

CardioScan Stress Test

User Guide

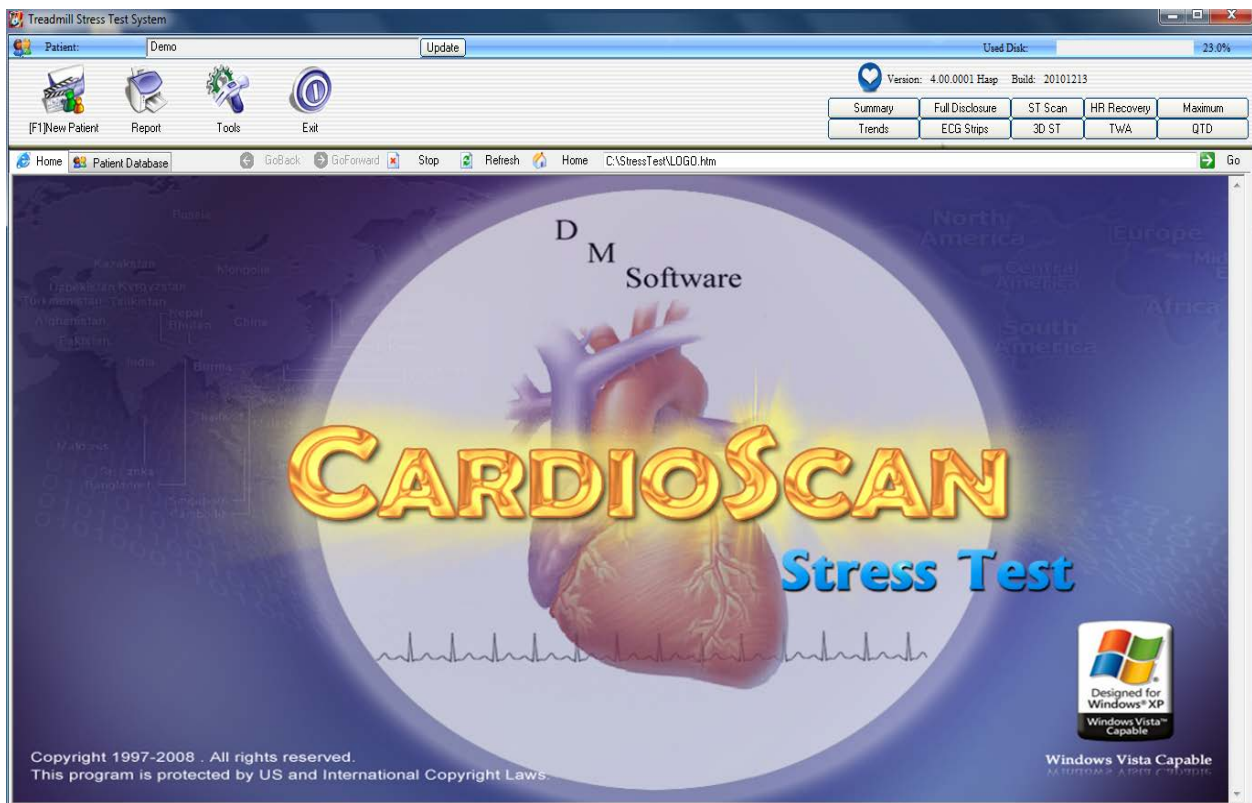


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Overview of the Home Screen

Home: Brings you back to the first screen display.

Patient Database: Provides a Database listing of all the prior Stress Test patients.

“Demo” in Patient Database: Double click to access demo Stress Test data. A “Demo” patient is provided to practice operating the system prior to use on the first patient.

New Patient: Click on “New Patient” to begin Stress Test process for the next new patient. For “Demo” practicing, click on “Copy from Selected Patient,” then click on “Demo,” then click on Age (67), then click on “Next.”

Report: View and print reports for Stress Test Patients accessed from the Patient Database.

Tools: This is the Settings menu for setting up / operating the system.

Exit: Closes Stress Test software program.

Summary: After the Stress Test is completed, several review programs can be accessed. The “Summary” provides a one-page report that includes most of the important results of the Stress Test. Each physician (from “Tools”) can build their own format for printing the “Conclusion”.

Trends: Provides a series of ST and Heart Rate trends that allow for instant access to ECG data.

Full Disclosure: 100% FD ECG data can be viewed or printed for any ECG Lead.

ECG Strips: 12-Lead ECG displayed. PgDn and PgUp keys can access each minute of Stress Test.

ST Scan: Algorithm shows J-Point and ST for each ECG Lead for each minute of Stress Test.

3D ST: 3D display of ST changes for all 12-Leads. Click and Drag will move and rotate display.

HR Recovery: Heart Rate recovery after the exercise portion of the Stress Test (“Chronotropic HR Recovery”) is of critical importance. Calculates HR changes for each minute in Recovery.

TWA: T-Wave Alternans. Algorithm measures the actual T-Wave amplitude of each T-Wave for all ECG Leads. Measured for each beat from the beginning of the Stress Test to the end of Recovery. No special electrodes are needed.

Maximum: Shows the maximum ST and Heart Rate data at various stages of the Stress Test. Also shows both Absolute and Delta ST measurements.

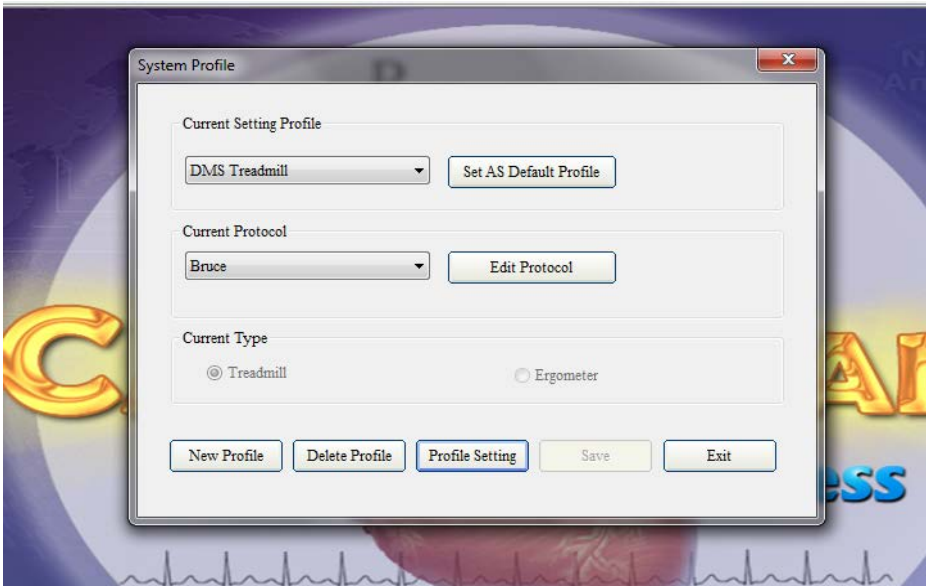
QTd: The purpose of the QTd measurement is an attempt to bring clarity to borderline ST changes for female Stress Test patients.

Recommendations for Setting-Up the CardioScan Stress Test

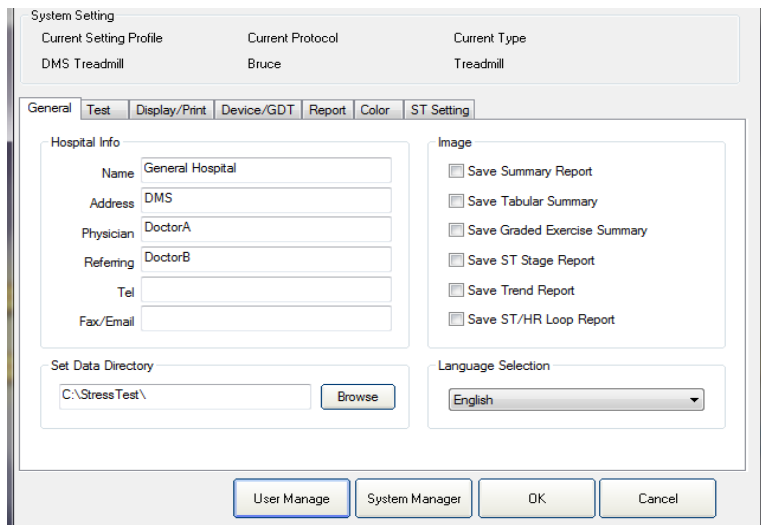
The recommendations below are a good way to get started in learning the operational characteristics of the CardioScan Stress Test system. These are merely suggestions and many users will change the Settings to fit their preferences.

It is recommended that the “Demo” file in the Patient Database be used to become familiar with the software. Subsequently, new users may create their own separate “Demo” files by going to the New Patient icon on the Home Screen, as indicated on Page 3 of this manual.

1. Click on **Tools** from either CardioScan Stress Test HOME display or from Patient Database display.
2. Select **System Settings**.
- 3.



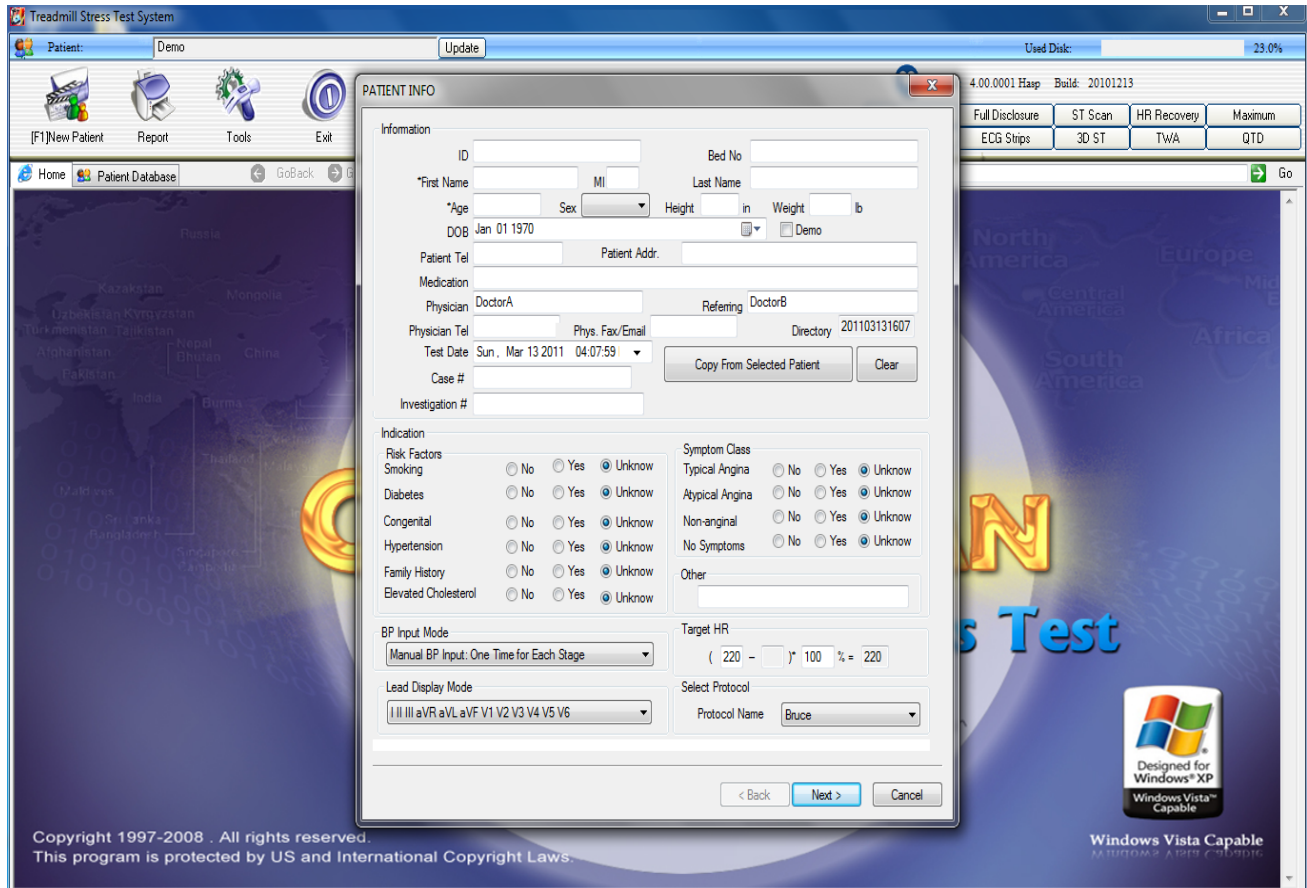
4. First, select either the treadmill or ergometer as the exercise device. Then select the desired Exercise Stress Test protocol. There is a separate menu that includes a number of various exercise stress test protocols. Exercise protocols are also customizable.
5. Next select the icon at the bottom entitled “**Profile Setting.**”
6. The screen display below appears.



7. The Profile Settings are: **General, Test, Display/Print, Device/GDT, Report, Color, and ST Setting.**
8. **General:** Type in the basic data for the owner of the Stress Test system. This information will appear on all reports. You can also set the data directory, which is where all patient data will be stored. You can also select from various language options.
9. **Test:** Under “HR Calculation” select “Beat Number” 4. Under “Compute Target HR” select 100% (or any other desired percentage). This tab also allows the user to determine the blood pressure input mode, as well as abnormal BP triggers and the leads for HR calculation.
10. **Display/Print:** Under “Unit” select metric or USA format. Under “Instant Print Format” select Thick for type of Wave. Under “Sample Display” select Gain at 5mm/mv. Under “Date Format” select your country’s format.
11. **Device/GDT:** Use default settings, assuming you are using BlueTooth ECG Transmitter and Receiver. For you reference, “Conventional Device” refers to a wired acquisition box, rather than a BlueTooth Device. The treadmill / ergometer is typically controlled through the serial port (RS232). Make sure the correct COM port is selected under Sample in the Com Settings (typically Com5).
12. **Report:** When first using the Stress Test system, leave all of the report and full disclosure boxes un-checked. You can select the desired font. The Conclusion Mode allows each physician to build their own custom format for the diagnosis (conclusion).

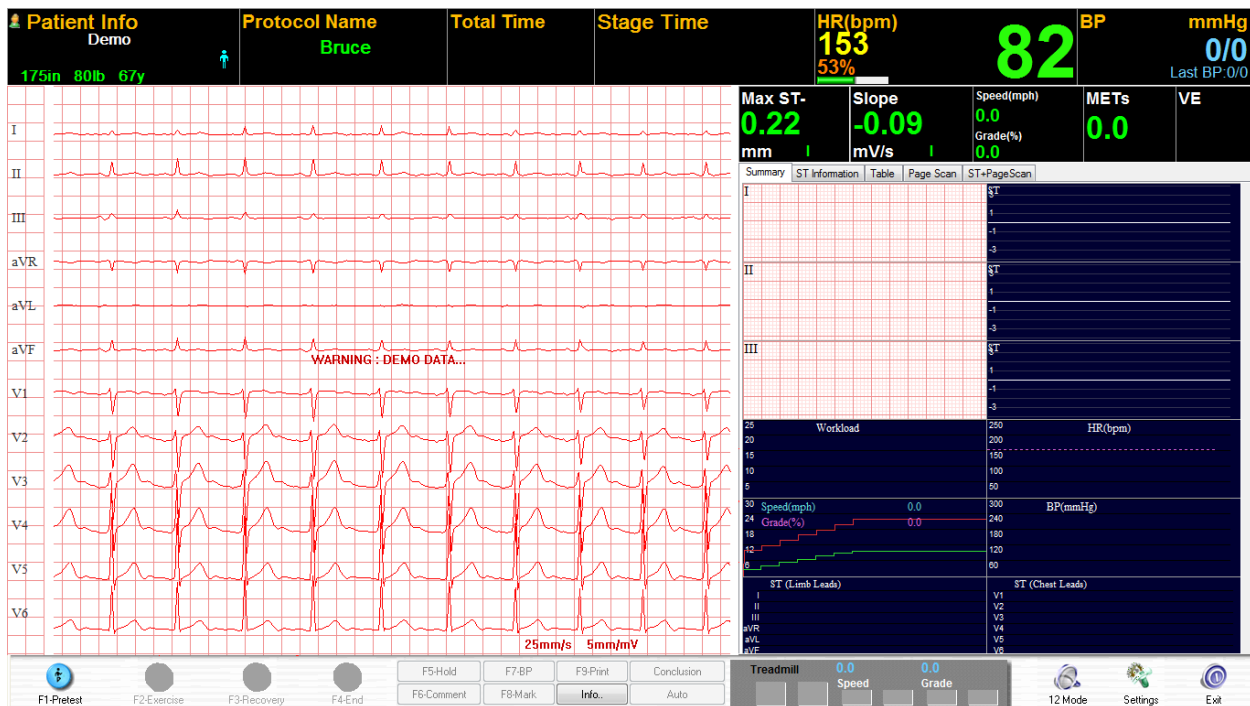
- 13. Color:** Under “Grid” go to “Background” and select the white color. Under “Wave” go to “Pretest” and select black, go to “Exercise/Recovery” and select blue, and go to “Other” and select red. Under “Averaged Wave” go to “Background” and select white, go to “Reference Beat” and select red, and go to “Actual Averaged Beat” and select blue.
- 14. ST Setting:** Under “ST Analysis” select “ST Point” and select (60) ms.
- 15.** You are now ready to test on a patient.
- 16. Note:** There is no good substitute for vigorous cleaning of the skin at the electrode sites, then applying the electrodes, and waiting 15-minutes before starting the exercise stress test.
- 17.** Please note that in addition to **System Settings**, the **Tools** icon also allows you to access lead placement diagrams (**Leads Placement**), the list of patients (**Patient Database**), and a list of protocols (**Protocol Database**).
- 18.** In order to obtain an optimum quality ECG signal during the Stress Test, it is recommended that you consider placing the right leg and left leg electrode sites at the bottom rib of the rib cage.

