



The Digital Cardiology Experts

QRS-Card™ Cardiology Suite 4.06 Software

QRS-Blue™ ECG Device

Operating Instructions



Operating Instructions

QRS-Card™ Cardiology Suite Version 4.06 QRS-Blue™ ECG Device

CS406-10-F

NOTICE The information contained in this manual is subject to change without notice. Names and data used in the examples are fictitious unless otherwise noted.

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CE Mark Declaration

The CE marking of conformity indicates that the device having this symbol on its immediate label meets the applicable requirements of the European Medical Device Directive.

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These operating instructions are related to Cardiology Suite version: V406 (130716)

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⚠ CAUTION US Federal law restricts this device to sale by or on the order of a physician.

⚠ CAUTION Use the QRS-Card™ system under the direction of a physician. All users should read and thoroughly understand the manual before use.[B1]

Pulse Biomedical, Inc. assumes no responsibility for any injury to anyone, or for any illegal or improper use of the product, that may result from failure to use this product in accordance with the instructions, cautions, warnings, or statement of intended use published in this manual.

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1. Safety

Chapter Contents:

1. Safety Conventions
2. User Responsibility
3. Warnings and Cautions

This chapter contains important safety and use information. Users should read and thoroughly understand all notes, warnings and cautions before

1.1 Safety Conventions

The symbols shown below identify potential hazard categories:

⚠ WARNING

Warning statements describe conditions or actions that can result in personal injury or loss of life.

⚠ CAUTION

Caution statements describe conditions or actions that can result in damage to product or property.

NOTICE

Notices contain additional information about usage.

1.2 User Responsibility

⚠ CAUTION The intended use of this system is for Patients undergoing ECG Testing, and/or ECG Stress, Blood Pressure, and Breathing analysis. The intended locations for use are in a physician's office, hospital, exercise rehabilitation facilities, or similar areas. The intended user is a trained medical professional and should have basic PC operational skills.

This product is designed to perform in conformity with the description thereof contained in this manual and accompanying labels and inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. A defective product should not be used.

Parts that are broken, plainly worn, missing or incomplete, distorted or contaminated should be replaced immediately. Should any repair or replacement become necessary, we recommend that service be performed at the nearest approved service center. The user of the product shall have the sole responsibility for any malfunction, which results from improper use, faulty maintenance, improper repair, damage or alteration by anyone other than Pulse Biomedical, Inc. or their authorized service personnel.

Use of accessories other than those purchased from Pulse Biomedical or an authorized dealer or distributor may compromise product performance and void Pulse Biomedical warranty.

1.3 Warnings and Cautions

⚠ CAUTION

1. UL Listed PC computers must be used for noise-free recording of ECG's.[u2][KB3]
2. To acquire good quality ECGs, only use AAMI EC-12 approved electrodes. Please check the expiration date of disposable electrodes. Do not use if past their expiration or if you cannot read the expiration.[u4]
3. To clean the QRS-Card™ first fully disconnect from computer. Use warm soap and water and surface disinfectant only. Do not immerse the QRS-Card™ in the cleaning solution as permanent damage to the QRS-Card™ may occur. [u5]

⚠ WARNING

The QRS-Card™ devices are an integral part of a personal computer based diagnostic system. The user shall adhere to all warnings in order to ensure safe and reliable performance of the system.

1. Only qualified service personnel should perform any service. Never use extension AC power cords with the PC computer, chassis leakage current may increase.[u6]
2. Routinely inspect cables/leads assemblies for cracks, holes, tears, cuts, etc. that could present problems to the system. [u7]
3. In case of ECG leadwire or cable replacement, use ONLY Pulse Biomedical lead wires and cables.[u8] Use of cables other than those specified or sold by Pulse Biomedical may result in increased emissions or decreased immunity of the QRS-Card™ Cardiology Suite system.[B9]
4. If using a Treadmill with QRS-Card™, use only FDA cleared treadmills.[u10]
5. If software CD becomes unusable, software can be downloaded from PBI web site (www.qrscard.com).[u11]
6. For Bluetooth Device: Batteries should not be kept beyond the manufacturer's published shelf life.[u12]
7. Use only devices sold by or recommended by PBI.[u13]. Contact PBI for further assistance, included sanctioned devices to interface with PBI system
8. For proper electrode placement, please see the diagram on the QRS-Card™ Device label or in the QRS-Card™ Cardiology Suite software.[u14]
9. Do not connect the patient cable to anything other than the QRS-Card™ Device. Be sure you know how to properly connect the patient cable to the QRS-Card™.[u15]
10. PBI products should only be maintained and serviced by PBI factory personnel.[u16]

11. The personal computer (non-medical electrical equipment) shall be situated outside the patient environment (reference IEC 60601-1-1). Ensure that the computer and printer are more than 6 feet away from the QRS-Card™ device and 6 feet away from the patient.[u17] Do not place a telephone near the device.
12. Personal Computers and peripherals are required to meet IEC 60950[u18]
13. PACEMAKER PATIENTS: The QRS-Card™ Cardiology Suite hardware and software does not provide or detect pacemaker pulses. Do not rely on the QRS-Card™ Cardiology Suite output or the heart rate meter for Pacemaker patients during cardiac arrest. Pacemaker patients must be closely observed.[u19]
14. MODEM USAGE DURING ELECTRICAL STORMS: For patient's safety during Electrical Storms, the telephone line to the modem and the patient ECG cable should NOT be hooked up at the same time.[u20]
15. QRS-Card™ ECG device must be at least 6 feet away from the computer.
16. LOW BATTERY: If the QRS-Card™ Cardiology Suite System is used with a battery operated computer, the low battery indicator warning of the computer must be checked before using the system on any patients.
17. PROPER ELECTRICAL GROUND: Proper electrical grounding to the AC lines is an **absolute necessity** for acquiring noise-free ECG recordings.
18. PATIENT DATA BACKUP: It is important for users to backup their patient ECG data regularly. In the case of accidental hard disk data loss, backup data can be restored to the hard disk.
19. SCREEN SAVERS that blank the computer screen must not be used while the QRS- Card™ Cardiology Suite ECG system software is running.
20. Use the QRS-Card™ software as stand-alone software. Do not run other software applications while running the QRS-Card™ software.
21. Do not use this device in areas where flammable, explosive, or anesthetic agents are used. The device is not intended for use during anesthesia.
22. Electromagnetic Compatibility- When using the QRS-Card™, electromagnetic compatibility with surrounding devices should be considered and evaluated. The QRS-Card™ complies with IEC 60601-1-2 limits for EMC.
23. Due to the shock hazard that can exist within the PC when the cover is removed, only qualified service personnel should perform service. Never use extension AC power cords with the PC computer, chassis leakage current may increase.
24. Erratic and/or non-rhythmic heartbeats, or artifacts can result in inaccurate ECG readings.
25. ECG lead changes during measurements can cause artifacts that can result in inaccurate readings.
26. Changing patient positions (e.g. supine, sitting, etc.) during measurements can cause artifacts that can give inaccurate readings.
27. Choose an ECG lead other than V5 for patients experiencing cardiac occlusion.

28. Use during fibrillation or with cardioplegic agents will result in artifacts that can result in inaccurate readings.
29. For better measuring results, select the optimum signal/lead for monitoring.
30. Avoid nearby electrical noise sources, if possible.
31. If questionable readings are obtained, re-check the patient's cardiac rhythms by an alternate means before administering any medication.
32. Secure the PC Monitor with the computer on the cart (if used) so that it does not tip over.
33. Consult the PC Monitor book for proper connection between the computer and the monitor.
34. Operation of the computer under low mains voltage conditions is established by the user's computer choice. Use only UL listed computers to avoid this potential problem.
35. If the QRS-Card™ fails, please refer to the troubleshooting section in the user manual.

Medical Device Directive

The PBI QRS-Card™ complies with the requirements of the Medical Device Directive 93/42/EEC and carries the CE 0366 mark accordingly.

1.4 Symbols and Markings



= Consult accompanying documents



= Caution, Consult accompanying documents.



= Defibrillation proof type CF applied part



= Serial Number of QRS-Blue™



= Manufacturers address and date of manufacture.



= Name and address of European Representative



= Temperature Limitation



= Keep Dry

2. Introduction & Welcome

Welcome to the Pulse Biomedical QRS-Card™ Cardiology Suite. QRS-Card™ Cardiology Suite serves as a complete cardiology diagnostic workstation. When interfaced to a Windows® compatible personal computer or mobile phone, users can manage resting ECG, stress ECG, Holter ECG and ABPM data in one easy to use system. Physicians can perform tests on patients using a standard desktop computer, laptop/notebook computer, tablet PC or a mobile phone. Results of the tests can be viewed on the computer screen, edited and printed at any time. The results of the tests can be saved on the computer hard disk for future referencing or report generating.

This guide walks users through QRS-Card™ Cardiology Suite software, for more information on device hardware, please refer to the particular hardware manual.

For stress/exercise ECG testing the QRS-Card™ Cardiology Suite interfaces with treadmills and ergometers. Input of blood pressure can be performed automatically (screen prompts or direct interface to BP device) at predefined intervals.

QRS-Card™ Cardiology Suite can also be interfaced with EMR software, please contact PBI for more information.

We thank you for purchasing QRS-Card™ Cardiology Suite and trust that our product will help you more efficiently manage your cardiology data.

We value your thoughts, comments and questions. Please contact Pulse Biomedical Inc to provide feedback:

Pulse Biomedical, Inc.
Phone: (610) 666-5510
www.QRSCard.com
Email: Info@QRSCard.com

NOTICE QRS-Card™ Cardiology Suite can provide automatic computer interpretations. A computer generated interpretation cannot replace sound medical reasoning by a trained professional. Therefore, a physician should always review the interpretation and final analysis should always be obtained by a Physician. Proper administration, diagnosis and implementation of the test is the Physician's responsibility.

Computer Skills

This manual assumes that the users have necessary computer skills and are capable of using Microsoft Windows based applications.

3. Installing QRS-Card™ Cardiology Suite Software

3.1 Hardware and Software Requirements

PBI QRS-Card™ Cardiology Suite is a Windows-based software system requiring a minimum of 80 GB of disk space.

In order to install and successfully use QRS-Card™ Cardiology Suite, your computer must meet the following minimum requirements:

1. Windows based PC with Windows 7 and Windows 8 with a minimum of 4GB RAM.
2. Windows-compatible keyboard, mouse, USB Port and CD-Rom Drive.
3. Color/TFT monitor with a minimum resolution of 1024 x 768.
(Optimal resolution: 1920 x 1200)
4. Color or Black and White Printer (optional)

NOTICE Your QRS-Card™ Hardware products may have additional requirements. Please refer to the applicable hardware guide for information.

NOTICE QRS-Card™ Cardiology Suite software uses your computer date information to calculate the age of patients which may be vital to some diagnostic statements. Therefore, it is important that your computer's date is accurate. Contact your system administrator for help with this function.

3.2 Software Installation

All PBI QRS-Card™ Cardiology Systems come with a software installation CD (you can also download a full software version from our web site www.QRSCard.com). Before installing QRS-Card™ Cardiology Suite on your computer, it is important that you understand and follow the instructions below:

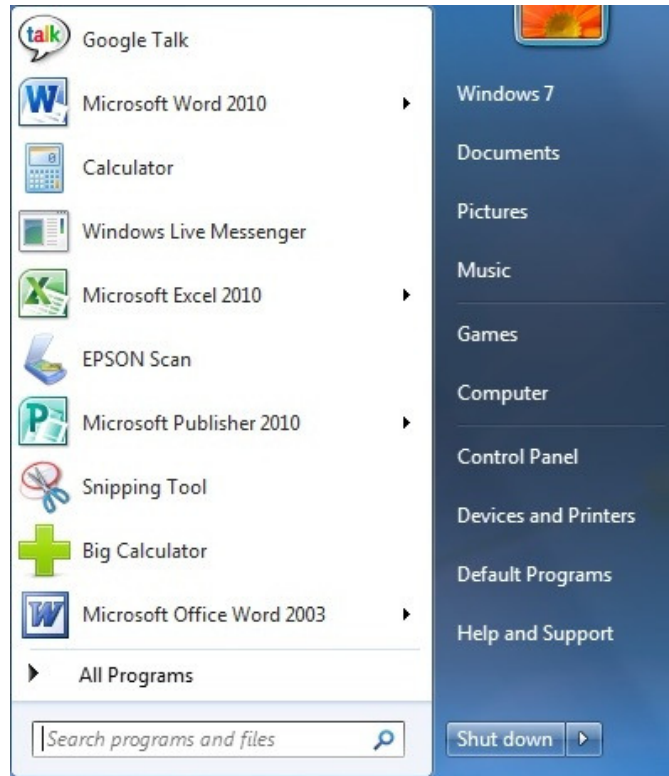
3.2.1 Upgrading Software^[B21]

If you are upgrading to QRS-Card™ Cardiology Suite 4.06 it is highly recommended that you backup your data before beginning the upgrade. If you are upgrading from any version earlier than 4.0, please contact Pulse Biomedical technical support for assistance.

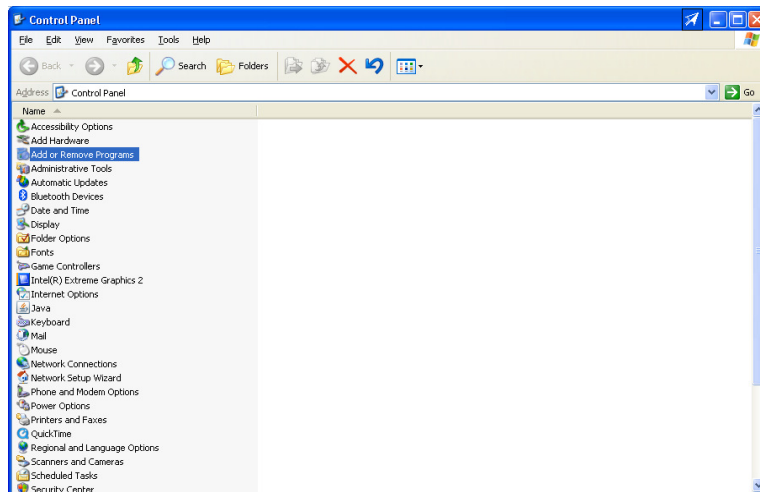
Upgrading from versions 4.0 or higher will not delete patient records or reports.^[B22]

To upgrade QRS-Card™ Cardiology Suite follow the instructions below (Note: these instructions are using Windows 7™ operating system, for help with other operating systems, contact PBI):

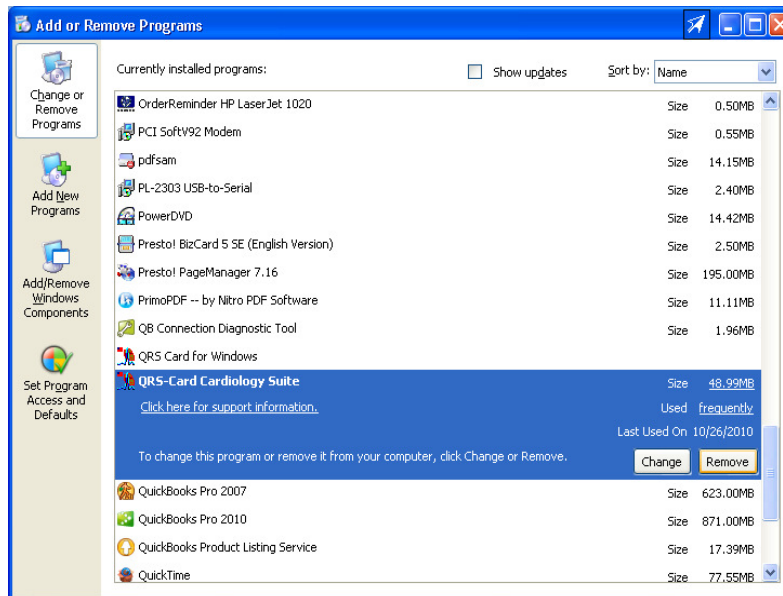
1. Uninstall the earlier QRS-Card™ Cardiology Suite.
 - Open your Start Menu and select “Control Panel”
 -



- Select “Add or Remove Programs.”



- Scroll down to “QRS Card Cardiology Suite,” highlight it, and click “Remove.” When it asks if you are sure, select “Yes.”



- Once uninstallation is complete, installing QRS-Card™ Cardiology Suite 4.06 software can start as normal

3.2.2 Installing New Software^[B23]

NOTICE If you are upgrading from a previous version of QRS-Card™ Cardiology Suite, please see “Upgrading Software” instructions above.

For installation instructions, please see installation guide sent with your QRS-Card™ System, located on the QRS-Card™ Cardiology Suite CD-ROM or at Pulse Biomedical Website (www.qrscard.com)

4. QRS-Blue™ Hardware Usage

The QRS-Card Blue hardware can be used as either a USB device or a Bluetooth wireless device.

⚠ WARNING No modification of this equipment is allowed

4.1 USB Usage

If the QRS-Blue™ is used as a USB device, the device is powered through the computer (you do not need batteries). Once your QRS-Blue™ is connected and drivers are installed properly, the status indicator light (next to the on/off button) will display a continuous orange light showing that the QRS-Blue™ is successfully powered.

4.2 Bluetooth Wireless Usage

If the QRS-Blue™ is used as a Bluetooth device, the device is powered through 2 AA 1.5V LR6 batteries. Minimum continuous operating time is 20 hours. To power on and off the device, press the power button for approximately 3 seconds. Once your QRS-Blue™ is powered on, the status indicator light (next to the on/off button) will display a flashing green light showing that the QRS-Blue™ is successfully powered. This green flashing light also indicates how much battery life is left. Please change batteries as necessary for consistent operation.

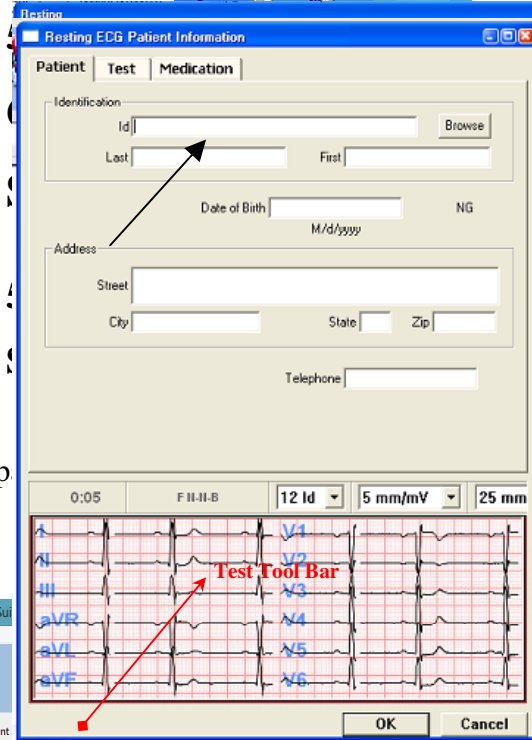
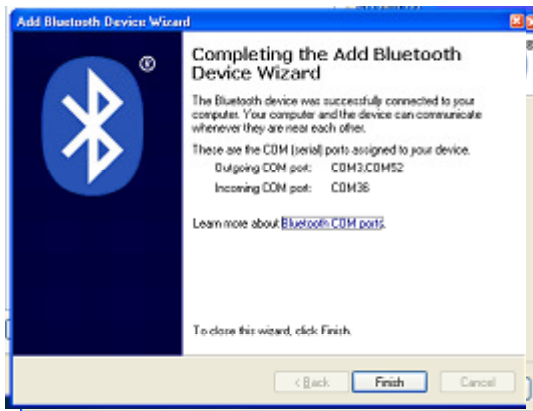
Battery Life	LED Light
Good Battery (Voltage above 2.7V)	Flashes 4 time consistently
OK Battery (Voltage above 2.5 V)	Flashes 3 times, pauses for 2 second
Low Battery (Voltage above 2.2V)	Flashes 2 times, pauses for 4 seconds
Bad Battery	Flashes 1 time, pauses for 6 seconds

To power off QRS-Blue™, press and hold the power button for a few seconds. The status indicator light will flash rapidly and then power off. If the device is left unused for 20 minutes, it will automatically power off to conserve battery.

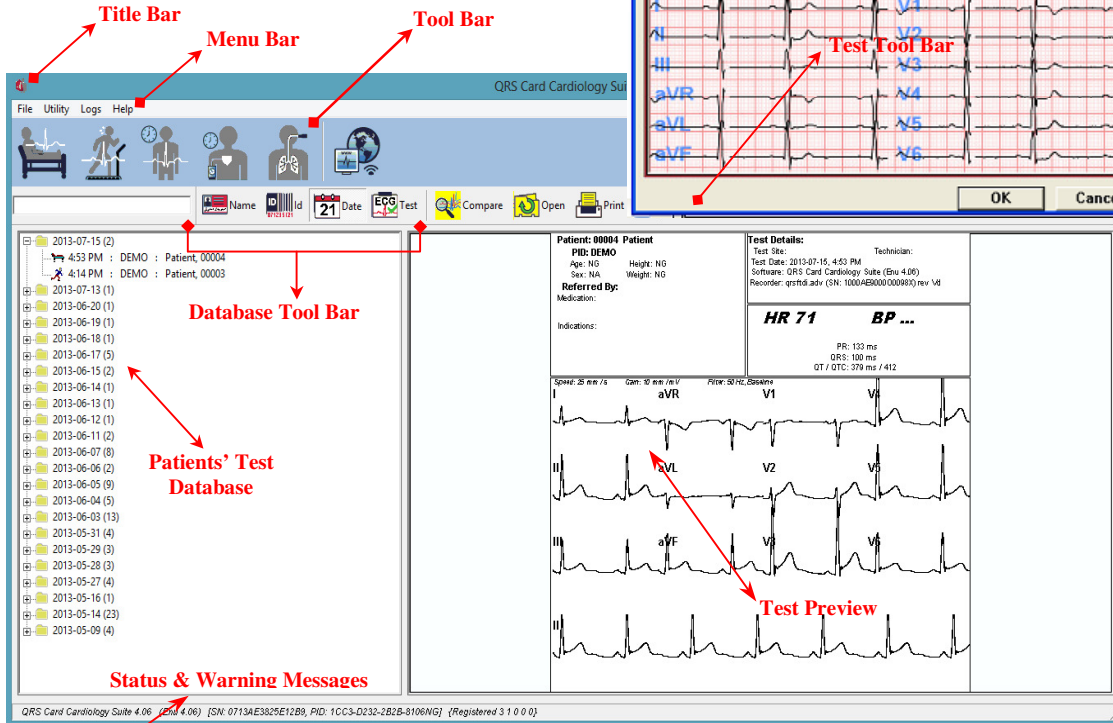
⚠ CAUTION If you plan on storing your QRS-Blue™ for an extended period of time, remove batteries. Leaving battery in QRS-Blue™ could cause the battery to leak.

4.3 Maintenance and Cleaning of QRS-Blue™

To clean the QRS-Card™ first fully disconnect from computer. Use warm soap and water and surface disinfectant only. Do not immerse the QRS-Card™ in the cleaning solution as permanent damage to the QRS-Card™ may occur. [u25]



This section will guide you around the various parts of the QRS-Card™ Cardiology Suite Software.



Title bar	The title bar displays the name of the program and contains three buttons on the far right that can be used to minimize, maximize and close the QRS-Card™ Cardiology Suite.
Menu bar	The menu bar contains additional functionality for the QRS-Card™ Cardiology Suite.

Tool bar	The tool bar contains buttons that give you easy access to the most common tasks in QRS-Card™ Cardiology Suite, such as testing modules.
Test Tool Bar	The Test Tool Bar contains buttons that allow you to work easier with saved tests. You can open, print, mail or compare ECG's and add or delete tests.
Patients' Test Database	The Patients' Test Database contains records for all of the tests performed. In this area you can find a patient, see which tests were recorded for that patient and see the kind of tests that were recorded. The test database is sorted according to the criteria selected on the Patient Database Toolbar (Name, ID, Date, Test)
Database Toolbar	You can sort the patient database by patient name, id, test date or type of test. The Quick Search Area allows you to quickly search for a test by typing a couple letters or numbers you are looking for within the selected search criteria. [KB28]
Test Preview	The Test Preview displays a brief overview of the file selected.
Status & Warning Messages	The Status message contains information about what version of QRS-Card™ Cardiology Suite you are running along with licensing information such as serial number and PID of your software license. Warning messages seeking user attention also appear here.

6. Resting ECG Module

QRS-Card™ Cardiology Suite 4.06 Resting ECG Module allows users to record, store and print ECG's quickly and easily. The best way to obtain a good quality ECG is for the administrator to be properly trained, to prep the patient correctly and to reduce artifact/noise. [B29]

Once you have the patient prepped and the electrodes securely attached you can begin a Resting ECG test.[B30]

6.1 RESTING ECG SETUP

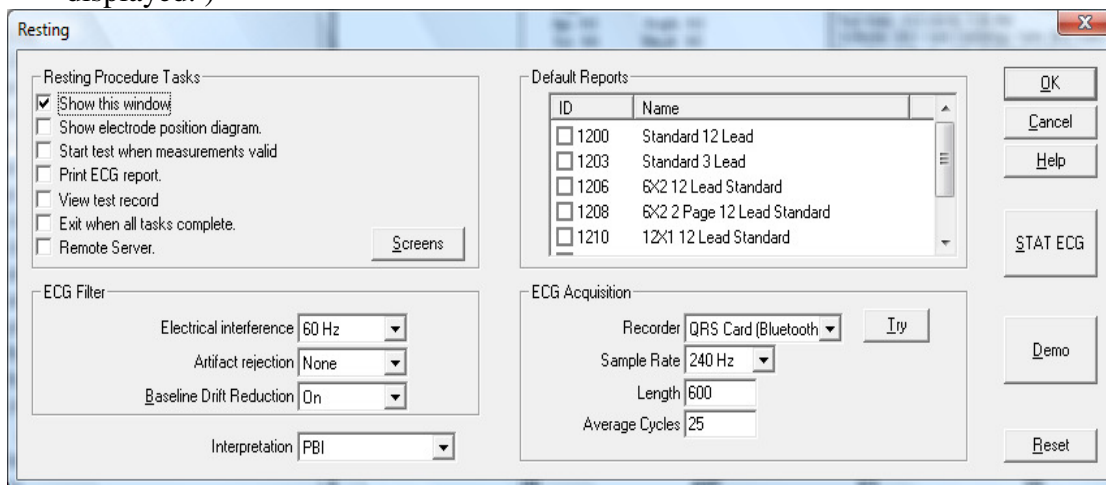
The Setup command is used to define settings for running a Resting ECG Test. It is recommended that before performing your first test, you define the setup.

Resting Setup can be accessed three ways:

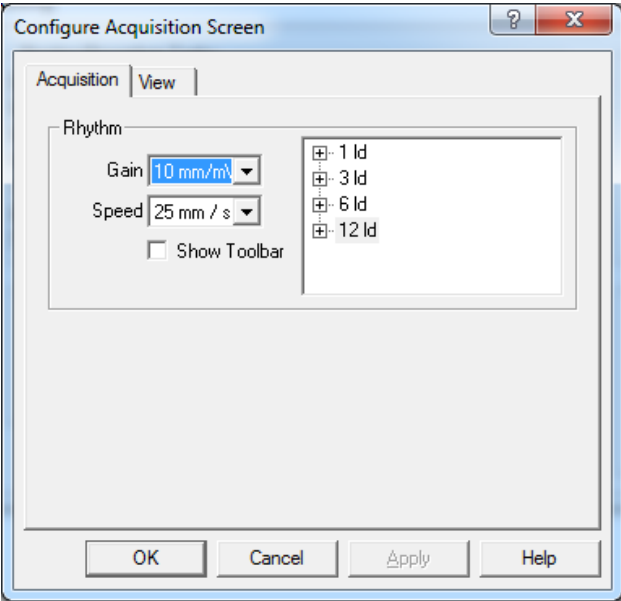
- From the Master Screen select File > Resting > Setup OR
- Simultaneously press CTRL + F2 OR



Click on the Rest ECG icon (If the "Show This Window" option in the Resting Setup has been selected, the Resting Setup screen will automatically be displayed.)




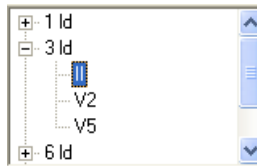
Resting Procedure Tasks	
Show This Window	If selected, the Resting setup box be displayed before the start of each Resting ECG Test. If you anticipate running STAT ECG tests, keep this box selected.
Show Electrode	If selected, the electrode positioning diagram will be displayed before performing each

Position Diagram	resting ECG test.
Start Test When Measurements Valid	If selected, the test will automatically start once it is determined that the ECG trace measurements are valid. If not selected, the ECG will begin but the test will not start unless the Save Strip icon is clicked on the Resting ECG toolbar.[B31]
Print ECG Report	<p>If selected, an ECG Test report will be printed automatically at the end of the test (based on the tests selected in the 'Default Reports' box of the setup screen) and will be saved to the computer hard drive.</p> <p>If unselected, no reports will print, but the test will be added to the test database. Printing can be done anytime after the test is acquired.</p>
View Test Record	<p>If selected, the ECG test record will be displayed automatically after the Resting ECG Test is finished.</p> <p>If unselected, after the test is finished, the software will return to the master screen.</p>
Exit When All Tasks Complete	If selected, the program will return to the Master Screen when all the tasks selected for the Resting ECG test are completed. (NOTE: If unselected, this feature can be used to save multiple Resting ECGs strips from the same test.)
Remote Server[B32]	This option allows users to define a Remote Server to remotely display the ECG test in real time. For more information, please contact Pulse Biomedical.
Screens	<p>Defines "Default" parameters for Screen display values during ECG acquisition and viewing. E.G. Gain, Speed, Lead Display etc.</p>  <p>In the "Acquisition" tab you can set the default gain and speed to be displayed when the ECG is being acquired. You can also define the leads you would like displayed by formatting the leads on the right hand side.</p>

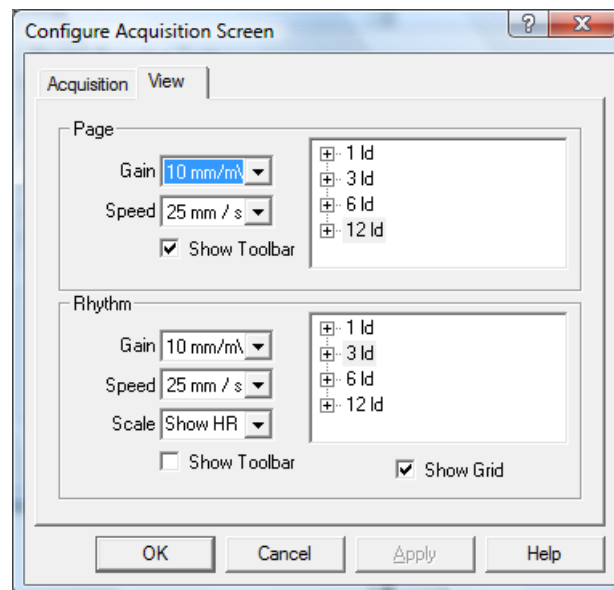
1 ld- defines the default lead displayed if you choose a one lead display
 3 ld- defines the default leads displayed if you choose a three lead display
 6 ld- defines the default leads displayed if you choose a six lead display
 12 ld- defines the default leads displayed if you choose a twelve lead display

To Define the Leads:

1. Click on the  next to the lead options.
2. This will open the leads for selection.



3. Double click on the lead to change (II, V2, V5) and a drop-down menu will open in which user can select a different lead.
4. When you are finished defining the leads, click “Apply“



In the “View“ tab you can set the default view on the Page screen and the Rhythm screen during dataview.

