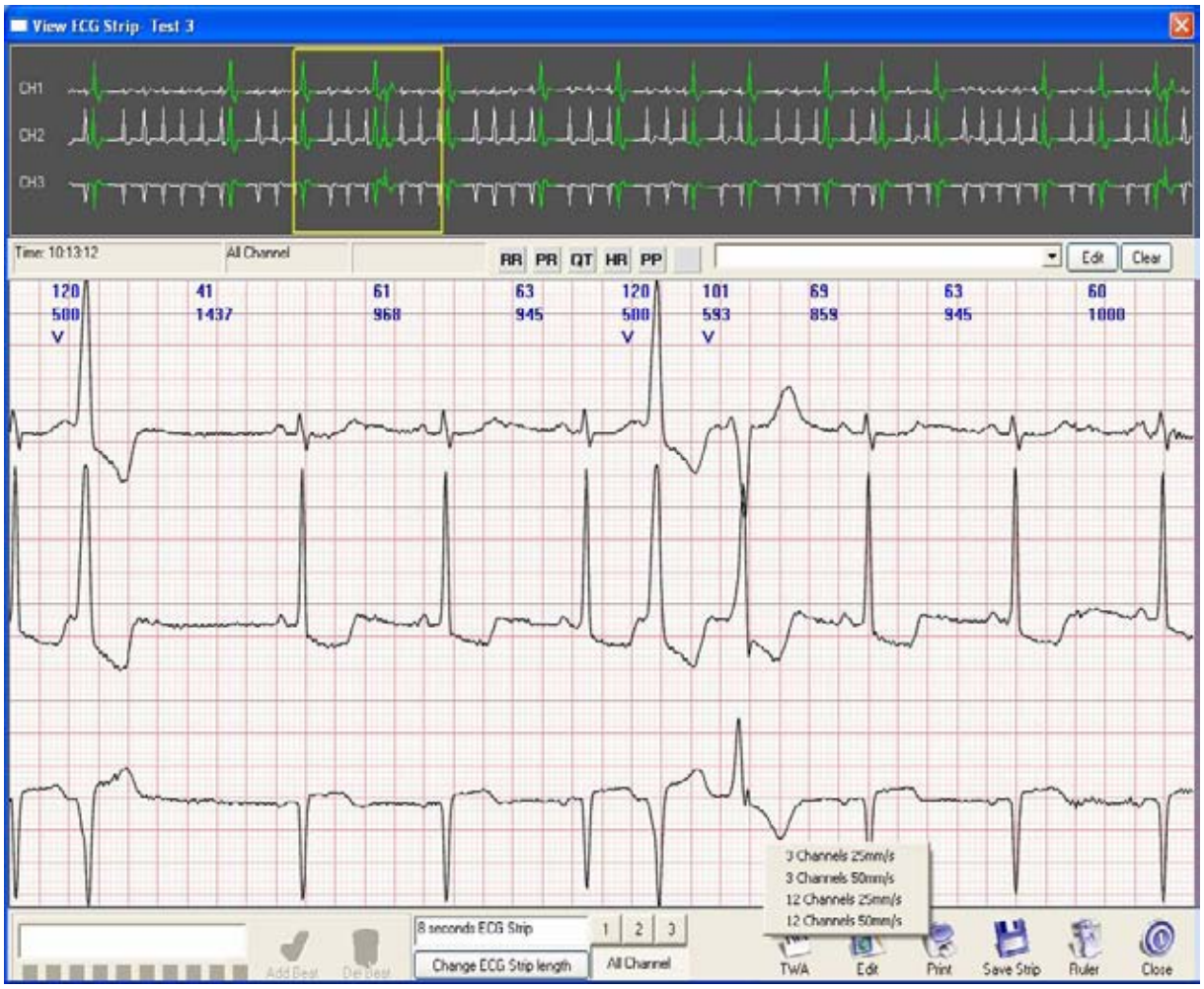
To view, print, label and edit additional strips, go to the Select Time To View Strips box in the upper right of the screen.

Point and click the mouse in the hour field. Using the up and down arrows, you may scroll to the hour you desire, or simply enter the hour using your keyboard. Press the TAB key on the keyboard and you will be moved to the minute field or point and click the mouse in the minute field. Using the up and down arrows, you may scroll to the minute you desire, or simply enter the minute using your keyboard. Click on the View bar or press the ENTER key on the keyboard. The following screen will appear.

The above screen shows an enlarged 8-second strip you have selected. There are many options available to you on this screen.

On the top of the screen you see a one channel sixty-second strip. To view the sixty second strip in another channel, click on the 1, 2, or 3 box on the bottom of the screen. As you select the channel you wish to view, it will be noted on the upper left-hand side of the screen.

The yellow highlight box is showing you the 8-second strip that you are seeing in the enlarged version. To look at another part of this sixty-second strip in the enlarged 8-second format, point your mouse to the section of the minute you desire and click. The yellow highlight box will move to the area you have just clicked on and the enlarged 8-second format will appear on the screen.



You can print out the 8-second ECG strip in various speeds.

To print out the enlarged 8-second strip, click on the Print icon on the bottom of the screen.

You can select a 3-Channel print out at either 25mm/s or 50mm/s or a 12-Channel print out at either 25mm/s or 50mm/s.

THE RULER

At the bottom left of the screen you will find the Ruler icon. Point and click on this icon and the mouse pointer turns into a small ruler with a little red cross.

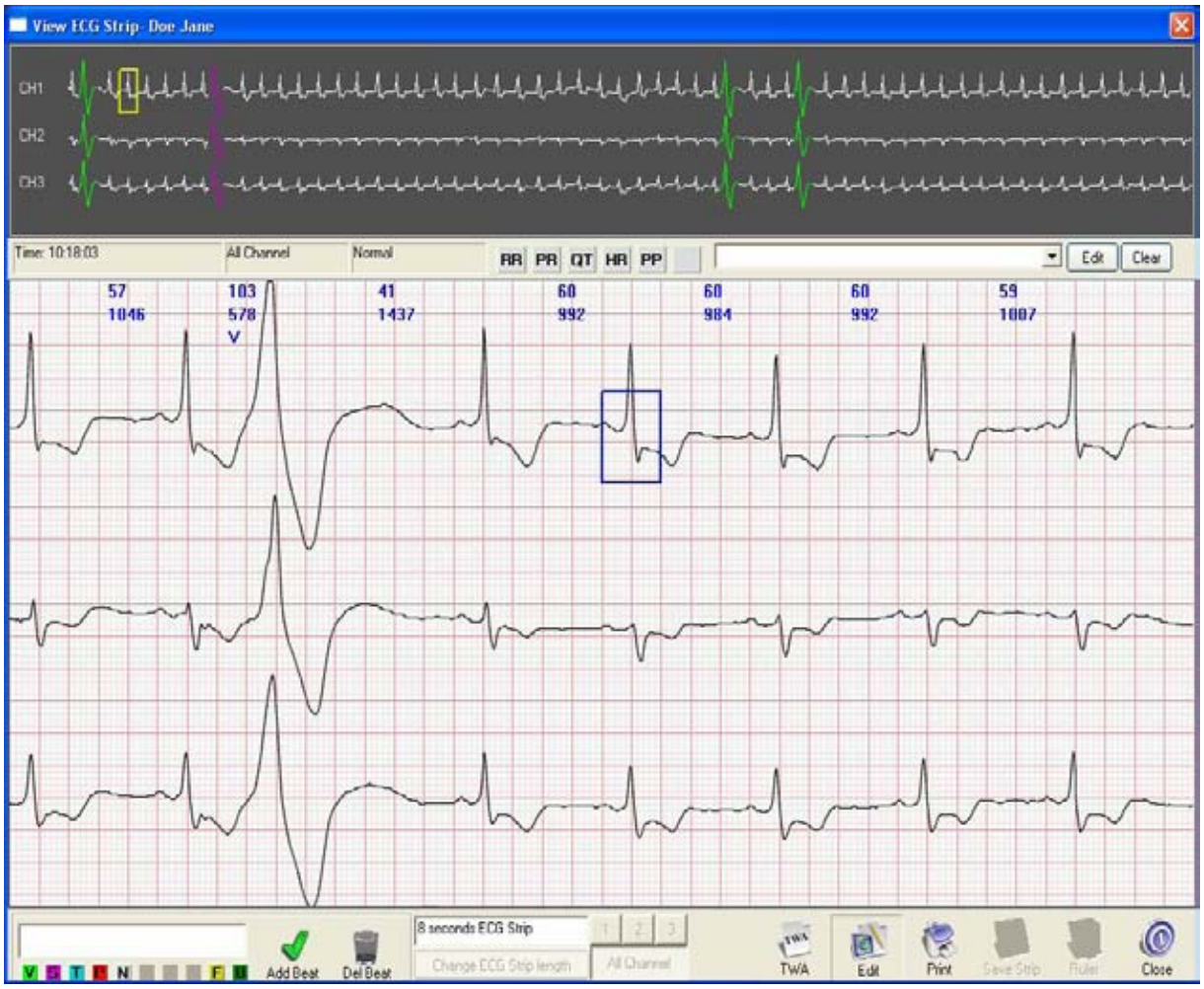
To take measurements place the red cross at the start point of the measurement. Click and drag the mouse to the measurement's end point. A box will mark the area you have measured (see above) and the measurements will be shown in the label box above the strip.

There are 5 pre-labeled measurement boxes above the enlarged 8-second strip. They are as follows:

RR	R-R Interval
PR	P-R Interval
QT	Q-T Interval
HR	Heart Rate
PP	P-P Interval

To label a strip with one of these measurements, point and click the mouse on the measurement you wish to take. The description will appear in the label field above the enlarged 8-second strip. Point and click on the Ruler icon at the bottom of the screen. Place the red cross at the beginning of the interval you wish to measure. Click and drag the mouse to the end of the measurement. The interval measurement you have just taken will appear in the label field (see above) and will be printed out on the strip.

NOTE: Click on the PP or RR icon. Click on the Ruler icon to activate the ruler. Measure the PP or RR. Five vertical lines will appear on the strip display until you click on the Close icon. This is very helpful to the doctor in making diagnostic decisions associated with PP and RR intervals.



EDITING IN THE 8-SECOND STRIP

You may also edit any of the beats it the enlarged 8-second strip. Simply right click the mouse on the beat you wish to edit. A blue box will surround the beat and the Edit icon on the bottom of the screen will be highlighted.

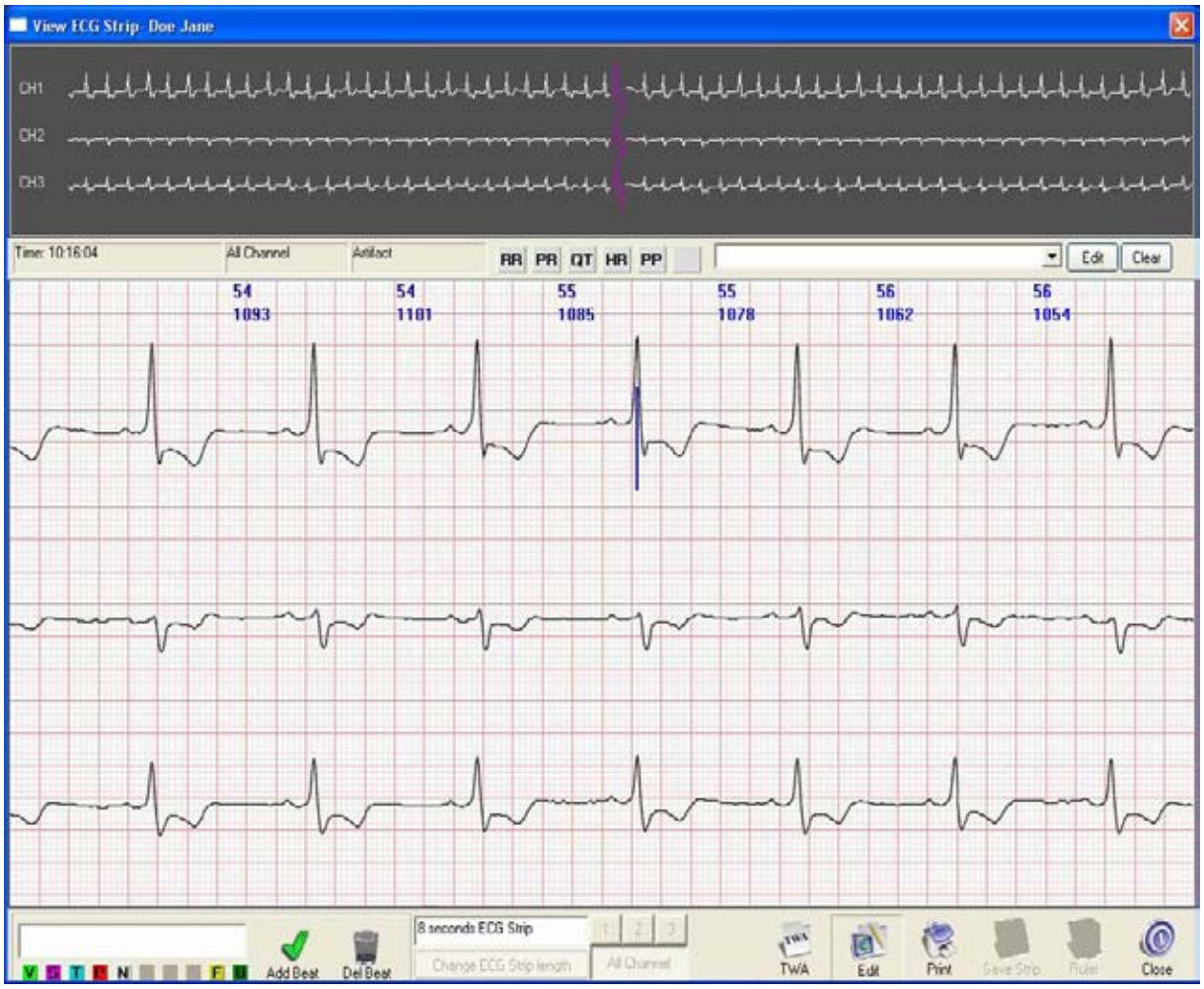
You may re-label the beat by clicking on the color code on the bottom left of the screen. The color code is as follows:

Green	Ventricular Ectopy
Magenta	Supra-Ventricular Ectopy
Blue	Aberrant
Red	Pause
White	Normal
Yellow	Artifact

NOTE: If the amplitude of the strip is too small, press the + key on the far right side of the keyboard (next to the number pad). The amplitude of the ECG's on the strip will increase. If the amplitude of the strip is too large, press the – key on the far right side of the keyboard (next to the number pad) and the amplitude of the strip will decrease.

Once you have clicked on the color code box, the label you have assigned to the beat will appear in the field above the color code boxes. In the above example, we have clicked on the N for Normal.

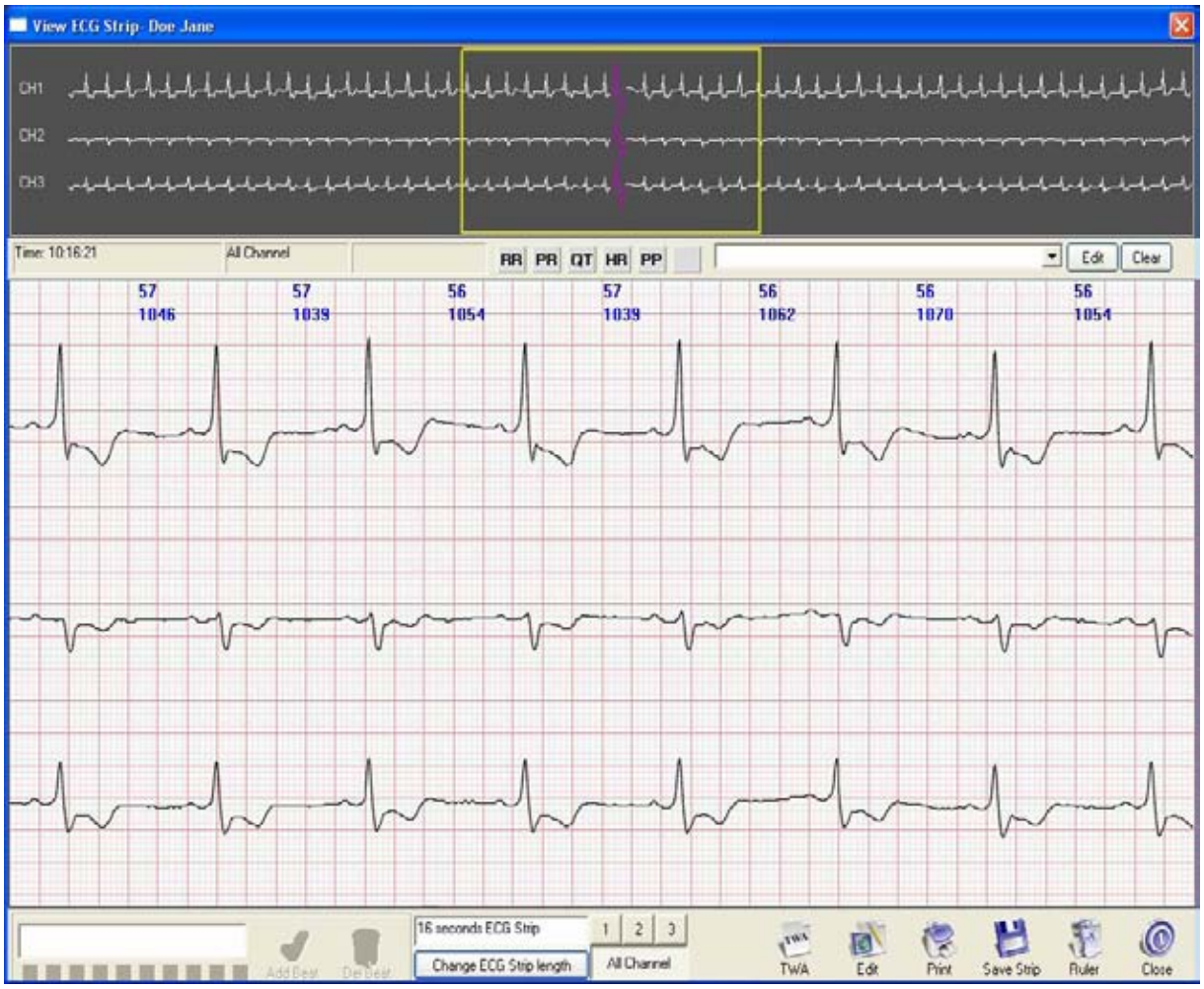
If you see that beat has not been counted, you may add the beat. Right click on the beat after the missed beat. Click on the Add Beat icon at the bottom left of the screen. The following screen will appear.



A blue marker will appear on the screen.

With the back arrow key on the keyboard, move the marker to the missed beat. Once the marker has been placed on the missed beat, click on the color code box that describes the beat. The beat will be labeled and the blue box will appear around the beat. Press the ESC key on the keyboard to exit this editing mode.

To delete a beat, right click on the mouse you wish to delete and click on the Del Beat icon at the bottom of the screen. Press the ESC key on the keyboard. The beat will have been removed from the count.



CHANGE THE LENGTH OF THE PRINTED ECG STRIP

To change the length of the printed ECG strip, point and click on the Change ECG Strip length bat at the bottom of the screen.

Click on the bar once and the length of the strip will change to 16 seconds as noted in the field above the bar. The 16 seconds that will be printed will be in a yellow highlight box in the sixty-second strip at the top of the screen.

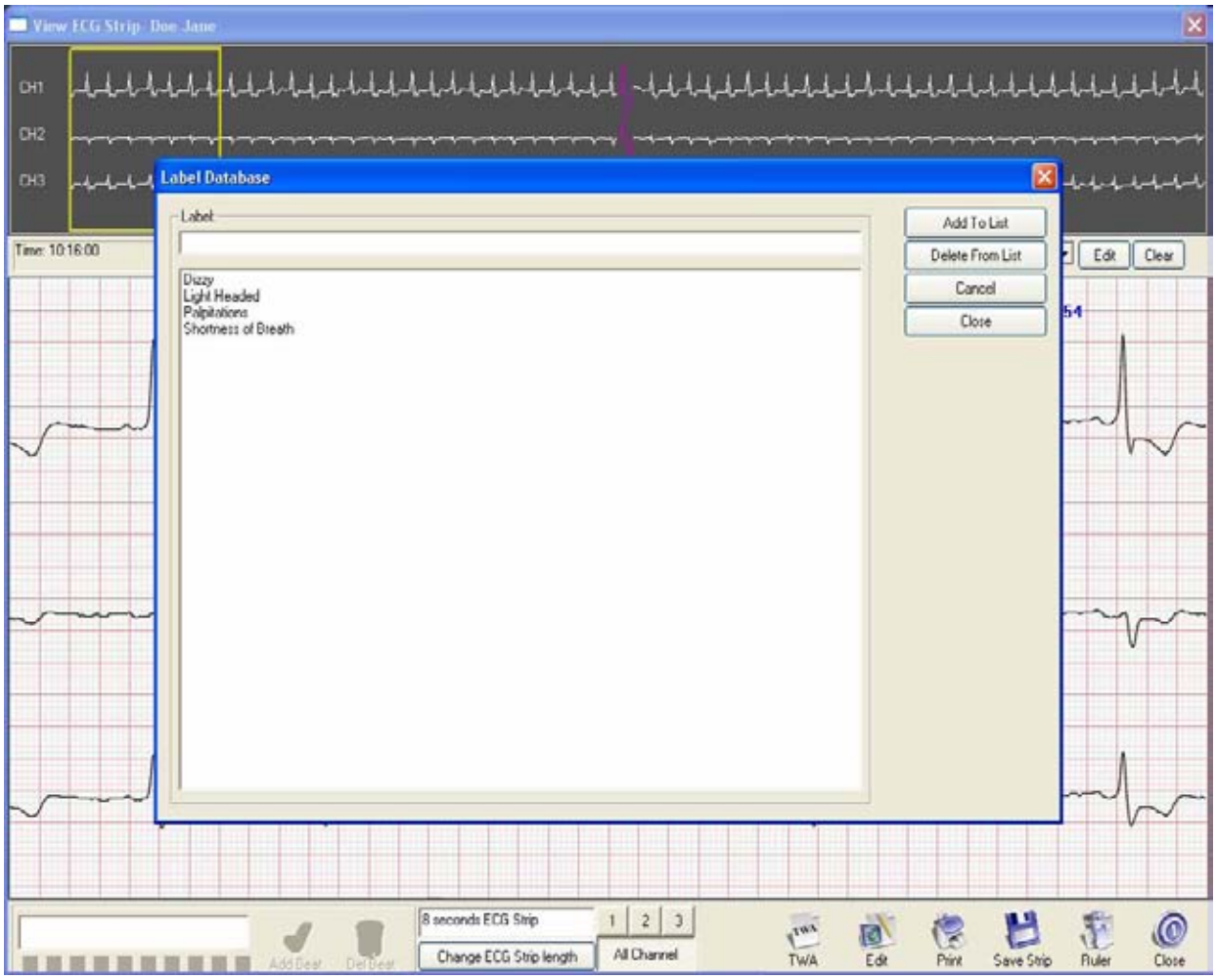
Click on the bar twice and the length of the strip will change to 24 seconds as noted in the field above the bar. The 24 seconds that will be printed will be in a yellow highlight box in the sixty-second strip at the top of the screen.

To print the strip immediately, click on the Print icon at the bottom of the screen. To save the strip and have it print out later with the report, click on the Save Strip icon at the bottom of the screen.

LABELING A STRIP

To label a strip, click on the down arrow at the end of the label field. A series of label descriptions will appear. Click on the description that you choose. It will now appear in the label field and will print out on the strip.

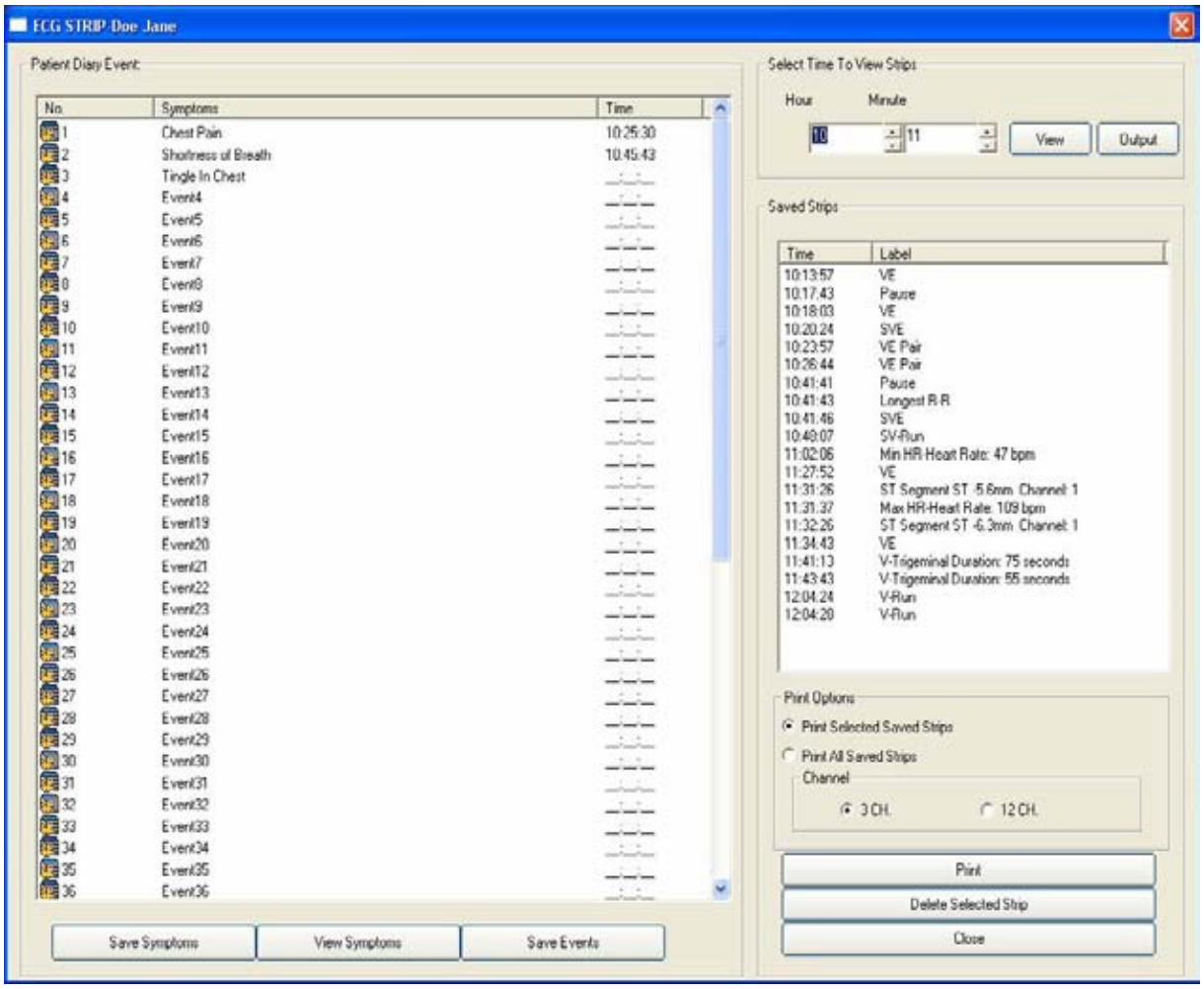
To enter your own label, simply mouse click in the label field. A cursor will appear. Using your keyboard, type in a description. When you have finished typing in the description, press the ENTER key on the keyboard.



To add more labels to your label database, click on the Edit bar next to the description field. The above screen will appear.

Click on the label field and type in the description. After you have finished typing in the description, click on the Add To List bar. You will see that it has been added to the list. Click on the Close bar.

If you decide that you do not want a certain description in your label database, simply click on the label you want to remove. It will be highlighted in blue. Click on the Delete From List bar and the description will be removed. Click on the Close bar.



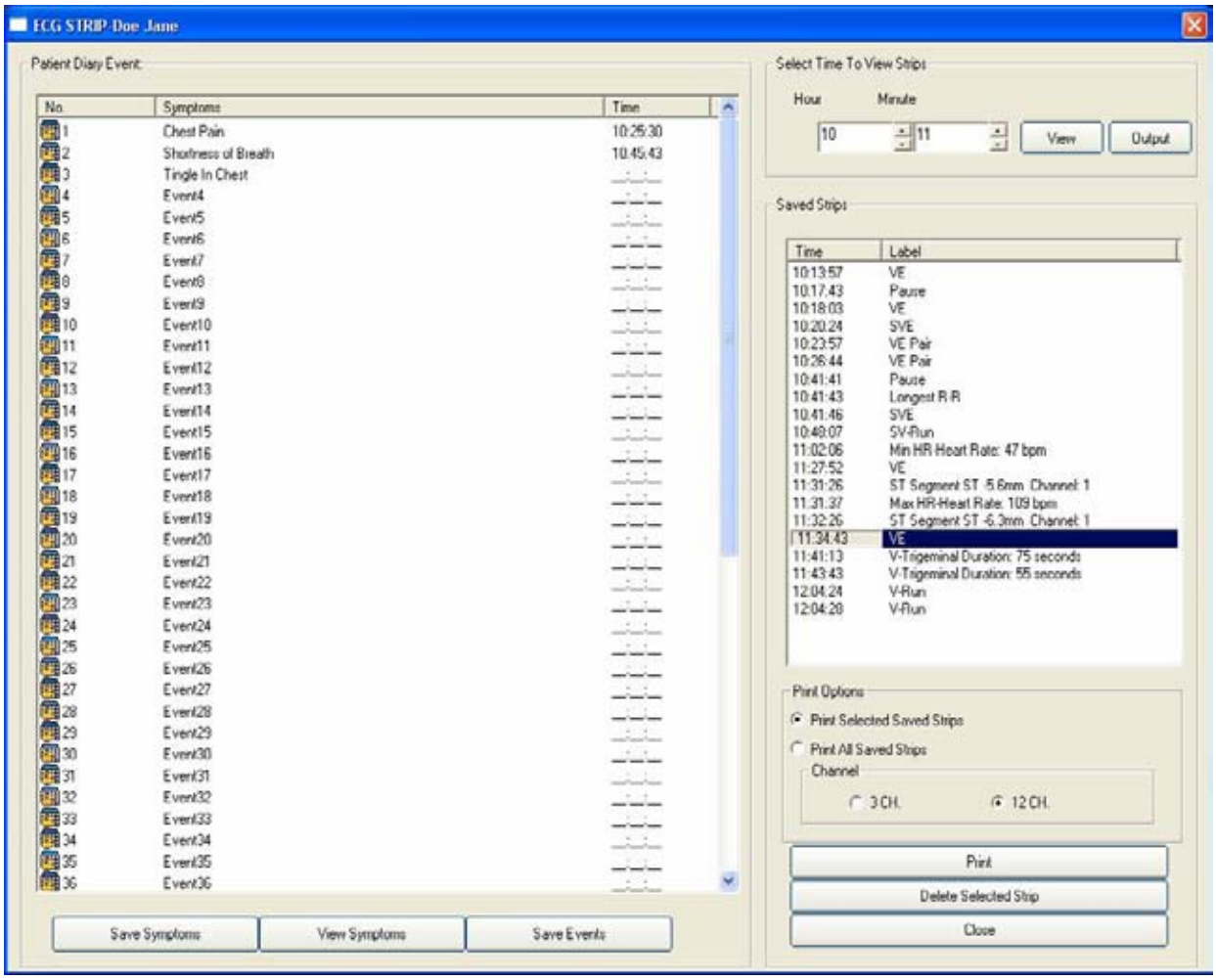
SAVED STRIPS

All the strips you have saved from all of your editing, selecting strips and labeling strips are noted in the Saved Strips box on the right side of the screen. Make sure to click on the Print All saved Strips option under the Print Options box. The black dot next to this option ensures that these strips will print out with the final Holter report. If this option is not selected, the saved strips will not print out with the report.

If you choose to delete any of these strips from the final report, simply point and click on the strip you wish to delete. The strip will be highlighted in blue. Click on the Delete Selected Strip bar at the bottom of the screen. The strip will be removed from the Saved Strips box and will not print out with the final Holter report.

If you wish to print out all of the saved strips at this time, click on Print all Saved Strips. A black dot will indicate this option is now active. Click on the Print bar. All the strips in the Saved Strips box will print out. If you want an immediate print out of a strip from the Saved Strips box, press the CTRL key on the keyboard and mouse click on the desired strip. Click on the Print bar at the bottom of the screen and the strip will print out.

To print a continuous group of strips from the Saved Strips box, press the SHIFT key on the keyboard and mouse click on the first of the strips you desire. Press the SHIFT key on the keyboard and mouse click on the last of the strips you desire. The first and last strip you selected, along with all strips in between, will be highlighted blue. Click on the Print bar at the bottom of the screen. The highlighted strips will print out



12 CHANNEL ECG STRIPS

To print any of the saved strips in a 12-channel format, click on the strip you desire. Click on the 12 CH. under print options. A dot next to the 12 CH. will indicate this option is now active. Click on the Print bar and a 12-lead ECG strip will print out.

NOTE: Always use a 7-lead Orthogonal hook-up on the patient when desiring 12-Lead printouts.

Click on the Close bar at the bottom of the screen. This will return you to the Data Access Choices screen.

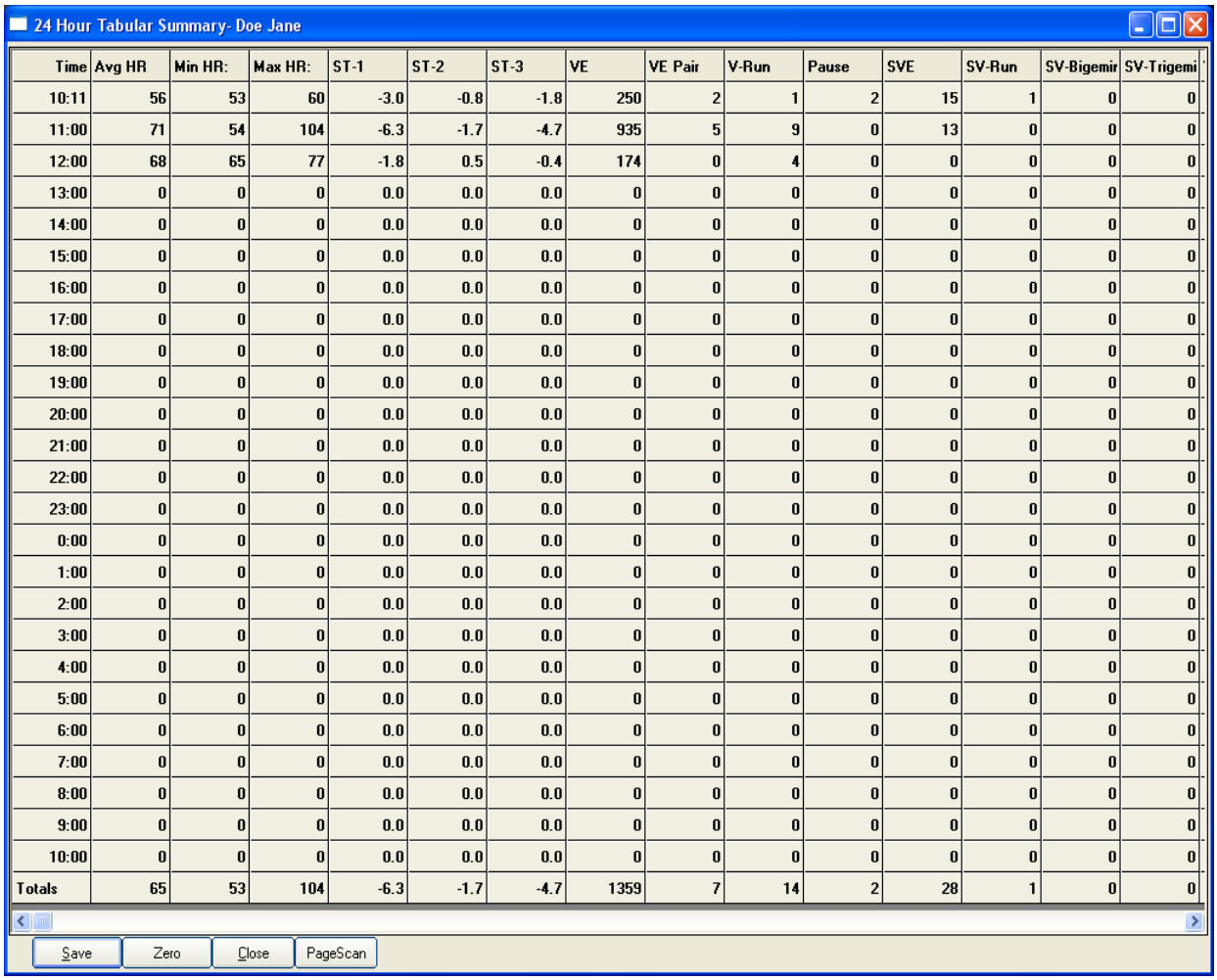
HOURLY MODE

Some users of Holter ECG Systems prefer to process their Holter recordings by printing out the full disclosure at one hour of ECG data per page.

The operator, in this technique, then looks at the one-hour full disclosure print-out and makes an estimate of the number of VE, SVE, Pause, V-Tach, etc. beats that occurred during the hour.

The purpose of the Hourly menu is to provide a display that makes it easy for the operator to enter the hourly quantities of abnormal beats into a worksheet type data bank.

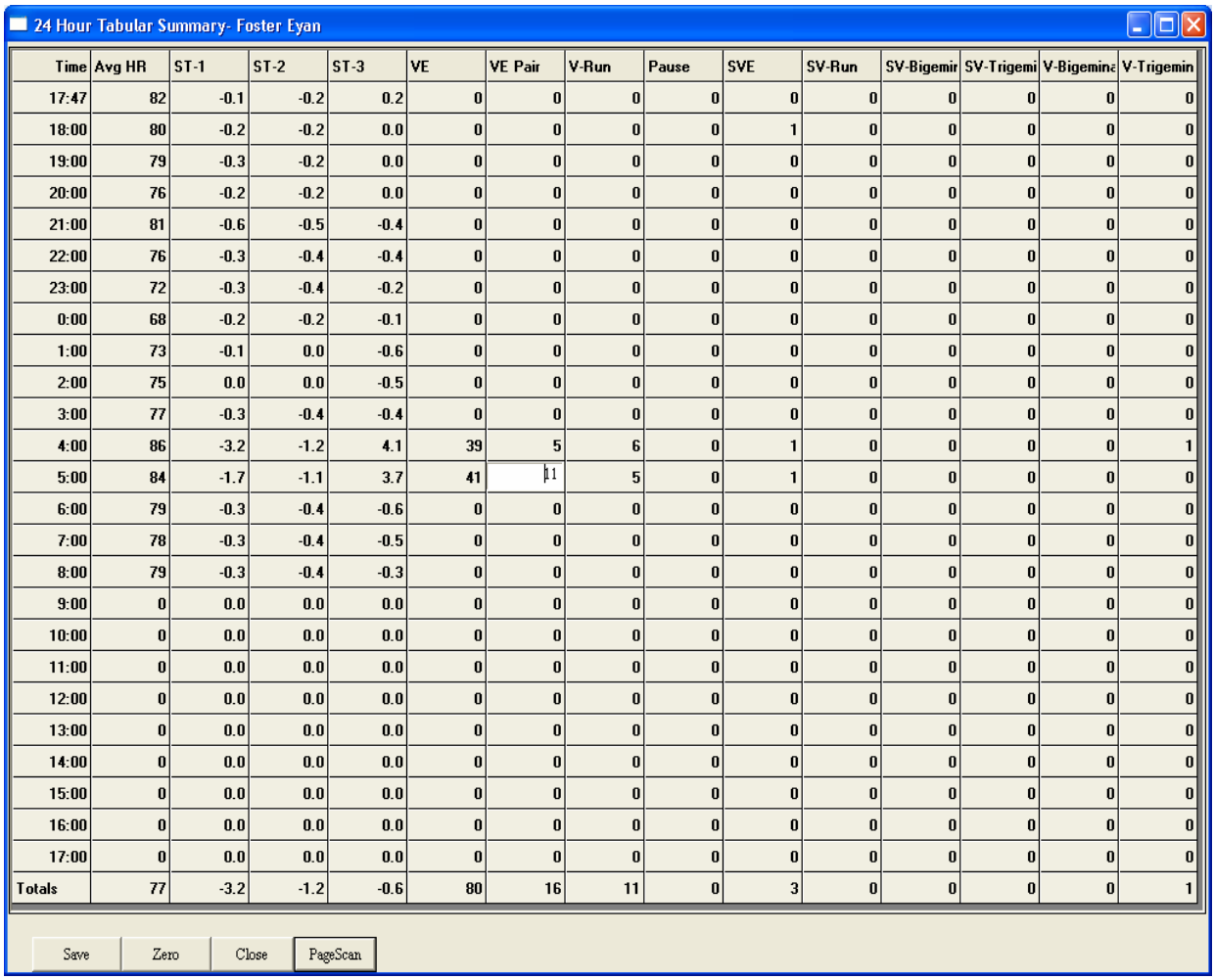
To activate the Hourly menu, point and click on the Hourly icon.



Time	Avg HR	Min HR:	Max HR:	ST-1	ST-2	ST-3	VE	VE Pair	V-Run	Pause	SVE	SV-Run	SV-Bigemir	SV-Trigemi
10:11	56	53	60	-3.0	-0.8	-1.8	250	2	1	2	15	1	0	0
11:00	71	54	104	-6.3	-1.7	-4.7	935	5	9	0	13	0	0	0
12:00	68	65	77	-1.8	0.5	-0.4	174	0	4	0	0	0	0	0
13:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
14:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
15:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
16:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
17:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
18:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
19:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
20:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
21:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
22:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
23:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
0:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
1:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
2:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
3:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
4:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
5:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
6:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
7:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
8:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
9:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
10:00	0	0	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0
Totals	65	53	104	-6.3	-1.7	-4.7	1359	7	14	2	28	1	0	0

Fourteen columns of data are available for manually entering hourly quantities of data after looking at the full disclosure print out.

Point and click on a location that you wish to enter data. The following screen will appear.



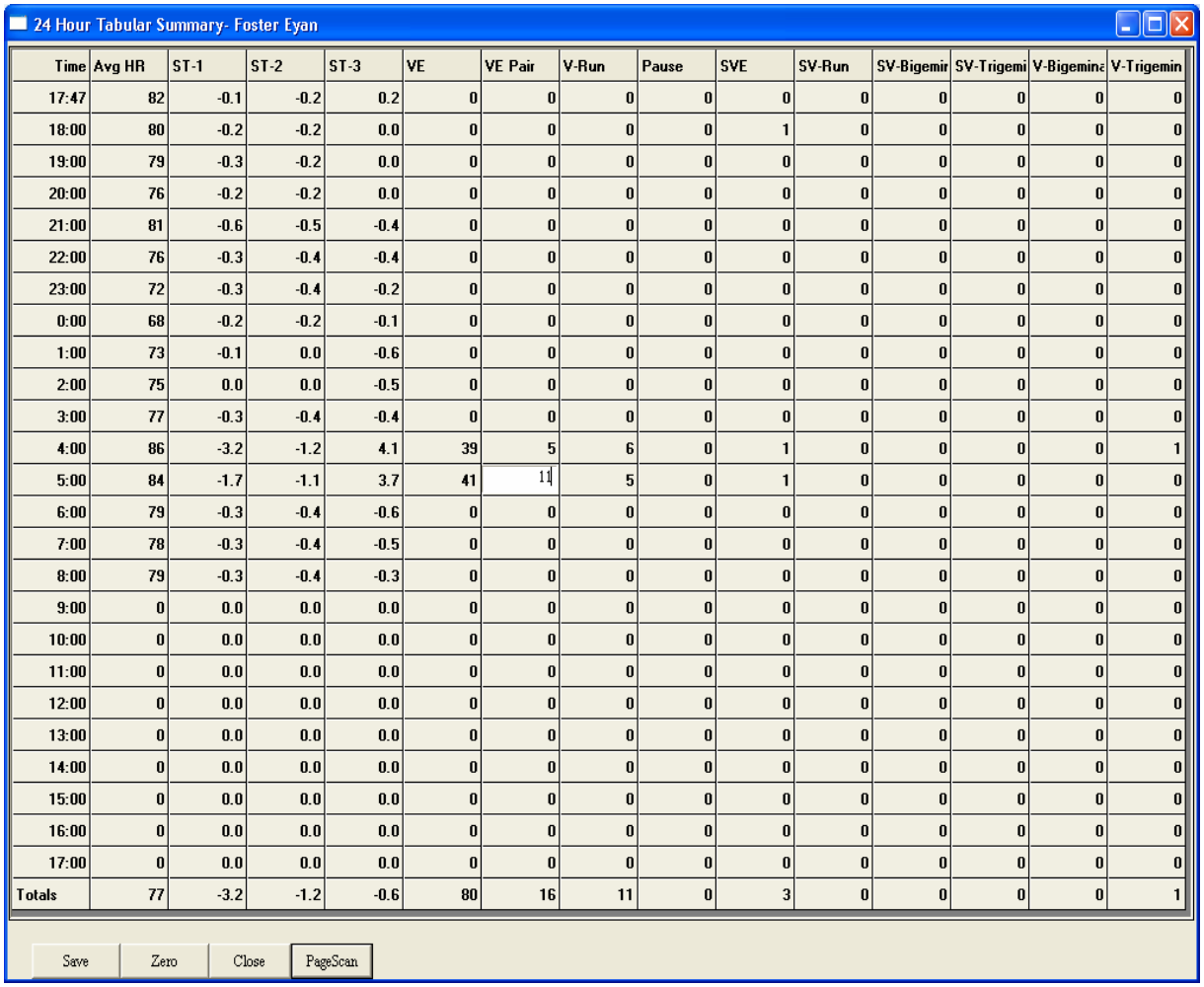
Time	Avg HR	ST-1	ST-2	ST-3	VE	VE Pair	V-Run	Pause	SVE	SV-Run	SV-Bigemir	SV-Trigemi	V-Bigemina	V-Trigemin
17:47	82	-0.1	-0.2	0.2	0	0	0	0	0	0	0	0	0	0
18:00	80	-0.2	-0.2	0.0	0	0	0	0	1	0	0	0	0	0
19:00	79	-0.3	-0.2	0.0	0	0	0	0	0	0	0	0	0	0
20:00	76	-0.2	-0.2	0.0	0	0	0	0	0	0	0	0	0	0
21:00	81	-0.6	-0.5	-0.4	0	0	0	0	0	0	0	0	0	0
22:00	76	-0.3	-0.4	-0.4	0	0	0	0	0	0	0	0	0	0
23:00	72	-0.3	-0.4	-0.2	0	0	0	0	0	0	0	0	0	0
0:00	68	-0.2	-0.2	-0.1	0	0	0	0	0	0	0	0	0	0
1:00	73	-0.1	0.0	-0.6	0	0	0	0	0	0	0	0	0	0
2:00	75	0.0	0.0	-0.5	0	0	0	0	0	0	0	0	0	0
3:00	77	-0.3	-0.4	-0.4	0	0	0	0	0	0	0	0	0	0
4:00	86	-3.2	-1.2	4.1	39	5	6	0	1	0	0	0	0	1
5:00	84	-1.7	-1.1	3.7	41	11	5	0	1	0	0	0	0	0
6:00	79	-0.3	-0.4	-0.6	0	0	0	0	0	0	0	0	0	0
7:00	78	-0.3	-0.4	-0.5	0	0	0	0	0	0	0	0	0	0
8:00	79	-0.3	-0.4	-0.3	0	0	0	0	0	0	0	0	0	0
9:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
10:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
11:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
12:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
13:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
14:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
15:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
16:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
17:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
Totals	77	-3.2	-1.2	-0.6	80	16	11	0	3	0	0	0	0	1

Using your keyboard, enter the numerical value you desire. This value can be an estimate or the actual count of the number of such beats that occurred during that hour.

NOTE: The box that you enter the numerical value in pops up on the screen after you have clicked the mouse. It may not appear exactly where you have clicked on the screen. This is okay. You will see that when you click on another location, the data you have entered will be located in the box you selected.

After entering all of the desired hourly numbers, point and click on the Save bar at the bottom of the screen.

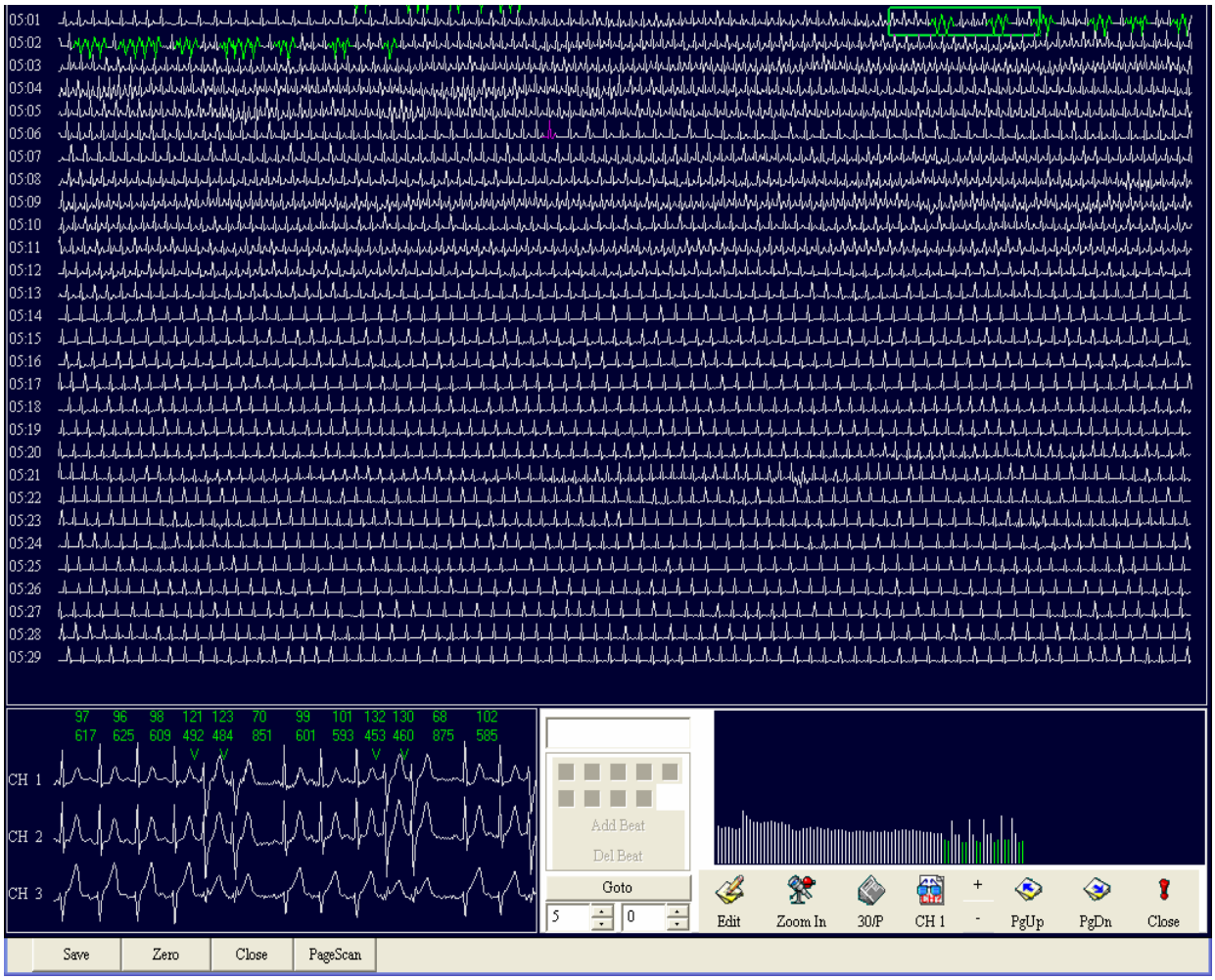
In some instances it may be quicker to zero out the columns and then enter the data. To zero out a column, point and click and the column you want zeroed out. Click on the Zero bar at the bottom of the screen. All values in the column will have changed to zero. Enter in the numerical values you desire. When you have finished entering in all the data, click on the Save bar at the bottom of the screen.



Time	Avg HR	ST-1	ST-2	ST-3	VE	VE Pair	V-Run	Pause	SVE	SV-Run	SV-Bigemir	SV-Trigemi	V-Bigemina	V-Trigemin
17:47	82	-0.1	-0.2	0.2	0	0	0	0	0	0	0	0	0	0
18:00	80	-0.2	-0.2	0.0	0	0	0	0	1	0	0	0	0	0
19:00	79	-0.3	-0.2	0.0	0	0	0	0	0	0	0	0	0	0
20:00	76	-0.2	-0.2	0.0	0	0	0	0	0	0	0	0	0	0
21:00	81	-0.6	-0.5	-0.4	0	0	0	0	0	0	0	0	0	0
22:00	76	-0.3	-0.4	-0.4	0	0	0	0	0	0	0	0	0	0
23:00	72	-0.3	-0.4	-0.2	0	0	0	0	0	0	0	0	0	0
0:00	68	-0.2	-0.2	-0.1	0	0	0	0	0	0	0	0	0	0
1:00	73	-0.1	0.0	-0.6	0	0	0	0	0	0	0	0	0	0
2:00	75	0.0	0.0	-0.5	0	0	0	0	0	0	0	0	0	0
3:00	77	-0.3	-0.4	-0.4	0	0	0	0	0	0	0	0	0	0
4:00	86	-3.2	-1.2	4.1	39	5	6	0	1	0	0	0	0	1
5:00	84	-1.7	-1.1	3.7	41	11	5	0	1	0	0	0	0	0
6:00	79	-0.3	-0.4	-0.6	0	0	0	0	0	0	0	0	0	0
7:00	78	-0.3	-0.4	-0.5	0	0	0	0	0	0	0	0	0	0
8:00	79	-0.3	-0.4	-0.3	0	0	0	0	0	0	0	0	0	0
9:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
10:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
11:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
12:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
13:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
14:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
15:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
16:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
17:00	0	0.0	0.0	0.0	0	0	0	0	0	0	0	0	0	0
Totals	77	-3.2	-1.2	-0.6	80	16	11	0	3	0	0	0	0	1

To verify data in from the Hourly menu, click on the number in the corresponding column of the data you wish to verify. The hourly event you have selected will have a white highlight over the number. In the above example, we have selected VE Pairs in the 5:00 o'clock hour.

Click on the PageScan bar at the bottom of the screen.



You will be taken to the first 30 minutes of the hour that you have selected. If you do not find the event you were looking for on this 30 minute screen, press the PageDown key on the keyboard or click on the PgDn icon at the bottom of the screen. You will be taken to the next 30 minute page from the corresponding hour.

Click on the event you were looking for (in our example it was a VE Pair).

The enlarged 8-second strip will appear on the screen. You may print out this strip by clicking on the Print icon at the bottom of the screen.

To return to the Hourly screen, click on the Close icon at the bottom of the screen. You will be taken back to the Page Scan screen. Click on the close icon at the bottom of the screen. You will be taken to the Hourly screen.

Upon finishing with this screen, click on the Close bar at the bottom of the screen. You will be returned to the Data Access Choices screen.

SLEEP APNEA REPORT

The Sleep Apnea report can be generated from the Report Menu Screen. A very large number of medical articles have been published in Japan, USA and Europe on using the Holter technique and HRV to be a practical monitor for detecting Sleep Apnea.

It is estimated that 8% of the male population over 40 years old has Sleep Apnea. The medical community has learned that most Sleep Apnea patients in their early 40's develop severe cardiac disease in their 50's.

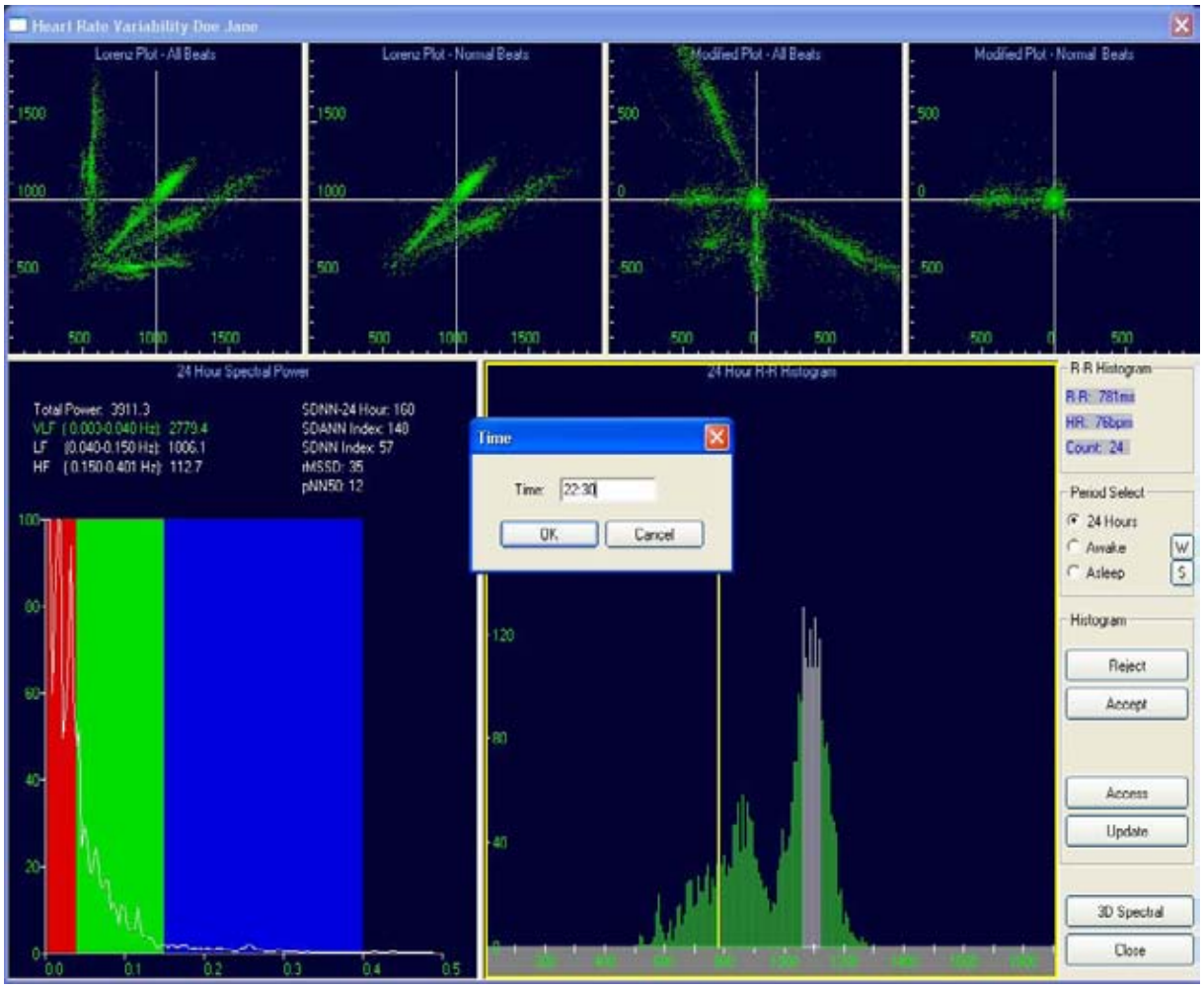
Please note the times in the patient's diary when the patient went to sleep and when the patient awoke. If the patient has not noted these times, then you must go to the Mega Scan screen to determine these times.

Click on the Mega Scan icon on the Data Access Screen.

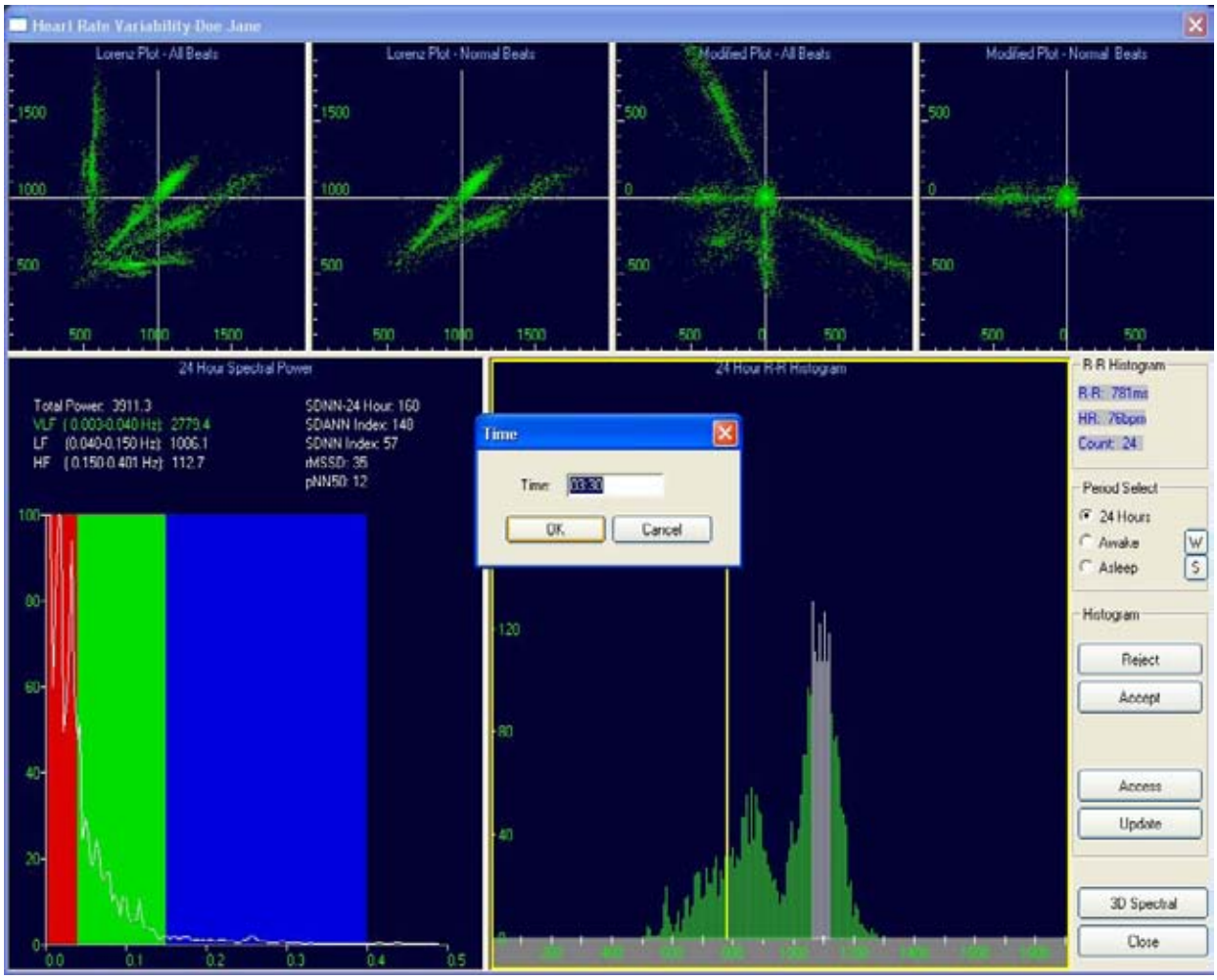
Look at the 24-hour graph to determine the times that the patient was asleep. In the above example, it appears that the sleep period was from 22:30 until about 3:30. Press the ESC key on the keyboard to leave this screen.