Performing the Exercise Stress Test

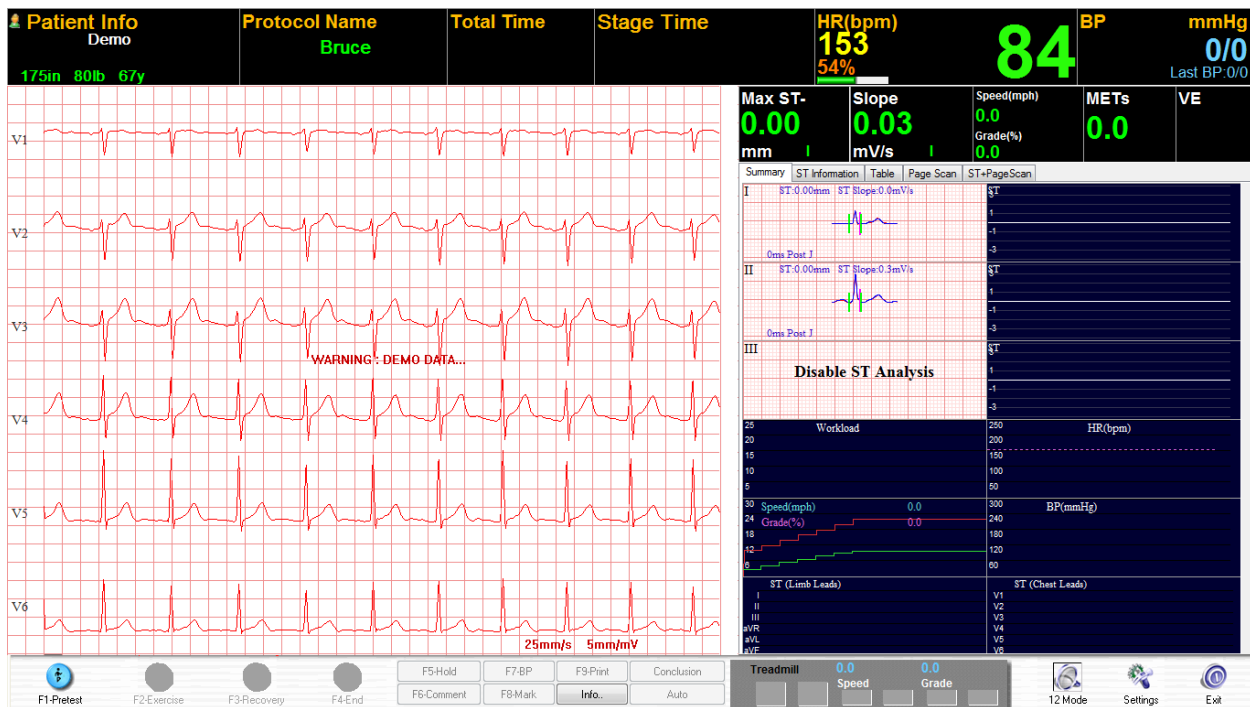


1. Click on New Patient icon shown at the top left above. You can also press the **F1** key shortcut. The displayed window will appear. After inputting the desired data, click on the “Next” icon at bottom of this display. You can also import data from your existing list of patients by selecting “Copy From Selected Patient”.
2. The next display shows a typical electrode placement. Click on the “Next” icon at the bottom of the display.
3. The following display shows the ECG. The ECG will be in red (assuming you used our prior recommendations). We recommend selecting the 6-V Lead display for the test.
4. Gently tap each electrode site with your finger, and look for artifact. *To test the electrode quality, you can do the following: Show the 12-Lead ECG. At the bottom right (see the screen display below) there is the “12 Mode” icon. Click on this icon. As you click on this*

icon, you can see the 12-Lead ECG, the 6-V Leads, the 6-Other Leads, or a 3-Lead ECG. Select the 12-Lead display and gently tap each electrode site. If you get artifact, you may want to re-clean that electrode site.



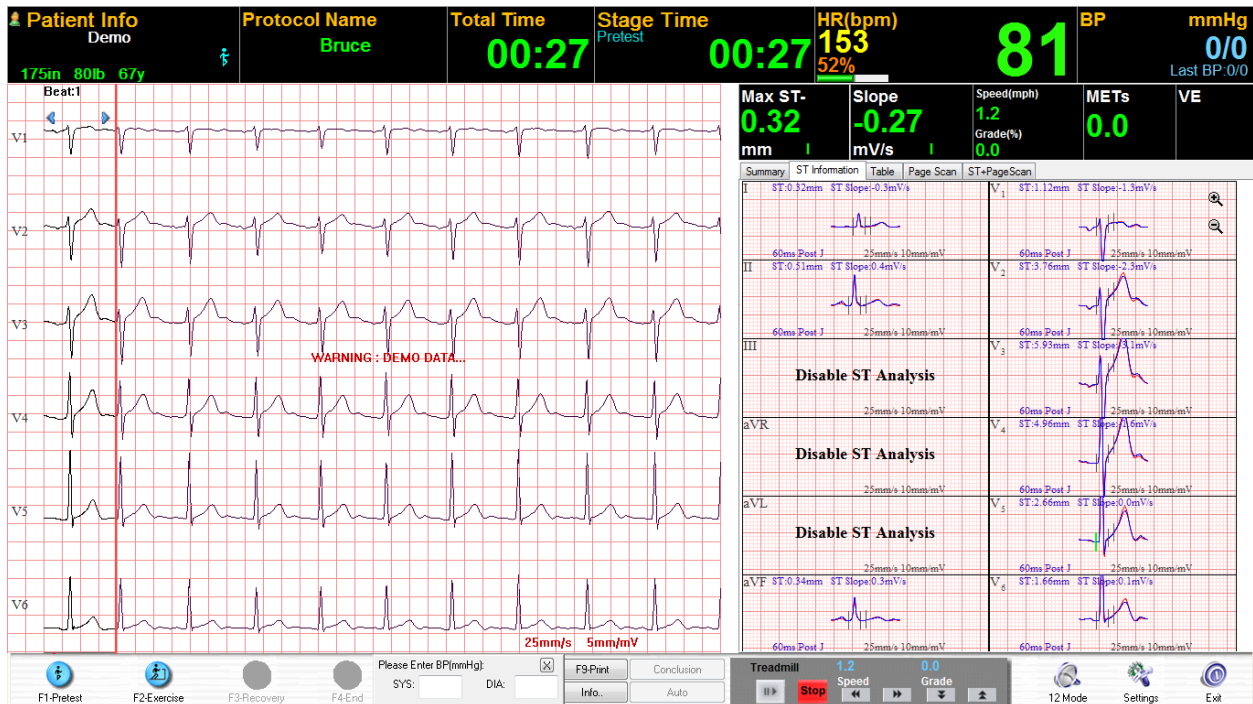
5. Click on 12 Mode icon to get the 6-V Lead display.



6. At the bottom right, there is also a Settings icon. Click on it. You may want to select the Gain at 5mm/mv. Also verify the selection of ST Point at 60 ms.

7. At bottom left, there is the icon “F1 Pretest.” Click on Pretest (note the color change in the ECG). The display below will appear. The user will have an initial option to “Disable ST Leads III, aVR, and aVL.”

8. To disable ST Analysis for Leads III, aVR, and aVL; follow these steps. There is a “ST Information” tab in the middle of the screen display below. In this screenshot, it is below the Max ST with a green color number of 0.32. Click on the ST Information icon, and the display will appear. Move your mouse arrow to the rectangular box for Lead III, do a right mouse click, and select Disable. Do the same for Leads aVR and aVL.

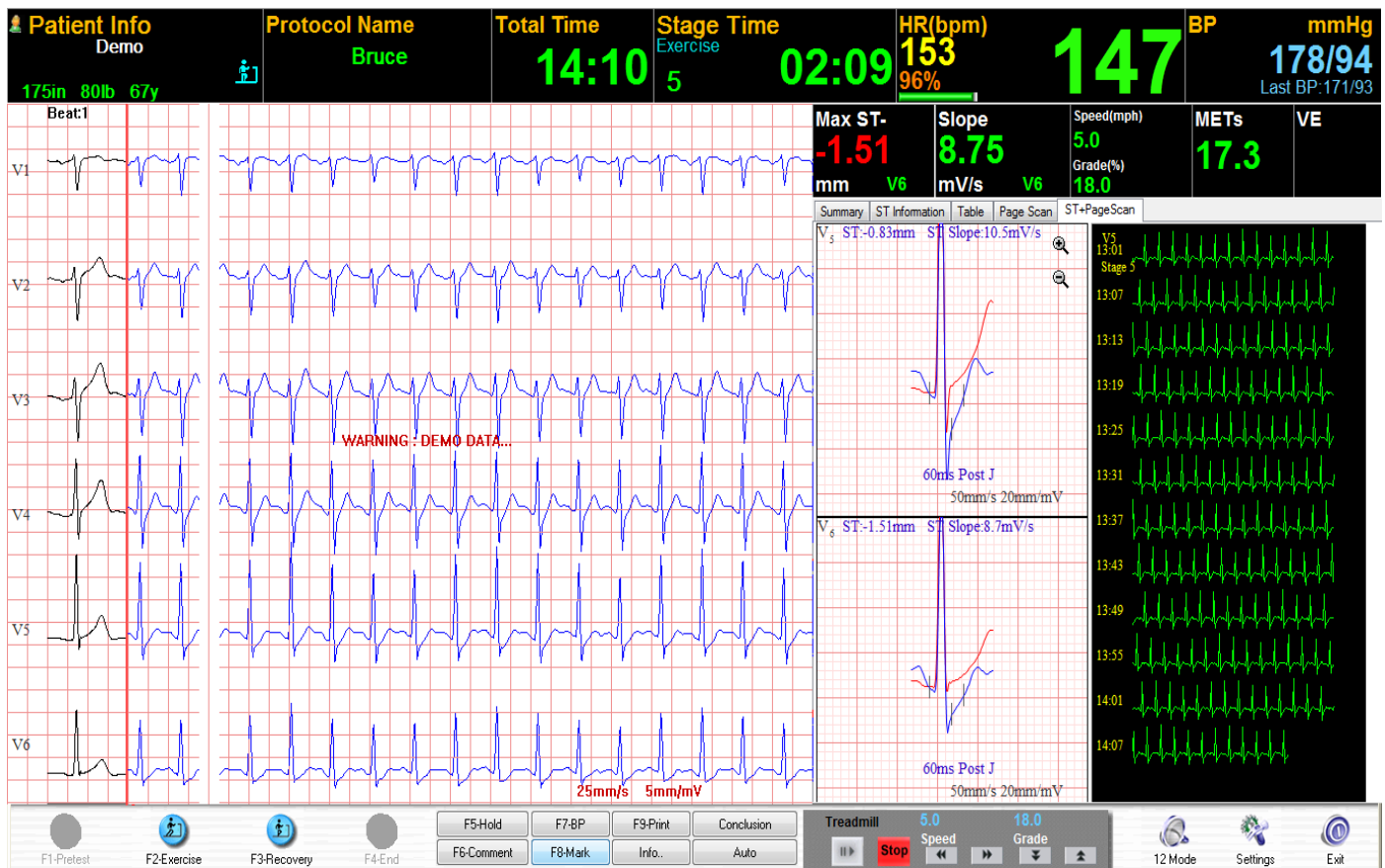


9. You will notice that the nine (9) active ST Leads show vertical markers for the PR baseline, the J-Point, and the ST-Point. You may want to change the location of the J-point and ST vertical markers for each patient (see next step).

10. Move the mouse arrow to the rectangular box for Lead I. Press the “Tab” key. You will notice the green vertical line for the PR baseline. Now press the “Tab” key again. You can now move the J-Point and ST-Point simultaneously by pressing either the “Home” or “End” keys. You may need to activate with the “Num Lock” key. The ST algorithm is now properly set.

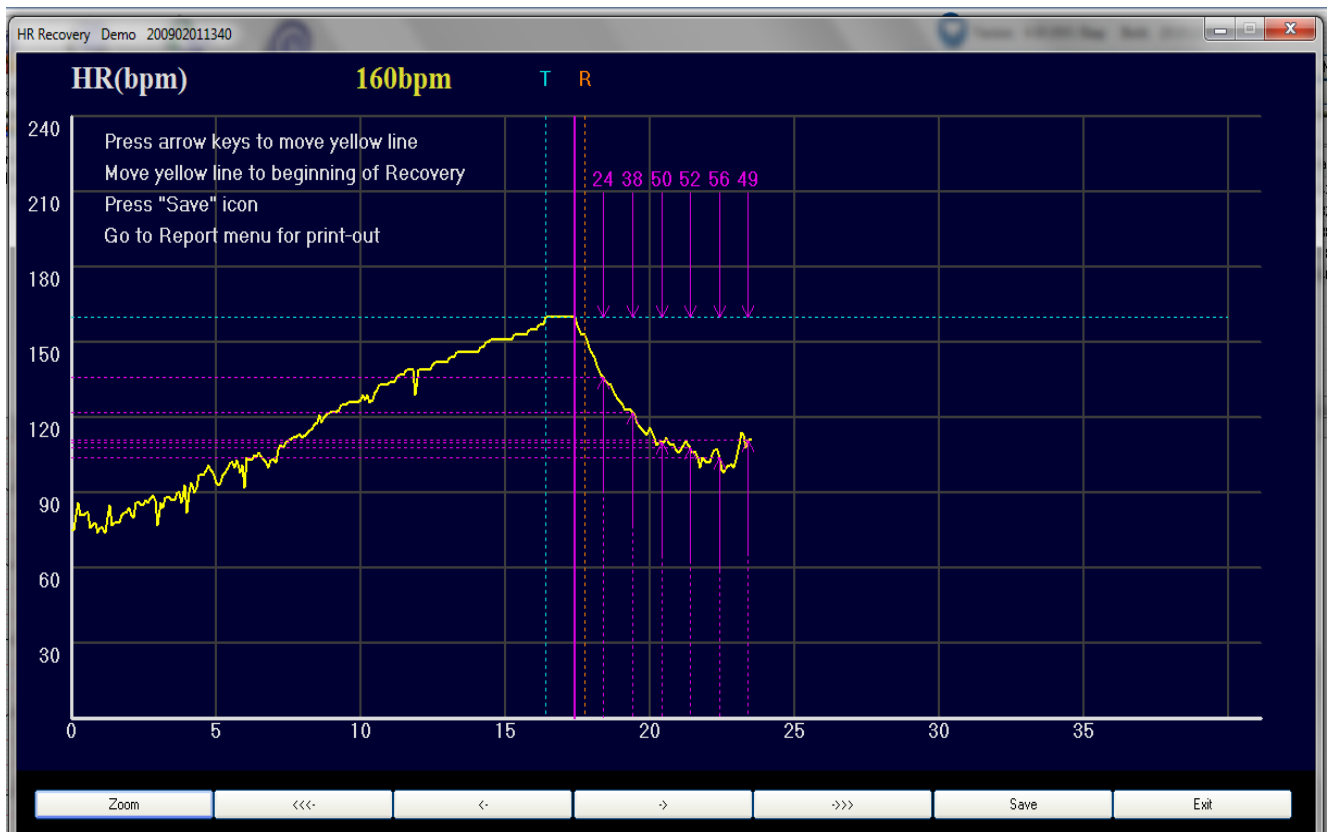
11. At the top of the 12 rectangular boxes are several tabbed icons. Click on the icon on the right side that is labeled “ST-PageScan.” You are ready to begin the Stress Test.