You can also define whether you would like the toolbar or grid displayed during ECG view during dataview.

Follow directions above to change the parameters and leads.

ECG Filter

Electrical


If selected, allows the user to apply a 50Hz or 60Hz electrical filter to the signal. The

Interference	filter can be turned off by selecting “None.”
Artifact Rejection	If selected by choosing “Standard,” artifacts such as those caused by muscle twitches or noise will be filtered.
Baseline Drift Reduction	If selected, drift of the baseline will be minimized.
Default Reports:	Selected reports can be printed (automatically or manually) as default reports to printer attached to the computer. Please see <i>Appendix 3: Sample Resting reports.</i>
Interpretation	User can select if they want Cardiology Suite software to automatically interpret measurements. Options are: 1) PBI algorithm, 2) HES algorithm, 3) LEUVEN algorithm or 4) No interpretation. NOTICE A computer generated interpretation cannot replace sound medical reasoning by a trained professional. Therefore, a physician should always review the interpretation and final analysis should always be obtained by a Physician. Proper administration, diagnosis and implementation of the test is the Physician’s responsibility.
ECG Acquisition	
Recorder	Defines the device that is being used to produce the ECG signal. To confirm device connection, click “Try”. An ECG trace should appear. Please see device hardware user manual for more instructions on device setup and troubleshooting or or call Pulse Biomedical technical support (610) 666-5510.
Sample Rate	Defines the sampling rate, per second.
Length	Defines the length of the ECG test, in seconds.
Average Cycles	Defines the number of beats averaged to make a complex ECG.
Demo	Allows user to run a demo Resting ECG test.
STAT ECG	Allows users to run a test immediately, bypassing patient demographic screen, electrode position diagram, etc. Test starts automatically.
Reset Button	Resets the setup to its default settings.

6.2 Recording a Resting ECG

A Resting ECG test can be executed using one of the following methods:

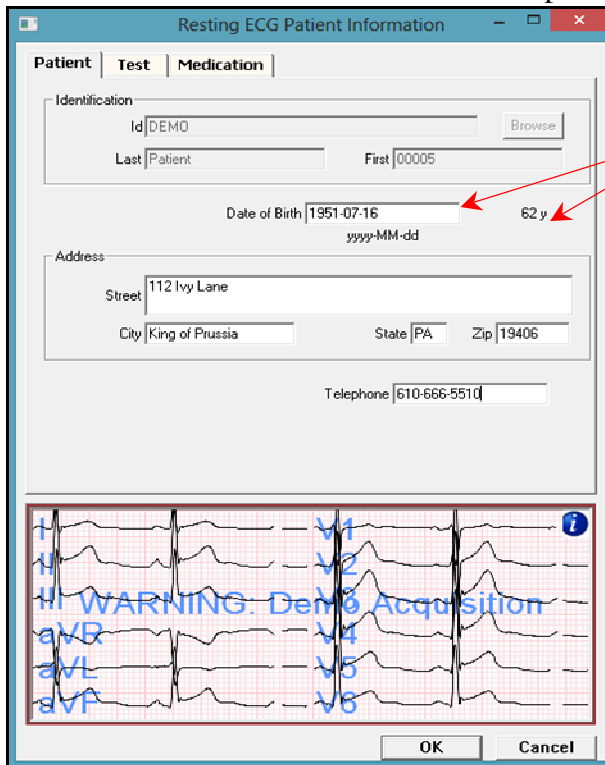
- From the master screen, select *File > Resting > Perform Test* OR

- From the toolbar, click:  OR

- Use the Hot Key F2

Depending on your settings (see section 4.1 Resting ECG Setup), you may see the electrode placement diagram or the setup screen, once you move through these screens you will see the ‘Resting ECG Patient Information’ card. The top half contains information about the patient, while the bottom displays traces from leads attached to the patient.

To use an existing patient from your database, click the ‘Browse’ button and search for the patient. To run a test on a new patient, fill out the fields on the ‘Patient’, ‘Test’ and ‘Medication’ tabs. When this form is complete, click ‘OK’.



NOTICE

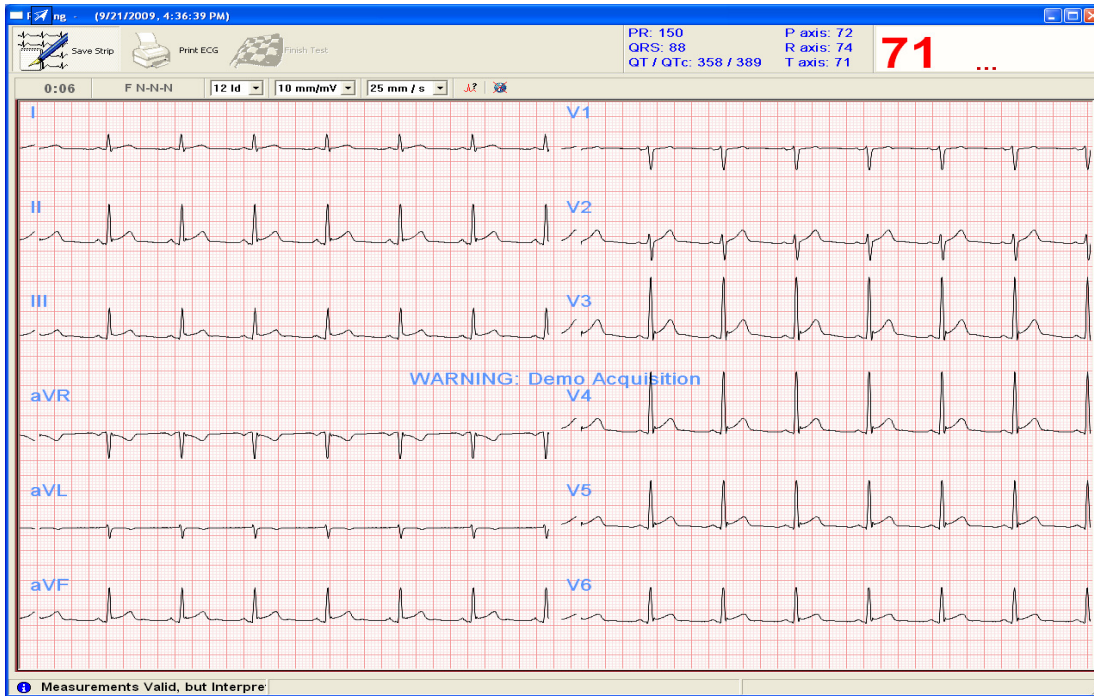
Patient Age is calculated from the computer date.

Before running any tests, confirm that the computer’s date is correct.

Date of Birth is also required for calculation of Target Heart Rate and correct automatic

The QRS-Card™ Cardiology Suite Resting ECG Acquisition Screen will be displayed and the test will begin.

Depending on your settings, the ECG test will do a number of things. If you are using default settings, the test will run for 10 seconds and automatically save the 10 second ECG strip. For more about resting test setup, see section 4.1 Resting ECG Setup.



[KB33]

Save Strip	Clicking this button will save an ECG strip for the time specified in Resting Setup (See Section 4.1). This option allows user to save multiple ECG strips from one ECG test. <i>Note: If you are using default Resting Test settings, selecting this button is not necessary as a 10 Second ECG strip is automatically saved.</i>
Print ECG	Clicking this button will print an ECG report. This option requires a HP PCL5 printer. [B34] <i>Note: If you are using default Resting Test settings, this option is not necessary because the 10 Seconds ECG trace is automatically saved and can later be printed.</i>
Finish Test	Clicking this button will finish the ECG test. <i>Note: If you are using default Resting Test settings, this option is not necessary as the test will automatically terminate after 10 seconds.</i>

After the test is finished, depending on user settings, reports will automatically print or software will return to the QRS-Card™ Cardiology Suite Master Screen with test previewed in the Workspace. Your test will be saved in the Test Database.

6.3 Reviewing a Resting ECG Test

To view (or edit) a Resting ECG test, highlight the desired test from the Cardiology Suite

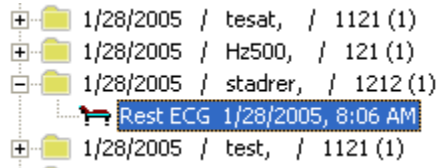


[50]

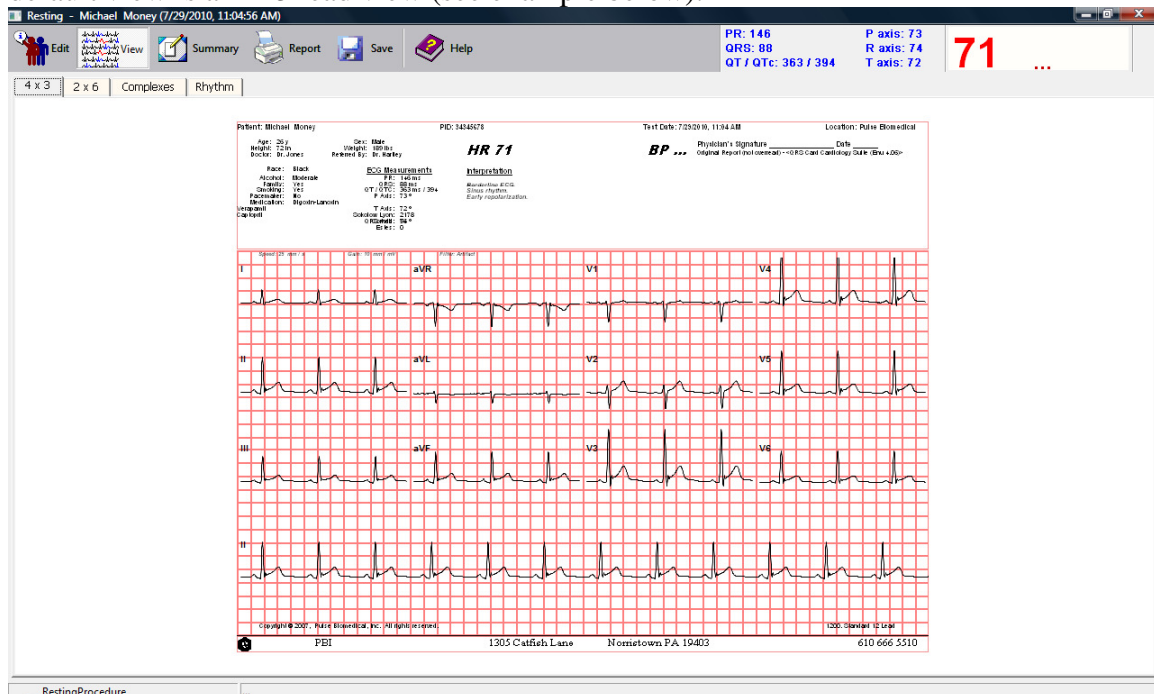
Master Screen test database and click

OR

Double click on the test to be reviewed.



The test record will be displayed in the Cardiology Suite Resting Dataview screen. The default view is a 4 x 3 lead view (see example below).

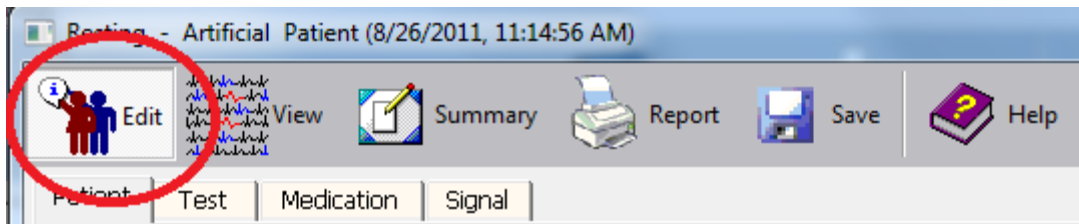


[KB35]

From this dataview screen, users can

- View/edit patient data
- View/edit test data
- Print and save reports

6.3.1 Edit Tab



Use the Edit option to view or edit information about the patient.

Patient-

In this area users can edit patient demographics.

Test-

Contains additional patient information.

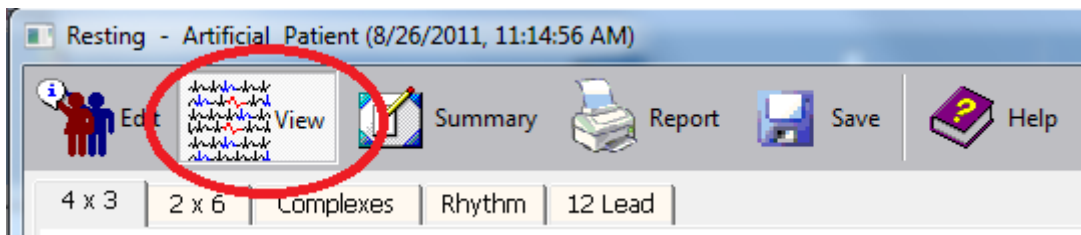
Medication-

Contains patient medication information.

Signal-

Contains information on how the ECG was obtained such as the sampling and use of filters. In this tab, you can also change Blood Pressure Information.

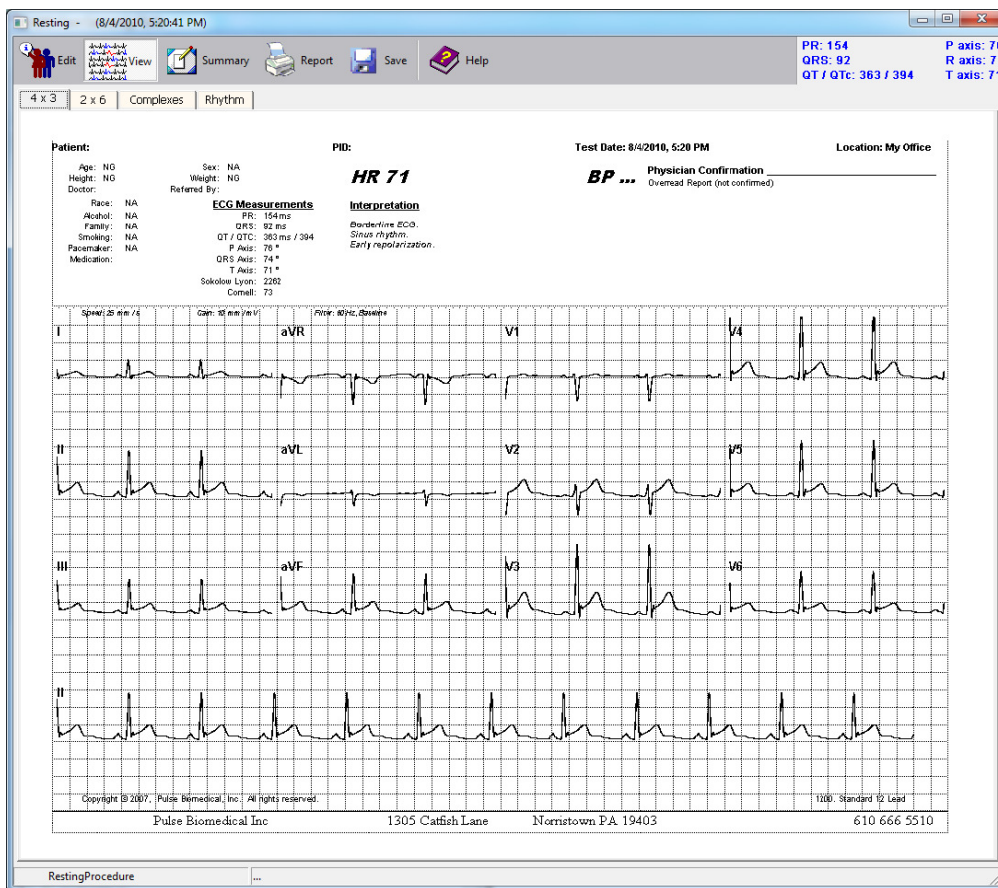
6.3.2 View



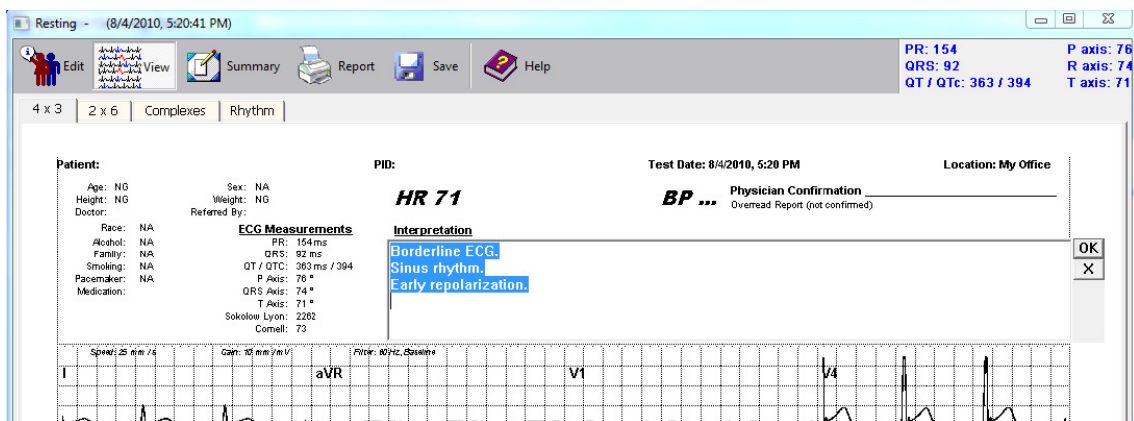
4 x 3 Screen

This view shows 12 leads organized in 4 columns, 3 rows and a rhythm strip on the bottom. Each lead (except for the rhythm strip) shows 2.5 seconds of data.

On the top of the screen you can review patient demographics, ECG measurements, Heart Rate, Interpretation, Blood Pressure, Test Date, Location and Physician Confirmation. On the top right hand side of the screen, ECG measurements are shown (PR, P axis, QRS, R axis, QT/QTc and T axis).



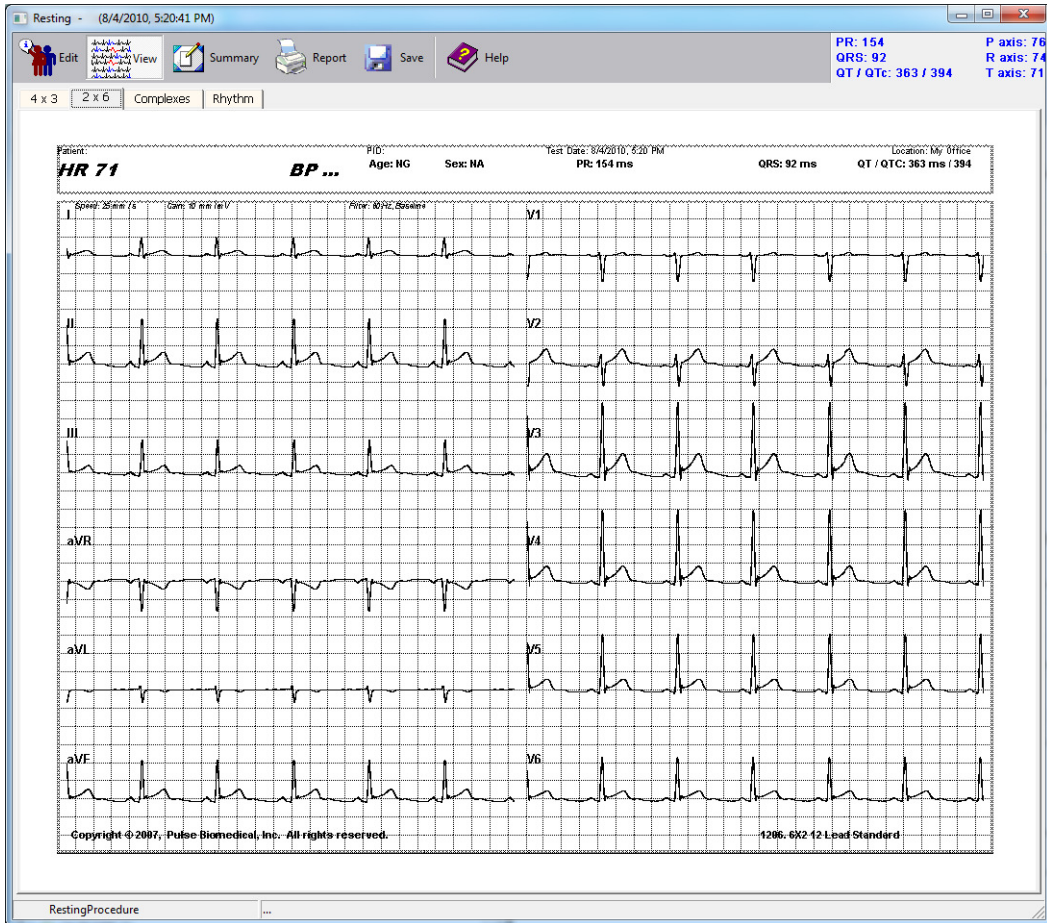
Users can edit the interpretation directly from this view by clicking inside the Interpretation box. Click **X** or **OK** to exit interpretation editing.



[KB37]

2 x 6 Screen

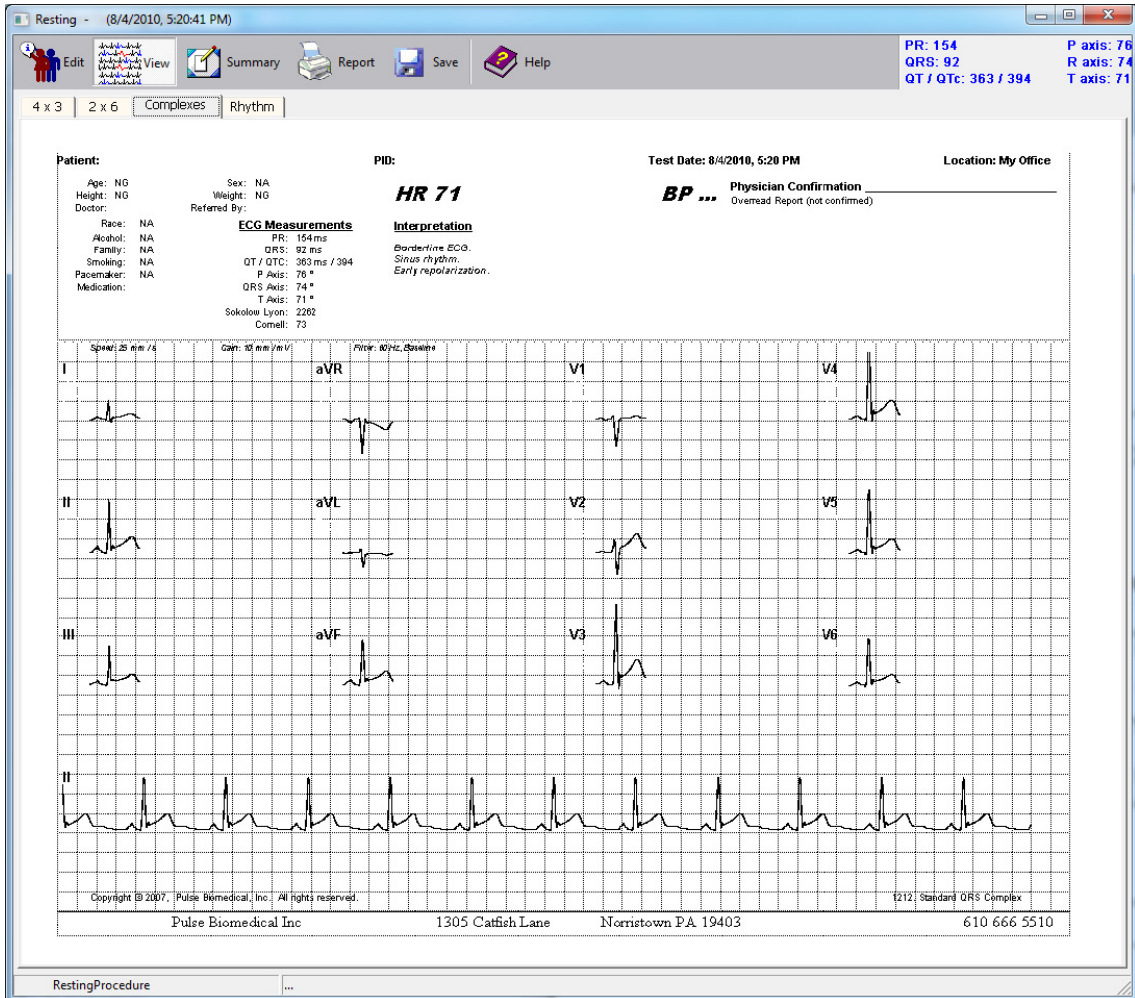
This view shows 12 leads organized in 2 columns, 6 rows.



[KB38]Co

Complex Screen

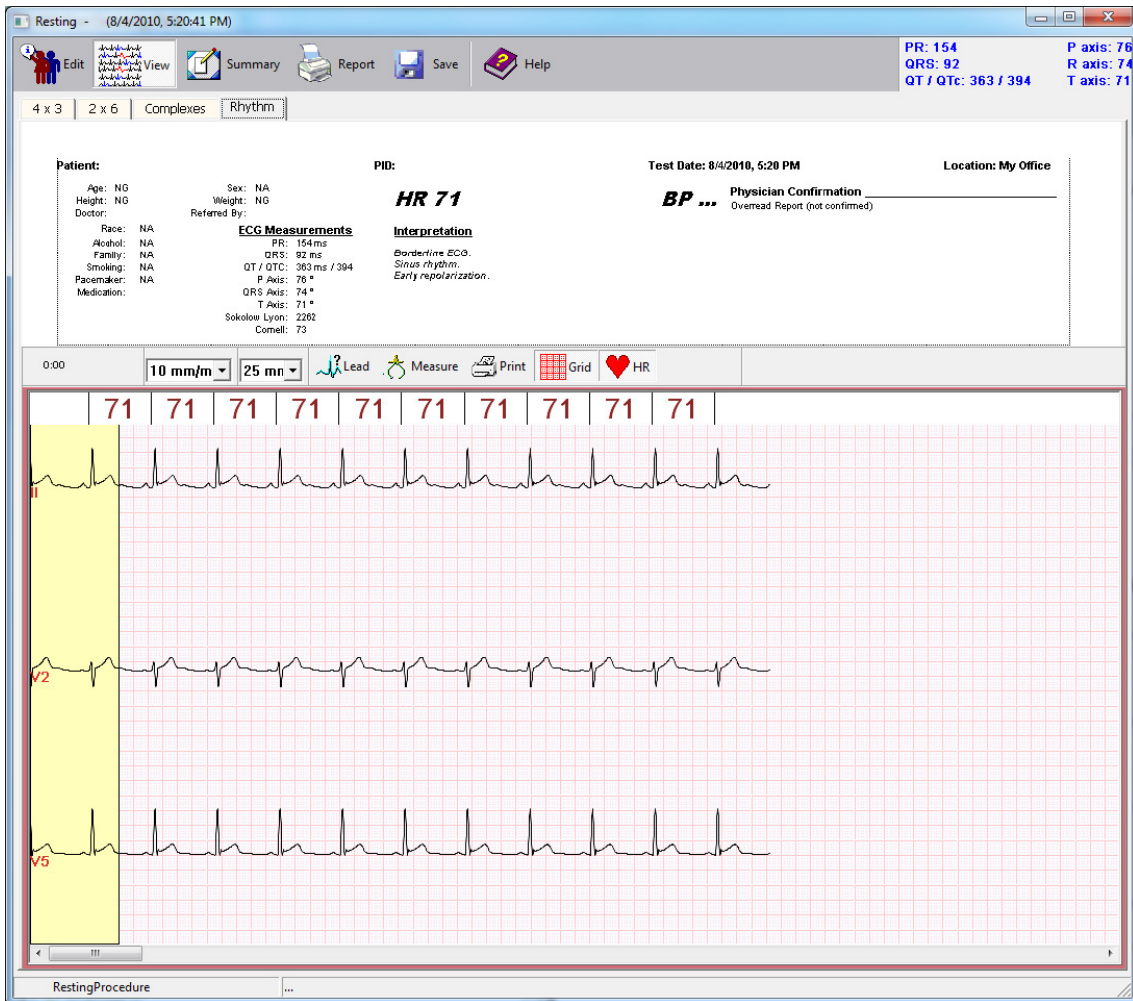
This view shows each lead and its average complexes.[B39]



[KB40]

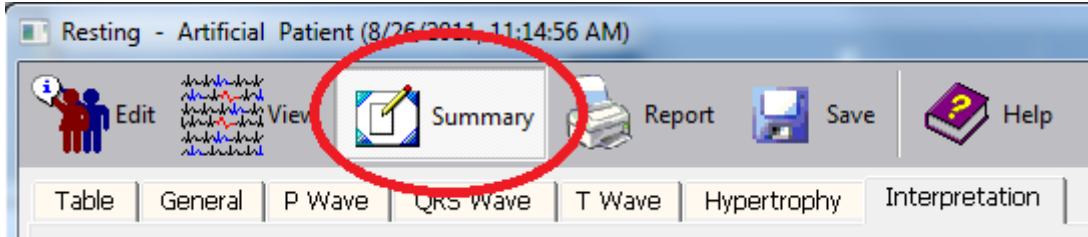
Rhythm Screen

This view shows ECG rhythm data. Users can scroll through all data saved during the test by using the navigation bar at the bottom of the screen.