Click on the HRV icon at the Data Access choices screen.

NOTE: If the patient's diary indicates the time the patient went to sleep and awoke, you may skip this step.



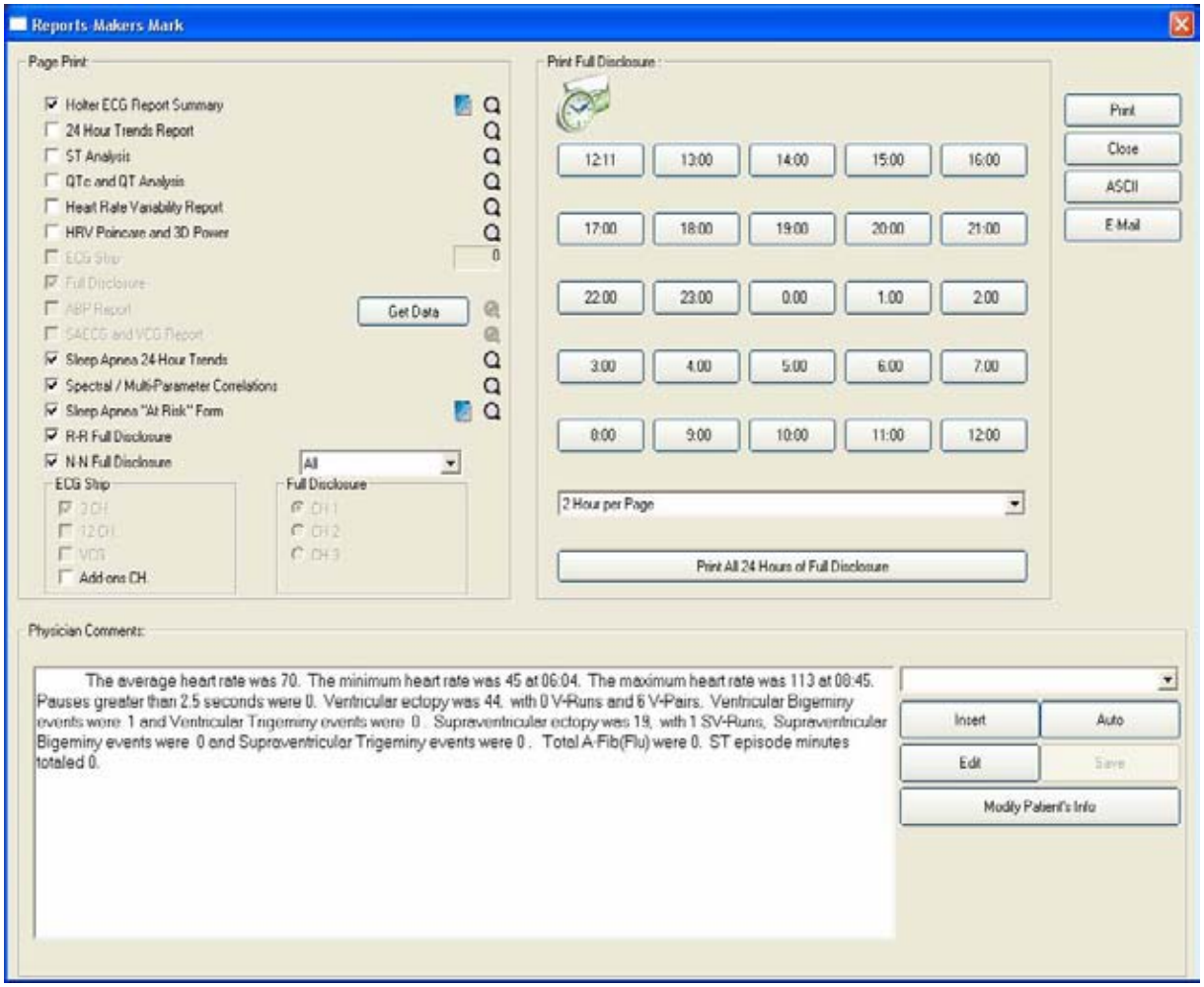
Click on the box next to Asleep on the right side of the screen. The above pop-up screen will appear. Type in the time the patient went to sleep per the patient diary, or if there is no diary, enter the time determined from the Mega Scan graph. In our example we are using 22:30. Click on OK.



Click on the box to the right of Awake on the right hand side of the screen. The above pop-up box will appear. Type in the time the patient woke up per the patient's diary or the time you determined from using the Mega Scan graph. In our example, we are using the time 3:30.

Click on OK. Click on the Update bar to the lower right of the screen and then click on the Close bar at the bottom right of the screen.

You will be returned to the Data Access Choices screen. Click on the Report icon.



To print the Sleep Apnea report make sure you have checked the boxes next to Sleep Apnea 24-Hour Trends, Spectral/Multi-Parameter Correlations, Sleep Apnea “At Risk” Form and the N-N Full Disclosure, as in the example above.

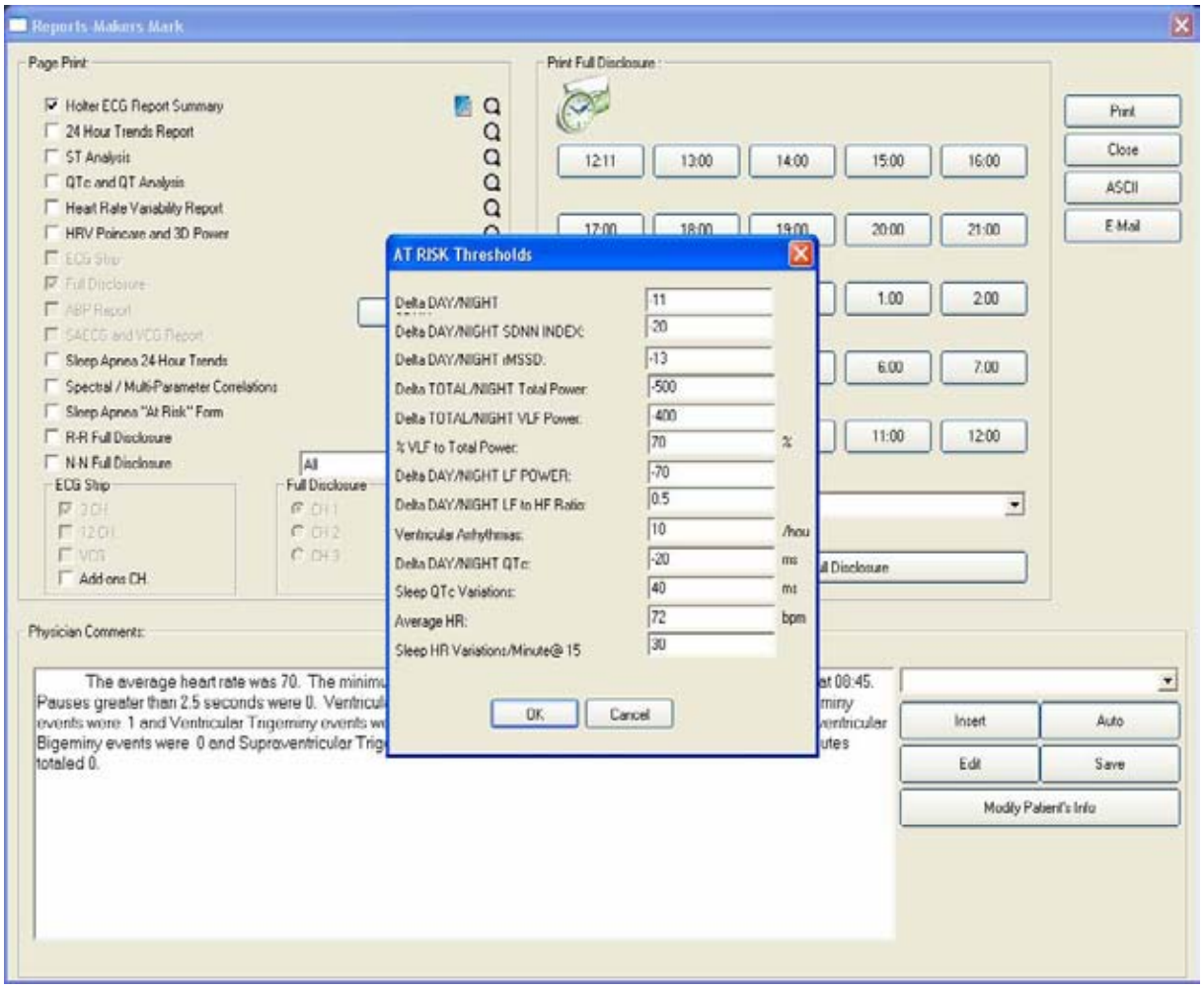
Age: 59	Sex: Male	Height:	Weight:

Factors:	Threshold	Actual	
Male Snorer:			
Obese Snorer:			
Delta DAY/NIGHT SDNN:	> -11	-25.0	✔
Delta DAY/NIGHT SDNN INDEX:	> -19	-18	
Delta DAY/NIGHT rMSSD:	> -13	-19	✔
Delta TOTAL/NIGHT Total Power:	> -500	-2066.9	✔
Delta TOTAL/NIGHT VLF Power:	> -400	-1376.1	✔
% VLF to Total Power:	> 70%	72.5%	✔
Delta DAY/NIGHT LF POWER:	> -70	-416.6	✔
Delta DAY/NIGHT LF to HF Ratio:	> 0.5	0.1	
Ventricular Arrhythmias:	> 10/hour	242	✔
Delta DAY/NIGHT QTc:	> -20ms	N/A	
Sleep QTc Variations:	> 40ms	N/A	
Average HR:	> 72bpm	62	
Sleep HR Variations/Minute@ 15 bpm:	> X30	11	

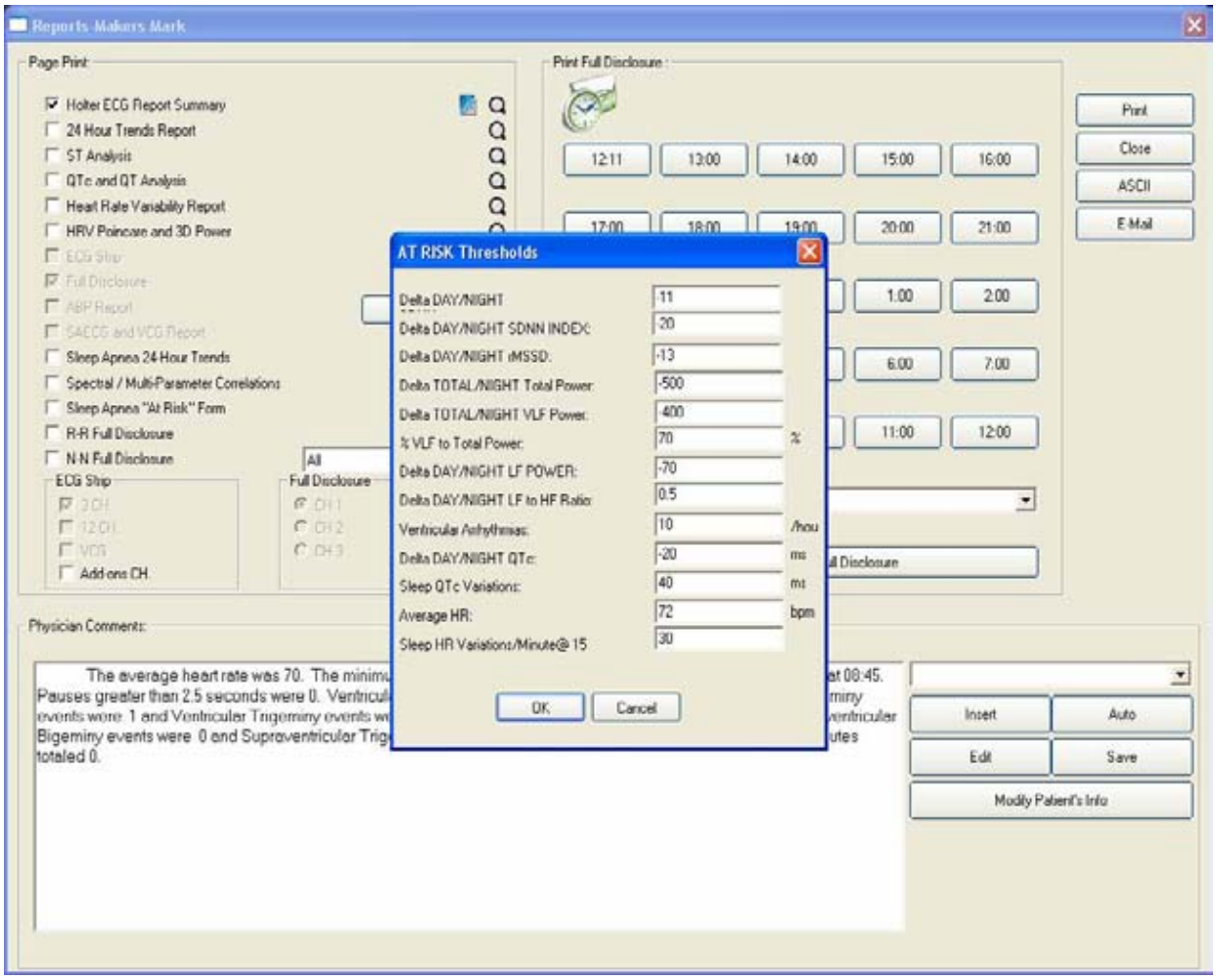
Comments

Physician Signature:

 CardioScan™ Version: 1.0010 Physician Must Review Data Printed: 3/18/2003 16:44:21 2003



The previous page shows the Sleep Apnea “At Risk” form generated by the Holter program for the patient. If you wish, you may change the thresholds by clicking on the blue tab that is adjacent to the “At Risk” page on the Report screen. The “At Risk Thresholds” screen will pop up.



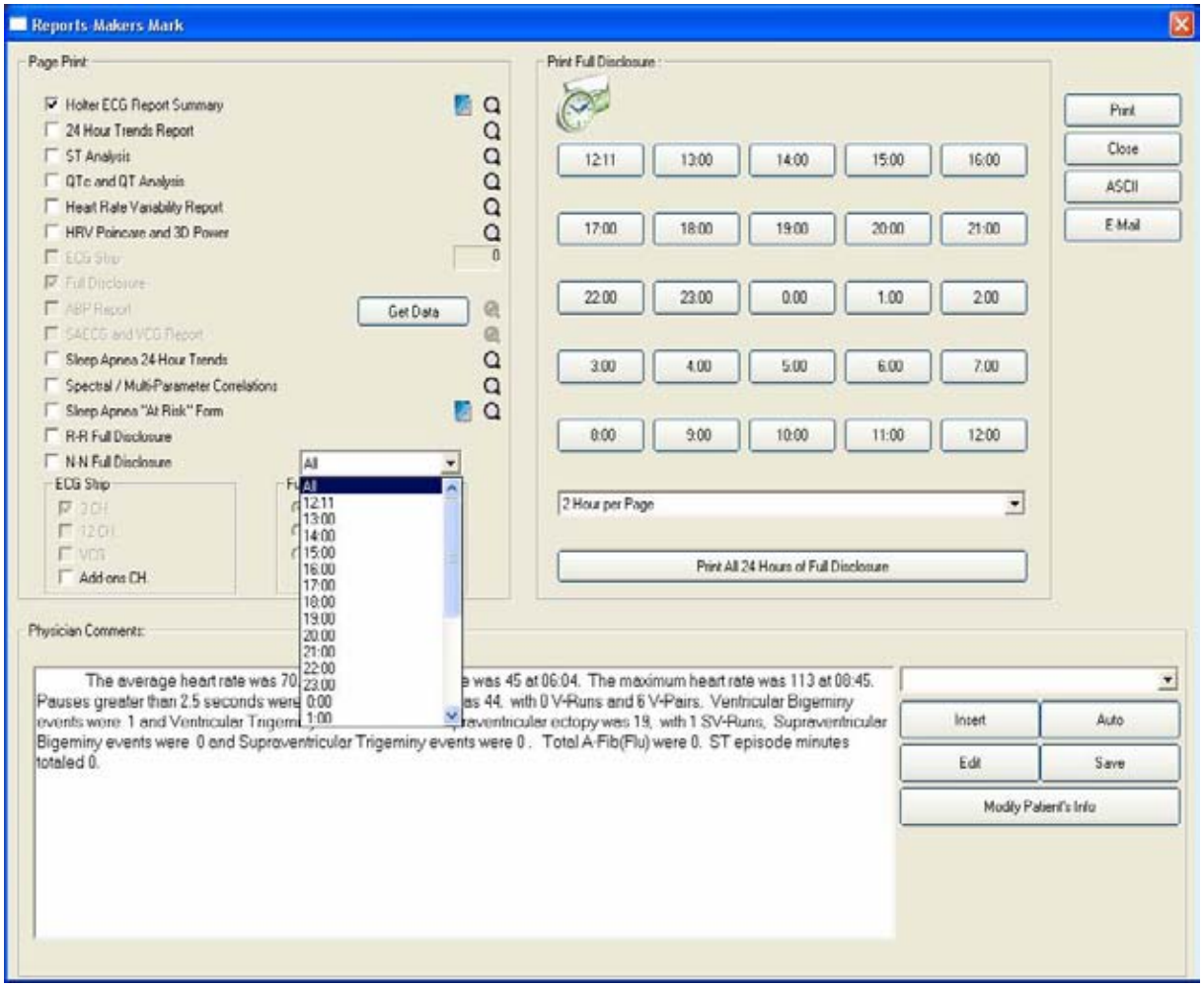
To change any of the thresholds, click in the field you wish to change and type in the new threshold number. In our example, we change the Delta DAY/NIGHT SDDN INDEX threshold to -17. Click on OK. When you print the report you will see the changes from the new thresholds you have entered (see the following page).

Age: 59	Sex: Male	Height:	Weight:

Factors:	Threshold	Actual	
Male Snorer:			
Obese Snorer:			
Delta DAY/NIGHT SDNN:	> -11	-25.0	✔
Delta DAY/NIGHT SDNN INDEX:	> -17	-18	✔
Delta DAY/NIGHT rMSSD:	> -13	-19	✔
Delta TOTAL/NIGHT Total Power:	> -500	-2066.9	✔
Delta TOTAL/NIGHT VLF Power:	> -400	-1376.1	✔
% VLF to Total Power:	> 70%	72.5%	✔
Delta DAY/NIGHT LF POWER:	> -70	-416.6	✔
Delta DAY/NIGHT LF to HF Ratio:	> 0.5	0.1	
Ventricular Arrhythmias:	> 10/hour	242	✔
Delta DAY/NIGHT QTc:	> -20ms	N/A	
Sleep QTc Variations:	> 40ms	N/A	
Average HR:	> 72bpm	62	
Sleep HR Variations/Minute@ 15 bpm:	> X30	11	

Comments

Physician Signature:



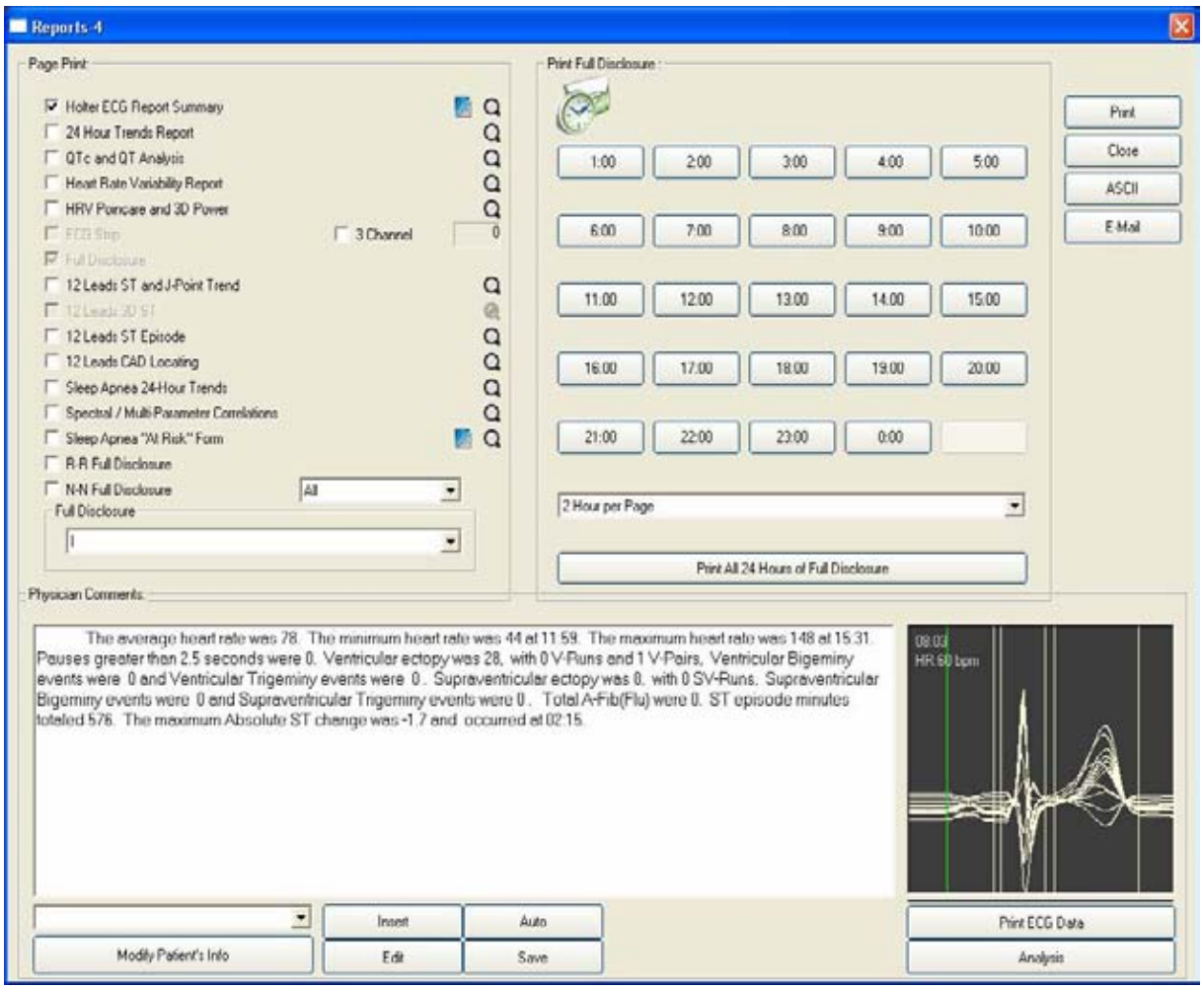
The Sleep Apnea 24-Hour Trends Report and Spectral /Multi-Parameter Correlations Report looks at day versus night differences between many HRV calculations. If the HRV factor during the sleep hours had a big increase, then we would label that as an indicator of Sleep Apnea. We have discovered that each Sleep Apnea event has a distinct signature of heart rate changes.

Click on the N-N Full Disclosure option on the Report screen. Click on the down arrow to the right of the N-N Full Disclosure option and scroll down to the sleep hours (in our example they would be 23:00, 0:00, 1:00, 2:00 and 3:00). Click on the 23:00 hour and then click on the Print bar at the upper right hand side of the screen. The page will print out 10 minute increments of the hour with a heart rate graph and QT/QTc calculations.

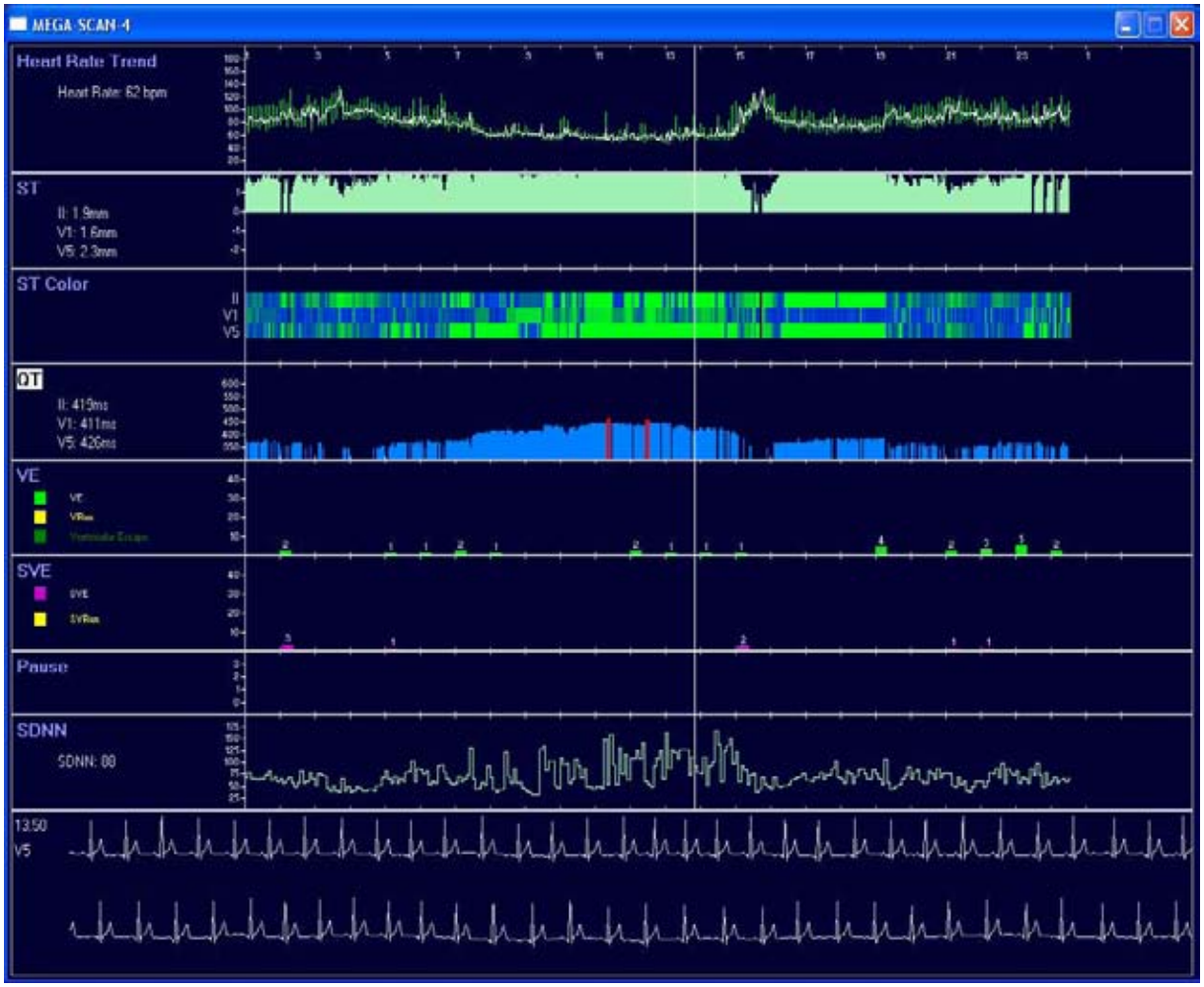
12-LEAD INTERPRETIVE ECG

To access a 12-Lead interpretive ECG from anywhere in the Holter recording period, click on the Report icon at the Data Access Choices screen.

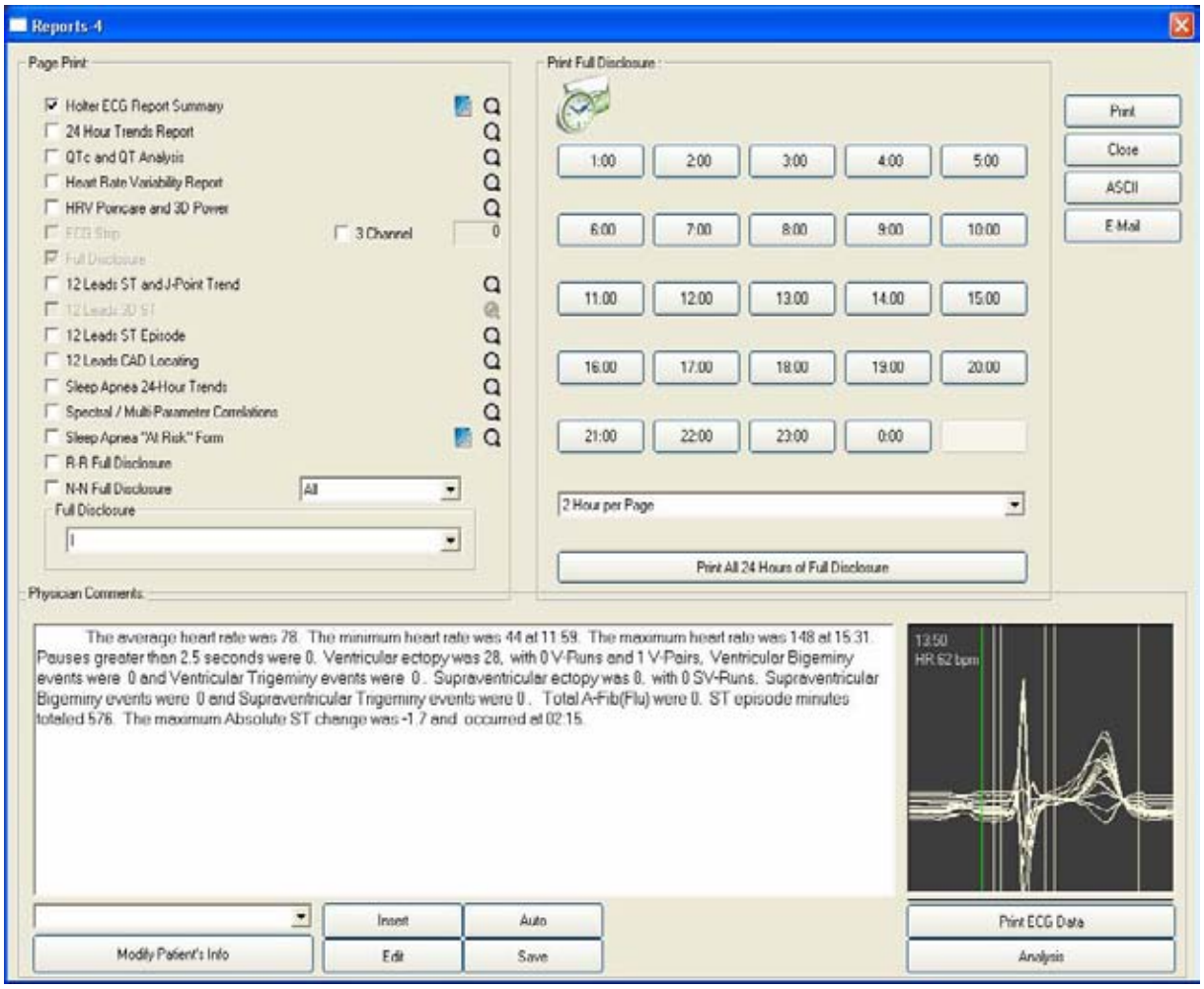
NOTE: You must have used either a 7-Lead Orthogonal Hookup with the DMS 300-7 recorder or a 10 lead hookup with the DMS 300-12 recorder to use this feature. Also, you must check the box for Convert to XYZ to 12 Leads on the patient information screen, if you were using the 300-7 recorder.



To select the time for the 12-lead ECG, double click on the time in the ECG box on the lower right side of the screen. You will be taken to the Mega Scan graph.



Click on the section of the graph you wish to do the 12-Lead ECG. A line will appear. To center the line on the section you want to do the 12-Lead ECG, use the arrow keys on the keyboard. Once the cursor is in the place you desire, press the ESC key on the keyboard. You will be returned to the Report screen.



You will notice the time in the upper left hand corner of the ECG beat box has changed to the time you selected in the Mega Scan screen.

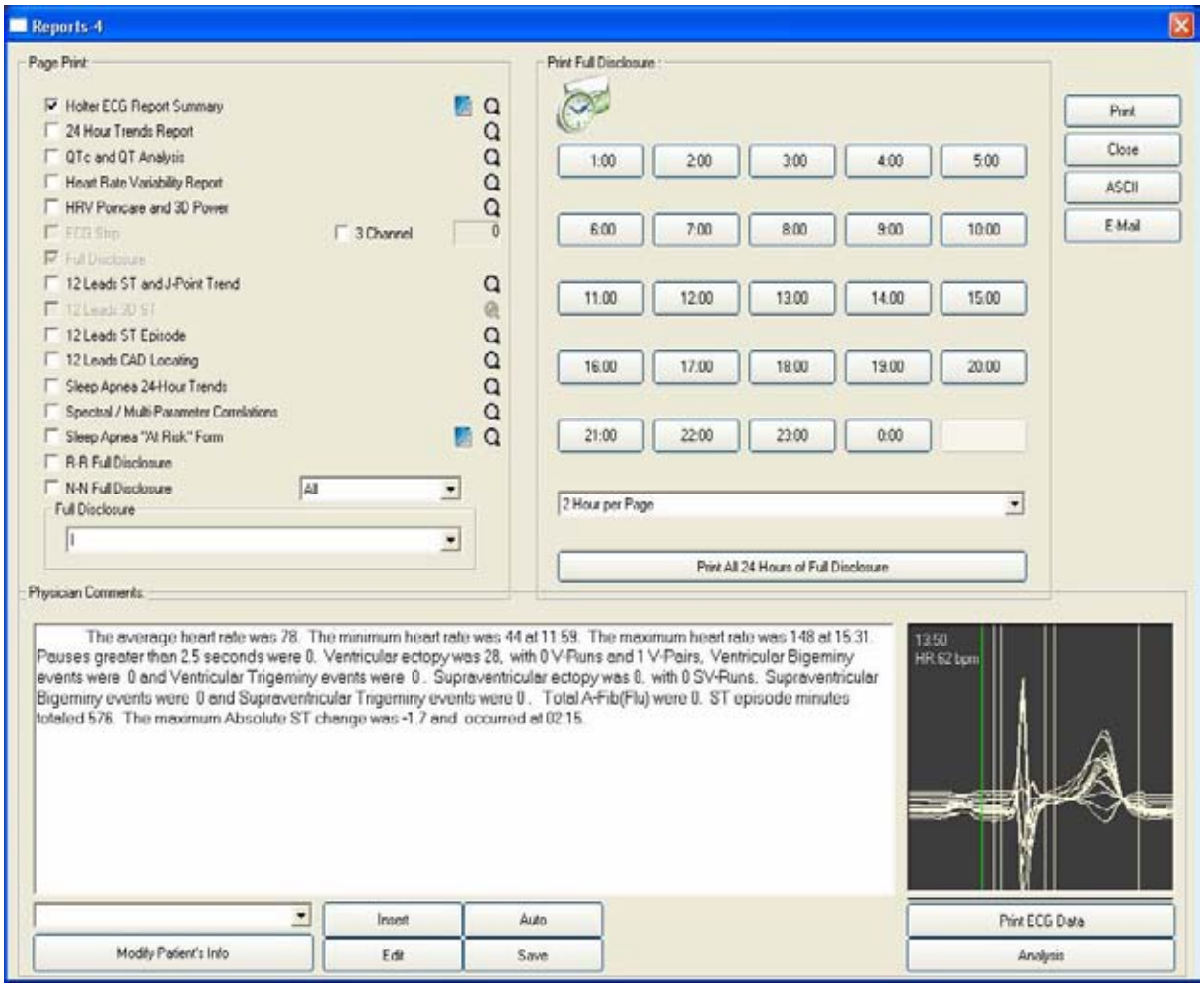
To set the markers on the ECG, point and drag the first marker to the beginning of the P-wave. Press the TAB key on the keyboard. Point and drag the second marker to the end of the P-wave. Press the TAB key on the keyboard. Point and drag the third marker to the Q. Press the TAB key on the keyboard. Point and drag the fourth marker to the J Point. Press the TAB key on the keyboard. Point and drag the fifth marker to the beginning of the T-wave. Press the TAB key on the keyboard. Point and drag the sixth marker to the end of the T-wave. Click on the Analysis bar below the ECG box.

Go to the Physicians Comments box. The 12-Lead Interpretive analysis has been printed after the asterisks. To print out the amplitude, intervals and axis derivation of the 12-Leads, click on the Print ECG Data bar under the ECG box.

You may select numerous times during the Holter recording period for the 12-Lead Interpretive ECG by repeating all of the above steps.

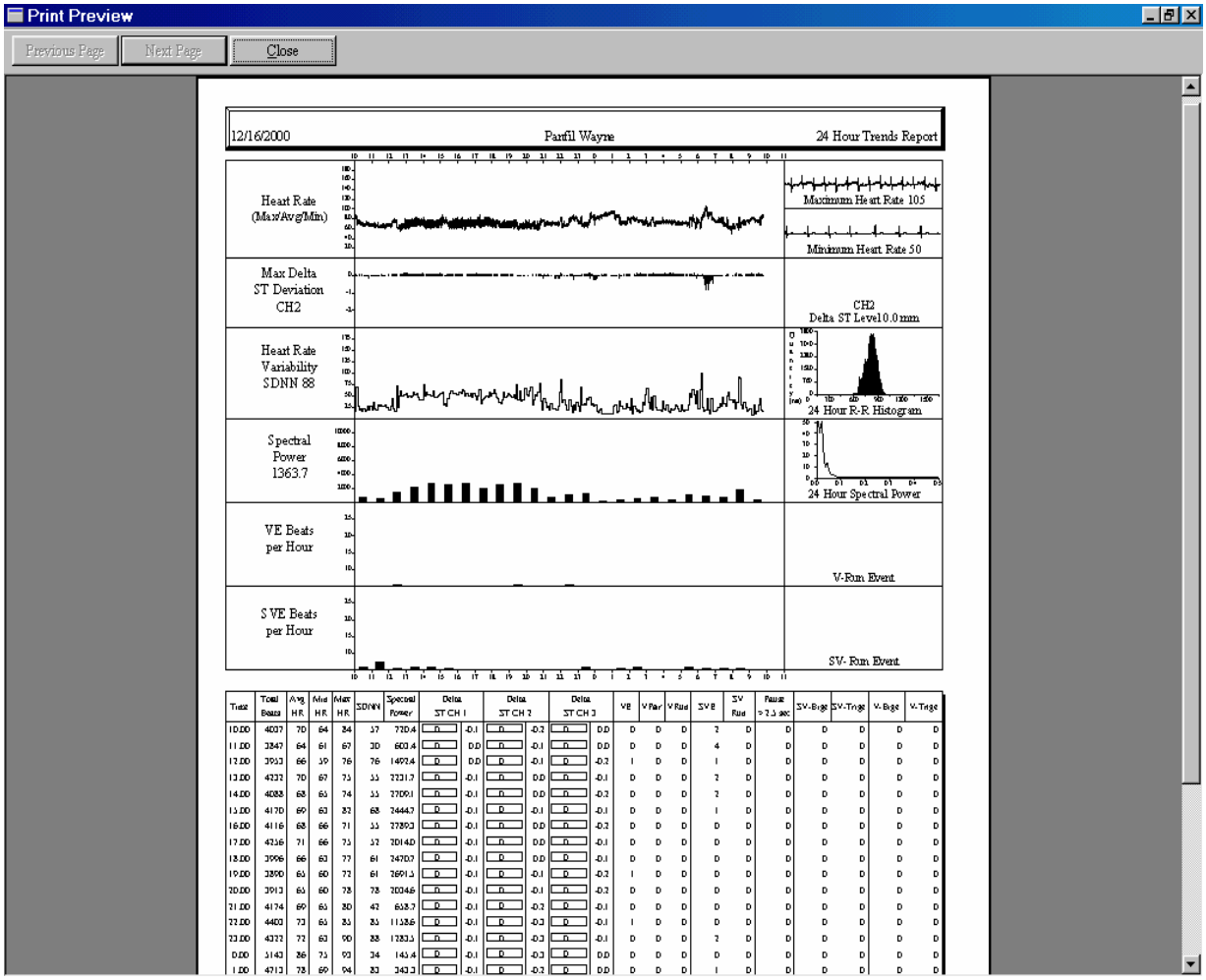
REPORT MENU

To access the Report menu, point and click on the Report icon.



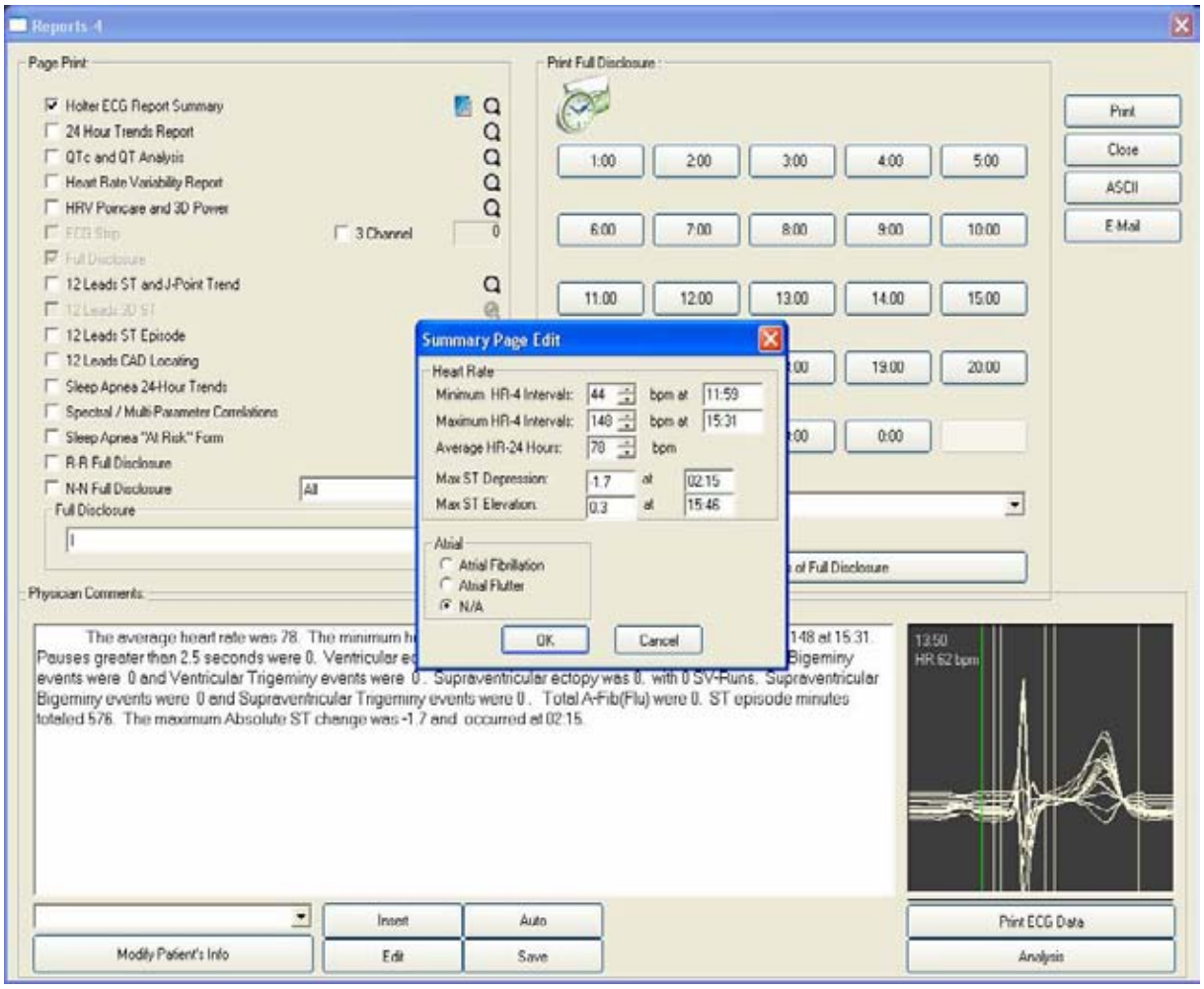
The Page Print section on the left side of the screen allows you to select which pages you want printed in the Holter ECG report. Move the mouse to the boxes to the left of each page print description and click. A check mark will appear. If you click again, the check mark will disappear. Those pages that have a check mark will be printed. Those pages with no check mark will not be printed.

You may preview each page of the report by clicking on the zoom icon to the right of each page print description.



A magnifying glass is now the icon on the screen. To enlarge any part of the report, point and click with the mouse. The area of the report page you have clicked on will be enlarged.

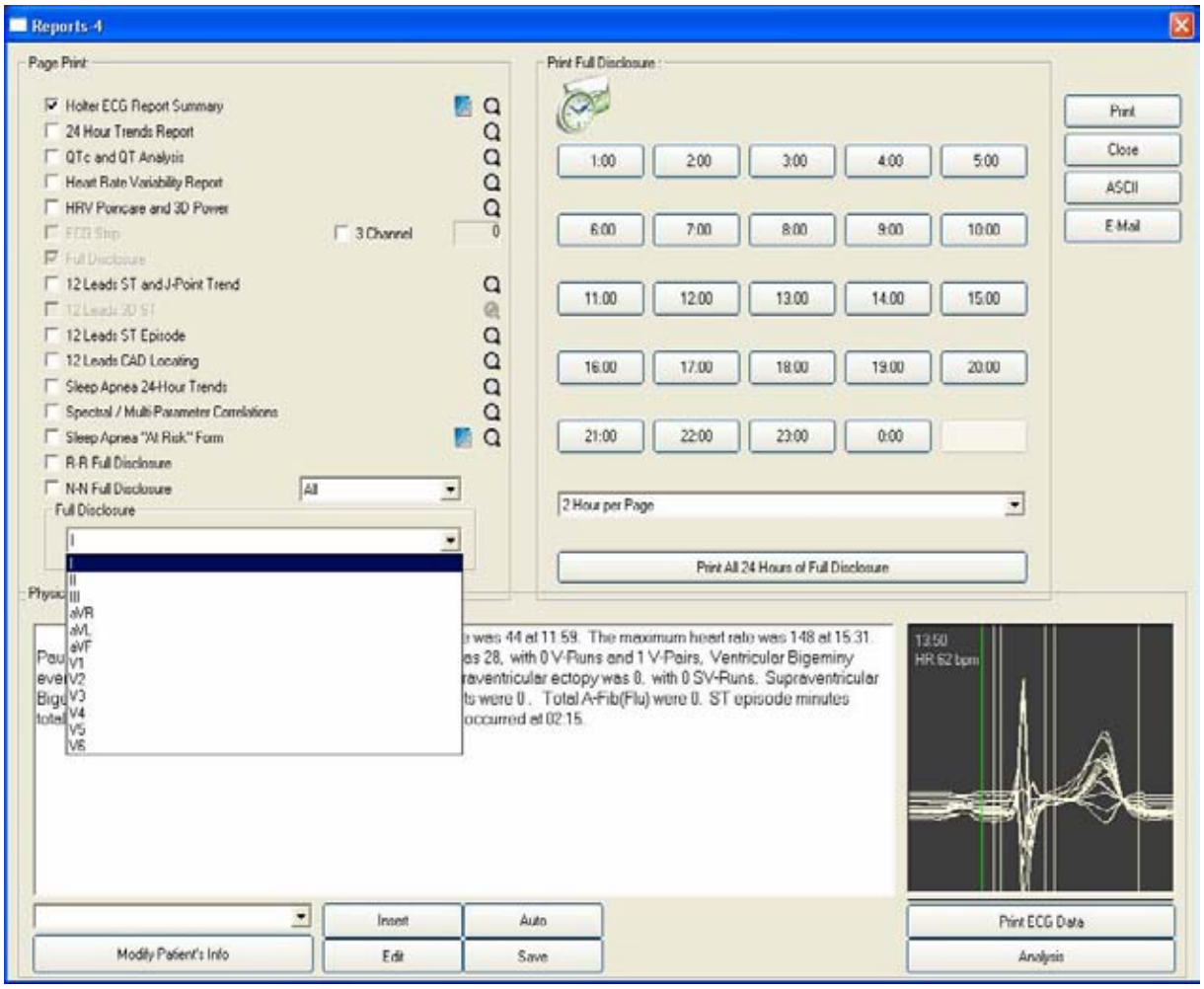
When you have finished previewing a page, press the ESC key on the keyboard.



Clicking on the Page Preview icon to the right of the Holter ECG Report Summary Page will bring up the above screen, the Summary Page Edit.

To edit the numbers of each category, move the mouse cursor to the up or down arrows next to each category and the numbers will increase or decrease OR point and click your mouse in the field next to each description and type in the number you desire.

Upon completion of this edit, click on the OK bar.



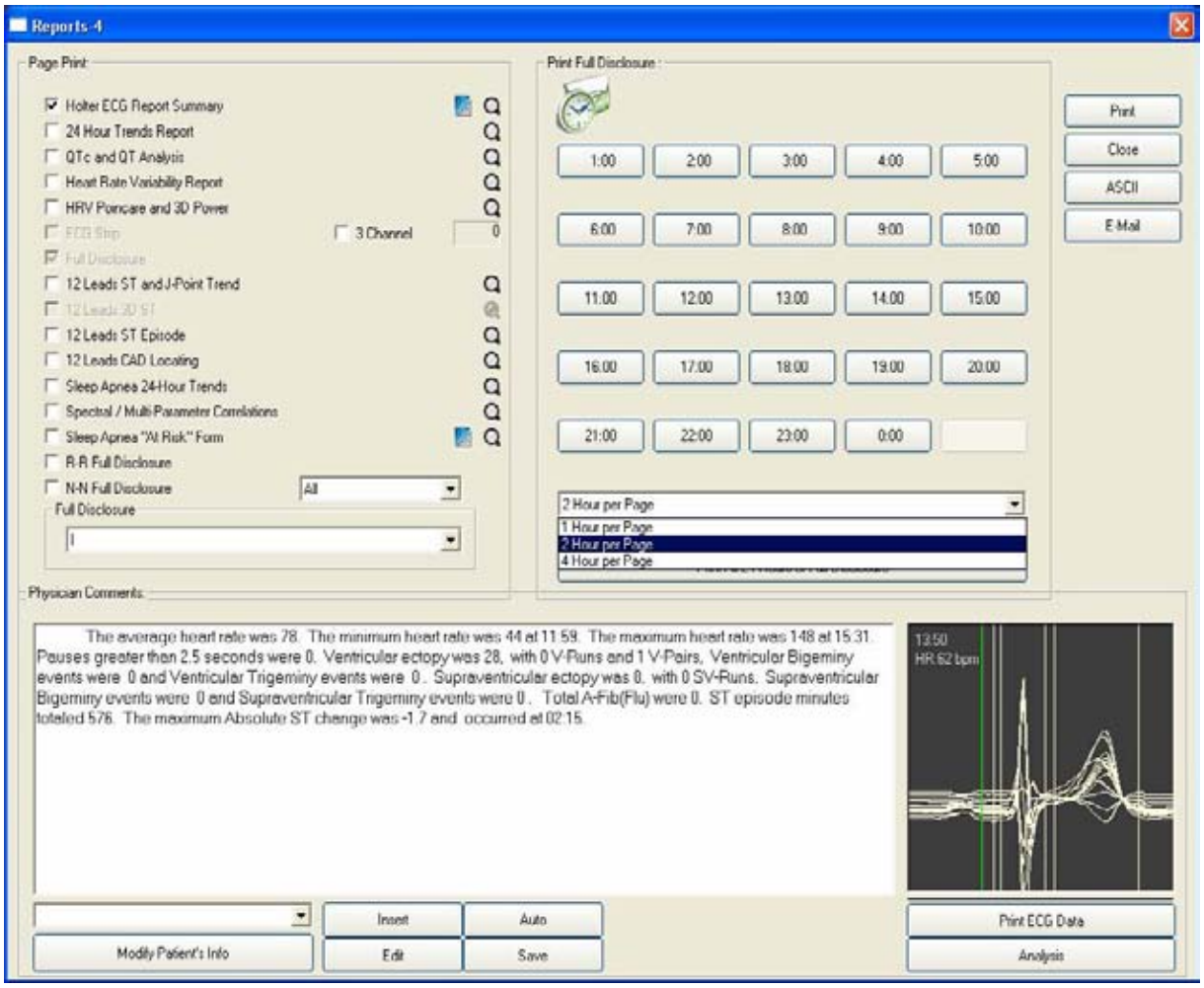
Full Disclosure ECG print outs can be obtained for selected pages as follows:

1. Point and click on the desired hour in the “Print Full Disclosure” box. The hour box will become lighter. Repeat this process for as many hours as desired.

2. Click on the down arrow in the Full Disclosure box. Scroll down and select the lead you want the Full Disclosure to print out in.

3. Click on the Print bar.

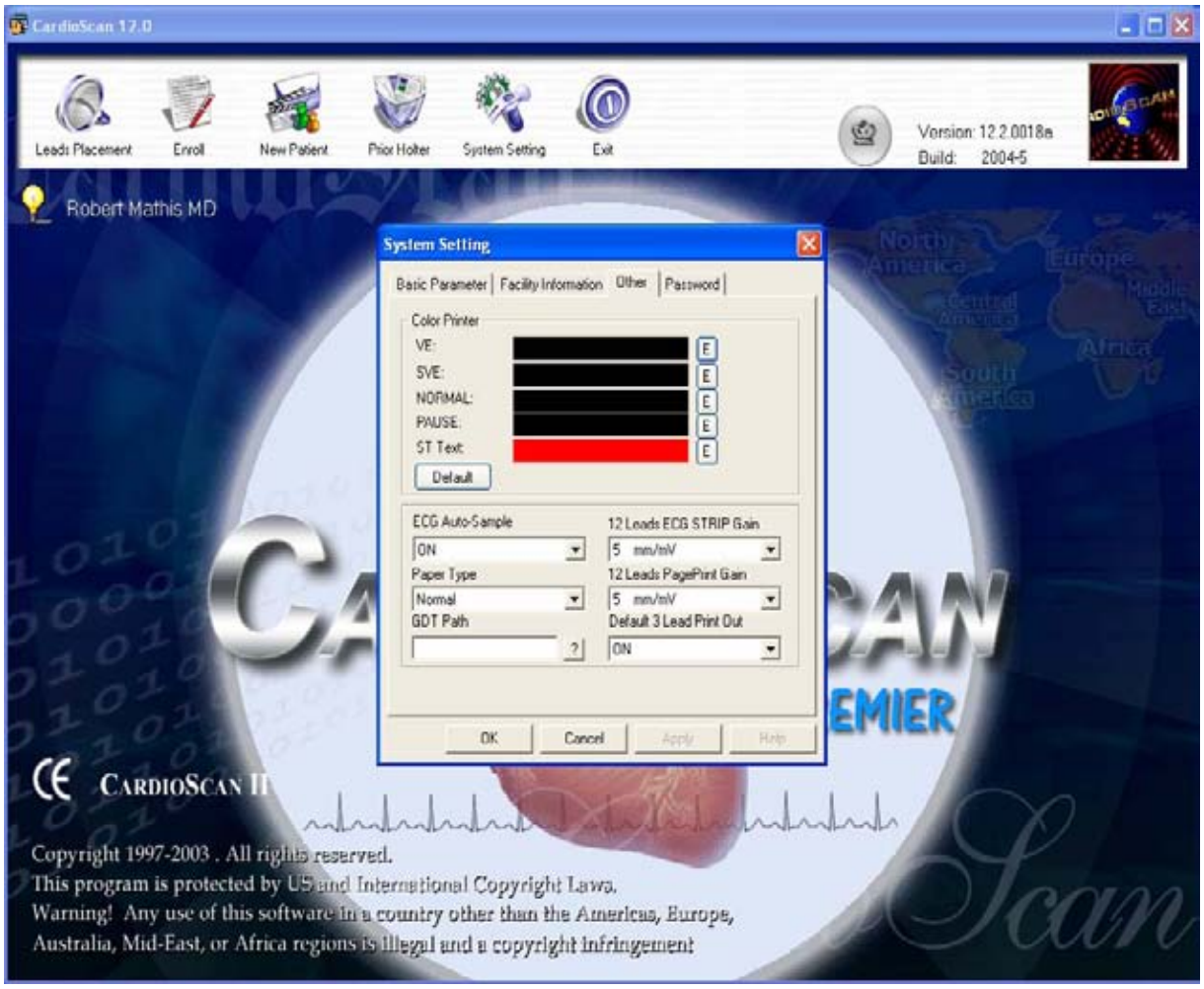
NOTE: If you only want the full disclosure pages to print out, make sure to deselect all the pages under report except for Full Disclosure.



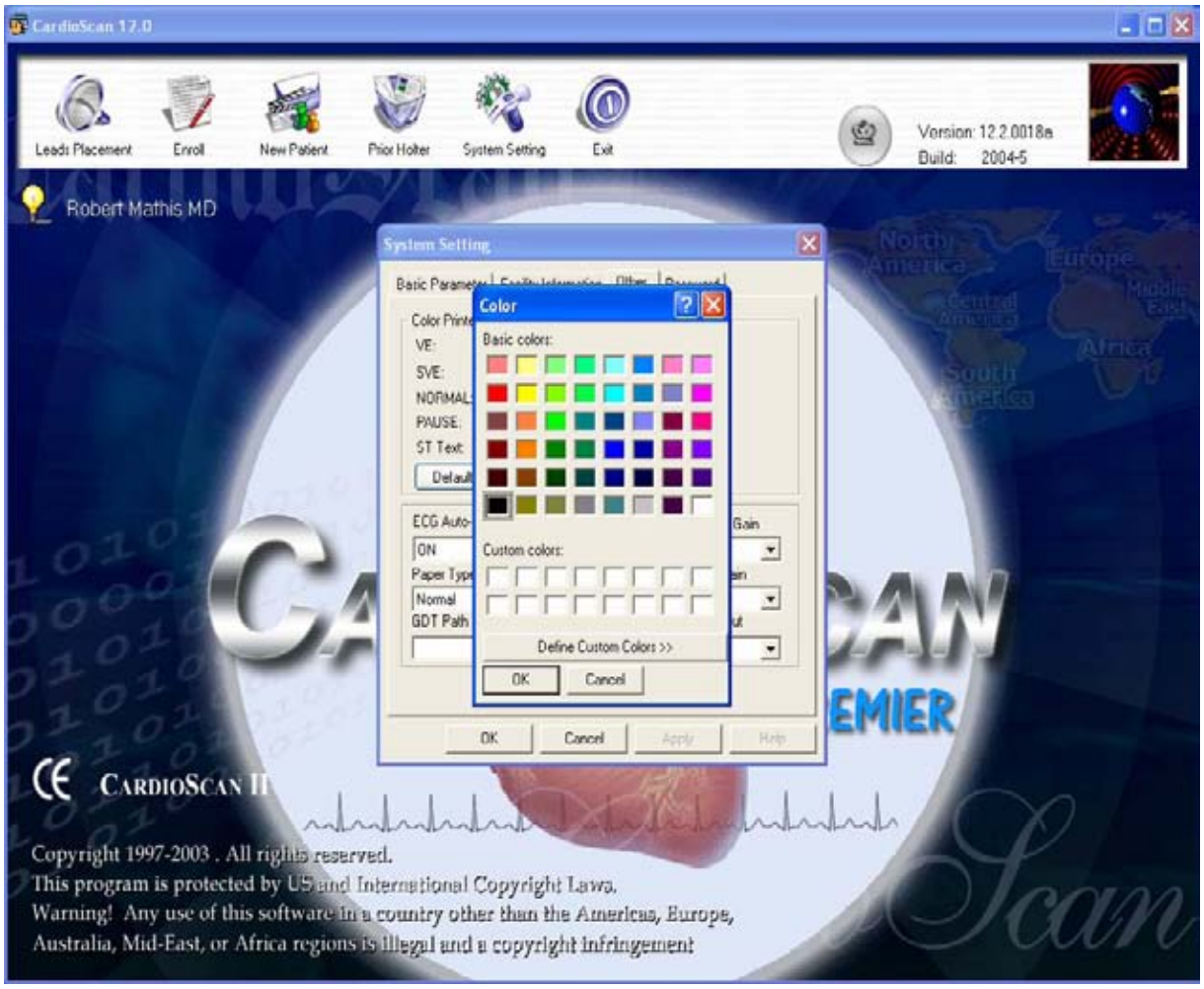
To print 24 hours of full disclosure, click on the down arrow next to the Hours per Page field. Select how many hours you want to print on one page. The options are 1 Hour per Page, 2 Hours per Page or 4 Hours per Page. Your selection will be highlighted in blue.

Click on the Print 24 Hours of Full Disclosure bar.

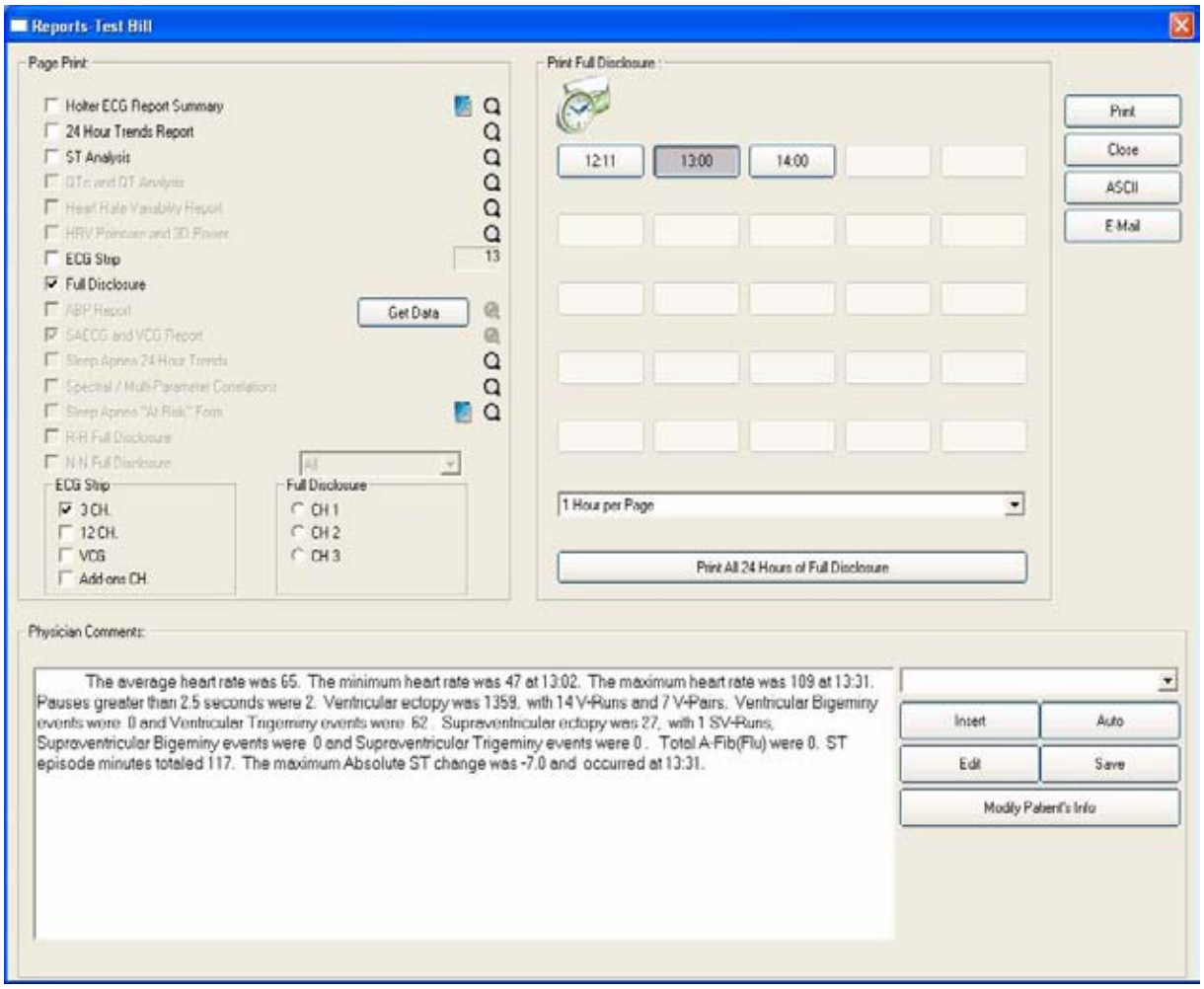
To print the Full Disclosure with the Black and White Intensification feature, return to the System Settings Menu at the Main Holter Screen.