- 12.** At the bottom left, there is an icon that shows “**F2 Exercise.**” Click on this icon to begin the Stress Test. At the far left of the ECG display is the Reference ECG in black; followed by the actual real-time ECG in blue.
- 13.** On the right side of the screen display is the enlarged superimposed ST data and the Full Disclosure. With a mouse arrow and right click, you can select any ECG Lead for ST boxes 1 & 2.
- 14.** These two (2) enlarged ST boxes show the Reference beginning ECG with the Actual Real-Time ECG superimposed over it. This will allow you to clearly see the amount of ST Level separation, as the ST begins to depress during the Stress Test.
- 15.** The benefit of the Full Disclosure ECG is to provide an important picture of the type and quantity of arrhythmias. With a mouse arrow and right click, you can select any ECG Lead for Full Disclosure display. Our standard recommendation is that you select V5.
- 16.** In following our settings recommendations, the Stress Test software will display a screen similar to what is seen below. The Reference ECG is in black and Real-Time ECG is in blue. ST changes are shown in V5 and V6. Full Disclosure shows no arrhythmias. Elapsed Time is at 14 minutes and 10 seconds in Stage 5 of Bruce. Target HR is 153 and Stage 5 heart rate is 147 at 96% of Target HR. Last BP was 178/94, and prior BP was 171/93 – showing that systolic BP is continually increasing during the Stress Test. Max ST is in V6 at upsloping -1.51mm. Treadmill is at speed of 5mph and 18% grade. METS at Stage 5 is at 17.3. Please note that this screenshot is not of a simulator ECG; but rather shows a demo patient who can exercise at high rates.

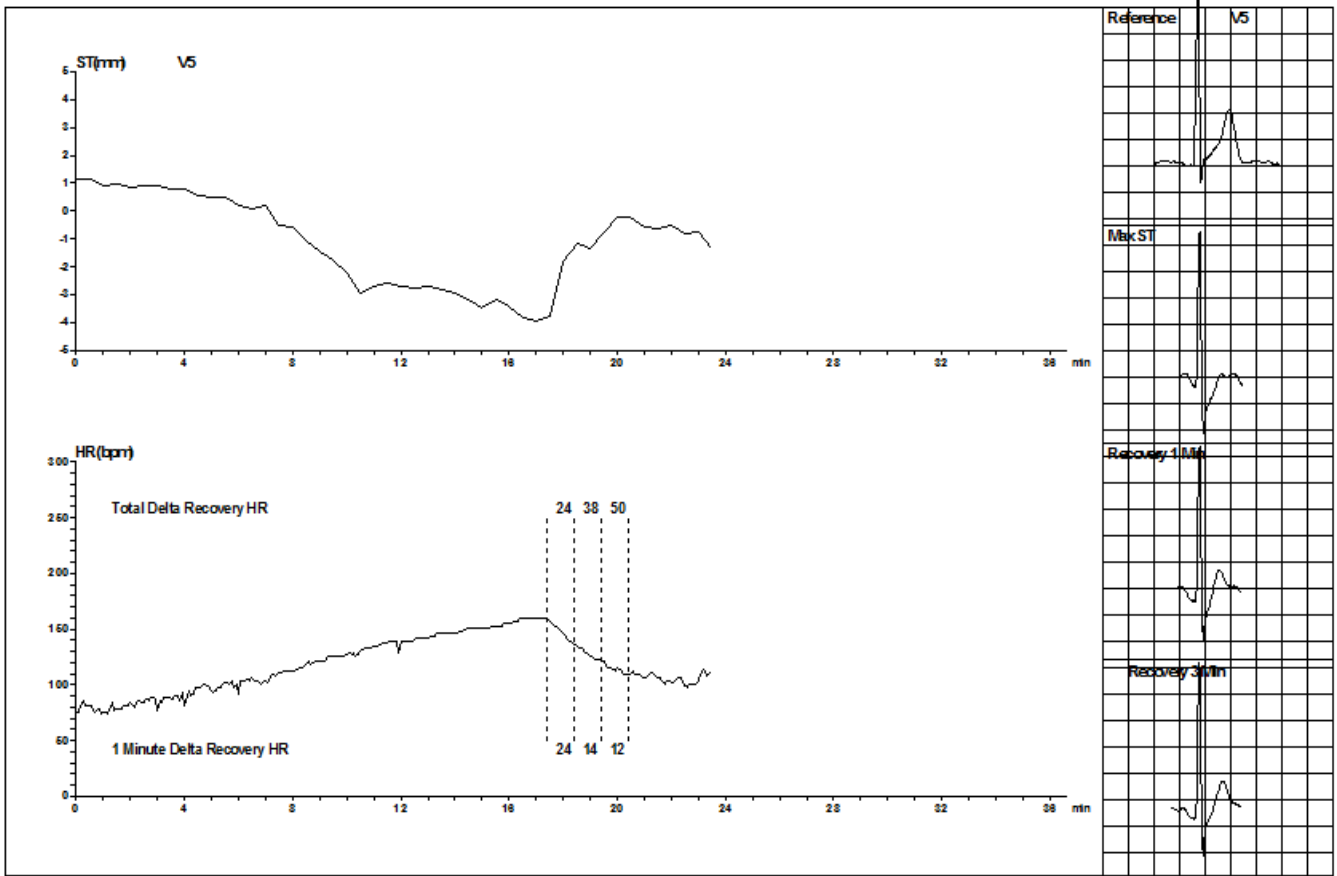


17. The Stress Test is typically ended with either the achieving of the target heart rate, or a patient problem in completing the exercise phase of the Stress Test.
18. The Recovery phase begins at the same time as the Exercise phase ends. Upon the end of Exercise, click on the “**F3 Recovery**” icon at the bottom left of the screen display.
19. Heart Rate and ST data continue to be analyzed during the Recovery period. Three (3) minutes is a typical time period for Recovery monitoring and analysis.
20. Quite often the Stress Test will include an Echocardiogram prior to the beginning of Exercise, and another Echo procedure at the termination of exercise. The back of the BlueTooth Receiver has two (2) outputs available for ECG data. One of these outputs can be used for the Echo.
21. When you end the Stress Test (“**F4 End**”), you can select (from a pop-up menu) a reason for terminating the test.
22. After the completion of the Stress Test, selecting the “HR Recovery” icon will show the following.

23. In our example, Recovery heart rate shows a cumulative 24bpm decrease for the first minute, 38bpm at the end of the second minute, and 50bpm at the end of the third minute of Recovery.



24. The above screen display can be quickly edited to ensure that the Heart Rate Recovery algorithm measures the heart rate change at exactly the time of the beginning of Recovery. Instructions are at top left of screen display.
25. To see the ST activity at the same time during Recovery, select the "Print" icon in the main menu and chose "Print HR Recovery Report".



26. The ST Trend is shown, during Exercise and during Recovery, on the top portion of the report above.
27. The Heart Rate Trend is shown, during Exercise and during Recovery, on the bottom portion of the report.
28. The four (4) ECGs show (1) the Reference beginning ECG, (2) the Max ST Depression, (3) the ECG at 1-minute into Recovery, and (4) the ECG at 3-minutes into Recovery.

Using the Various Review Programs

After the Stress Test is completed, several review programs can be accessed. These review programs include:

- A. Summary
- B. Trends
- C. Full Disclosure
- D. ECG Strips
- E. ST Scan
- F. 3D ST
- G. HR Recovery
- H. TWA (T-Wave Alternans)
- I. Maximum
- J. QTd (QT Dispersion)

The review programs can be accessed by clicking on the icons found on the top right from either the "Home" display or the "Patient Database" display. It is preferable to access the review programs from the "Patient Database" display as it will allow the user to select from any of the prior patient tests.

A. SUMMARY

Phase	Stage	Time	Speed(mph)	Grade	Workload	HR	BP	RPP (*100)	VE	SVE	ST V5(mm)	Comment
Pretest		00:15	0.0	0.0	1.0	86			0	0	1.05	
Exercise	Stage1	01:00	1.7	10.0	2.8	87			0	0	1.05	
		01:00	1.7	10.0	4.7	85			0	0	0.90	
		01:00	1.7	10.0	4.7	91			0	0	0.88	
	Stage2	01:00	2.5	12.0	5.8	98			0	0	0.76	
		01:00	2.5	12.0	7.0	101			0	0	0.56	
		01:00	2.5	12.0	7.0	104			0	0	0.34	
	Stage3	01:00	3.4	14.0	8.6	107			0	0	0.05	
		01:00	3.4	14.0	10.2	113			0	0	-0.49	
		01:00	3.4	14.0	10.2	122			0	0	-1.29	
	Stage4	01:00	4.2	16.0	11.7	127			0	0	-2.05	
		01:00	4.2	16.0	13.3	134			0	0	-2.86	

Conclusion

The Bruce protocol was used for this Stress Test.
 The total duration of Exercise time was 17:44, and was terminated at Stage 6.
 The maximum METS workload was 20.5 METS.

Resting Heart Rate was 86 bpm, and increased to a maximum Heart Rate of 160 bpm.
 The Max HR of 160 represents 122% of the Target Heart Rate of 131 bpm (Stage 6 at 02:20) (17:20).
 At 1-minute post exercise the Heart Rate decreased 21 bpm from 150 to 129.
 The Heart Rate at end of Recovery was 88 bpm.
 Max ST Depression was -3.86 mm in V5 at Stage 6 Exercise.
 The reason for terminating Exercise was Other reasons.

Header Info

Bruce Total Test Time: 23:40

Max HR: 160 bpm, 122 % of Target HR 131 bpm

Max BP: 0 / 0 mmHg Max Workload: 20.5 METS

Max ST Depression: -3.86 mm in V5 at Exercise Stage 6

Reason of Termination: Other reasons

Custom Format: Auto

ADD DEL

- 2:1 AV block
- Atrial fibrillation
- Atrial flutter
- Atrioventricular reentry
- Bigeminal rhythm
- Bradycardia
- Bundle branch block, BBB
- Chest Pain
- Complete AV block
- Dizziness
- Escape beat
- Exit block
- Fusion beat
- High grade AV block
- I grade AV block
- II grade AV block
- III grade AV block

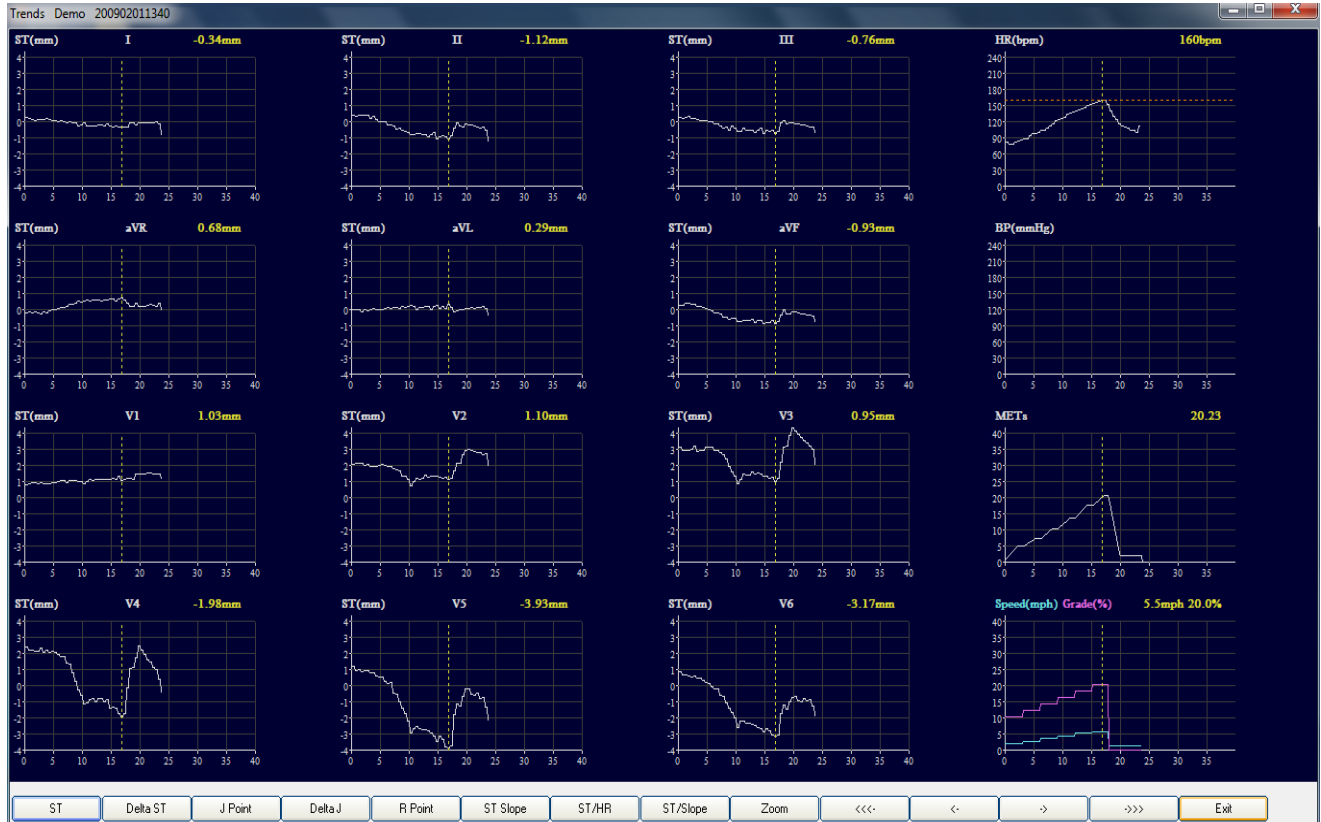
Table+Graph+Text Table+Text Text only Graph+Text Print Report Print Recalculate Save Modify Exit

The Conclusion section can be freely edited. The physician can modify the information contained here, or re-write it altogether. Each physician can pre-program the format and text that they want. The Conclusion automatically incorporates numerical data from the Stress Test.

- ST and Heart Rate numbers can be edited
- A library of statements can be created
- The Summary page print-out can be created in several different data formats

Under "Custom Format" several physician names can be listed, each with their own data format. A click on the above "Auto" field will bring up the list of physicians. Select the desired physician's name, and that customized format will be reflected in the Conclusion section.

B. TRENDS

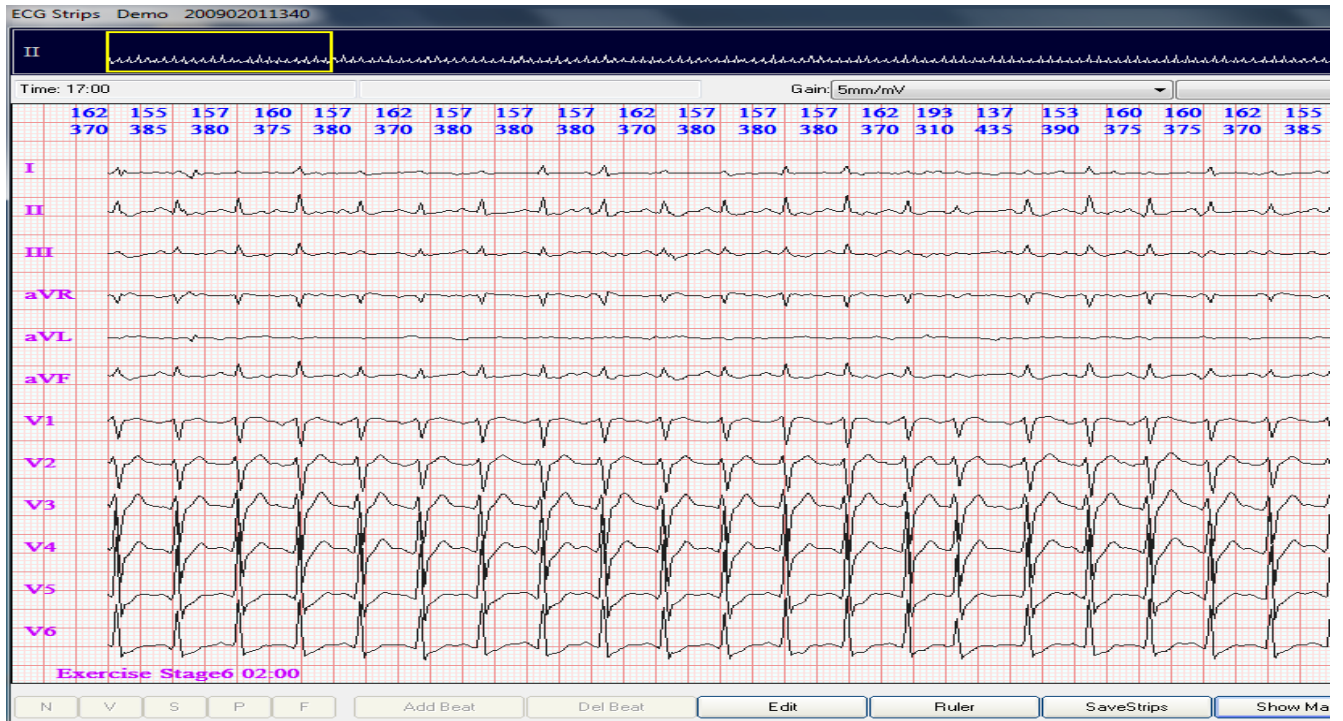


The ST for all 12 Leads is shown, as well as the Heart Rate, Blood Pressure, and METS.