[KB41]

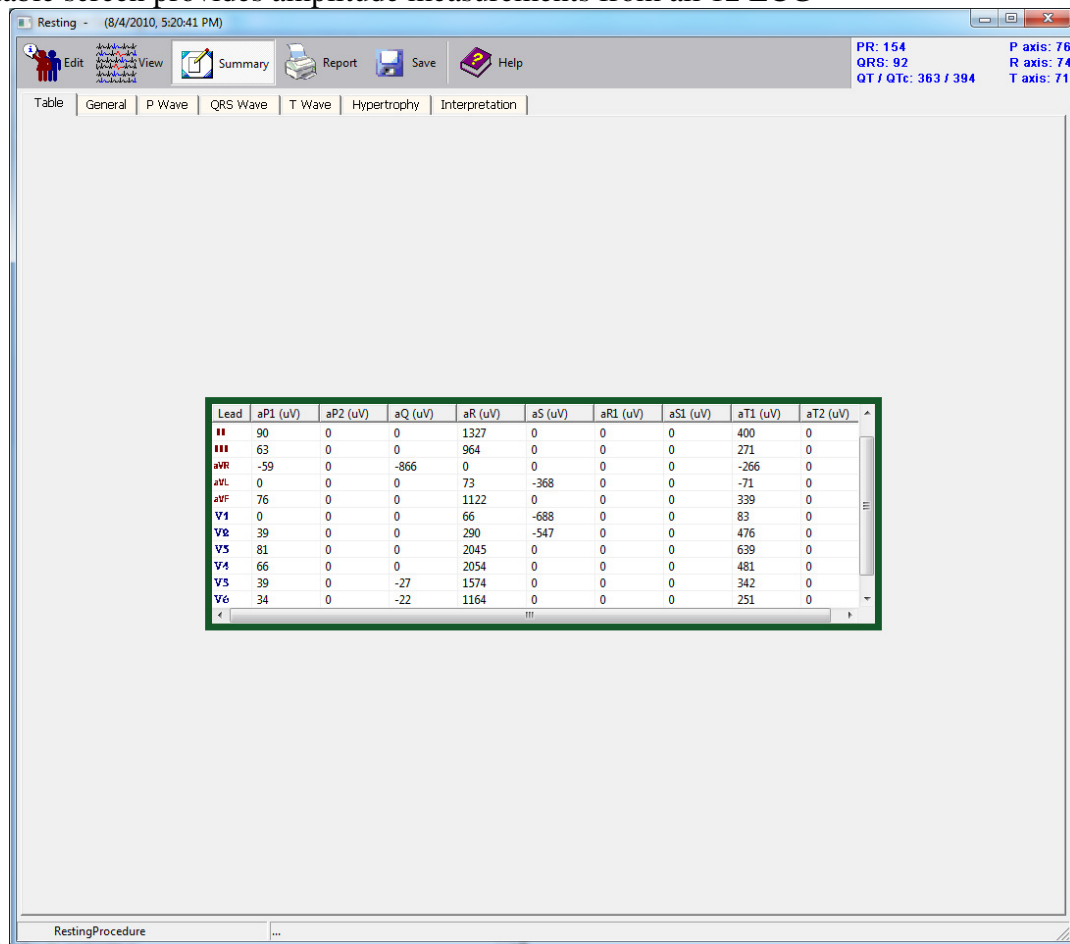
6.3.3 Summary



Pressing the Summary button provides summarized data for ECG measurements and automatic ECG Interpretation.

Table Screen

The table screen provides amplitude measurements from all 12 ECG

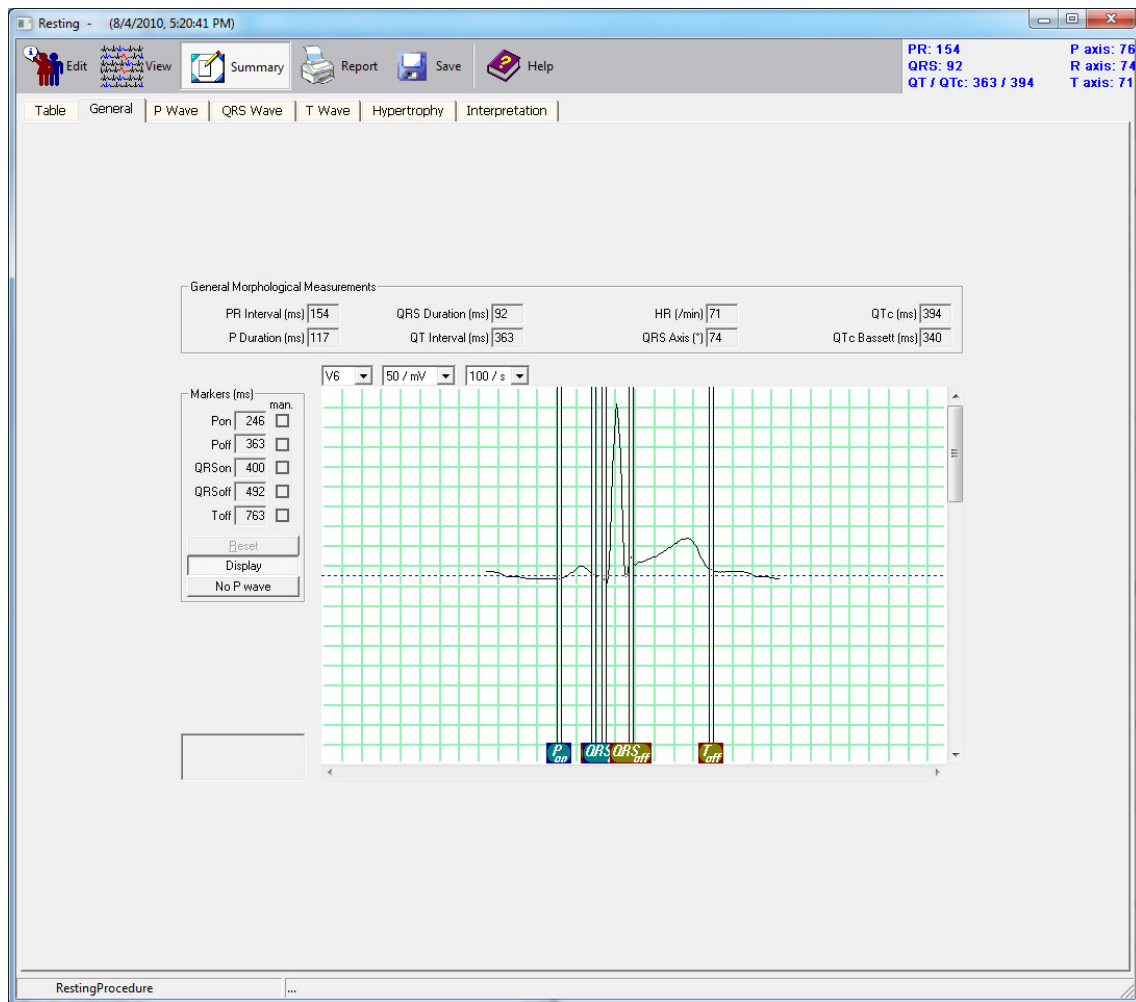


Lead	aP1 (uV)	aP2 (uV)	aQ (uV)	aR (uV)	aS (uV)	aR1 (uV)	aS1 (uV)	aT1 (uV)	aT2 (uV)
II	90	0	0	1327	0	0	0	400	0
III	63	0	0	964	0	0	0	271	0
aVR	-59	0	-866	0	0	0	0	-266	0
aVL	0	0	0	73	-368	0	0	-71	0
aVF	76	0	0	1122	0	0	0	339	0
V1	0	0	0	66	-688	0	0	83	0
V2	39	0	0	290	-547	0	0	476	0
V3	81	0	0	2045	0	0	0	639	0
V4	66	0	0	2054	0	0	0	481	0
V5	39	0	-27	1574	0	0	0	342	0
V6	34	0	-22	1164	0	0	0	251	0

leads. RestingProcedure ...

General Screen

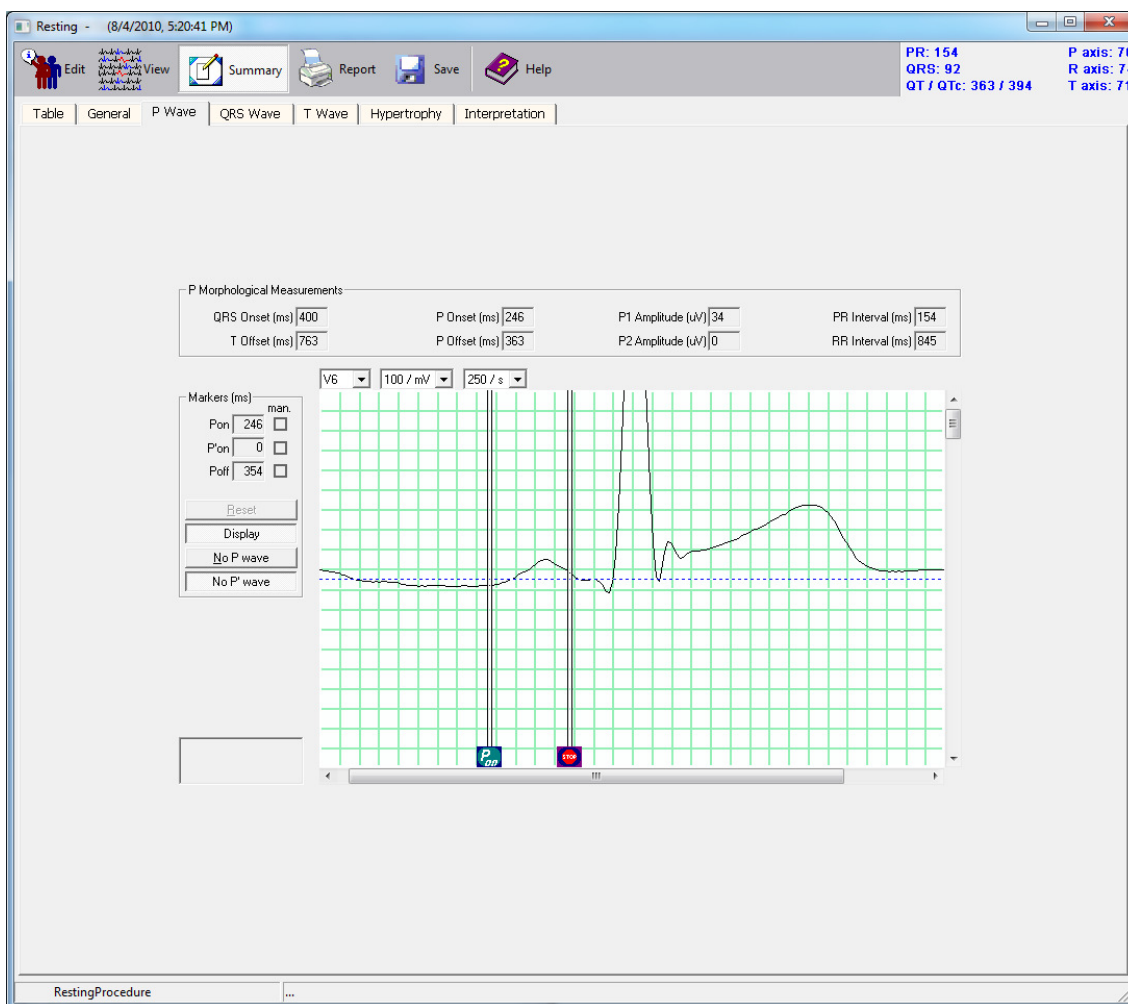
Provides ECG Complex measurements. Users can override the automatic ECG measurements by moving the measurements marker. (Drag markers using left mouse button)



[KB42]

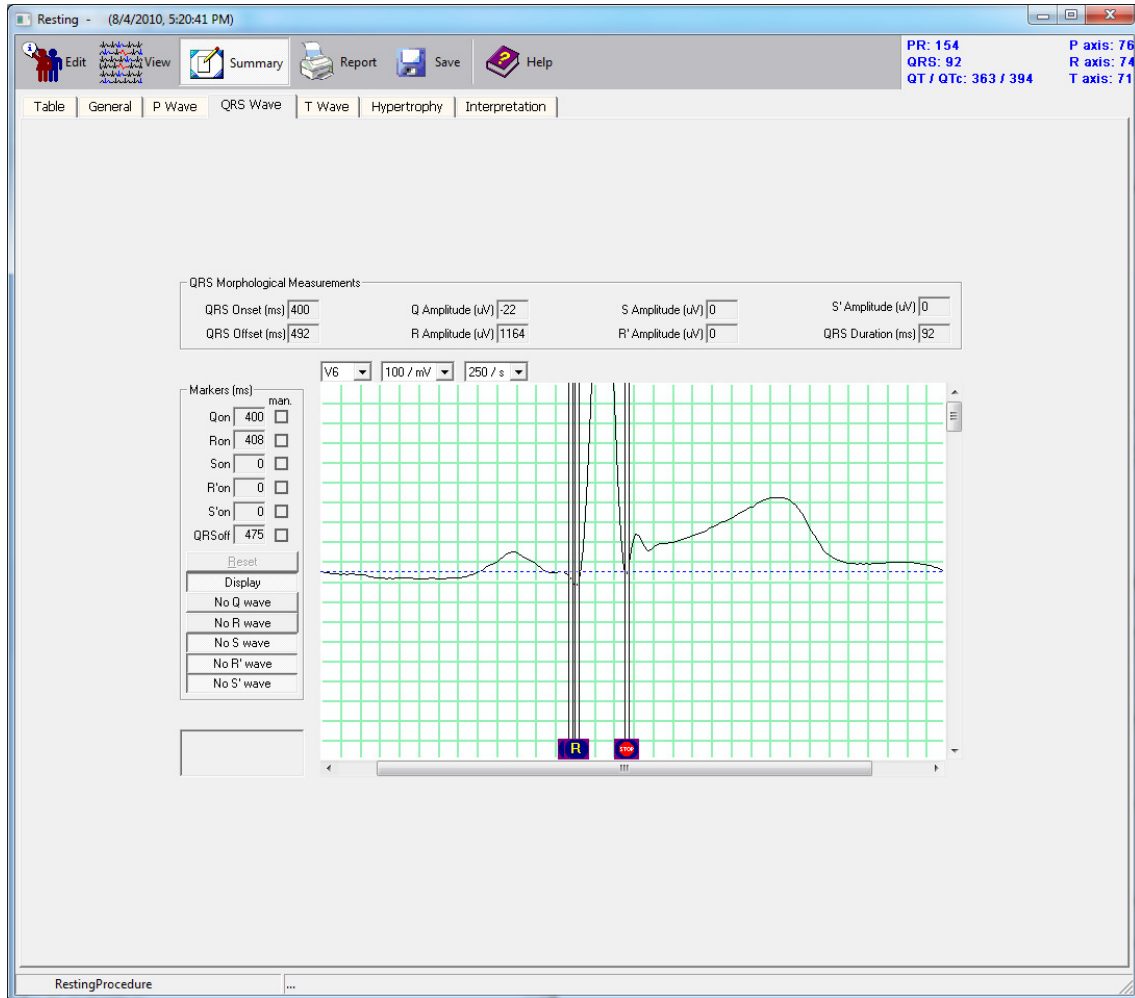
P Wave Screen

provides P wave morphological measurement markers. Users can override the automatic ECG measurements by moving the measurements marker. (Drag markers using left mouse button)



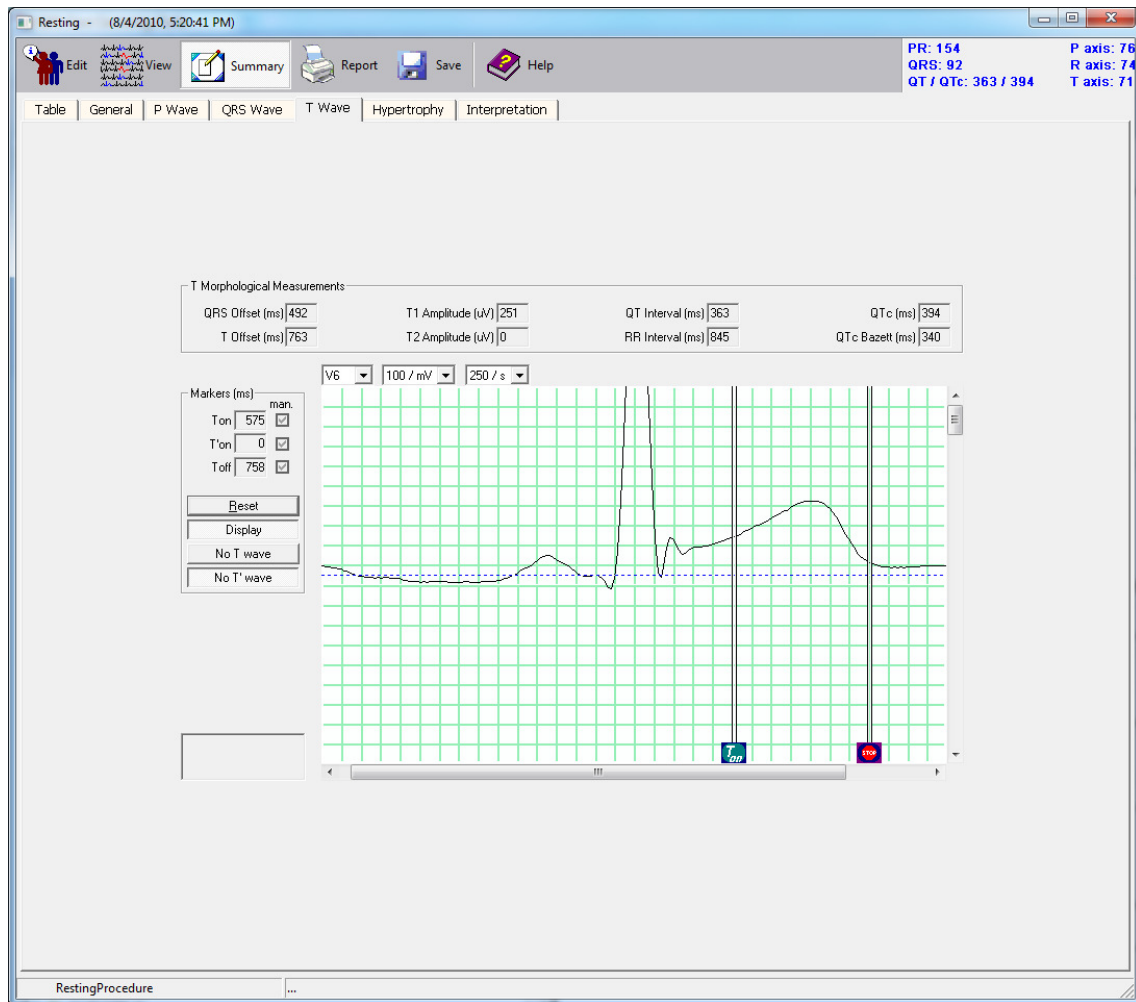
QRS Wave Screen

Provides QRS Complex measurement markers. Users can override the automatic QRS Complex measurements by moving the measurements marker. (Drag markers using left mouse button)



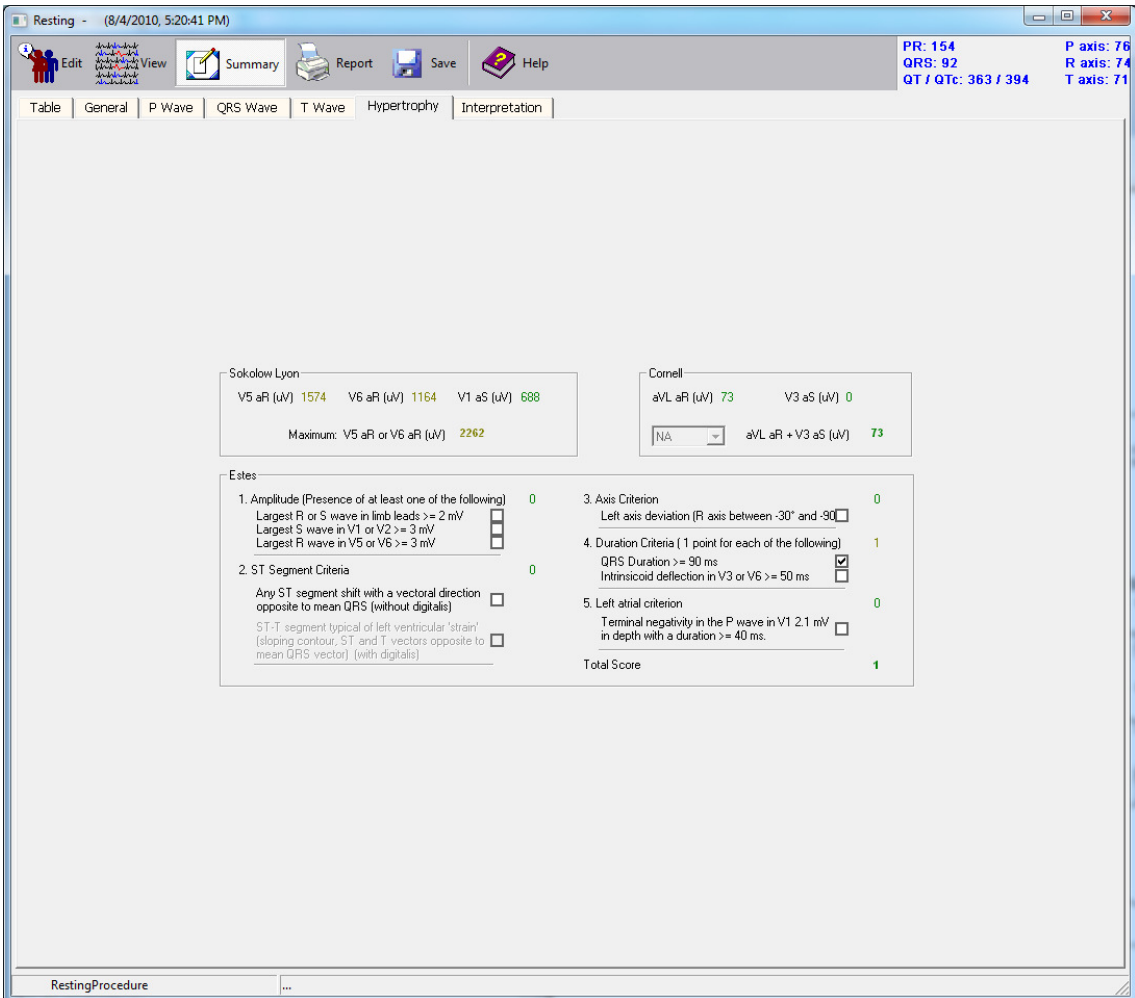
T Wave Screen

provides T wave measurement markers. Users can override the automatic T wave measurements by moving the measurements marker. (Drag markers using left mouse button)



Hypertrophy Screen

Provides Hypertrophy scores for Sokolow Lyon, Cornell and Estes.[KB43]



Resting - (8/4/2010, 5:20:41 PM)

PR: 154 P axis: 76
QRS: 92 R axis: 74
QT / QTc: 363 / 394 T axis: 71

Table | General | P Wave | QRS Wave | T Wave | **Hypertrophy** | Interpretation

Sokolow Lyon

V5 aR (uV) 1574 V6 aR (uV) 1164 V1 aS (uV) 688

Maximum: V5 aR or V6 aR (uV) 2262

Cornell

aVL aR (uV) 73 V3 aS (uV) 0

NA aVL aR + V3 aS (uV) 73

Estes

1. Amplitude (Presence of at least one of the following) 0

Largest R or S wave in limb leads ≥ 2 mV

Largest S wave in V1 or V2 ≥ 3 mV

Largest R wave in V5 or V6 ≥ 3 mV

2. ST Segment Criteria 0

Any ST segment shift with a vectoral direction opposite to mean QRS (without digitalis)

ST-T segment typical of left ventricular 'strain' (sloping contour, ST and T vectors opposite to mean QRS vector) (with digitalis)

3. Axis Criterion 0

Left axis deviation (R axis between -30° and -90°)

4. Duration Criteria (1 point for each of the following) 1

QRS Duration ≥ 90 ms

Intrinsicoid deflection in V3 or V6 ≥ 50 ms

5. Left atrial criterion 0

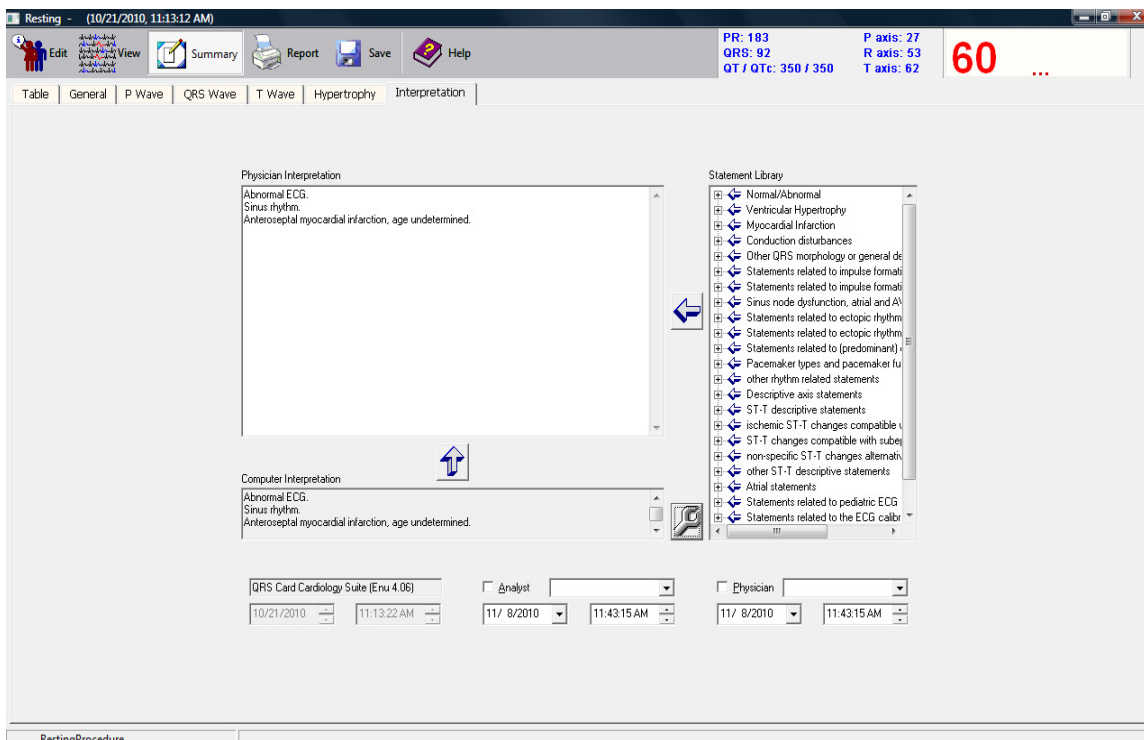
Terminal negativity in the P wave in V1 2.1 mV in depth with a duration ≥ 40 ms.

Total Score 1

RestingProcedure

Interpretation Screen

- provides computer generated Automatic ECG Interpretation. [B44] Interpretation can also be edited by typing free text or accepting statements from the Statement Library. For the Automatic Computer Interpretation to work in the Resting test, this option has to be selected in the Resting Setup.
- To add statements from the statement library, select the statement desired and click on the arrow to transfer it over to the Physician's Interpretation box.
- In a view-only box at the bottom of the screen, the date and time of the computer-generated interpretation is displayed. The name of the analyst who overread the interpretation and the physician that confirmed it, along with the date and time, can be entered in the applicable boxes.




[KB45]

NOTICE QRS-Card™ Cardiology Suite can provide automatic computer interpretations. A computer generated interpretation cannot replace sound medical reasoning by a trained professional. Therefore, a physician should always review the interpretation and final analysis should always be obtained by a Physician. Proper administration, diagnosis and implementation of the test is the Physician's responsibility.

Updating Custom Dictionary



By clicking the  icon in the Interpretation screen, user can update the custom dictionary. Follow 'Edit Instructions' at the bottom of the screen.

Update Custom Dictionary
✕

Group Normal/Abnormal

OK
 Cancel
 Help

normal ECG	X
normal QRS	X
normal P wave	X
normal ST-T	X
ECG within normal limits for ag	X
possibly normal ECG	X
borderline ECG	X
abnormal ECG	X
possibly abnormal ECG	X
abnormal QRS	X
abnormal ST-T	X
normal for age	X
normal for build	X
abnormal for age	X
abnormal for build	X
unusual for build	X
X	X
X	X

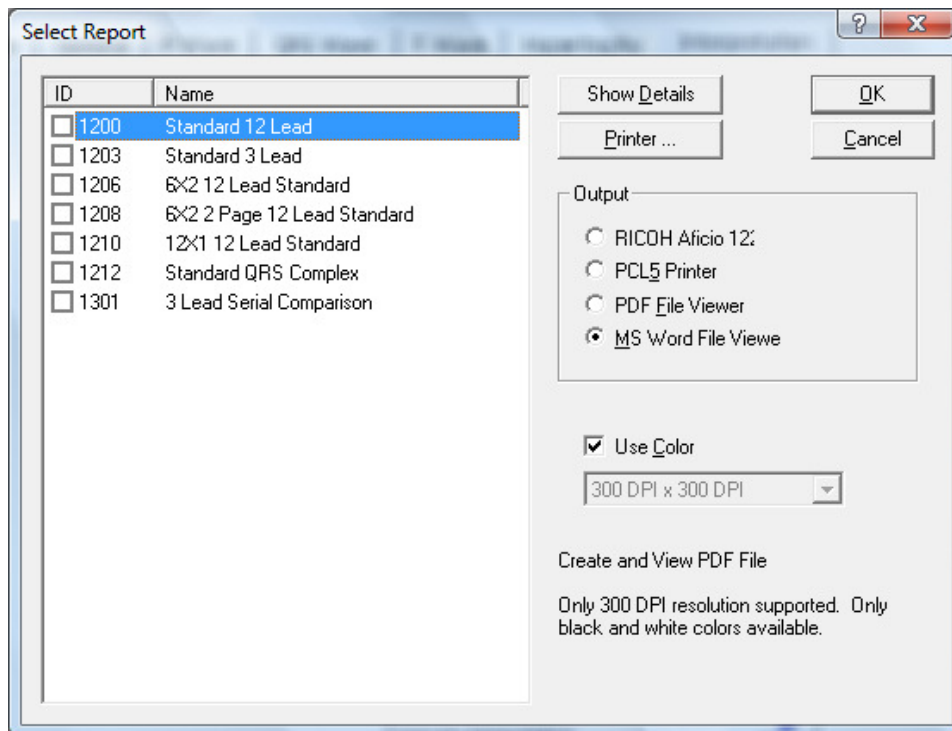
Normal/Abnormal

Edit Instructions

Left Click any button to edit text.
 Remove all characters to hide a button.
 Those buttons displayed with a red 'X' will be hidden.
 Press 'OK' to save changes.
 Press 'Cancel' to discard changes.