Click on the Other tab. You need to change the colors for the VE, SVE and Pause to black.

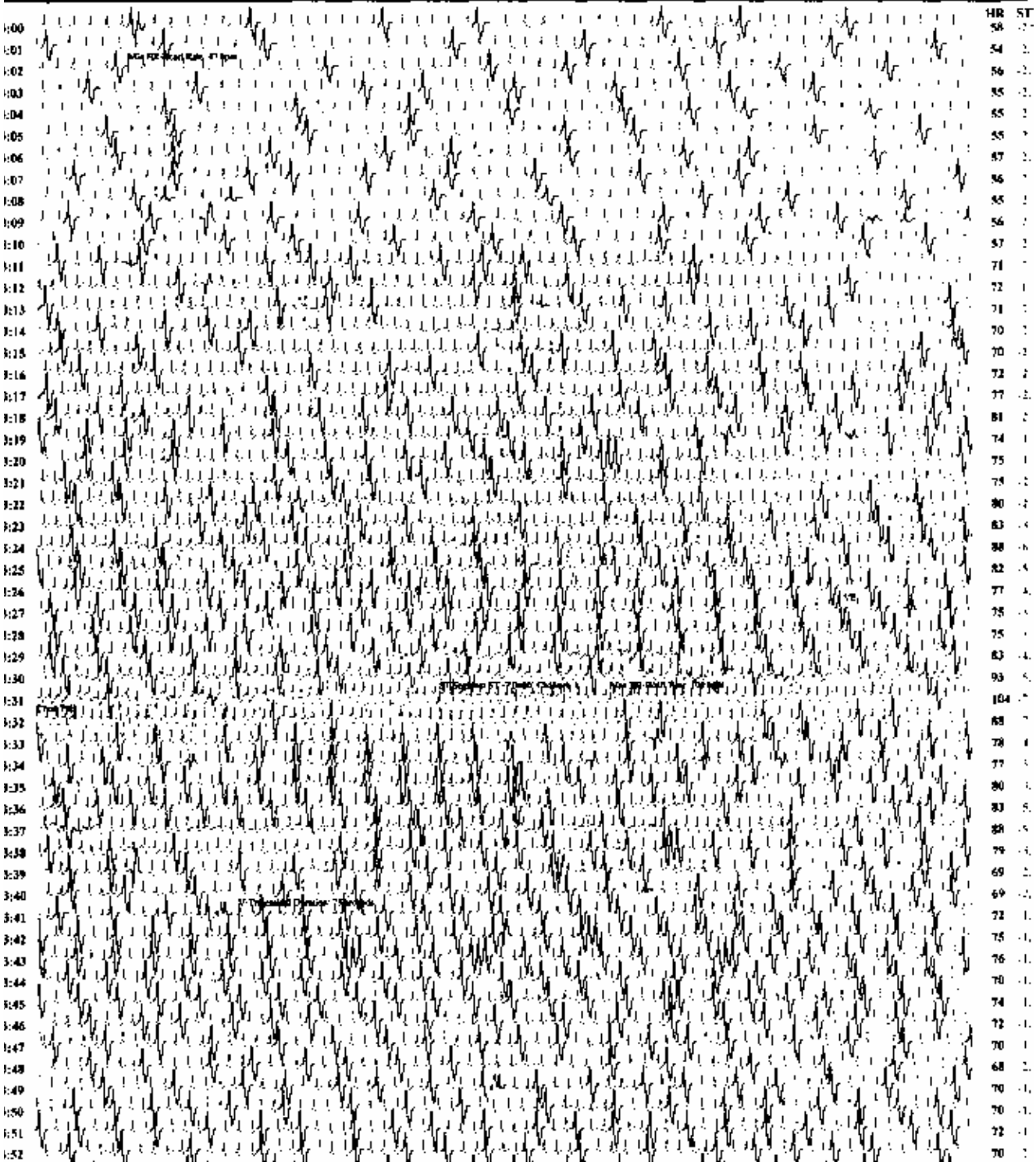


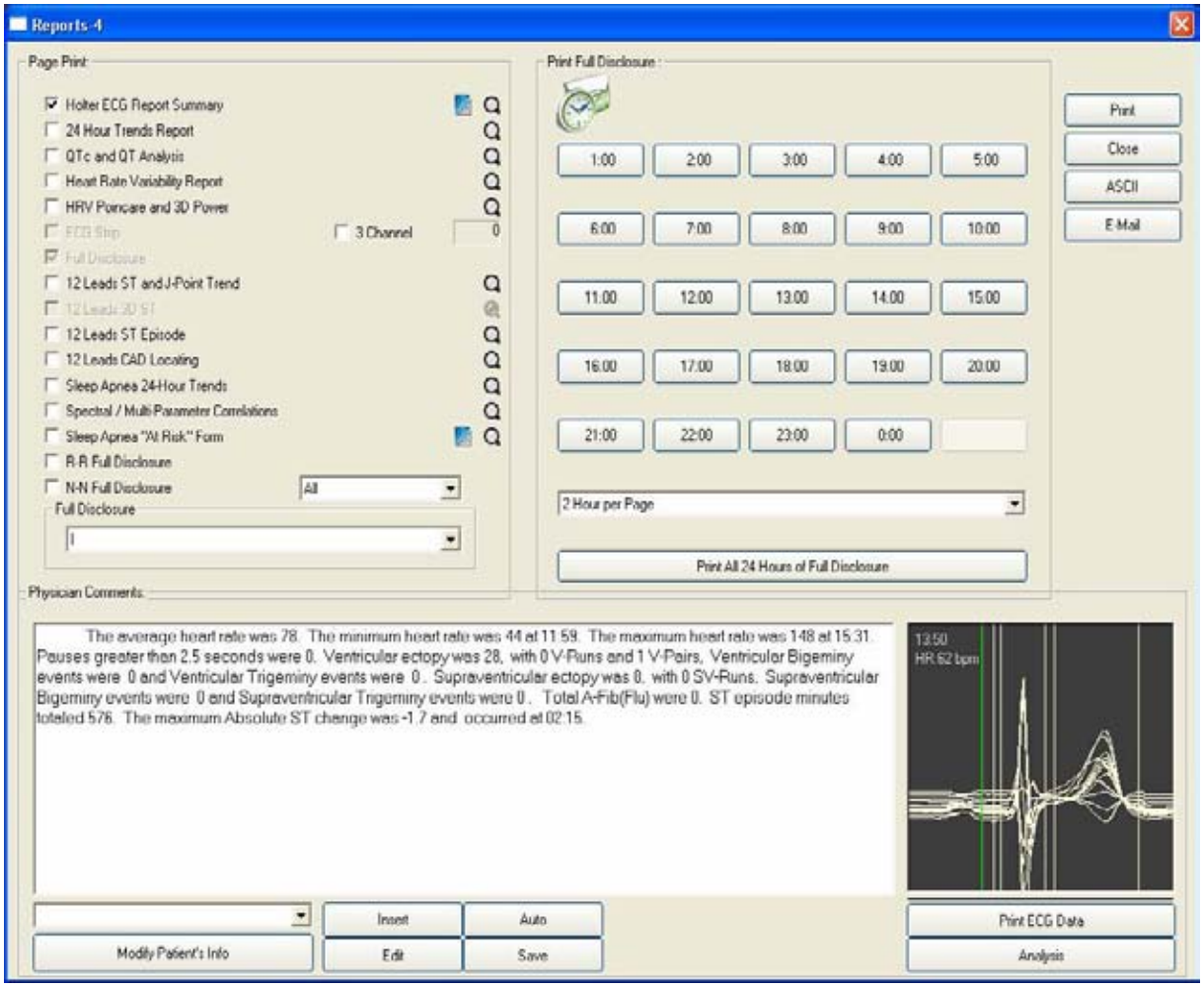
Click on the E button to the right of VE. The above color palette will appear. Click on the lower left corner. This is the black color. Click on OK. You must repeat the same steps for changing the SVE and Pause to the black color. Once you have changed the color for each category, click on OK. Go the Prior Menu and select the patient you desire.



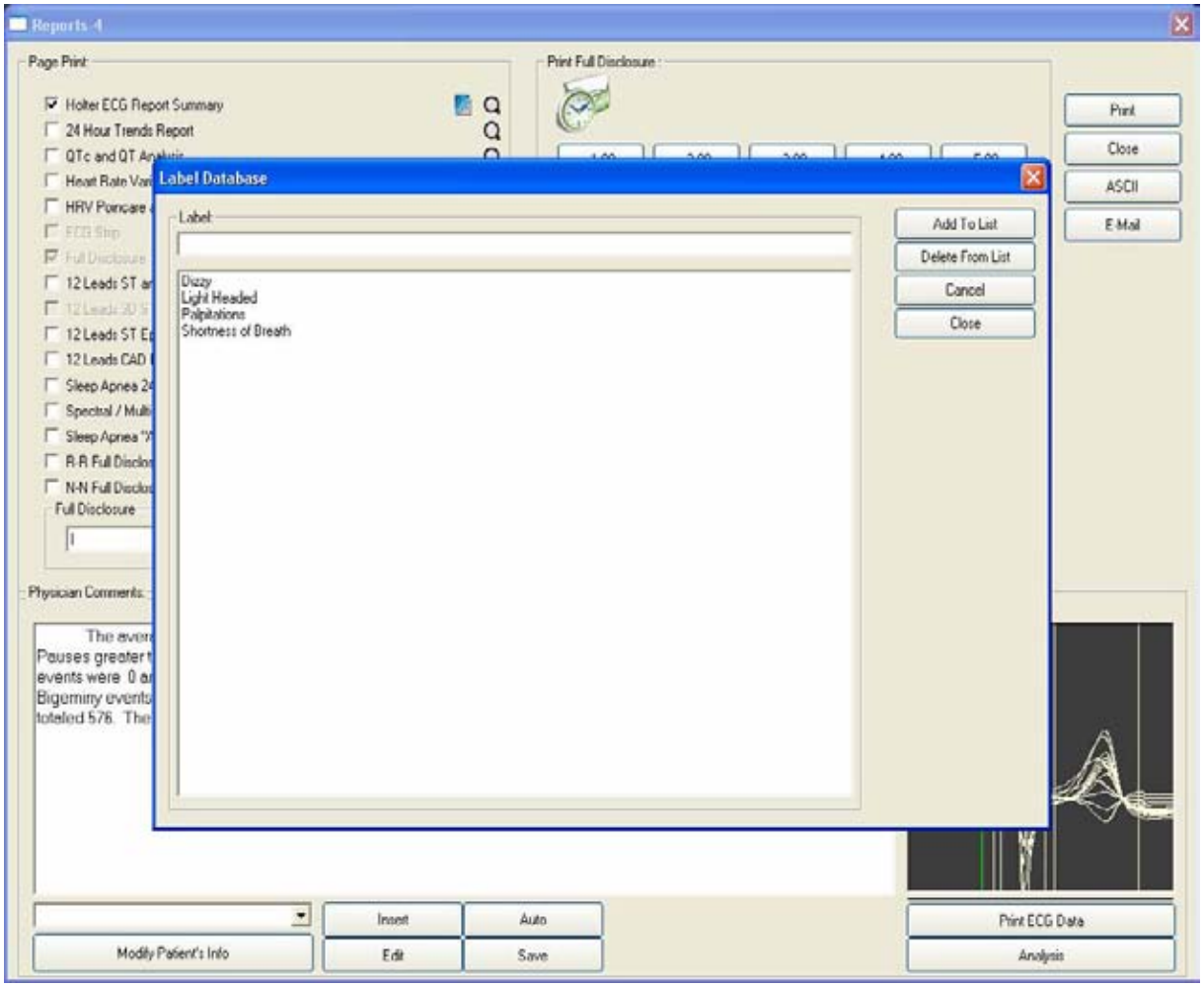
Click on the Report icon and you will be returned to the Report page. Click on Print All 24 Hours of Full Disclosure or click on the hour of full disclosure you desire.

As well as the highlighted arrhythmias, all saved ECG strips (including Event and Symptom strips) are highlighted on the full disclosure. See the following page for an example.


HR
ST

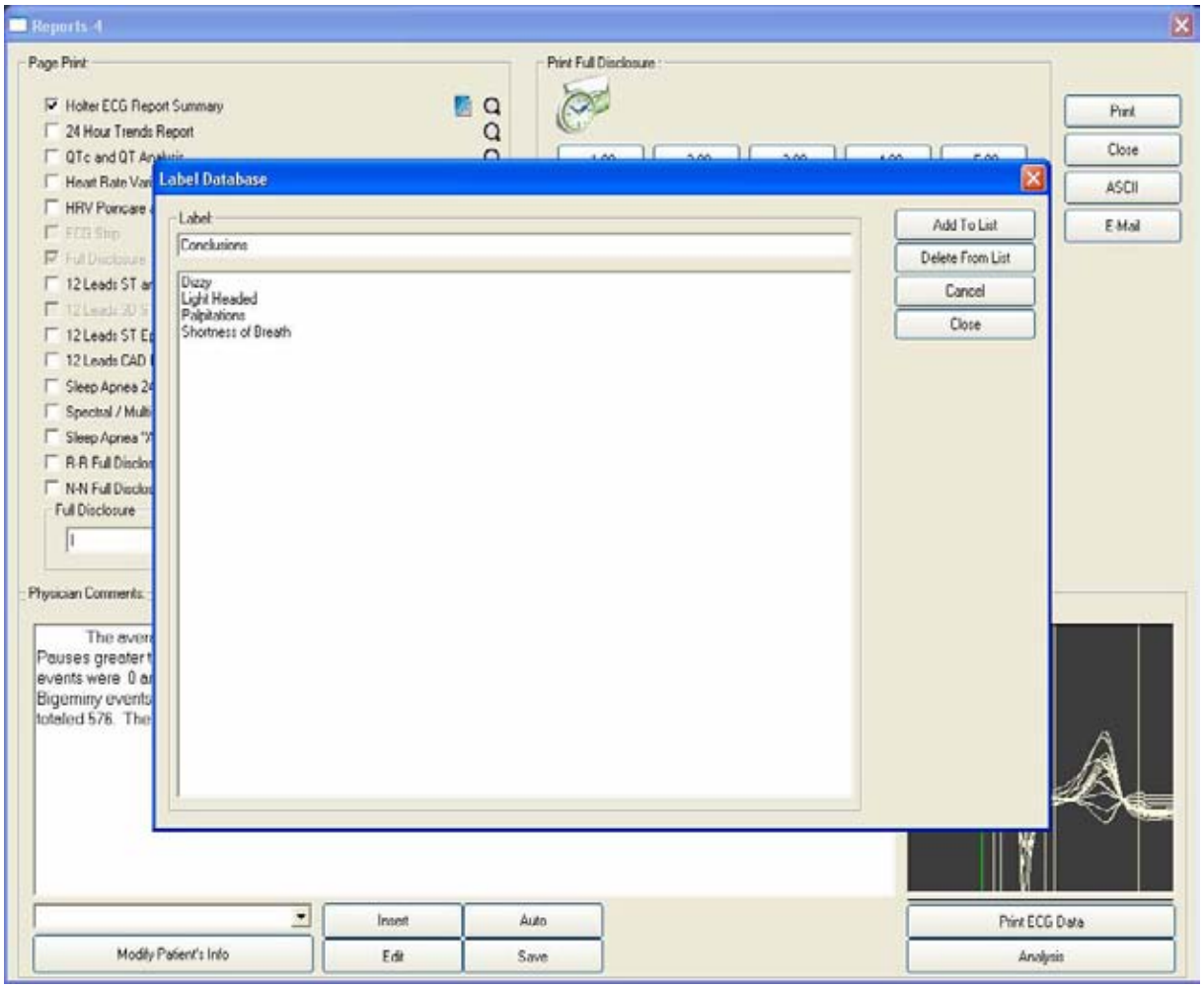


To edit the Physician Comments, point and click in the comment field. A cursor will appear on the screen. You may begin adding or deleting comments at this time. Upon completion of your editing, click on the SAVE bar underneath the Physician Comments section.



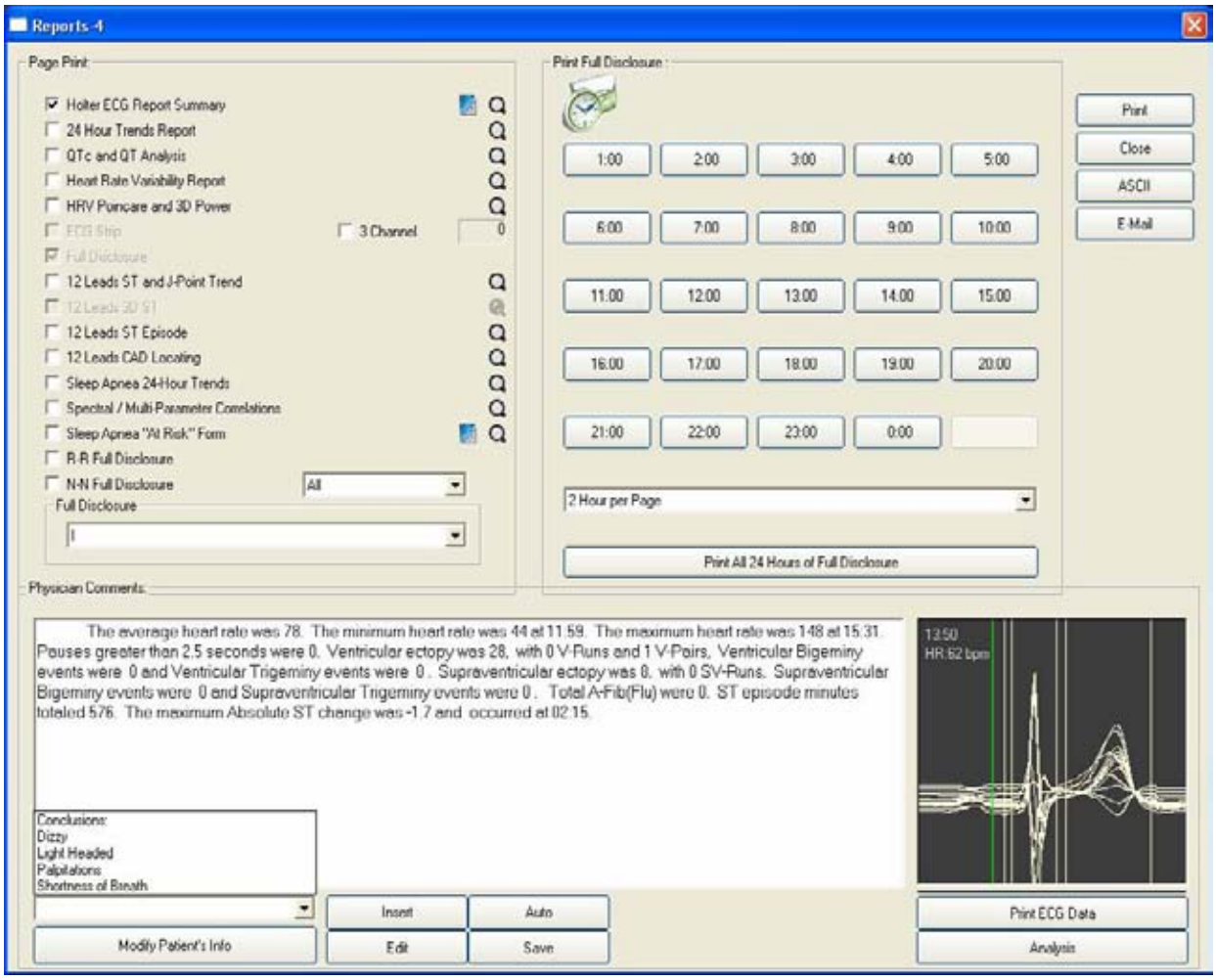
You may have some standard comments or descriptive phrases you regularly use on reports. You may keep them in the LABEL DATABASE. To access this database, click on the EDIT bar on the bottom right of the screen. The above screen will come up.

To add phrases or words to the Label Database, point and click in the Label field at the top of the screen. A cursor will appear in the field. Type in the word or phrase you desire and then click on the ADD TO LIST bar at the right of the screen. The phrase or word will be added to the list.

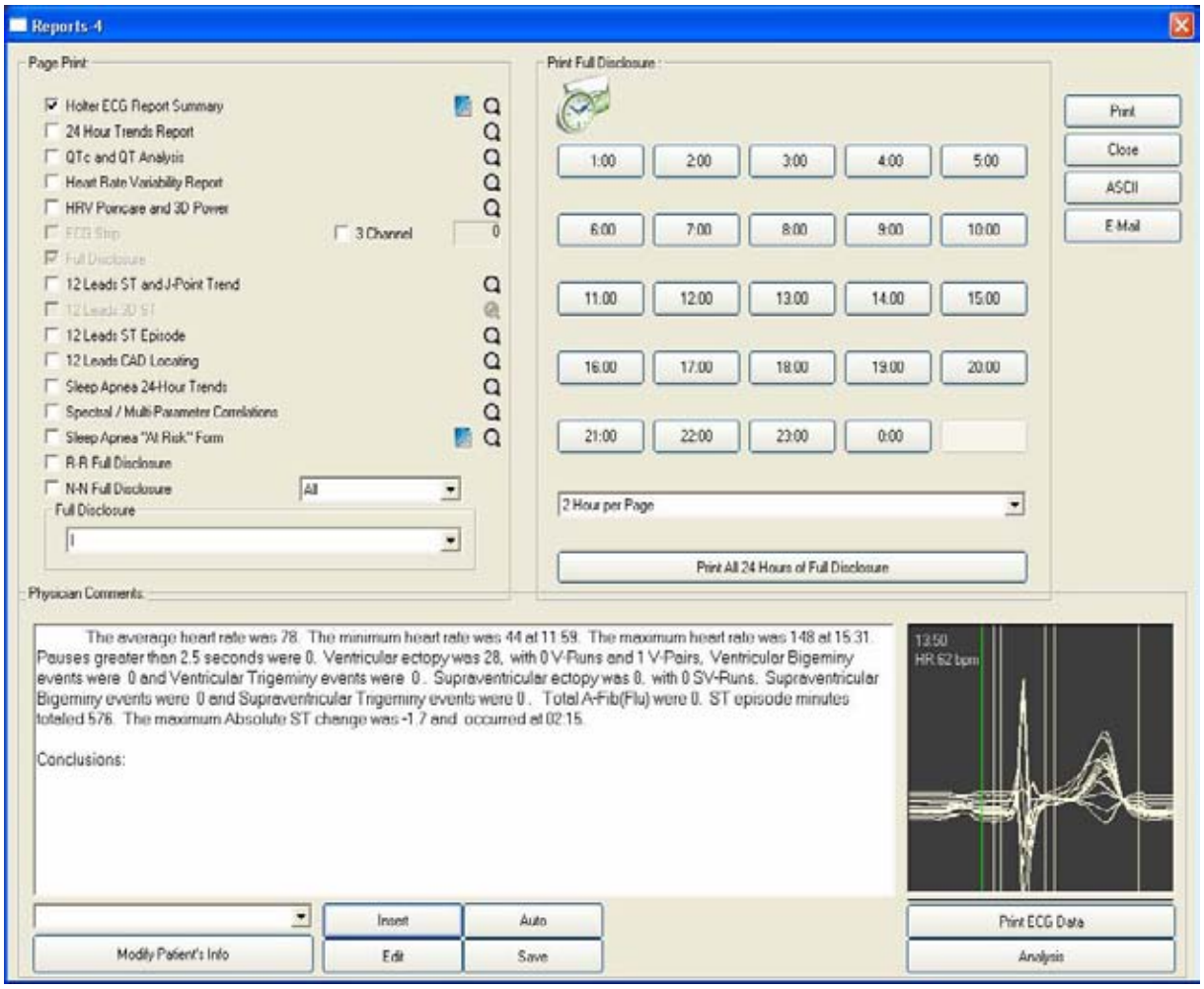


In the above example we added the word Conclusions: to the list.

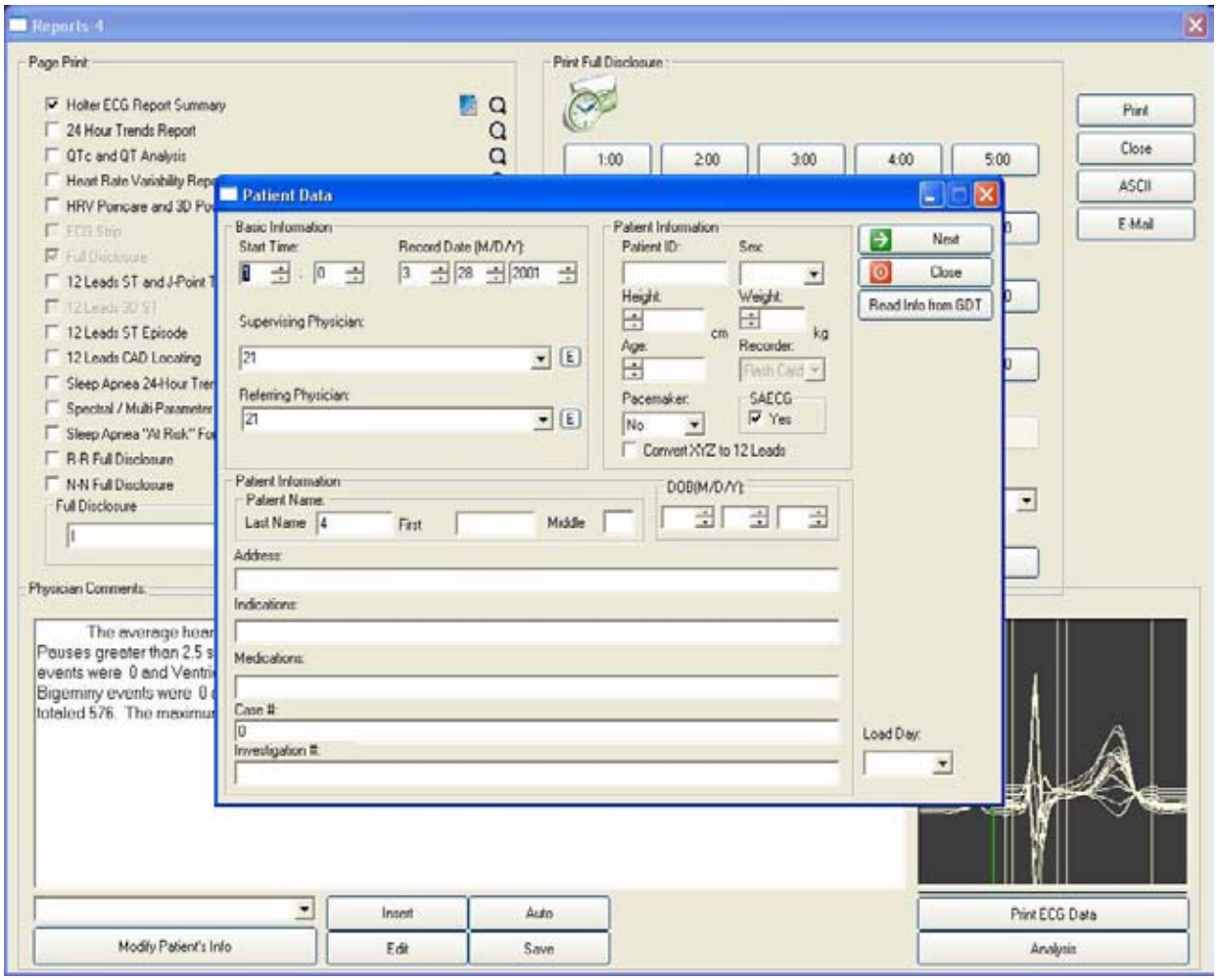
To remove a word or phrase from the list, simply point and click on the word or phrase you wish to remove. A blue highlight bar will appear over the word. Point and click on the CANCEL bar to the right of the screen. The word will be deleted from the list.



To use the words or phrases in the Label Database, point and click on the down arrow in the empty field underneath the Physician Comments box. A drop screen will appear that will include all the words and phrases in the Label Database. Click on the word or phrase you desire. Double click on the INSERT bar.



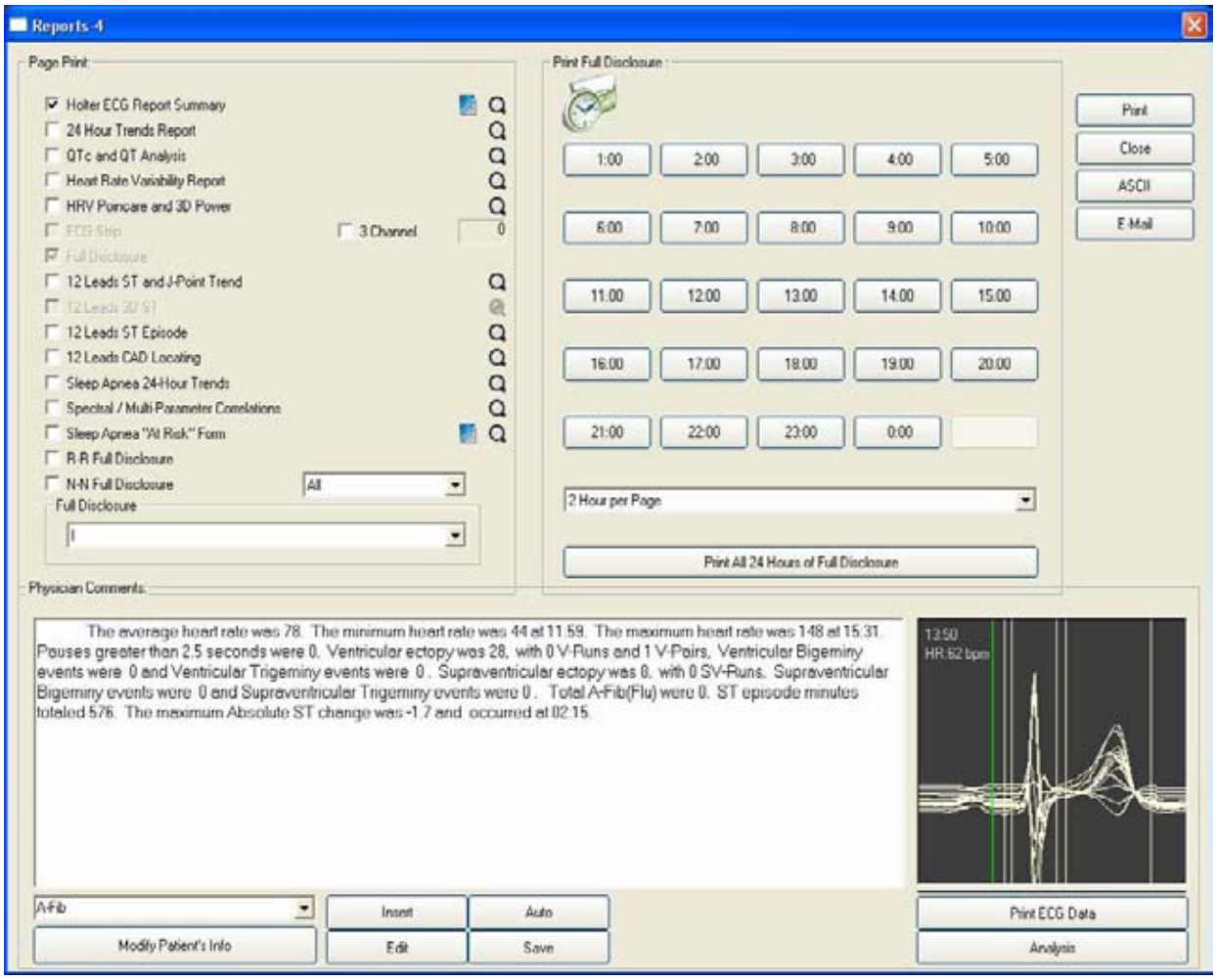
The word or phrase will be added to the Physicians Comments. In the above example, we used the word Conclusions.



To edit the patient's information, click on the Modify Patient's Info bar on the lower left of the screen. The above screen will appear.

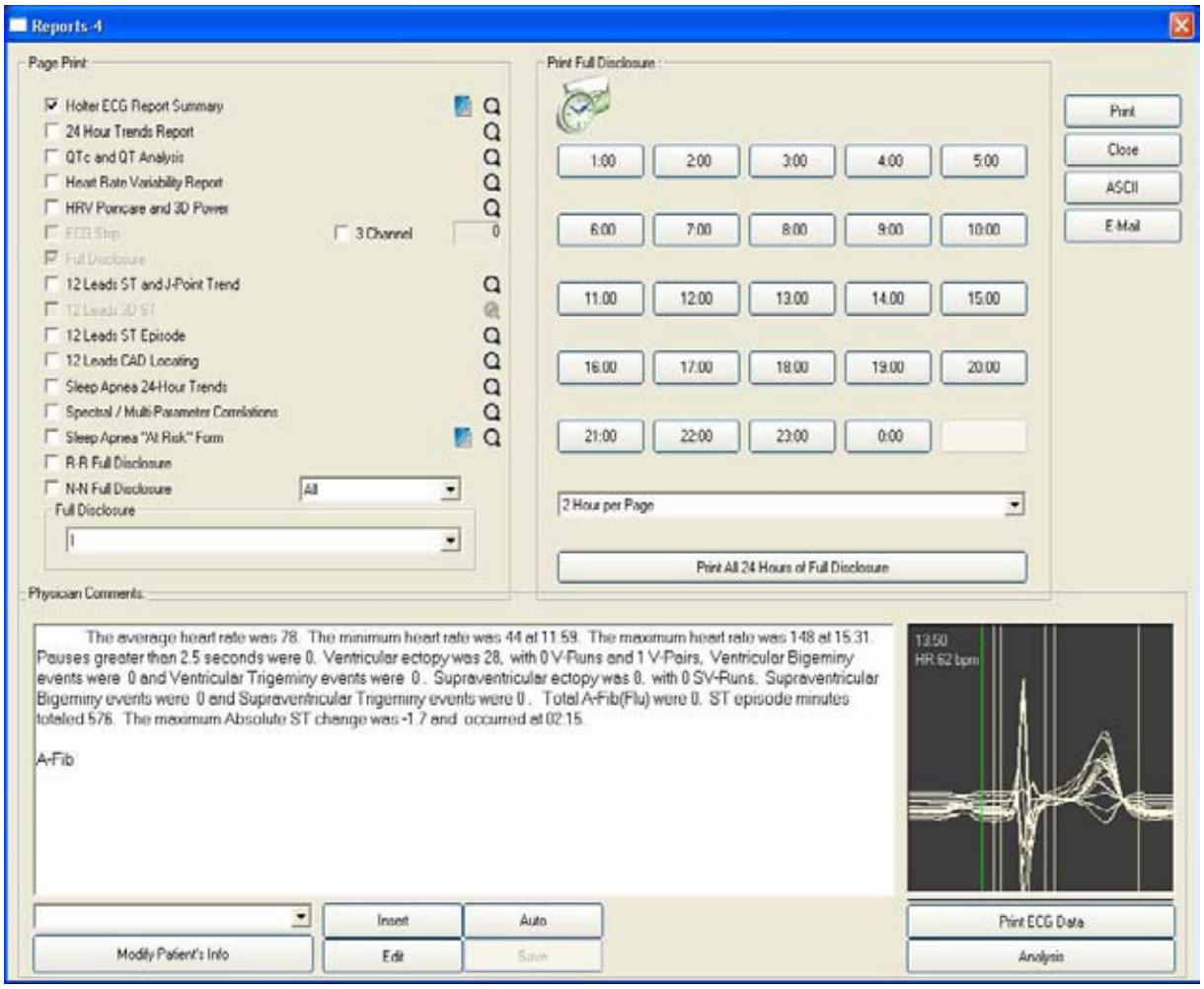
You may add or change any of the data in these fields, including the Start Time and Record Date.

When you have completed the edit, click on the Next icon.



The field next to the Physician Comments field is an identification tag field. You may enter a descriptive word that would identify this type of Holter recording, in the above example we have put in the description of A-Fib.

After entering the word in this field, click on the Insert bar.



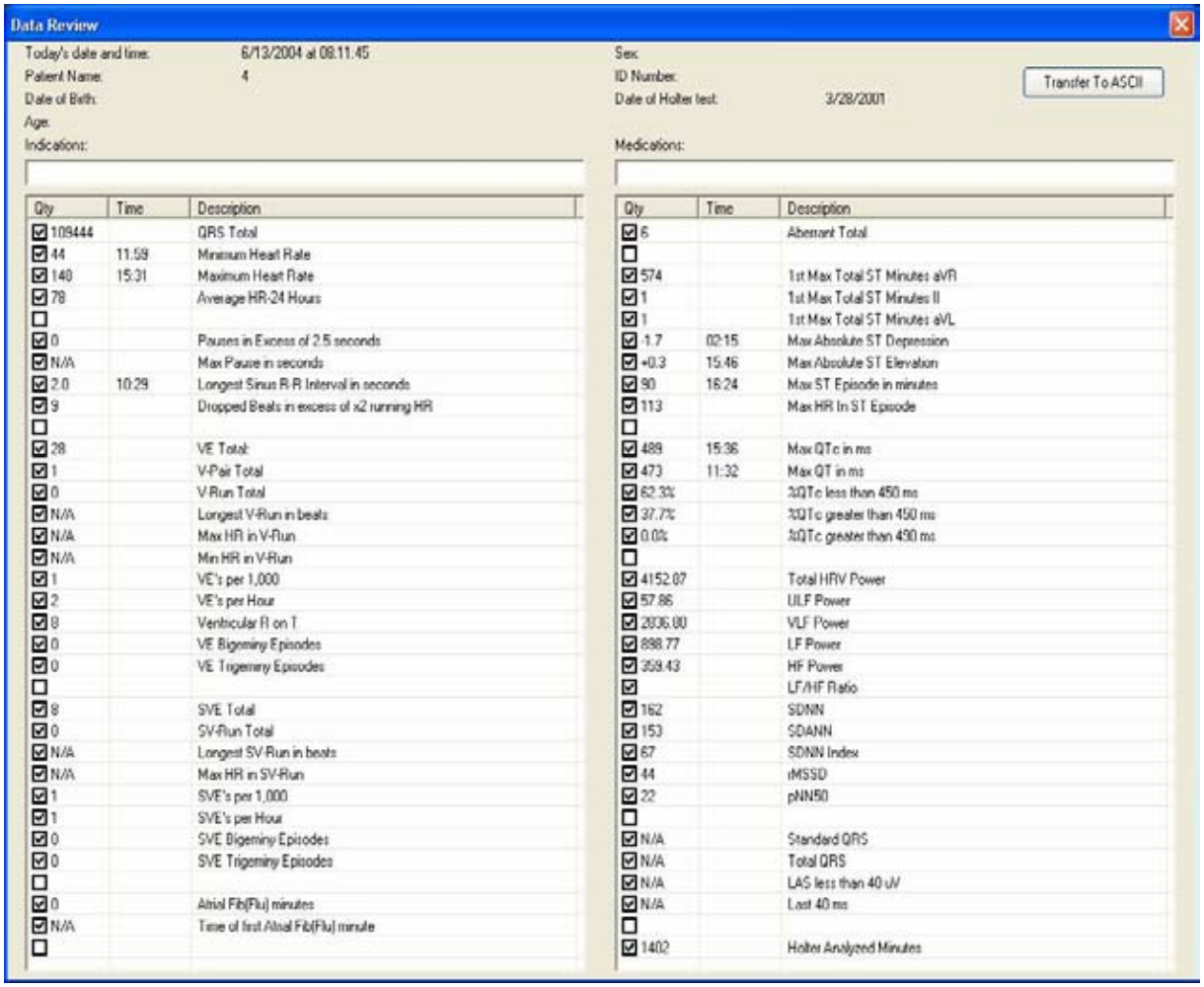
A-Fib has now been added in the Physician Comments field.

This Holter report has now been included in a subdirectory of all A-Fib reports. At a later date, the physician may wish to access all of his A-Fib Holter reports. This report would now be included in the A-Fib reports.

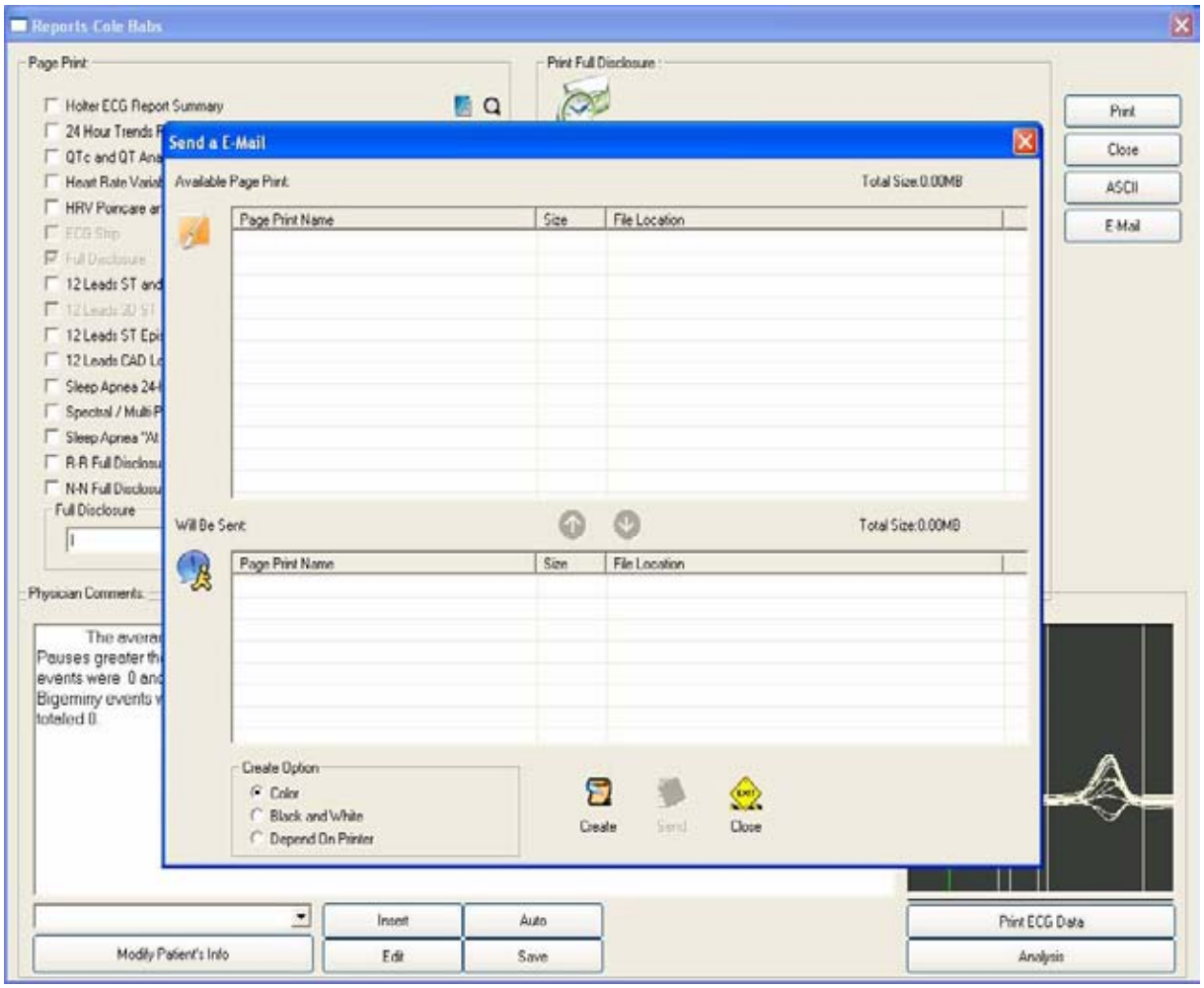
At a later date the physician may want to do a study on the A-Fib patients (or V-Tach patients, etc.) By inserting this descriptive identification tag, the physician will have access to all those prior Holter reports.

To learn how to access reports via a descriptive tag, go to the PRIOR feature in this manual.

Clicking on the “Auto” bar allows you to restore the original narrative in the Physician Comments section. Using this command will delete the descriptive identification tag.



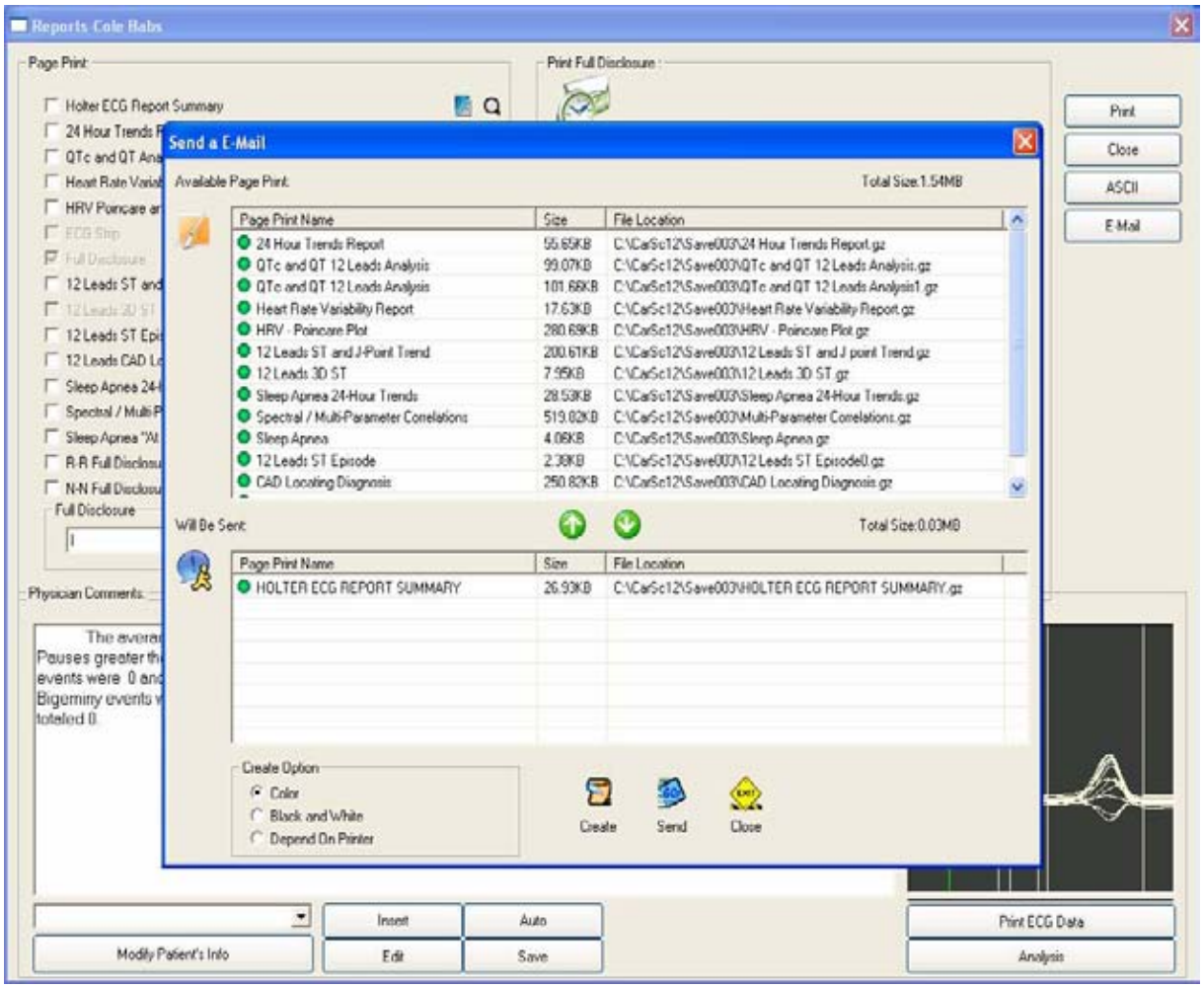
To save the Holter report data to an ASCII file, click on the ASCII bar at the upper right side of the screen. The above screen will appear. To transfer the data to an ASCII file, click on the Transfer to ASCII bar at the upper right hand side of the screen.



To E-Mail a Holter report, click the E-Mail button on the upper right side of the screen.

NOTE: You must have Outlook Express setup for your e-mail.

The above screen will appear. Click on the Create icon at the bottom center of the screen.

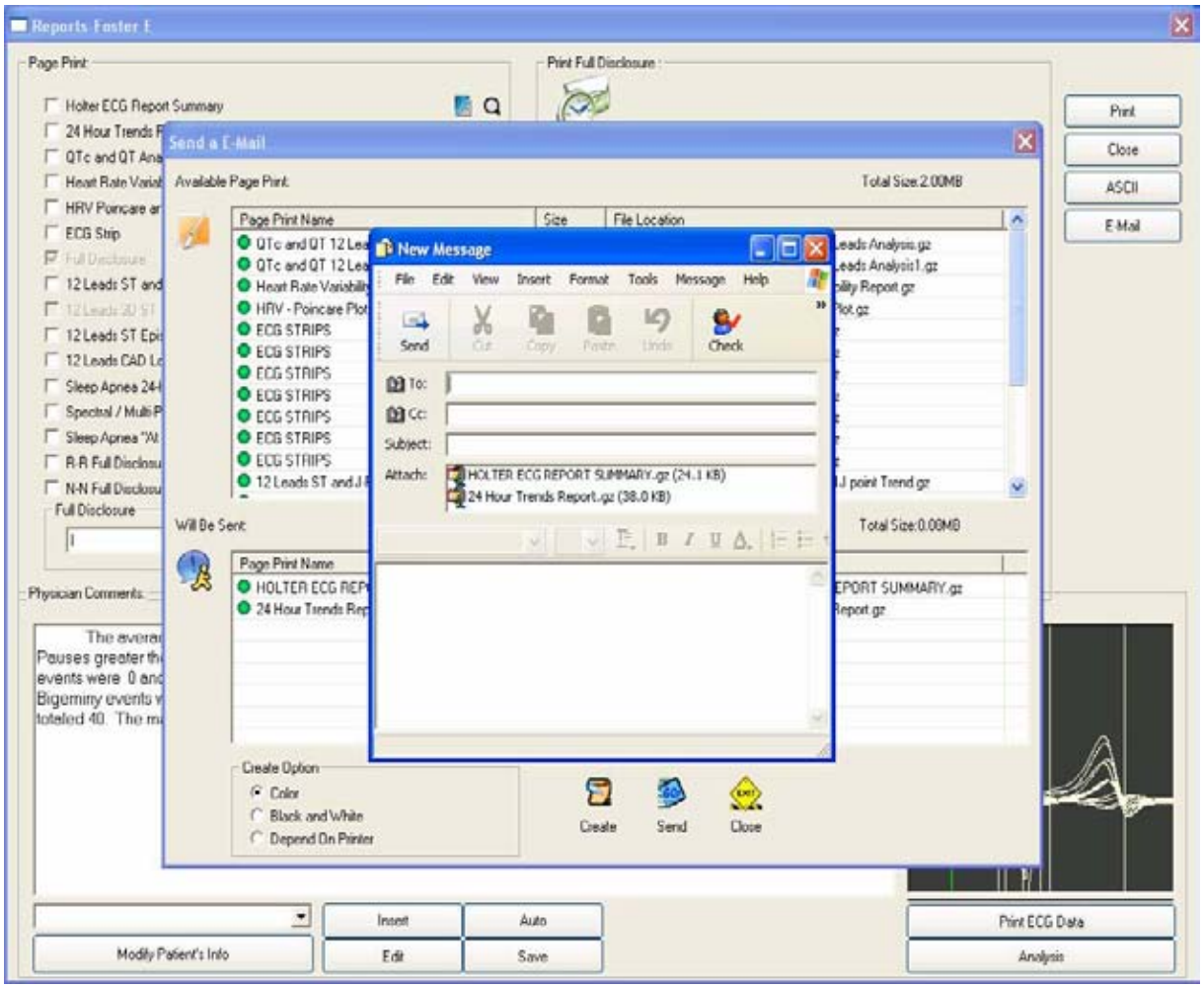


All pages of the Holter report will appear in the top half of the screen.

To select the page you desire, click on the page and then click on the green Down arrow in the center of the screen. This will move the selected page of the report into the Send area. If you make a mistake and add a page you do not want, click on the page in the Send area and then click on the green Up arrow in the middle of the screen.

Once you have selected all of the pages you wish to send, you can choose if you want the page to be sent in color or black and white. On the lower left side of the screen, click on either Color, Black and White or Depend On Printer for the selection.

After selecting the pages and printer, click on Send. The following screen will appear.



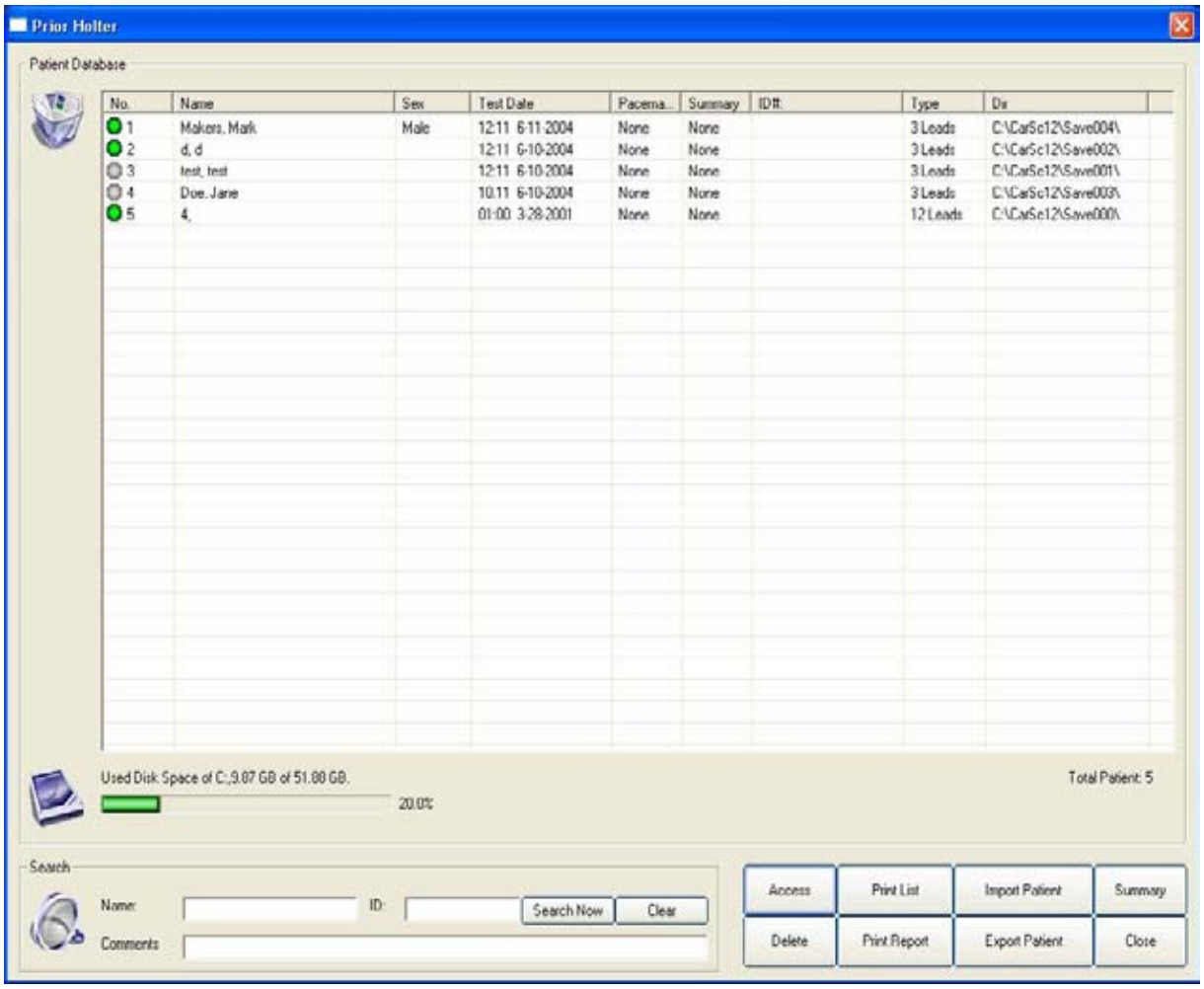
Enter the recipients address in the To: field. You may enter a note in the bottom half of the screen or type in the subject matter at the Subject: field.

To send the e-mail and report, click on the Send icon in the upper left side of the screen.

PRIOR MENU

The purpose of the “Prior” menu is to be able to store Holter recordings and to have instant access of saved Holter recordings. If you selected Yes for the Auto Save in the “Settings” menu, then all of the recordings will automatically be saved in the “Prior” menu. If you selected No for the Auto Save in the “Settings” menu, then only the last Holter recording processed will be saved.

To access the “Prior” menu, point and click on Prior at the main CardioScan 12 screen.

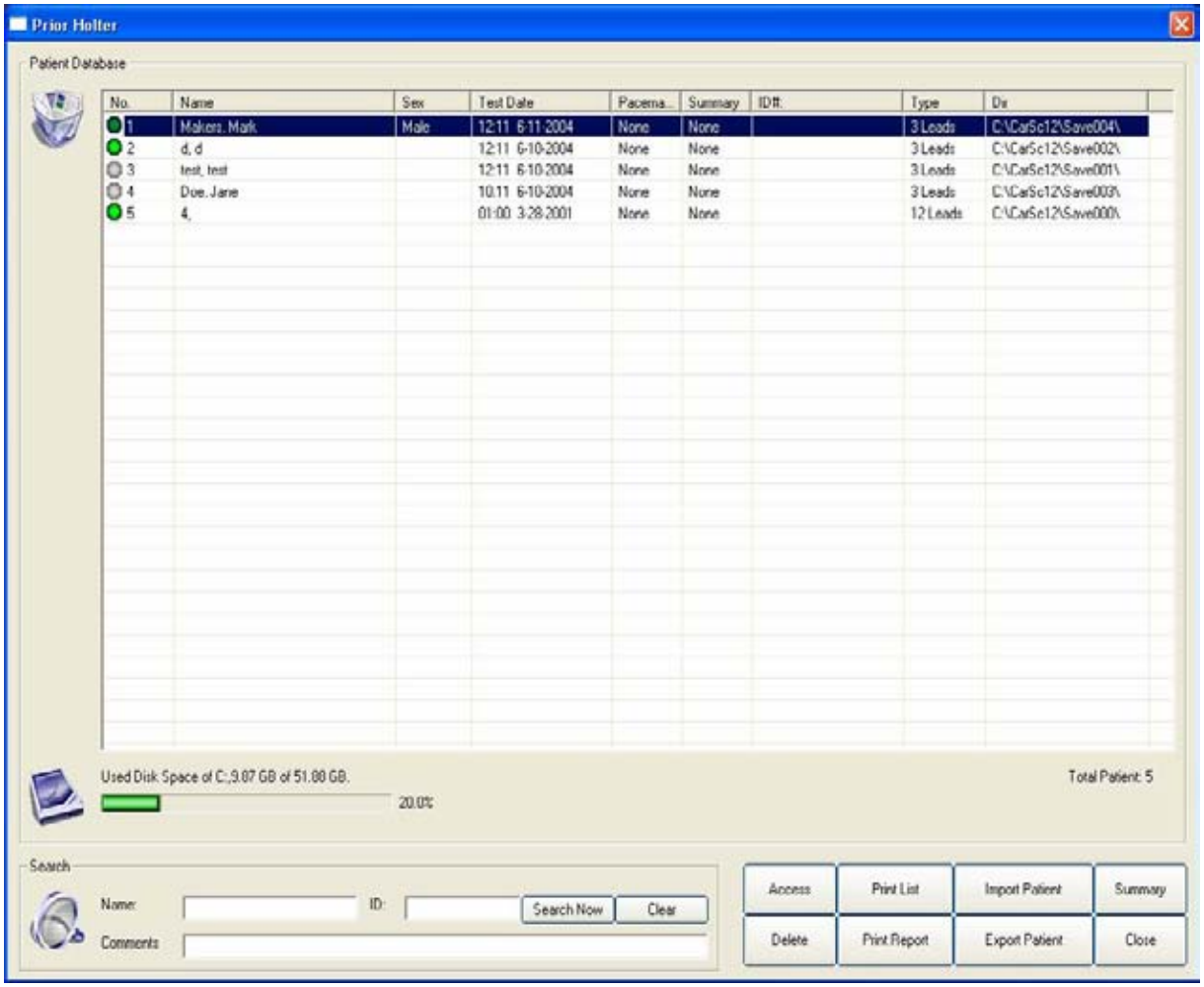


The Patient Database shows you the name of the patient saved, the sex of the patient, the test date and start time, if the recording was a pacemaker study, if it is a Summary Report only, the patient's identification number (if you entered one when entering the patient information at the beginning of the scan), and the directory that the Holter study is saved in. Up to 999 patients can be stored in the PRIOR menu.

On the far left side, under the No. category, you will see a page icon for each patient that is colored gray or green. The green color indicates that the Holter file has been edited.