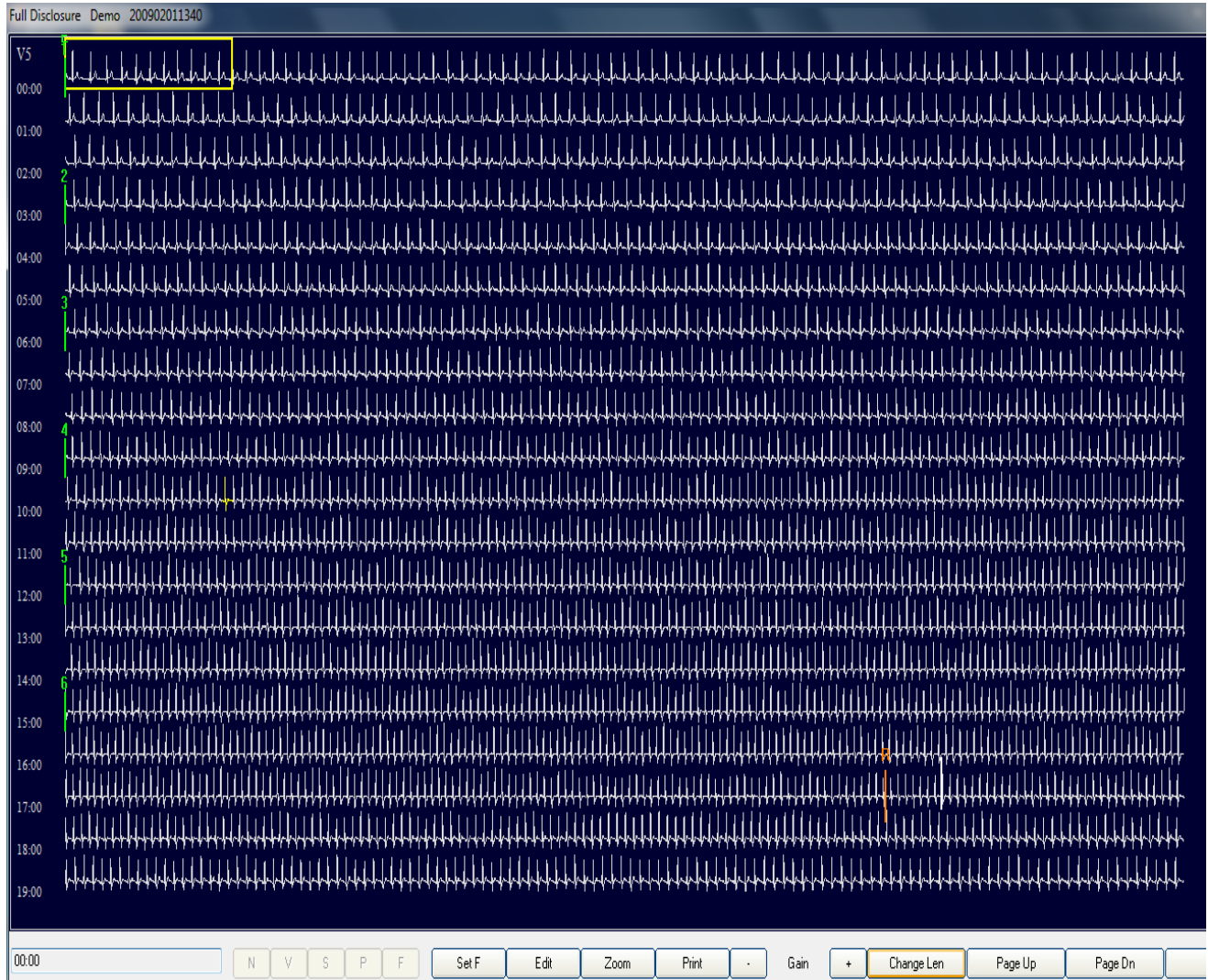
Clicking on the icons at the bottom of the page will change the referenced graph values, accordingly, for all 12 Leads.

By placing the cursor over a graph and left clicking, the user will cause a vertical, dotted (yellow) line to appear. Using the right and left arrows will result in the yellow line shifting and displaying the relevant values for any minute of the test.

Click on "Zoom" or double-click for an ECG display (see below).



C. FULL DISCLOSURE



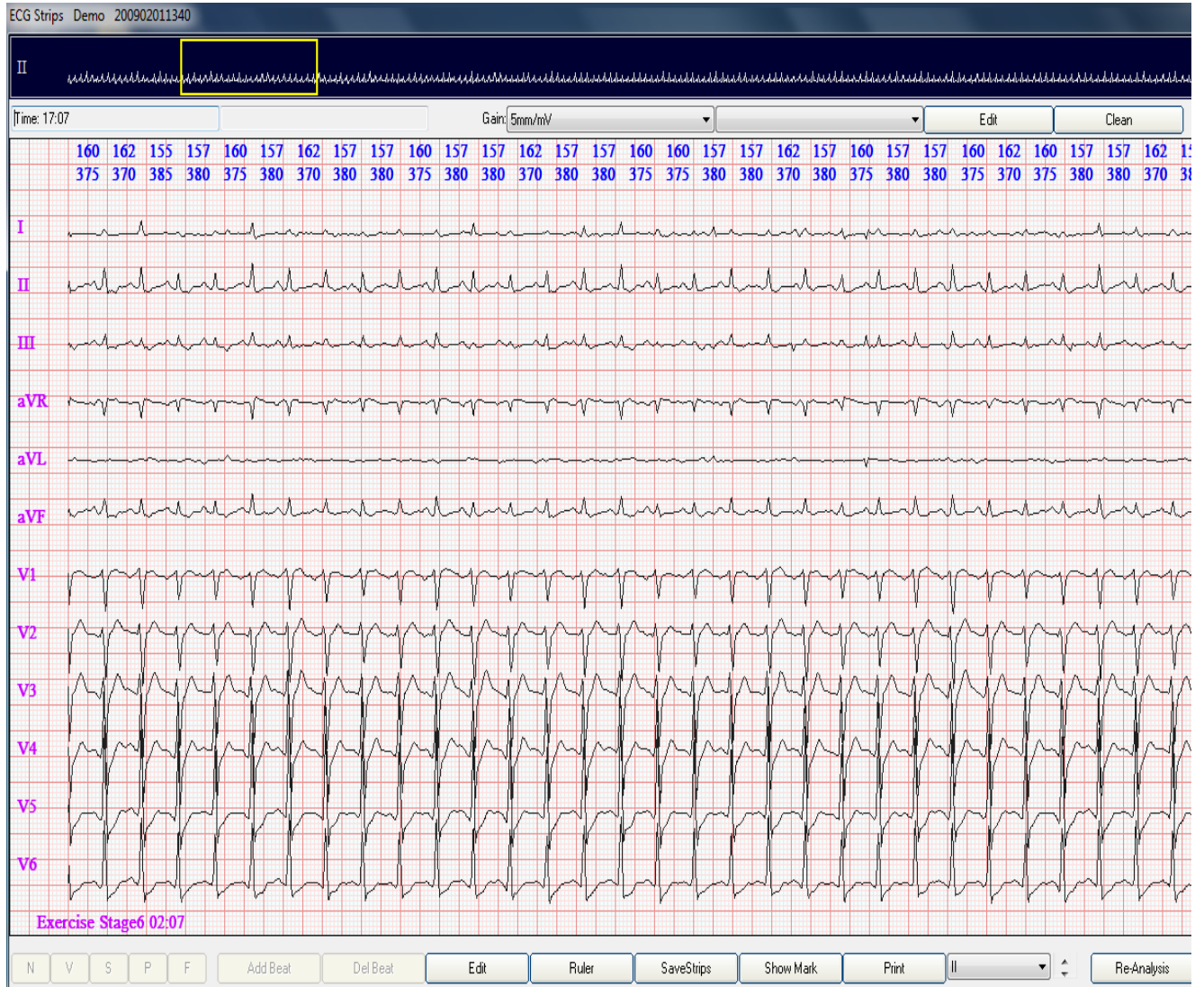
The above Full Disclosure display shows every beat for V5 from the beginning of the Stress Test to the end of Recovery. This display shows 19 minutes of Exercise and Recovery (each minute is on the left side of the display). A quick look by the physician shows the complete picture of arrhythmias during Exercise and Recovery.

The green vertical markers show the beginning of each Stage of the Stress Test. The brown vertical marker shows the beginning of Recovery.

The “Edit” icon allows the user to edit beats – Normal (N), VE (V), SVE (S), Pause (P), Artifact (F). The “Change Len” icon allows for various sizing of the ECG.

At any location on the Full Disclosure, the enlarged 12-Lead ECG can be accessed with the “Zoom” icon (or a double-click). You can use the arrow keys to place the yellow box (“area of focus”) on the desired location.

D. ECG STRIPS



The top of the screen shows 1-minute of ECG. Use the arrow keys to view different time periods. Press PgDn or PgUp to move forward or backward by one minute increments.

Heart Rate and R-R in ms are shown above each beat.

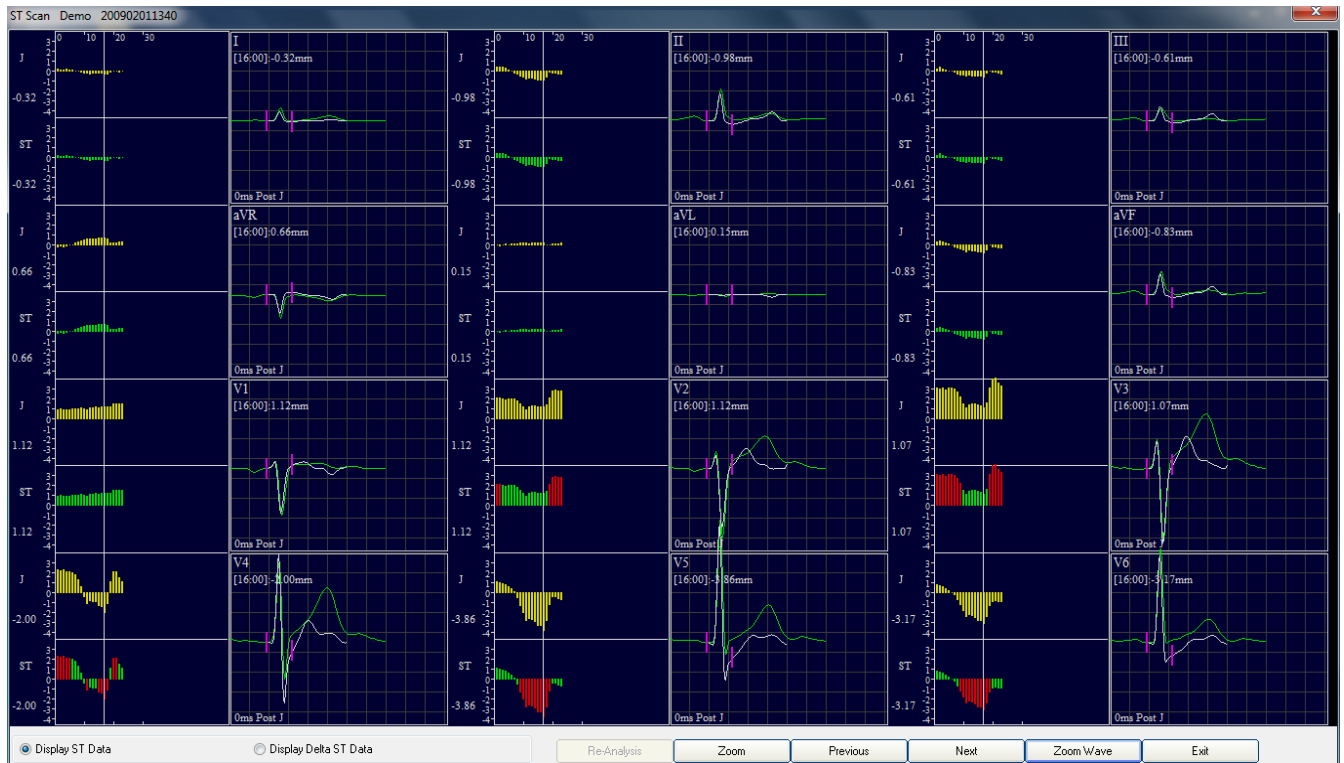
Any ECG marking during the Stress Test is auto-displayed.

An electronic Ruler is built into this display to precisely measure any intervals or amplitudes.

Any selected data from the Exercise or Recovery periods can be saved and/or instantly printed from this display.

E. ST SCAN

The display below shows Max J-Point and ST Depressions for all 12 Leads.



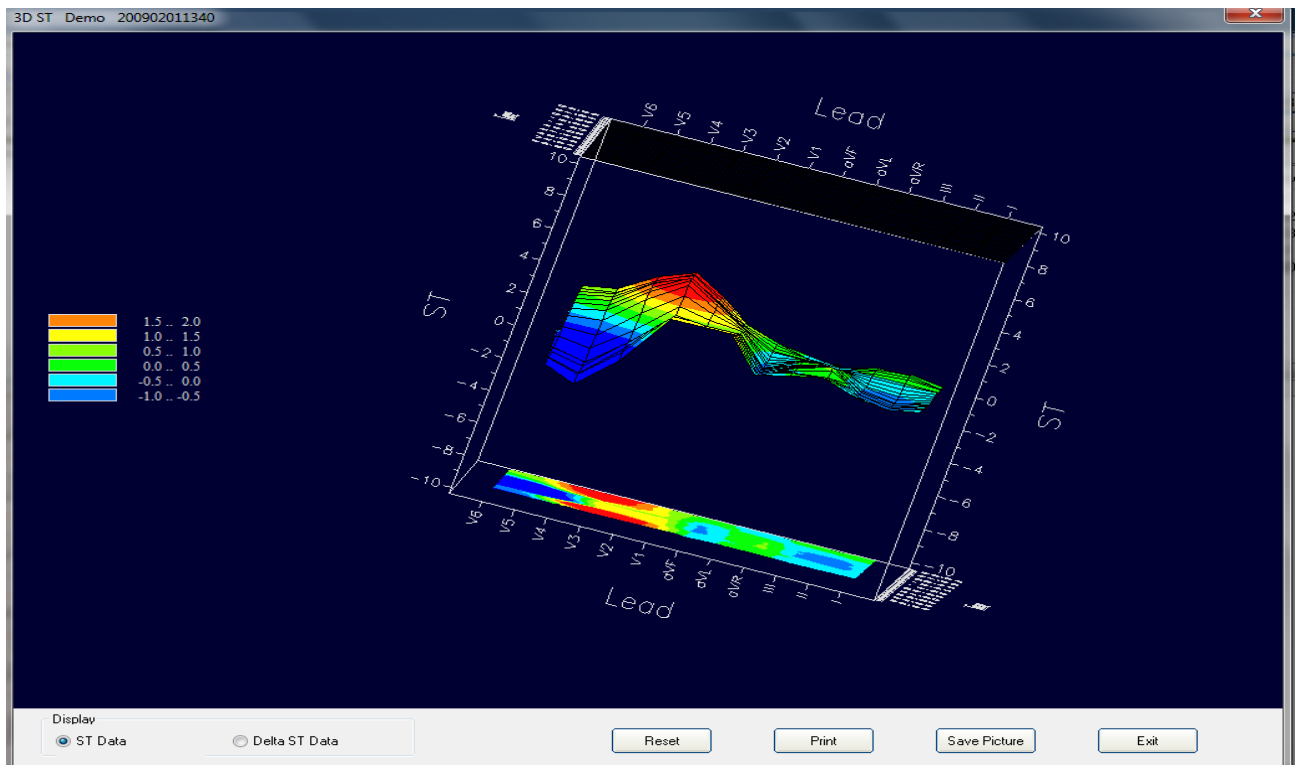
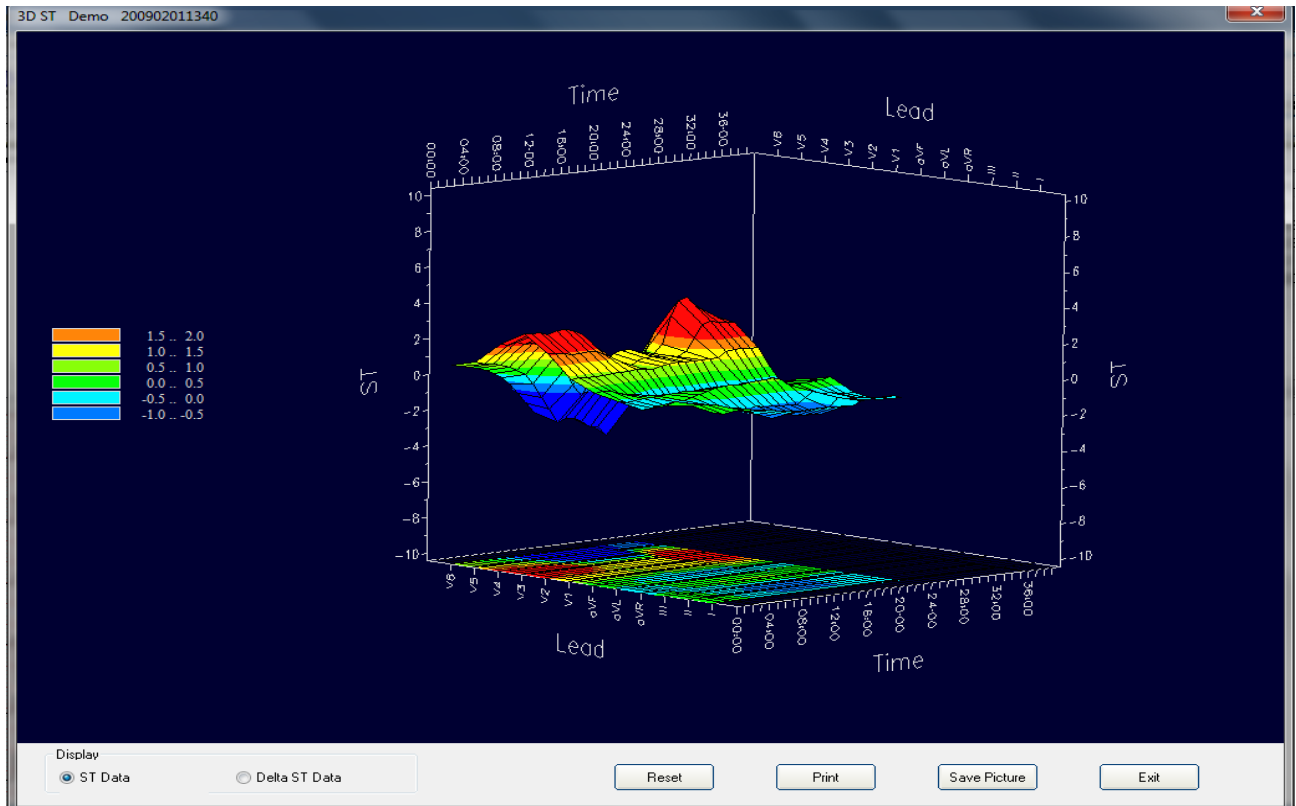
This minute-by-minute view of J-Point and ST Depression allows for a full review of Exercise and Recovery in less than 30-seconds.