6.3.4 Report

Clicking the “Report” button allows users to select reports to be printed, PDF reports to be created or the report to be viewed in Microsoft Word (*See Appendix 3 for Sample Resting Reports*).



Show Details	Pressing this button will either hide or show printing details.
Printer...	Pressing this button with show printer details.
Output	Under output you can select which printer you want to print to. Your default printer will show as the first option (<i>In this example, RICOH Aficio is the default printer</i>)
PCL5 Printer [B46]	Selecting this option will print the report to the default printer
PDF File Viewer	By selecting this option, the report will be printed to a PDF file and displayed on the computer screen. The Save button from Adobe Acrobat Reader will save the report in PDF format, which can be printed or emailed by the user, if required. Note: <i>In order to print PDF File Viewer to computer screen, installation of Adobe Acrobat Reader 6.0 or higher on user computer is required (also make confirm that version of Acrobat Reader is selected under “\Utility\Configuration\Option\PDF”. To confirm, select “Detect”)</i> [B47]

MS Word File Viewer	Selecting this option will open the report in Microsoft™ Word. The save button from Microsoft work will save the report as a Word file for editing, printing, etc. <i>Note: In order to view in Microsoft Word, installation of Microsoft Word on user computer is required.</i>
Use Color	Selecting this button will allow user to print ECG reports in color depending on printer options.

7. Stress ECG Module


QRS-Card™ Cardiology Suite 4.06 software allows user to record, store and print Stress ECG's quickly and easily. The best way to get a good quality ECG is for the administrator to be properly trained, to prep the patient correctly and to reduce artifact/noise. [B48]

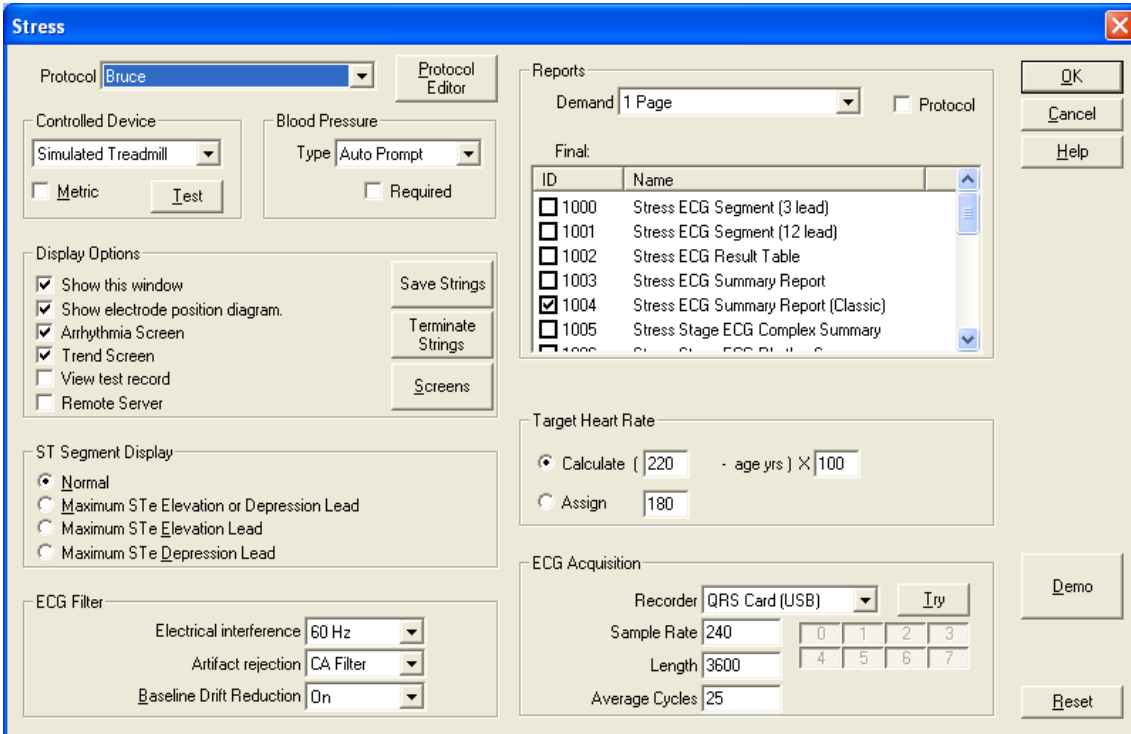
Once you have the patient prepped and the electrodes securely attached you can begin a Stress ECG test.[B49]

7.1 Stress ECG Setup

The Stress ECG Setup screen is used to define settings for running a Stress ECG Test. It is recommended that before performing your first test, you define the setup.

Stress ECG Setup can be accessed three ways:

- From the Master Screen select File > Stress > Setup OR
- Simultaneously press CTRL + F3 OR
- Click on the Stress ECG icon  "Show This Window" option in the Stress Setup has been selected, the Stress Setup screen will automatically be displayed.)



[KB50]

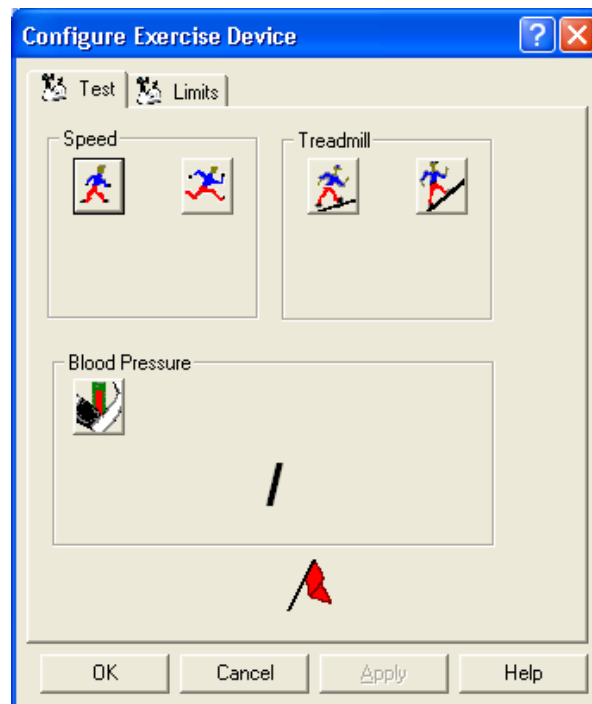
Protocol	Defines the Stress Test Protocol to be used during the Stress ECG Test. [B51]
Protocol Editor	Users can edit and customize protocols using the protocol editor. (See Appendix 7:Stress Protocols)
Controlled Device	Defines the stress test exercise device (either treadmill or ergometer). You can confirm device hookup by click the “Try” button.[B52]

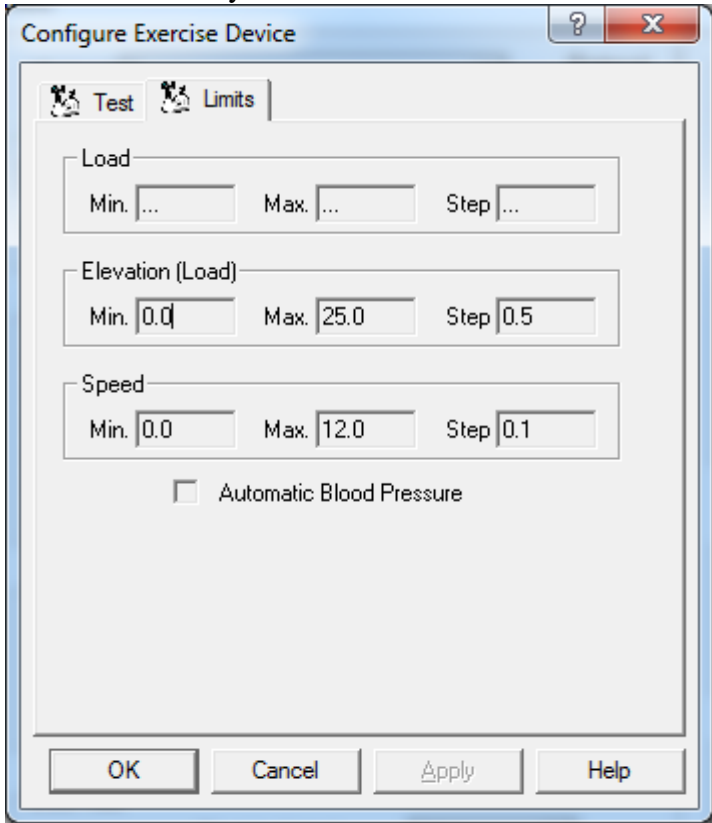
Try

Tests the functionality and the connection between the computer and the Exercise device. To test a device, Select the Device in the Controlled Device menu. Click “Test“. The “Configure Exercise Device“ screen appears.

Test Tab:

To test a device, click on the icons under Speed to increase and decrease the speed of the device. Click on the icons under Treadmill to increase and decrease the elevation of the device. The Blood Pressure can also be tested to verify the automatic blood pressure device interfaces with the software is functioning properly.



	<p>Limits Tab</p> <p>Lists the limits of treadmill or ergometer driver.</p> <p>Automatic Blood Pressure – defines if Blood Pressure measurements will be taken automatically by a BP machine interfaced to the QRS-Card™ Cardiology Suite Software or whether the program will prompt the user to enter the BP manually.</p> <p>If ‘Automatic Blood Pressure’ is selected, the user will NOT be prompted for blood pressure input unless the blood pressure tool button is manually executed. [B53]</p> 
<p>Display Options</p>	
<p>Show This Window</p>	<p>If selected, the Stress setup box will be displayed before the start of each Stress ECG test.</p> <p>If it is not selected, the Stress setup box will not appear at the start of each Stress ECG test.</p>
<p>Show Electrode</p>	<p>If selected, the electrode positioning diagram will be displayed</p>

Position Diagram	before the start of each Stress ECG test.[B54]
Arrhythmia Screen	If selected, the Arrhythmia screen will be displayed during the Stress ECG test.[B55]
Trend Screen	If selected, the Trend screen will be displayed during the Stress ECG test.[B56]
View Test Record	If selected, the ECG record will be displayed immediately after the data is collected and the stress test is finished. If unselected, the software will return to the master screen after the data is collected and the stress test is finished.
Remote Server[B57]	This option allows users to define a Remote Server to remotely display the ECG test in real time. For more information, please contact Pulse Biomedical.
ST Segment Display	Selects the display lead for the ST Trend Window.
Normal	Provides the display of ST for the user selected lead.
Maximum ST Elevation or Depression Lead	Automatically displays the ST values for the lead that has either the maximum elevation or the maximum depression.
Maximum ST Elevation Lead	Displays the ST values for the lead that has the maximum ST elevation.
Maximum ST Depression Lead	Displays the ST value for the lead that has the maximum ST depression.
Save Strings	Allows the user to mark and annotate abnormalities during a Stress ECG Test.[B58]
Terminate Strings	Ends the Stress ECG Test so the user can review any annotations that have been made.[B59]
Screens	Defines “Default” parameters for Screen display (e.g. Gain, Speed, Lead Display, etc.) for Acquisition and Dataview Screens. [B60]
ECG Filter	
Electrical Interference	This allows the user to apply a 50Hz or 60Hz filter to the signal. The filter can also be turned off by selecting ‘None’.[B61]
Artifact Rejection	If selected artifacts, such as those caused by muscle twitches, will be filtered.
Baseline Drift	If selected, drift of the baseline will be minimized.

Reduction	
Reports	
Demand	If desired, a printout of the ECG trace can be obtained while the test is running. Chose the number of pages to be printed (1 to 6 pages or a continuous printout). Start the Stress test. Click on the Print ECG icon and the printout will start from that point. If Continuous is chosen, the printout will continue until the Print ECG icon is clicked again.
Final	Specifies the type(s) of final reports to be printed automatically after the Stress test is completed.
Target Heart Rate	Defines whether the Target Heart Rate is to be calculated from the patient's age or be manually assigned. NOTICE Patient age is calculated from computer date. Before running any tests, confirm that the computer date is correct.
ECG Acquisition	
Recorder	Defines the device that is being used to produce the ECG signal. To confirm device connection, click "Try". An ECG trace should appear. Please see device user manual for more instructions on device setup and troubleshooting or or call Pulse Biomedical technical support (610) 666-5510.
Sample Rate	Defines the sampling rate, per second.
Length	Defines the maximum length of the ECG trace, in seconds, that is saved.
Average Cycles	Defines the number of beats averaged to make a complex ECG.
Demo	Allows user to run a demo Stress ECG test.
Reset	Resets setting to default.

7.2 Recording a Stress ECG

7.2.1 Phases and Stages

In general QRS-Card™ Stress ECG Test has three phases:

Pre-Test Phase
Exercise Phase
Recovery Phase

NOTICE User Intervention is required in moving during Stages while in Pre-Test phase. Exercise and Recovery stages are timed according to the selected protocol (e.g. Each Exercise Stage in Bruce protocol is 3 minutes each).

Each Phase can have multiple stages:

Pre-Test Phase (*User intervention is needed to complete/forward Pre-Test Stages*)

 Supine
 Hyperventilation
 Warm-up

Exercise Phase
 Stage E1
 Stage E2
 Stage Ex

Recovery Phase
 Stage R1
 Stage Rx

*See Appendix 7 for more information on Stress Protocols

7.2.2 Starting a Stress ECG Test

A Stress ECG Test can be executed using one of the following methods:

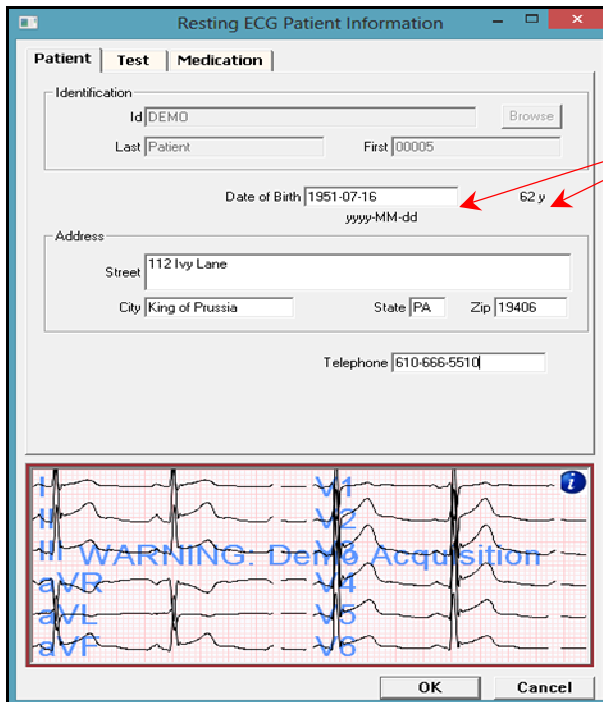
- From the master screen, select *File > Stress > Perform Test* OR

- From the toolbar, click:  OR

- Use the Hot Key **F3**

Depending on your setup (see section 5.1 Stress ECG Setup), you may see the electrode placement diagram or the Stress ECG setup screen, once you move through these screens you will see the ‘Stress ECG Patient Information’ card. The top half contains information about the patient, while the bottom displays traces from leads attached to the patient.

NOTICE





Patient Age is calculated from the computer date.

Before running any tests, confirm that the computer's date is correct.

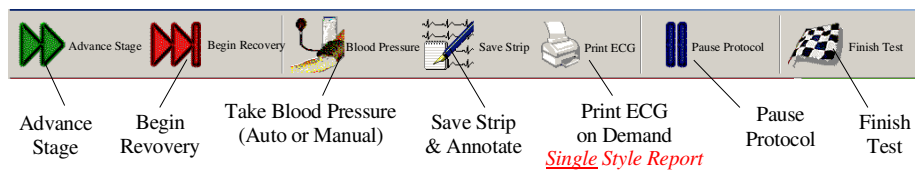
Date of Birth is also required for calculation of Target Heart Rate





To use an existing patient from your database, click the ‘Browse’ button and search for the patient. To add a new patient, fill out the fields on the ‘Patient’, ‘Test’ and ‘Medication’ tabs. When this form is complete, click ok.

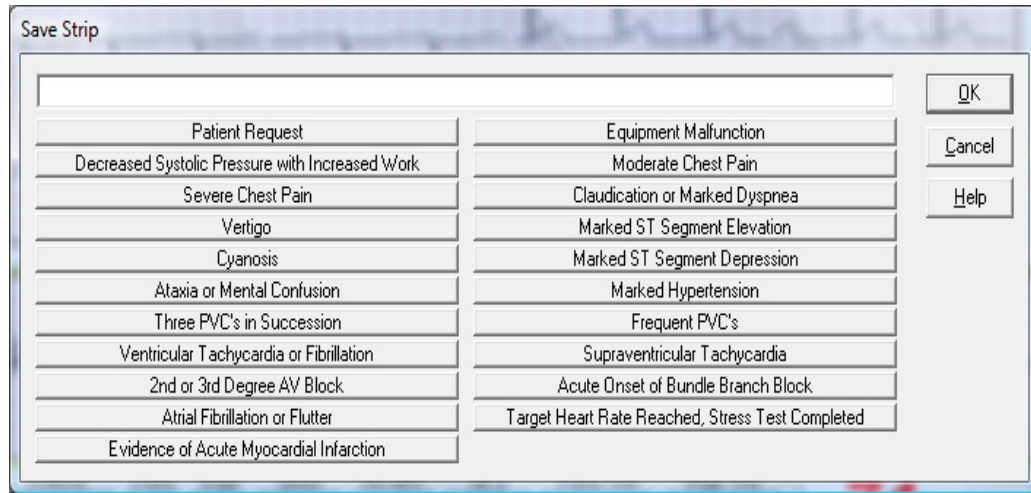
The Stress ECG Acquisition screen will appear and an ECG test will start.


Clicking on the blue  in the upper right hand corner of the window will display the toolbar. Clicking on the crossed out  will hide the toolbar. [B62]

7.2.3 Tasks Performed During a Stress Test:




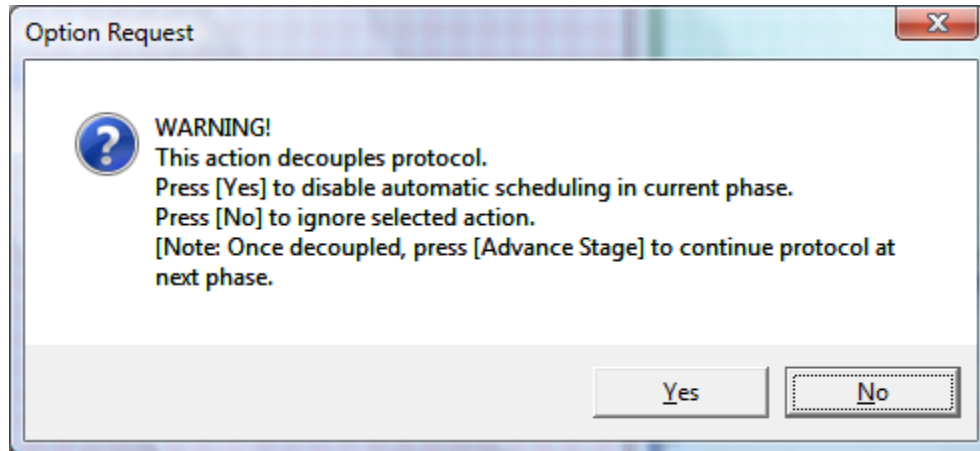
- Use the Advance Stage  command to advance the Stress Test to the next Stage. [B63][KB64]
- To begin Recovery, press the  button.
- To enter a blood pressure measurement, press the  button. Blood pressure prompts will also appear automatically according to settings in the protocol.
 - Reference HR
 - Current HR
 - Pre-Change of Target HR
 - Current BP
- To annotate or mark a Strip to print during final reports, press the  button. The 'Save Strip' window will appear, allowing the user to select an annotation to add to the strip. [B65]



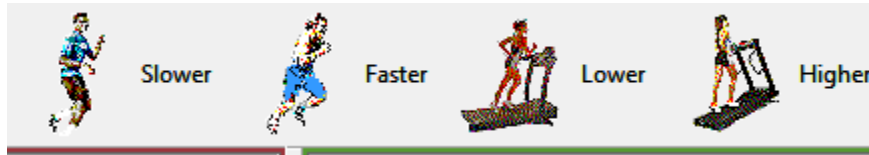
- To print a real-time ECG strip, press the  button on the Stress Status Bar.

Note: Number of pages (or continuous print) to print under “Stress/Setup” HP PCL5 Printer is REQUIRED to perform real-time print [B66]


- To pause (and manually control) the exercise stage and the protocol, press the  button. Once you press the “Pause Protocol” button, a warning box will appear. Click ‘Yes’ to disable the protocol and control the exercise driver (treadmill or ergometer) manually, Click ‘No’ to ignore and go back to stress ECG test.



Four additional buttons will appear on the Stress Status bar.



These additional buttons are then used to manually control the Exercise Device (Treadmill or Ergometer).

- To finish or stop the test, press the  button. This button is usually pressed while in recovery phase, however the test can be stopped anytime during a test. Once the Finish button has been pressed, the ‘Terminate Stress Test’ window will appear. [KB67] User can select from predefined options or free type reason for stopping the test.

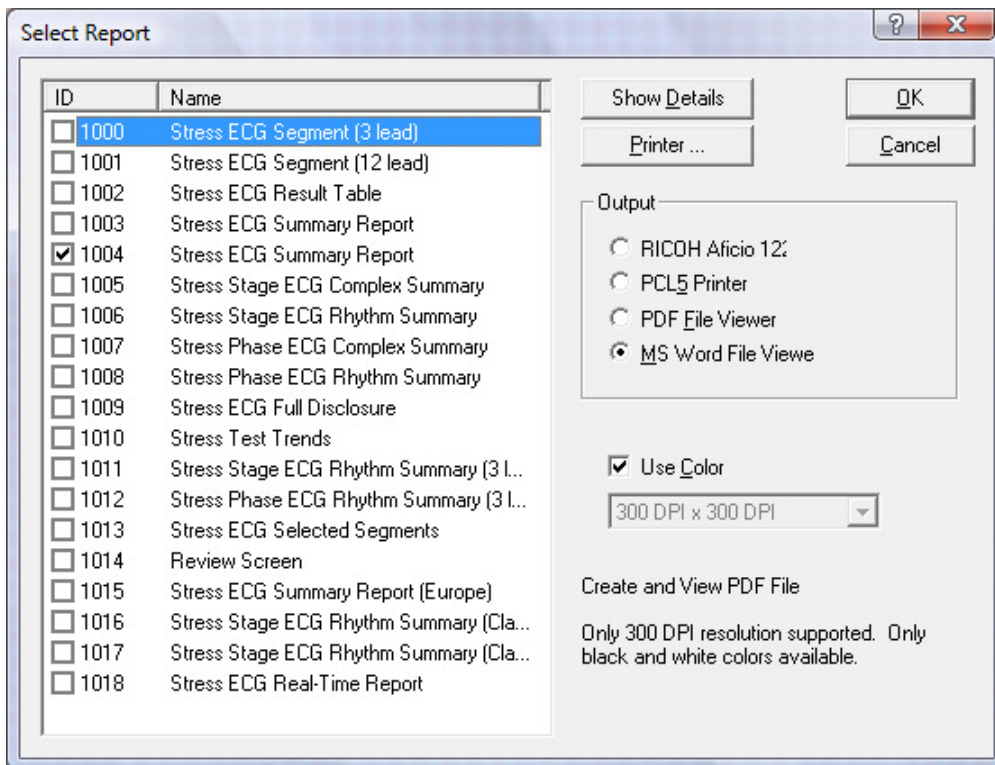
NOTICE: *In order to stop a test in an emergency situation use TREADMILL EMERGENCY STOP BUTTON*

Terminate Stress Test

		OK
Patient Request	Equipment Malfunction	Cancel
Decreased Systolic Pressure with Increased Work	Moderate Chest Pain	Help
Severe Chest Pain	Claudication or Marked Dyspnea	
Vertigo	Marked ST Segment Elevation	
Cyanosis	Marked ST Segment Depression	
Ataxia or Mental Confusion	Marked Hypertension	
Three PVC's in Succession	Frequent PVC's	
Ventricular Tachycardia or Fibrillation	Supraventricular Tachycardia	
2nd or 3rd Degree AV Block	Acute Onset of Bundle Branch Block	
Atrial Fibrillation or Flutter	Target Heart Rate Reached, Stress Test Completed	
Evidence of Acute Myocardial Infarction		

REPORTS:

Once the stress test has been finished, the ‘Select Reports’ screen will appear which allows user to print, create a PDF or view reports in Microsoft Word.



A list of reports will be on the left side. (For sample stress reports, see Appendix 4: Stress Sample Reports.)

Show Details	Pressing this button will either hide or show printing details.
Printer...	Pressing this button with show printer details.
Output	Under output you can select which printer you want to print to. Your default printer will show as the first option (<i>In this example, RICOH Aficio is the default printer</i>)
PCL5[B68] Printer	Selecting this option with send the selected report to the default printer
PDF File Viewer	By selecting this option, the report will be printed to a PDF file and displayed on the computer screen. The Save button from Adobe Acrobat Reader will save the report in PDF format, which can be printed or emailed by the user, if required. <i>Note: In order to print PDF File Viewer to computer screen, installation of Adobe Acrobat Reader 6.0 or higher on user computer is required (also make confirm that version of Acrobat Reader is selected under “\Utility\Configuration\Option\PDF”. To confirm, select “Detect”)[B69]</i>
MS Word File	Selecting this option will open the report in Microsoft™ Word. The save button

Viewer	from Microsoft work will save the report as a Word file for editing, printing, etc. <i>Note: In order to view in Microsoft Word, installation of Microsoft Word on user computer is required.</i>
Use Color	Selecting this button will allow user to print ECG reports in color depending on printer options.

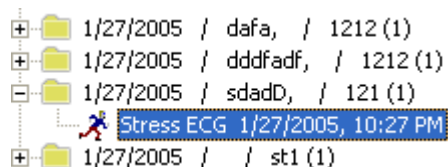
7.3 Reviewing a Stress Test

To view or edit a stress test, go to the Master Screen and select the desired Stress ECG

Test and click the button  on the toolbar

OR

Double click on the test to be viewed.



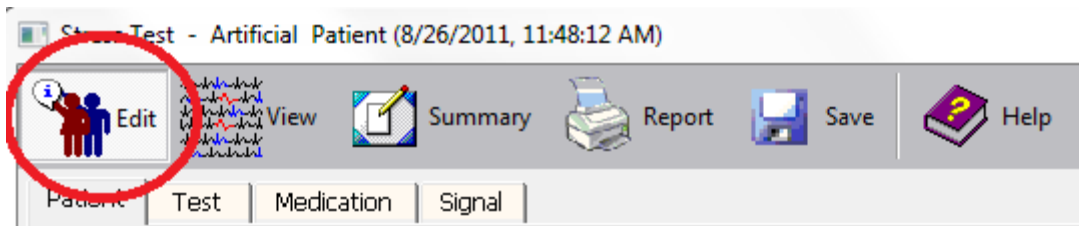
Stress ECG Dataview Screen

The test record will be displayed in the QRS-Card™ Cardiology Suite Stress Dataview screen.

This screen allows the user to:

- View/edit patient data
- View test data
- Print reports

7.3.1 Edit



Select 'Edit' to view or edit information about the patient.

Patient Screen

- In this area users can edit patient demographics

Test Screen

- Contains additional patient information.

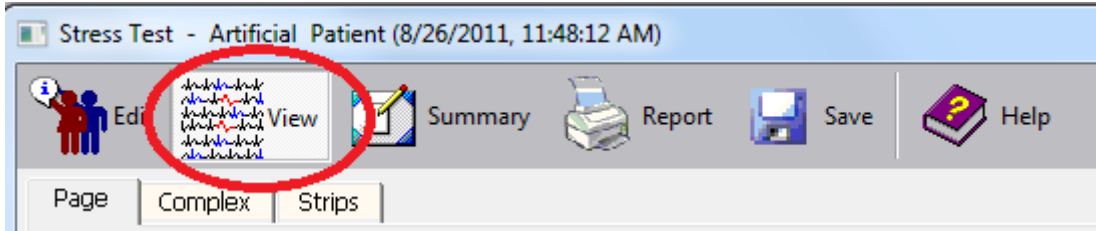
Medication Screen

- Contains patient medication information.

Signal Screen

- Contains information on how the ECG was obtained such as the sampling and use of filters. In this tab, you can also change Blood Pressure Information.

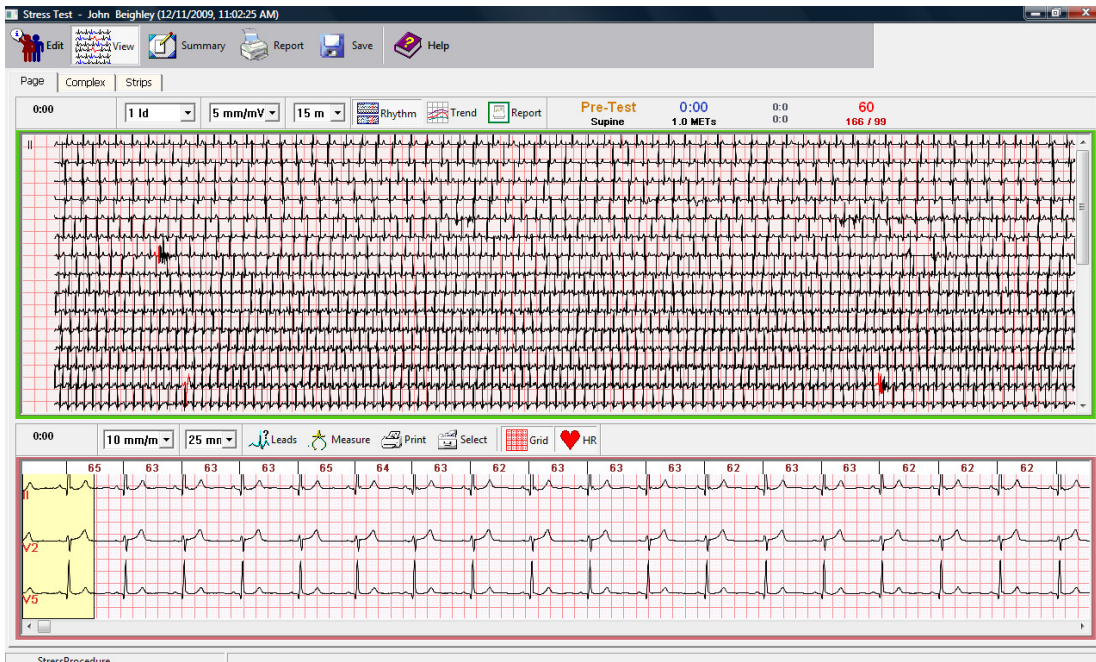
7.3.2 View



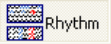
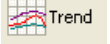

Select 'View' to review (and edit) acquired Stress Test ECG data in various formats.