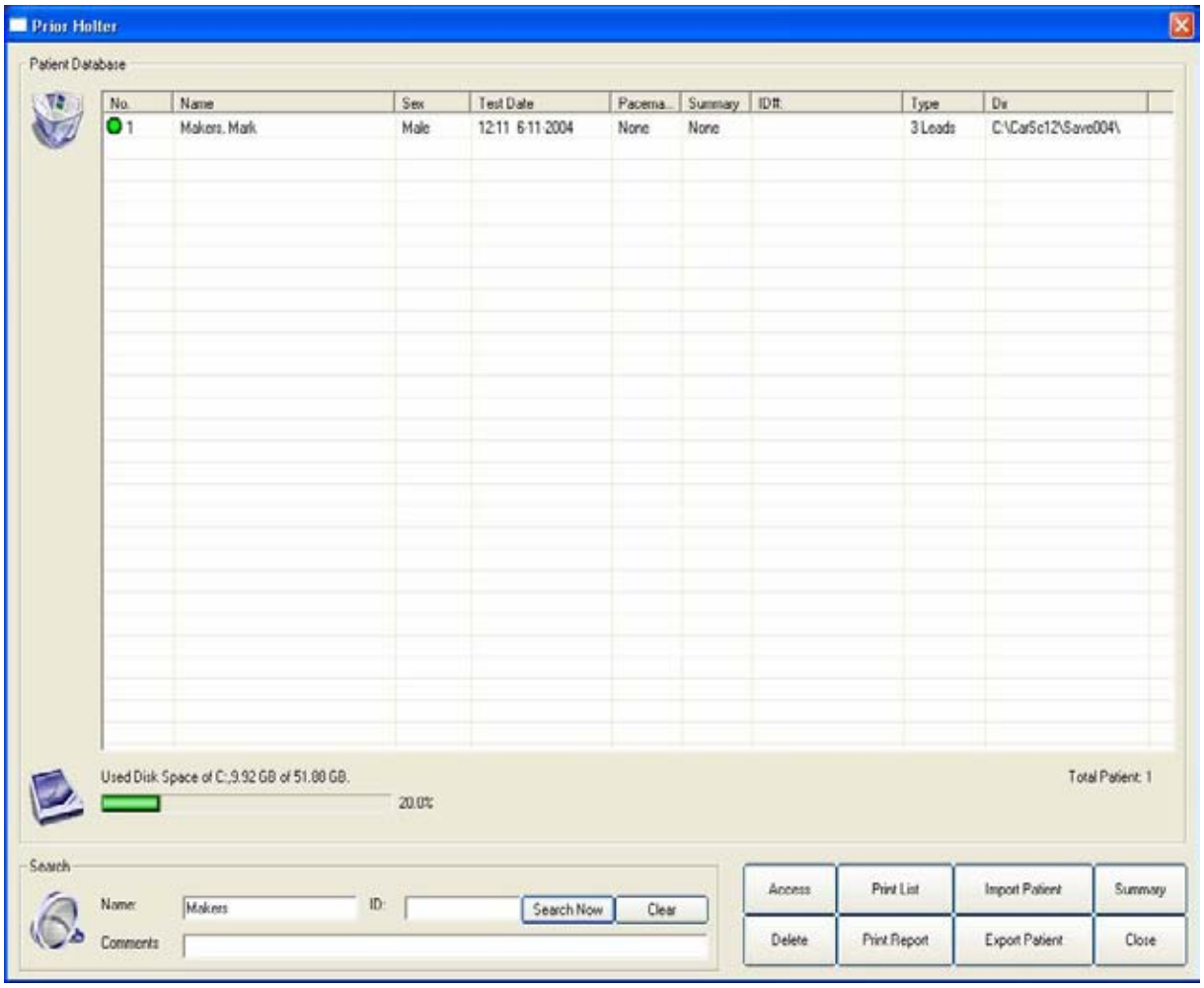
Below the Patient Database an indicator shows how mush disk space is available.

To access a patient's entire Holter study, point and click on the patient's name. A blue highlight bar will appear over the patient's name and information.



Double click on the patients name or click on the Access bar at the bottom of the screen. You will be taken to the Data Access Choices screen of that patient's Holter study.

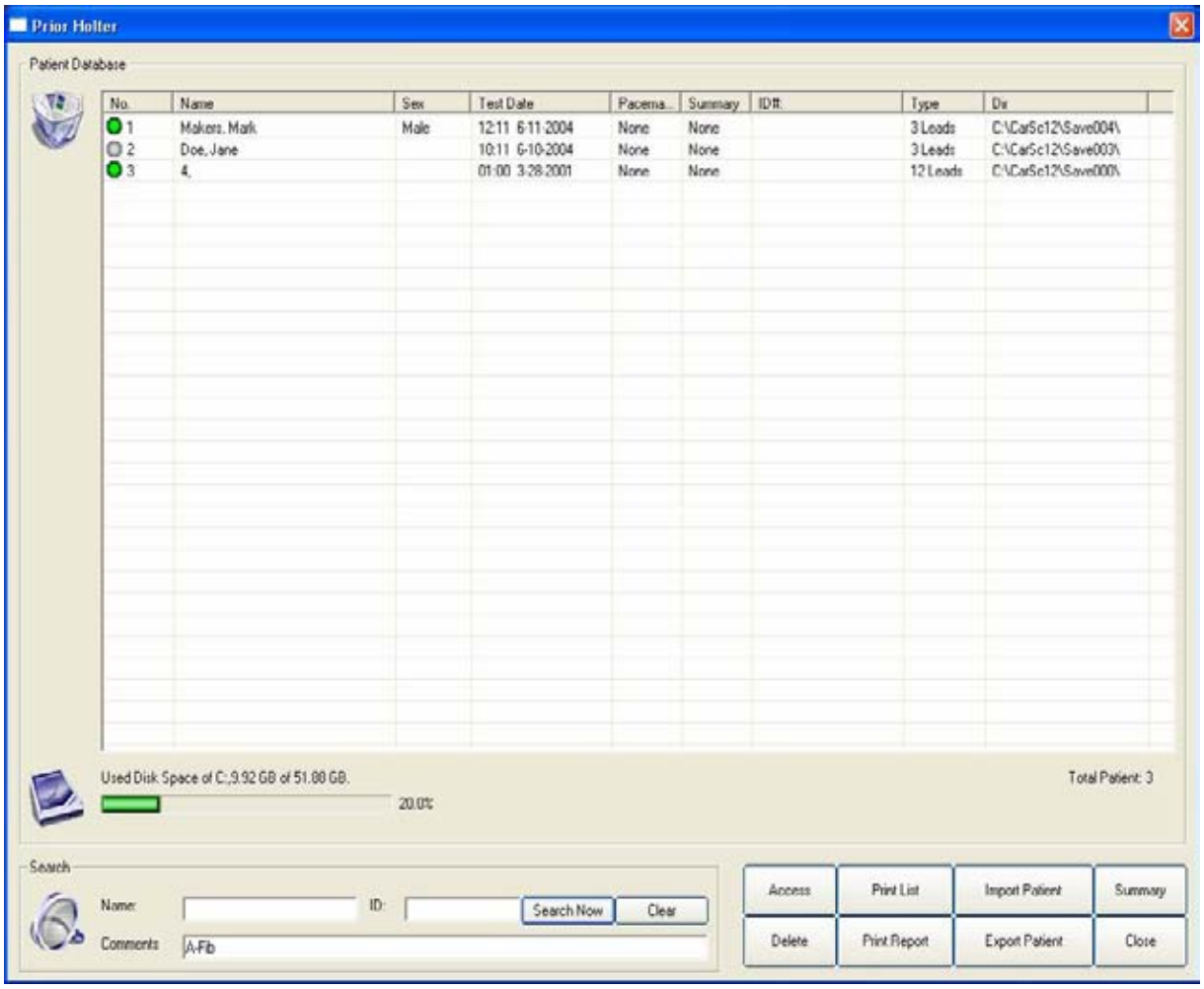
From this screen you may edit and/or retrieve any of the data from this Holter study. To return to the Prior menu, close out the Data Access Choices box by clicking on the X in the upper right hand corner of the Data Access Choices box.



Another way to access a patient's Holter study is to use the Search option.

Type the patient's name and click on the Search Now bar at the center bottom of the screen. All studies that have been saved with this patient's name will appear on the screen. To access the patient's Holter study, double click on the patient's. If there are multiple studies with the same name, verify the date of the study and double click on the study that corresponds with the patient's name and the date desired.

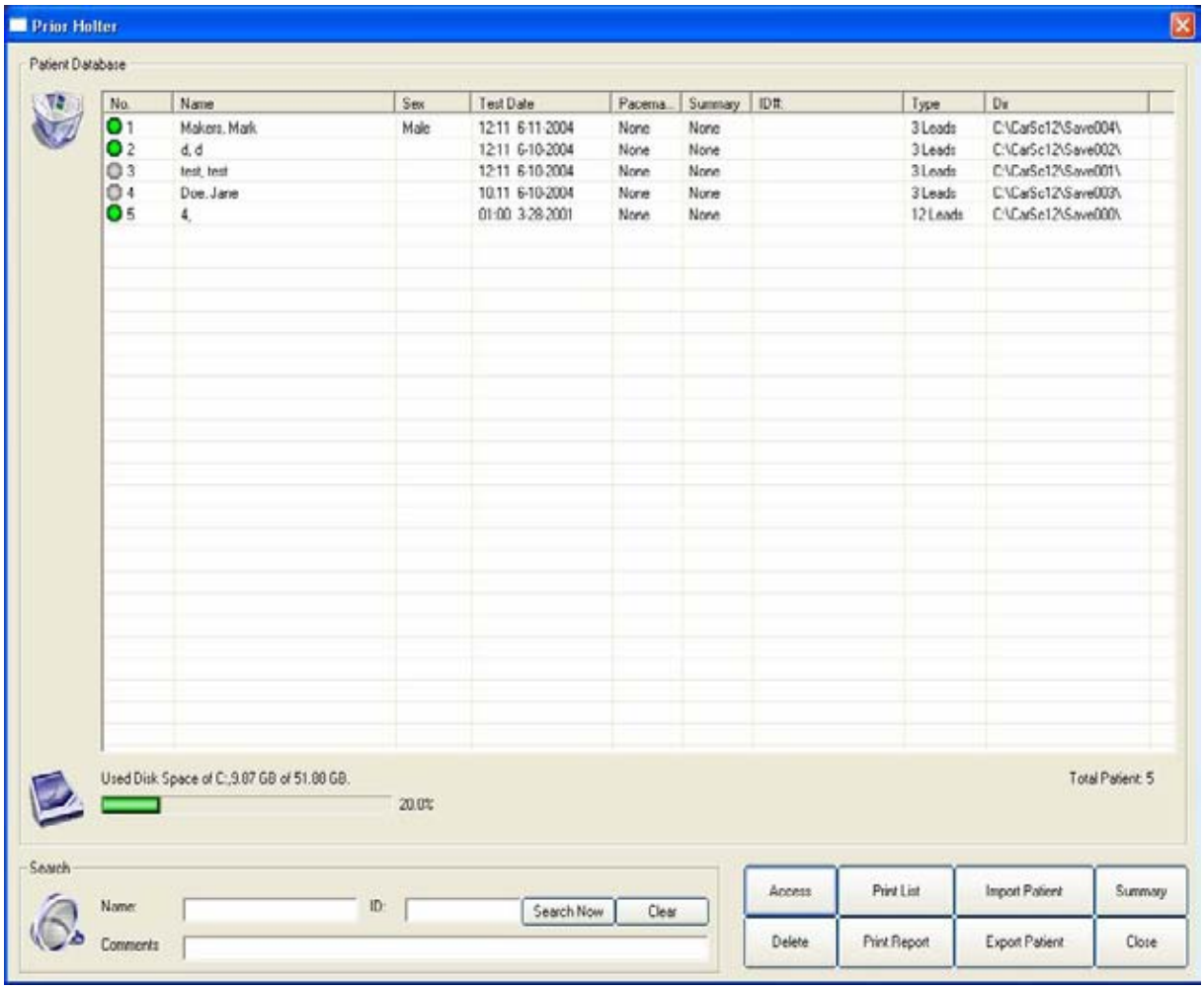
If you have assigned the patient's identification numbers when you initially entered the patient data, you may access the Holter study by entering the identification number in the ID field and then click on the Search Now bar at the center bottom of the screen. The studies that have been saved with this patient's identification number will appear on the screen. To access the patient's Holter study, double click on the patient's name. If there are multiple studies with the same identification number, verify the date of the study and double click on the study that corresponds with the patient's identification number and the date desired.



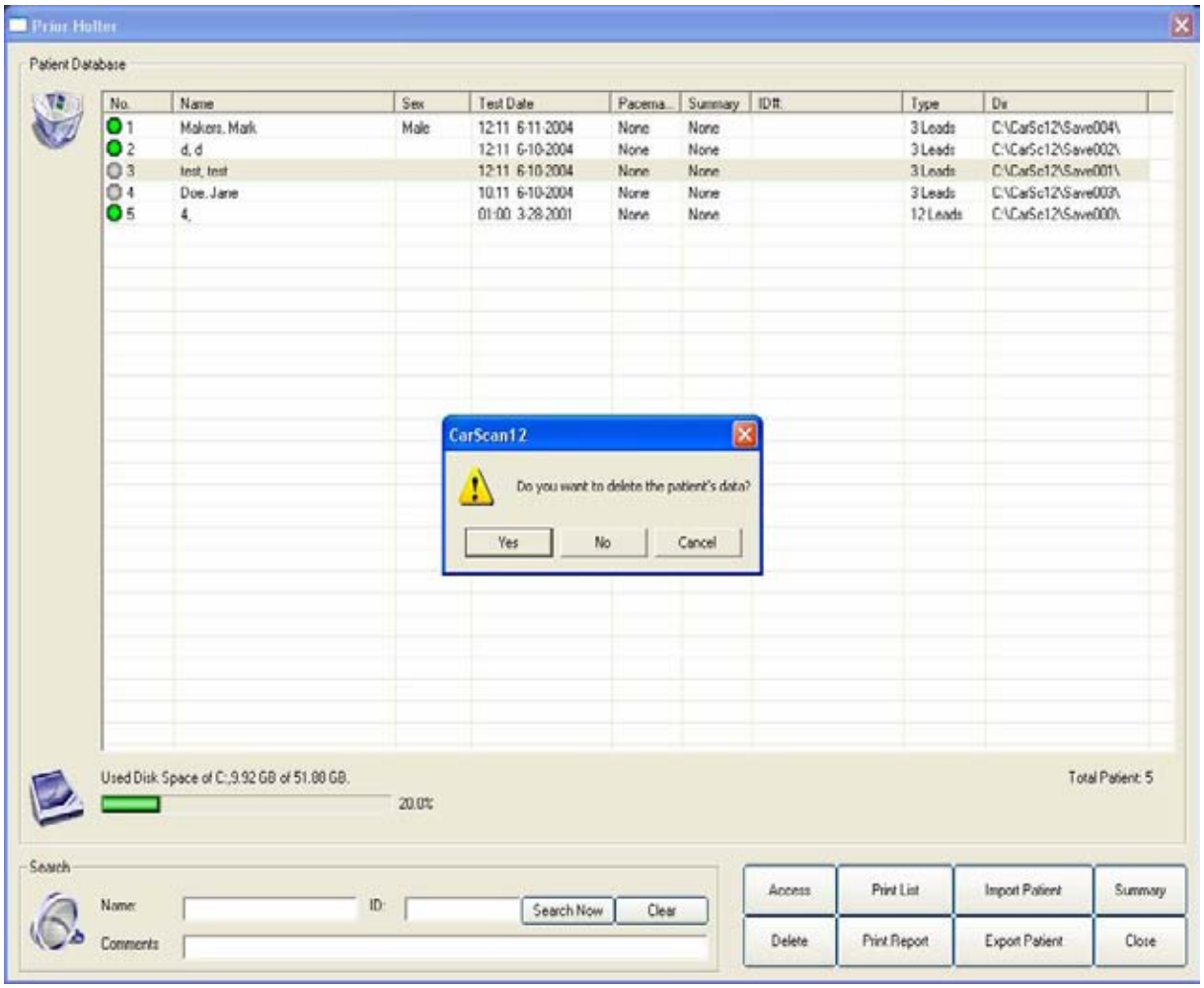
Another way to access a patient's Holter study is to use the Comments option. If you used the identification tag feature when you edited the report, you may enter the identification tag in the Comments field under Search.

Point and click your mouse in the Comments field and enter the identification tag. Click on the Search Now bar at the center bottom of the page. All Holter studies that have this identification tag in the Physician Comments section of their Holter report will be shown on the screen. To select the patient's study you desire, double click on the patient's name.

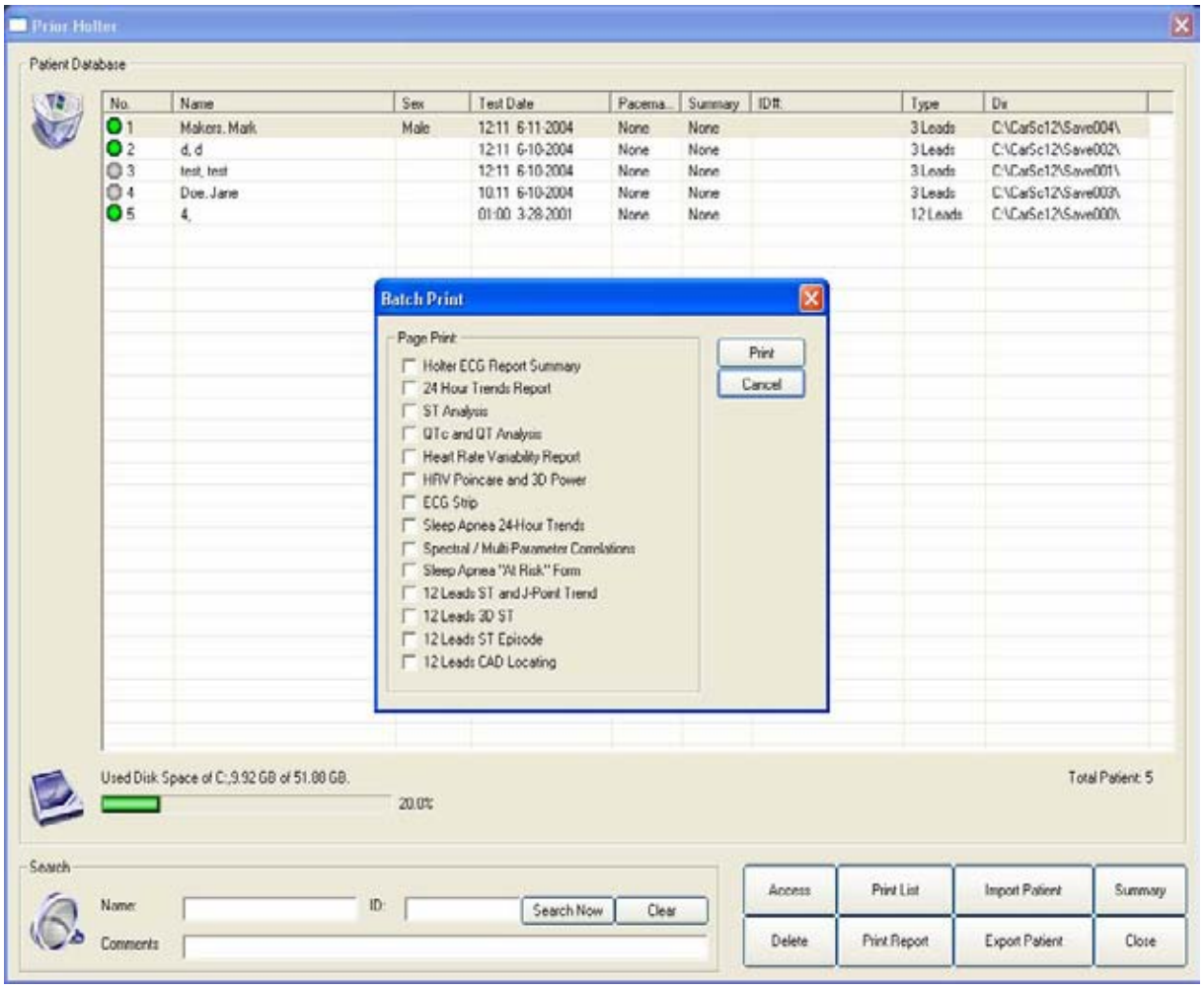
This feature is also useful if the doctor desires to see all of the patient's studies done that have a certain ailment, such as V-Tach, A-Fib, etc. By following the above instructions you will be able to call up all of a particular type of study with just a few clicks of the mouse.



To print a list of all the patients in the Patient Database, point and click on the Print List bar at the bottom of the screen. Click on OK for your printer and the list will print out.

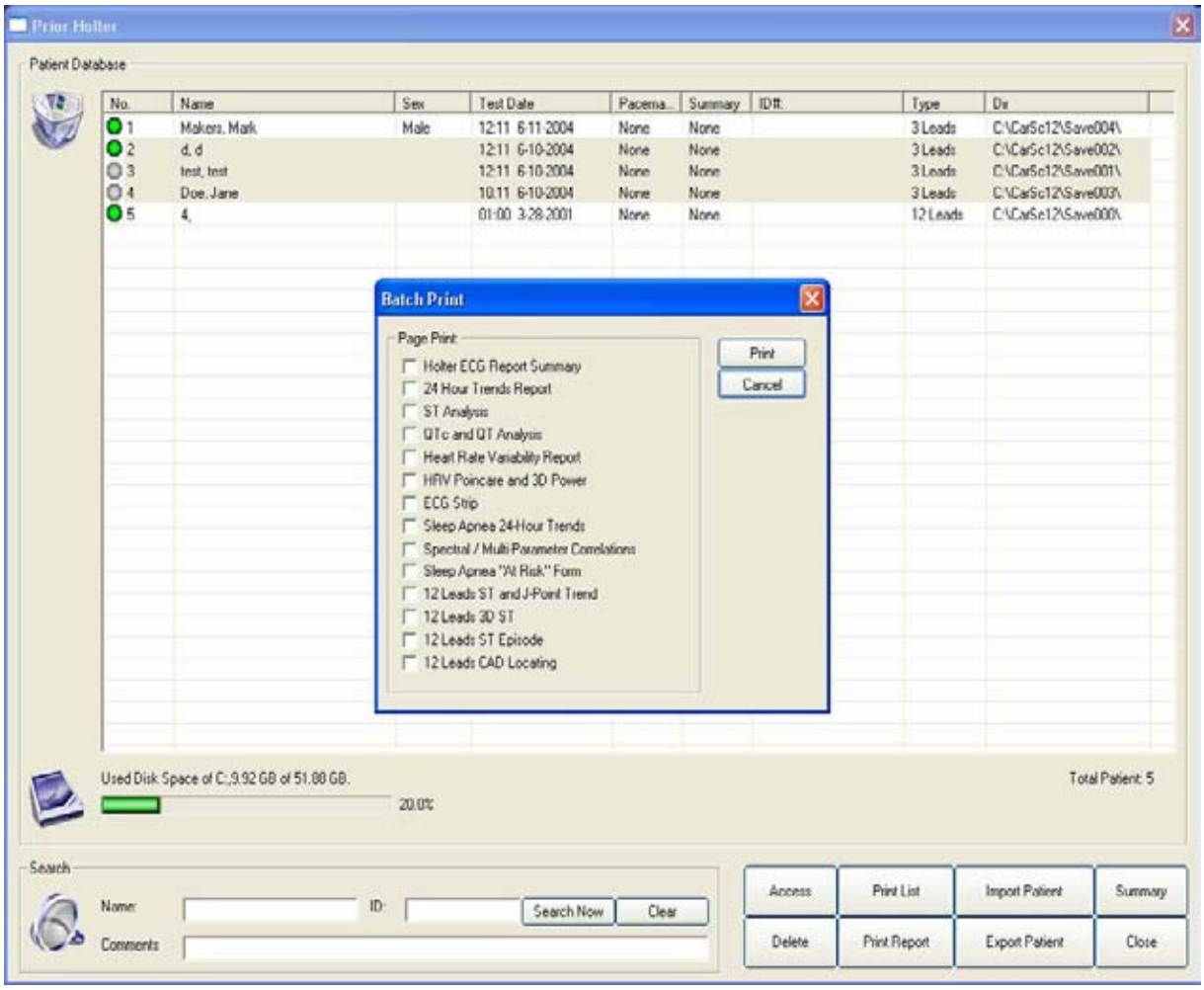


To delete a patient's study from the Patient Database, point and click on the study you wish to delete. A blue highlight bar will appear over the study. Point and click on the Delete bar at the bottom of the screen. A prompt will appear on the screen asking you if you wish to delete the patient's data. Click on Yes if you want to delete the patient's study, click on No if you decide you do not want to delete the patient's study or click on Cancel to cancel the action.



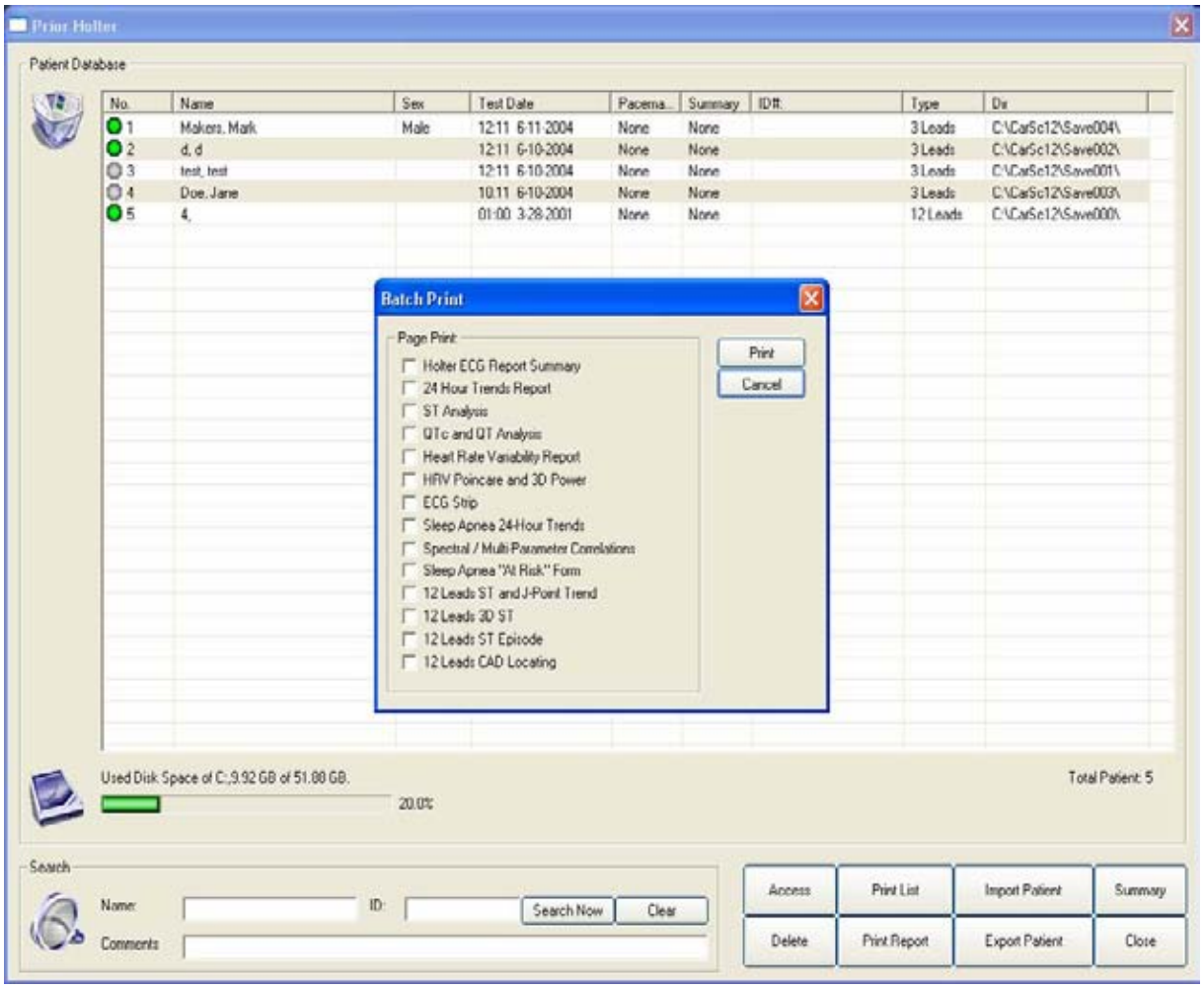
To automatically print a report of a patient's Holter study from the Patient Database, point and click on the patient's report you wish to print. A blue highlight bar will appear over the study you have selected. Click on the Print Report bar at the bottom of the screen. A Batch Print menu will appear.

Point and click on the boxes next to the pages of the report you wish to print. A check mark indicates a page will print. To deselect a page, point and click again on the box next to the page you wish to deselect. The check mark will disappear. After you have selected all the pages you wish to print, click on the Print bar. The printer prompt will appear on the screen. Click on OK. The report will then print out.



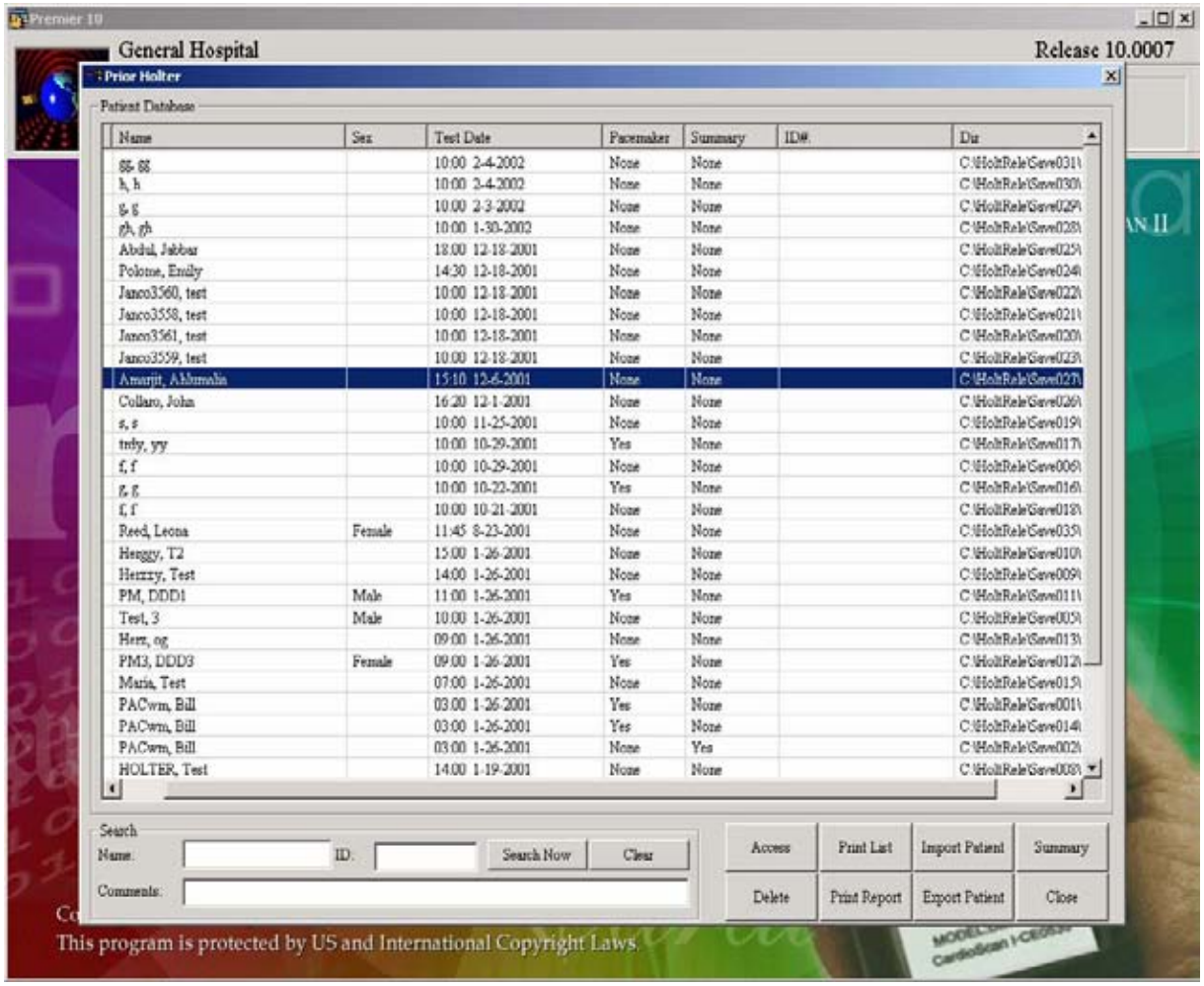
To Batch Print multiple reports, click on the name of the first name of the patient you desire. Hold down the Shift key on the keyboard. Click on the name of the last patient on the list you desire. Release the Shift key on the keyboard. The first patient you selected and the last patient you selected will be shaded in gray, as well as all the patients in between. These patient's reports will be included in the Batch Print.

Click on the Print Report button at the bottom of the screen. The above Batch Print menu will appear on the screen. Select the pages of the reports you want to print out by clicking in the box next to the report page you desire. A black check mark will appear, indicating the report page will be printed. To de-select a page, click on the box again and the check mark will disappear. After you have selected the report pages you want to print out, click on the Print bar in the Batch Print menu. The reports will print out.



To Batch Print multiple, isolated reports, click on the name of the patient's report you desire. Hold down the CTRL key on the keyboard. Continue to click on the names of the patient's report you desire. After you have click on the last patient your desire, release the CTRL key on the keyboard.

Click on the Print Report button at the bottom of the screen. The above Batch Print menu will appear on the screen. Select the pages of the reports you want to print out by clicking in the box next to the report page you desire. A black check mark will appear, indicating the report page will be printed. To de-select a page, click on the box again and the check mark will disappear. After you have selected the report pages you want to print out, click on the Print bar in the Batch Print menu. The reports will print out.



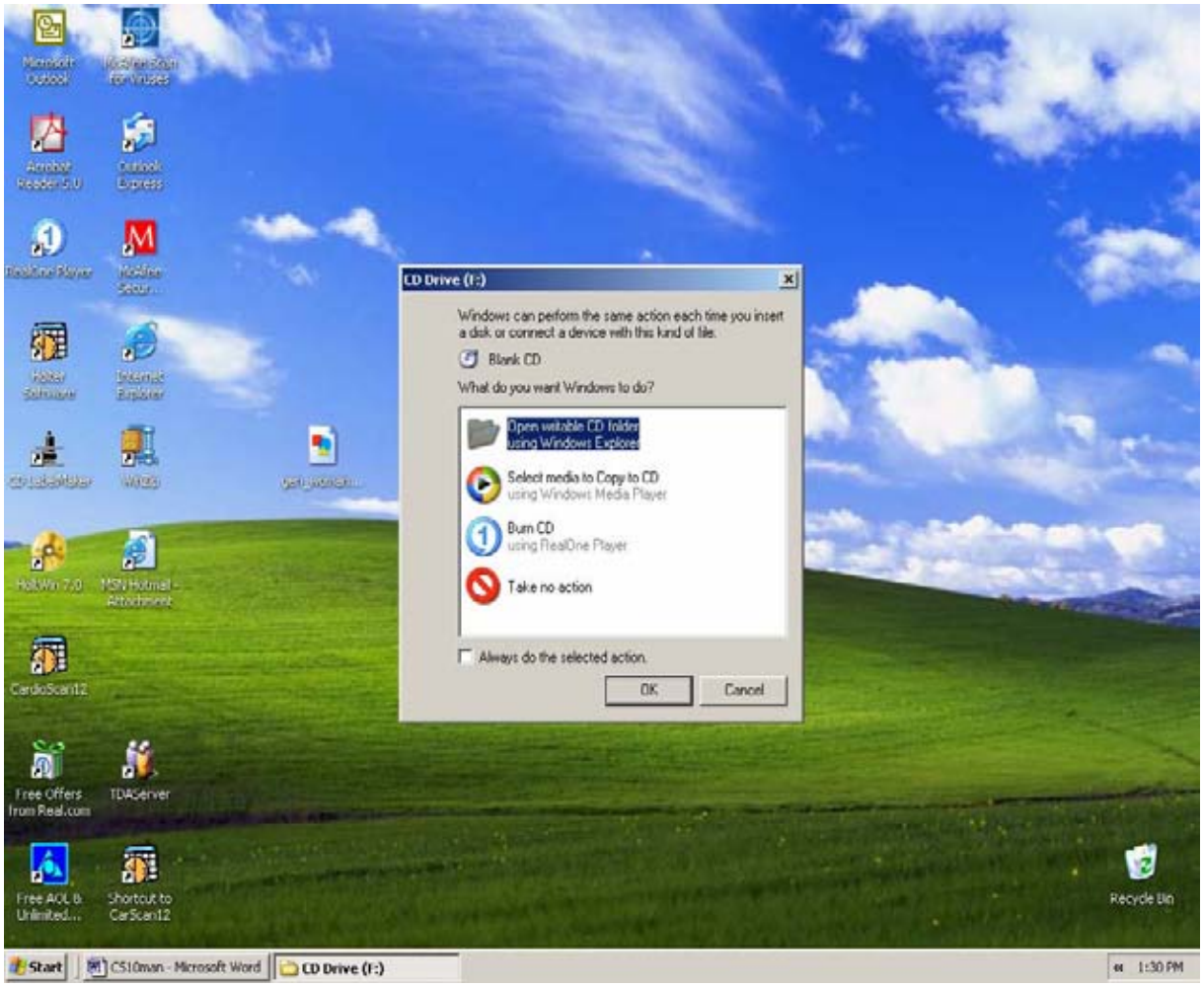
Prior to exporting data to a CDR, verify the patient Holter studies you wish to transfer are in the Patient Database. Note the patient's names and directory the study is saved under. To see the full directory name the patient's study is saved under, click on the right arrow on the bottom of the screen until the entire directory name is shown. Make a list of the patient's names, study dates and full directory names you wish to copy to the CDR.

Prior to exporting patient data to a CDR, you must have a CDR-W installed in the computer along with its driver (The driver is supplied by the manufacturer of the CDR-W. Do not use any driver other than the manufacturer's driver supplied with your CDR-W).

The CDR disk that you want to export the patient studies to must be formatted. To format a CDR disk using the Adaptec Easy CD Creator 4 Deluxe Program, do the following:

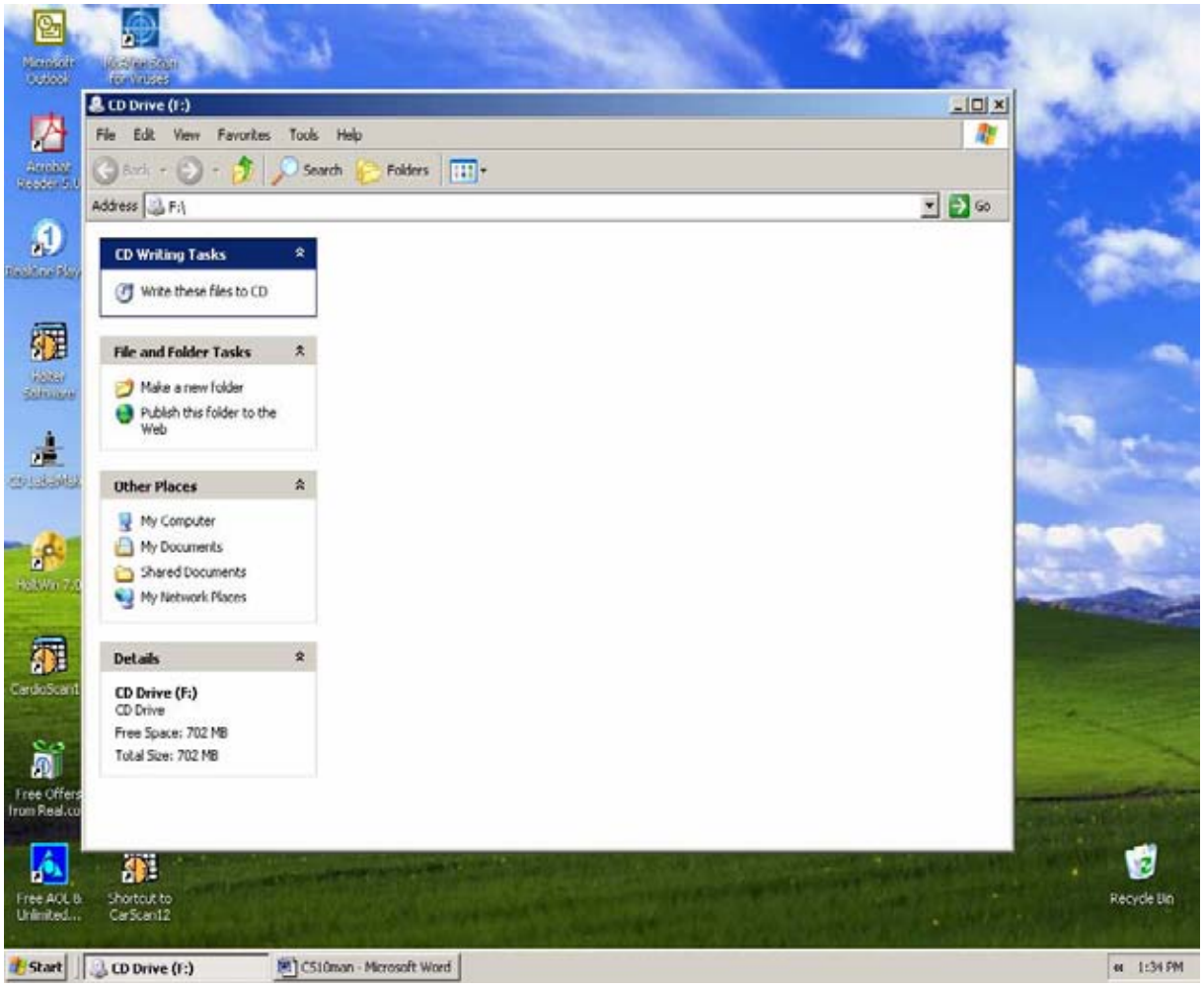
1. Insert a blank CDR in the CDR-W drive. The Adaptec program will come on the screen.
2. Click on the DATA bar of the main menu that appears on the screen.
3. Click on Direct CD.
4. Type in CarSc12 for the name of the disk and then click on FINISH.
5. A message will appear on the screen to let you know the CD is ready for copying. Click on OK.

NOTE: If you are not using the Adaptec software, please follow your software manufacturer's directions on how to format a CDR.

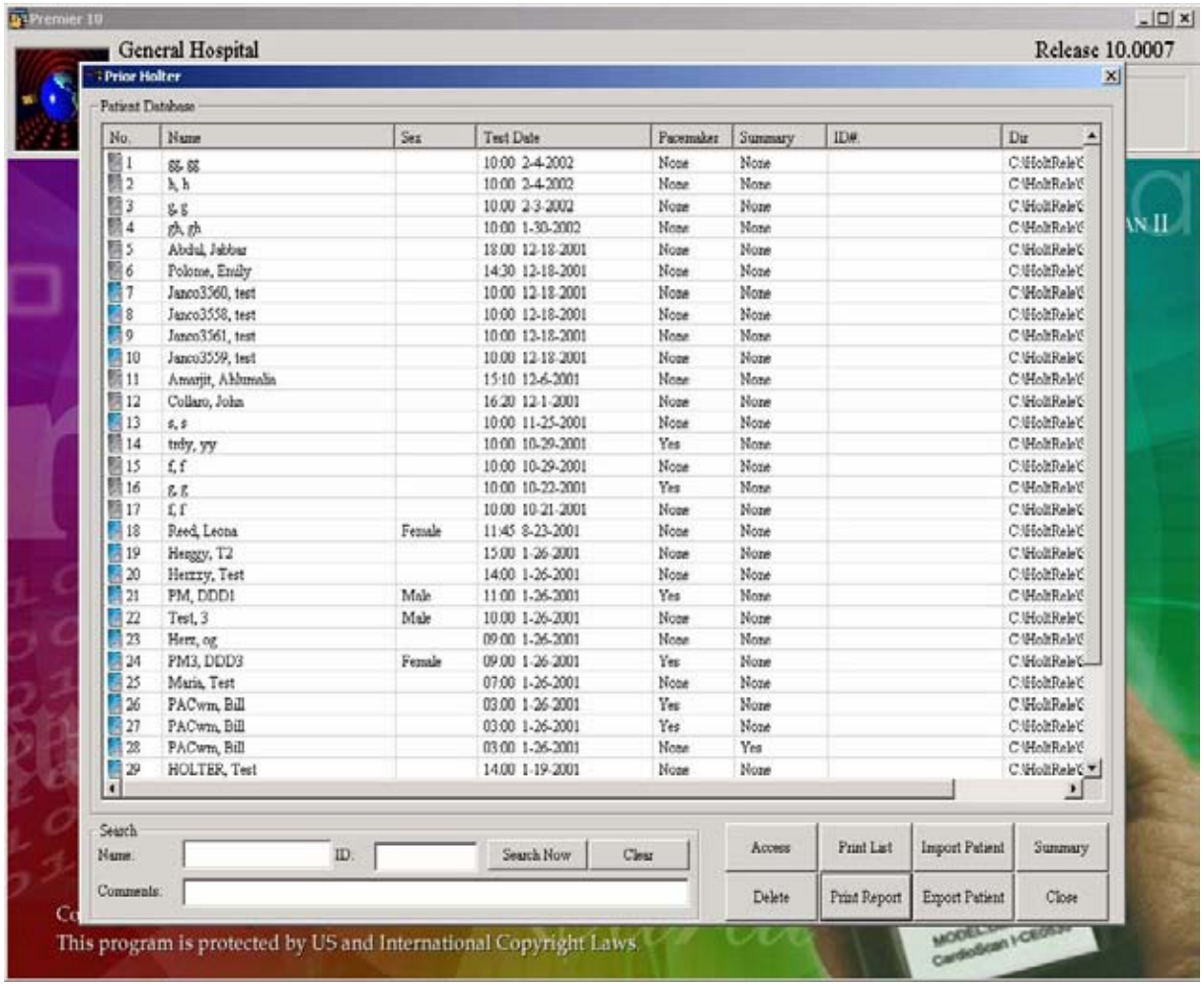


If you are using Windows XP, insert the CD into the CDR drive. The above pop up box will appear on your screen.

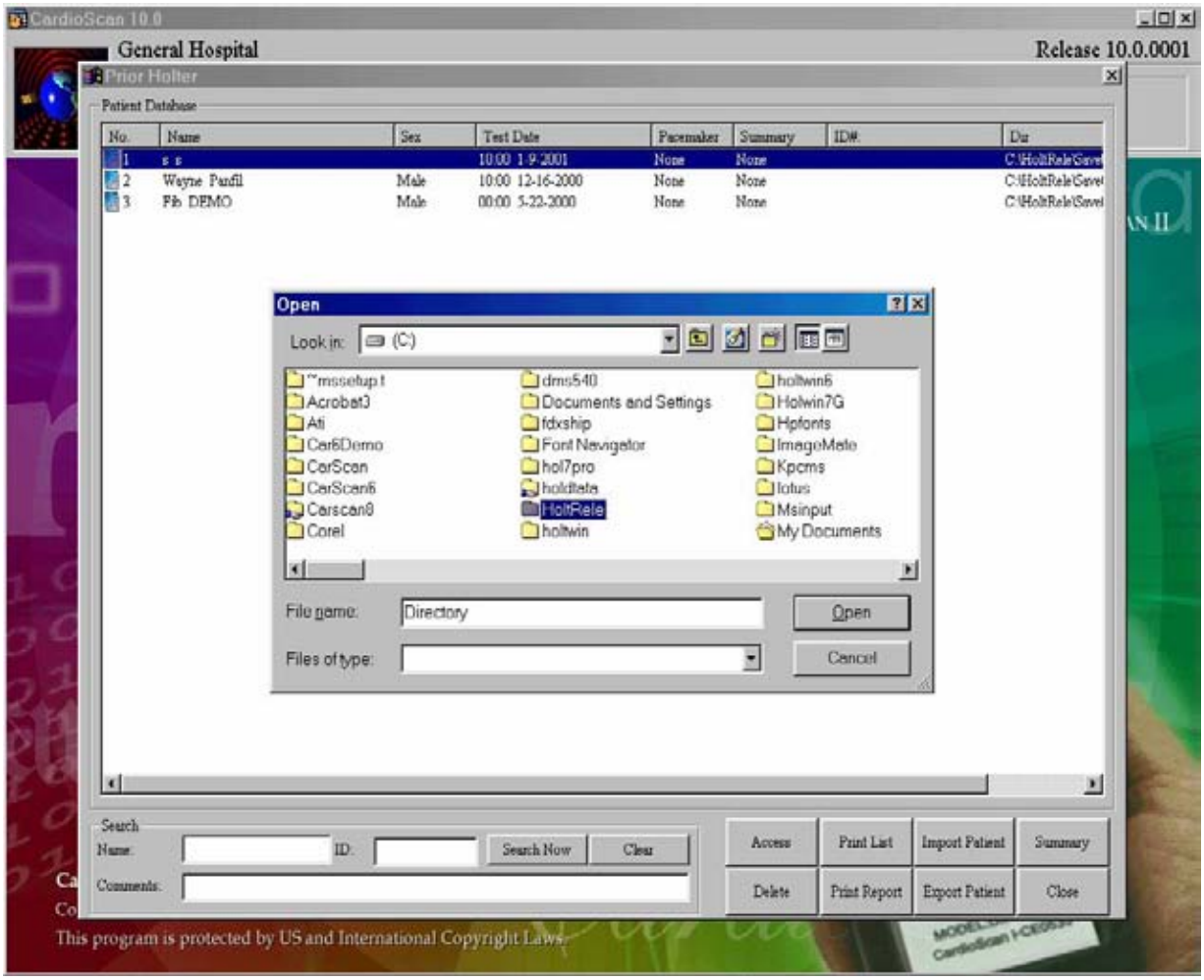
Click on “Open writable CD folder using Windows Explorer.” Click on OK.



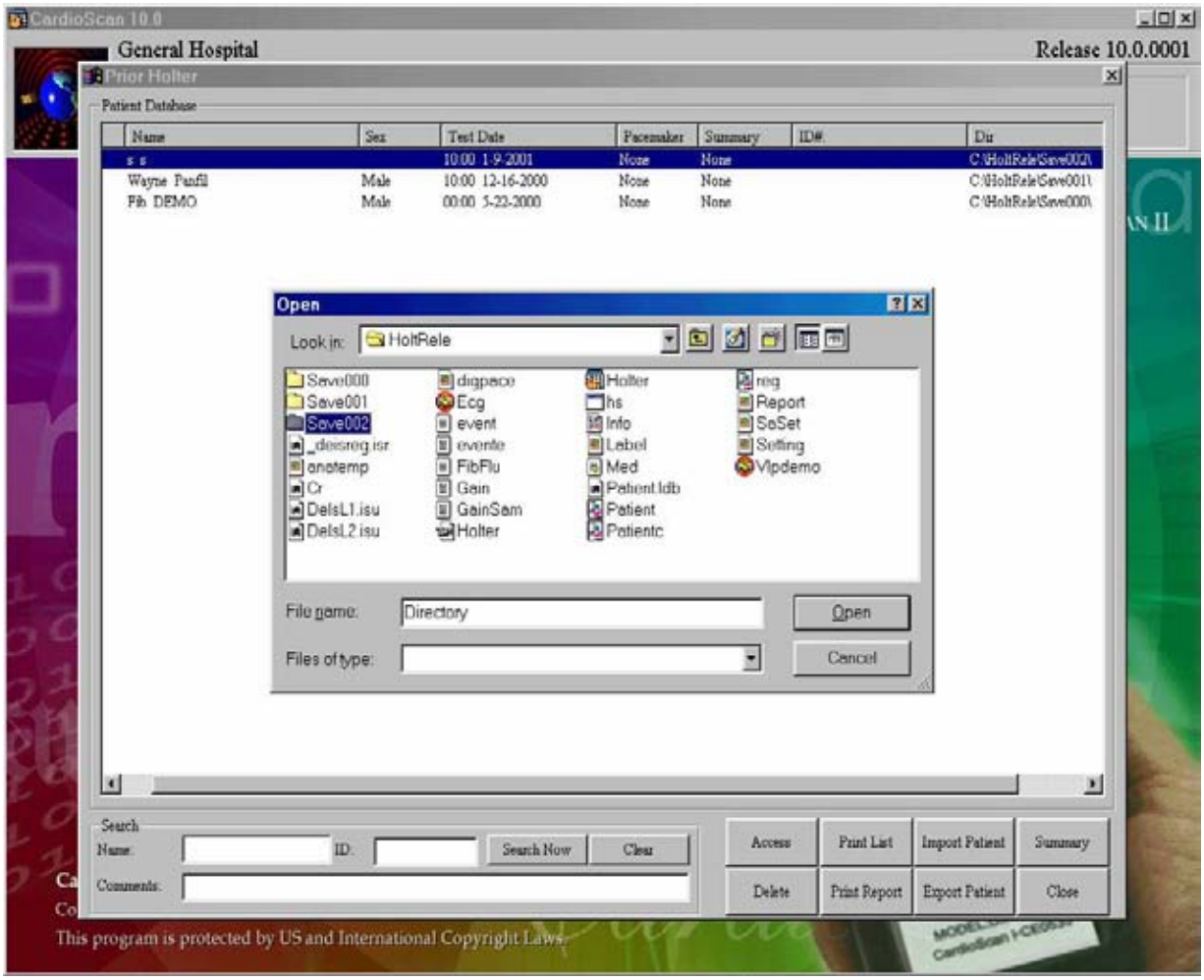
The above screen will appear, showing that there are no files on the CD. Click on the – sign in the upper right hand corner to minimize this screen display. Double click on the Holter icon. Click on the Prior icon at the top of the Holter screen.



To export a patient's file to the CDR, go to the Patient Database of the Prior menu. Point and click on the study you wish to transfer to the CDR. A blue highlight bar will cover the patient study you have selected. Click on the Export Patient bar at the bottom of the screen. A search screen will appear.

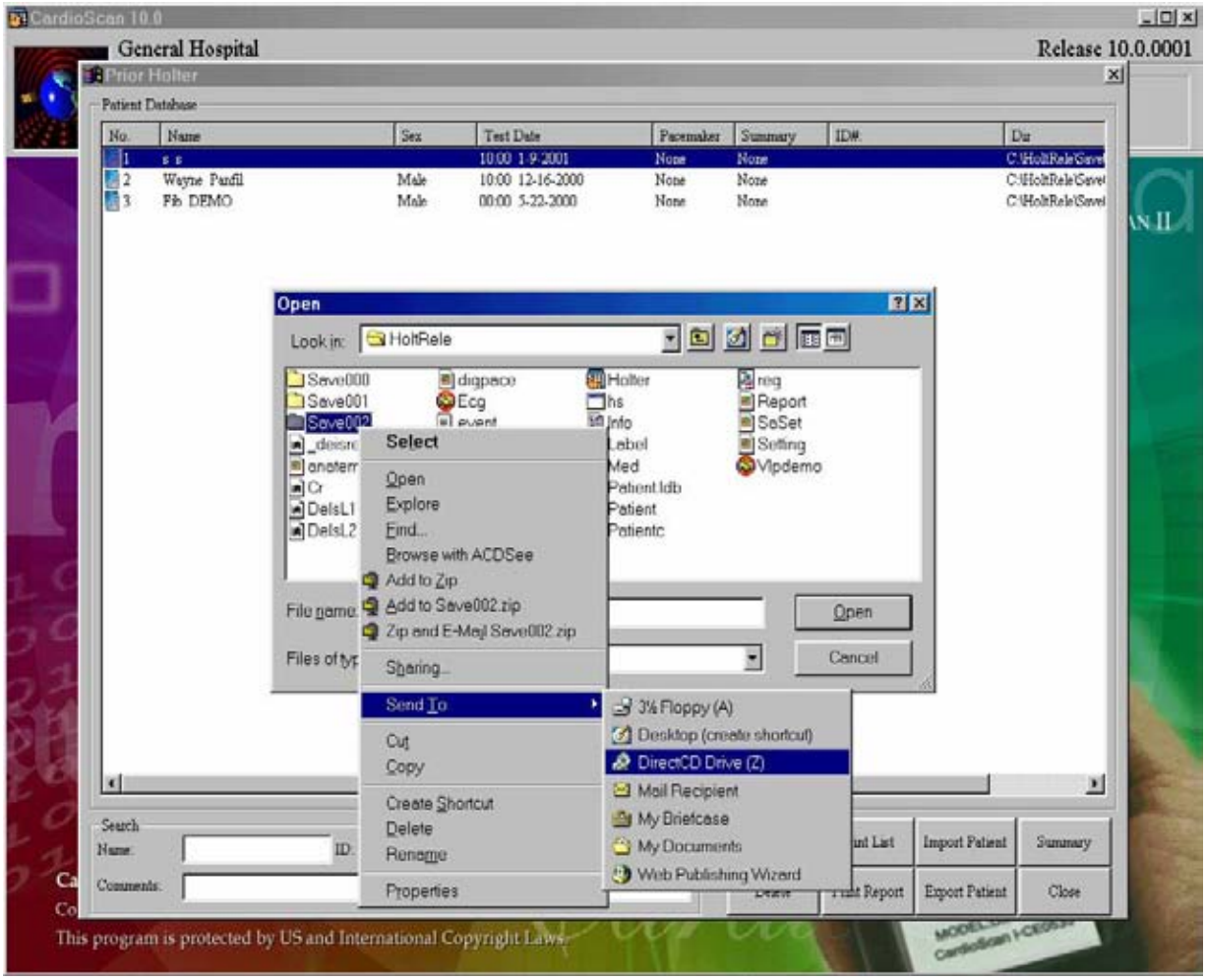


Point and click on the down arrow next to the Look In field. Click on the (C:) drive. Double click on the CarSc12 file.

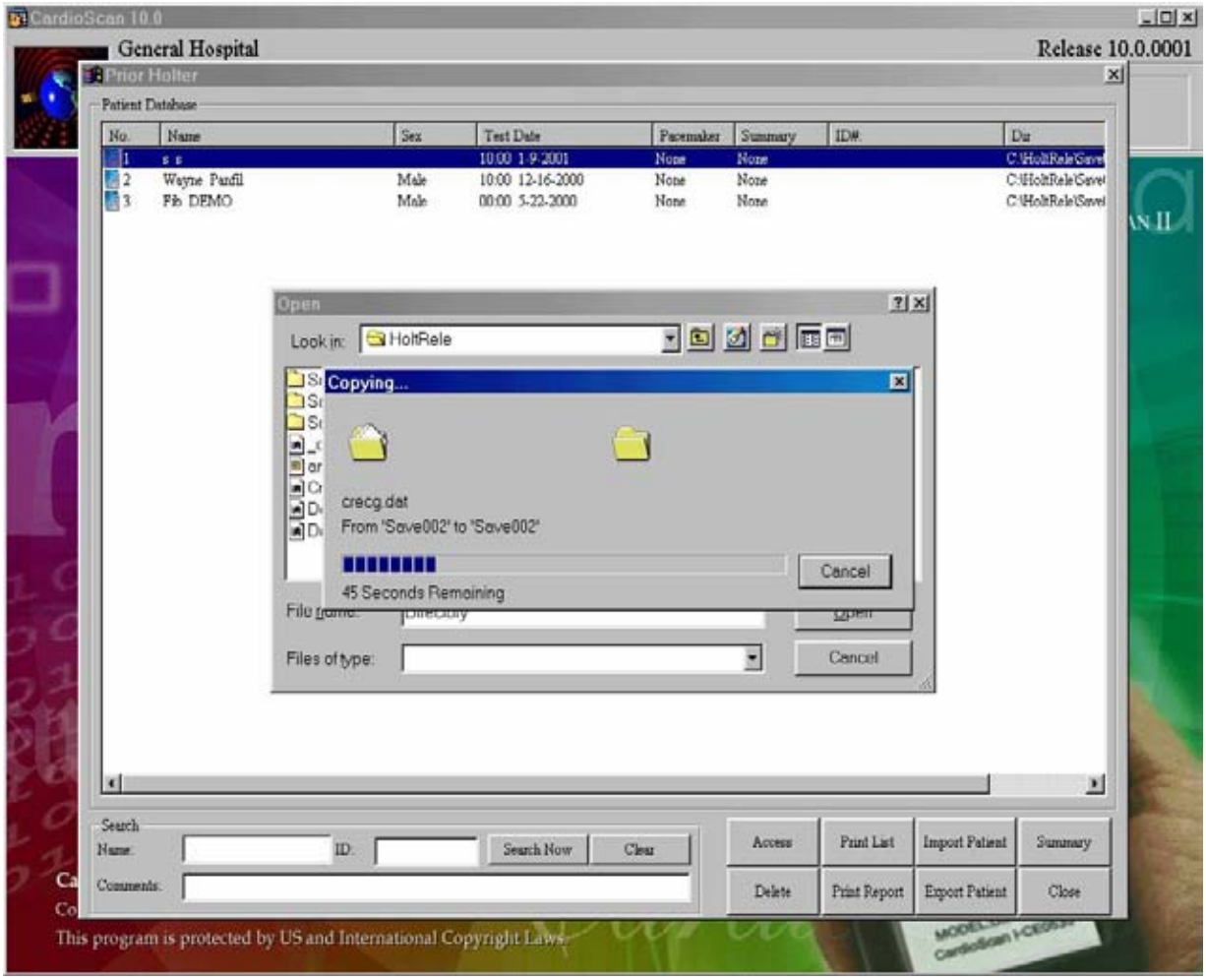


The CarSc12 file will appear on the screen. Right click on the file you wish to move to the CDR.

NOTE: The file name is the last of the full directory name located in the Patient Database. In our example, we wanted to transfer patient S S to the CDR. This patient's full directory name was C:\CarSc12\Save002, so we would select the file that is Save002.