Purple vertical markers verify that the ST algorithm measured the PR baseline, the J-Point, and the ST at the proper locations. The Yellow bars represent minute-by-minute J-Point Depressions. The Red & Green graph is minute-by-minute ST Depressions. Move along the White line (using arrow keys) to view superimposed J and ST displays. Zoom to see 12-Lead ST.

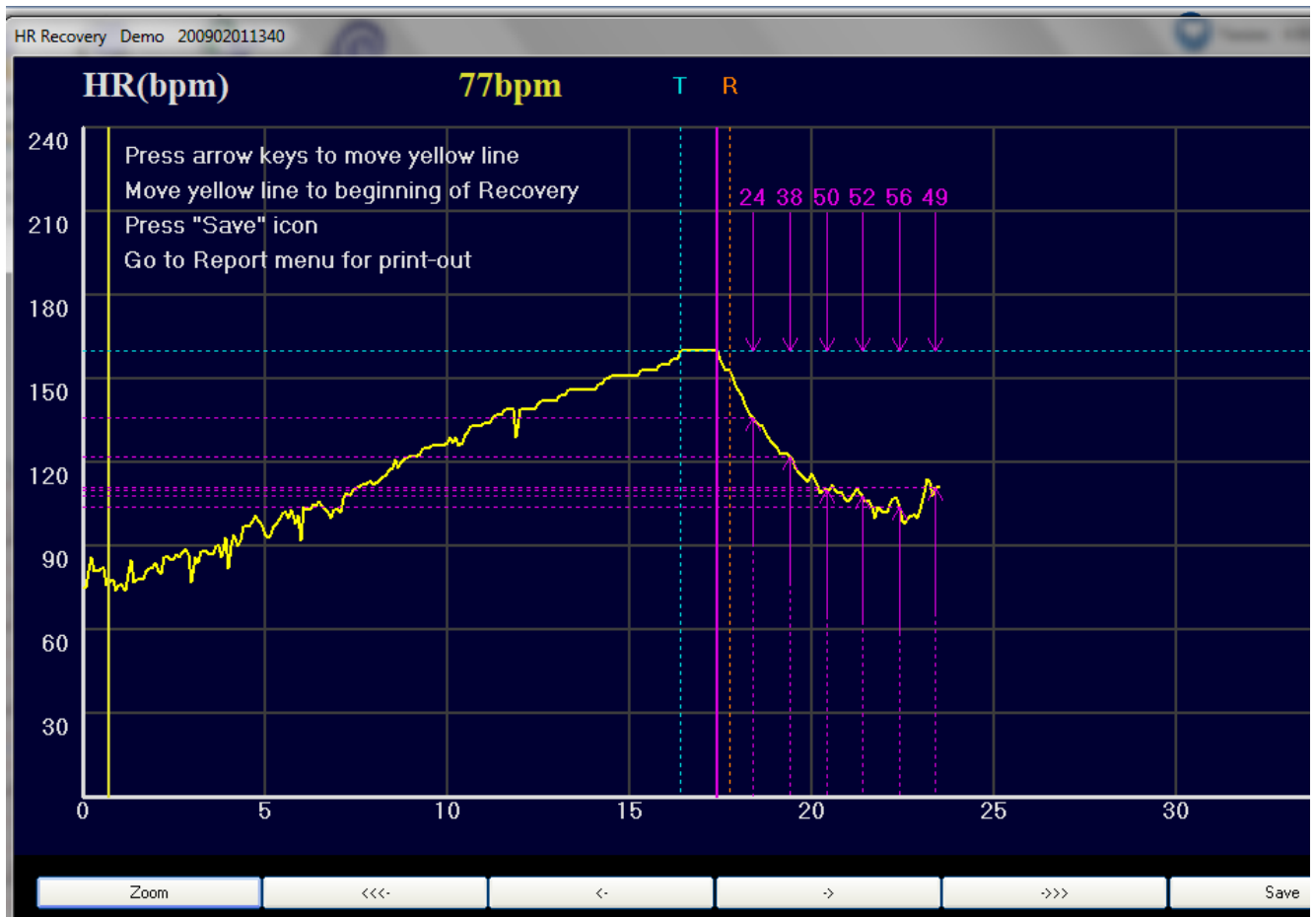
F. 3D ST

Point and Drag to change aspect of 3D presentation of ST changes during the Stress Test.



G. HR RECOVERY

The rate of HR decrease during Recovery is an important diagnostic marker for an Exercise Stress Test. The less the HR decrease each minute, the more likely a positive Stress Test.



The yellow graph shows HR increase during Exercise, and decrease during Recovery.

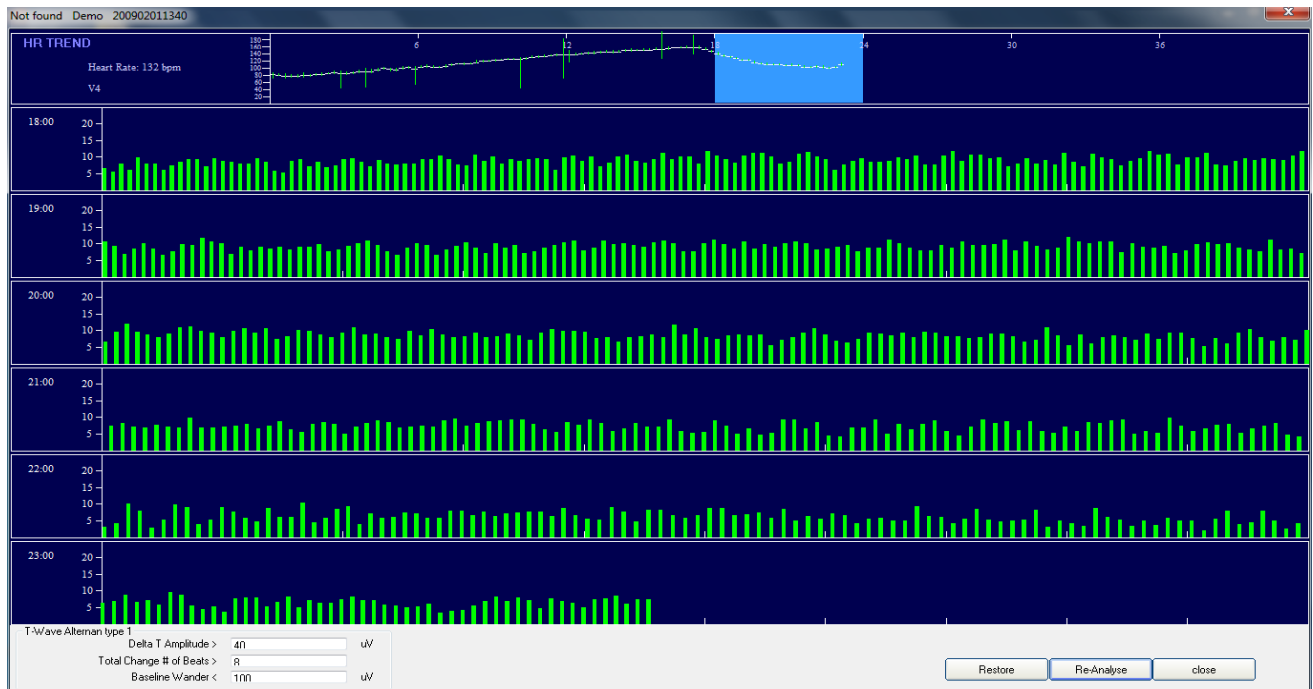
The solid vertical purple line is the software's selection of the beginning of Recovery.

The vertical yellow line at the left side of the graph can be moved with the arrow keys. Move the long yellow line to the visual beginning of recovery to re-confirm the HR Recovery algorithm. As you can see, instructions are provided in the upper left of the display.

At the end of each minute in Recovery, the Heart Rate Recovery decrease is calculated and reported. This example shows a cumulative 24bpm HR decrease for the first minute, 38bpm at the end of the second minute, and 50bpm at the end of the third minute of Recovery.

H. TWA (T-Wave Alternans)

The CardioScan Stress Test software allows for T-Wave Alternans analysis without the need for special electrodes. Each beat is analyzed for TWA along each ECG Lead from the beginning of the Stress Test to the end of Recovery.



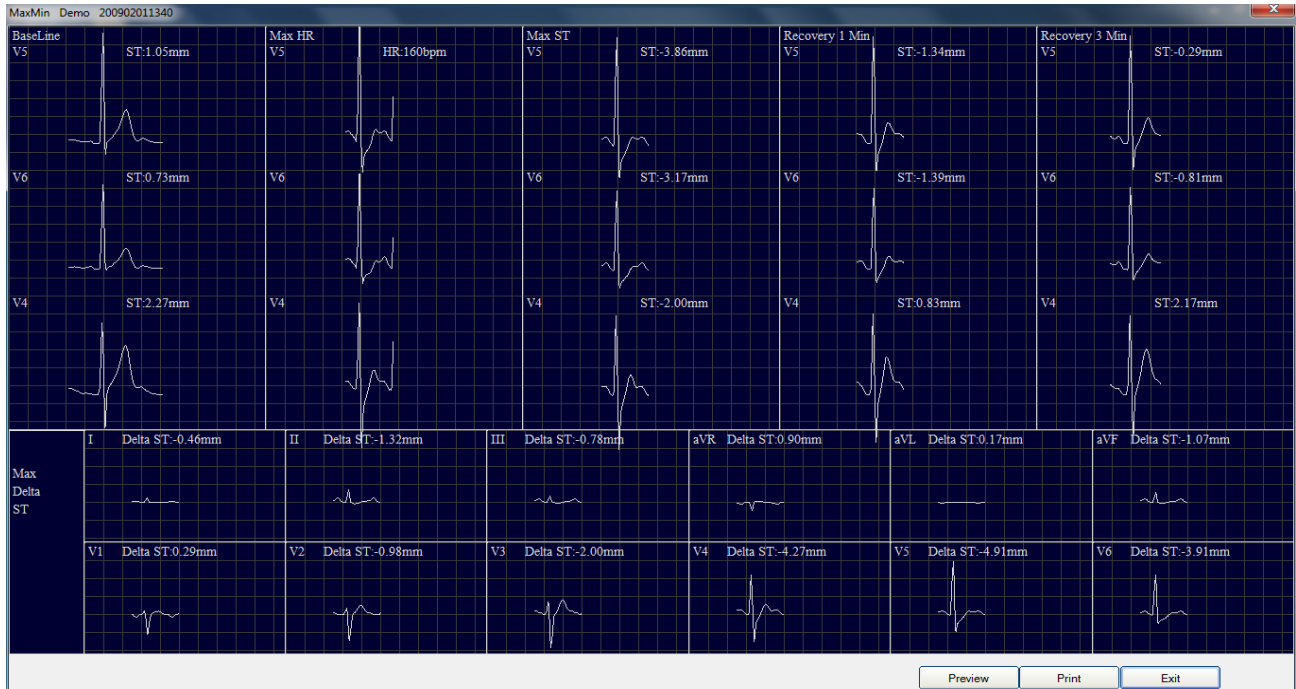
The top portion of the display shows the HR trend. The light blue section represents the 6-minutes of ECG displayed in the TWA analysis. The green vertical lines are the amplitudes of each T-Wave. If TWA is detected, the green lines will change to red. The "Re-Analyze" button in the lower right will allow the user to select the desired Lead. A double-click on the green lines will display the enlarged ECG, with the Gain multiplied (see below).



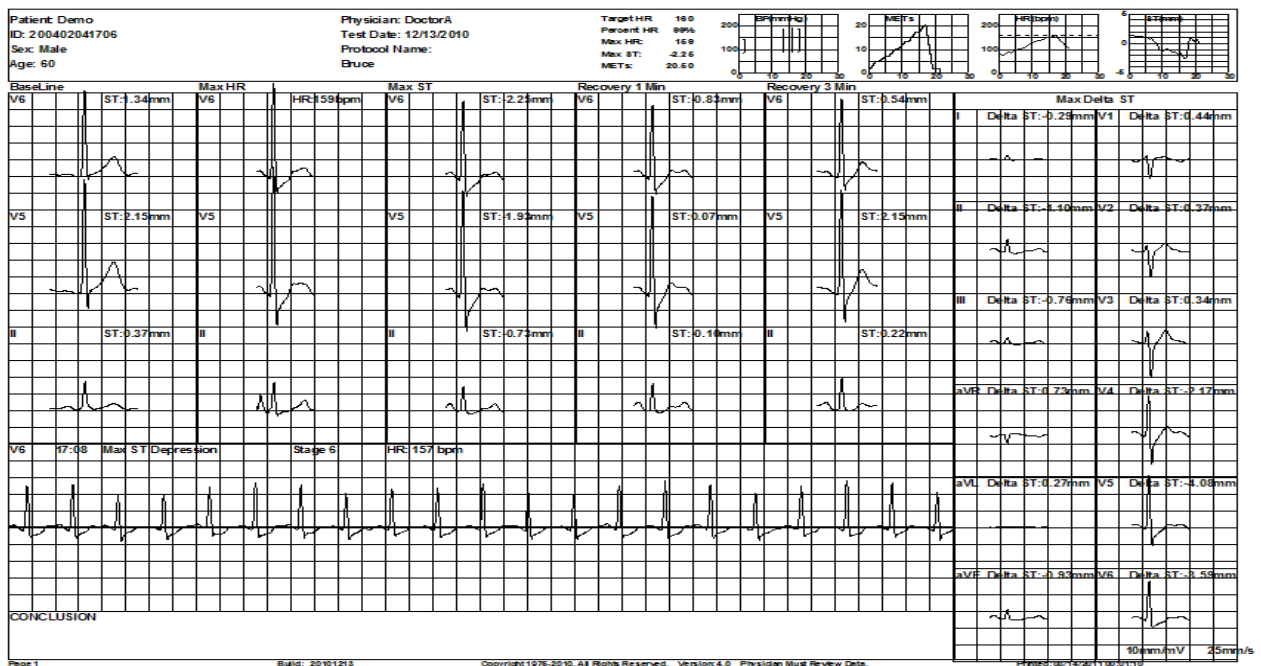
I. MAXIMUM

The top half of display shows the Max ST changes with the Absolute ST algorithm.