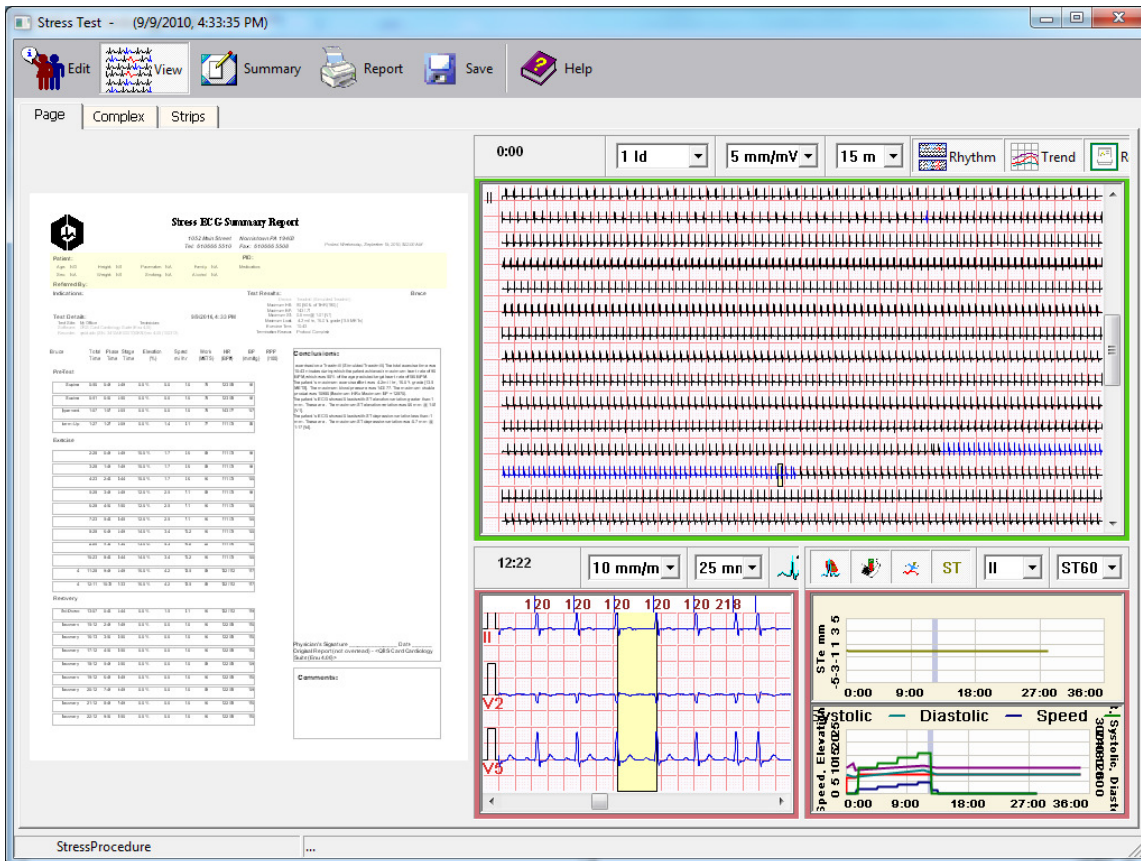
Page Screen

The Page screen shows a full disclosure view of the complete stress test. The example below shows the default view. As you can see, the 'Rhythm' button is selected and the rhythm view is shown below the 'Full Disclosure' View.



[KB70]

By Pressing  or  or  buttons, user can see Rhythm data, Trend Data or a view of the Report in conjunction with the page/full disclosure ECG data. The example below shows the expanded view (if Rhythm button, Trend button and Report button are selected.)



The screenshot displays the 'Stress Test' software interface. The main window is titled 'Stress Test - (9/9/2010, 4:33:35 PM)'. The interface includes a menu bar with 'Edit', 'View', 'Summary', 'Report', 'Save', and 'Help'. Below the menu bar, there are tabs for 'Page', 'Complex', and 'Strips'. The central area is divided into several sections:

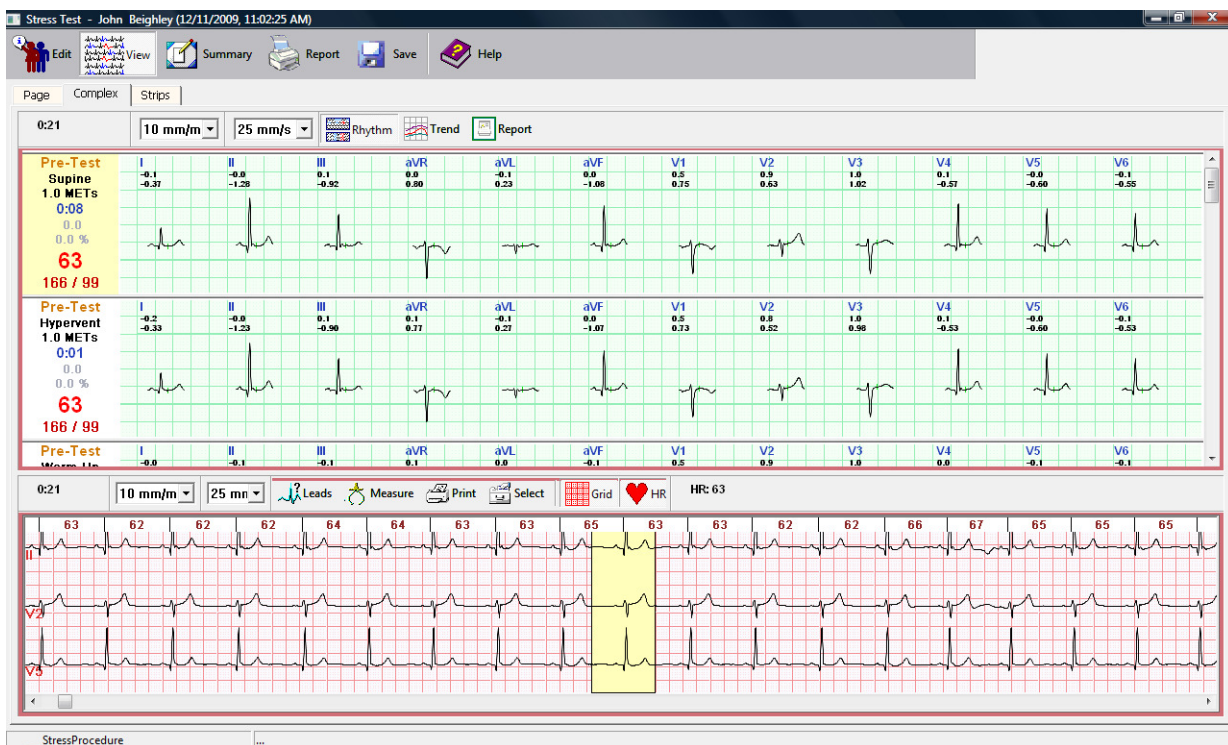
- Stress ECG Summary Report:** Located on the left, it contains patient information, test details, and a table of ECG data.
- ECG Strips:** The top right section shows a series of ECG strips with a time scale from 0:00 to 12:22. The strips are displayed with a 5 mm/mV sensitivity and a 15 m time scale. The Rhythm button is selected.
- Physiological Trend Graphs:** The bottom right section shows two graphs. The top graph displays 'Speed, Systolic, Diastolic' pressure over time. The bottom graph displays 'Speed, Systolic, Diastolic' pressure over time. The graphs are displayed with a 10 mm/m sensitivity and a 25 m time scale.

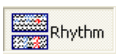
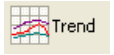
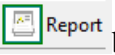
The 'Stress ECG Summary Report' section includes the following data:

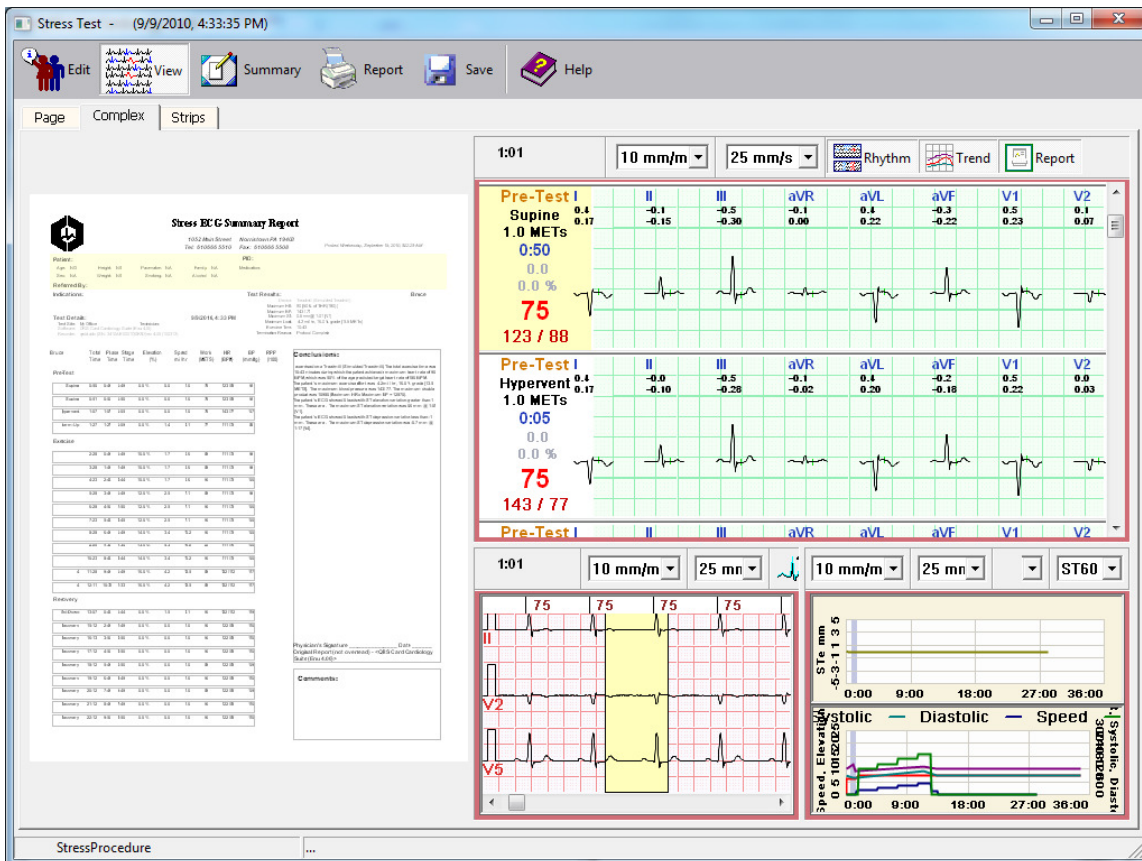
Block	Total	Filter	Strip	Elapsed	Speed	HR	SBP	DBP	PRP
Time	Time	Time	Time	Time	Time	Time	Time	Time	Time
1:00	1:00	1:00	1:00	1:00	1:00	1:00	1:00	1:00	1:00
2:00	2:00	2:00	2:00	2:00	2:00	2:00	2:00	2:00	2:00
3:00	3:00	3:00	3:00	3:00	3:00	3:00	3:00	3:00	3:00
4:00	4:00	4:00	4:00	4:00	4:00	4:00	4:00	4:00	4:00
5:00	5:00	5:00	5:00	5:00	5:00	5:00	5:00	5:00	5:00
6:00	6:00	6:00	6:00	6:00	6:00	6:00	6:00	6:00	6:00
7:00	7:00	7:00	7:00	7:00	7:00	7:00	7:00	7:00	7:00
8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00	8:00
9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00	9:00
10:00	10:00	10:00	10:00	10:00	10:00	10:00	10:00	10:00	10:00
11:00	11:00	11:00	11:00	11:00	11:00	11:00	11:00	11:00	11:00
12:00	12:00	12:00	12:00	12:00	12:00	12:00	12:00	12:00	12:00
13:00	13:00	13:00	13:00	13:00	13:00	13:00	13:00	13:00	13:00
14:00	14:00	14:00	14:00	14:00	14:00	14:00	14:00	14:00	14:00
15:00	15:00	15:00	15:00	15:00	15:00	15:00	15:00	15:00	15:00
16:00	16:00	16:00	16:00	16:00	16:00	16:00	16:00	16:00	16:00
17:00	17:00	17:00	17:00	17:00	17:00	17:00	17:00	17:00	17:00
18:00	18:00	18:00	18:00	18:00	18:00	18:00	18:00	18:00	18:00
19:00	19:00	19:00	19:00	19:00	19:00	19:00	19:00	19:00	19:00
20:00	20:00	20:00	20:00	20:00	20:00	20:00	20:00	20:00	20:00
21:00	21:00	21:00	21:00	21:00	21:00	21:00	21:00	21:00	21:00
22:00	22:00	22:00	22:00	22:00	22:00	22:00	22:00	22:00	22:00
23:00	23:00	23:00	23:00	23:00	23:00	23:00	23:00	23:00	23:00
24:00	24:00	24:00	24:00	24:00	24:00	24:00	24:00	24:00	24:00
25:00	25:00	25:00	25:00	25:00	25:00	25:00	25:00	25:00	25:00
26:00	26:00	26:00	26:00	26:00	26:00	26:00	26:00	26:00	26:00
27:00	27:00	27:00	27:00	27:00	27:00	27:00	27:00	27:00	27:00
28:00	28:00	28:00	28:00	28:00	28:00	28:00	28:00	28:00	28:00
29:00	29:00	29:00	29:00	29:00	29:00	29:00	29:00	29:00	29:00
30:00	30:00	30:00	30:00	30:00	30:00	30:00	30:00	30:00	30:00
31:00	31:00	31:00	31:00	31:00	31:00	31:00	31:00	31:00	31:00
32:00	32:00	32:00	32:00	32:00	32:00	32:00	32:00	32:00	32:00
33:00	33:00	33:00	33:00	33:00	33:00	33:00	33:00	33:00	33:00
34:00	34:00	34:00	34:00	34:00	34:00	34:00	34:00	34:00	34:00
35:00	35:00	35:00	35:00	35:00	35:00	35:00	35:00	35:00	35:00
36:00	36:00	36:00	36:00	36:00	36:00	36:00	36:00	36:00	36:00

Complex Screen

The Complex Screen shows average complexes during different stages of the Stress Test. The example below shows the default view. As you can see, the 'Rhythm' button is selected and the rhythm view is shown below the 'Average Complex' View.



By Pressing  or  or  buttons, user can see Rhythm data, Trend Data or a view of the Report in conjunction with the Average Complex view. The example below shows the expanded view (if Rhythm button, Trend button and Report button are selected.)

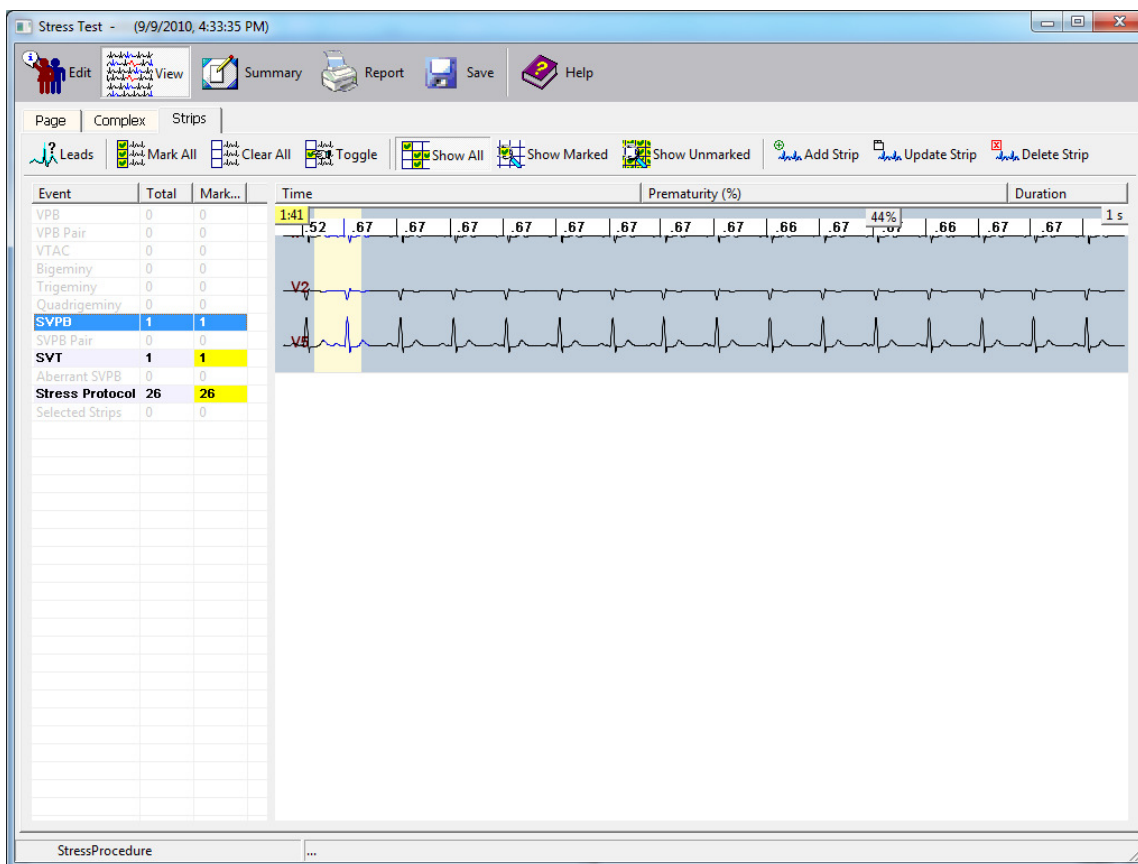


Strips Screen

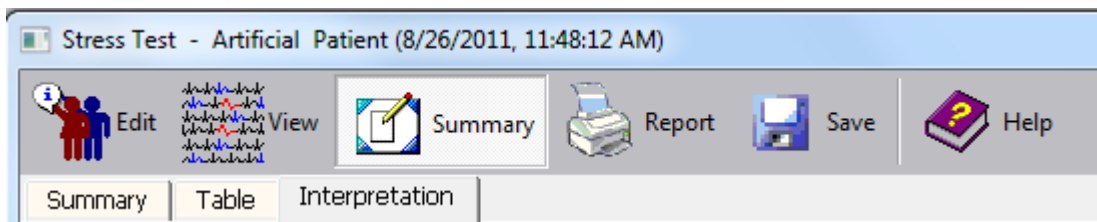
Shows:

- Automatically Selected Arrhythmia Strips
- Stress Event Strip (e.g. every minute save for Bruce protocol)
- Custom Save/Annotated Strips.

The strips shown with time stamps highlighted in yellow are the ones that are marked to be printed. These strips can be marked and unmarked by using the tool bar buttons for marking/unmarking. [B71]



7.3.3 Summary



This selection is used to review Stress Test Summary Data. This data include Stress Summary, Table Data for Stress Test and Summarized Stress Test Interpretation.

Summary Screen

Shows summary information of stress ECG test and the reason for the termination of the test (user can overwrite information in the 'Reason for termination' box).

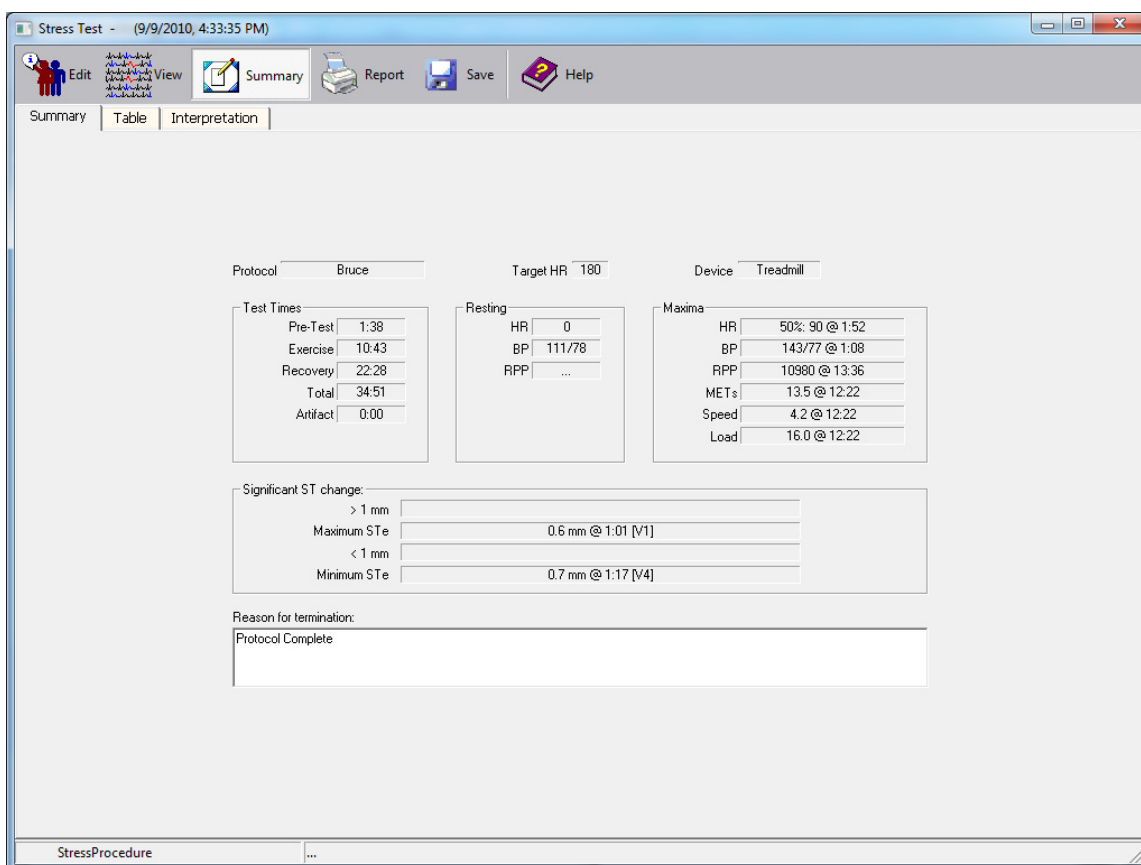
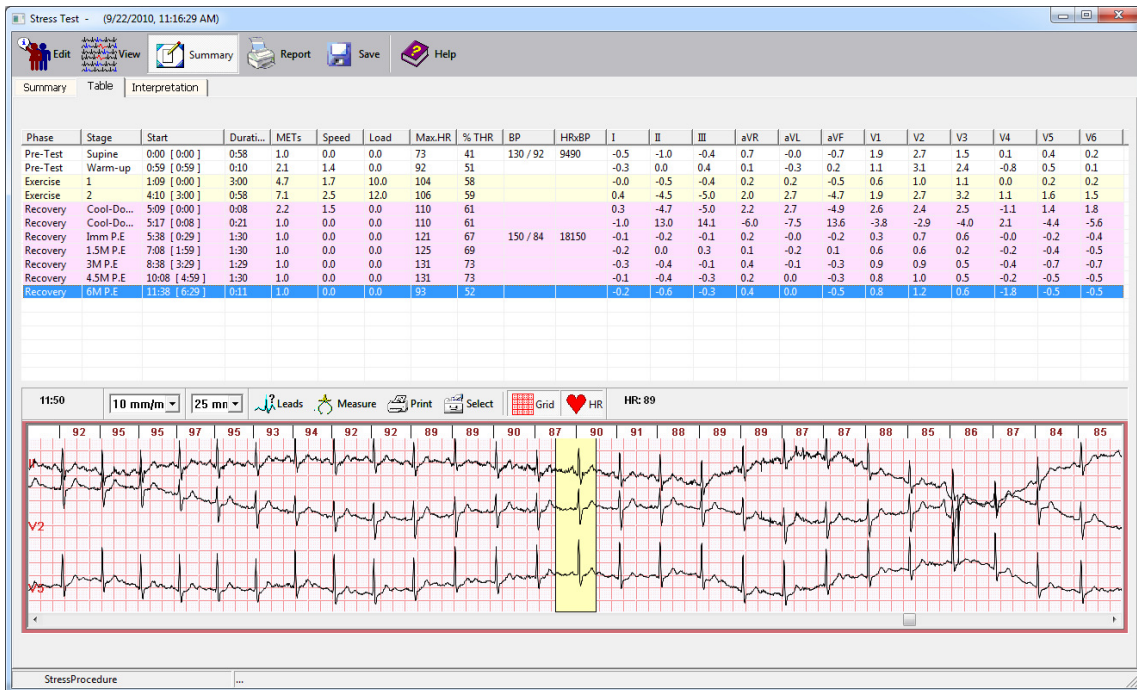


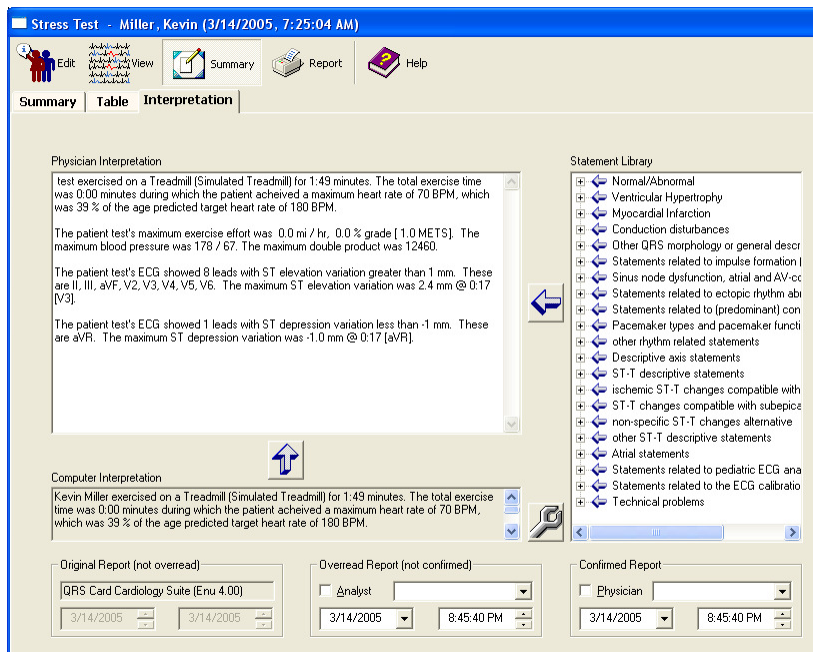
Table Screen

Shows summary information from stress ECG test in a tabular format.



Interpretation Screen


- provides computer generated Automatic ECG Interpretation. [B72] Interpretation can also be edited by typing free text or accepting statements from the Statement Library. For the Automatic Computer Interpretation to work in the Resting test, this option has to be selected in the Resting Setup.
- To add statements from the statement library, select the statement desired and click on the arrow to transfer it over to the Physician's Interpretation box.
- In a view-only box at the bottom of the screen, the date and time of the computer-generated interpretation is displayed. The name of the analyst who overread the interpretation and the physician that confirmed it, along with the date and time, can be entered in the applicable boxes.



NOTICE QRS-Card™ Cardiology Suite can provide automatic computer interpretations. A computer generated interpretation cannot replace sound medical reasoning by a trained professional. Therefore, a physician should always review the interpretation and final analysis should always be obtained by a Physician. Proper administration, diagnosis and implementation of the test is the Physician's responsibility.

Updating Custom Dictionary



By clicking the  icon in the Interpretation screen, user can update the custom dictionary.

Update Custom Dictionary ✕

Group: Normal/Abnormal OK

Cancel

Help

normal ECG	X
normal QRS	X
normal P wave	X
normal ST-T	X
ECG within normal limits for ag	X
possibly normal ECG	X
borderline ECG	X
abnormal ECG	X
possibly abnormal ECG	X
abnormal QRS	X
abnormal ST-T	X
normal for age	X
normal for build	X
abnormal for age	X
abnormal for build	X
unusual for build	X
X	X
X	X

Normal/Abnormal

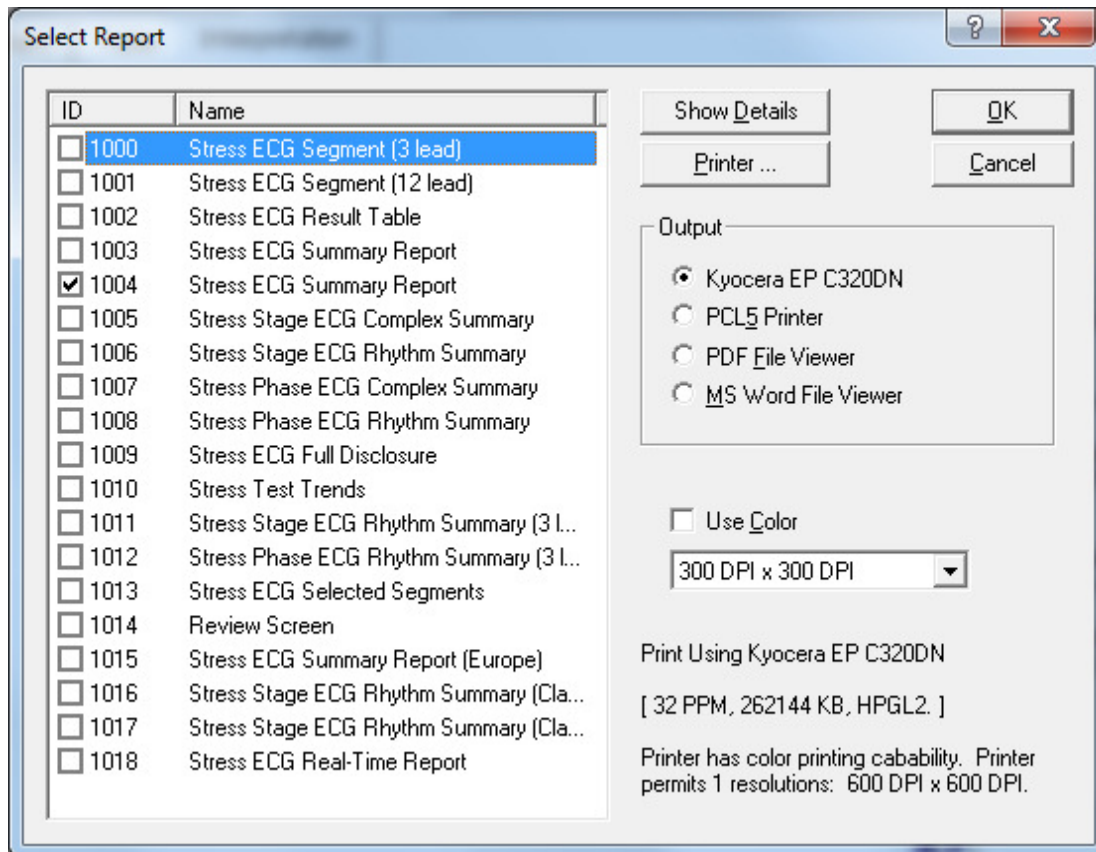
Edit Instructions

Left Click any button to edit text.
 Remove all characters to hide a button.
 Those buttons displayed with a red 'X' will be hidden.
 Press 'OK' to save changes.
 Press 'Cancel' to discard changes.