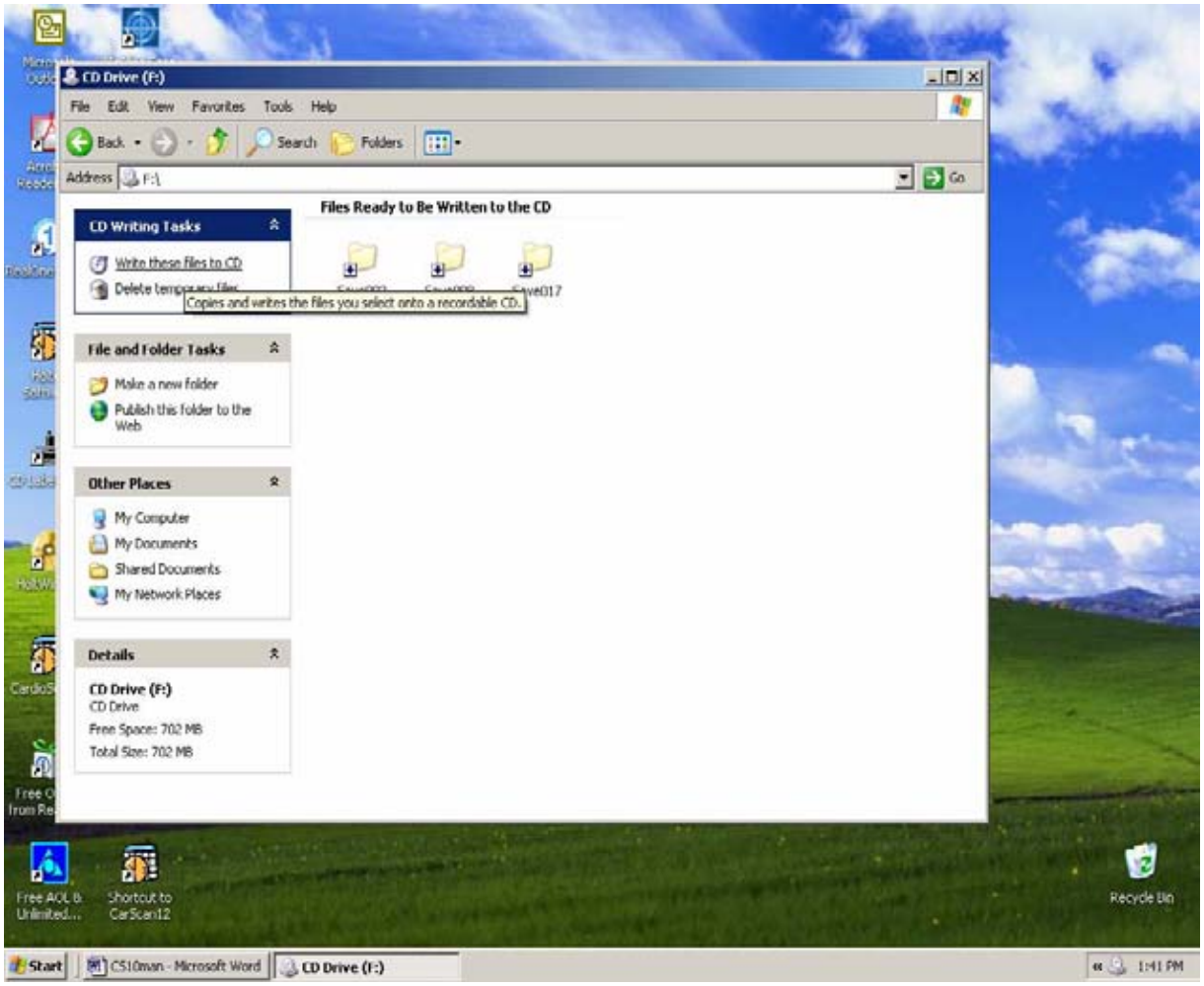


After you have done a right click with your mouse on the file you desire, in this case Save002, another drop screen will appear. Click on Send To. Another drop screen will appear. Click on DirectCD Drive (this is where your CDR is located).



The file will be copied to the CDR. Once the file has been copied to the CDR you will be returned to the CarSc12 file. If you wish to copy other files to the CDR, right click on the file you desire and follow the instructions on the previous page (page 128). The CDR will hold up to 14 Holter studies.

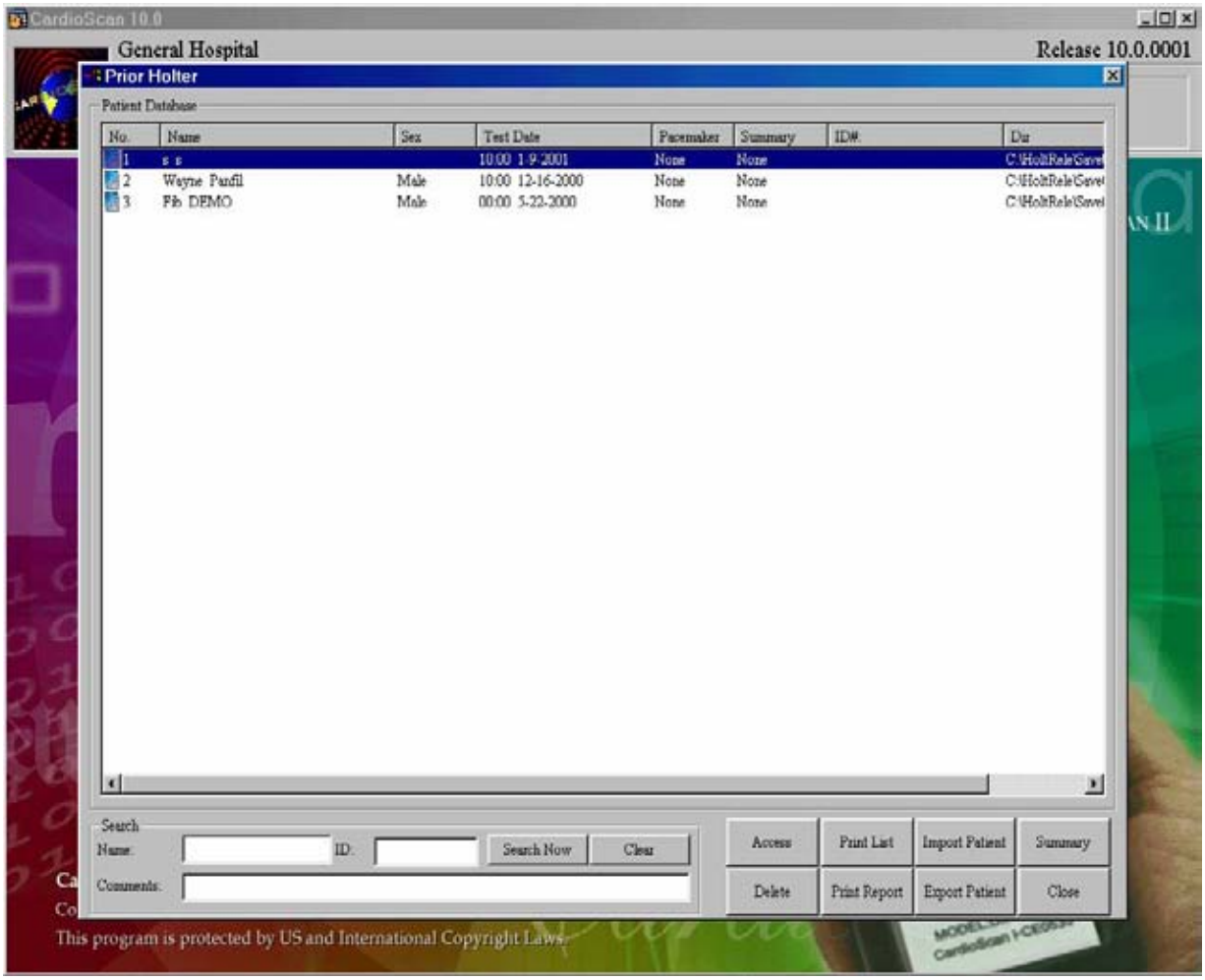
NOTE: Make sure to keep the list of the patient study names and directory names you have copied down with each CDR so you will be able to identify the patients.



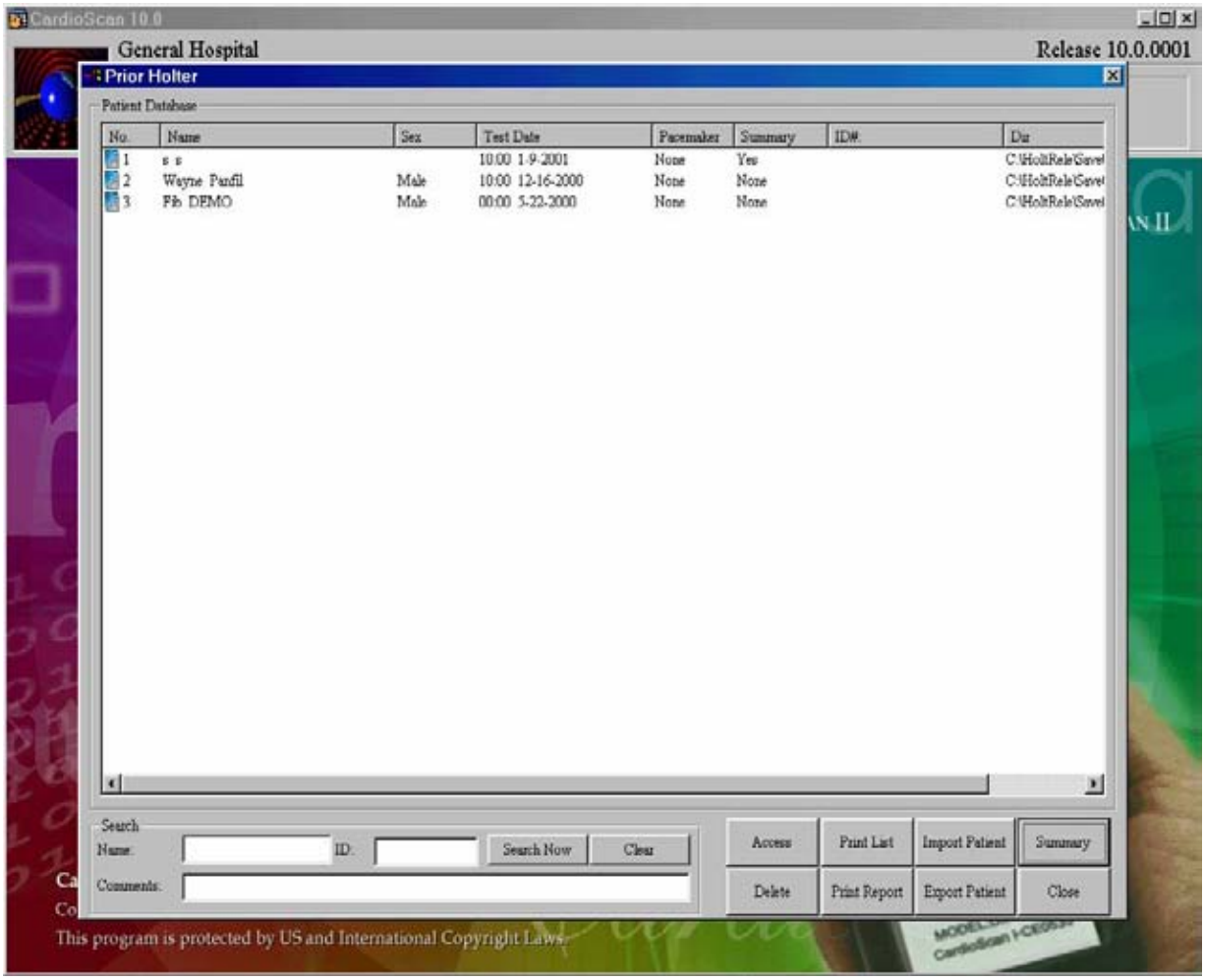
Enlarge the CD drive information by clicking on the CD drive bar at the bottom of the screen. The above screen shows the patient files you have selected to save to the CDR.

Click on “Write these files to CD” in the upper left hand corner under CD Writing Tasks. Enter a name for the CD and click on the Next bar.

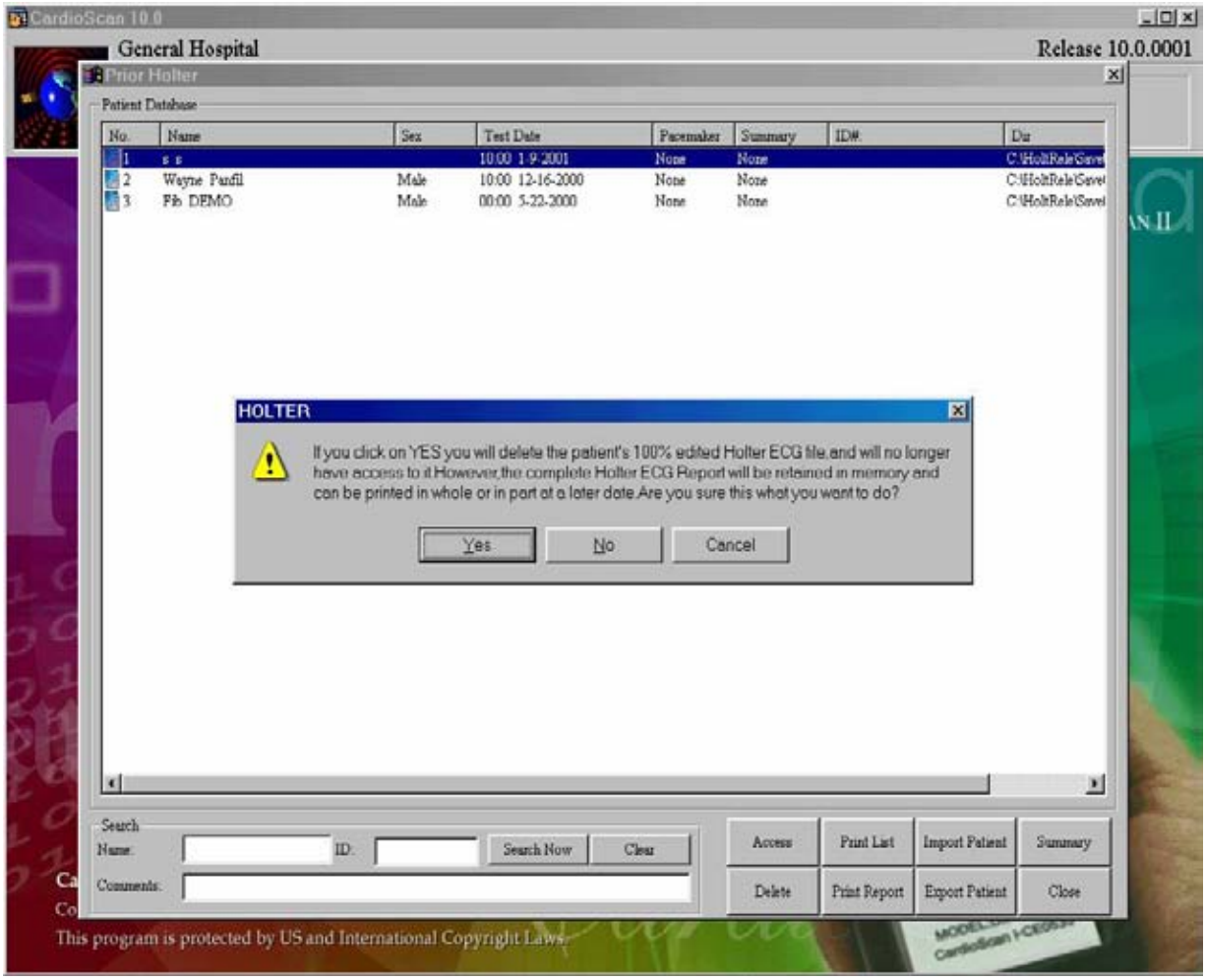
The CD will be ejected once all of the files are copied to it.



After you have copied the files to the CDR you may want to keep only the Holter reports stored in the Patient Database. To keep a Holter report only, click on the patient study you wish to keep only a Holter report on. A blue highlight bar will cover this patient's name. Click on the Summary bar at the bottom right of the screen.



The patient's information line in the Patient Database will now say YES under Summary, reflecting that only the Summary report is stored in the Patient Database.

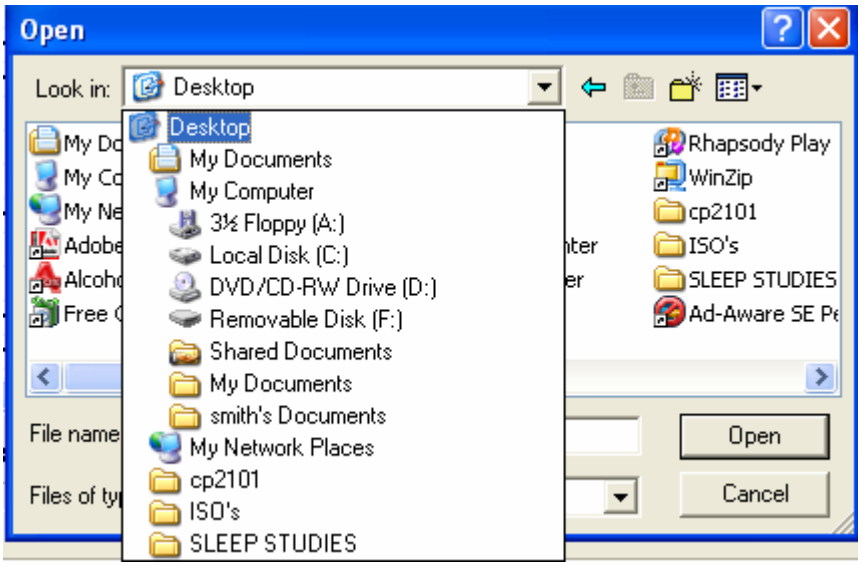


To delete a patient's file, click on the Delete button on the bottom of the screen.

Click on Yes if you wish to delete the patient's 100% edited Holter ECG file and retain the Holter ECG report only.

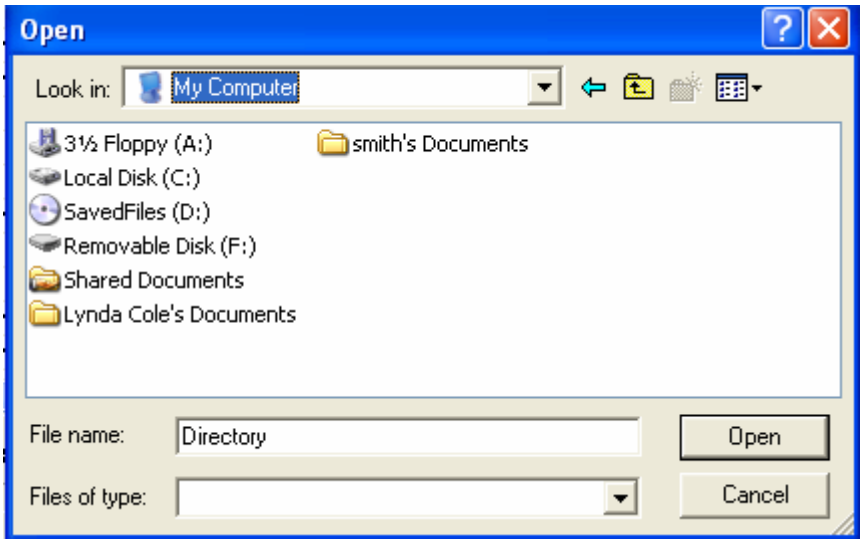
Click on No if you wish to retain the patient's entire Holter study.

Click on Cancel if you wish to cancel this action.



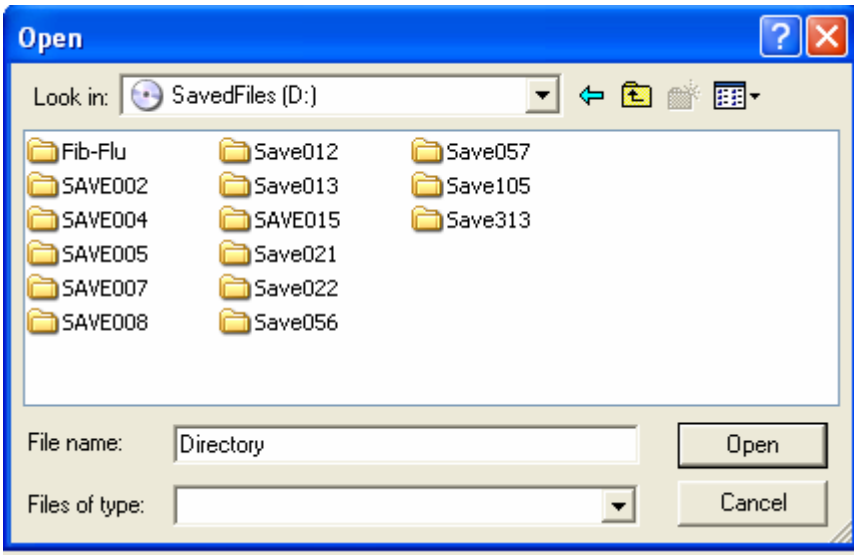
To import a patient's Holter study from a CDR, click on the "Prior" menu from the Premier main screen. Click on the Import Patient bar at the bottom right of the screen. Click on the down arrow across from the Look In field, and click on Desktop. The above drop down screen will appear.

NOTE: In this example the CD-RW drive is Drive D:



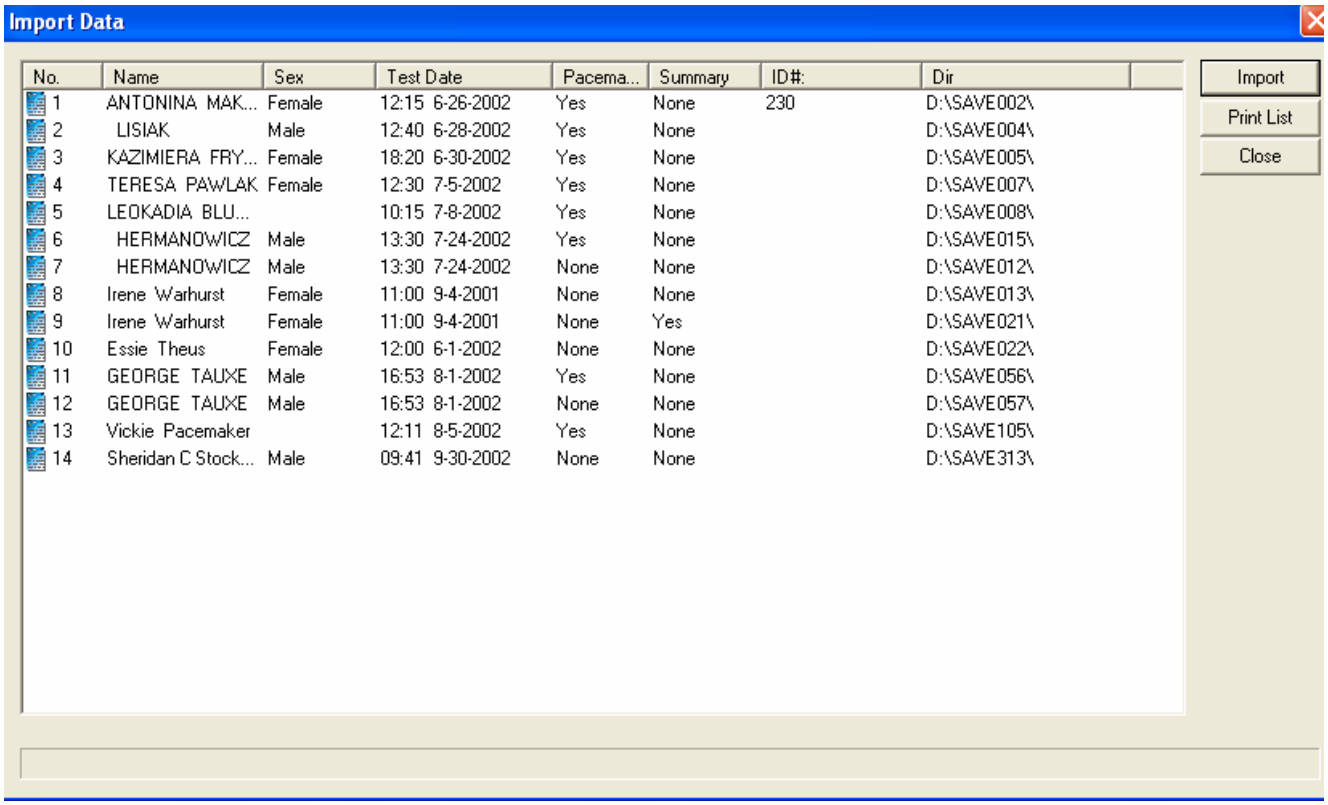
Insert the CD in the CD drive. Click on My Computer from the drop down list. The above screen will appear.

NOTE: The D: drive is now labeled Saved Files (this is the name of the CD with the stored patient files).



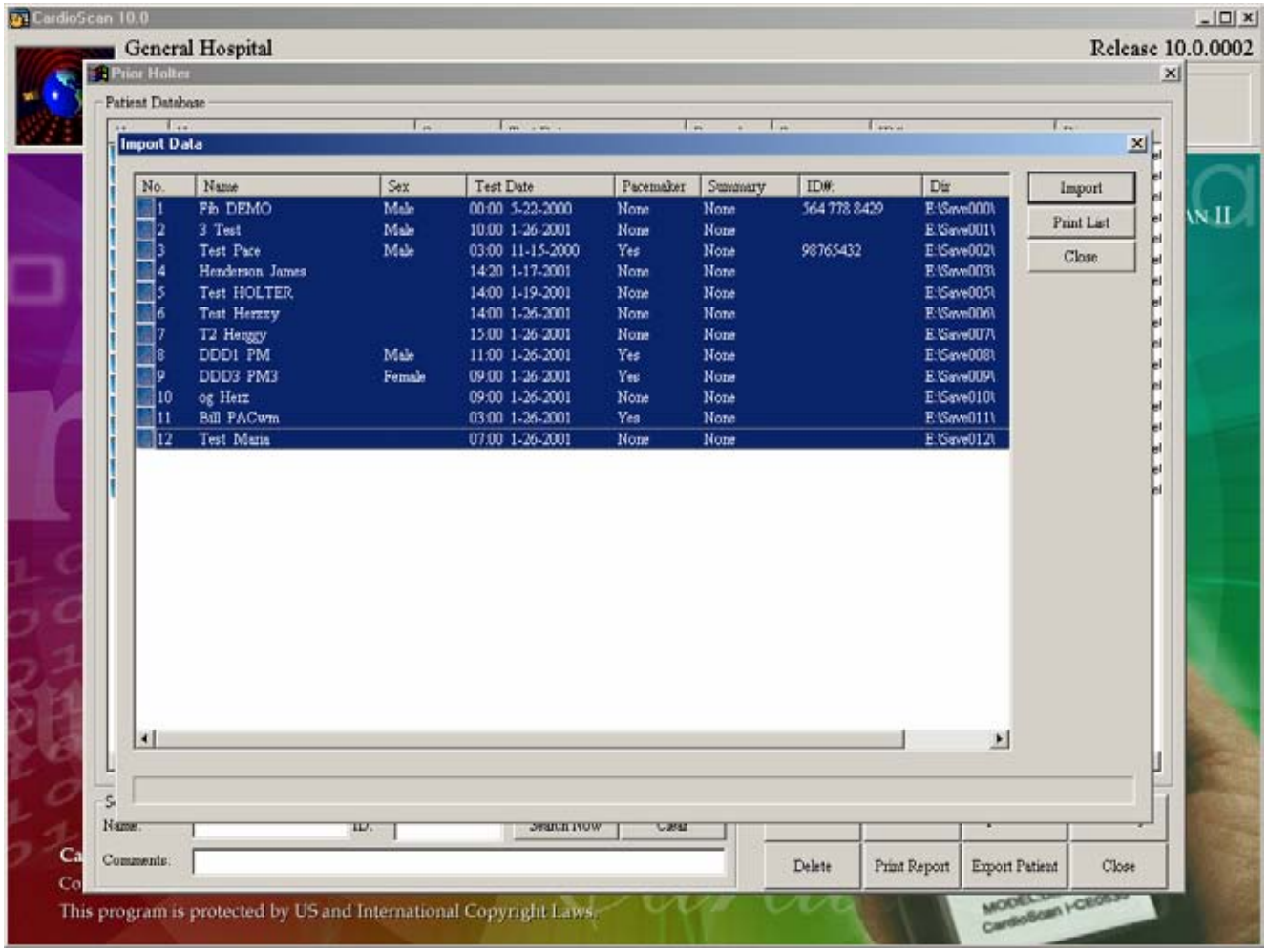
Double click on the drive with the stored Holter files (in our example it is SavedFiles (D:) The Save Files are the stored patient Holter files.

Click on the Open bar at the lower right of the screen.



A listing of all of the patients stored on the CD will appear on your screen.

Click on the patient's name of the study you wish to import. Click on the IMPORT bar. The patient's study will be copied to the hard drive and listed under the PRIOR menu.



To import all of the patient studies on the CDR, click on the name of the first patient in the file (in the above example it is Fib DEMO). Press down on the SHIFT and CONTROL keys on the keyboard at the same time and hold. Click on the name of the last patient. Release the keys on the keyboard. A blue highlight bar will cover all of the names on the list. Click on the IMPORT bar. All of the patient's studies will be copied to the hard drive of the computer and listed under the PRIOR menu.

HOLTER REANALYSIS

On occasion you may want to Re-Analyze the Holter recording. This could happen because you want to select different sample points for the ST-QT analysis, or place the primary focus of arrhythmia analysis on different channels, etc.

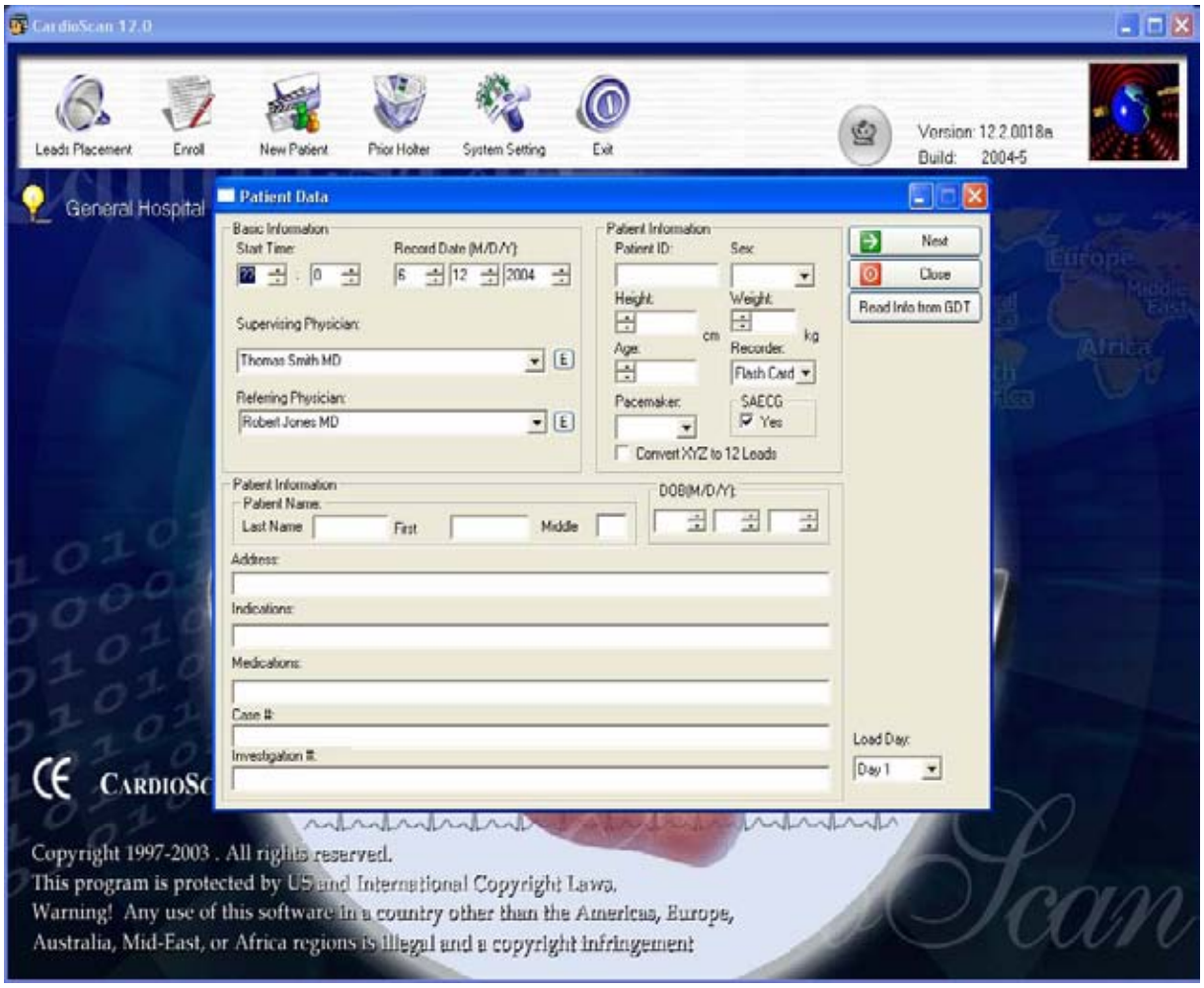
To start the Re-Analysis process, go t your Data Access Choices screen. Point and click on the ReAnaly icon.

A pop-up window will appear on the screen and ask you to confirm reanalysis of the patient. Point and click the mouse on “Yes”. You may follow all the previous instructions for analyzing the patient’s data.

PACEMAKER ANALYSIS

To process a new Pacemaker recording or to practice with the Pacemaker Demo file, point and click on the NEW icon on the CardioScan 12 Main Screen.

NOTE: If you have used the ENROLL feature, insert the compact flash card into the ImageMate reader and then click on the NEW icon.



The above patient menu screen will appear. There are six fields that must be filled in with data in order to proceed. They are Start Time, Record Date, Supervising Physician, Recorder, Pacemaker and Patient Name.

Enter the data in each data field. To move to the next field, press the TAB key on your keyboard or point and click in the field with your mouse.

The Recorder field allows you to select a Flash Card (Digital) Holter recorder or a DEMO practice field. This setting will default to its last setting when you power up the computer.

The CLOSE icon will return you to the CardioScan 12 main screen.

After entering all of the data, click on the START icon.
NOTE: If you have used the ENROLL feature, the patient information will load in automatically. After the data comes up on the screen, click the START icon.

You will be prompted to insert the compact flash card into the reader. Insert the compact flash card and after you hear the beep click on OK. If you have used the ENROLL feature, click on OK. Do not remove your compact flash card.

PACEMAKER SETUP

The top of the screen shows a 60-second strip of all three channels. The green box is the cursor that indicates the enlarged 8-second strip shown below. To choose another 8-second strip from the minute, simple point and click on the area you desire and the cursor will move to that area and a new enlarged 8-second strip will be shown on the screen.

The enlarged 8-second strip is the Pacemaker Setup Graph. Click on the first vertical line (marked S1) and drag it to a pacemaker spike. If dual spikes, place on atrial. If atrial or ventricular spikes, place on atrial. If ventricular spike only, place on ventricular. Click on the second vertical line (marked B) and drag it to the end of the QRS following the pacemaker spike. Click on the third vertical line (marked S2) and drag it to the spike immediately following the beat marked by the second line (B).

Locate the Pacemaker Type at the bottom left of the screen. Click on the arrow and scroll down until you find the type of pacemaker the patient has.

Locate the Firing Type at the bottom left of the screen. Click on the arrow and scroll down and choose between Dual Firing and Single Firing.

Locate the Beat to Beat (Upper Limit) field on the lower part of the screen. Click in the field and enter the upper heart rate limit for the patient's pacemaker. Locate the Beat to Beat (Lower Limit) field on the lower part of the screen. Click in the field and enter the lower heart rate limit for the patient's pacemaker.

Click on the Channel you desire for Full Disclosure.

The Arrhythmia Analysis box at the bottom of the screen allows you to select which channels will be analyzed for arrhythmias.

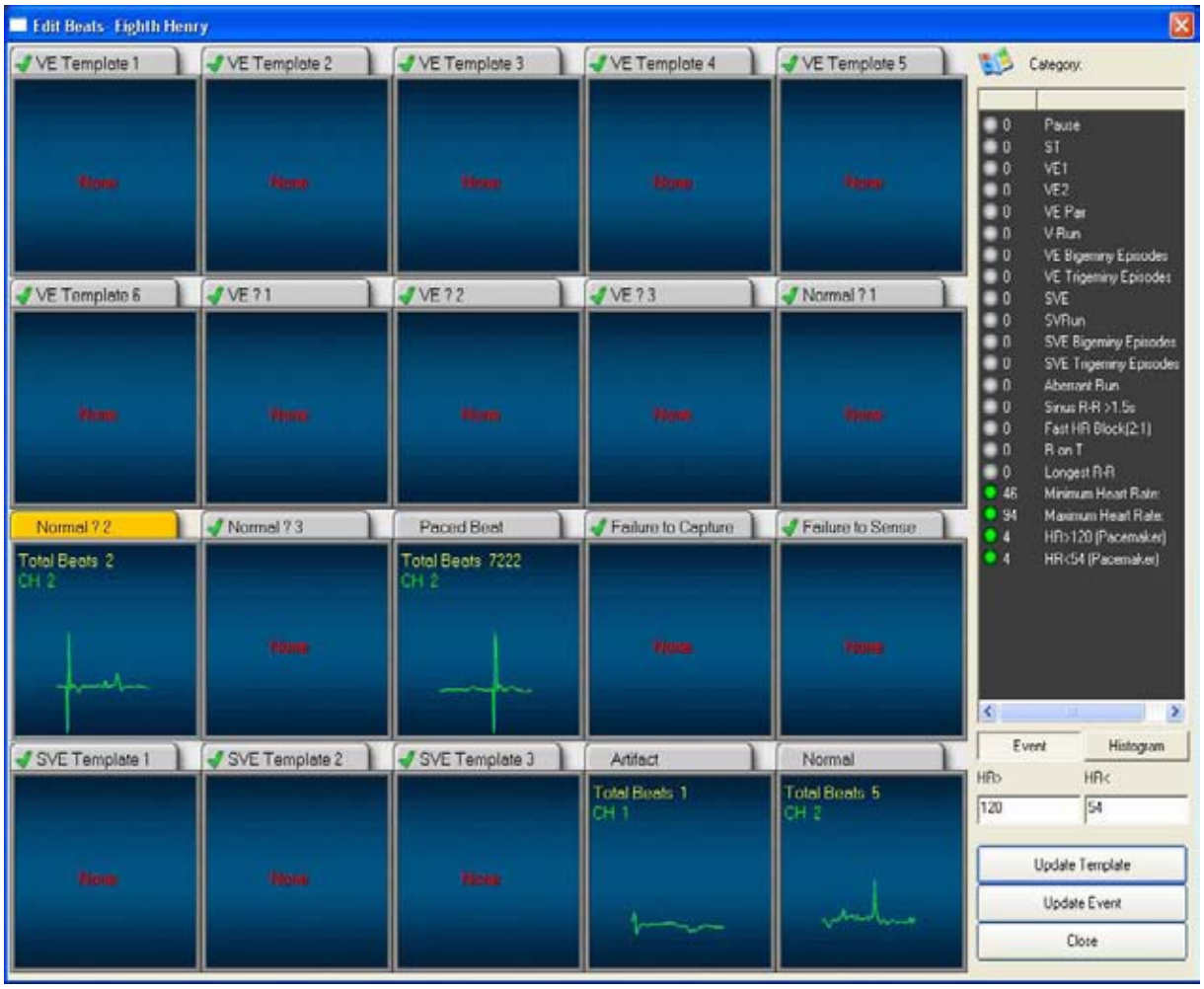
Clicking on the Full Size box under ECG Gain will double the amplitude of the signal on the enlarged eight-second strip.

If you desire another minute of ECG to select the eight-second strip from, click on the PgUp or PgDn icon at the bottom of the screen.

After you have the pacemaker setup to your liking, point and click on the ACCEPT icon at the bottom of the screen. The program will do the pacemaker analysis and take you to the Data Access Choices screen.

EDIT BEATS

At the Data Access Choices screen, point and click on the EDIT icon.



The purpose of the Edit Beats display is for you to review and edit the various arrhythmia templates for VE, SVE, Paced Beats, Failures to Capture, Failures to Sense, Beats over the Upper Limit and Beats under the Lower Limit. After you have completed editing these beats you may then review eight-second ECG strips of a broad range of Abnormal ECG events.

Point and click your mouse to the first template with ECG data in its box OR press the ENTER key on the keyboard. This will be the template with the yellow box around it. In the above example, it would be VE Template 1. This will prompt a new screen display that shows all the beats assigned to that particular template.

NOTE: Pressing the F1 key at any place in the program will automatically print out a page screen.

On the left side of the screen, you see a column of ECG strips. These strips correlate to the column of beats (labeled A-T). The beat in the column is the colored beat in the strip. As you move the beat box (either by mouse or by arrow key) across the different columns of beats, the strips will change accordingly.

Each beat is color coded per the "Color Panel" description at the bottom of the screen. The Label Code and Color Code for the beats are as follows:

LABEL CODE	**COLOR CODE**	**DESCRIPTION**
V	Green	Ventricular Ectopy
S	Magenta	Supra-Ventricular Ectopy
T	Blue	Aberrant
N	White	Normal
F	Yellow	Artifact
D	Purple	Paced
C	Olive	Failure to Capture
E	Orange	Failure to Sense

This screen shows the “Double Morphology” templates. The “Double Morphology” helps you edit entire morphologies in a quick and concise method.

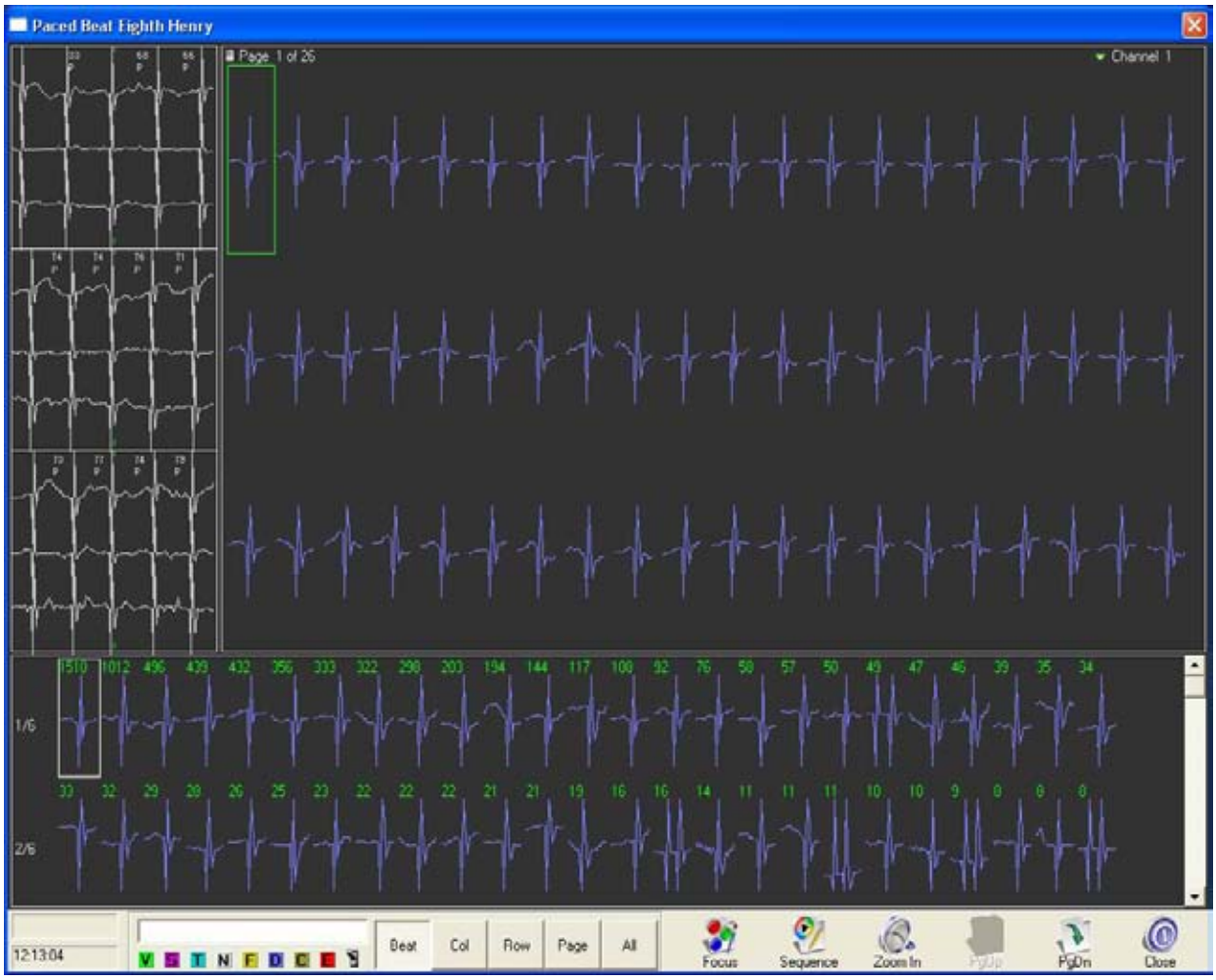
The first beat in the bottom half of the screen shows that there are 1510 of this particular morphology in the template. There is no need to go through the viewing of all 1510 beats, though if you choose to do so, you may look at the upper half of the screen and see the first 60 beats.

If you have more than 60 beats in a morphology template you may click on the PgDn icon at the bottom of the screen to move to a new page of beats. The top of the screen will show you which page you are viewing out of the total number of pages for this morphology.

If you have more than two rows of morphology templates on the bottom of the screen, point and drag the mouse on the slide bar at the bottom right of the screen to see the remaining morphology templates.

In the above example you are viewing beats from Channel 2. If you choose to view beats from another Channel, click on the Channel notation in the upper left hand corner of the screen.

A pop up box will appear. Scroll down and select the channel you wish to view.

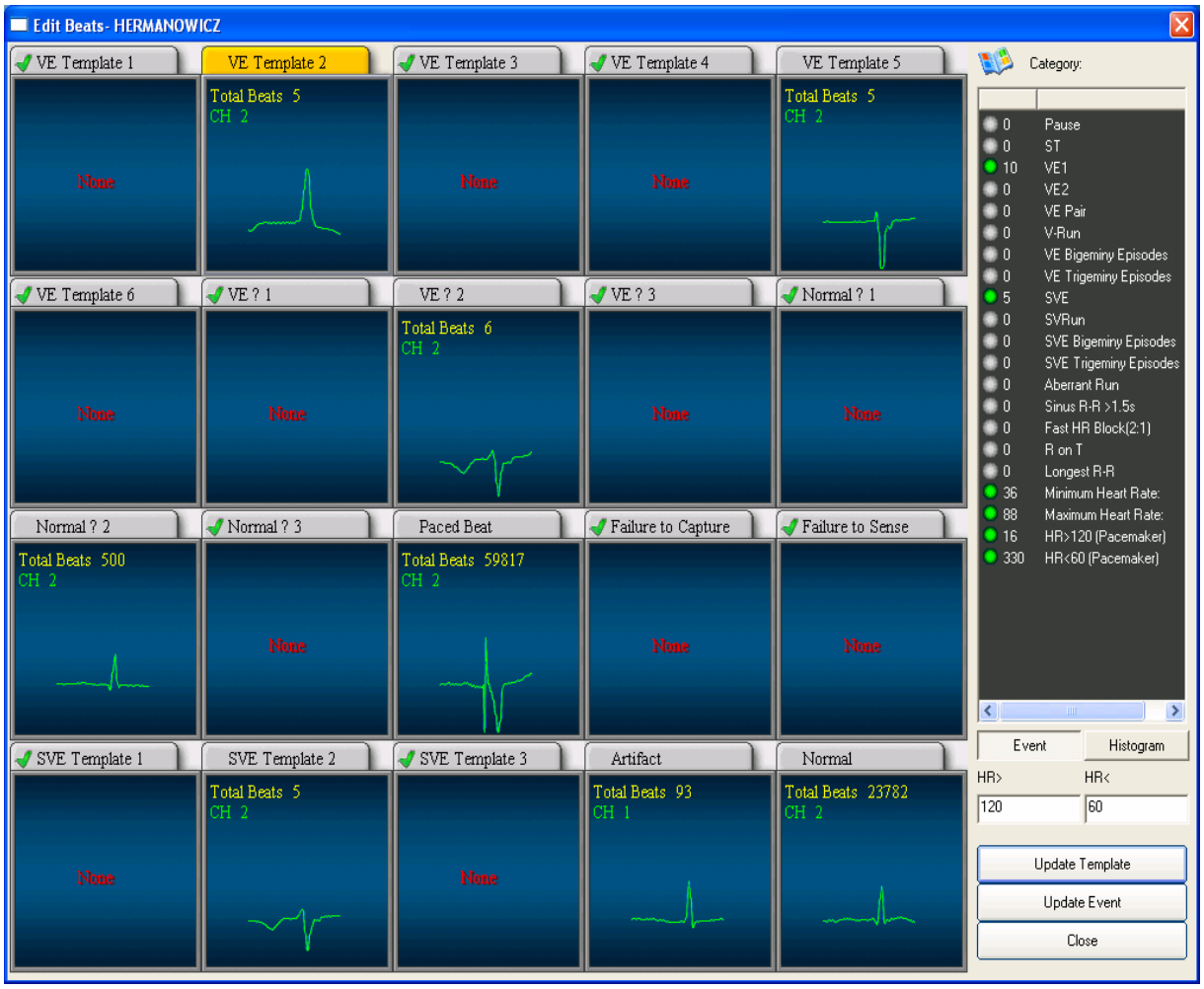


You will now view the beats in the channel you have selected. In our above example, we have selected channel 1.

A total of 7222 Paced beats were detected in this template. The bottom of the display shows the beats placed into 145 wave shapes (morphologies). 1510 beats were placed in Template 1, 012 beats were placed in Template 2, 486 beats in Templates 3 etc.

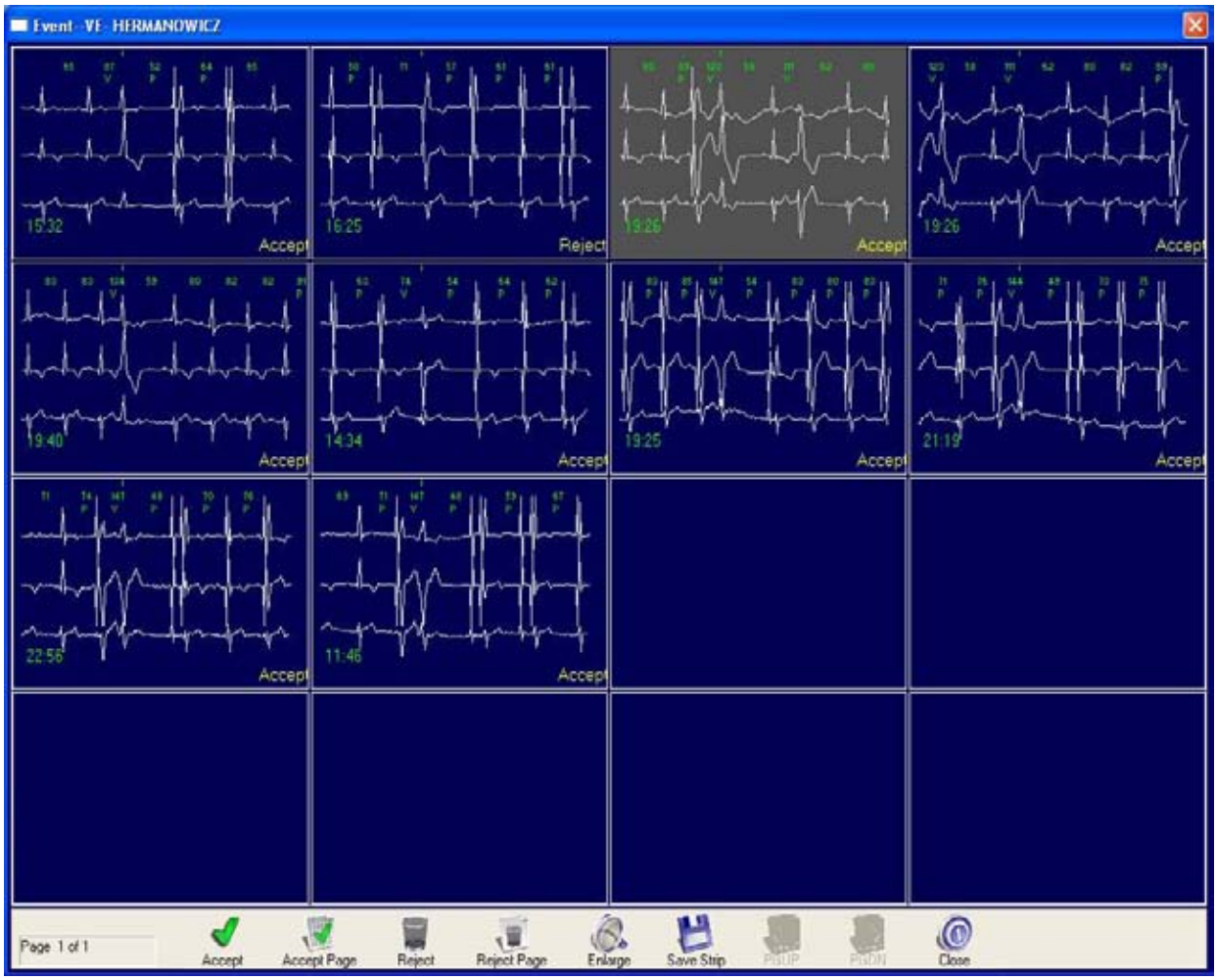
The white rectangular box at the bottom shows the Paced Template for the 1510 Paced beats above. To view the 1012 beats in Template 2, press the X key on the keyboard or point the mouse arrow and left click. To go back to the first 1510 Paced beats you may press the Z key on the keyboard or point the mouse arrow and left click.

For complete Template editing instructions, refer to Editing Templates beginning on page 46 of this manual.



After finishing the Template Editing, click on the Update Template bar.

To edit the Abnormal Event categories, click on the first abnormal event that has a green light next to it. In the above example, it would be VE1.



This screen will show you up to 16 ECG Events. There may be several pages of events, as indicated by the page count on the lower left of the screen. In this example, there are three pages.

The green marker at the top of the strip indicates the Abnormal Event. All of the events displayed have been accepted. To reject an ECG event, move the mouse to the appropriate ECG event strip and click OR use the arrow keys on the keyboard to the appropriate ECG event strip. The strip will lighten to gray. Click on the REJECT icon at the bottom of the screen or press the letter R key on the keyboard.

To view this strip in an enlarged eight-second strip, click on the ENLARGE icon at the bottom of the screen or press the ENTER key on the keyboard.

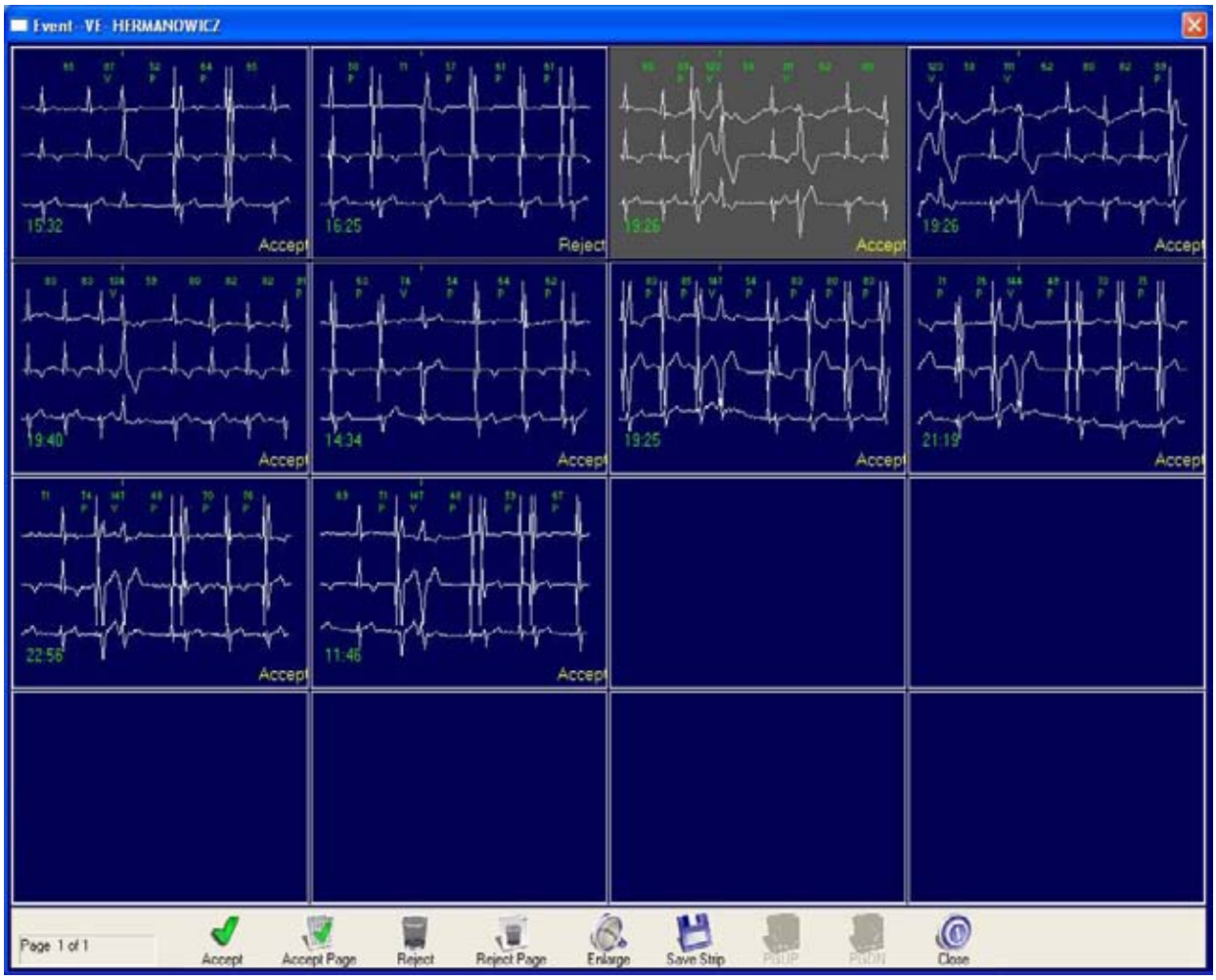
To save this strip to be printed with the report, click on the SAVE STRIP icon at the bottom of the screen.

To reject an entire page of events, click on the REJECT PAGE icon at the bottom of the screen.

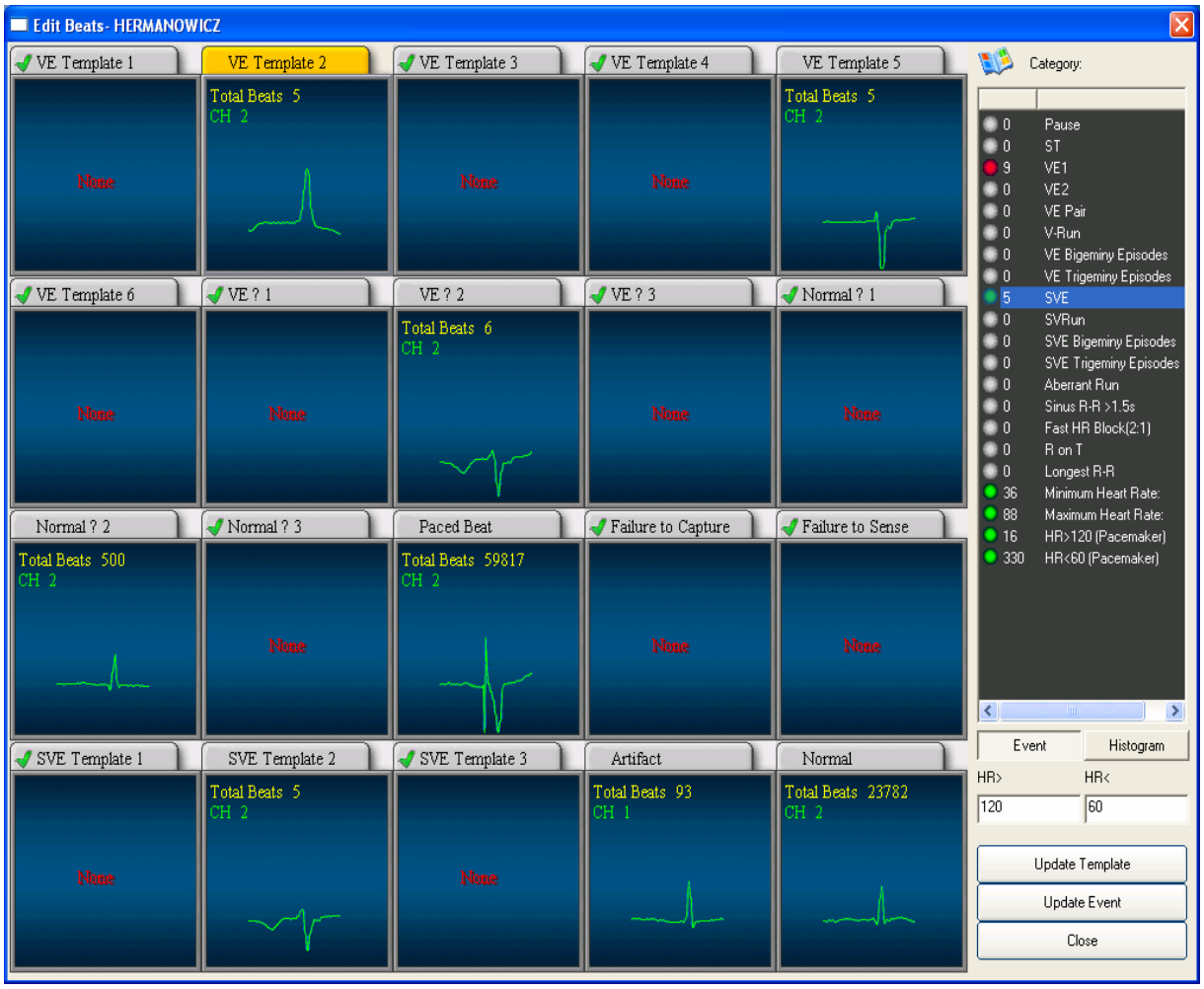
To accept an entire page of events, click on the ACCEPT PAGE icon at the bottom of the screen.

To reject the entire category, click on the REJECT ALL icon at the bottom of the screen.

To view other pages of events in this category, click on the PGUP or PGDN icon on the bottom of the screen OR you may press the Page Up or Page Down key on the keyboard.



To go to the next Abnormal ECG Event category, click on the CLOSE icon at the bottom of the screen OR press the ESC key on the keyboard.