The bottom half shows the Max ST changes in the Delta ST mode for all 12 ECG Leads.

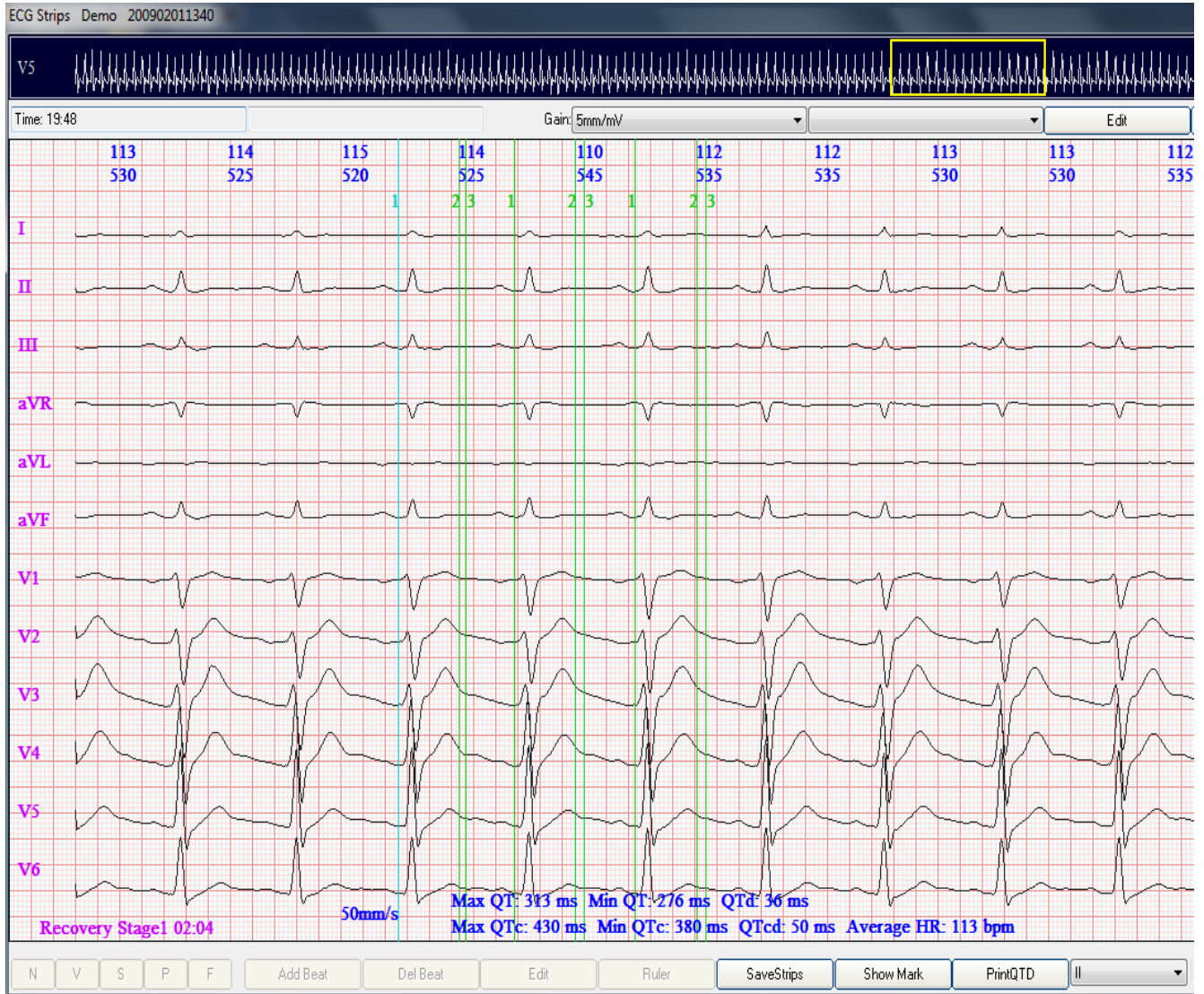


The screenshot below shows the resulting printable report. Max ST Averaged data is shown for Baseline, Max HR, Max ST, and Recovery ECG for Absolute ST measurements. There is a long rhythm strip for the Max ST Depression Lead at the bottom. At the upper right are graphs for BP, METS, HR, and ST. The right side shows Max Delta ST for the 12-Leads.



J. QTd (QT Dispersion)

The purpose of the QTd measurement is to bring clarity to borderline ST changes for female Stress Test patients. Selecting this option will take the user to the Full Disclosure ECG display. Use the arrow keys to move the yellow rectangle to the desired location. Press “Enter” or double-click to access the review widow shown below.



QTd is the average of 3 successive beats. Move mouse arrow to the first green line near the beginning of Q at the first beat. Click and the line will turn blue. Use arrow key to move this blue line to the beginning of Q. Press the Tab key, and next vertical line will turn blue. Use the arrow keys to move to the ECG Lead with the minimum QT interval. Press the Tab key. Use arrow key to move third line (now blue) to the ECG Lead with the maximum QT interval.

Press Tab key, and repeat process for second and third beats.

QT Dispersion is reported at bottom of ECG Strip.

Overview of Available Reports

The Stress Test software offers a number of useful reports. This section highlights the main features of ten (10) such reports.

1. Summary Stress Test Report

This summary report displays five (5) data sections: 1) patient information; 2) numerical data for exercise and recovery; 3) ECG at various stages of the stress test; 4) trends of HR, ST and BP; and 5) a written section of detailed statements specific to each stress test performed.

The numerical data section details the common data sets for stress tests, plus Workload, RPP (HR * Systolic BP), Ventricular Ectopics, and Supraventricular Ectopics.

The ECG section shows the ECG Lead of maximum ST depression. It displays four (4) different ECGs: 1) Pre-Test Baseline; 2) Peak Exercise; 3) Max ST Depression; and 4) Test End.

The trend section selects the ECG Lead of Max ST depression, and then prints a time-correlation graph of Heart Rate, ST, and Systolic / Diastolic BP.

The section for the written description of the Stress Test is physician-specific. Each physician can choose his/her own format (paragraph or line-by-line) and data sets - selected from a menu of approximately 15 data-set sentences. These preferences are saved. Thus, when the physician selects his/her name in conducting a test, that physician's chosen written format appears on the report page. The physician can also create a library of impressions and diagnosis, and then incorporate such statements into the report. The physician can also add or delete text from the report in typical word processing methodology.

Prior to printing the report, the physician or technician can review and edit the data content. The summary report section can be changed. For example, perhaps the physician wants a larger section for comments, impressions or diagnosis.

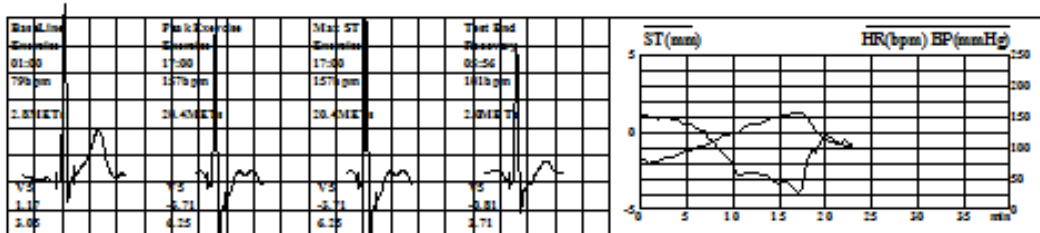
SUMMARY STRESS TEST REPORT

General Hospital DMS Test Date: 02/01/2009 13:40	Tel: Fax: Test Type: Treadmill (Bruce)
EXERCISE STRESS TEST REPORT	

Patient: <u>Demo</u>	Address: _____
ID: <u>200402041706</u>	Age: <u>65</u> DOB: <u>01/01/1944</u> Sex: <u>Male</u> Height: <u>175cm</u> Weight: <u>80kg</u>
Physician: <u>DoctorA</u>	Referring: <u>DocuB</u>
Indication: _____	
Medication: _____	
The reason for terminating Exercise was: <u>Other reasons</u>	

Exercise Test Summary

Phase	Stage	Time (min:sec)	Total Time (min:sec)	Speed (km/h)	Grade (%)	Workload (METs)	HR (bpm)	BP (mmHg)	RPP (*100)	VE	SVE	ST V5 (mm)	Comment
Pretest		00:15		0.0	0.0	1.0	86			0	0	0.05	
Exercise	1	03:00	03:00	2.8	10.0	4.7	93			0	0	0.05	
	2	03:00	06:00	4.0	12.0	7.0	106			0	0	0.46	
	3	03:00	09:00	5.5	14.0	10.2	123			0	0	-1.15	
	4	03:00	12:00	6.7	16.0	13.4	141			0	0	-2.76	
	5	03:00	15:00	8.1	18.0	17.4	153			0	0	-3.17	
	6	02:44	17:44	8.9	20.0	20.5	162			0	1	-3.71	
Recovery		01:00		2.0	0.0	11.5	130			0	0	-1.29	
		01:00		2.0	0.0	2.3	113			0	0	-0.76	
		01:00		2.0	0.0	2.0	107			0	0	-0.27	
		01:00		2.0	0.0	2.0	100			0	0	-0.29	
		01:00		2.0	0.0	2.0	97			0	0	-0.66	
		00:00		2.0	0.0	2.0	100			0	0	-0.81	



CONCLUSION

The Bruce protocol was used for this Stress Test. The total duration of Exercise time was 17:44, and was terminated at stage 6. The maximum METS workload was 20.5 METS. Resting Heart Rate was 86 bpm, and increased to a maximum Heart Rate of 162 bpm. The Max HR of 162 represents 123% of the Target Heart Rate of 131 bpm (Stage 6 at 01:26) (16:26). At 1-minute post exercise the Heart Rate decreased 22 bpm from 151 to 129. The Heart Rate at end of recovery was 82 bpm. Max ST Depression was -3.71 mm in V5 at Stage 6 Exercise. Total SVE beats were 1, with 0 SV-Runs. The minimum Blood Pressure at rest was 0/0 mmHg. The reason for terminating Exercise was Other reasons.

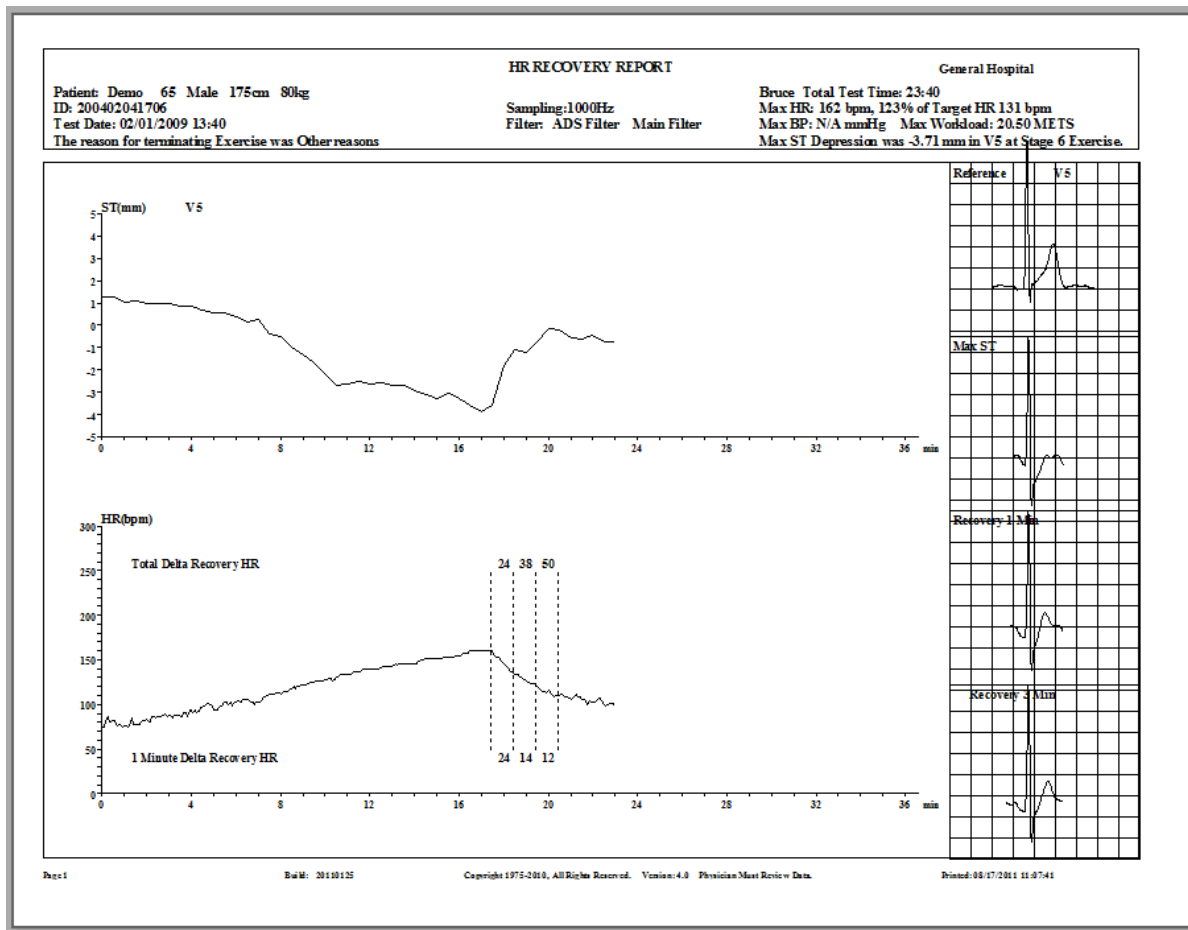
Physician Confirmation: _____

2. HR (Heart Rate) Recovery Report

This report is presented in three (3) sections. The top section displays the most important relevant data during the stress test.

The graph section shows detailed trends for the Max ST depression and the Heart Rate. The Heart Rate graph displays vital information, such as Heart Rate Recovery after Peak Exercise. The first dotted vertical line shows the exact start time of Heart Rate Recovery. The next three dotted lines are one, two, and three minutes into recovery. The numbers at the top of the dotted vertical lines represent the accumulated heart rate decrease each minute after the beginning of recovery. The bottom numbers display the one-minute changes in recovery.

The ECG section selects the ECG Lead of Max ST depression. The user can select either the Absolute or Delta ST algorithm. The J-point or ST-point algorithm can be selected by the user. The user can also choose the number of MS past the J-Point for both ST measurements and ST Slope. This section prints the ECG at: 1) Pre-Test Reference; 2) Max ST; 3) Recovery at 1-minute; and 4) Recovery at 3-minutes.