7.3.4 Report

Clicking the “Report” button allows users to select reports to be printed, PDF reports to be created or the report to be viewed in Microsoft Word (See Appendix 3 for Sample Resting Reports).

(For sample stress reports, see appendix 4: Sample Stress Reports.)



Show Details	Pressing this button will either hide or show printing details.
Printer...	Pressing this button with show printer details.
Output	Under output you can select which printer you want to print to. Your default printer will show as the first option (<i>In this example, RICOH Aficio is the default printer</i>)
PCL5 Printer^[B73]	Selecting this option will print the reports to default printer
PDF File Viewer	By selecting this option, the report will be printed to a PDF file and displayed on the computer screen.

	<p>The Save button from Adobe Acrobat Reader will save the report in PDF format, which can be printed or emailed by the user, if required.</p> <p><i>Note: In order to print PDF File Viewer to computer screen, installation of Adobe Acrobat Reader 6.0 or higher on user computer is required (also make confirm that version of Acrobat Reader is selected under “\Utility\Configuration\Option\PDF”. To confirm, select “Detect”)[B74]</i></p>
<p>MS Word File Viewer</p>	<p>Selecting this option will open the report in Microsoft™ Word. The save button from Microsoft work will save the report as a Word file for editing, printing, etc.</p> <p><i>Note: In order to view in Microsoft Word, installation of Microsoft Word on user computer is required.</i></p>
<p>Use Color</p>	<p>Selecting this button will allow user to print ECG reports in color depending on printer options.</p>

Save Button

Reports can be saved if modifications are made.

8. Holter ECG Module

The QRS-Card™ Cardiology Suite offers advanced Holter ECG technology with many standard features in one package. By using advanced analysis techniques QRS-Card™ Cardiology Suite provides accurate results that can be systematically reviewed with minimal technician involvement. [KB75]

Standard features include:

- Accurate arrhythmia analysis
- Preset artifact detection
- Simple user interface
- Fast load and analysis
- Color coded beats and trends
- Full disclosure (24 or 48 hours)
- 3-channel ST analysis
- Split-screen superimposition
- Multiple report formats
- Multiple format page mode
- Network compatibility

Optional features include:

- HRV (Heart Rate Variability) analysis
- 12-lead ECG analysis
- Pacemaker function analysis
- QT analysis

The best way to get a good quality ECG is for the administrator to be properly trained, to prep the patient correctly and to reduce artifact/noise. [B77]

Once you have the patient prepped and the electrodes securely attached you can begin a Holter ECG test.[B78]

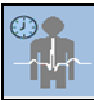
See 'Holter Hardware' user guide for information on how to begin the test. Once the patient returns, remove memory card from Holter recorder and place in the card reader attached to your computer.[B79]

8.1 Holter ECG Setup and Download

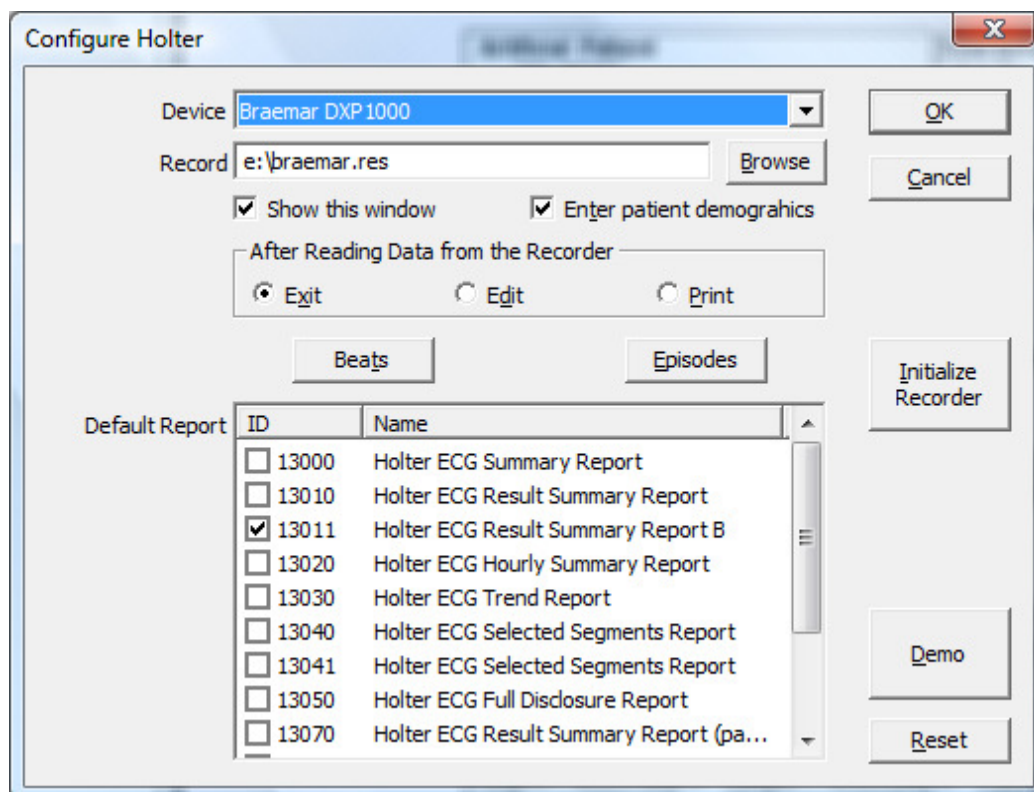
The Holter Setup screen is used to define settings for downloading a Holter ECG Test. It is recommended that before downloading your first test, you define the setup.

Holter ECG Setup can be accessed three ways:

- From the Master Screen select File > Holter > Setup OR
- Simultaneously press CTRL + F5 OR

- Click on the Holter ECG icon. 

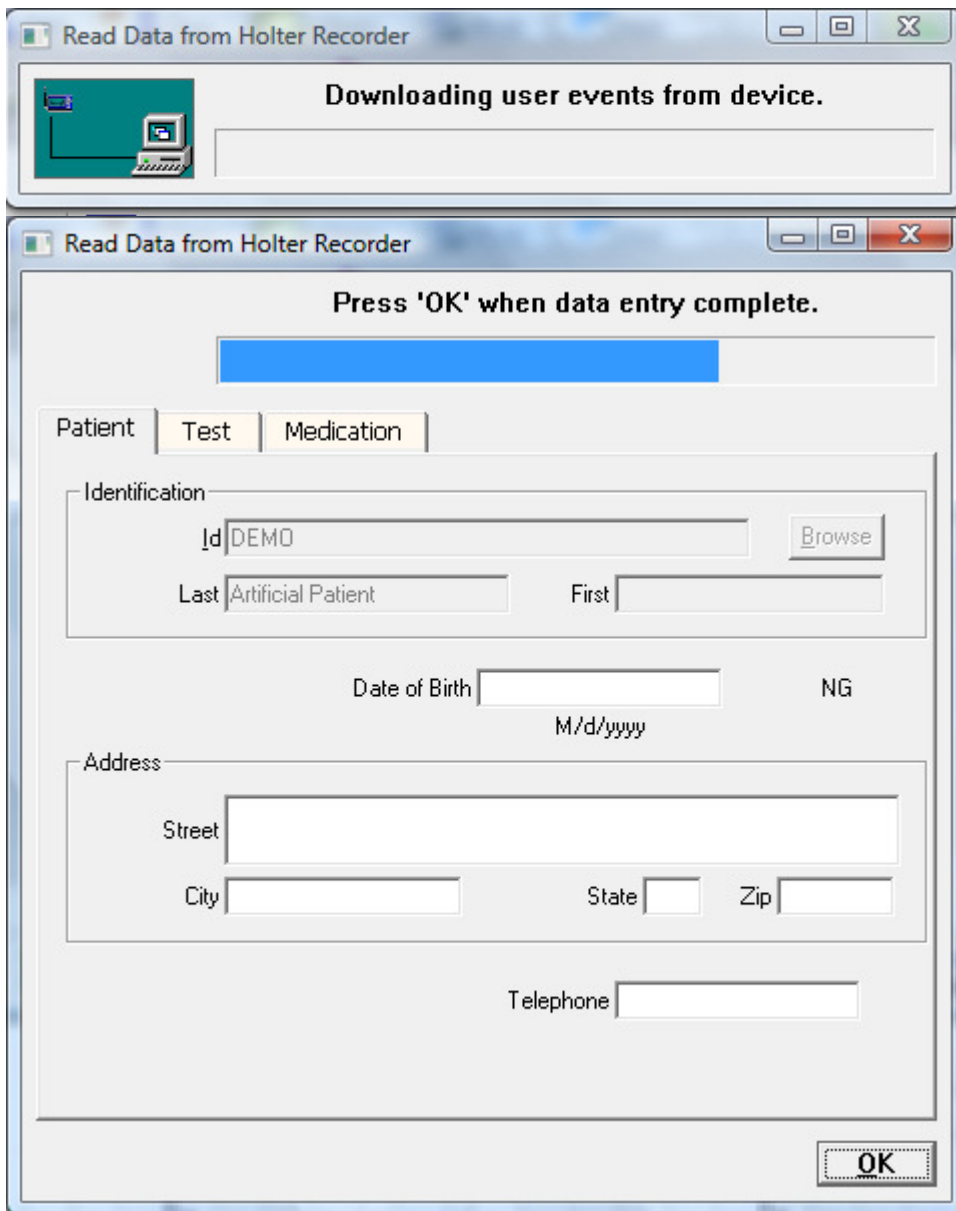
(If the "Show This Window" option in the Holter Setup has been selected, the Holter Setup screen will automatically be displayed.)



ID	Name
<input type="checkbox"/> 13000	Holter ECG Summary Report
<input type="checkbox"/> 13010	Holter ECG Result Summary Report
<input checked="" type="checkbox"/> 13011	Holter ECG Result Summary Report B
<input type="checkbox"/> 13020	Holter ECG Hourly Summary Report
<input type="checkbox"/> 13030	Holter ECG Trend Report
<input type="checkbox"/> 13040	Holter ECG Selected Segments Report
<input type="checkbox"/> 13041	Holter ECG Selected Segments Report
<input type="checkbox"/> 13050	Holter ECG Full Disclosure Report
<input type="checkbox"/> 13070	Holter ECG Result Summary Report (pa...

Device	Select the device you have recorded Holter ECG data with. Options include: <ul style="list-style-type: none"> - Braemar DXP1000 (also used for Braemar DL800 and Braemar DL900)^[B80] - Cardioline File Importer - Datrix DR512 VX3 (128 Hz) - Datrix DR512 VX3 (224 Hz) - CardioRemote Holter - Rozin File Importer
Record	Use this option to select file you are downloading from. To select a different file, click the 'Browse' button. ^[B81]
Show this Window	If selected, the Holter Setup window will display each time you are downloading Holter ECG tests.
Enter Patient Demographics	If selected, the Holter ECG Patient Information dialog box will appear during Holter ECG download.
After Reading Data from the Recorder:	
Exit	If selected, the QRS-Card™ Cardiology Suite master software screen will be displayed after download.
Edit	If selected, the Holter test will open for editing after it is downloaded.
Print	If selected, default reports will be printed after it is downloaded.
Beats	Opens the Configure Beat Detection dialog box. There are 3 tabs, Noise, Beat Detect and Pacemaker. ^[B82]
Episodes	Opens the Configure Episode Detection dialog box. ^[B83]
Default Report	Specifies the type(s) of final reports to be printed automatically after the Holter test is completed.
Initialize Recorder	Patient data can be uploaded to the recorder. (Note: Only if recorder supports this option)
Demo	Allows user to download a demo Holter ECG test.
Reset	Resets setup to default positions.

When finished defining setup, click 'Ok' to begin downloading Holter ECG data.



The screenshot shows two instances of the 'Read Data from Holter Recorder' dialog box. The top instance displays the message 'Downloading user events from device.' with a progress bar. The bottom instance is in the data entry phase, showing the following fields:

- Tabs:** Patient (selected), Test, Medication
- Identification:**
 - Id: DEMO (with a 'Browse' button)
 - Last: Artificial Patient
 - First: (empty)
- Date of Birth:** (empty) NG (with a hint 'M/d/yyyy')
- Address:**
 - Street: (empty)
 - City: (empty)
 - State: (empty)
 - Zip: (empty)
- Telephone:** (empty)
- Buttons:** OK

Enter patient information by filling in the 'Patient', 'Test' and 'Medication' tabs. Click 'Ok' when complete.

Holter will download and be saved in the Test Database.

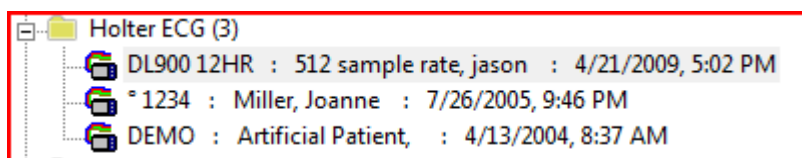
8.2 Reviewing a Holter ECG Test

To view or edit a Holter test, go to the QRS-Card™ Cardiology Suite Master Screen and select

the desired Holter ECG Test and click the button  on the toolbar

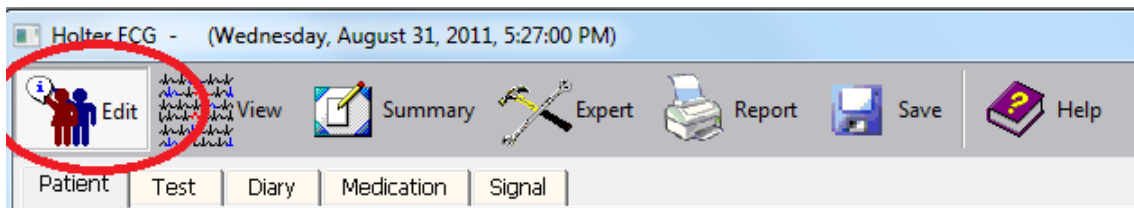
OR

Double click on the test to be viewed.



The test record will be displayed in the QRS-Card™ Cardiology Suite Holter ECG Dataview screen.

8.2.1 Edit Tab



Select 'Edit' to view or edit information about the patient.

Patient Screen –

- in this area you can edit patient demographics

Test Screen –

- Contains additional patient information

Diary Screen-

- Used to add or remove strips to the patient diary

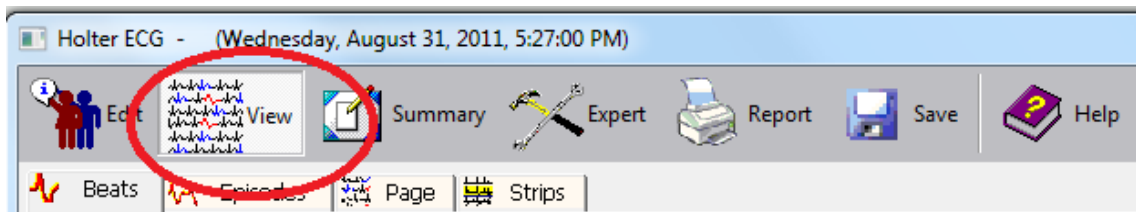
Medication Screen –

- Contains patient medication information

Signal Screen -

- Contains information on how the ECG was obtained such as the sampling and use of filters. In this tab, you can also change Blood Pressure Information.

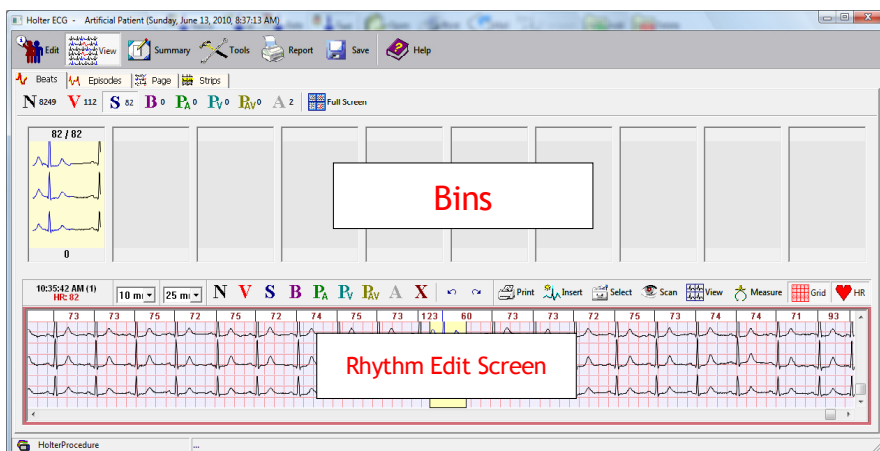
8.2.2 View



Select 'View' to review (and edit) the Holter Test ECG data in various formats.

The View Holter ECG module has been divided into different categories (Beats, Episodes, Page and Strips) to allow for easy navigation and reclassification of the Holter ECG data.

Beats Screen



Beats are automatically classified according to the QRS-Card™ Cardiology Suite software algorithm and are defined as follows:

- **N** = Normal
- **V** = Ventricular Ectopic Beats
- **S** = Supraventricular Ectopic Beats
- **B** = Aberrant
- **P_A** = Atrial Paced
- **P_V** = Ventricular Paced
- **P_{AV}** = Atrio-Ventricular Paced
- **A** = Beats that are in segments too noisy to process (artifact)

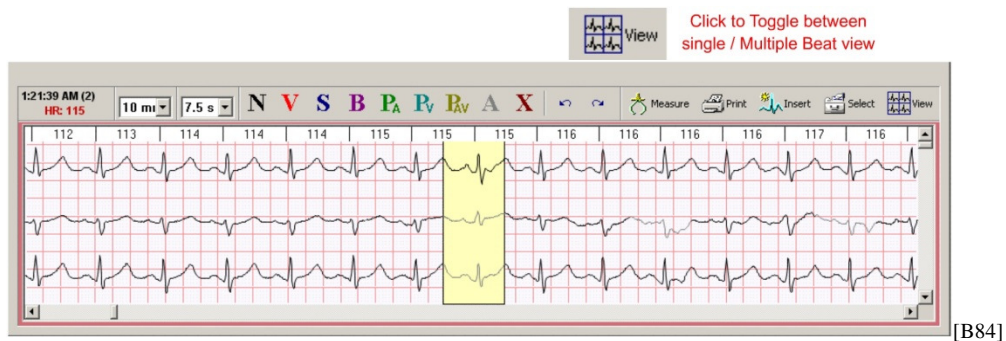
Bins are displayed below which allows the user to view all similar beats within a single template as a group and the beats from the selected Bin are displayed in the Rhythm Edit Screen.

To reclassify beats

1. Select the beat(s) from the Bins that you want to reclassify in the Rhythm Edit Screen.

To select a single beat click on the R-wave. To select multiple beats drag the R-waves that you want to include.

2. Click the desired reclassify button that you want the beat to be reclassified to.
3. The Selected beat(s) will be reclassified (or deleted if you clicked on **A** or **X**)



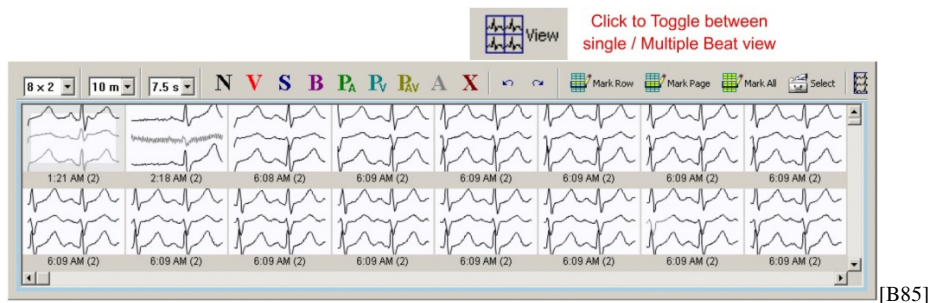
Reclassify Multiple Beats

The beats can be viewed in *multiple view mode* also.

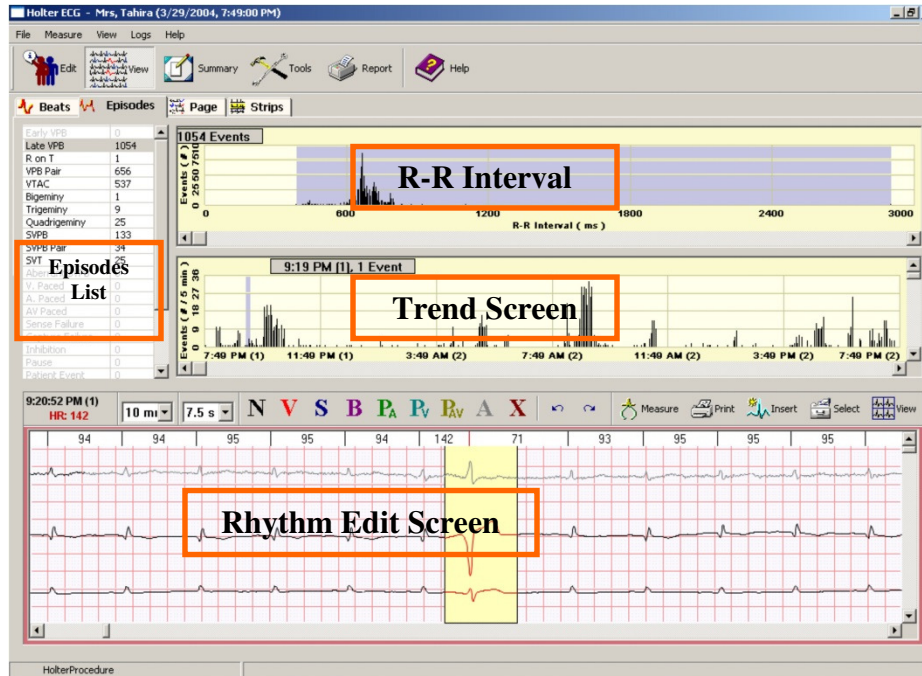
To reclassify multiple beats

1. Select the template class (VE, Normal, SVE, etc.).
2. Select the desired bin.
3. Click view button to **Toggle** view single/multiple template beats in the Rhythm Edit Screen.
4. Select the template beats you want the edit by clicking on multiple beats or clicking **Mark Row, Mark Page, Mark All**.
5. Click **N, V, P, A, S, B, or X** to reclassify the beats.

The selected beats will be reclassified and the Rhythm Edit Screen will be updated with the remaining template beats in the selected Template pane.



Episodes Screen



The Episodes Screen enables the user to review ECG data through the R-R interval window and the trend window. Data in both windows is synchronized with the Rhythm Edit Screen as the user highlights the data.

As the ECG data is analyzed the Episodes are evaluated against predefined criteria and are stored in the following categories:

- Fastest Rates
- Slowest Rates
- Bradycardia
- Pause
- Isolated VEB
- VEB Pair
- VEB Run
- Bigemny
- SVEB Pair
- SVEB Run
- Recorder Episode
- STe Abnormalities

To reclassify Episodes

1. Select the Episode(s) from the Episodes list that you want to reclassify in Rhythm Edit Screen

To select a single Episode click on the R-wave. To select multiple Episodes drag the R-waves that you want to include.

2. Click the desired reclassify button that you want the Episode to be reclassified to.

The Episode(s) will be reclassified (or deleted if you clicked on **A** or **X**)

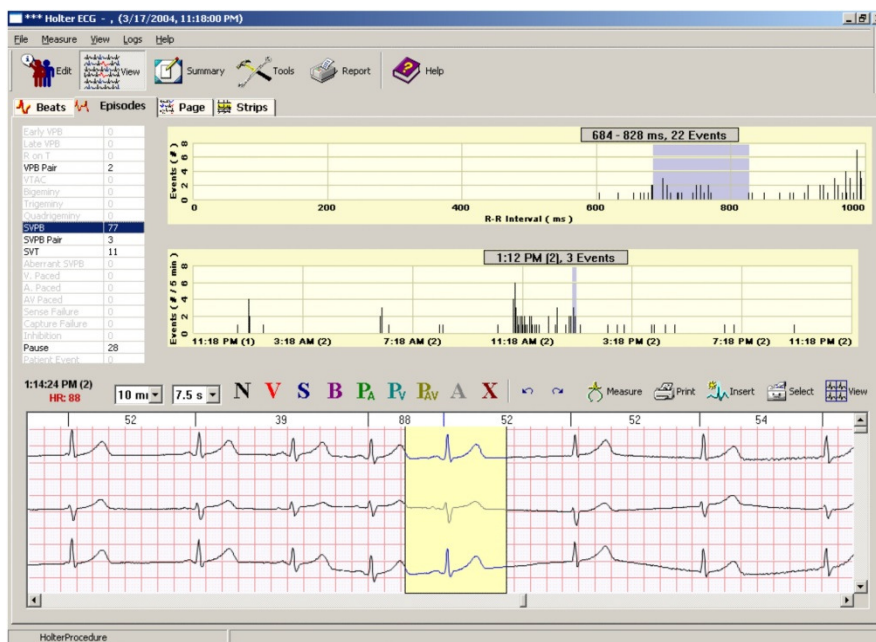


Lessons – Reclassify Multiple Episodes using R-R Interval Histogram

To edit multiple Episodes using the Episode R-R Interval Histogram

1. In the Episode List box select the Episode type that you want to edit.
2. Drag the Episodes in the Episode R-R Interval Histogram to select the range of R-R intervals to edit.
3. Click **Toggle** to view multiple Episodes in the Rhythm Edit Screen if it isn't already.
4. Select the Episodes you want the edit by clicking on multiple Episodes or click **Mark Row**, **Mark Page**, or **Mark All**.
5. Click **N**, **V**, **P**, **A**, **S**, **B**, or **X** reclassify button to edit the Episodes

The selected Episodes will be reclassified and the ECG Edit window will be updated



Lessons – Reclassify Multiple Episodes using Trend Screen

To edit multiple Episodes using the Event Trend

1. In the Episode List box select the Episode type that you want to edit.
2. Drag the episodes in the Episode Trend to select the time period that you want edit.
3. Click **Toggle** to view episodes in the Rhythm Edit Screen if it isn't already.
4. Select the template beats you want the edit by clicking on multiple episodes or click **Mark Row**, **Mark Page**, or **Mark All**.
5. Click **N**, **V**, **P**, **A**, **S**, **B**, or **X** reclassify button to edit the episodes.

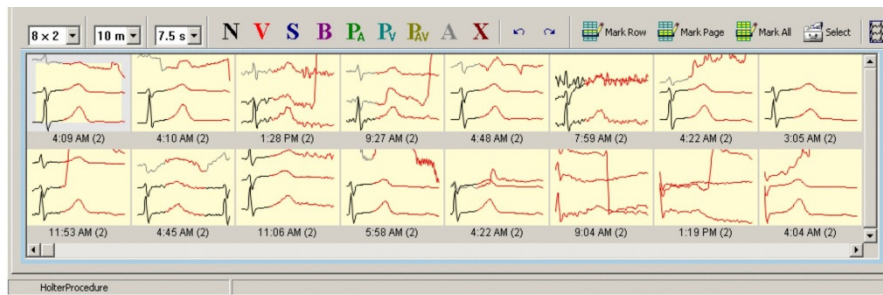
The selected episodes will be reclassified and the ECG Edit window will be updated



Lessons – To Delete all Episodes of one Event Type

To delete all Episodes of one Episode type

1. In the Episode List box select the Episode type that you want to delete.
2. Drag all of the Episodes in the Episodes R-R Interval Histogram or Episode Trend.
3. Click **Toggle** to view multiple Episodes in the Rhythm Edit Screen if it isn't already.
4. Click **Mark All**.
5. Click **X** to delete beats and the template



Lessons – Strips Screen Functions

The Strips window contains the following controls:

Event	Total	Marked
Category		
Late VPB	1054	10
R on T	1	1
VPB Pair	656	0
VTAC	537	0
Bigeminy	1	0
Trigeminy	9	0
Quadrigeminy	25	0
SVPB	133	0
SVPB Pair	34	0
SVT	25	0
Aberrant SVPB	0	0
V. Paced	0	0
A. Paced	0	0
AV Paced	0	0
Sense Failure	0	0
Capture Failure	0	0
Inhibition	0	0
Pause / Asystole	0	0
Brady	2	2
Tachy	48	10
Minimum HR	95	1
Maximum HR	95	1
STe deviation	0	0
Patient Event	0	0
Selected Strips	0	0

Strip category List Box

The Strips list box is located above the ECG Data View window. The list box displays ECG strips from the following categories:

VPB, VPB Pair, VTAC, SVPB, SVPB Pair, SVT, Pause/Asystole, Patient event, Selected strips, STe deviation, Tachy/Brady, Fast rate, Slow rate.

Display Strips

These control which ECG strips are displayed in the Strips mode.

- **All** - Use to display all strips for a category.
- **Marked** -Used to display all marked strips from a category.
- **Unmarked** - Used to display all unmarked strips from a category.



Mark / Unmark Strips

These control which ECG strips are marked or unmarked. Marked strips are included the Holter report. When a strip is selected (marked) it's start time is highlighted in yellow.