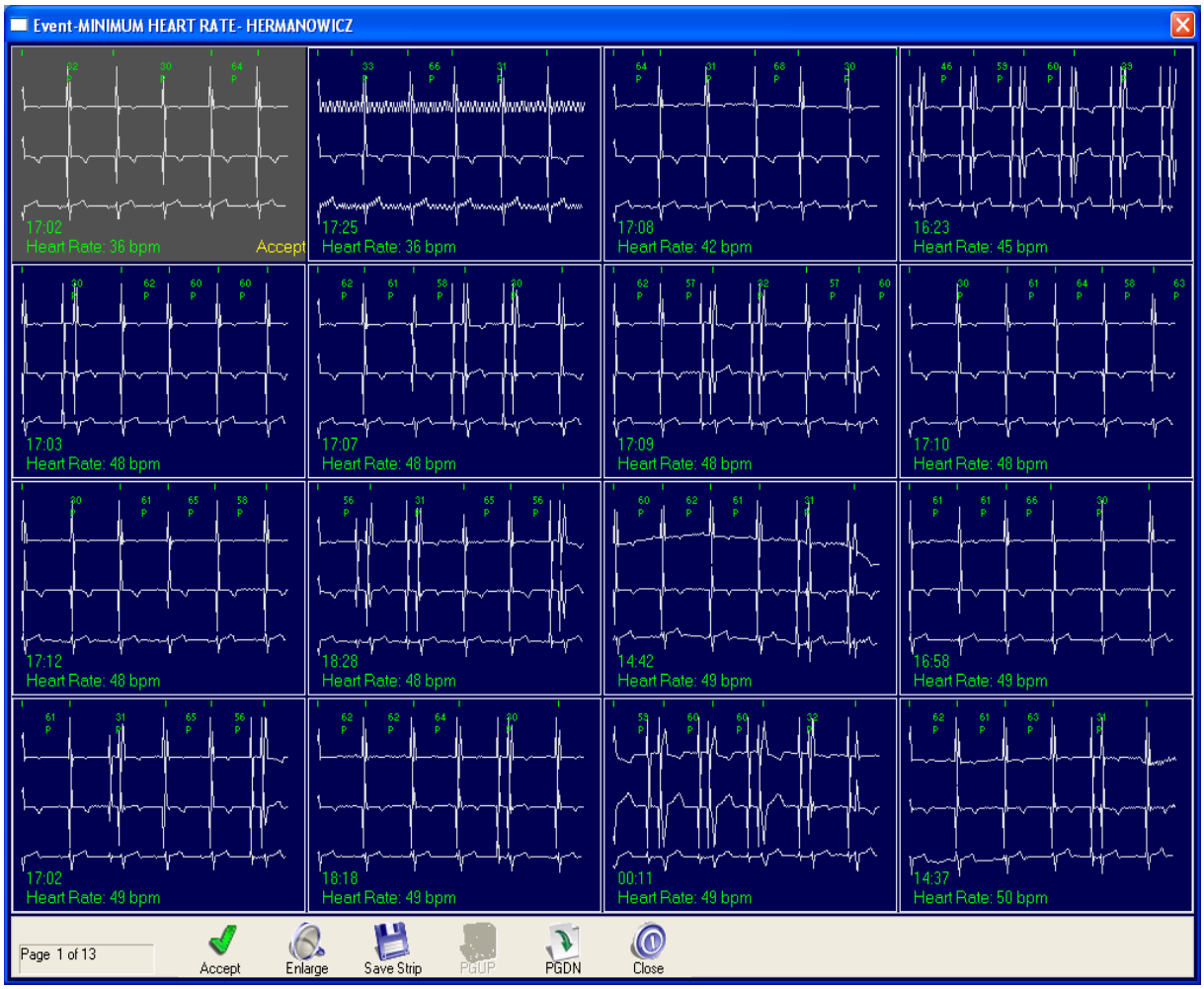


Select the next Abnormal ECG Event category you choose to edit and click on the category bar OR press the ENTER key on the keyboard. Repeat the aforementioned editing techniques for the remaining categories.

NOTE: If there is a zero in a category, the category name will be in gray and you will not be able to edit this category. That is because the category had no events.

NOTE: After you have edited the category, the button next to the category will turn red.

The editing for the Minimum Heart Rate and Maximum Heart Rate categories is different.



EDITING MINIMUM AND MAXIMUM HEART RATE

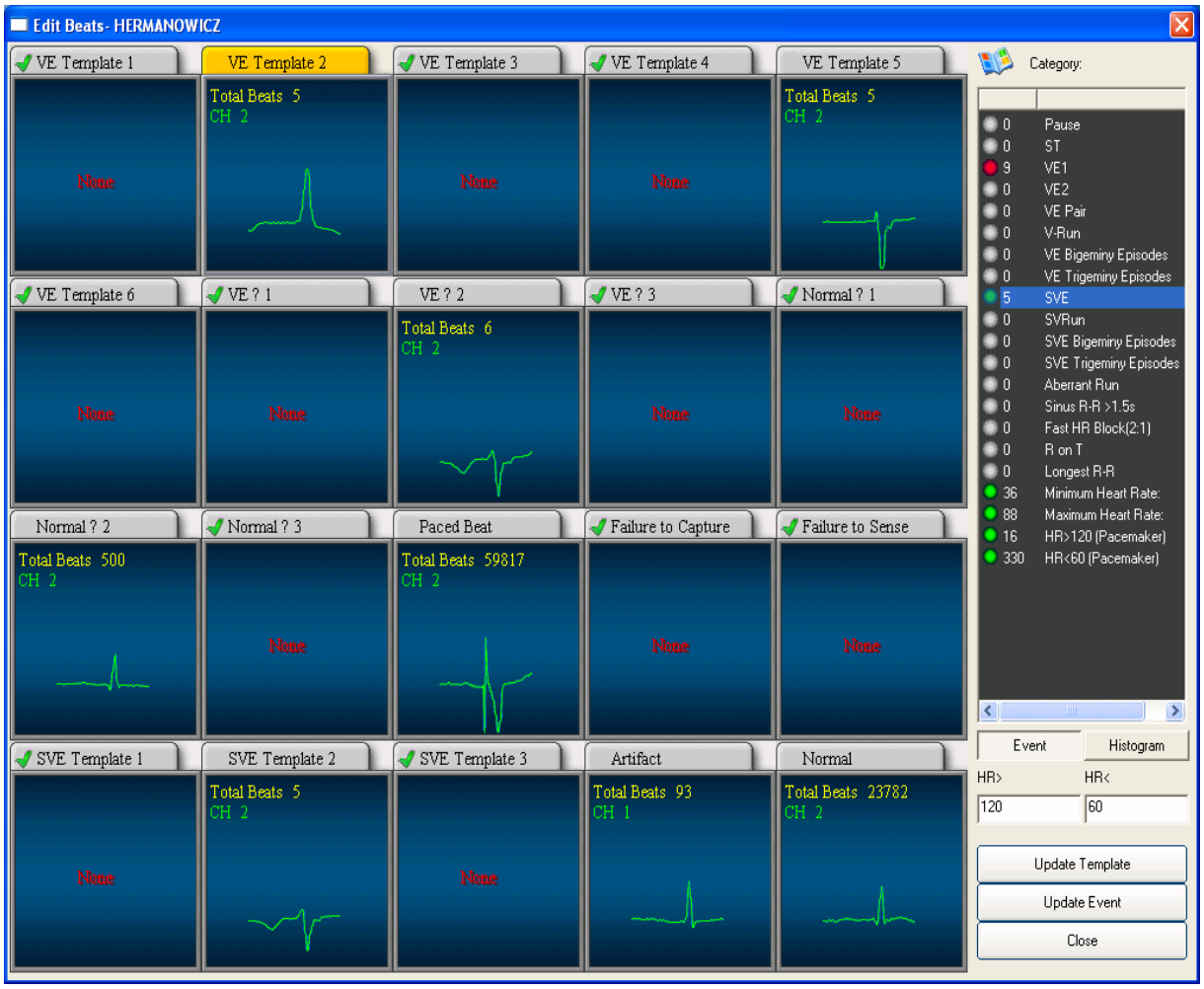
Only one event is accepted as the Minimum Heart Rate and Maximum Heart Rate.

The green vertical markers at the top of each strip should be located above successive R-waves. If this is the case for the first selected event, click on the CLOSE icon at the bottom of the screen OR press the ESC key on the keyboard. You will be taken to the Edit Beats screen.

NOTE: In the Settings Menu, you chose how many intervals would be counted to determine your minimum and maximum heart rate, either 1 interval, 2 intervals, 3 intervals, 4 intervals or 5 intervals. The interval count determines how many consecutive R-waves should be counted.

If the green markers are not located above successive R-waves, click on the first heart rate strip that has successive R-waves marked and click on the ACCEPT icon OR use the arrow keys on the keyboard to move to the desired strip and press the letter A on the keyboard. The word Accept will appear in the lower right corner of the selected ECG Event strip.

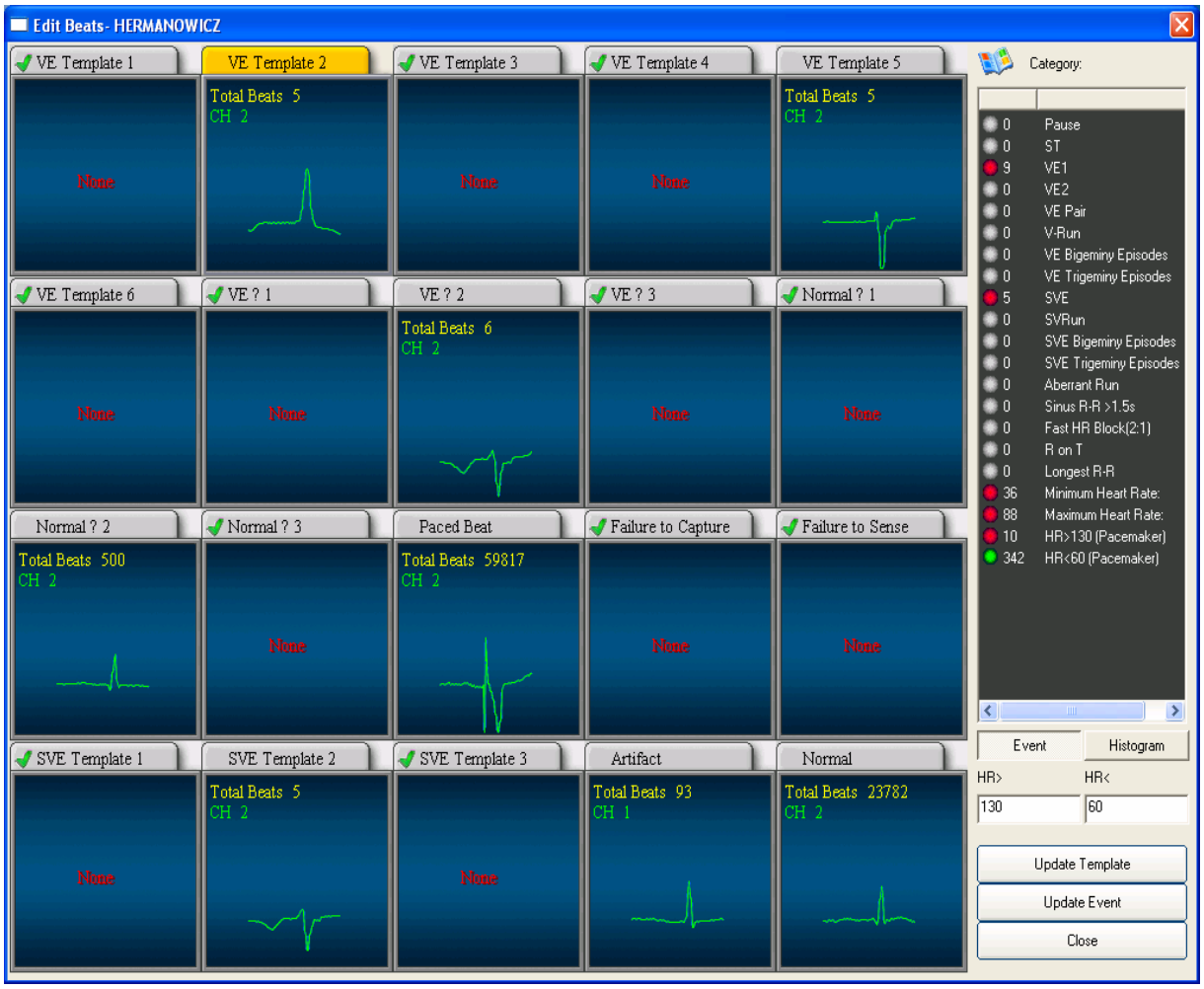
NOTE: There may be more than one ECG Event strip with the same Heart Rate with the intervals being counted correctly. In an instance like this, it is always preferable to choose the ECG Event strip with the least amount of artifact.



EDITING HR> AND HR< CATEGORIES

In the above example you can see that there are two categories, HR>120 and HR<60. The numbers for the over and under are set on the Pacemaker set up screen.

If you see that all the beats in the HR>120 are more than 120bpm you can change the analysis to >130 beats. Simply point and drag the mouse over the 120 under the HR> category and type in 130.



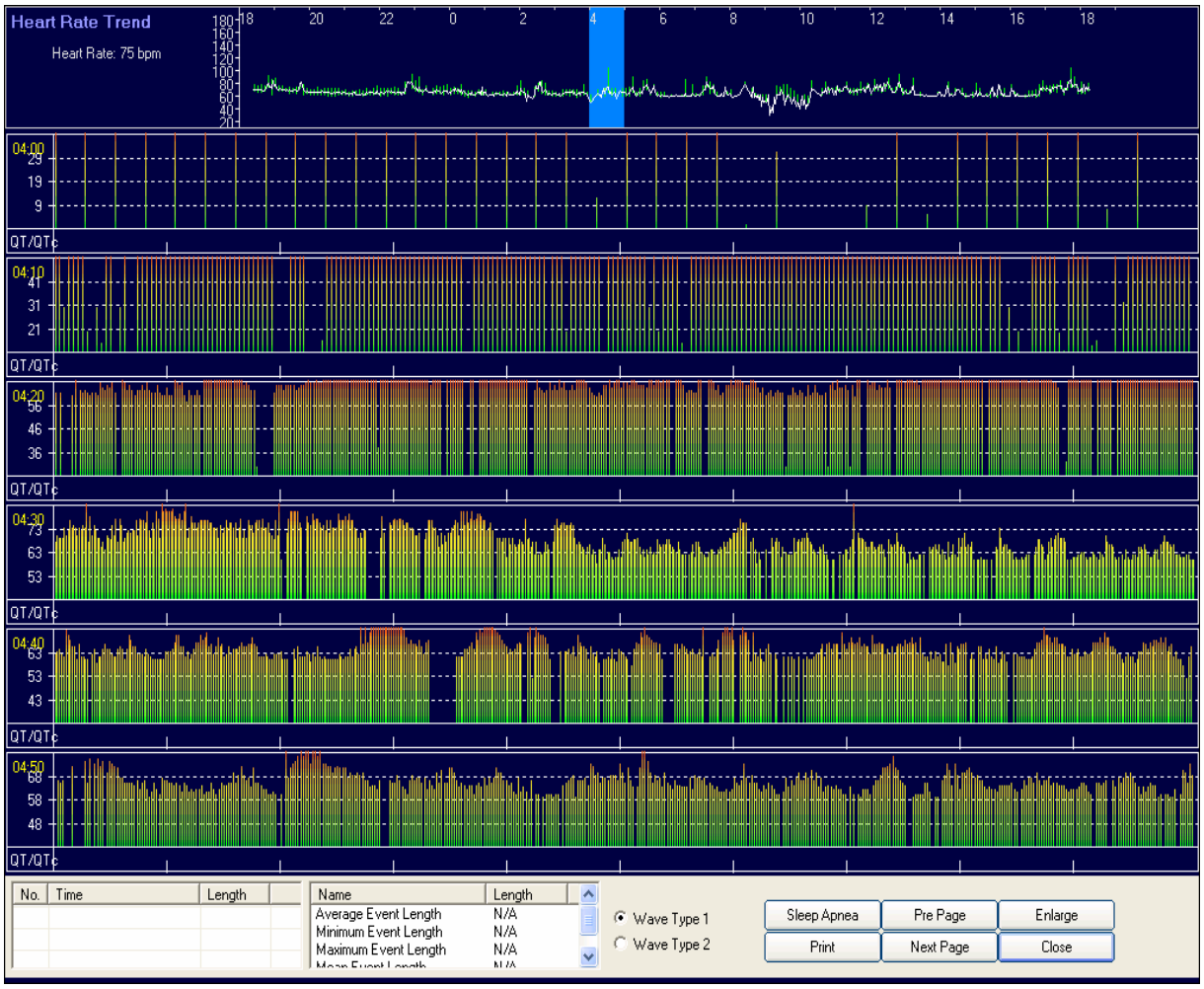
Click on the HR>130 (Pacemaker) in the Category column. The program will recalculate the number of beats in the HR>130 category.

Double click on the category and you can view and edit the selected beats.

You can repeat this process for the HR<60 category if you desire.

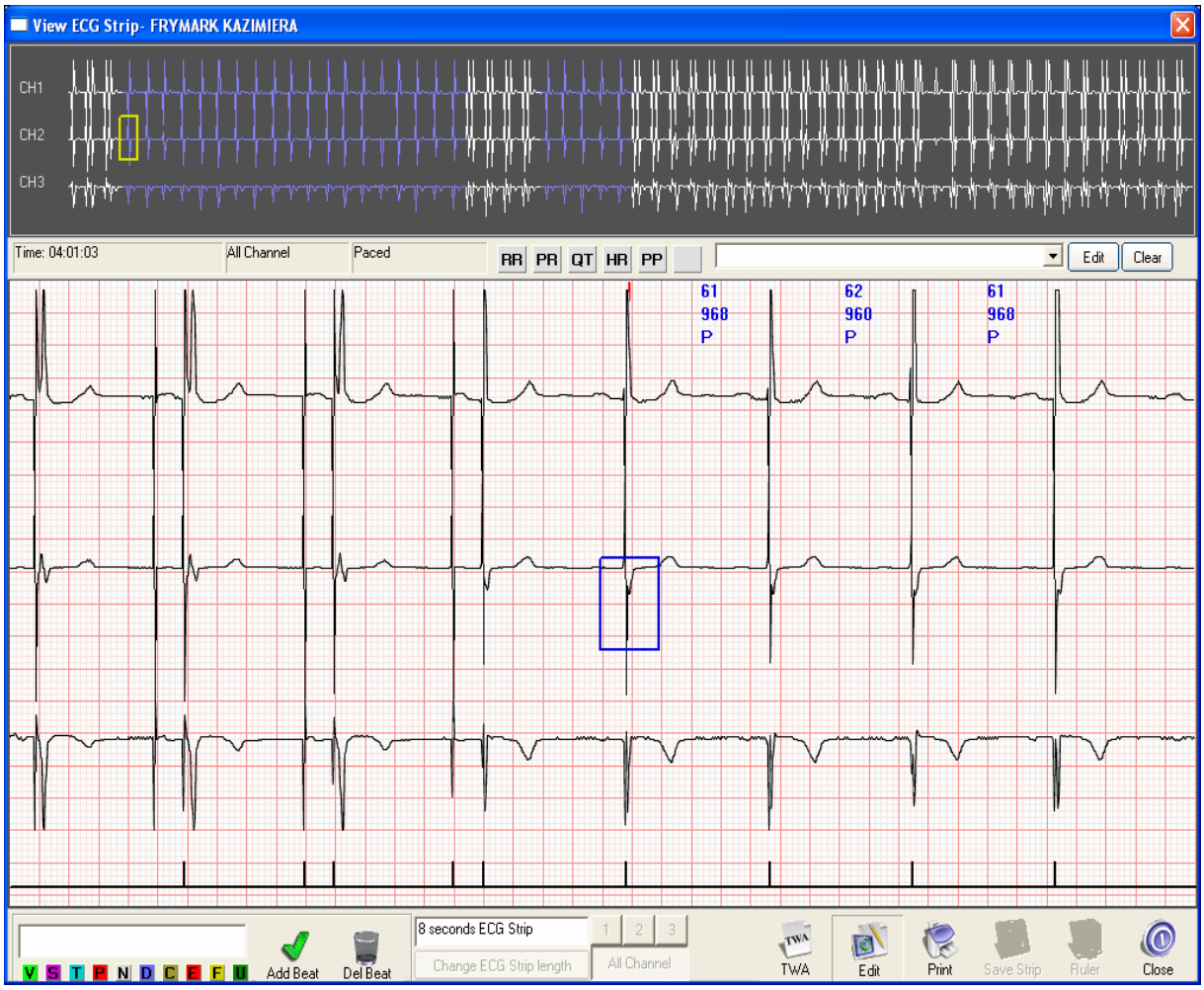
In addition to the Page Scan and Page Scan Artifact categories, explained on pages in this manual, the Pacemaker program also has a Page Scan Spike-to-Spike menu.

To access this, click on the Page Scan icon at the Data Access Choices. Scroll down to Page Scan Spike-to-Spike. The following screen will appear.



The above screen display shows 1-hour of Spike-to-Spike intervals. Each horizontal sweep equals 10-minutes. Each horizontal sweep is made up from a series of vertical lines. Each vertical line represents the length of a Spike-to-Spike interval.

You can see some occasional long vertical lines. Move your mouse arrow just to the right of a long vertical line and do a double left click. The following screen will appear.



You can see what cause the long spike to occur. The pacemaker went from dual firing to single firing and you can see the significant change in interval readings.

Quite often a long interval line from the prior page will show when the pacemaker goes from dual firing to single firing.

To use the Mega Scan features, please refer to Page 126 in this manual.

To use the ECG Strip features, please refer to Page 186 in this manual.

To use the Hourly features, please refer to Page 208 in this manual.

To use the SAECG & VCG features, please refer to Page 93 in this manual.

To generate a Report, please refer to Page 228 in this manual.

To Re-Analyze this patient's data, please refer to Page 278 in this manual.

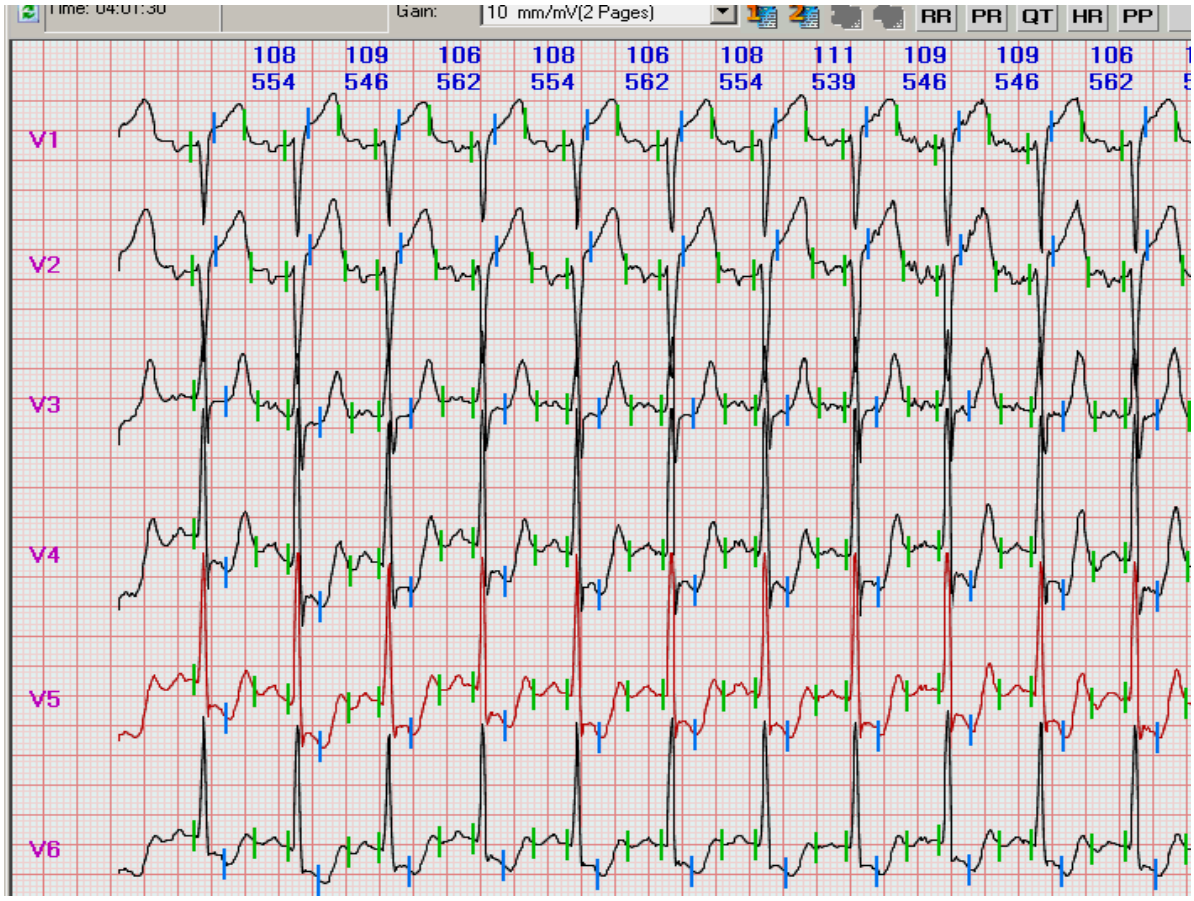
DMSoftware

CardioScan-12 Holter ECG System

ST Segment

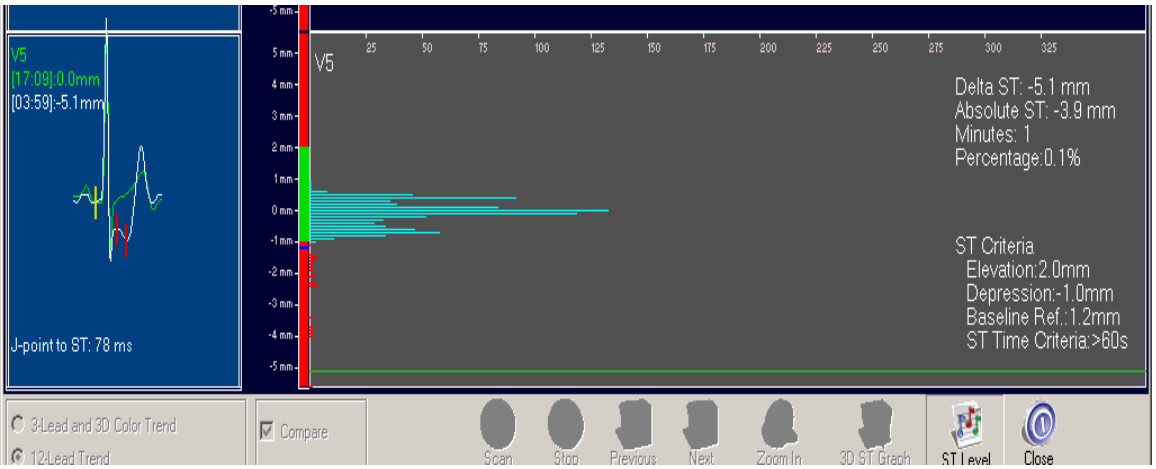
ST analysis is done for both 3-Lead and 12-Lead ECG recordings. The 3-Lead ECG recordings are up to a 7-day time period. The 12-Lead ECG recordings are up to a 3-day time period.

This is a 12-Lead ST graph showing significant ST Depression in Leads II, aVF, and V5.

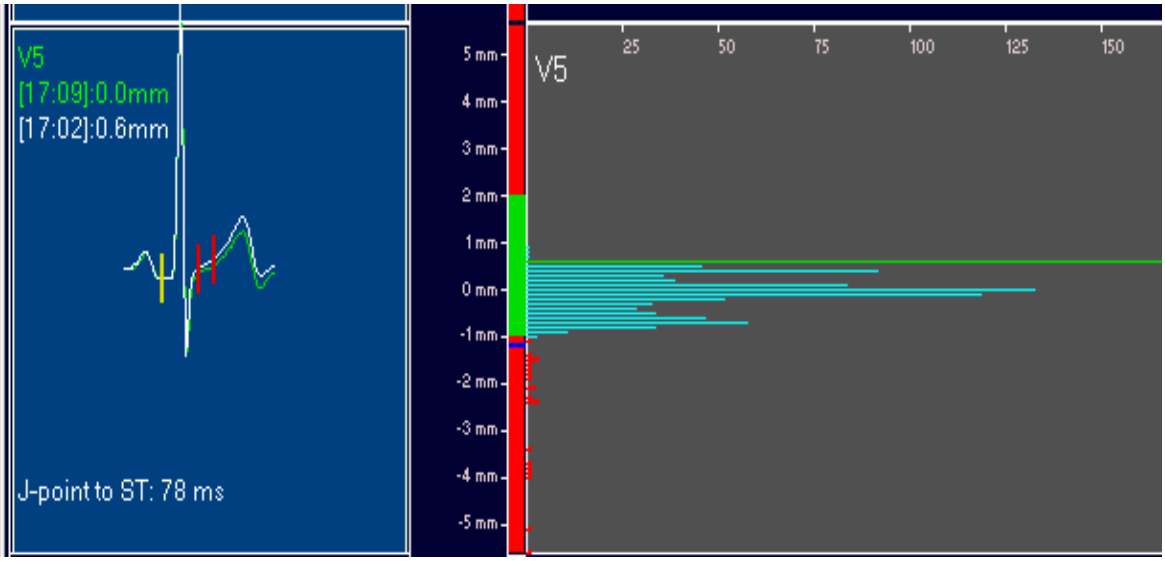


The ST Depression is shown with green markers showing the QT interval, and the blue markers showing the location for selecting the ST depression measurement. The blue marker provides verification and validation that the ST analysis was performed accurately.

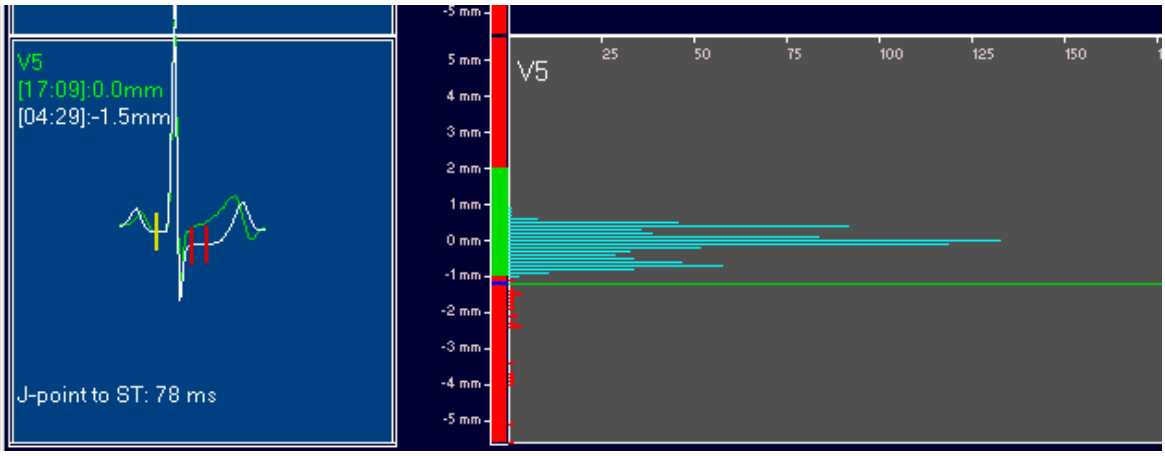
The next screen display shows that any Lead can have its entire 24-hour time period be analyzed for ST in less than five (5) seconds.



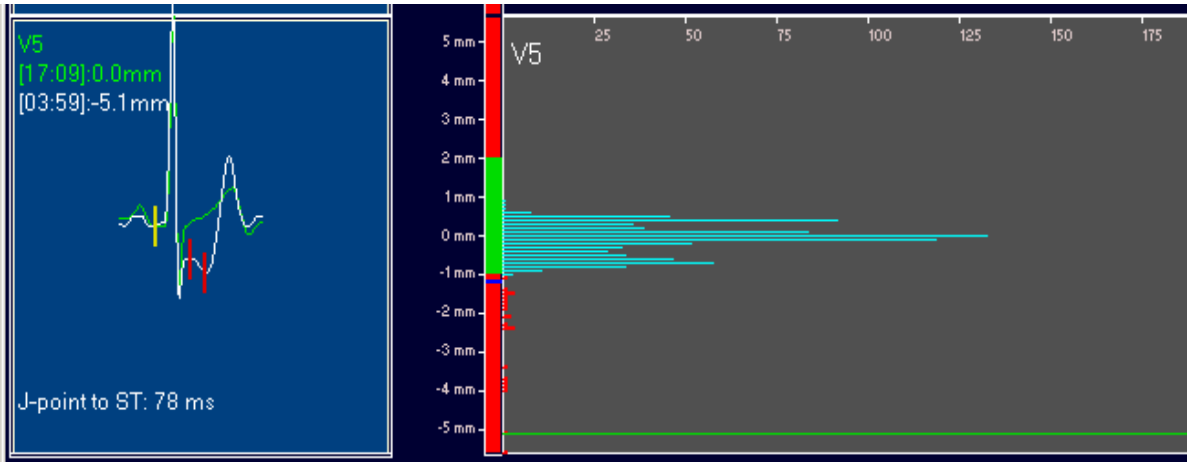
This screen display shows V5 and all the ST levels that occurred during the 24-hour Holter ECG recording.



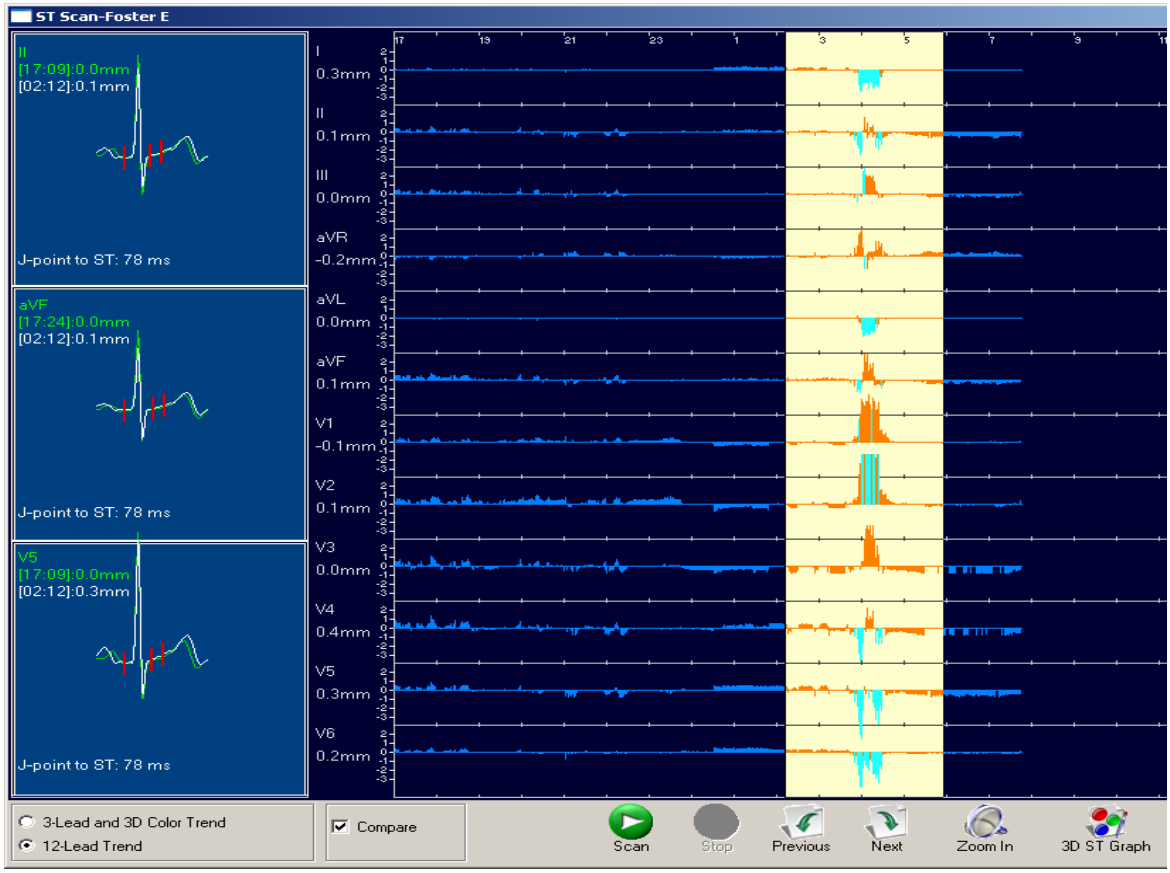
- The V5 ECG is a superimposed ECG.
- The green ECG is the ST at the patient's normal Delta 0 level.
- The white ECG is the ST level at all ST levels above and below the Delta 0 baseline reference.
- The horizontal blue lines at the right side of the display are the quantity of minutes at the various ST levels during the 24-hour recording.
- By pressing the down arrow key, the long green line will move downward through the various ST levels.
- To go from top to bottom takes less than 5-seconds.



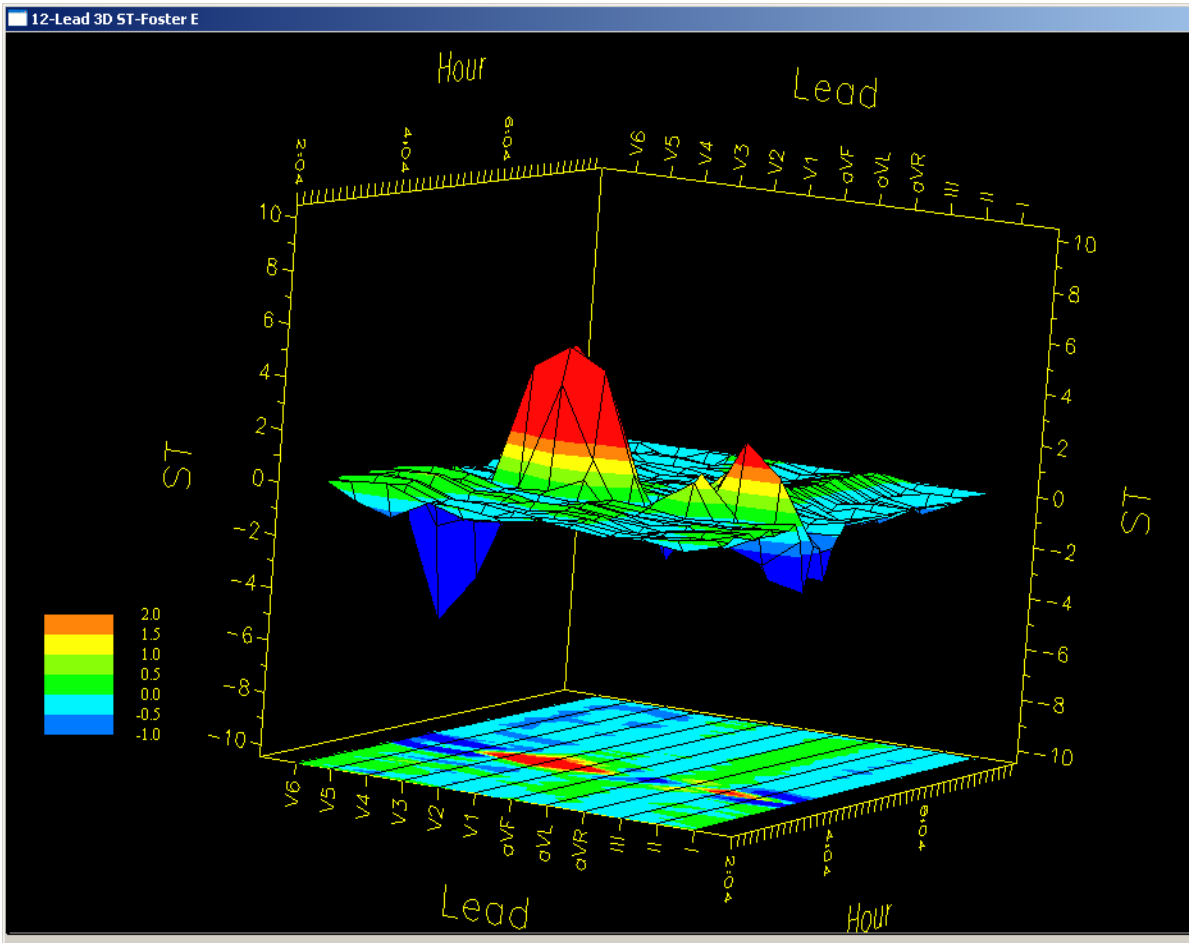
As the green marker is moved down, the ST depression becomes obvious. The white ST is significantly depressed versus the patient's normal ST level. The vertical markers show the location of the PR baseline, the J-point, and the ST-point. The ST is 78 ms post the J-point, and the depression is -1.5 mm.



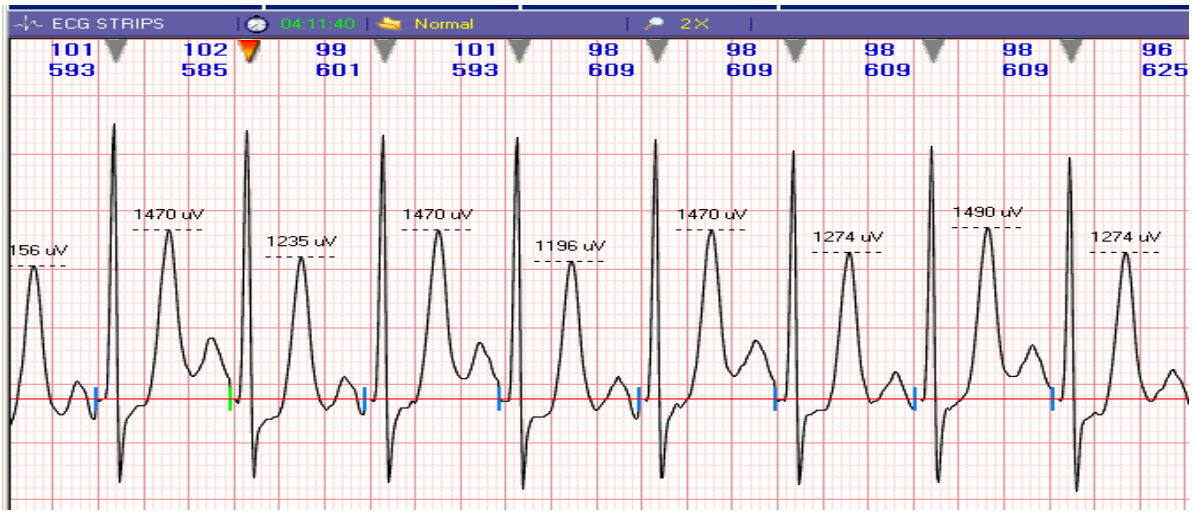
In less than 5-seconds all ST levels have been viewed for the 24-hours. The long green horizontal line is at the bottom of the ST levels, and the ST depression is shown at -5.1 mm.



When you do a point and drag pre and post the ST depression in the 24-hour ST graph, you start the process for viewing the 3D ST activity. After the point and drag, click on the icon for 3D ST Graph.



The blue color shows the significant ST depression in the V4, V5, and V6 Leads, as well as Lead II.

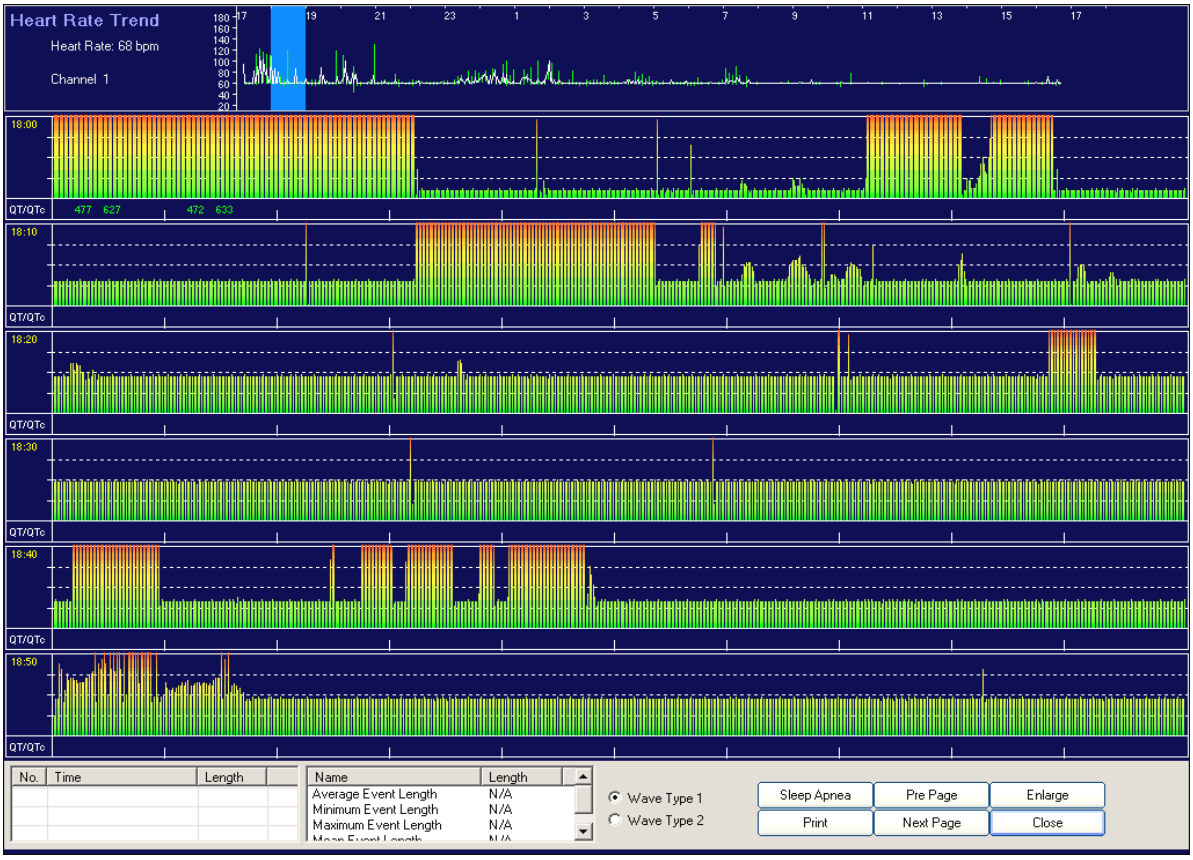


Note the T-wave Alternans which was recorded a few minutes after the significant ST depression shown on the prior displays.

DMSoftware

CardioScan-12 Holter ECG System

Pacemaker

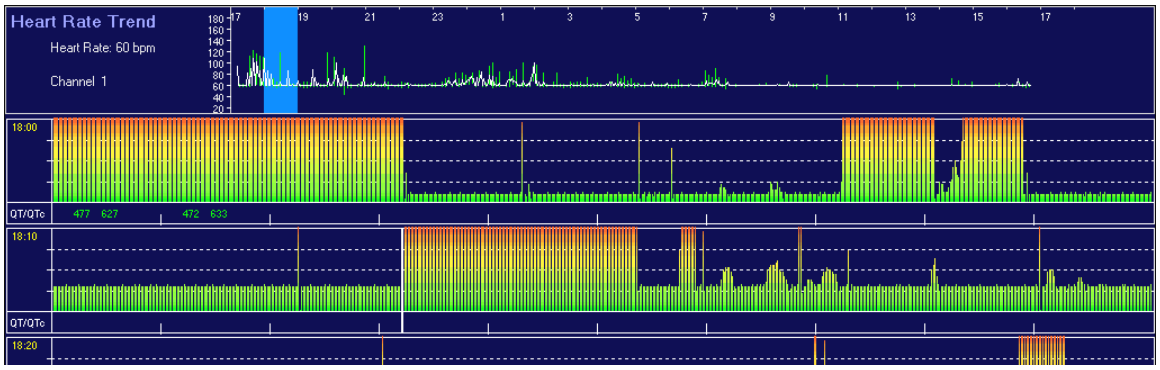


Pacemaker displays are for the following:

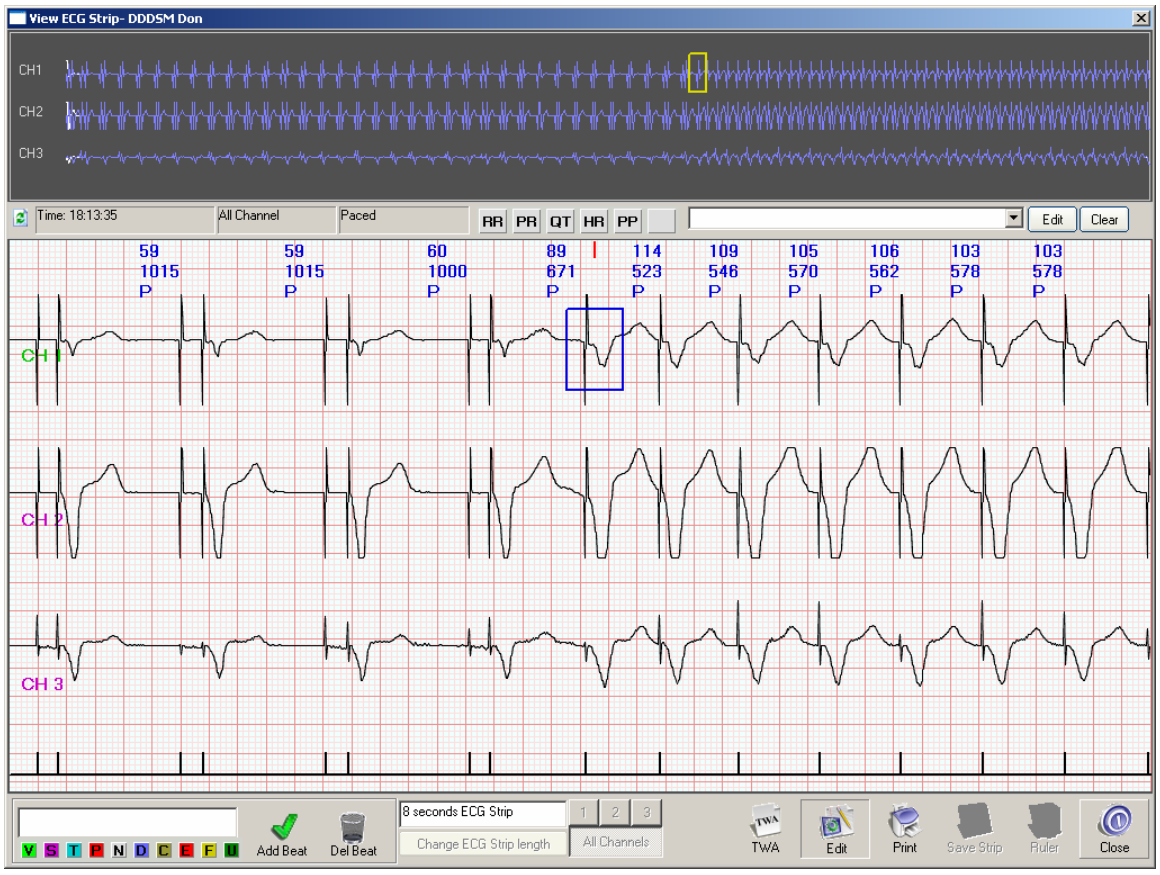
- Beat-to-Beat
- Spike-to-Spike
- Beat-to-Spike
- Spike-to-Beat

The above is a Beat-to-Beat display. The length of each R-R interval is shown as a vertical line. When there is a sudden change in the length of these lines, there are probably ECG events of interest.

Place the mouse arrow at a change of interest, and then double left click.

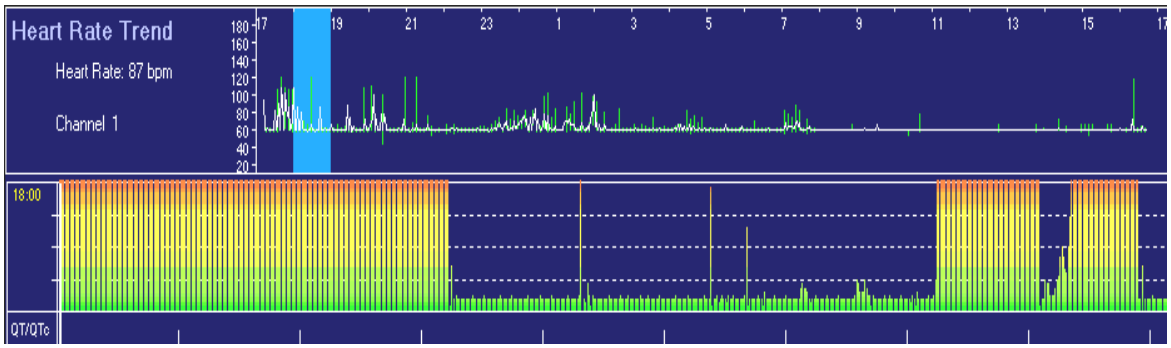


When you double left click at the point where there is a sudden Beat-to-Beat change, you see the below display.

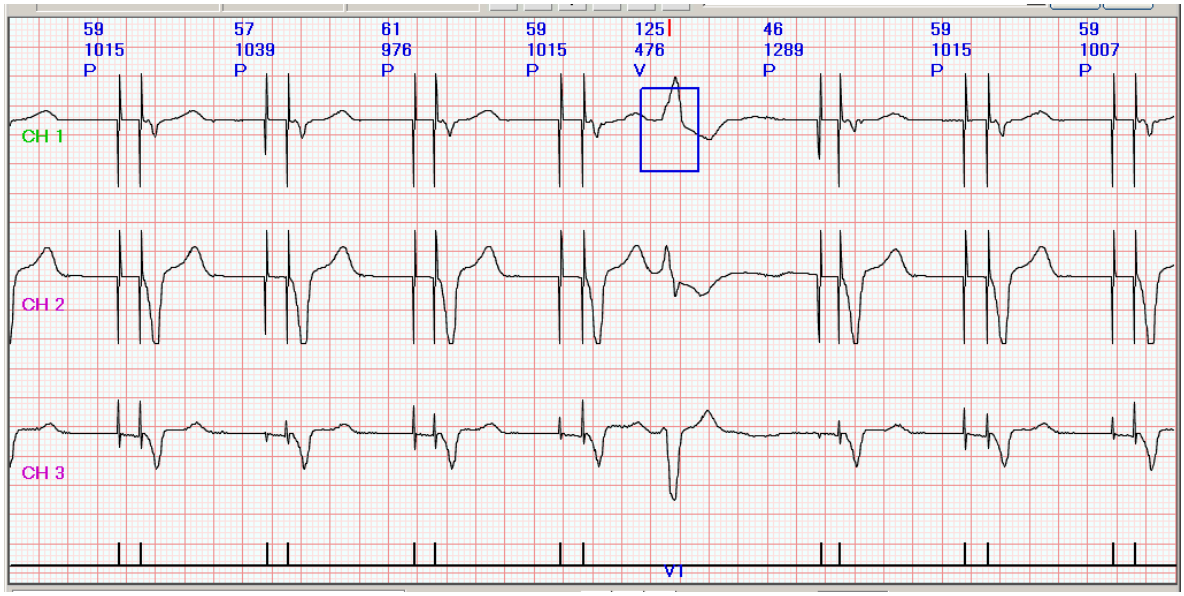


The sudden change in Heart Rate was caused by the pacemaker transferring from dual firing to ventricular paced beats.

Note the quality of the pacemaker spikes. The Holter recorder's high sample rate of 1,024 samples per second and the high frequency of 500 Hz produces the best pacemaker spikes in Holter ECG.

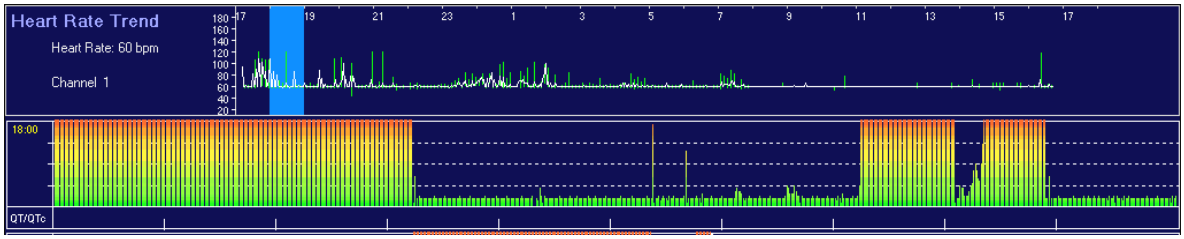


Doing a double left click on the single long line above resulted in the below display.

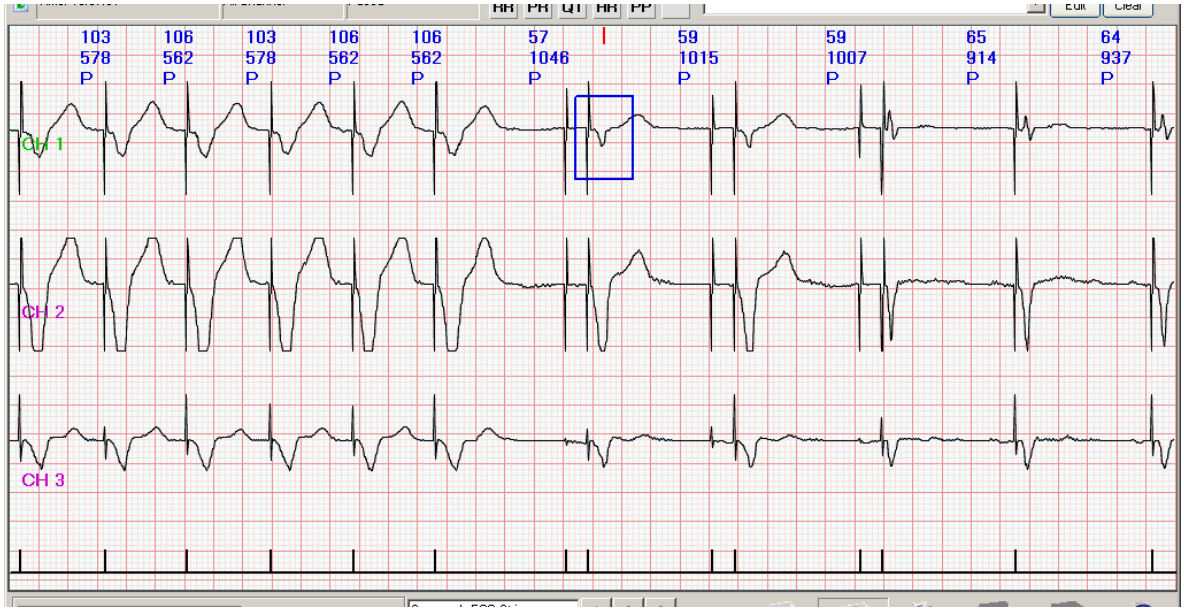


The single long line was the above VE beat.

The below display is an example of using the Spike-to-Spike display.

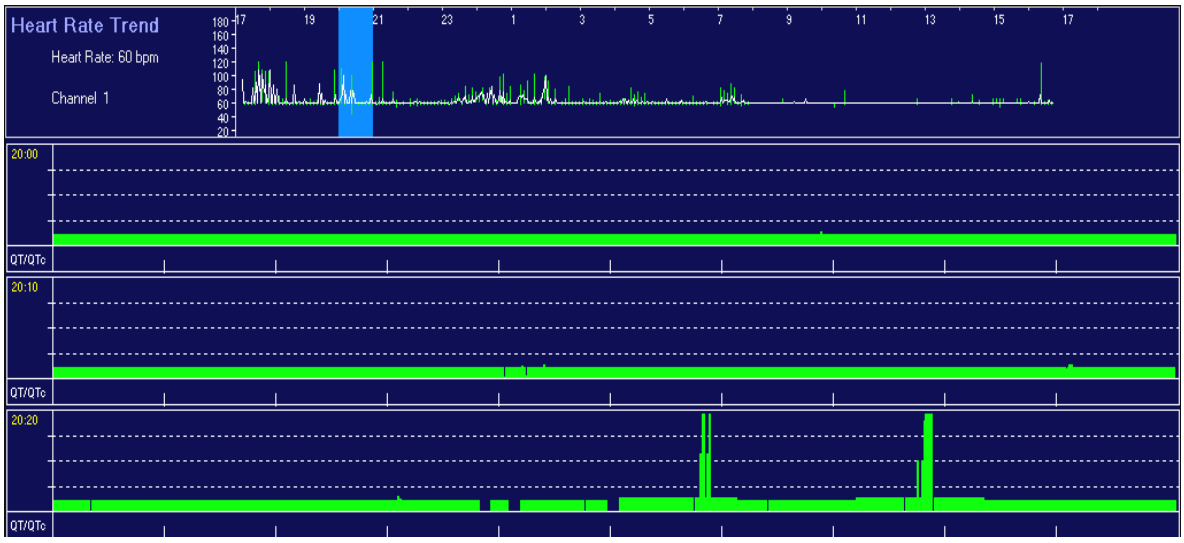


By doing a double left click where there was a sudden change from the long lines to the short lines, you can see the pacemaker change in the next display.

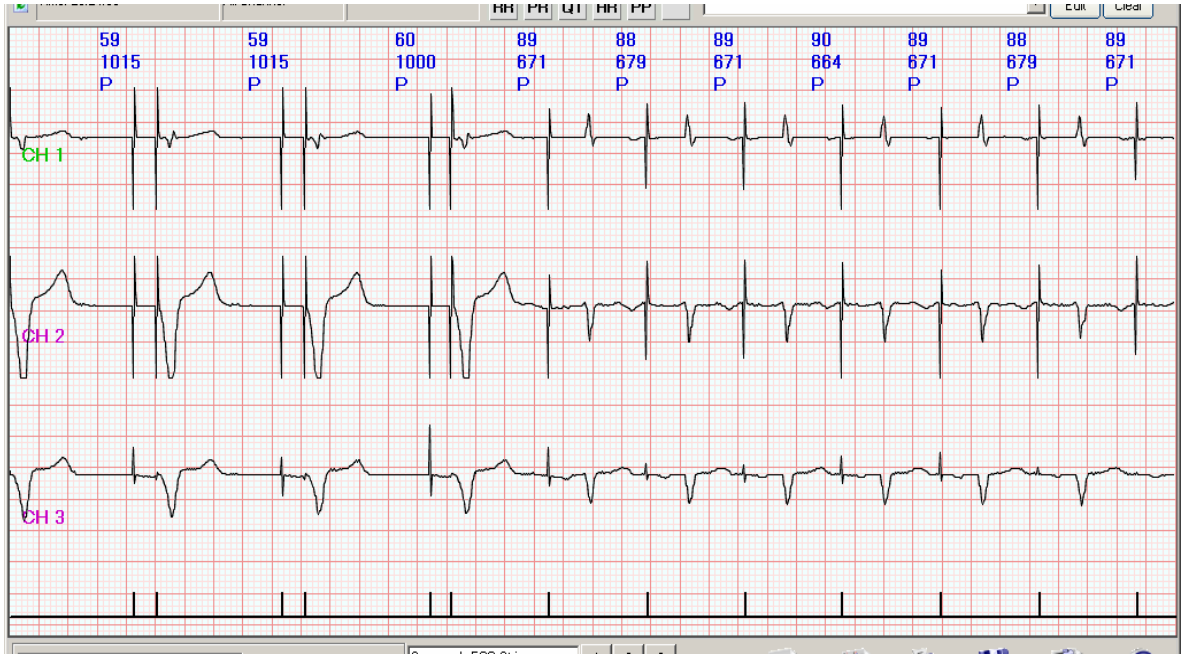


The sudden change in the length of the Spike-to-Spike intervals shows the pacemaker transferring from a single ventricular spike at rates of about 105 to dual firing spikes at rates of about 60.

The next display is for the Spike-to-Beat mode. This would be the mode for detecting Failures to Capture. If there was a failure of the QRS to follow the pacemaker spike, then you would see a long single line.