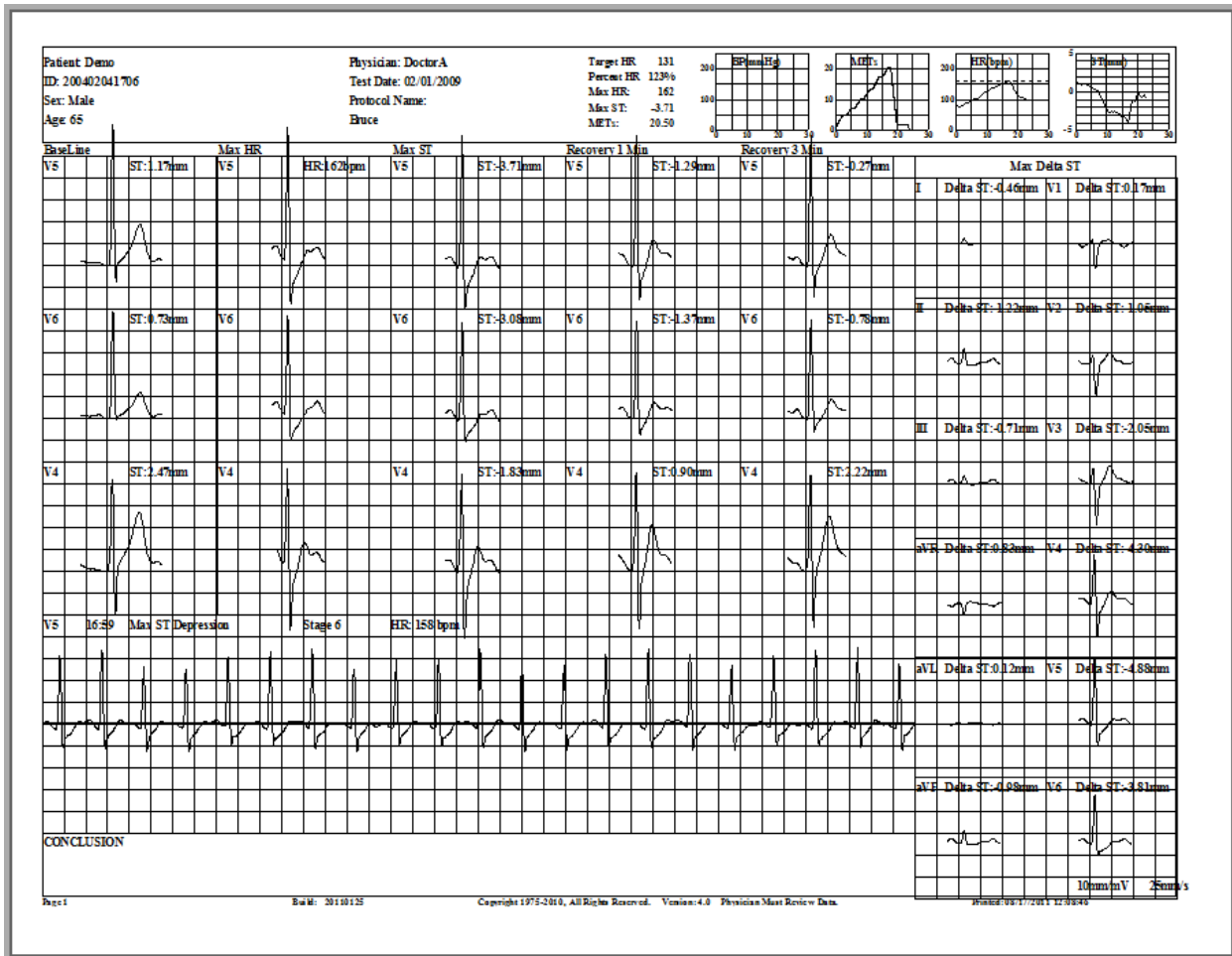


3. Maximum Significant EGG Data Points

This report clearly highlights the significant ECG events during the Stress Test, and reports both the Absolute and Delta ST algorithms.

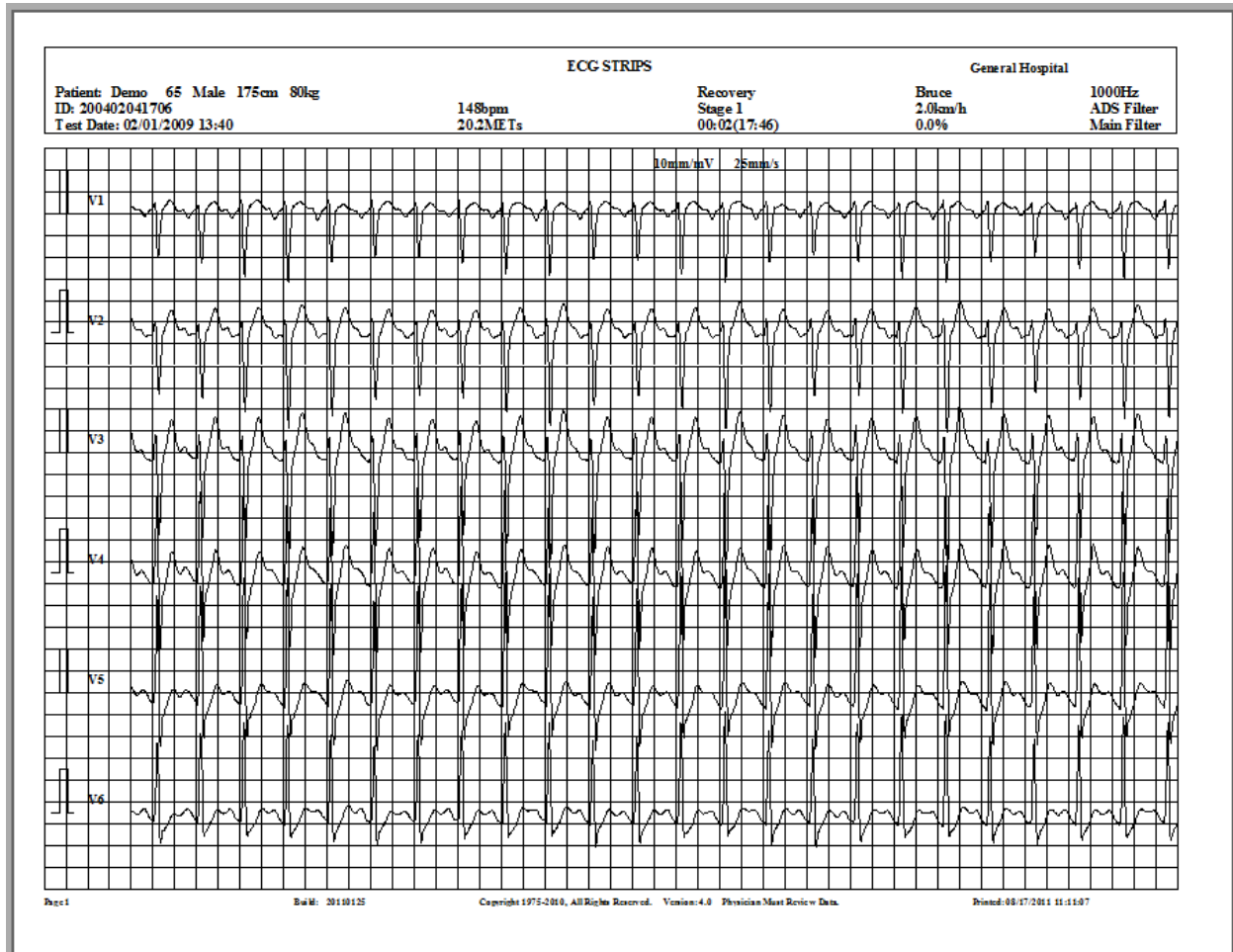
The top section includes the Target HR, Max HR, % of Target HR, Max ST, and METs. Also included are graphs of BP, METs, HR, and ST.

The large ECG section shows the three (3) ECG Leads with the Max ST using the Absolute ST algorithm. The ECG data is printed at Baseline, Max HR, Max ST, Recovery at 1-minute, and Recovery at 3-minutes. Below this is the rhythm ECG (V5) at the time of Max ST Depression.



4. ECG Strips

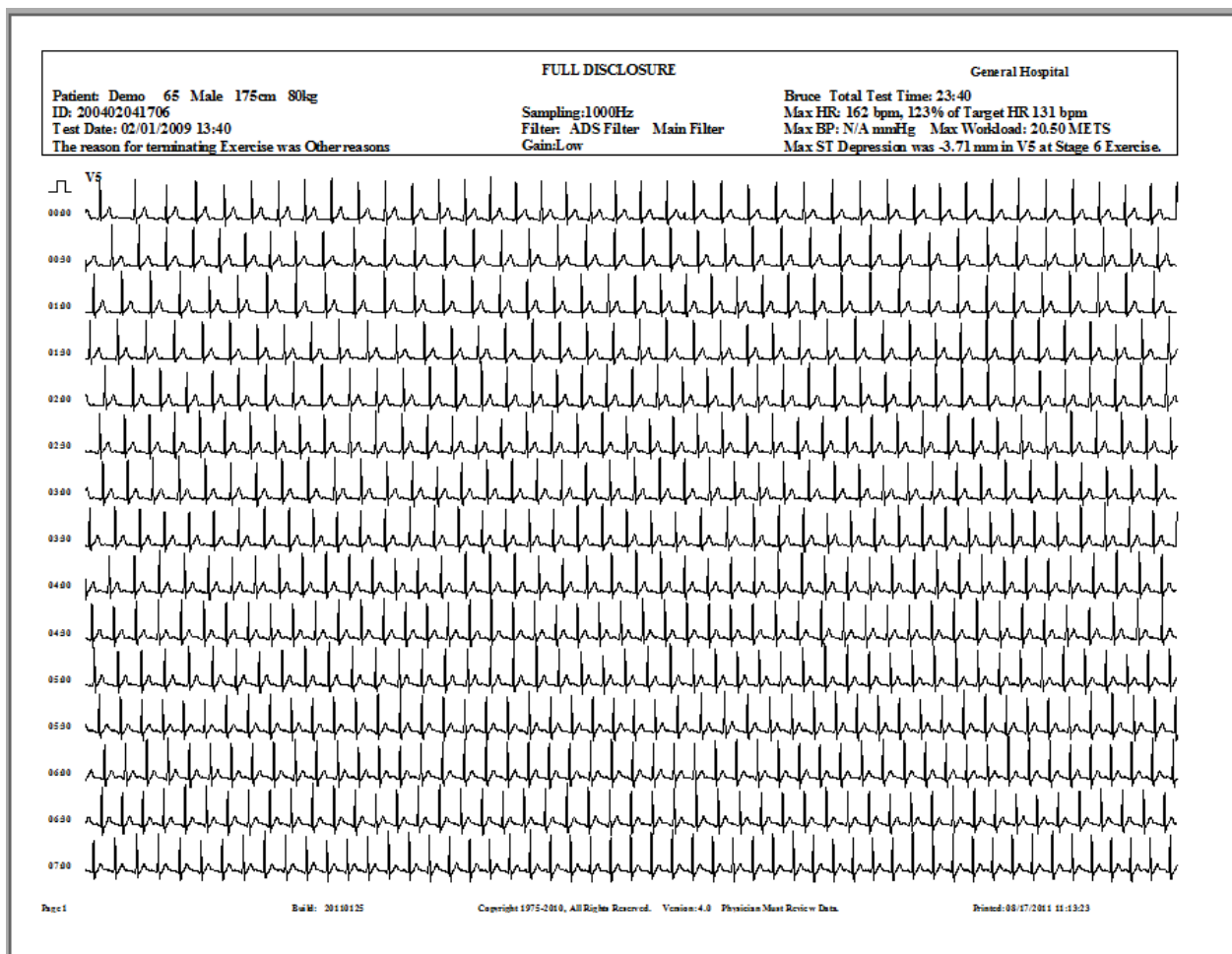
The software allows for many forms of ECG Strip print-out. The example that we show is of an auto-generated one at the exact time of transfer from Peak Exercise to the beginning of Recovery. This is a rhythm ECG Strip of all the V-Leads.



5. Full Disclosure ECG

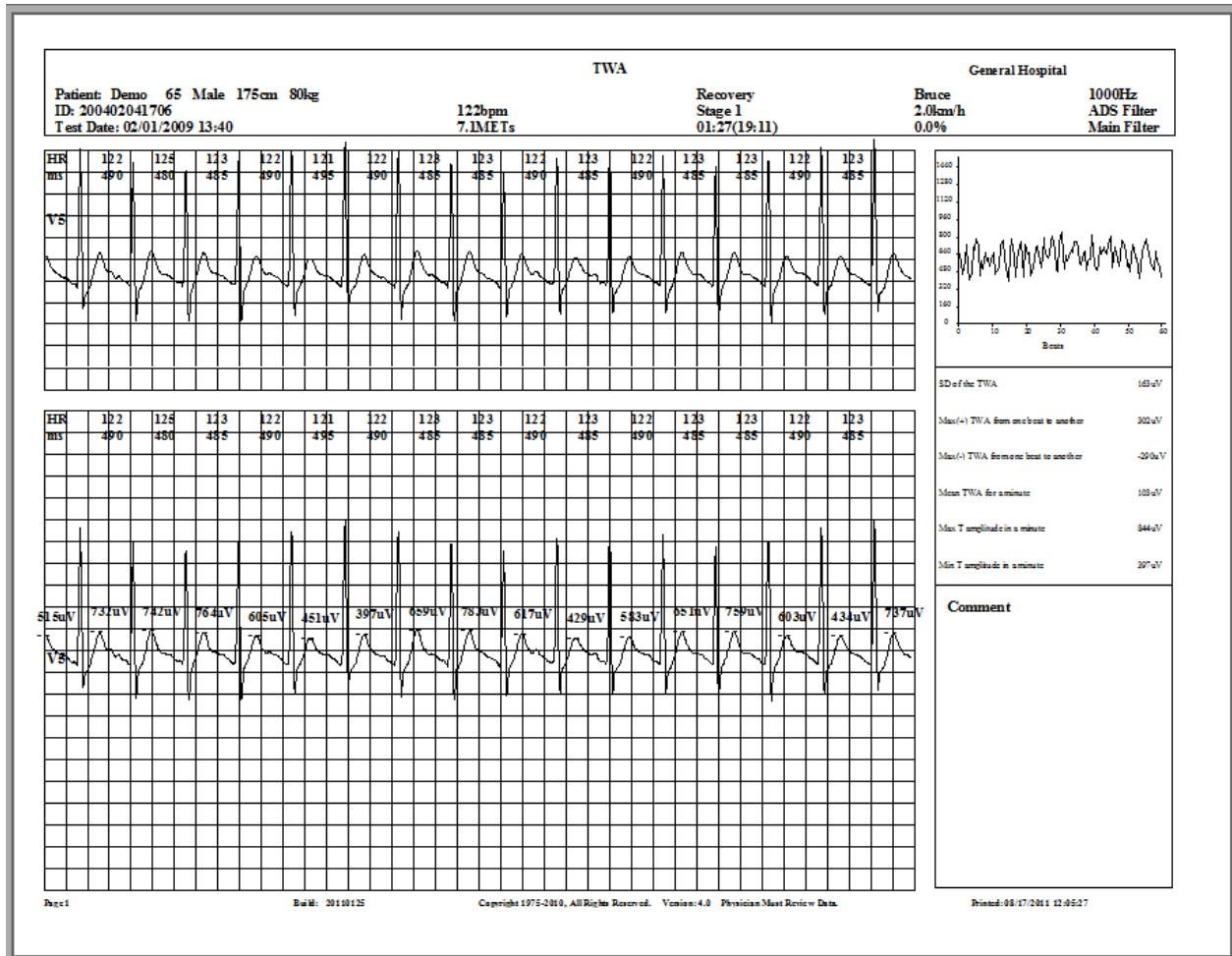
In light of the fact that DMS possesses the original patent for Full Disclosure in Holter, we have incorporated various formats of Full Disclosure into our Stress Test software. Any ECG lead can be selected. Various time frames can be selected per page of print-out. The 7.5 and 15.0 minute formats are the most popular.

At a quick glance, one can view the entire arrhythmia picture. In the event of a significant ST segment depression, the complete pattern of ST activity can be reviewed in less than five seconds. Viewing options include screen display mode, as well as report print-outs.



6. T-Wave Alternans (TWA)

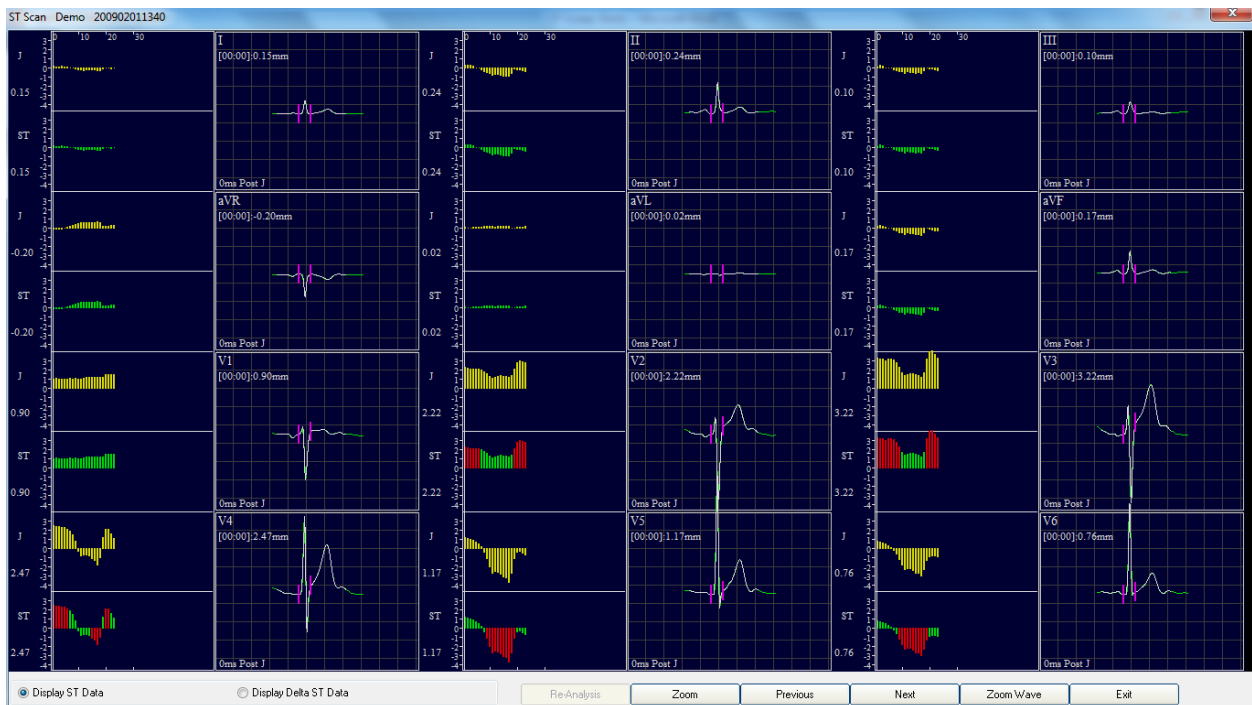
Every DMS Stress Test system includes T-Wave Alternans analysis functionality. DMS' approach to TWA is one of Full Disclosure. The user can see the amplitude of each and every T-Wave. The entire review process takes less than 30 seconds. The TWA report is the actual ECG with the gain increased for visual validation.