- **Mark All** - Used to mark all strips in a category.
- **Unmark All** - Used to unmark all strips in a category.
- **Toggle** - Used to Mark or Unmark the current highlighted strip. Click on a strip to highlight it.

Strip sorting criteria

These controls are located above the top-most ECG strip. These are used to control the order that strips are displayed in the window.

- **Time** - Used to sort the strips in chronological order.
- **Prematurity (%)** - Used to sort the strips according to the degree of prematurity.
- **Duration (seconds)** - Used to sort the strips according to the strip duration.

Page Screen

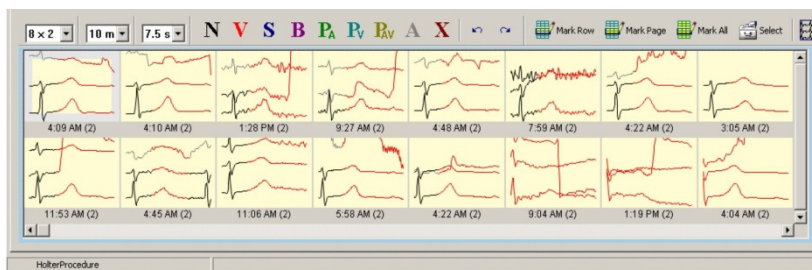


The page screen shows another view of the Holter data.

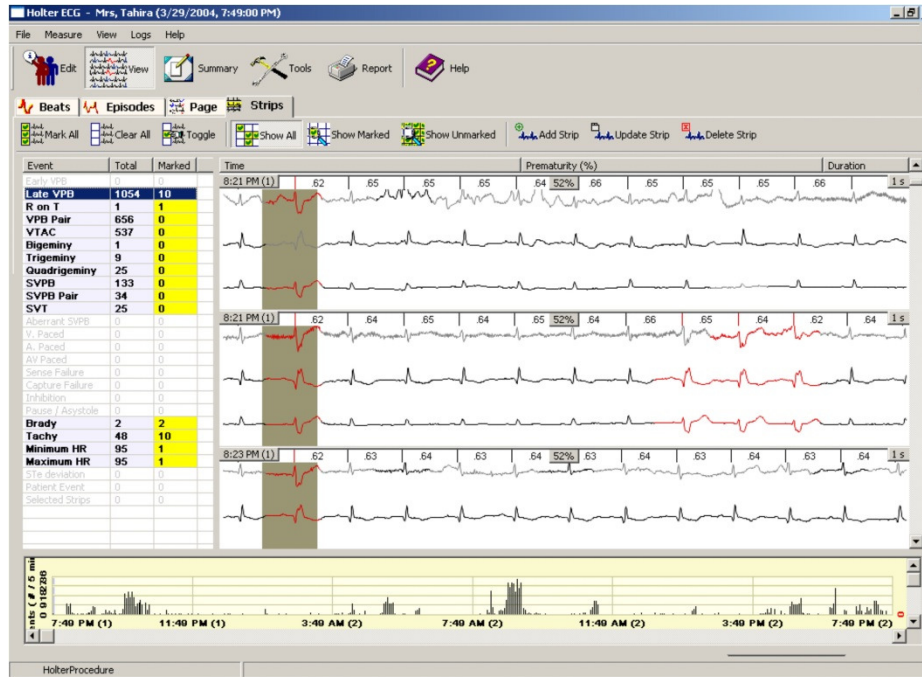
To edit multiple beats on Page screen

1. Drag the beats on the page window that you want to edit.
2. Click **N**, **V**, **P**, **A**, **S**, **B**, or **X** to reclassify the beats.

The selected beats will be reclassified and the Rhythm window will be updated.



Strips Screen



The Strips screen allows the user to review and select which Episodes should be printed in the selected report. Strips are displayed in the following categories:

- VPB
- VPB Pairs
- Bigeminy
- SVPB
- SVPB Pair
- SVT
- Pause/Asystole
- Patient Episodes
- Selected Strips
- ST Episodes
- Tachy/Brady
- Fast rate
- Slow rate

8.2.3 Summary Tab

General Screen

Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)

Edit
 View
 Summary
 Expert
 Report
 Save
 Help

General | **Supraventricular** | Ventricular | Supraventricular Runs | Ventricular Runs | Bigeminy | Tachy / Brady | Atrial Fibrillation | Paced | ST | Interpretation

General Interval Table

Start Time	Min.HR	Avg.HR	Max.HR	Total Beats	Total SVPB	Total VPB	Pauses	Time Analyzed
8:37 AM (1)	64	69	74	1561	0	0	0	22:46
8:59 AM (1)	64	70	109	4201	0	0	0	59:58
9:59 AM (1)	68	73	87	2683	0	0	0	37:36

Supraventricular Screen

Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)

Edit
 View
 Summary
 Expert
 Report
 Save
 Help

General | **Supraventricular** | Ventricular | Supraventricular Runs | Ventricular Runs | Bigeminy | Tachy / Brady | Atrial Fibrillation | Paced | ST | Interpretation

Supraventricular Interval Table

Start Time	Total Beat	Total SVPB	Single SVPB	Paired SVPB	SVT Runs	SVT Beats	Aberrant	Time Analyzed
8:37 AM (1)	1561	0	0	0	0	0	0	22:46
8:59 AM (1)	4201	0	0	0	0	0	0	59:58
9:59 AM (1)	2683	0	0	0	0	0	0	37:36

Ventricular Screen

Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)

Edit
 View
 Summary
 Expert
 Report
 Save
 Help








General | Supraventricular | **Ventricular** | Supraventricular Runs | Ventricular Runs | Bigeminy | Tachy / Brady | Atrial Fibrillation | Paced | ST | Interpretation

Ventricular Interval Table

Start Time	Total Beat	Total VPB	Paired V...	VT Beats	Bi Beats	Tri Beats	Qua Beats	Time Analyz...
8:37 AM...	1561	0	0	0	0	0	0	22:46
8:59 AM...	4201	0	0	0	0	0	0	59:58
9:59 AM...	2683	0	0	0	0	0	0	37:36

Supraventricular Runs Screen

Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)








General | **Supraventricular** | Ventricular | Supraventricular Runs | Ventricular Runs | Bigeminy | Tachy / Brady | Atrial Fibrillation | Paced | ST | Interpretation

Supraventricular Runs Interval Table

Start Time	3 <120	4 <120	5 <120	6-9 <120	10+ <120	3 >=120	4 >=120	5 >=120	6-9 >=120	10+ >=120	Time Analy...
8:37 AM ...	0	0	0	0	0	0	0	0	0	0	22:46
8:59 AM ...	0	0	0	0	0	0	0	0	0	0	59:58
9:59 AM ...	0	0	0	0	0	0	0	0	0	0	37:36

Ventricular Runs Screen

Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)








General | **Supraventricular** | Ventricular | Supraventricular Runs | **Ventricular Runs** | Bigeminy | Tachy / Brady | Atrial Fibrillation | Paced | ST | Interpretation

Ventricular Runs Interval Table

Start Time	3 <120	4 <120	5 <120	6-9 <120	10+ <120	3 >=120	4 >=120	5 >=120	6-9 >=120	10+ >=120	Time Analy...
8:37 AM ...	0	0	0	0	0	0	0	0	0	0	22:46
8:59 AM ...	0	0	0	0	0	0	0	0	0	0	59:58
9:59 AM ...	0	0	0	0	0	0	0	0	0	0	37:36

Bigeminy Screen

Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)








General | **Supraventricular** | Ventricular | Supraventricular Runs | Ventricular Runs | **Bigeminy** | Tachy / Brady | Atrial Fibrillation | Paced | ST | Interpretation

Bigeminy Interval Table

Start Time	Total Beat	Bigeminy Beats	3	4 - 9	10 - 24	25+	Time Analyzed
8:37 AM (1)	1561	0	0	0	0	0	22:46
8:59 AM (1)	4201	0	0	0	0	0	59:58
9:59 AM (1)	2683	0	0	0	0	0	37:36

Tachy / Brady Screen

Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)

General | **Supraventricular** | Ventricular | Supraventricular Runs | Ventricular Runs | Bigeminy | **Tachy / Brady** | Atrial Fibrillation | Paced | ST | Interpretation

Tachycardia / Bradycardia Interval Table

Start Time	Total Beat	Brady Beats	Time in Brady	Tachy Beats	Time in Tachy	Time Analyzed
8:37 AM (1)	1561	0	0:00	0	0:00	22:46
8:59 AM (1)	4201	0	0:00	0	0:00	59:58
9:59 AM (1)	2683	0	0:00	0	0:00	37:36

Atrial Fibrillation Screen

Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)

Atrial Fibrillation Interval Table

Start Time	Total Beat	AFIB Beats	Time in AFIB	Time Analyzed
8:37 AM (1)	1561	0	0:00	22:46
8:59 AM (1)	4201	0	0:00	59:58
9:59 AM (1)	2683	0	0:00	37:36

Paced Screen

Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)

Paced Beats Interval Table

Start Time	Total Beat	Total Pa...	A Paced	V Paced	AV Paced	Sense Fail	Capture...	Inhib. Fail	% A	% V	% AV	% Paced
8:37 AM...	1561	0	0	0	0	0	0	0	0.00	0.00	0.00	0.00
8:59 AM...	4201	0	0	0	0	0	0	0	0.00	0.00	0.00	0.00
9:59 AM...	2683	0	0	0	0	0	0	0	0.00	0.00	0.00	0.00

ST Screen

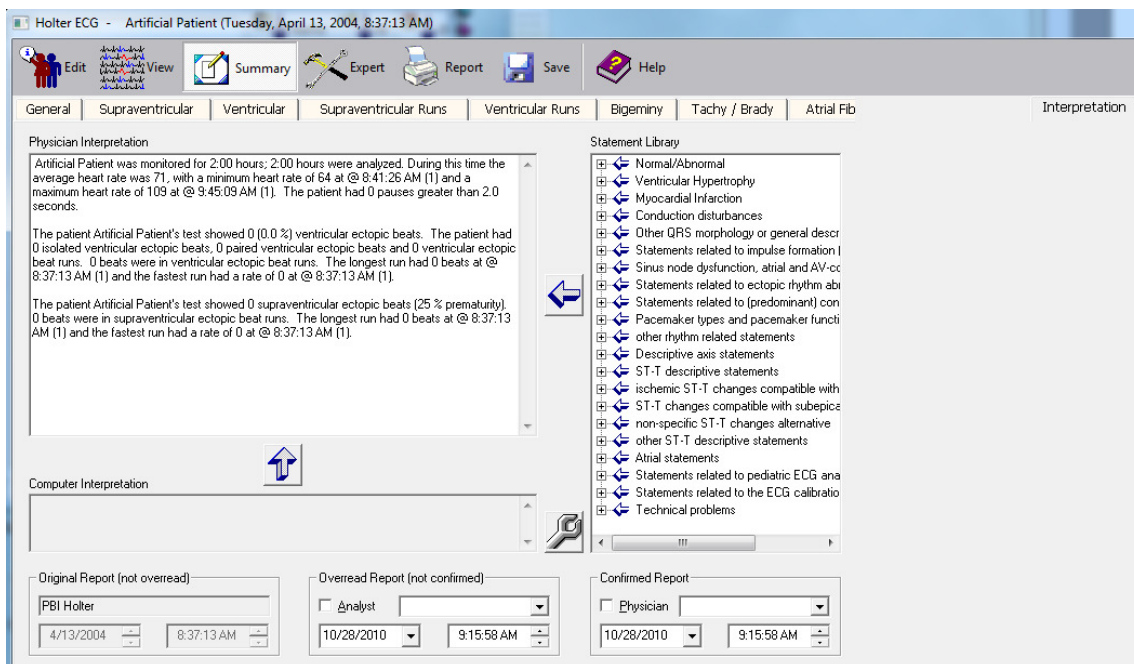
Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)

ST Table

Start Time	Total Beat	Avg.HR	ST Episo...	ST Durat...	Max.STe	Max.STd	Analyze...
8:37 AM...	1561	69	0	0:00	0.0 mm	0.0 mm	22:46
8:59 AM...	4201	70	0	0:00	0.0 mm	0.0 mm	59:58
9:59 AM...	2683	73	0	0:00	0.0 mm	0.0 mm	37:36

Interpretation Screen

- provides computer generated Automatic ECG Interpretation. [B88] Interpretation can also be edited by typing free text or accepting statements from the Statement Library. For the Automatic Computer Interpretation to work in the Resting test, this option has to be selected in the Resting Setup.
- To add statements from the statement library, select the statement desired and click on the arrow to transfer it over to the Physician's Interpretation box.
- In a view-only box at the bottom of the screen, the date and time of the computer-generated interpretation is displayed. The name of the analyst who overread the interpretation and the physician that confirmed it, along with the date and time, can be entered in the applicable boxes.



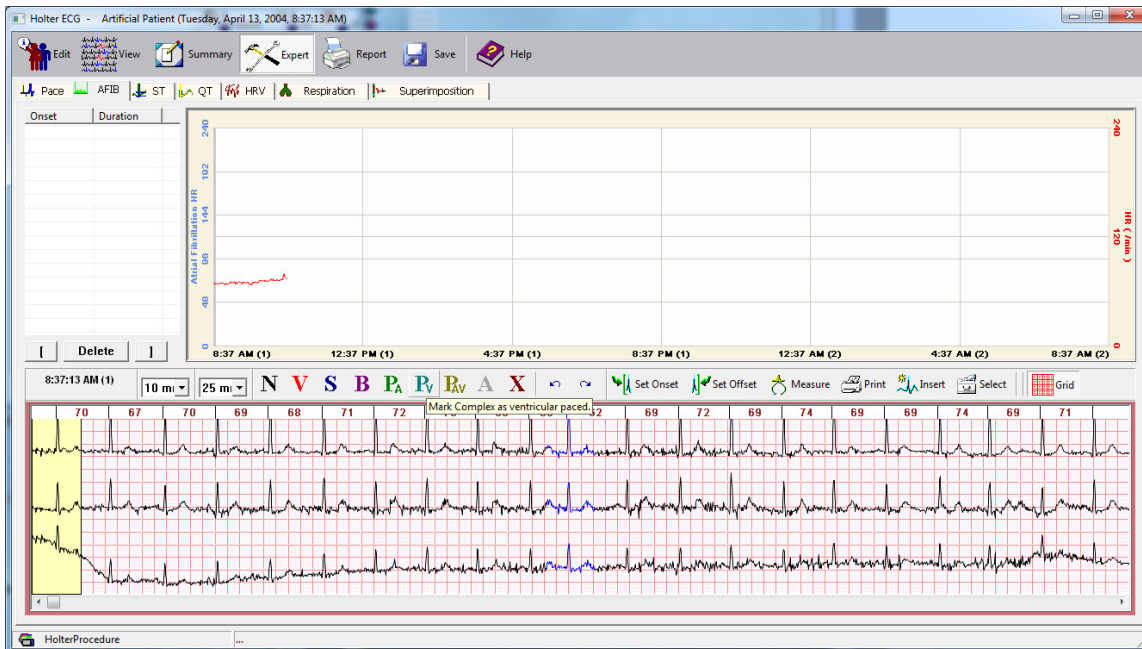
8.2.4 Expert

This tab contains additional functionality only available in our Extended and Elite Software versions.

Pace Screen



Afib Screen



ST Screen



9. Ambulatory Blood Pressure Monitoring

NOTICE US Customers will receive ONLY the software supplied by the device manufacturer (and not the Cardiology Suite ABPM software module).

9.1 ABPM Setup and Download

Use the Configure Ambulatory Blood Pressure Download setup box to transfer the ABPM data from the device to the QRS-Card™ program. This dialog box can be accessed by the following methods:

From the QRS-Card™ Cardiology Suite Master Screen select Setup > Ambulatory BP Download

OR

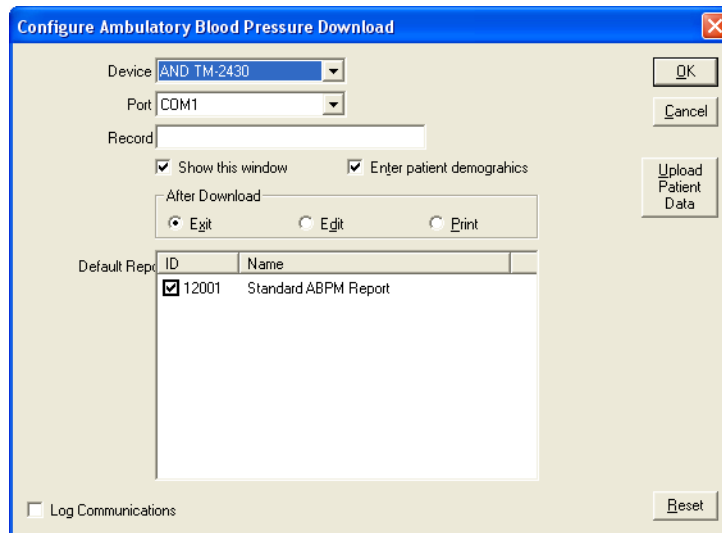


From the toolbar, click on the ABPM icon

OR

Use the hot key F6.

The Configure Ambulatory Blood Pressure Download dialog box primarily allows the user to specify the device used and the data file location.



ID	Name
<input checked="" type="checkbox"/> 12001	Standard ABPM Report

Device

Specify the ABPM device used.

Port

Defines which empty com port the device will be using or if a file is being downloaded.

Record

Specifies the location of the data file to be downloaded, including the drive.

Show this Window

If this box is checked the Setup dialog box will appear before each ABPM download. If the box is unchecked the Setup dialog box will not appear before each download. The download will proceed in the predesignated fashion.

Enter Patient Demographics

Checking this box will allow for the entering of patient demographics while the ABPM data is being downloaded. Click on the Finish button when data entry is completed.

After Download

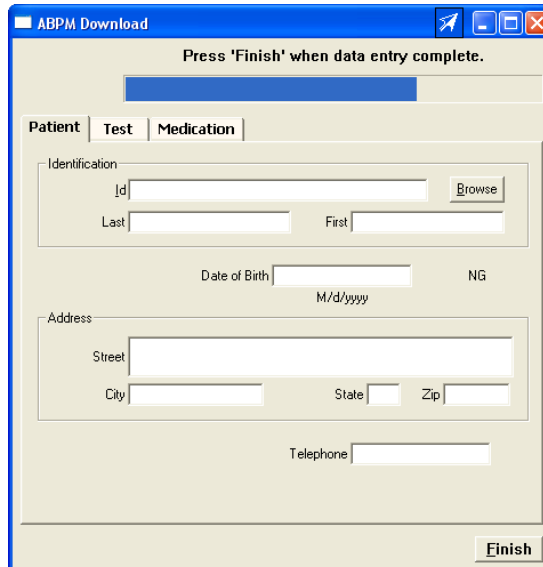
- Exit If the Exit option is selected, the program will wait in standby in the Acquisition Screen after the ABPM file is downloaded.
- Edit If Edit is selected, the ABPM file will be downloaded and then the Dataview screen will appear to allow review and editing of the data.
- Print The Print option will download the ABPM file and proceed with printing the report selected.

Default Report

Allows for selection of a default report at the time of download. The type of report can be changed after the download by opening the ABPM test and selecting File > Print Report in the ABPM Dataview screen.

Upload Patient Data

The Upload Patient Data button allows the upload of ABPM data from the QRS system to the ABPM Device.



Press 'Finish' when data entry complete.

Patient | Test | Medication

Identification

[d]

Last First

Date of Birth M/d/yyyy NG

Address

Street

City State Zip

Telephone

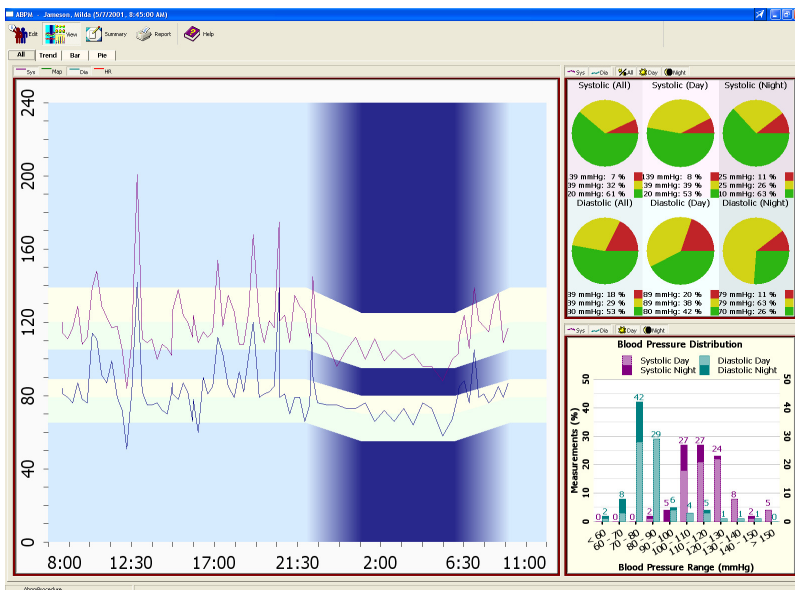
9.2 Viewing an ABPM Test

To view (or edit) a ABPM test, highlight from Main Screen the ABPM Test desired then click on the button  on the toolbar. OR

Double click on the Test to be reviewed.

- 12/28/2004 / burdick, / 3453 (1)
- 6/25/2003 / mahdavi, mahdavi / 20 (1)
- 5/7/2001 / ABPM, / 4646 (1)
- 5/7/2001 / Jameson, Milda / 1212 (1)
- ABPM 5/7/2001, 8:45 AM

When a ABPM test record is opened, the ABPM Dataview screen is displayed. Information about the patient can be viewed and/or edited, data from the test viewed and reports printed. An outline of the features and options displayed on the ABPM Dataview screen is given below, along with any available links to other relevant topics.



9.2.1 Edit

Use the Edit option to view or edit information about the patient and trace recalled from the database. The Edit option can be executed by the following methods:

9.2.1.1 Patient and Test Property Sheets

Information about the patient is present in these two property sheets. If necessary, the information can be edited.

9.2.1.2 Medication

Information about Patient medication is contained is contained in this property sheet.

9.2.1.3 Signal

Parameters on how the ECG was obtained, such as the sampling rate and use of filters, are contained on this property sheet.

9.2.2 View

Use View option to see ABPM data in four different ways:

ALL views seen simultaneously

Trend data only

Pie data only

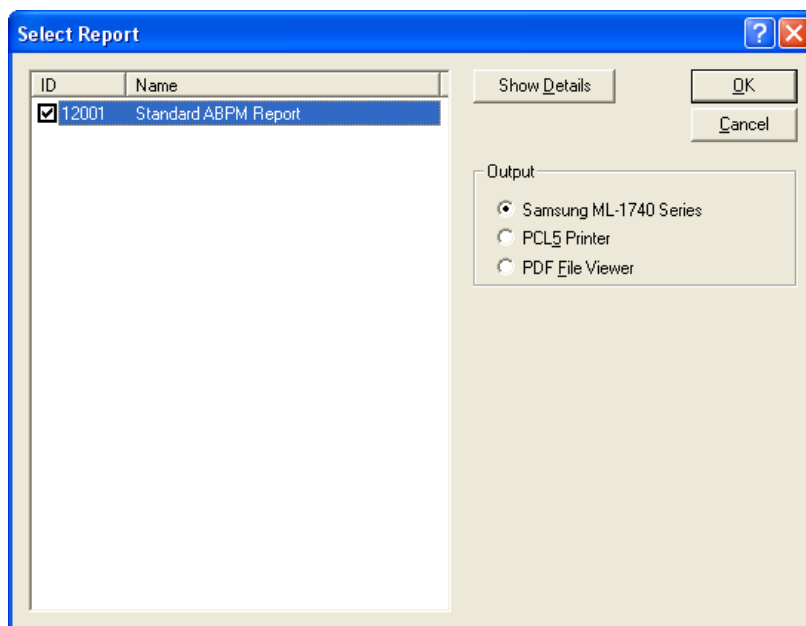
Bar data only

9.2.3 Summary

Pressing summary button provides summarized data for ABPM measurements (Summary, Hourly, Actual Measurements) and location to type physician Interpretation.

9.2.4 Report

Checked Off reports can be printed (automatically or manually) to printer attached to the computer.



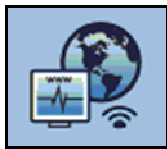
10. Spirometry

Coming Soon!

11. Remote Server/Cloud Database

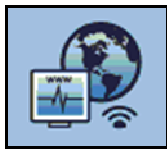


Remote Server Database Toggle



Press  Button to toggle and remote database.

id remote

Cardiology Suite software provide  e local computer (or mobile phone) and also at the same time in the cloud (remote server). Cloud ECG data is available for review/editing remotely using Cardiology Suite Software or a standard Internet browser.

Following procedure under "Utility/Configuration/Login" is needed for customer to save, review and edit data remotely using cloud/remote operation:

1. Generate their own User Name and Password
2. Request a Confirmation Code from PBI
3. Enter Confirmation code (which customer received from PBI)
4. Setup of frequency for data synchronization between local computer and remote server.

12. Utilities

12.1 Topics

12.1.1 Configuration

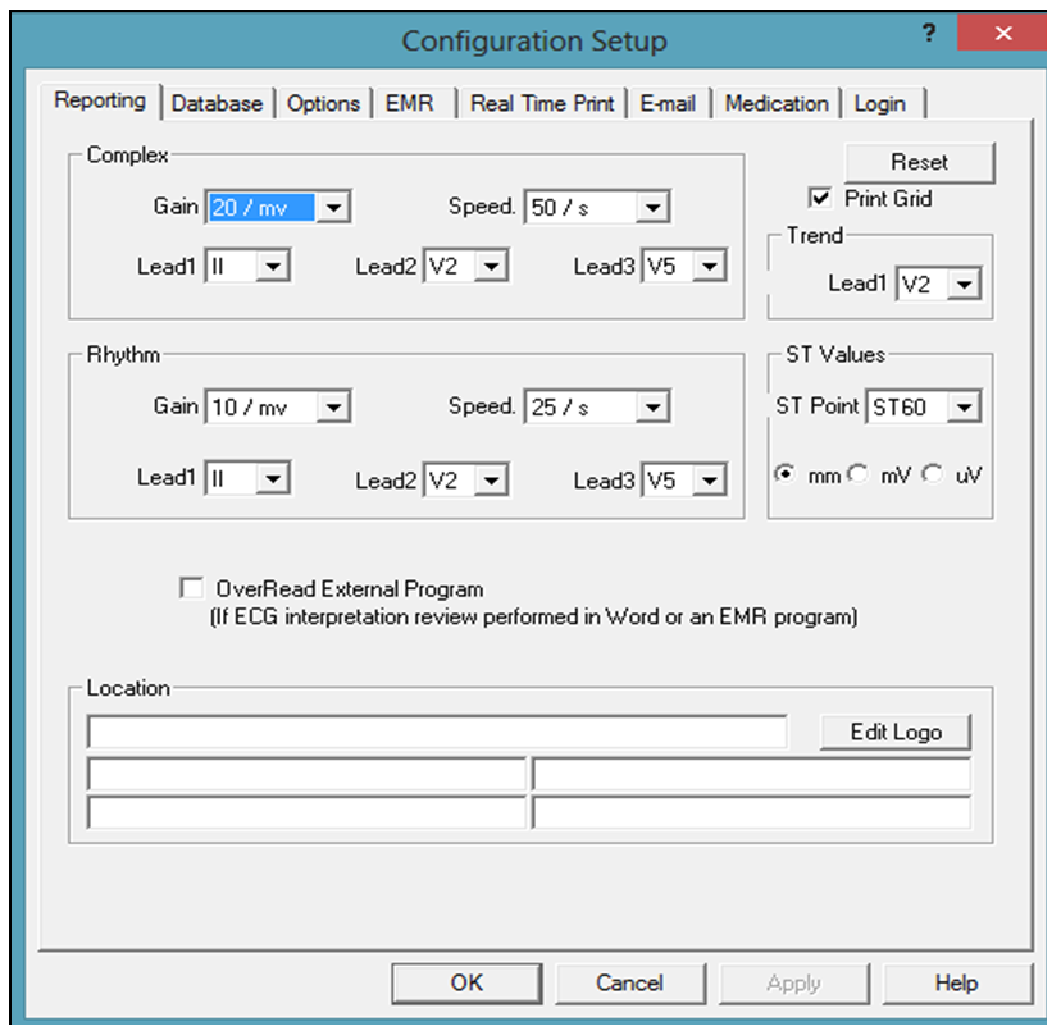
Configuration Section is used to setup various default parameters of using QRS-Card™ Cardiology Suite Software. These options include:

- Reporting
- Database
- Measurements
- Options
- GDT Interface
- Real-Time Print
- Email
- Login

REPORTING

Use the Reporting Configuration Property Sheet to set the default values for reporting ECG results. Access the property sheet by the following method:

Select Utility > Configuration and click on the Reporting tab in the Configuration Setup property box.



Complex

Gain- Defines the Gain for ECG complexes to be printed on the Stress ECG reports. Options are 5, 10, 20 or 40 mm/mV.

Speed- Defines the Speed for ECG complexes to be printed on the Stress ECG reports. Options are 25, 50 or 100 mm/sec.

Lead 1- Defines the 1st complex lead to be printed on the Stress ECG reports.

Lead 2- Defines the 2nd complex lead to be printed on the Stress or Hi-Res ECG reports.

Lead 3- Defines the 3rd complex lead to be printed on the Stress or Hi-Res ECG reports.

Rhythm

Gain- Defines the Gain for the ECG to be printed on the ECG reports. Options are 5, 10 or 20 mm/mV.

Speed- Defines the Speed for the ECG to be printed on the ECG reports. Options are 5, 10, 25 or 50 mm/sec.

Lead 1- Defines the 1st ECG Lead for the three lead ECG reports.