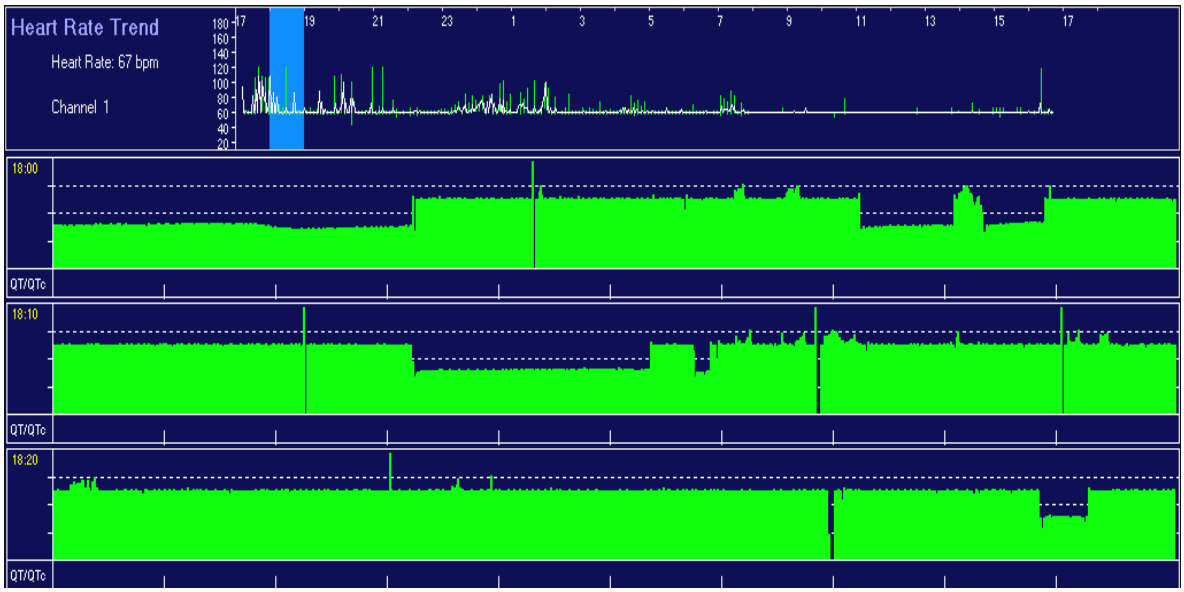


The sudden changes in the length of the vertical green lines indicate a change in the pacemaker function, and the spike to beat relationship. The next screen display shows the change in pacemaker function.

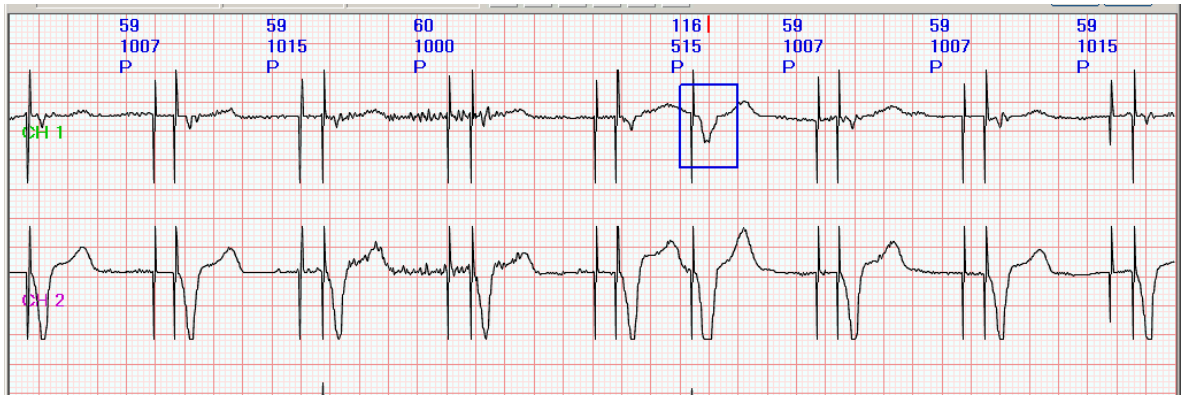


The resulting ECG shows the change in the pacemaker spike relationship to the following QRS.

The next display is for the Beat-to-Spike mode. This would show an indication of Failure to Sense.

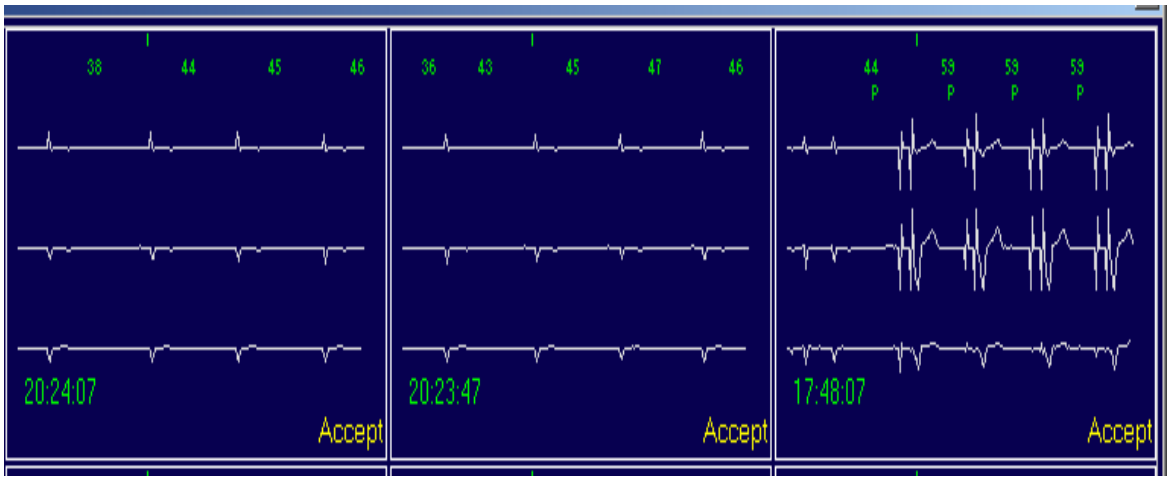


The above Beat-to-Spike shows occasional and sudden changes in the Beat-to-Spike interval. The next display shows the resulting ECG.

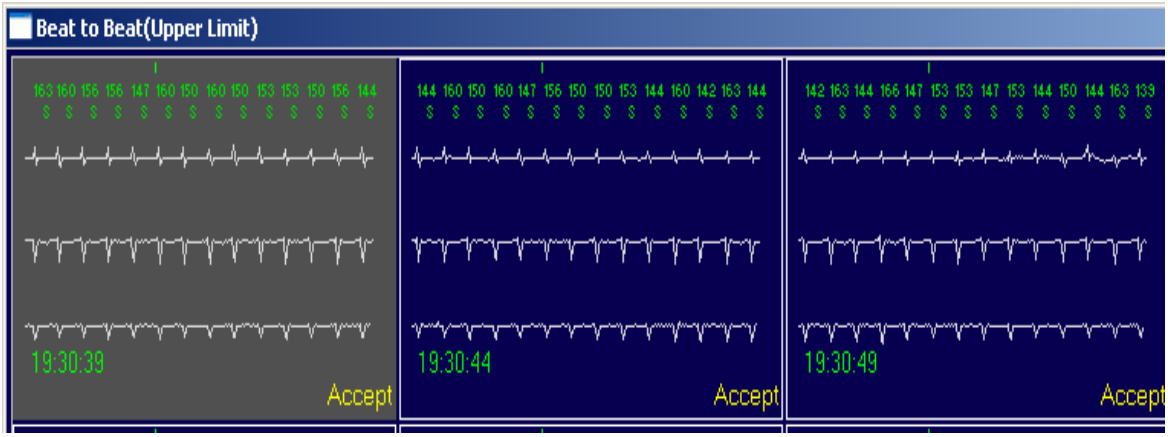


Above there is a single ventricular spike and QRS at a rate of 118 that is surrounded by dual firing pacemaker function at a rate of about 60.

The below screen display shows the minimum QRS rate.



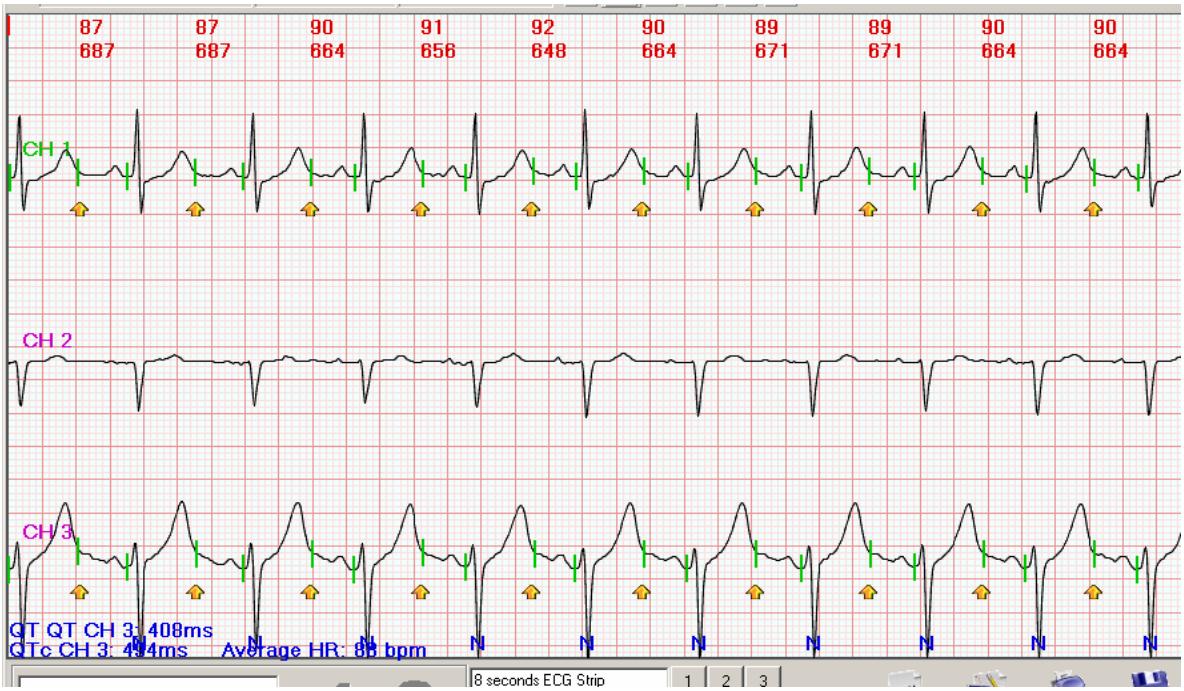
The below screen display shows the maximum QRS rate during the pacemaker recording.



DMSoftware

CardioScan-12 Holter ECG System

Elongated QTc



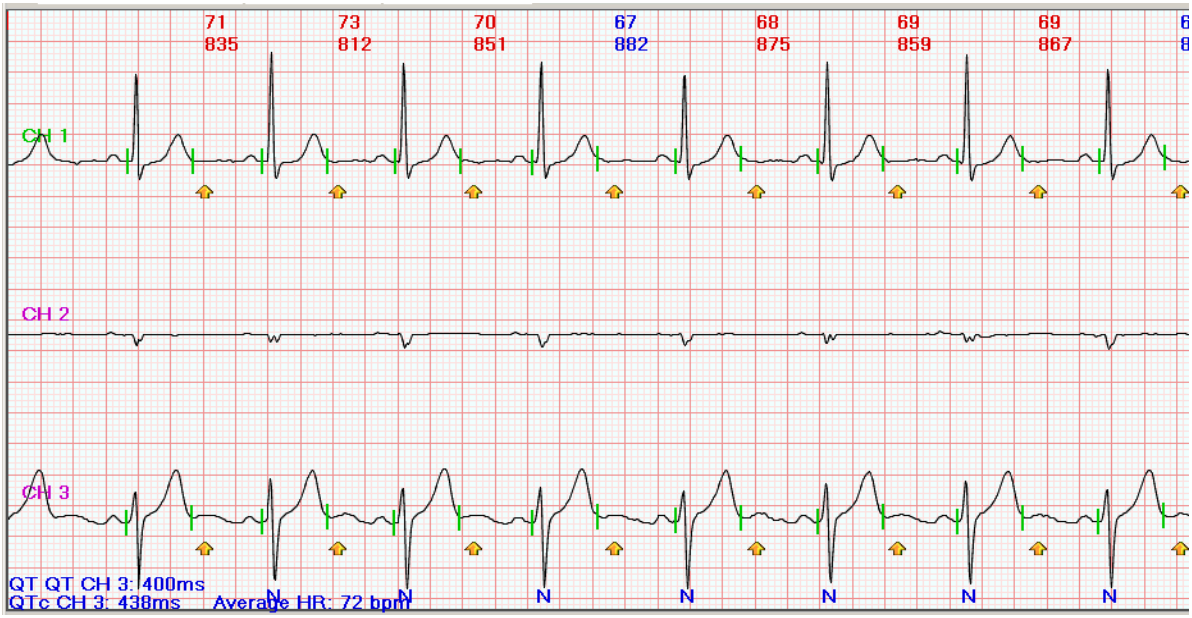
Channel 3 is the analyzed QTc lead. The heart rate is about 90 bpm (see top numbers). The QT is 408 ms (see lower left). The QTc is 494 ms (see lower left).

The QT interval is measured from (a) the right side of the green vertical marker at the beginning of Q, to (b) the left side of the green vertical marker at the end of T.

The thick yellow arrow markers at the bottom of the ECG are located at 50% of the R-R interval.

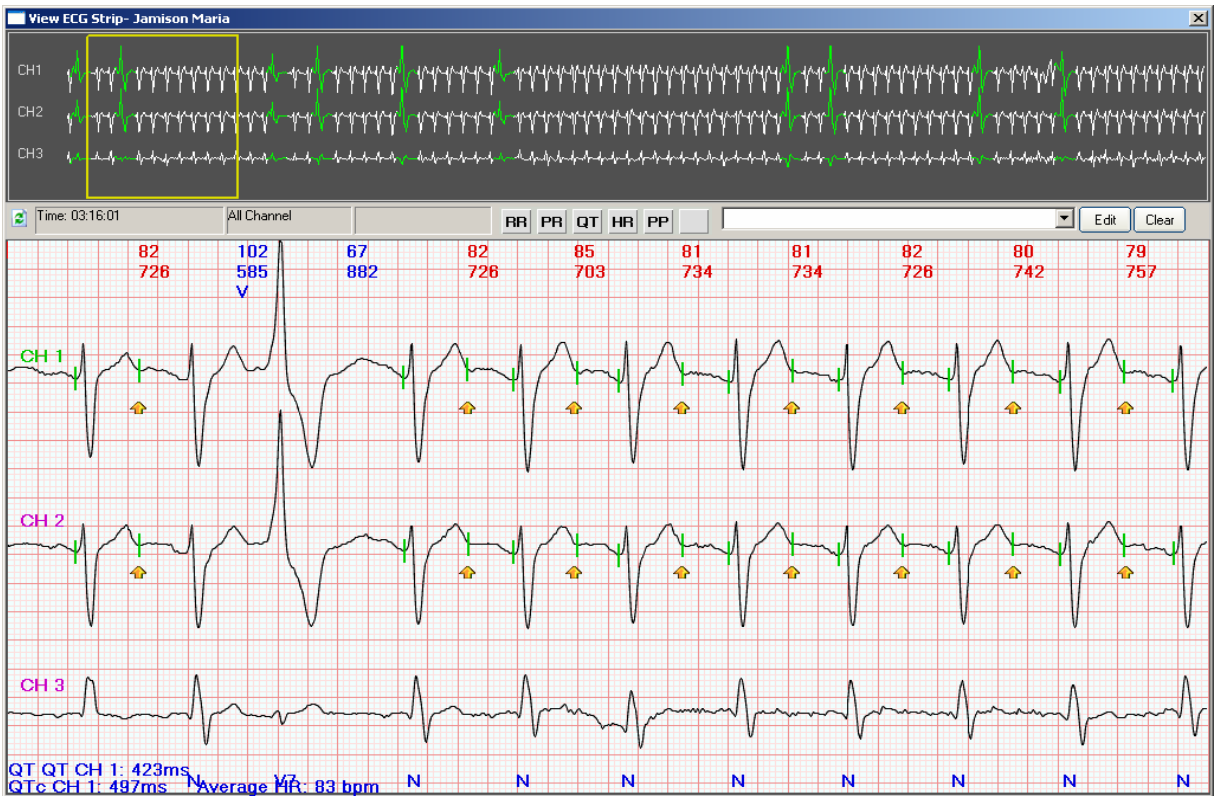
When the Holter algorithm locates a transient QTc interval of interest, a quick and user-friendly process is provided for the physician or technician to visually verify and validate the QTc measurement, Any QTc measurement can be accepted or rejected from the Holter ECG report.

QTc in normal range. QT at 400 ms. QTc at 438 ms. Heart rate at about 70.



Note that this normal QTc shows the end of T marker significantly before the yellow thick arrow, which is placed at 50% of the R-R.

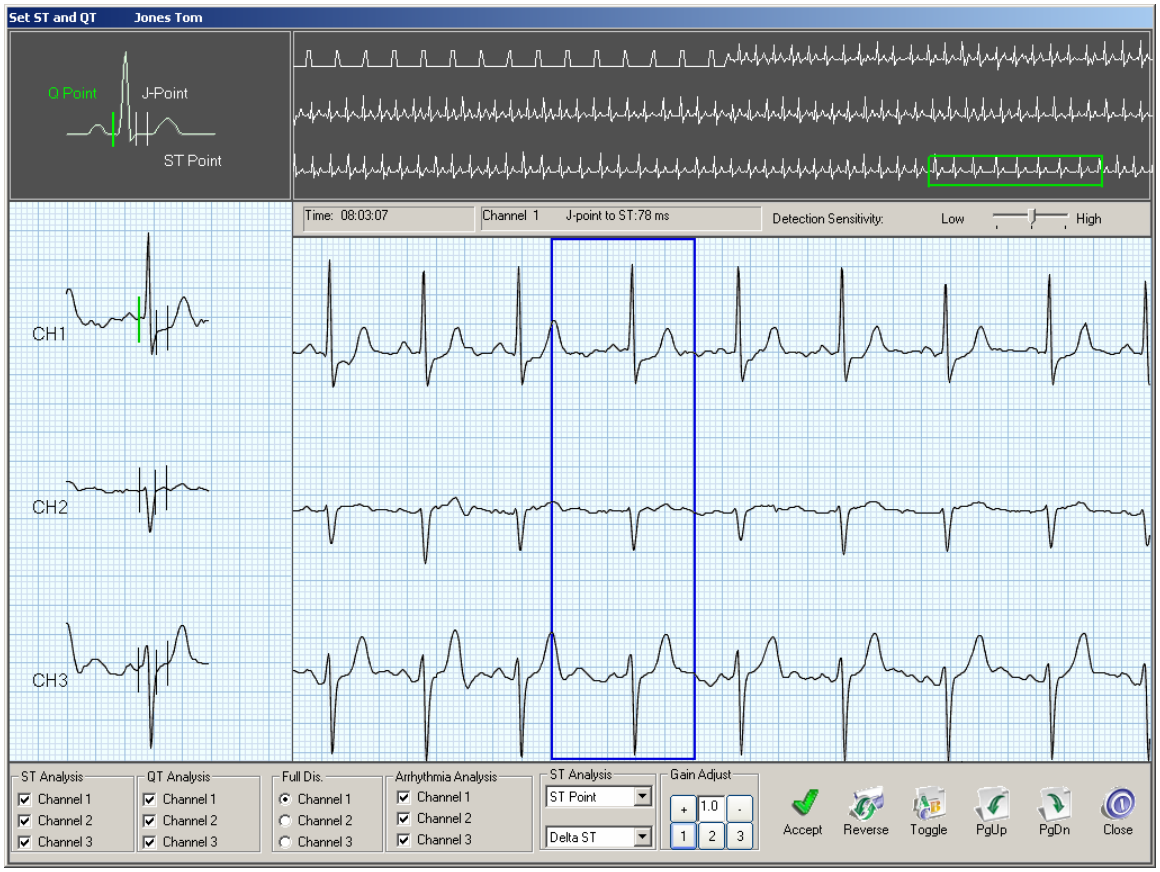
QTc at 487 ms. QT at 423 ms. Heart rate at about 83.



Arrhythmias are deleted from QT analysis. QTc is 487 ms, and end of T and 50% yellow thick arrow line up; thus, indicating a transient elongated QTc.

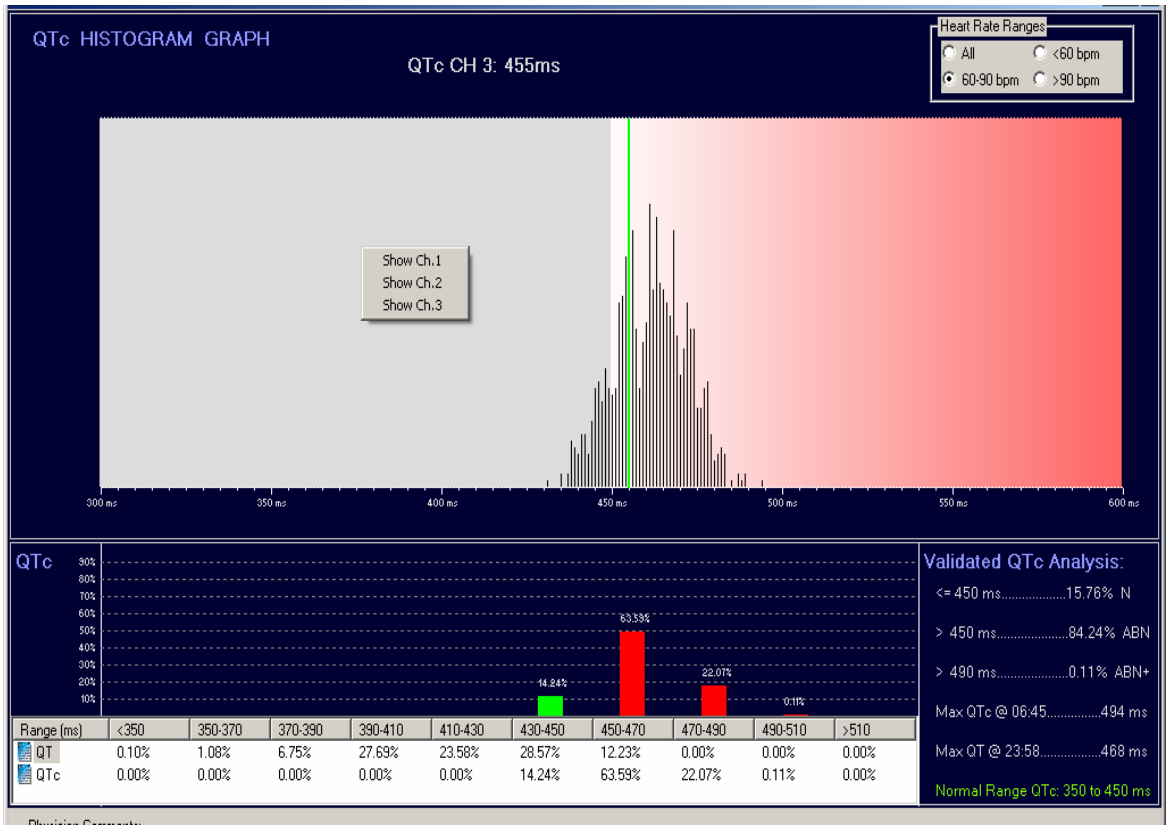
The process for using and editing the QT function.

1. In the ST-QT Set-Up menu, set the first vertical marker to the left of the beginning of Q.



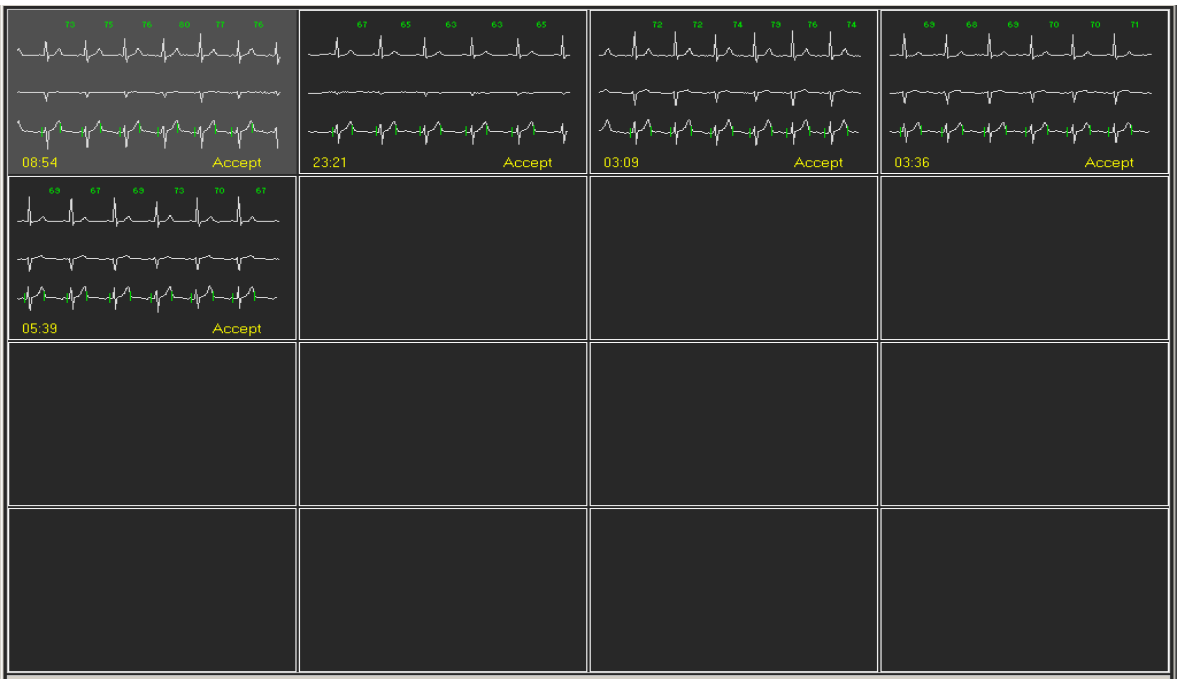
2. Quite often there is no Q-wave to visualize. However, the Q-wave is generally 40 ms in width.
3. When you move the green vertical marker to the left and right, the distance moved with each press of the left or right arrow button is 8 ms.
4. Therefore, place the first green vertical marker at the beginning of the R-wave, and then press the left arrow key for five (5) times. This is the proper location for the first green vertical marker for both ST and QT analysis.
5. This is an essential step for QT analysis.
6. Repeat this process all 3 or 12 Leads.
7. If you are interested in QT analysis for this patient, we recommend that the physician or technician first edits the QT, before editing the Arrhythmia Templates.
8. If the QT data is bad because the first green vertical marker was in the wrong location, the penalty is small. You simply “Re-Analyze” and the penalty is only about 30 seconds of time. If you first edit the Arrhythmia Templates, and then see that the QT needs a new Set-Up, you have wasted a lot of time with editing the arrhythmias.

After analysis, and a mouse click on QT Validation, the QTc histogram appears.



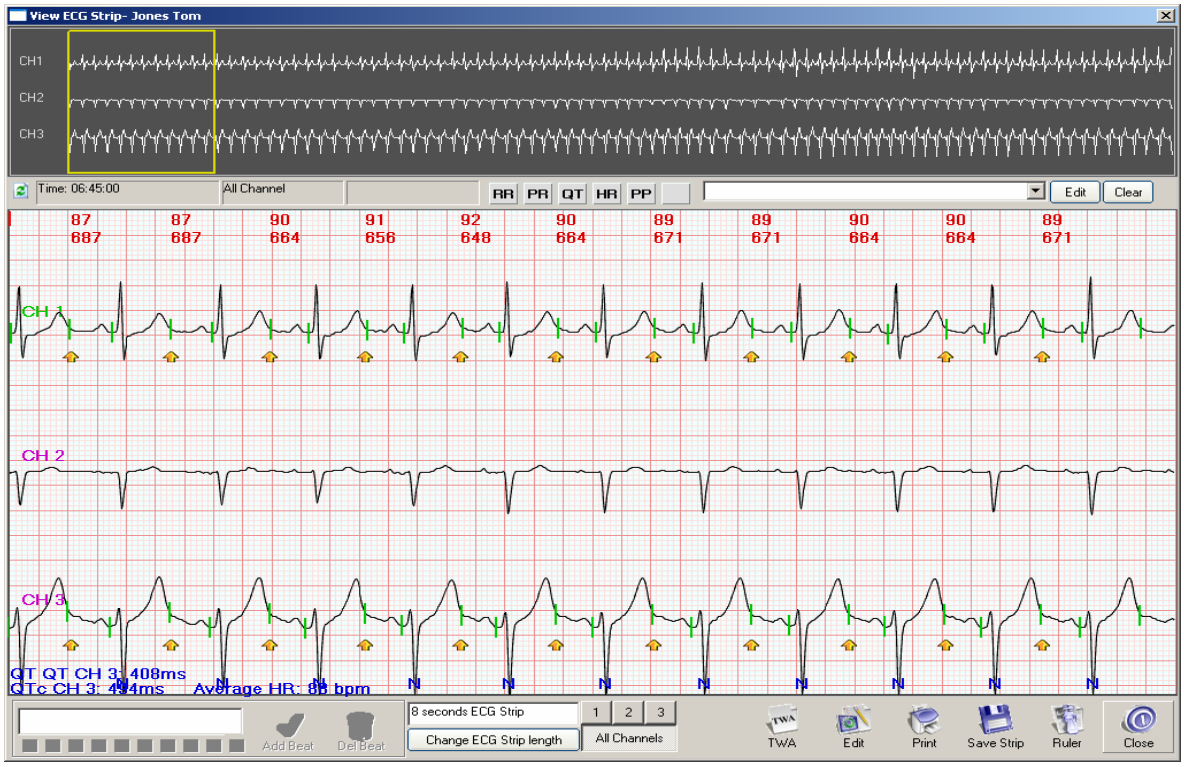
- A right mouse click allows you to select the QTc histogram for Ch. 1, 2, or 3.
- At the top right, you can select QTc analysis for Heart Rates of All, 60-90 bpm, less than 60 bpm, or more than 90 bpm.
- The long green marker in the QTc histogram can be moved by the mouse to any location in the histogram.
- The data of interest is at the far right side of the histogram
- For any analysis in Holter ECG to be valid, you always want to visually verify its accuracy. The QT/QTc is no different.
- The vertical axis of the histogram shows the quantity of QTc measurements.
- The horizontal axis shows the QTc intervals. The more elongated the QTc, the more to the right of the histogram.
- The bar graphs below the histogram show the percentages of QTc at various QTc ms ranges.
- The data at the lower right are the Max QT/QTc readings, and Percentages of QTc,
- To view the max QTc intervals, move the long green cursor to the far right of the histogram, and either double mouse click or press the Enter key.

The below screen display begins the verification and validation process.



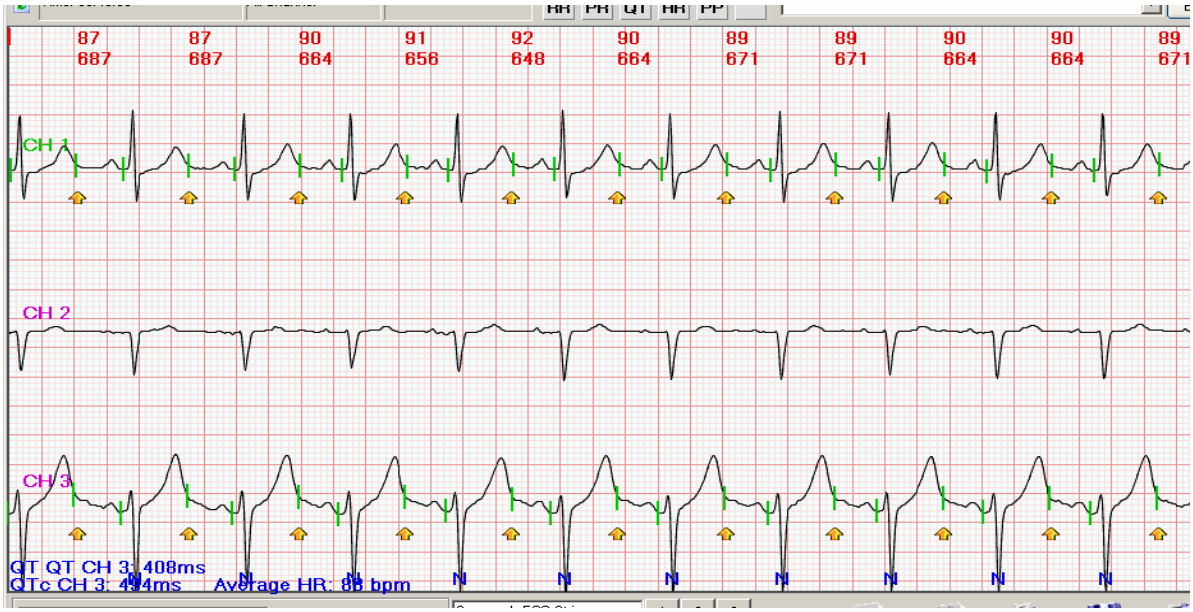
There may be several QTc's at the ms location on the QTc histogram.

Double mouse click on any desired ECG strip.



The QTc editing process is as follows.

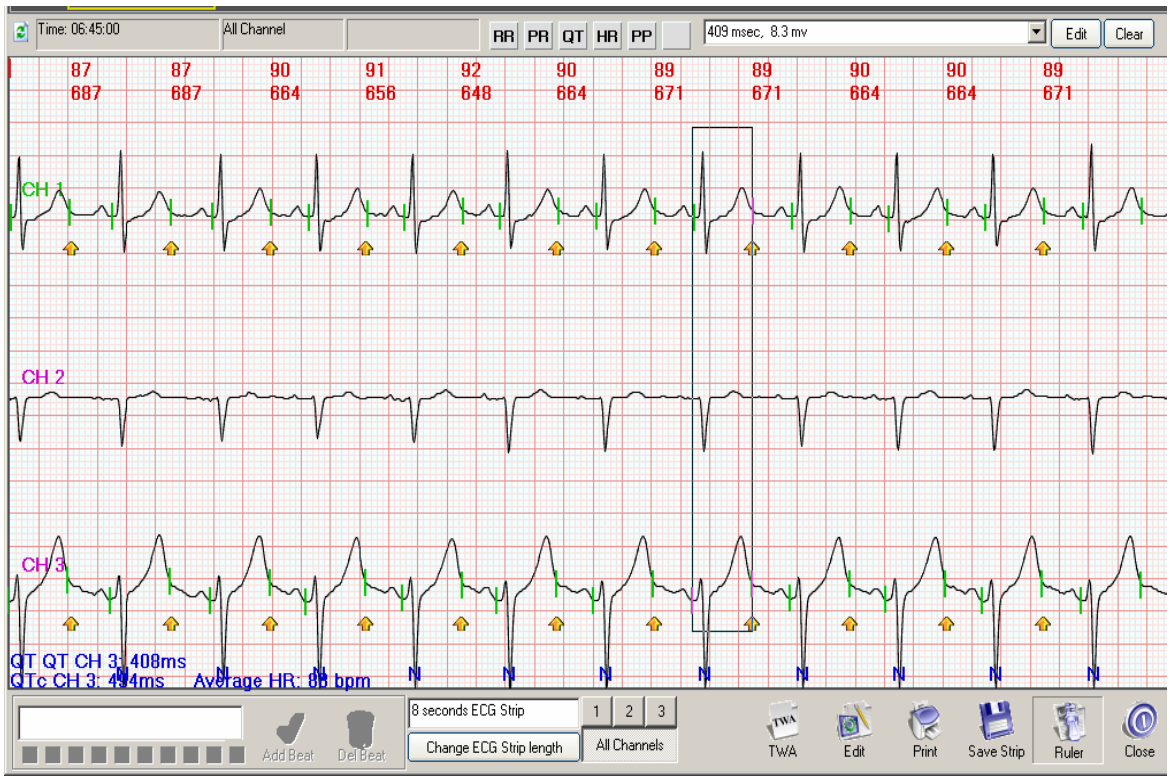
The first step is to verify that the QT vertical markers accurately reflect the QT.



- If the QT markers are not acceptable, then reject this QTc event by ESC, followed by “R” for Reject.
- If the QT markers are acceptable, then the verification process has passed its first test.
- You can slide through this data for the entire 1-minute.
- The red Heart Rate numbers at the top of the display represent the beats from which QTc should be verified.
- You want to see acceptable QT markers for any four (4) or more successive beats with red heart rate numbers at any location in the 1-minute of data.
- The purpose of the yellow thick arrow at the bottom of the display is to provide a visual reference for the “rule-of-thumb” that a QT of 50% of the R-R interval indicates an abnormal QT interval.
- Another purpose of the yellow arrow is that the standard Bazzet formula for QTc does not perform well outside of a resting heart rate range. Holter heart rates are quite often outside the resting heart rate range. Thus, the 50% yellow arrow markers make for a good visual reference, especially when the Bazzet formula is ineffective.
- At the lower left, the QT, QTc, and average Heart Rate are shown.

To continue verification, click on Ruler icon at lower right. *

After clicking on the Ruler icon, move the cross hairs to the beginning of Q at Channel 3, and then drag the mouse to above Channel 1 and over to end of T.



Just above the electronic Ruler measurement, you see a field with the number of 409 ms. This is the QT interval measurement. Look to the lower left, and you see the computer measurement of QT on CH. 3 at 408 ms. This is verification that the computer measurement of QT at 408 ms and the corresponding QTc measurement of 494 ms are accurate.

The goal of the transient elongated QTc detection is simply to find, verify, and validate the presence of one or two abnormal QTc events. Therefore, you only need to validate one or two abnormal QTc events. This should only take one or two minutes of time.

Because of this Validation process, the DMS program for finding transient elongated QTc is believed to be the best in the industry.

Recently, serious attention has been spotlighted on the elongated QTc syndrome because of the findings that many common medications are not well-tolerated by certain patients, and the implications can be worrisome. These medications are mainly anti-arrhythmia, allergy, psychiatric, and malaria. A listing of over 100 of these medications are listed by the European Society of Cardiology, and other medical associations. A standard Holter ECG test is probably the most cost-effective method of testing for this abnormality. As stated in the textbook by Bayes de Luna (Professor of Cardiology), “Clinically, the lengthened QT sometimes indicates a very poor prognosis.”

DMSoftware

CardioScan-12 Holter ECG System

Serial Atrial Fib

The Atrial Fib program includes the following features:

1. Each minute in a 24-hour time period is analyzed for either sinus rhythm or A-Fib.

2. The recording period can be for up to 7-days. A single battery will last for 7-days of continuous Holter 3-Lead ECG recording. The memory built into the Mini-Holter recorder can store the entire 7-day recording.

3. A minimum of 2-days of Holter recording is recommended for A-Fib patients. If the A-Fib begins in the 22nd hour, then ending the Holter recording at 24-hours would prevent the knowing of the important factor of length of time of the A-Fib rhythm.

4. Serial Holter recordings show if and when there is an increase in the length of time of the A-Fib minutes. The lengthening of time periods of A-Fib minutes alerts the cardiologist to consider changing the drug therapy, or other medical strategies.

5. It is important to show a clear 24-hour trending of the average, minimum, and maximum heart rate during each minute of Sinus and A-Fib rhythm.

6. In general, A-Fib rhythm is accompanied by a significant increase in the average heart rate, along with dramatic decreases in minimum heart rates and dramatic increases in maximum heart rates.

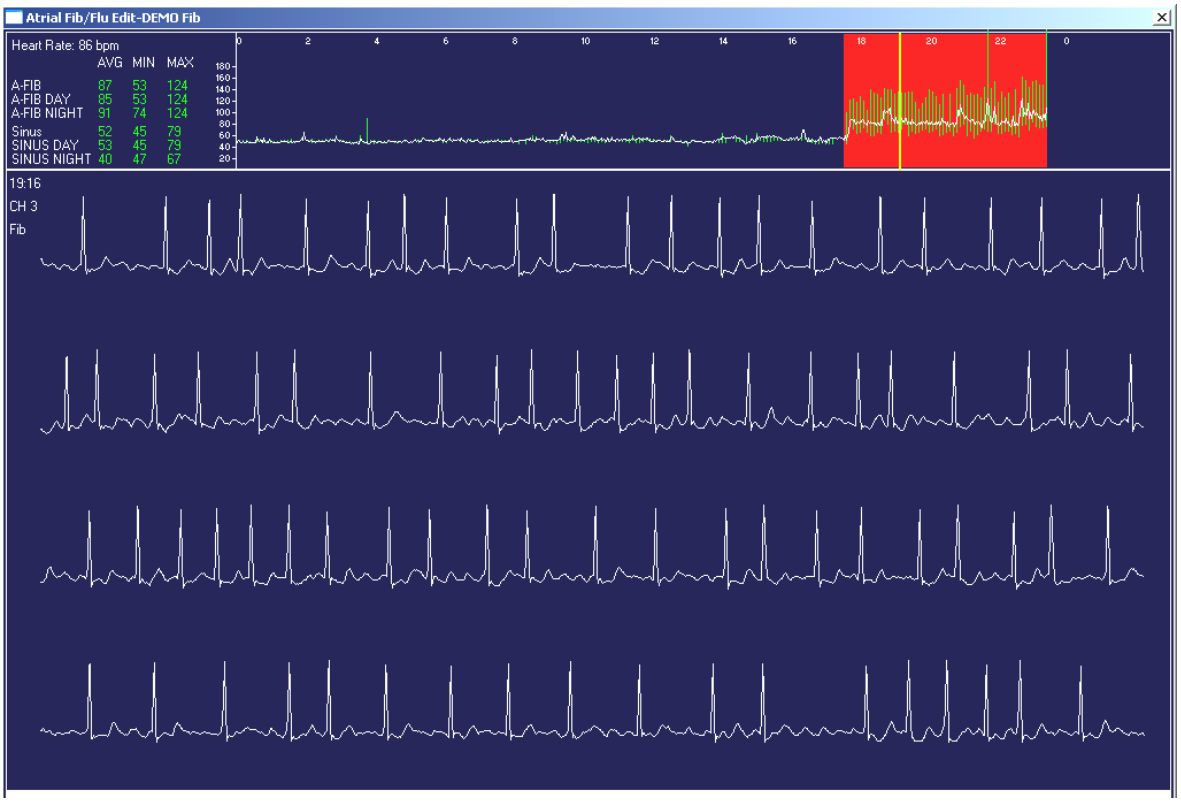
7. All of this heart rate data needs to be shown on a minute-by-minute basis.

8. Each minute of detected Sinus or A-Fib rhythm must include an instant process for verifying the minute's analysis of Sinus or A-Fib rhythm.

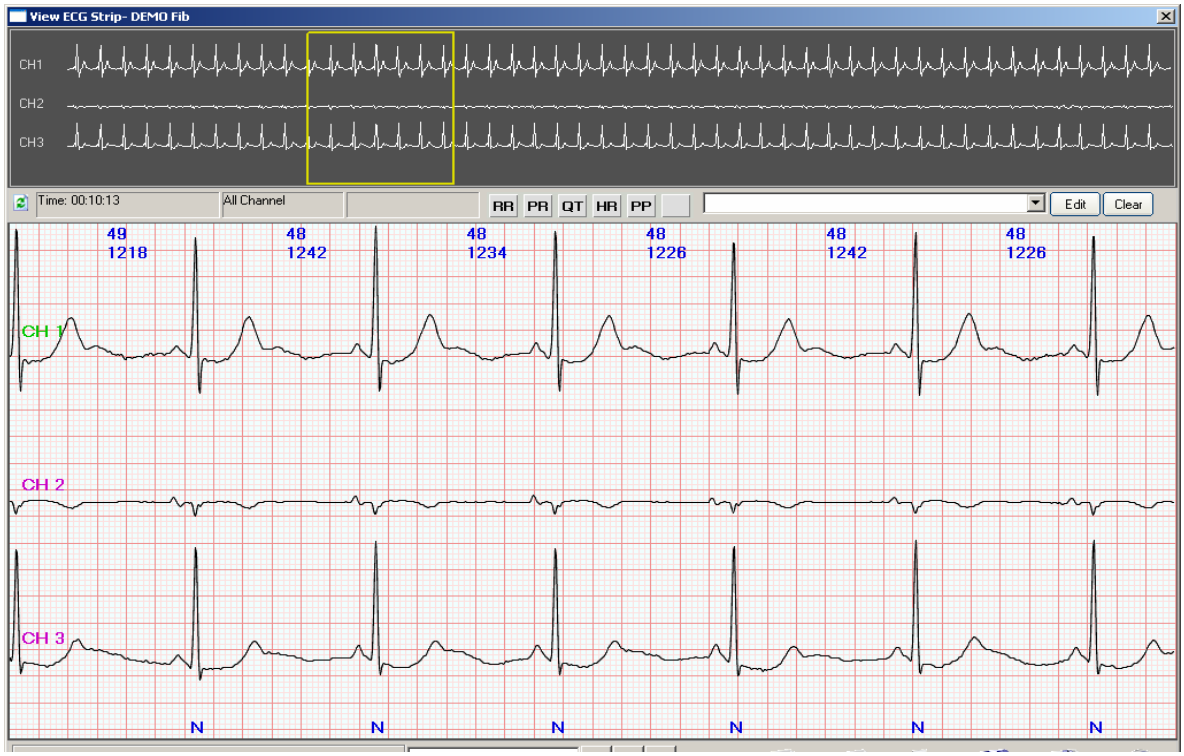
9. Just as Template editing provides quick processing of arrhythmias, the A-Fib program also requires fast and user-friendly editing of Sinus or A-Fib minutes.

10. The following displays show the quality serial comparisons of A-Fib rhythms.

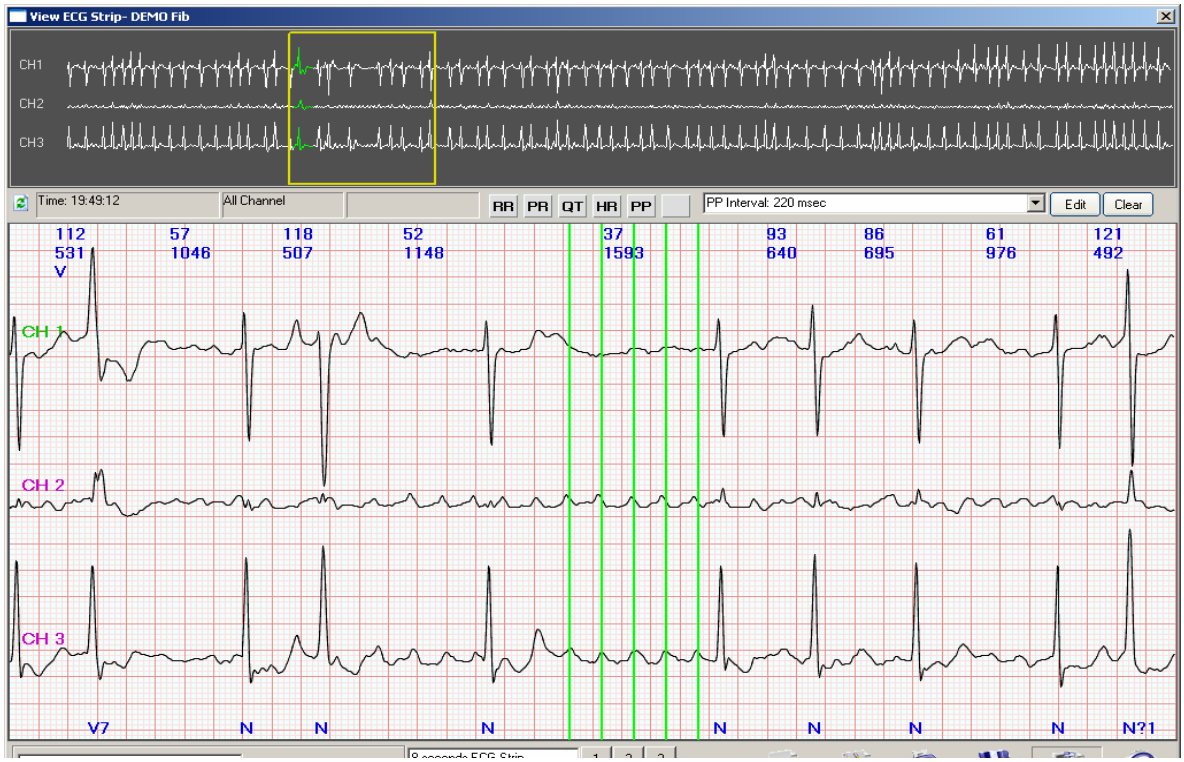
24-Hour Display of Sinus and A-Fib minutes



- The top of the display shows a 24-hour Rhythm graph. The first 17 hours are Sinus rhythm, followed by about 6 hours of A-Fib.
- The red area is the A-Fib rhythm.
- Each minute of the graph shows the average, minimum, and maximum heart rate.
- Note the change in increased heart rate during the A-Fib minutes.
- The vertical lines seen in the red area are the minimum and maximum heart rates.
- The long yellow cursor seen in the red area can be moved with the mouse to any location in the 24-hour graph. Wherever you place the long yellow marker, that one-minute of ECG is immediately displayed.
- This is how you validate the minute for either Sinus or A-Fib.
- Any minute, or group of minutes, of data can be quickly edited.
- The top left of the display shows the average, minimum, and maximum heart rate for daytime Sinus minutes and nighttime Sinus minutes; and shows the same heart rate data for daytime and nighttime A-Fib minutes.
- The A-Fib patient can be recorded for a 1 to 7 day period.
- By Holter monitoring the A-Fib patient periodically, the above analysis and associated report gives the cardiologist a clear picture as to whether or not the A-Fib minutes are growing.

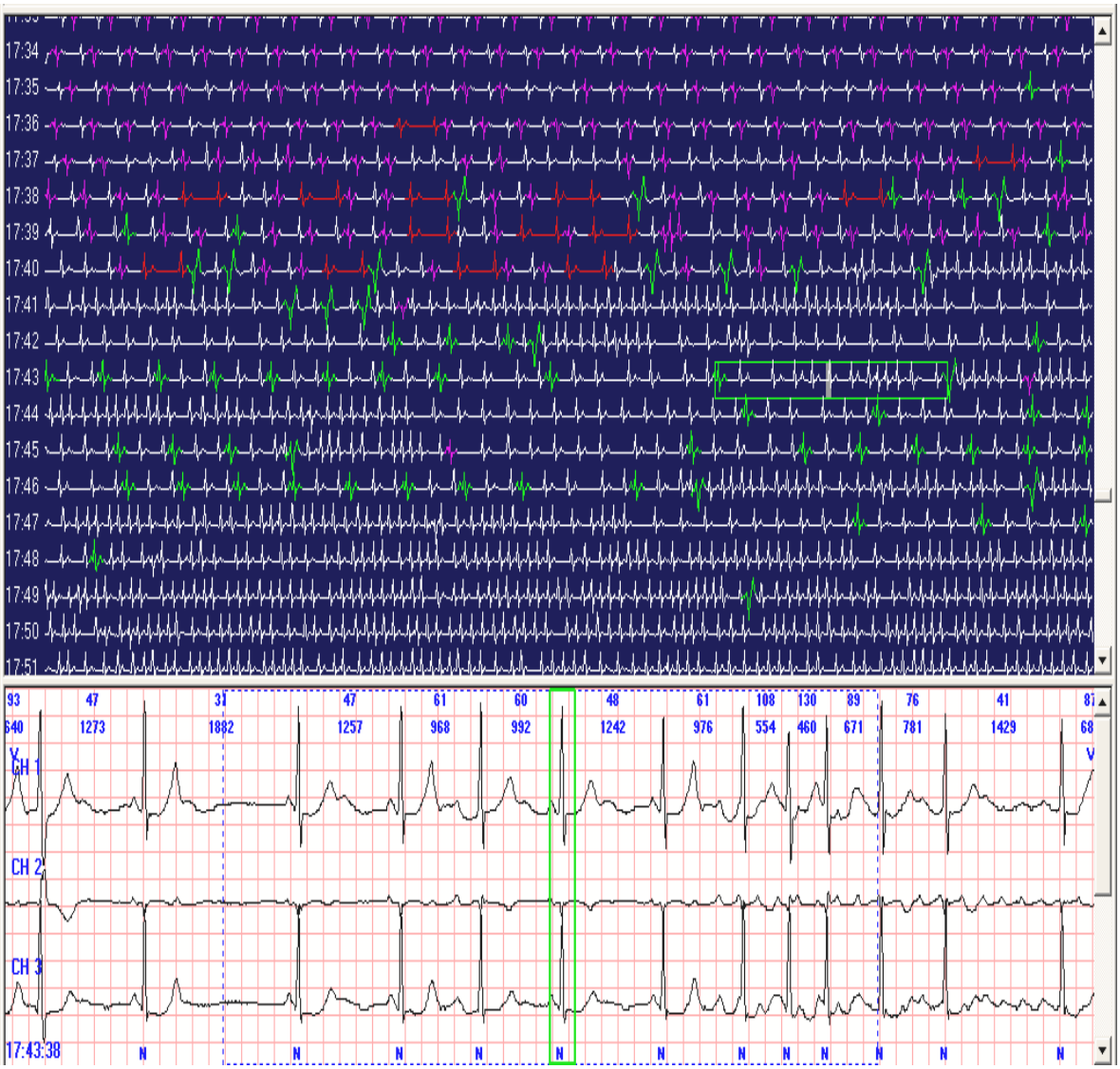


Normal Sinus rhythm for a patient with A-Fib.



Same patient with A-Fib. Note the auto-measure of P-P intervals.

Clear Picture of ECG Activity Entering Into A-Fib:



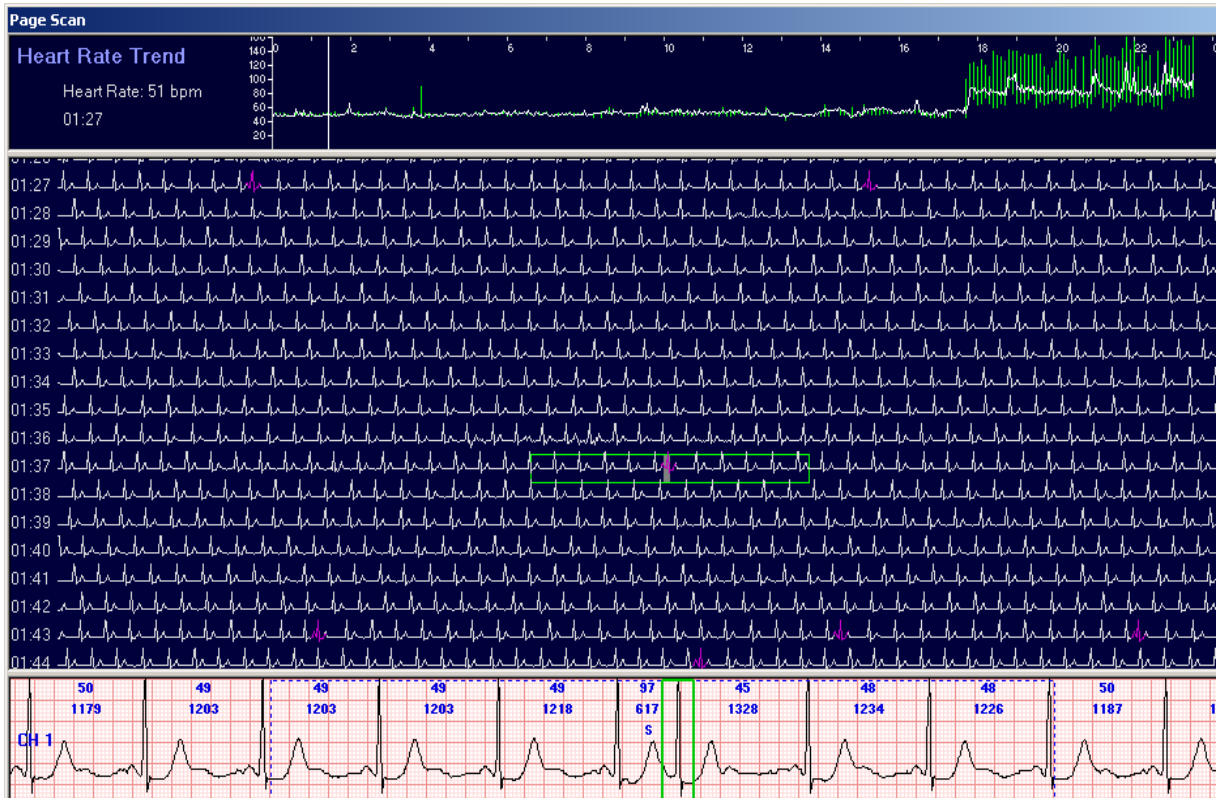
The above display from Page Scan shows the normal beats in white, the VE beats green, the SVE beats in majenta, and the non-compensatory pause R-R intervals > 1.5 seconds in red.

A rectangular green box at the 17:43 minute is selected with a mouse click.

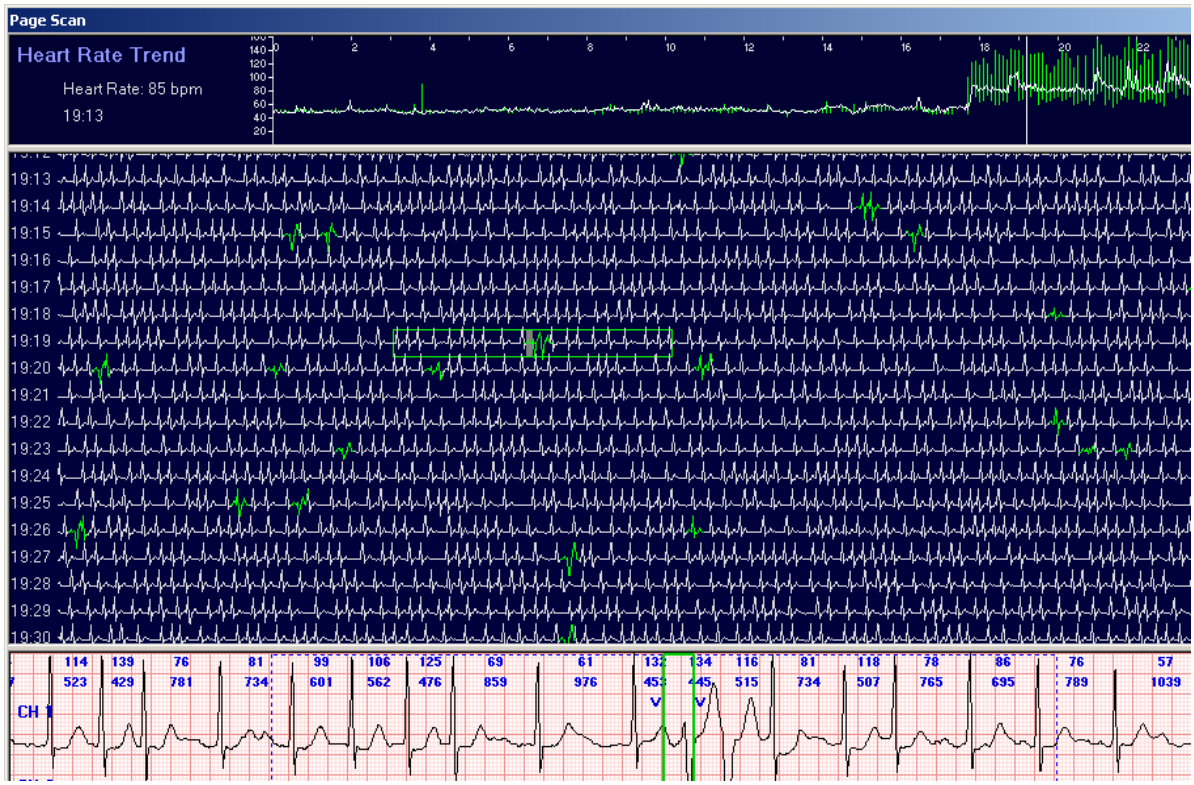
The 3-channel ECG strip shows the rhythm changing from Sinus to A-Fib.

There was significant SVE activity and long R-R intervals just prior to the patient entering into the A-Fib rhythm.