7. J-Point and ST Review

The entire Stress Test can be fully reviewed in less than one minute. All 12-Leads can be viewed for any significant J-Point or ST changes. Instant 12-Lead ECGs can be viewed and printed.

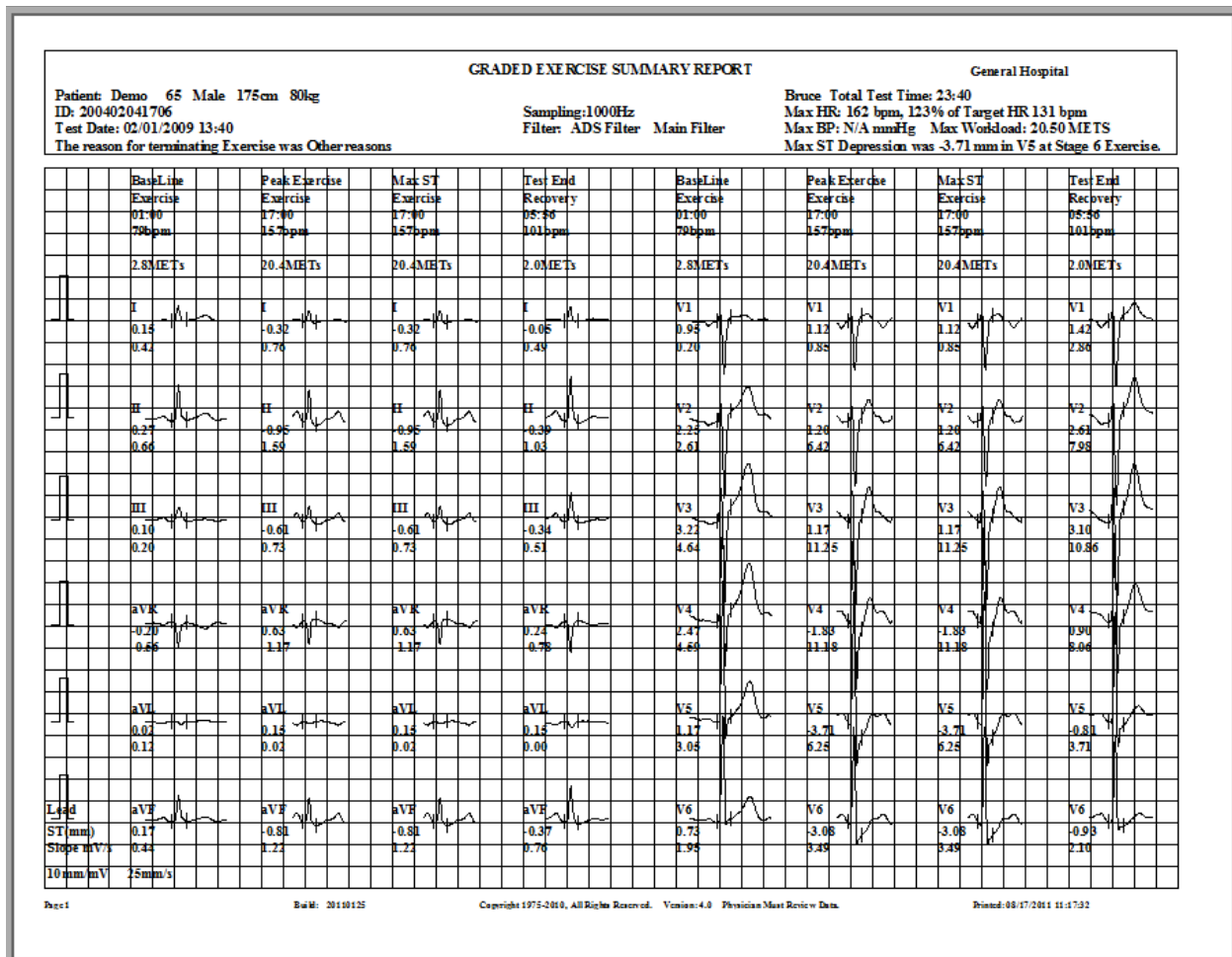
A mouse click or press of the keyboard arrow key will move a vertical cursor from minute-to-minute of the Stress Test. The ECG graphs displayed represent the averaged ECG at the end of each minute. The current ECG is superimposed over the Baseline ECG for each Lead, so that the change in J-Point and ST Level is immediately seen.



8. Graded Exercise Summary Report

On a single print-out, the ECG progress for all 12-Leads can be viewed. For each ECG Lead, the user can review the Baseline ECG, the Peak Exercise ECG, the Max ST ECG, and the End of Recovery ECG.

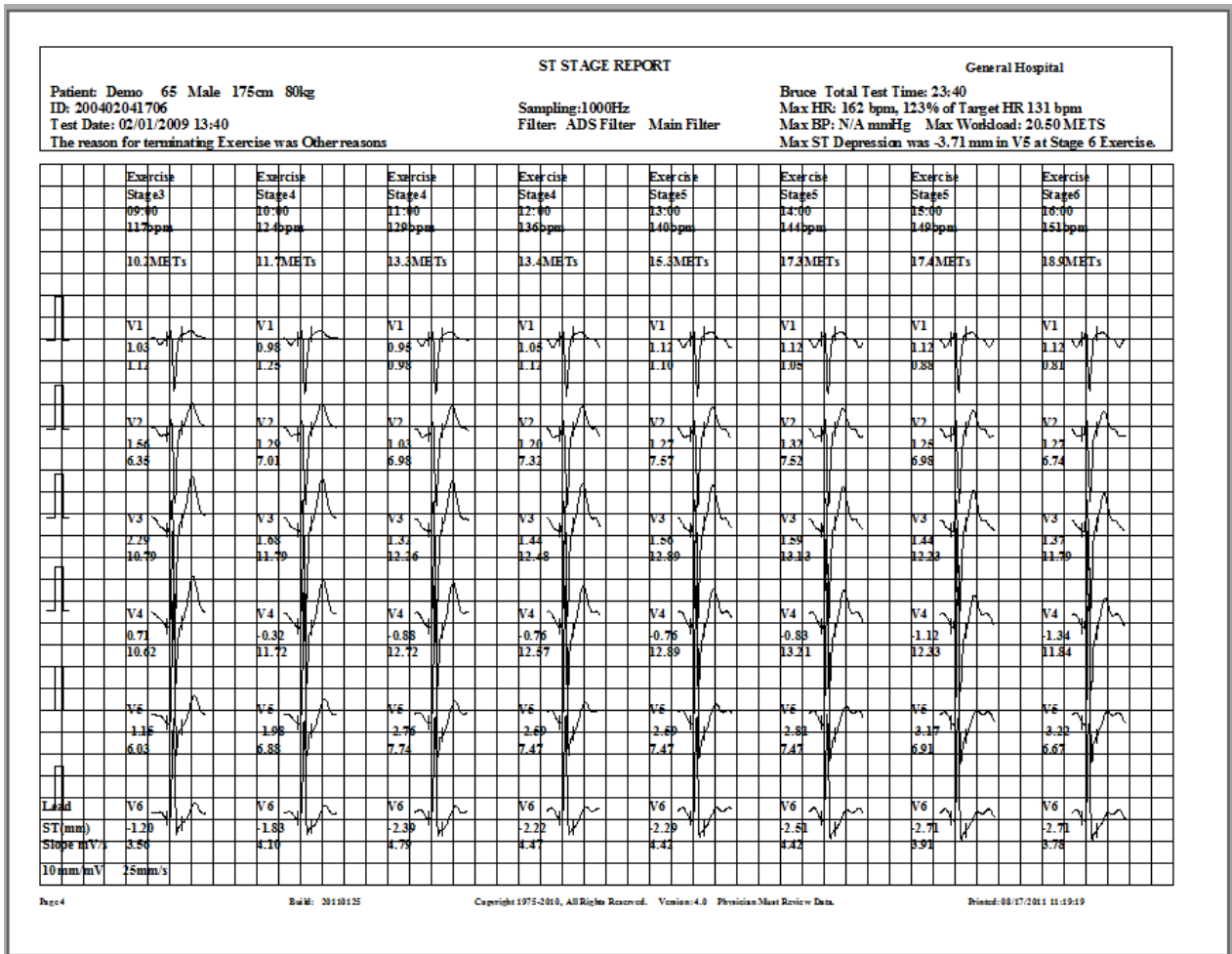
For data validation purposes, the user can view the vertical markers for each PR Baseline maker, J-Point marker, and ST Sample Point marker. The analysis also provides the Time, Heart Rate, Blood Pressure, METS, ST Level, and ST Slope.



9. ST Stage Report

In addition to the aforementioned Graded Exercise Summary Report, the DMS Stress Test System also provides an ST Stage Report. This report can display the end-of-minute averaged ECG for every minute and exercise stage, for all 12-Leads.

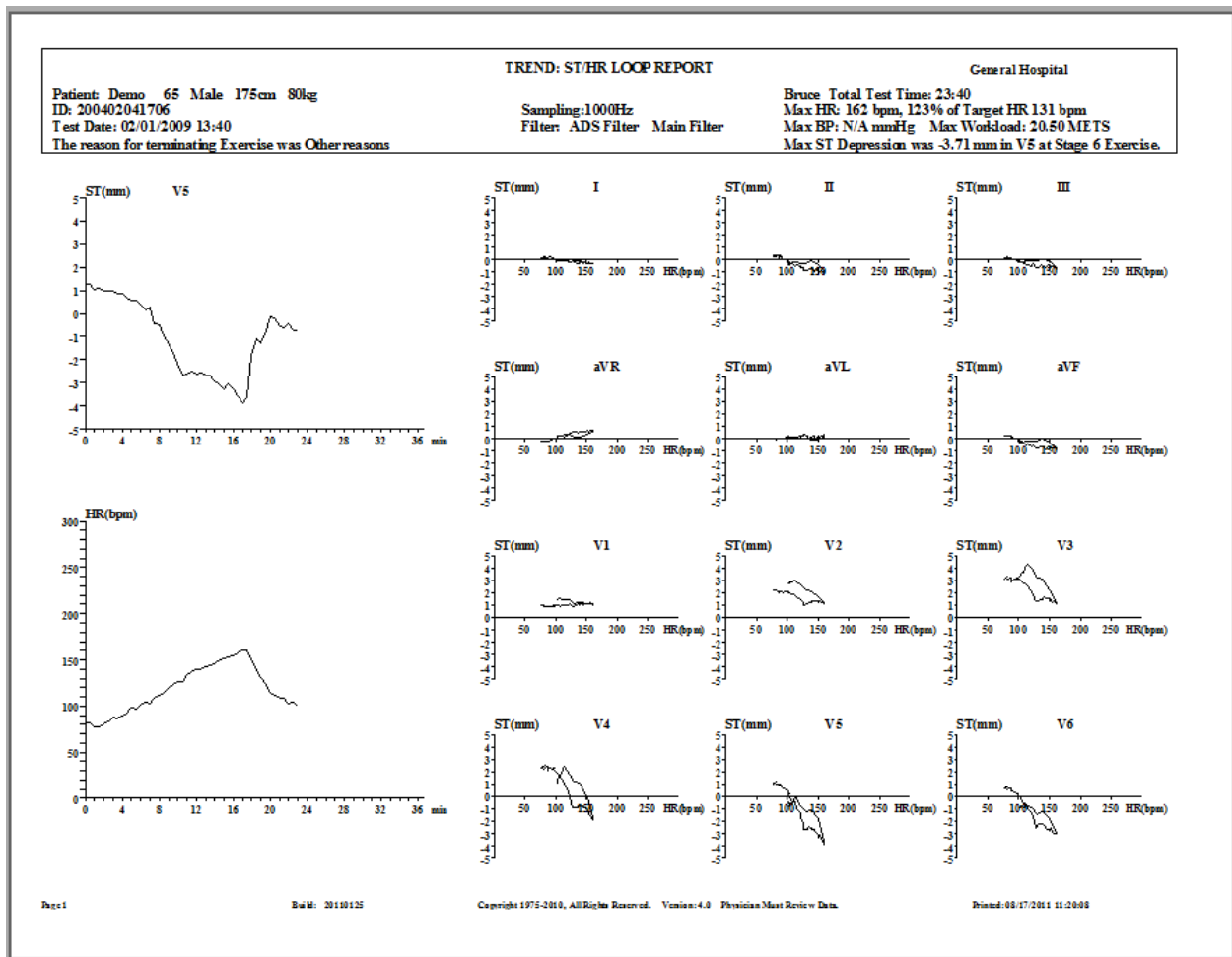
Included are Heart Rate, % of Target HR, Blood Pressure, METS, ST Level and ST Slope.



10. Trend: ST/HR Loop Report

This report shows the relationship of Heart Rate and ST Level during the Stress Test.

Significant ST deviations that cause the ST/HR Loop to go below a "0" horizontal baseline value should be carefully reviewed, according to relevant published medical literature



In addition to the reports highlighted above, it should be noted that the DMS Stress Test System provides significant additional report functionality, such as QT Dispersion (for borderline female Stress Tests).

List of Selected Keyboard Shortcuts

Below is a summary of useful shortcuts. With the exception of the **F1** key, all other shortcut commands are used solely when performing the Stress Test.

F1 New Patient: Opens the New Patient data input window. Can be accessed from either the Home or Patient Database tabs.

F1 Pretest: Enter the Pretest Phase of the Stress Test. Note ECG color change. ECG waves begin to be recorded.

F2 Exercise: Enter Stage 1 of the test. ECG will change in color. Each subsequent click of F2 will proceed to the next stage. *Note: It is not recommended to manually control the exercise stages by clicking on F2, as this may interfere with the protocol time settings.*

F3 Recovery: Enter the Recovery Phase. The treadmill / ergometer will come to a stop. Speed and grade will become zero. ECG will change in color. ECG is still being recorded.

F4 End: The test is concluded. ECG waves can be viewed but are not recorded.

F5 Hold: This will “hold” the current station. The present speed and slope will be maintained. The test will not return to the preset protocols until F5 is clicked again.

F6 Comment: This allows for physician comments to be inserted. They will appear in the final report.

F7 BP: Click F7 to manually input blood pressure. BP should be measured at every stage.

F8 Mark: The displayed ECG and time will be recorded for further analysis.

F9 Print: Click to get a real-time printout of ECG strips. *Note: Every protocol has its own preset auto-print time, usually at the start of the Recovery Phase.*

Notices

- This Stress Test system is designed and manufactured according to the specific requirements and regulations of the relevant government agencies involved. The software, structures, and components of the system must not be modified unless authorized by the manufacturer.
- The emergency stop button of the treadmill should be tested at least once every week in order to ensure that it is functioning properly. The exercise device must have an independent power outlet.
- It should be noted that any Stress Test involves potential risks to the patient. These include abnormal blood pressure, fainting, and disorders of the heart, among others. Required medical equipment (e.g., defibrillator) and medicine should be present at all times.
- Please ensure that the appropriate number of operating personnel is present to perform the Stress Test, as well as handle any potential emergency that could arise.

How to Contact Us

DM Software (Main Office)

P.O. Box 3109
290 Kingsbury, #3
Stateline, NV 89449
United States of America

Phone: (775) 589-6049
Fax: (714) 953-0260
Email: info@holterdms.com

DM Software (Support Office)

360 E. 1st Street, #631
Tustin, CA 92780
United States of America

Phone: (714) 953-2653
Fax: (714) 953-0260