Typical Full Disclosure look at this patient's Sinus rhythm:



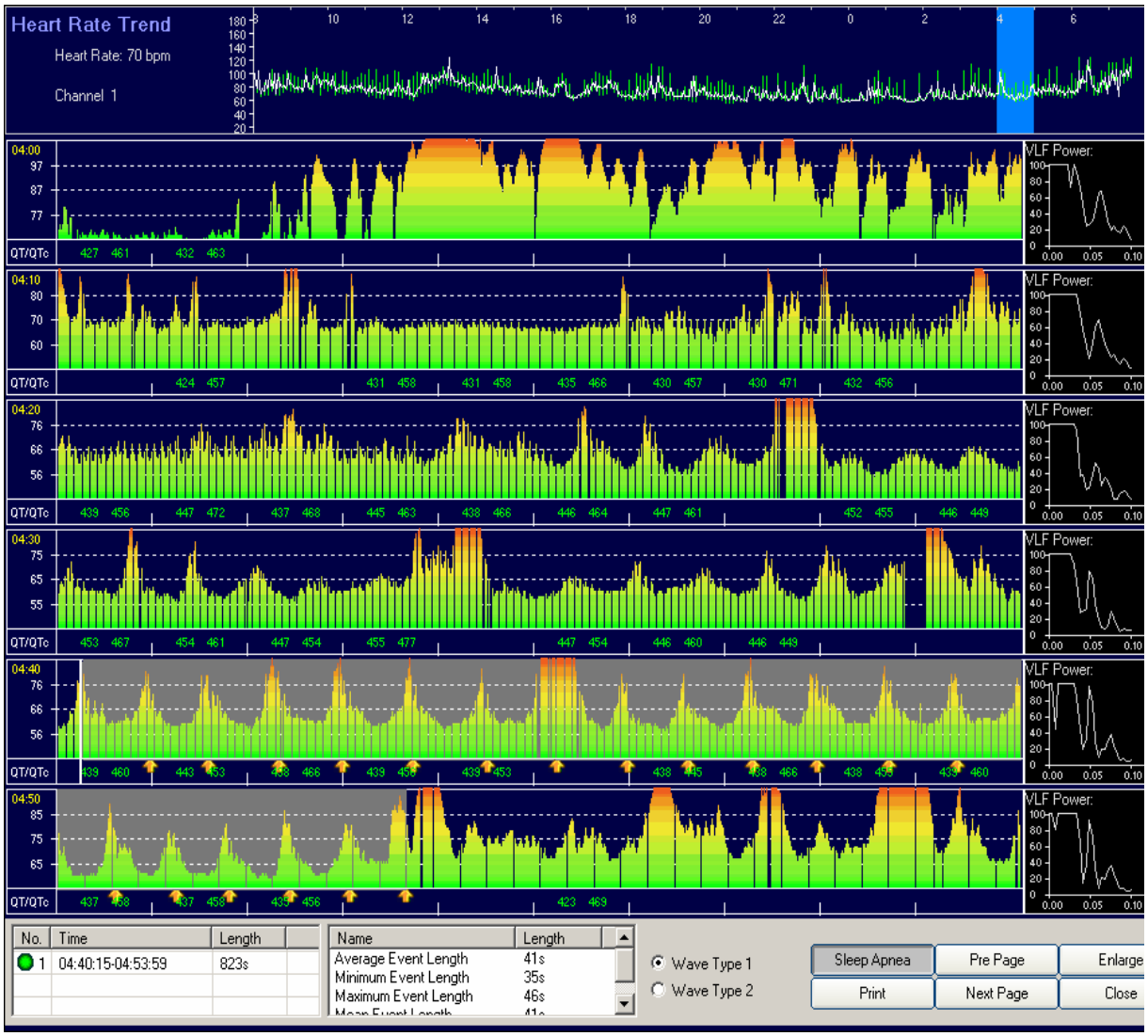
Typical Full Disclosure look at the patient's A-Fib rhythm:



DMSoftware

CardioScan-12 Holter ECG Systems

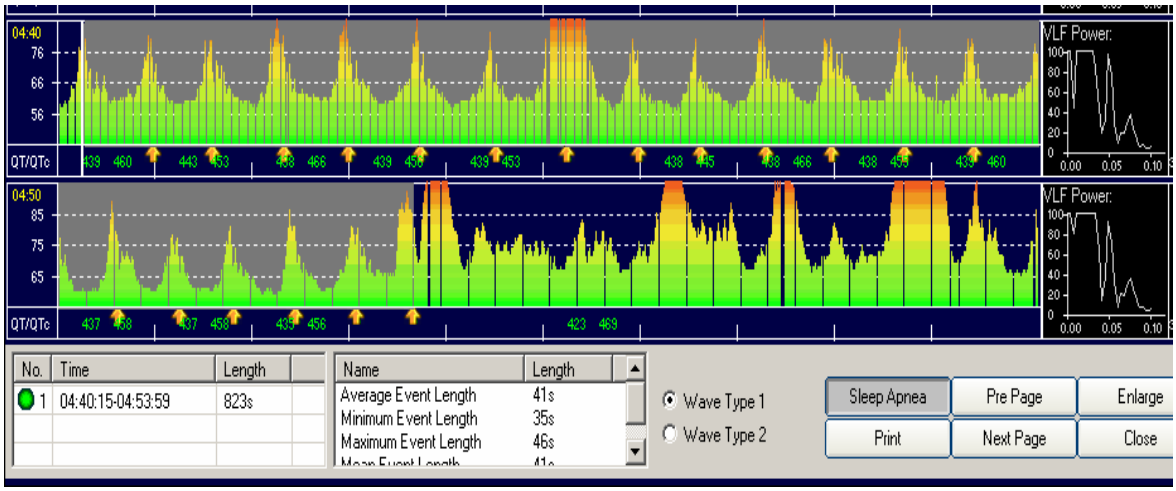
Sleep Apnea



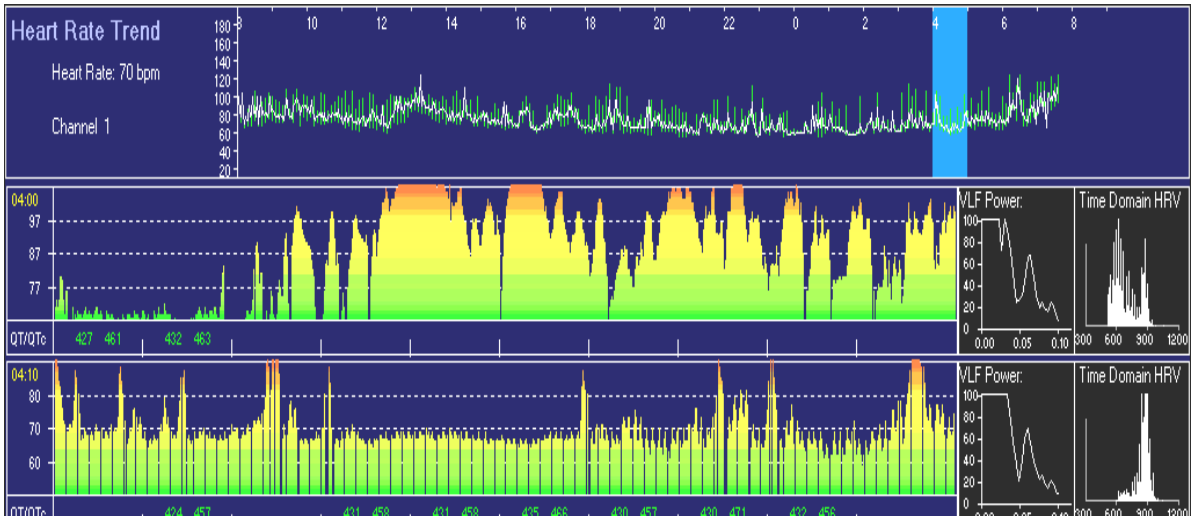
The above display shows a sleep disorder starting at 4:40 AM and ending at 4:53 AM. The sleep disorder episode is shown with the gray background, and each of the individual sleep events are shown with the yellow arrow markers.

Cardiac Sleep Disorders:

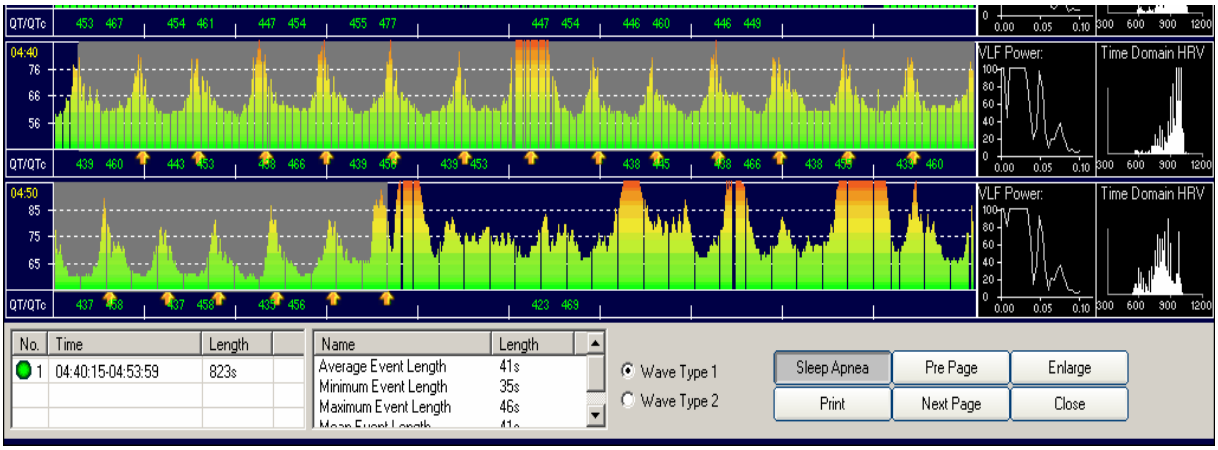
- Over the past 5-years there has been a shift of sleep disorders from pulmonary and neurology problems to cardiac problems.
- The credible medical literature has reported hundreds of studies on the cardiac association with sleep disorders.
- This was prompted by the observation that a high percentage of patients with documented sleep apnea from polysomnography tests evolved into cardiac disease. The source reasons for this evolution are controversial, but it appears to be quite clear that early detection of sleep apnea disorders may be a major factor in early detection and preventive programs for cardiac disease.
- The vast majority of cardiology studies on detecting sleep apnea disorders use Heart Rate Variability (HRV) techniques to detect transient sleep apnea disorders.
- The below display is the premier visual display of HRV activity in detecting these transient sleep disorders.



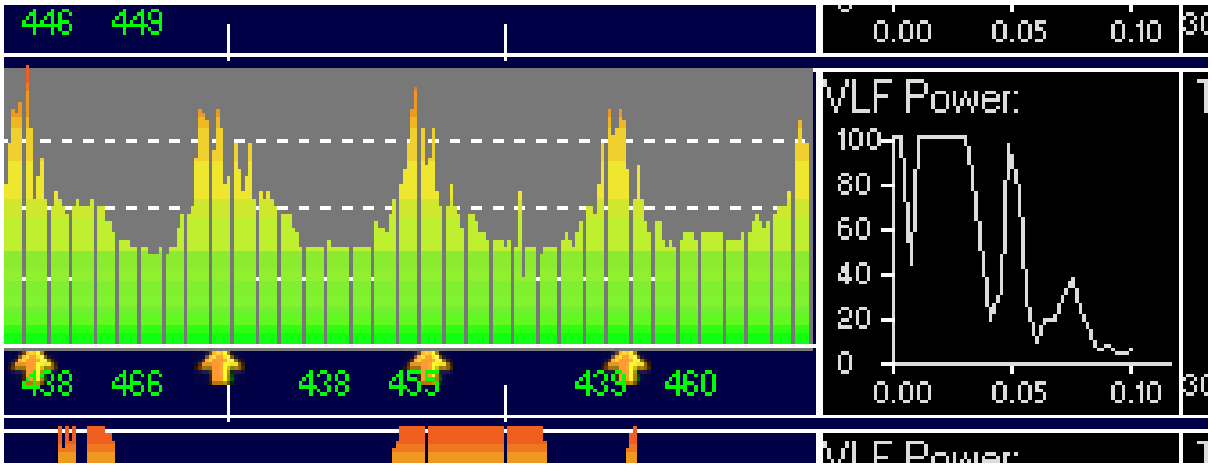
- The green vertical lines are all the normal R-R intervals in 10-minutes. These two horizontal sweeps represent 20-minutes of normal R-R intervals.
- The classic HRV activity in sleep disorders is a gradual brady-tachy change in Heart Rate during each abnormal breathing event.
- Each cycle of the ocean-wave-like look of the R-R intervals is an abnormal breathing event.
- It is clear that the R-R interval data pre and post the Sleep episode do not have the smooth brady-tachy R-R transition that matches the elongated abnormal breathing disorder events.



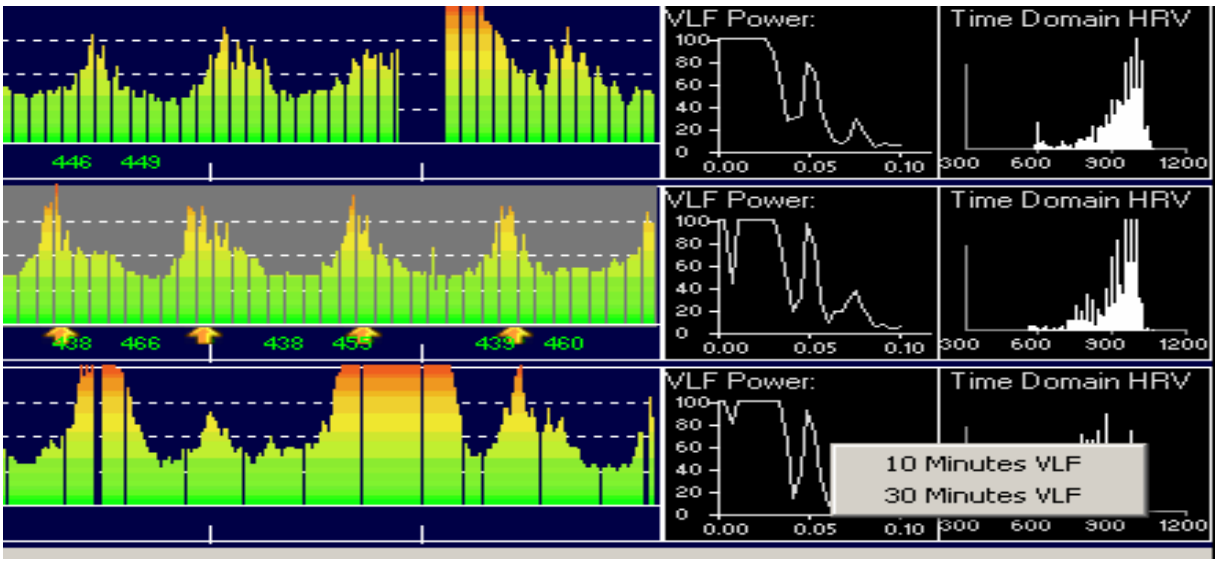
- This display is accessed from Page Scan.
- The top of the display shows the 24-hour heart rate with min, max, & avg. HR.
- With the mouse arrow you can select the desired 1-hour of R-R data. The light blue color shows the selected hour.
- With suspected sleep disorder patients, you would want to view the usual 6 to 8 hours of sleep. These sleep hours are usually the hours of slowest HR.
- By double clicking on the selected hour, the corresponding 1-hour of normal R-R intervals are displayed in 10-minute horizontal sweeps.
- In less than 1-minute all sleep hours are easily reviewed, and sleep disorder episodes are easily recognized.



- The directly above data shows that the Sleep Disorder episode lasted for 823 seconds; with the Average Sleep Event at 41 seconds, the Minimum Sleep Event at 35 seconds, and the Maximum Sleep Event at 46 seconds.
- To the right of the wave-like R-R intervals is a Frequency graph of Heart Rate Variability that is spotlighted on the VLF (Very Low Frequency). A sudden drop in VLF power is clearly depicted, and many cardiology studies have associated this type of VLF function with Sleep Apnea Disorders.
- Thus, you have two independent confirmations of a Sleep Disorder episode.



- The VLF Power graph clearly shows a sudden drop in power at the far left side of the Frequency graph.
- Each 10-minute time period is subject to HRV analysis.
- The physician can choose to show the VLF Power for only those beats in the 10-minute time period, or you can choose a 30-minute time period that includes 10 minutes pre and 10 minutes post this 10 minute time period.



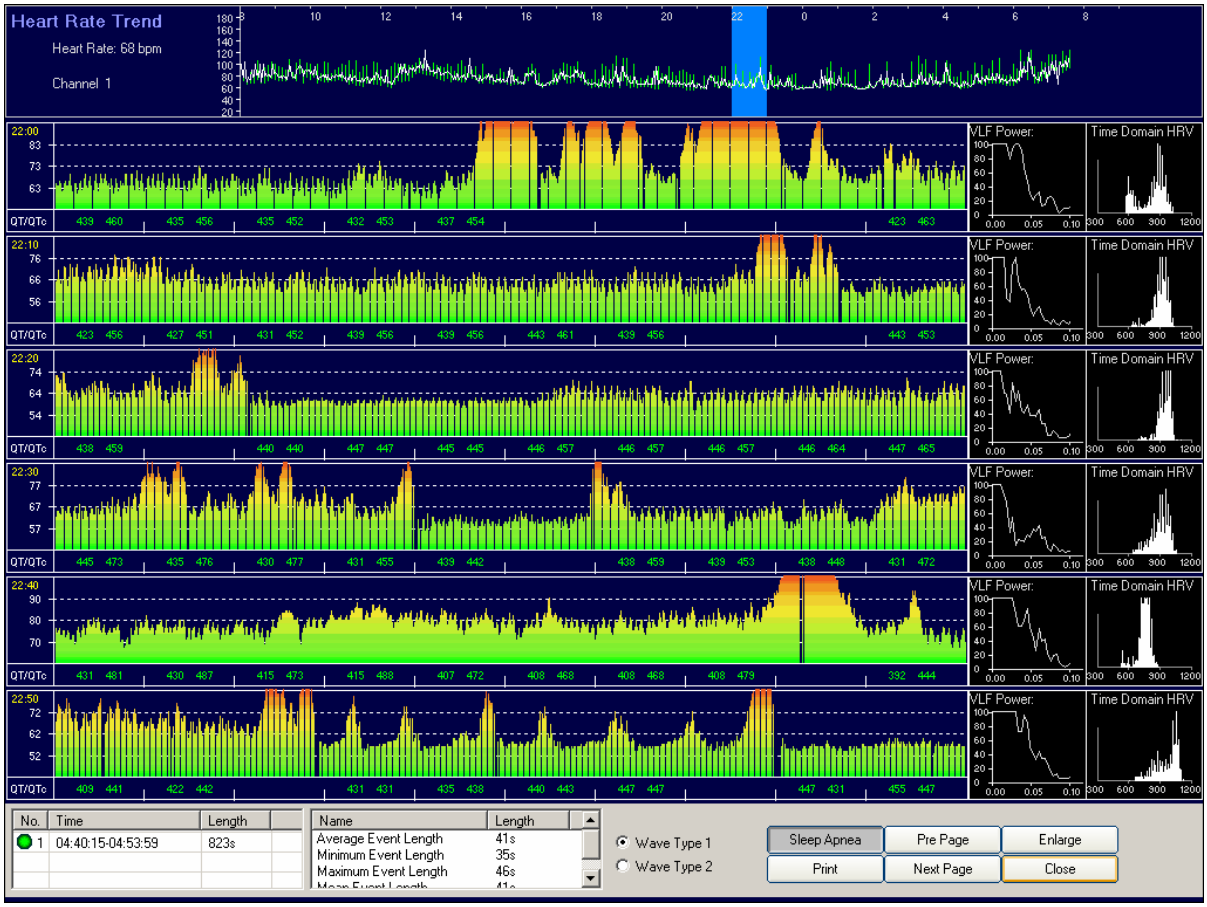
- You can select the 10 or 30 minute HRV analysis for each 10-minute horizontal sweep by placing the mouse arrow in the VLF Power area, and then doing a right mouse click.
- This VLF Power graph shows that there was no indication of a Sleep Disorder during the top 10-minute time period. The middle time period (which had the wave like display of R-R intervals throughout the 10-minute time period) has a significant drop in VLF Power. The next 10-minutes of R-R intervals shows a small VLF Power drop, which matches the wave-like R-R intervals during the first half of the 10-minute time period.

The purpose of this test is to provide the physician with a simple and low cost procedure that can be a good indication for a Polysomnography overnight sleep study.

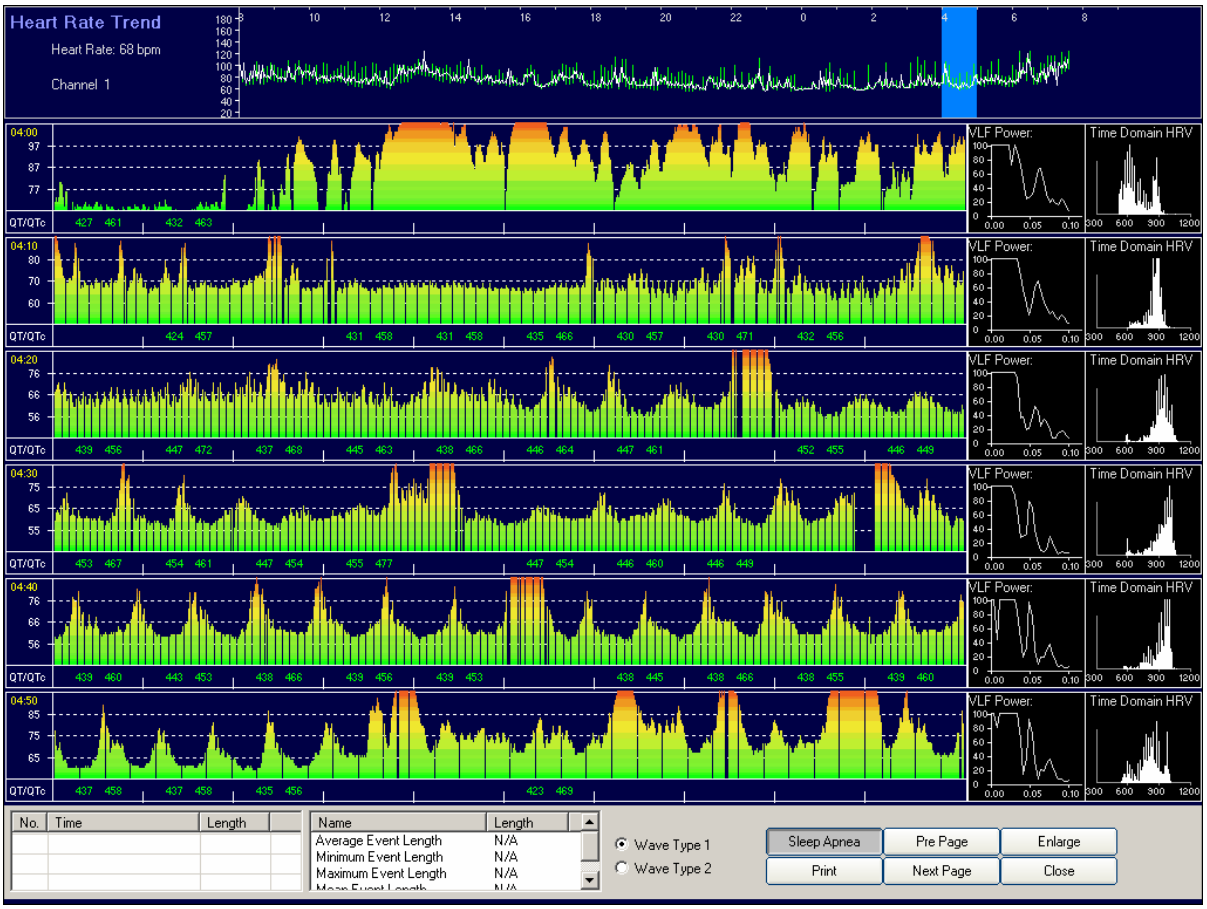
1. Accessing the internet for HRV Sleep Apnea studies will reveal a very large number of cardiology studies using Holter recorders and Heart Rate Variability for an efficient and economical method for the early detection of Sleep Apnea Disorders.
2. The general patient indications are males, over 40 years old, overweight, and snore. For females it is post-menopause, overweight, and snore.
3. This represents a huge quantity of patients presenting with these above indications.
4. The CardioScan 12 includes this Sleep Disorder analysis for each processing of a Holter recording.
5. There is no charge for this capability.
6. The data can be used as an early detection of a significant Sleep Disorder. However, a positive test should only be considered an indication for more traditional sleep disorder testing.
7. This capability can also be used as a follow-up to drug therapy or C-Pap therapy.
8. Since the time for viewing and verifying apparent sleep disorder events only takes about 1-minute of time and there is no additional cost, the CardioScan is the best choice for a quick and economical procedure for finding a transient and positive indication.
9. The basic Holter ECG function of reporting on heart rate changes has been found by the cardiology research community to be the key to the early detection of this very serious patient abnormality.

You access this Sleep Apnea Disorder data by clicking on Page Scan, and then clicking on Page Scan Sleep Apnea. Then click on each hour during the patient sleep hours. Within 1-minute you will know if there are any wave-like R-R events.

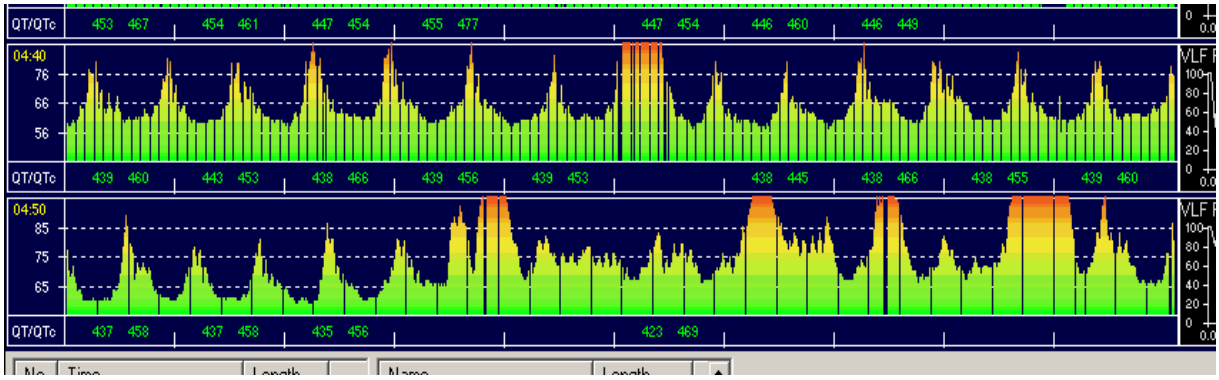
Procedure for Marking the length of time for the Sleep episode, plus each individual abnormal breathing event.



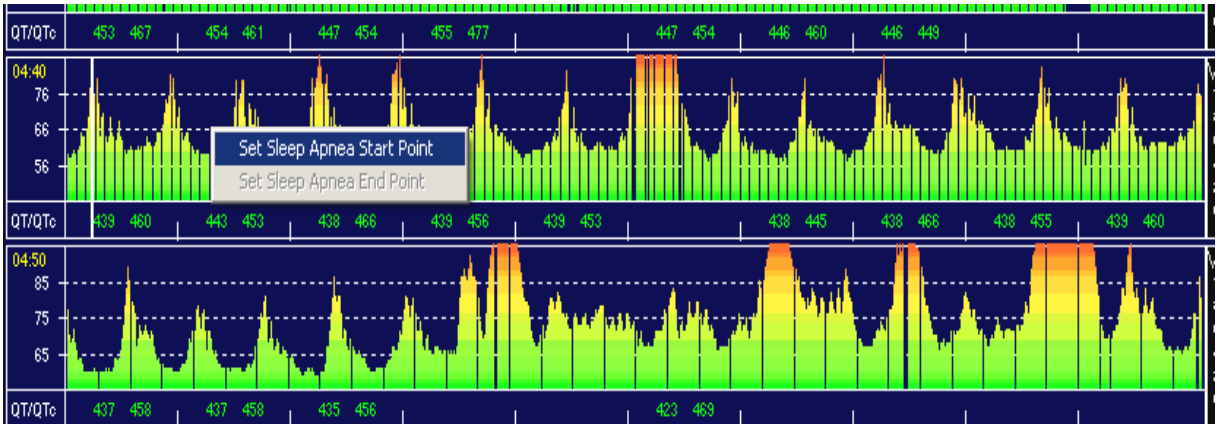
1. Click on the Sleep Apnea icon at bottom right of display.
2. The 24-hour heart rate graph is at the top of the display.
3. Assuming the sleep hours are usually from 10:00 PM to 6:00 AM, move the mouse arrow to the first sleep hour, and left click.
4. If the sleep hours are unknown, the time period of lowest heart rate probably represents the sleep hours.
5. When you click on the 10:00 PM hour in the heart rate graph will make that hour a light blue color in the 24-hour heart rate graph.
6. There appears to be a short period of breathing disorders on the bottom 10-minute display of normal R-R intervals.
7. Move from hour to hour with the mouse clicks until you find an hour of wave-like R-R intervals.
8. This will take less than 1-minute.
9. The 4:00 AM hour has the classic brady-tachy wave like display of R-R intervals.
10. Now use the mouse to mark the abnormal episode and events.



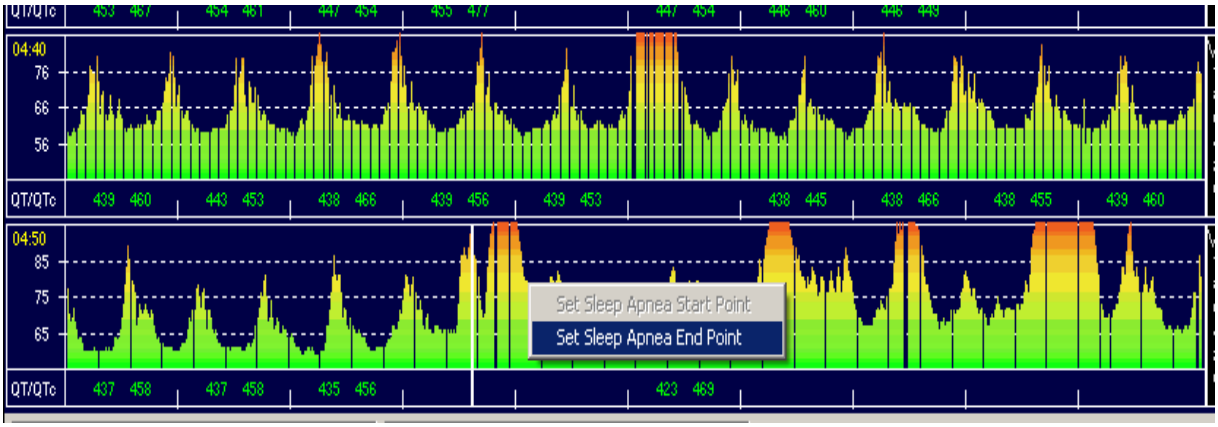
1. At the 4:00 AM hour, you can see the wave-like R-R intervals. The vertical length of each green line equals the width of an R-R interval. Only normal R-R intervals are displayed.
2. The fifth sweep shows the wave-shape, and the first part of the sixth sweep shows the same.



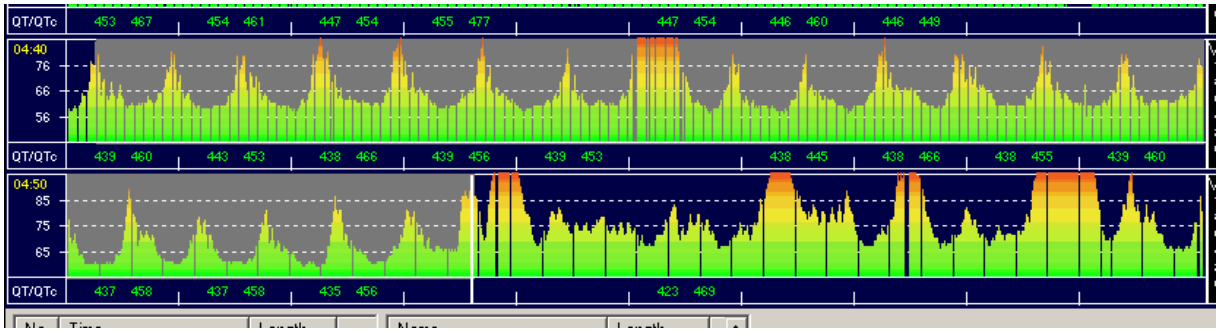
The mouse arrow will now be used to mark the Sleep Disorder episode, and the individual breathing events.



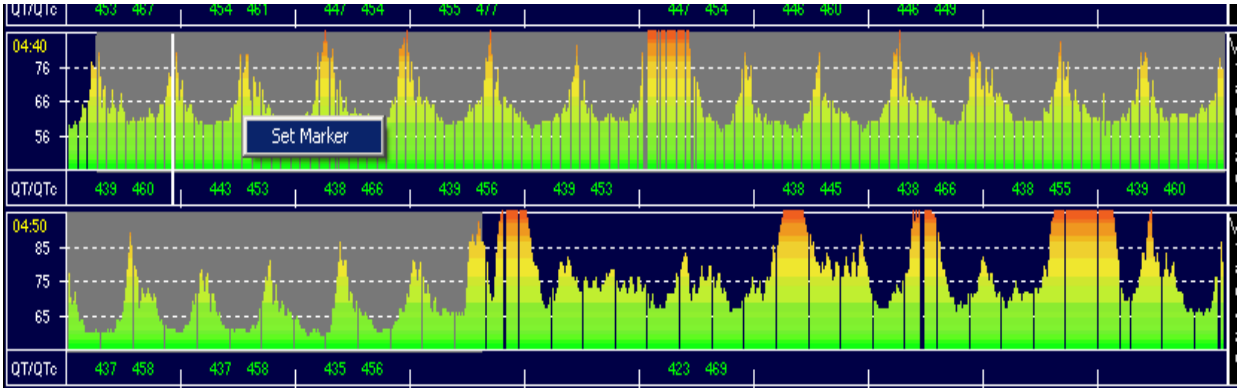
1. Place the mouse arrow at the beginning of the Sleep Apnea episode and do a left mouse click.
2. Then do a right mouse click, and do a left mouse click on “Set Sleep Apnea Start Point.”



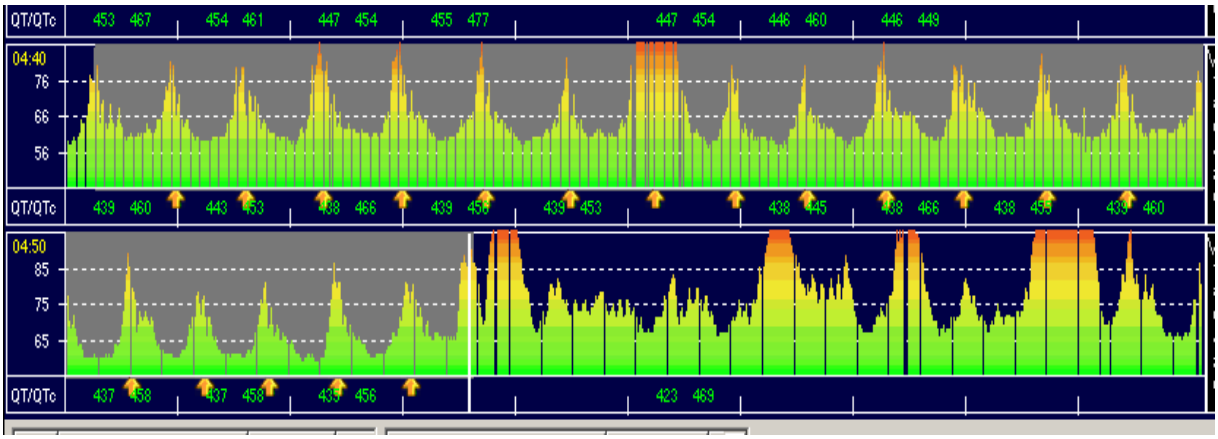
1. Place the mouse arrow at the end of the Sleep Apnea episode and do a left mouse click.
2. Then do a right mouse click, and do a left mouse click on “Set Sleep Apnea End Point.”



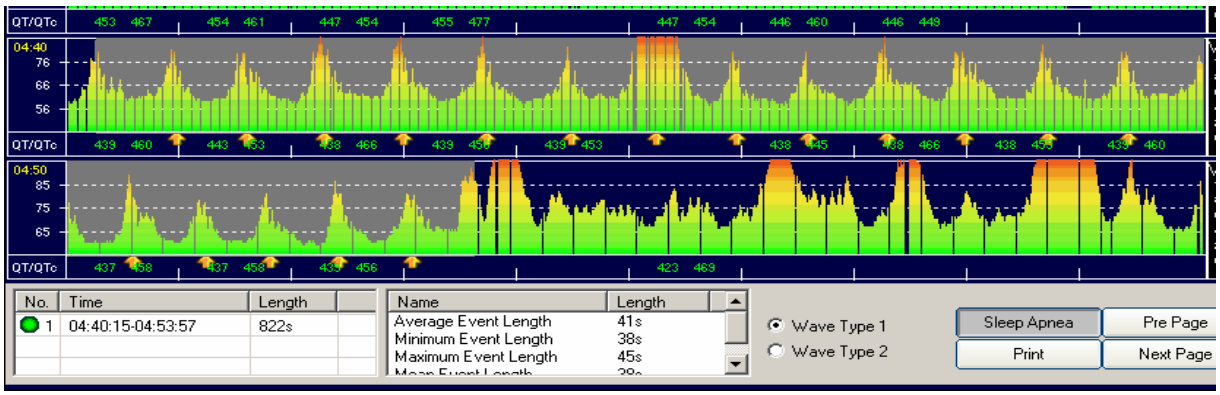
- The gray background area represents the Sleep Apnea episode.



1. To measure the length of the individual breathing events within the Sleep Apnea episode, place the mouse arrow on the peak of the first wave-like display, then do a left louse click, then a right mouse click, and then do a left mouse click on “Set Marker.”
2. Repeat this process on the following peaks.



1. When doing the “Set Marker” for each peak, you will see the yellow marker arrow inserted for each Event.



After setting the markers, the ST Episode length is shown above at 822 seconds. And the average, minimum, and maximum Event lengths are also displayed above. A right mouse click on the above green dot will erase the ST Episode. After completing the marker process, click on the Print icon to print the report.

DMSoftware

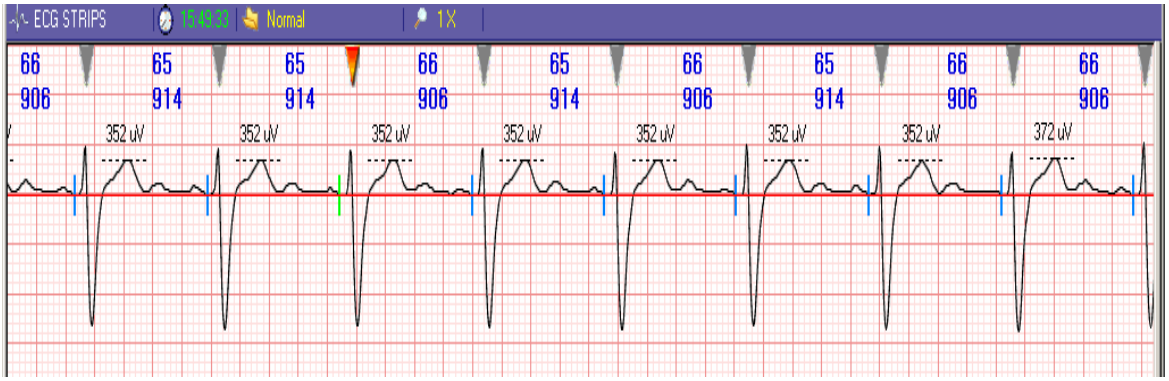
CardioScan-12 Holter ECG System

T-Wave Alternans

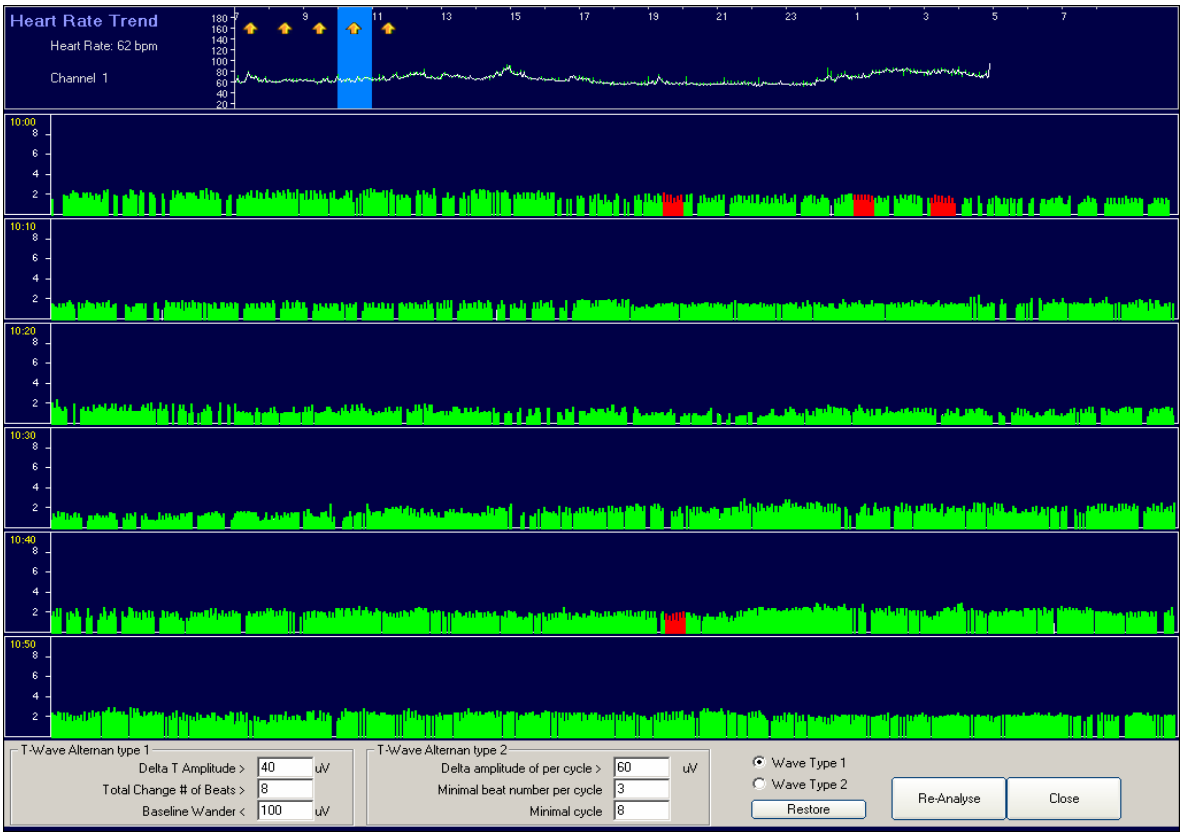
T-Wave Alternans includes the following features:

- It is believed that T-Wave Alternans is a predictor of V-Tach events.
- TWA are transient events.
- TWA events occur at heart rates from 50 bpm to 130 bpm.
- TWA events are quite recognizable from 20 micro-volts to 300 micro-volts.
- TWA events are not valid when following peak R-wave changes, which are caused by body position changes.
- TWA events should always be validated by viewing the peaks of both the R-wave and the T-wave.
- TWA events of 20 to 300 micro-volts occur in many Holter ECG recordings.
- Holter ECG is the methodology of choice for finding transient ECG events.
- The CardioScan 12 Holter system analyzes the peaks of all T-waves, and displays time periods of alternating T-wave amplitudes. Such time periods are then subjected to visual verification of the actual R-waves and T-waves, so that the physician or technician can validate the actual occurrence of TWA.
- Many studies are required to determine the diagnostic significance of detecting TWA in 1 to 7 day Holter ECG recordings. Are any TWA's diagnostic predictors, or is there a requirement for a certain percentage of time of TWA? What is the significance in the difference among 3, 30, and 300 micro-volts of TWA? Do heart rate ranges play a role in TWA's being diagnostic predictors? And on and on?

How Does The CardioScan 12 Detect TWA

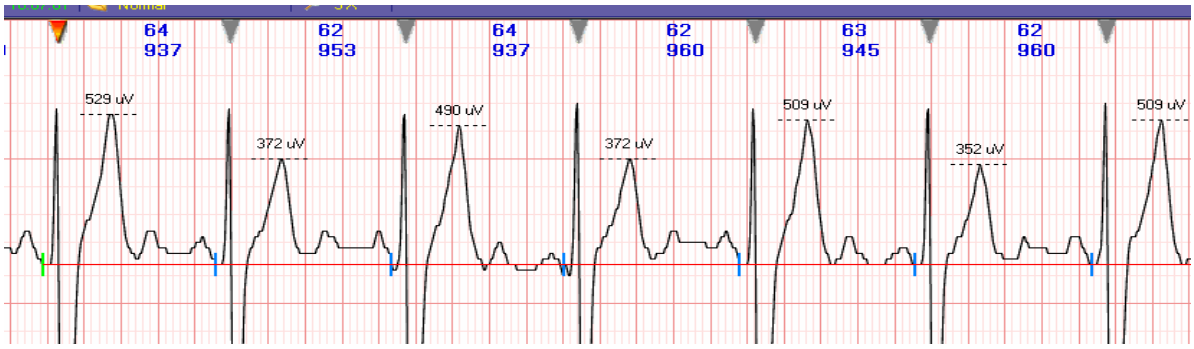


This is a normal series of T-wave amplitudes in a 24-hour Holter ECG at 15:49.



This is a 1-hour display of all T-wave amplitudes during the 10:00 AM time period. At the top is a 24-hour trend display of T-wave amplitudes. Those 1-hour time periods with detected TWA are highlighted with a thick yellow arrow. The light blue cursor is on the 10:00 AM hour. The six rows of green vertical lines are ten minute displays of each T-wave amplitude during the 10:00 AM time period. The red time periods are successive T-wave amplitudes that are alternating in amplitude. Placing the mouse arrow on a red area will show the following display.

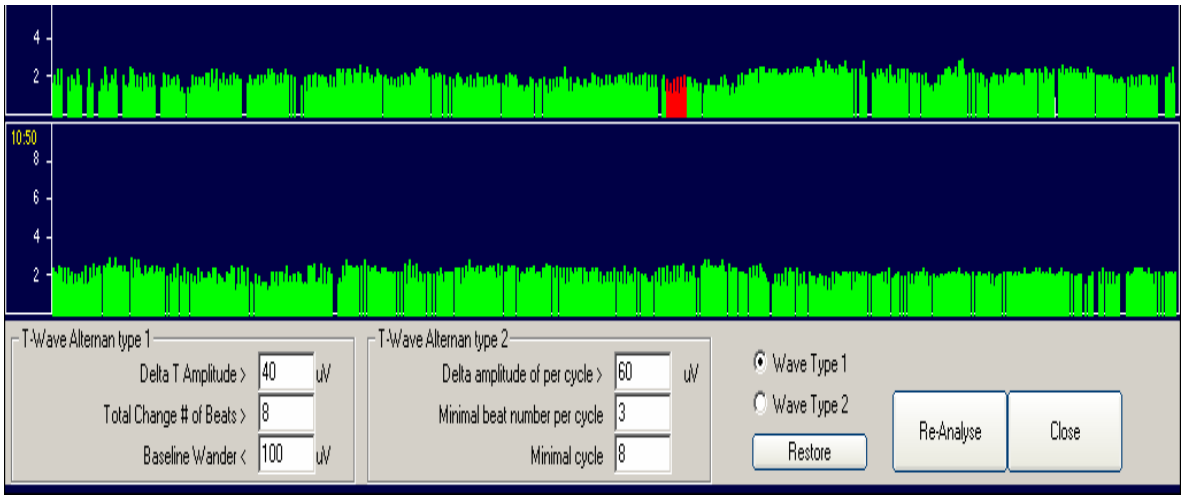
This is the resulting display when clicking the mouse in the red area. The upper left part of the display shows 128 successive normal beats superimposed on top of each other. For the T-waves, the red shows the average T-wave amplitude, and the green shows the min to max spread of T-wave amplitudes for the 128 beats. In the middle top, you see a series of vertical appearing green lines. This is a display of the same 128 beats in which the up and down green lines are tracking the amplitude of each T-wave amplitude. The mouse cursor can move to any part of these 128 beats. The below shows the validated TWA when you increase the Gain from a range of x2 to x10.



This expanded amplitude ECG gives visual validation of T-wave Alternans. The R-wave is not changing in amplitude, but the alternating T-waves are 529 to 372 to 490 to 372 to 509 to 352 to 509 micro-volts.

A subsequent mouse click on the Print icon will produce a 1-page report of TWA.

Since many studies are needed to establish diagnostic criteria for the detection of TWA in 24-hour Holter ECG recordings, optional tools are provided for detecting events of TWA. This is shown below.

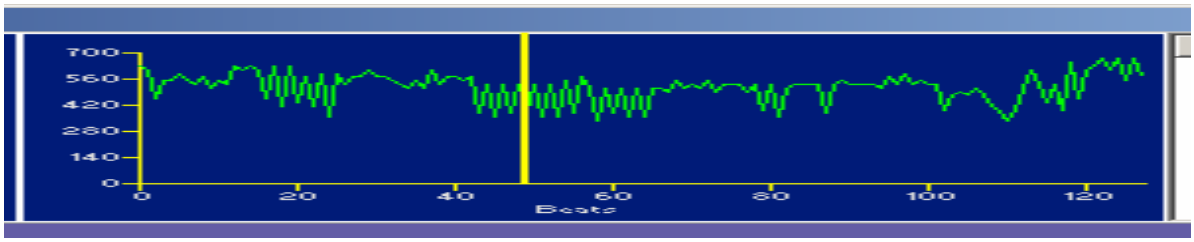


The bottom of the 1-hour T-wave amplitude display shows that the user can select different criteria for detecting TWA. You can select an amount of Delta T-wave amplitude change, you can select how many alternating beats are required, you can decide how much baseline wander will be allowed, etc. The TWA analysis applies to both 3-Lead and 12-Lead Holter ECG recordings. The “Re-Analyze” icon allows any lead to be analyzed and displayed. When a different ECG lead is selected, it only takes 10-seconds to re-analyze and display the 24-hours of T-wave amplitudes.

Important considerations in developing the Holter TWA program.

1. DMS does not believe that a “frequency analysis” is the proper method for determining the existence or non-existence of TWA.
2. Heart Rate Variability is a good example.
3. A review of the DMS program for HRV shows the high sophistication of the DMS programs for Time Domain and Frequency analysis and reports.
4. There are thousands of studies reporting on the value of HRV.
5. However, after over 20 years of reporting in the medical literature about the value of HRV, the majority of cardiologists today are still uncomfortable with the mathematical presentations of Time Domain and Frequency analysis. Cardiologists in general understand that low HRV indicates poor cardiac health, and that high HRV indicates good cardiac health. However, when you ask the majority of cardiologists about the meanings of the HRV Frequency reports, you usually get a blank stare.
6. There is no need to subject the majority of cardiologists to the same confusion in T-wave Alternans detection. This is especially true because T-wave Alternans is not a massive mathematical computation, as is the case with HRV.

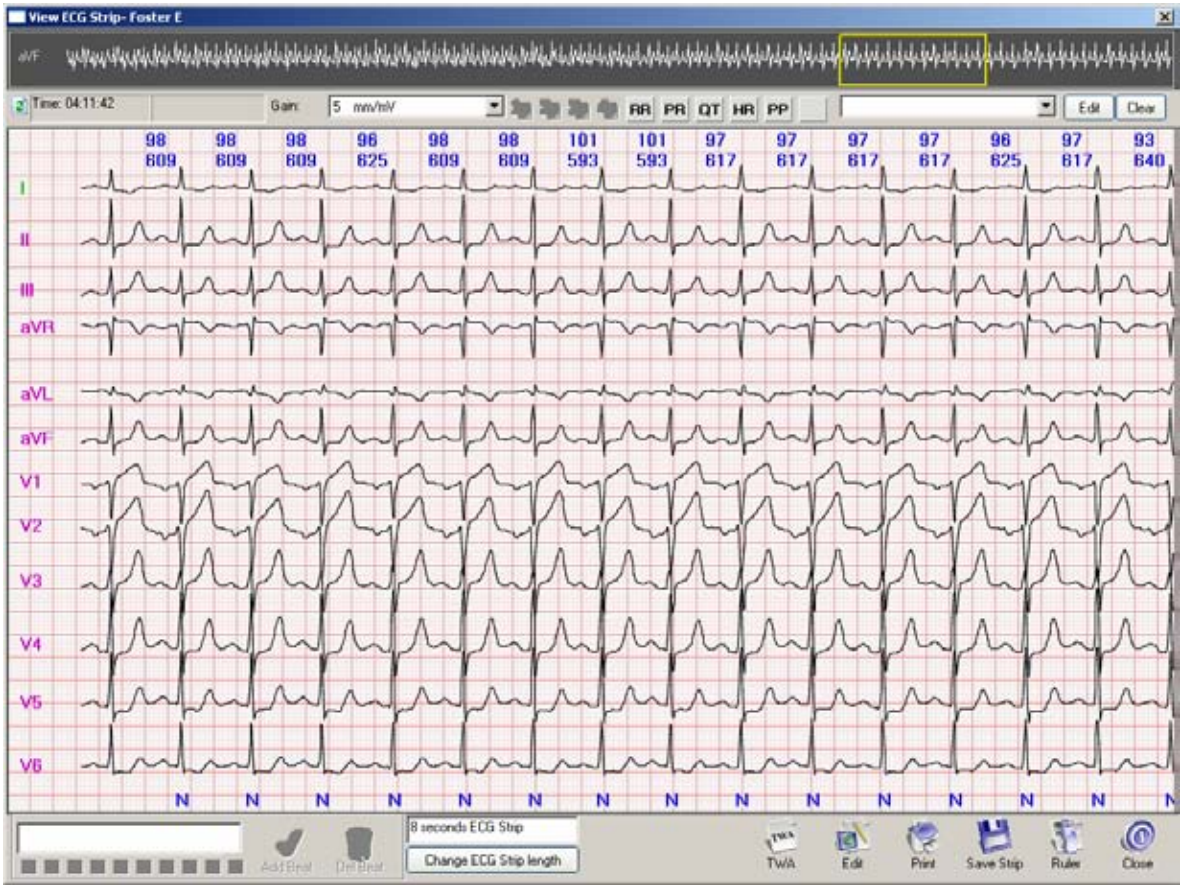
7. Regardless of the explanations, there is nothing difficult about selecting any 128 beat cluster, followed by subjecting such to many different types of detection algorithms, and then after supposedly detecting such, do the right thing, and show the cardiologist the actual ECG in a manner that can be easily be expanded in amplitude size.
8. Verifying that the alternating amplitudes of the T-wave are not caused by corresponding R-wave changes or slight baseline wander should be essential to satisfying a cardiologist.
9. Because of the legitimate controversy of the meaning and accuracy of reporting T-wave amplitude changes in the very small range of 1 to 20 micro-volts, DMS has focused on detecting and reporting the many T-wave Alternans found in Holter ECG recordings that exceed 20 micro-volts.
10. DMS analyzes all Holter leads individually for TWA.
11. When the DMS algorithm believes it detects TWA, it does not hide the actual TWA event in a mathematical presentation without actual ECG verification. Why would anyone not want to show the actual ECG upon supposed detection of TWA? Even if a detected TWA event was only of about 20 micro-volts, it is the most simple of technical tasks to expand the ECG amplitude by a factor of 10, so that the cardiologist can have confidence that a detected TWA event was not caused by very slight baseline wander or body position changes.
12. DMS is not in the position of determining the diagnostic relevance of changes in T-wave amplitudes. Our position is to develop algorithms and displays that detect what appear to be T-wave amplitude changes. Then, it is our obligation to provide as much full disclosure as possible for the visual verification and validation of such, so that the physician decides about the presence or non-presence of TWA based on being led to the specific ECG event of interest.
13. Perhaps the time of a transient TWA event is the time to also have the Holter system report on QTc, SAECG, HRV, QT Dispersion, and the presence of repetitive VE beats.
14. The CardioScan 12 has programs for detecting and reporting on each of the above.



128 beat display of the peaks of each T-wave amplitude. Up & down equals TWA.

Criteria for TWA analysis.

1. TWA analysis is performed on 3-Lead and 12-Lead Holter ECG recordings.



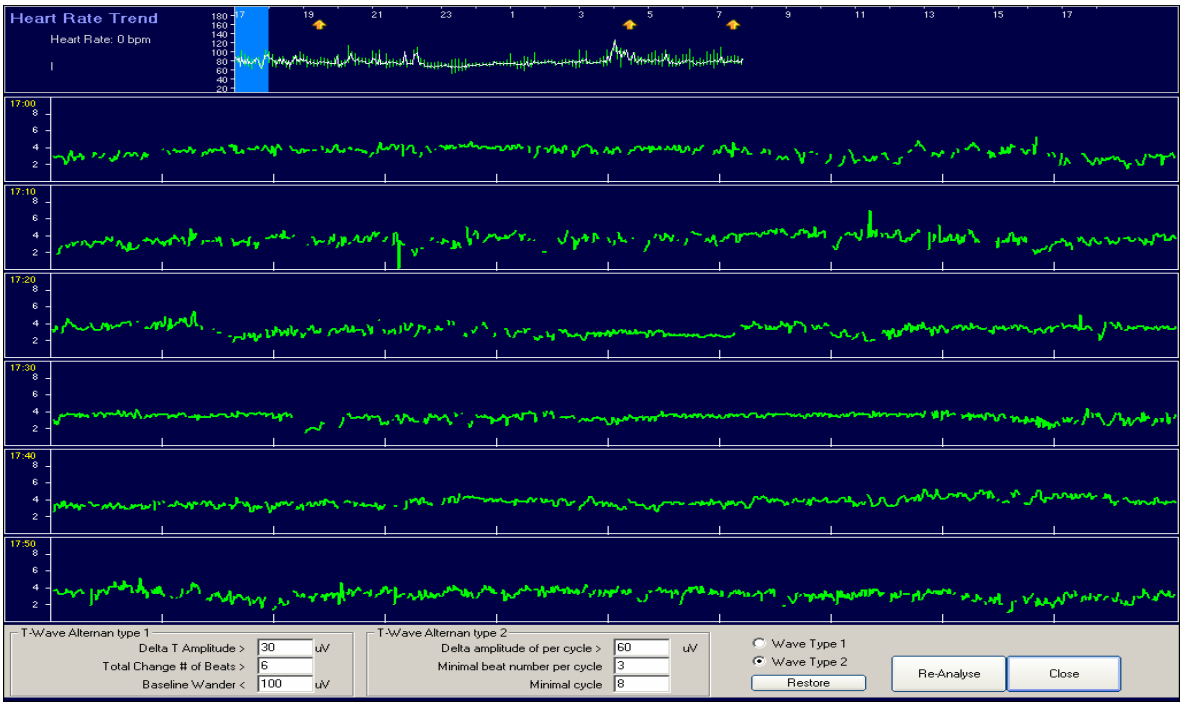
2. Each lead is analyzed individually for T-wave amplitude.
3. Only beats that qualify for the HRV normal-to-normal (N-N) beat file are analyzed for TWA. This deletes VE, SVE, Aberrant, and Pause beats.
4. Only ECG leads with positive going T-waves are analyzed for TWA.
5. T-wave amplitude must exceed 2 mm.
6. All beats subject to the TWA analysis are baseline straightened prior to TWA analysis.
7. 24-hour TWA analysis of any ECG lead is accomplished in less than ten (10) seconds.
8. Minimum amount of Delta T-wave change is user selected.
9. Minimum number of consecutive beats is user selected.
10. T-wave amplitudes for each analyzed beat are converted to vertical green lines in the TWA one-hour displays. The peak of each T-wave is depicted by the height of each vertical green line.
11. Vertical red lines indicate time periods of detected TWA. Mouse click in the red vertical line area to view, verify, and validate the TWA event.

Methodology for operating TWA program.

- From the Access Choices menu, select Page Scan.

- After clicking on Page Scan, click on T-wave Alternans.

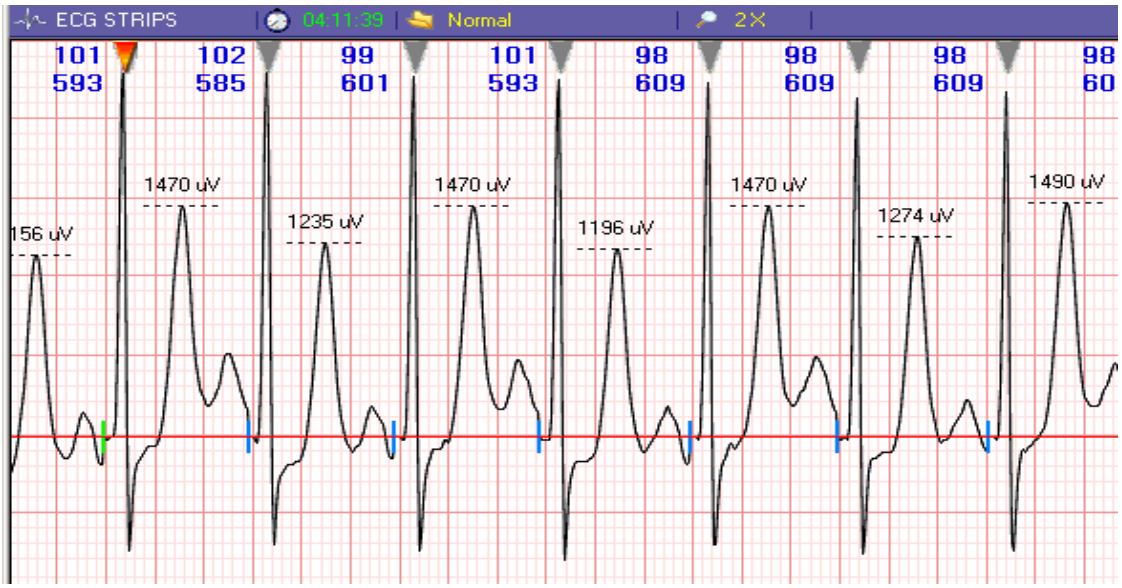
- The below screen display will appear.



- In the lower right part of display, click on Wave Type 1, and the display will change to the below.

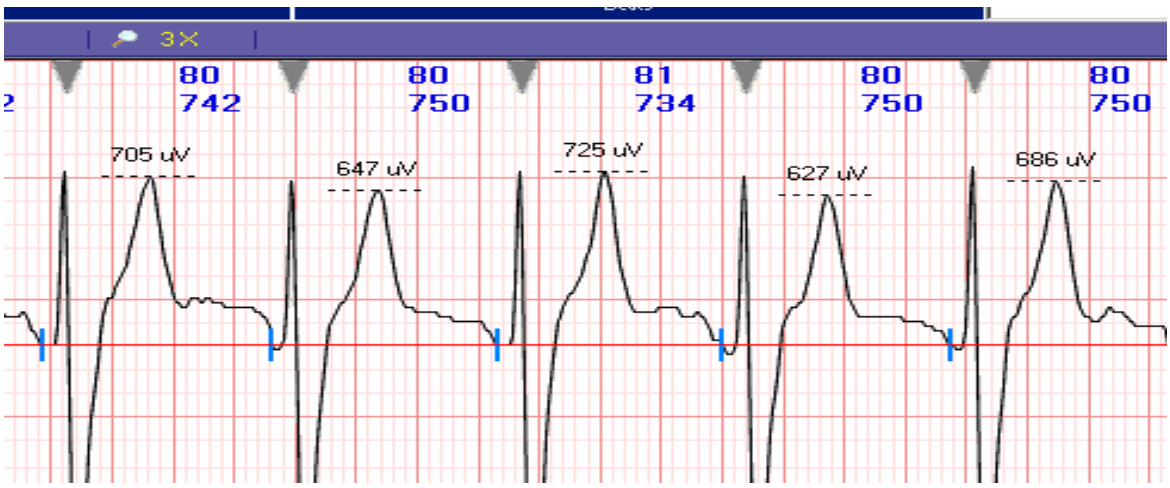
- The screen display on the prior page shows a mouse click on the hour with the thick yellow arrow. The yellow area indicates a detection of TWA. The light blue color shows that this is the 4:00 hour. During this hour the red area in the second 10-minute sweep indicates TWA. At the bottom right is the “Re-Analyze” icon. When you click on this icon, any of the 12-Leads can be analyzed. V4 was selected. Double click on the red vertical line area, and the below display will appear.

- This is the TWA visual validation menu.
- Move the mouse to the bright red line in the middle of the ECG strip. Drag the ECG to the desired location.
- Increase the ECG amplitude by pressing the “+” key. You can increase the Gain from x2 to x10.
- At the top middle of the display, you have the 128 beat T-wave amplitude trend. Move the long yellow cursor to a location showing up and down T-wave peaks.
- A closer look at the TWA shown for the V4 lead is displayed on the next page.



- Note the steady amplitude of the R-waves and the significant changes in the T-wave amplitudes.
- Also note the ST depression in this V4 lead.
- The heart rate and R-R ms are shown at the top of each beat.
- Note that the heart rate of the above TWA is about 100 bpm, and the TWA in the ECG in the earlier pages had a heart rate of about 60 bpm.

Rejection of TWA detection.



- This is an example of the T-wave alternating in its amplitude. However, note that the R-wave is also alternating in its amplitude, and the T-wave is following the R-wave peak changes. The cardiologist may want to reject this based on body position changes.