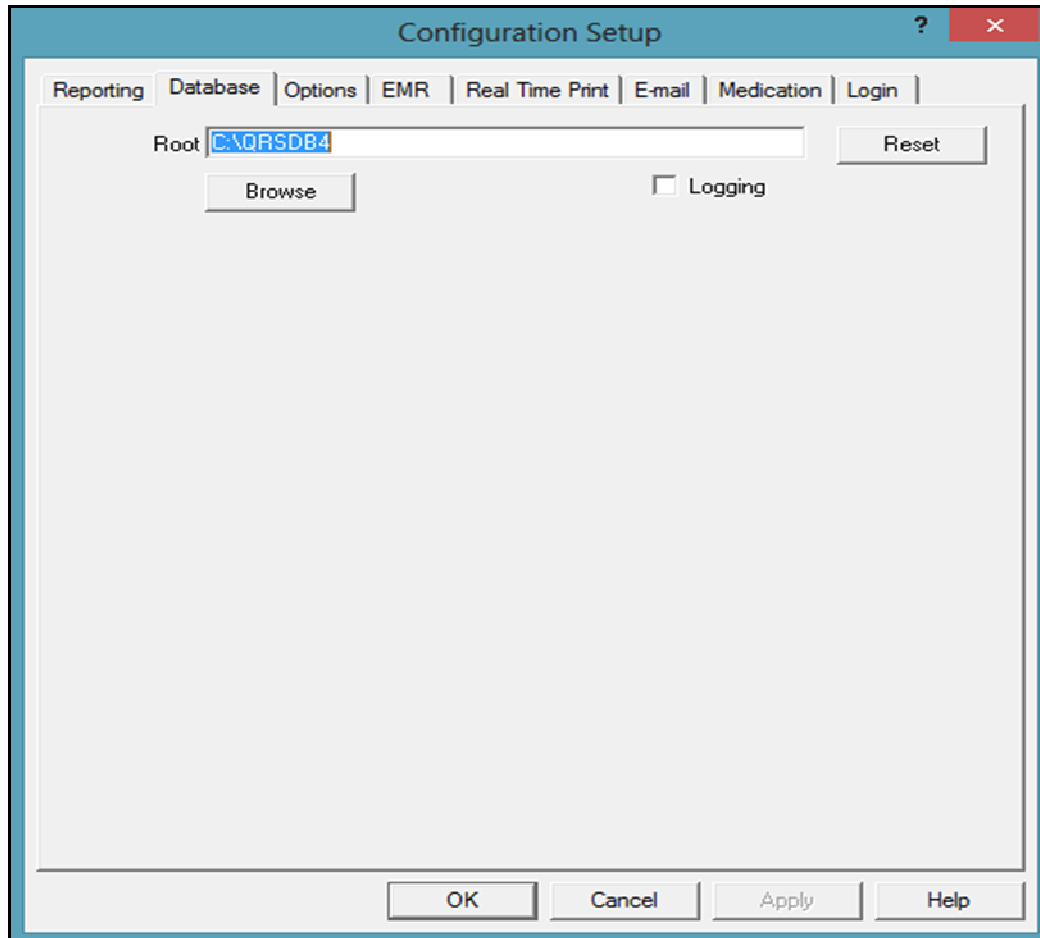
Lead 2- Defines the 2nd ECG Lead for the three lead ECG reports.

Lead 3- Defines the 3rd ECG Lead for the three lead ECG reports.

DATABASE

The Database property sheet allows the user to select the location that the ECG data files will be stored. This property sheet can be accessed by the following method:

Select Utility > Configuration and select the Database tab in the Configuration Setup property box.



Root: Defines the default root directory for all ECG data files. To change the directory, click the “Browse“ button and select the directory.

Reset- use the Reset button to bring all parameters back to their factory defaults.

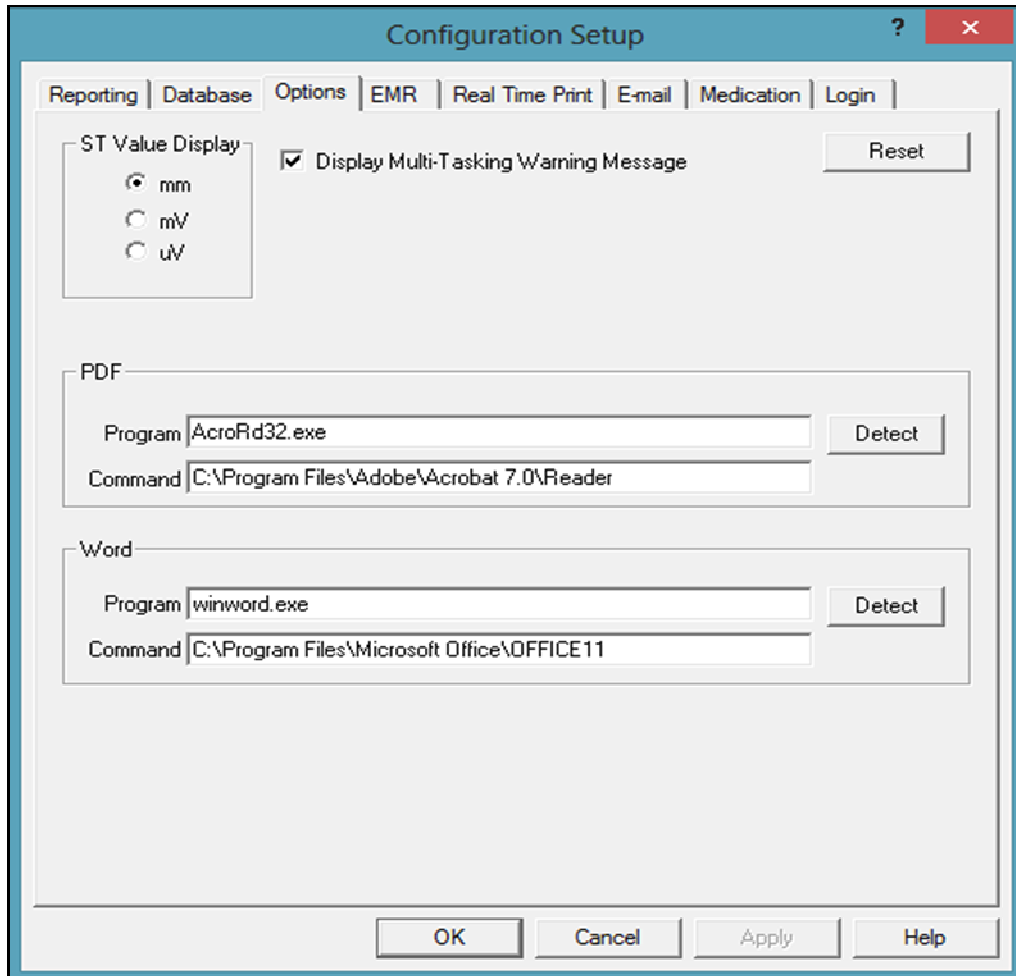
Logging- Customer support may ask for this to be selected in order to pinpoint a problem.

NOTICE ECG database is in published “SCP” format. Each test is a separate file. These files are stored in “qrsdb4/files” folder. It is important the user backup these individual SCP file for data security purposes.

OPTIONS:

Select Utility > Configuration and select the “Option” tab.

This option selects ST Value’s parameters, Multitask message display, PDF File Viewer Setup and Word program setup.



The screenshot shows the "Configuration Setup" dialog box with the "Options" tab selected. The dialog has a title bar with a question mark and a close button. Below the title bar are several tabs: Reporting, Database, Options (selected), EMR, Real Time Print, E-mail, Medication, and Login. The "Options" tab contains three main sections:

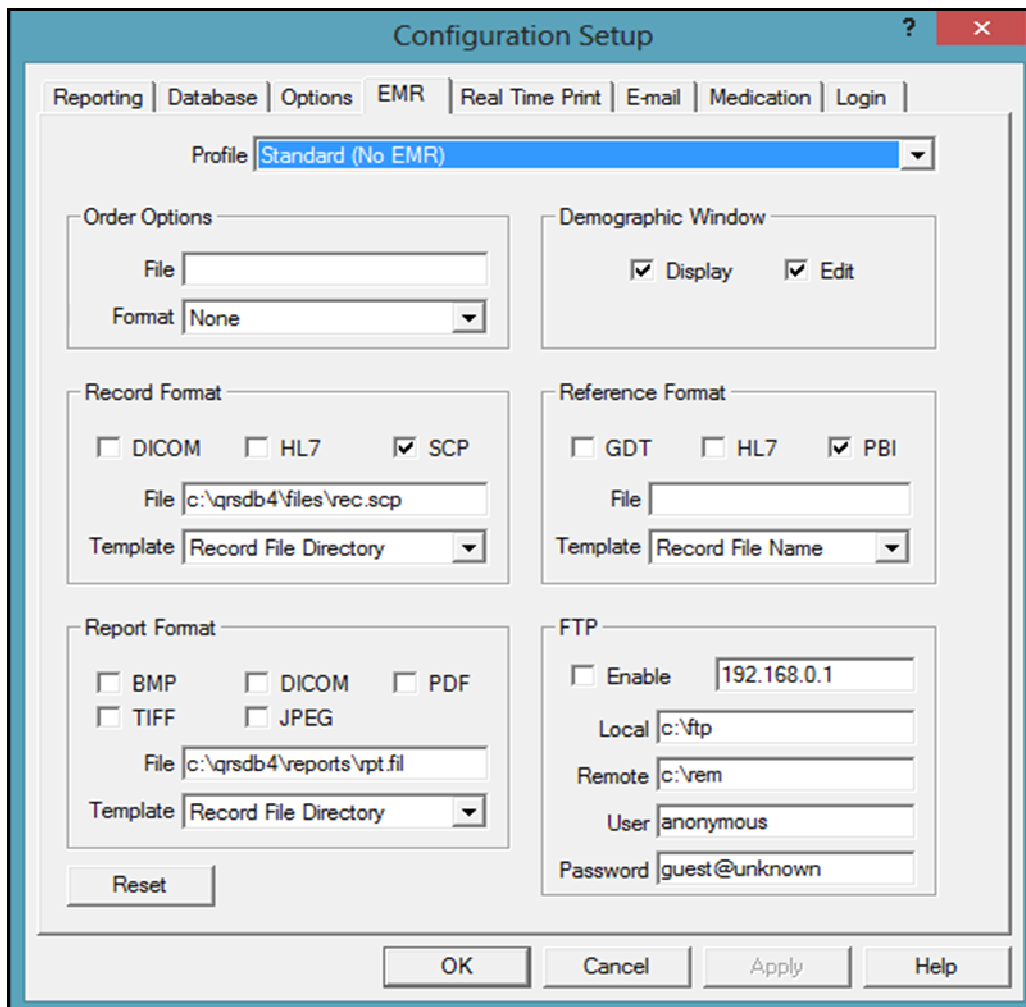
- ST Value Display:** A group box containing three radio buttons: "mm" (selected), "mV", and "uV". To the right of this group is a checked checkbox labeled "Display Multi-Tasking Warning Message" and a "Reset" button.
- PDF:** A group box containing two text input fields. The "Program" field contains "AcroRd32.exe" and the "Command" field contains "C:\Program Files\Adobe\Acrobat 7.0\Reader". A "Detect" button is located to the right of the Command field.
- Word:** A group box containing two text input fields. The "Program" field contains "winword.exe" and the "Command" field contains "C:\Program Files\Microsoft Office\OFFICE11". A "Detect" button is located to the right of the Command field.

At the bottom of the dialog are four buttons: "OK", "Cancel", "Apply", and "Help".

EMR:

Select Utility > Configuration and select the “EMR” tab.

This option is for EMR interfacing setups. For more help with setup, please contact Pulse Biomedical Technical support team.

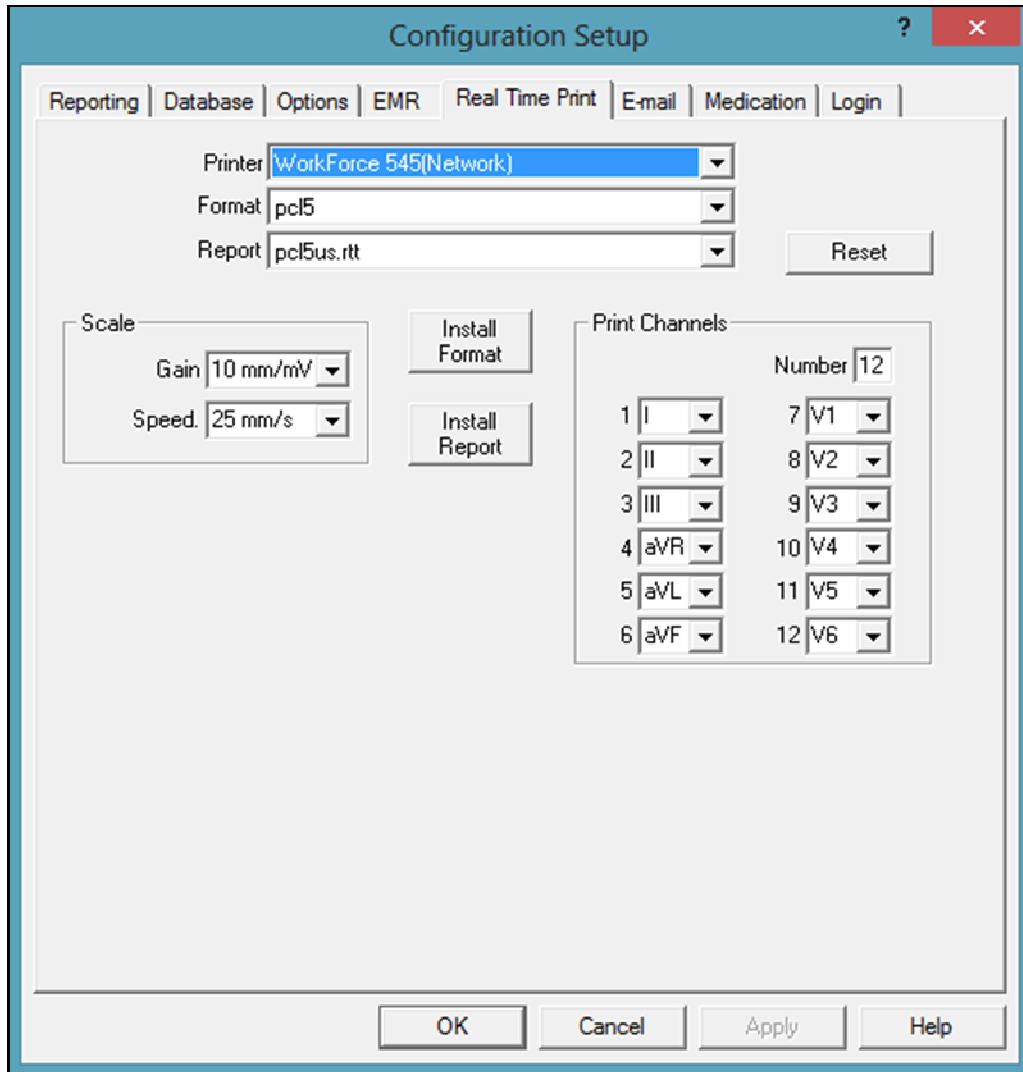


The screenshot shows the 'Configuration Setup' dialog box with the 'EMR' tab selected. The 'Profile' dropdown is set to 'Standard (No EMR)'. The 'Order Options' section has an empty 'File' field and 'Format' set to 'None'. The 'Demographic Window' section has 'Display' and 'Edit' checked. The 'Record Format' section has 'SCP' checked, with 'File' set to 'c:\qrsdb4\files\rec.scp' and 'Template' set to 'Record File Directory'. The 'Reference Format' section has 'PBI' checked, with an empty 'File' field and 'Template' set to 'Record File Name'. The 'Report Format' section has 'BMP', 'TIFF', 'DICOM', and 'JPEG' unchecked, with 'File' set to 'c:\qrsdb4\reports\vpt.fil' and 'Template' set to 'Record File Directory'. The 'FTP' section has 'Enable' unchecked, 'Local' set to 'c:\ftp', 'Remote' set to 'c:\rem', 'User' set to 'anonymous', and 'Password' set to 'guest@unknown'. A 'Reset' button is located at the bottom left of the dialog. At the bottom of the dialog are 'OK', 'Cancel', 'Apply', and 'Help' buttons.

REALTIME PRINT

Select Utility > Configuration and select the “Real Time Print” tab.

This option is used to Enable or Disable Real Time Printer and to Setup Real Time Report Parameters.



Configuration Setup ? [X]

Reporting Database Options EMR **Real Time Print** E-mail Medication Login

Printer: WorkForce 545(Network) [v]
 Format: pcl5 [v]
 Report: pcl5us.rtt [v] [Reset]

Scale
 Gain: 10 mm/mV [v]
 Speed: 25 mm/s [v] [Install Format] [Install Report]

Print Channels
 Number: 12

1	I	7	V1
2	II	8	V2
3	III	9	V3
4	aVR	10	V4
5	aVL	11	V5
6	aVF	12	V6

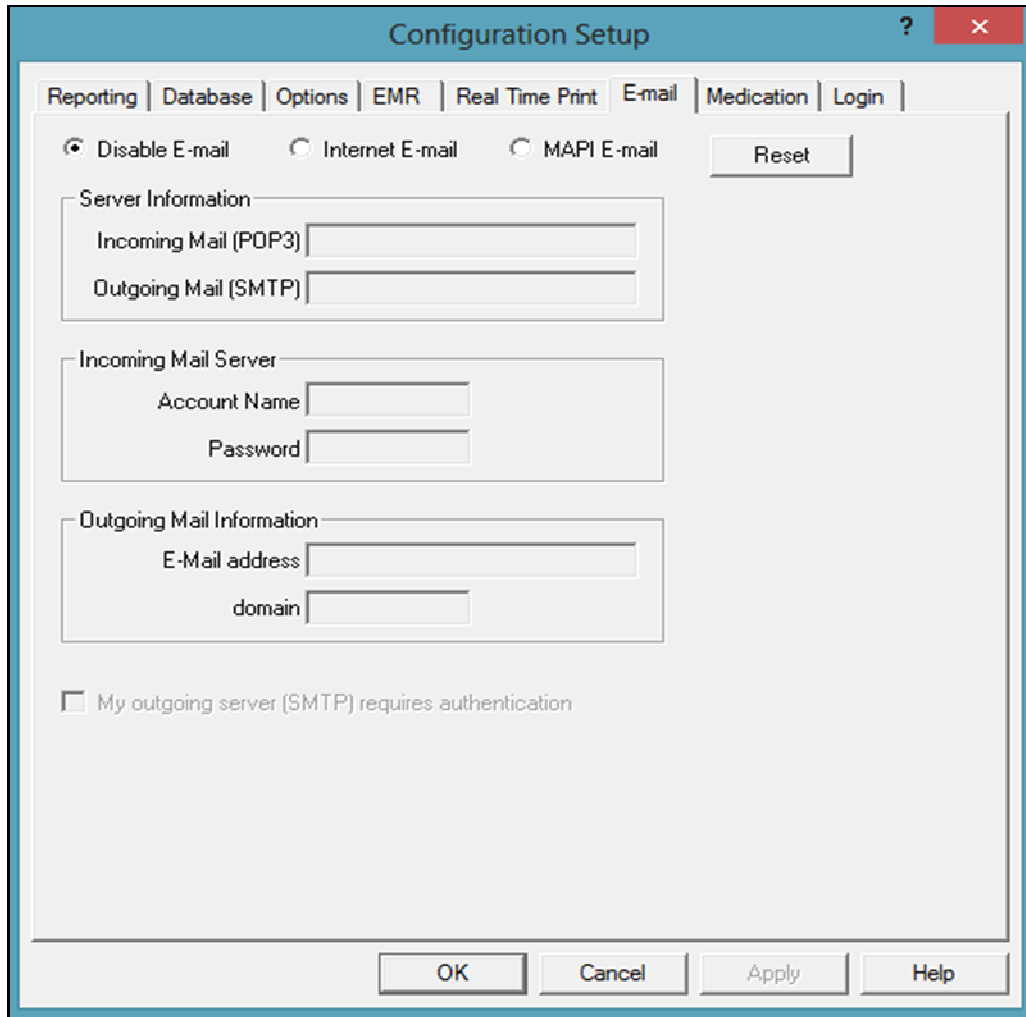
[OK] [Cancel] [Apply] [Help]

NOTICE Real Time Print requires a PCL5 compatible printer “pcl5us.rtt” is the default report but, in case of printing errors select “genrtp.rtt” report.

EMAIL

Select Utility > Configuration and select the “EMAIL” tab.

This option is used to Setup Server Parameter for Sending and Receiving ECG’s via Email.



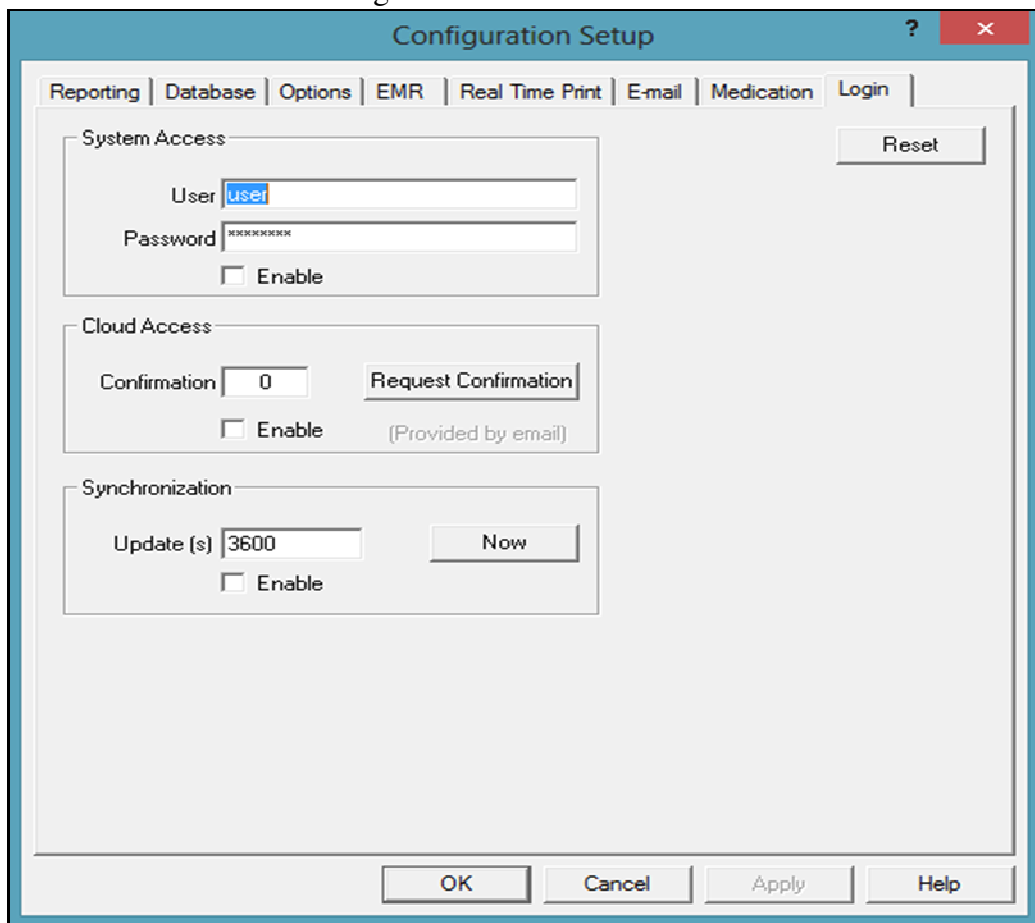
The screenshot shows the "Configuration Setup" dialog box with the "Email" tab selected. The dialog has a title bar with a question mark and a close button. The tabs include Reporting, Database, Options, EMR, Real Time Print, Email, Medication, and Login. The "Email" tab contains the following options and fields:

- Radio buttons for "Disable E-mail" (selected), "Internet E-mail", and "MAPI E-mail".
- A "Reset" button.
- A "Server Information" section with two text boxes: "Incoming Mail (POP3)" and "Outgoing Mail (SMTP)".
- An "Incoming Mail Server" section with two text boxes: "Account Name" and "Password".
- An "Outgoing Mail Information" section with two text boxes: "E-Mail address" and "domain".
- A checkbox labeled "My outgoing server (SMTP) requires authentication".
- Buttons for "OK", "Cancel", "Apply", and "Help" at the bottom.

LOGIN

Select Utility > Configuration and select the “LOGIN” tab.

This utility is designed for increased security: a) Software Access; b) Remote Server/Cloud Access. See Page “101” for detail on **Remote/Cloud Server**



Systems Access: Allows user to set unique user name and password to prevent unauthorized access to the Cardiology Suite & Remote/Cloud Database Server

- User** : Remote/Cloud Server & System Access account username, chosen by the user.
- Password** : Remote/Cloud Server & System Access password, chosen by the user.
- Enable** : Enable or disable Remote/Cloud Server account options.

Cloud Access : User will set up his Remote/Cloud Server Account which will be activated through a verification email to the email address provided by the user

Confirmation Request : Remote/Cloud Server account confirmation code, used to verify the account.

Confirmation : E-mails the user a Remote/Cloud Server account confirmation code.

Enable : Enable or disable the use of the Remote/Cloud Server account confirmation code.

Synchronization: After receiving confirmation of cloud access login credentials, user can synchronize the local database on remote/cloud server.

Update : Sets the rate of the Remote/Cloud Server synchronization utility in seconds.

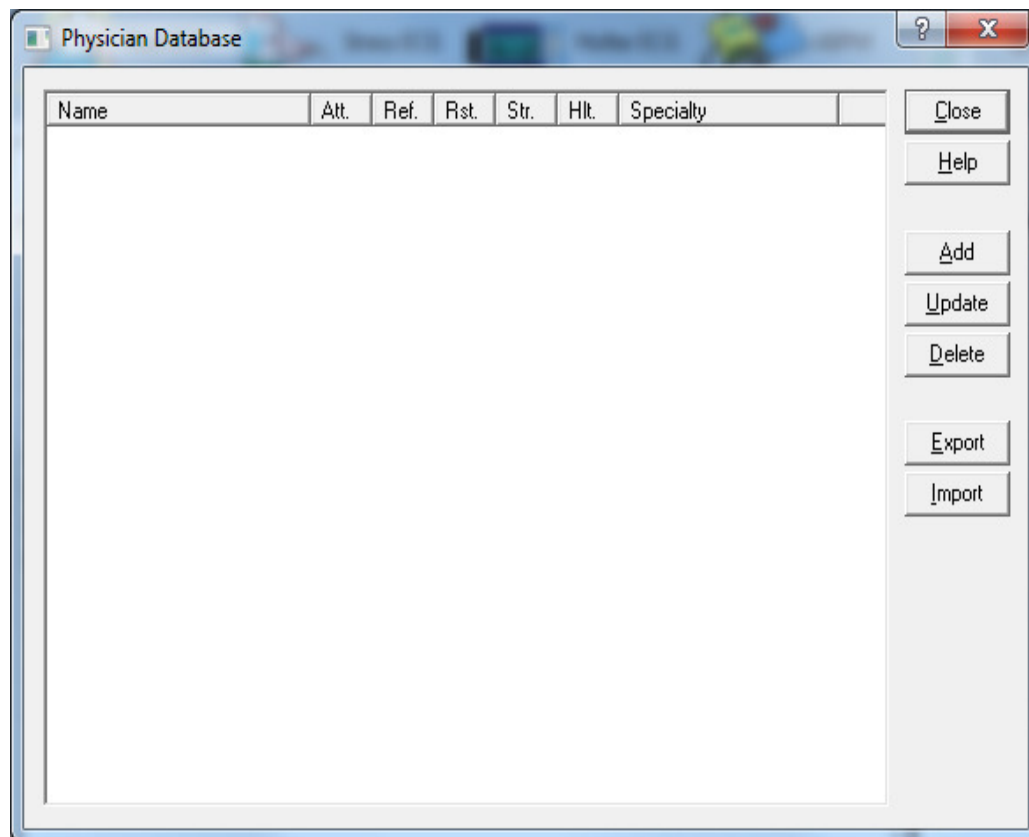
Now : Forces Remote/Cloud Server synchronization utility to run.

Enable : Enable or disable Remote/Cloud Server synchronization.

12.1.2 Physicians

Select Utility > Physician then property box will appear

Names of attending and referring Physicians database are stored using this option.



Add: Select to enter new Physician or Referring Physician name

Update: Select to update on an existing entry in Physician database

Delete: Select to delete an entry in Physician database

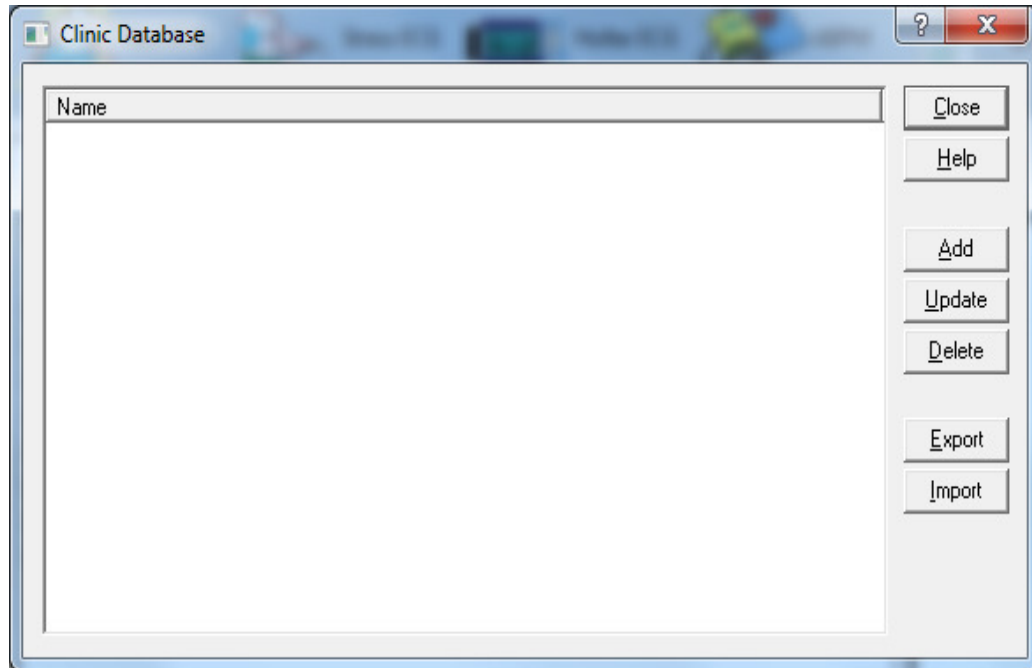
Export: Select to Export a listing of an existing Physician database in text format

Import: Select to Import an existing text format Physician list into Physician database

12.1.3 Clinics

Select Utility > “Clinics” then property box will appear

This option is use to Enter Clinics Names for a multi-practice medical office.



Add: Select to Add a new Clinic name in the Clinic database

Update: Select to update an existing Clinic name and address

Delete: Select to Delete an existing Clinic name in the database

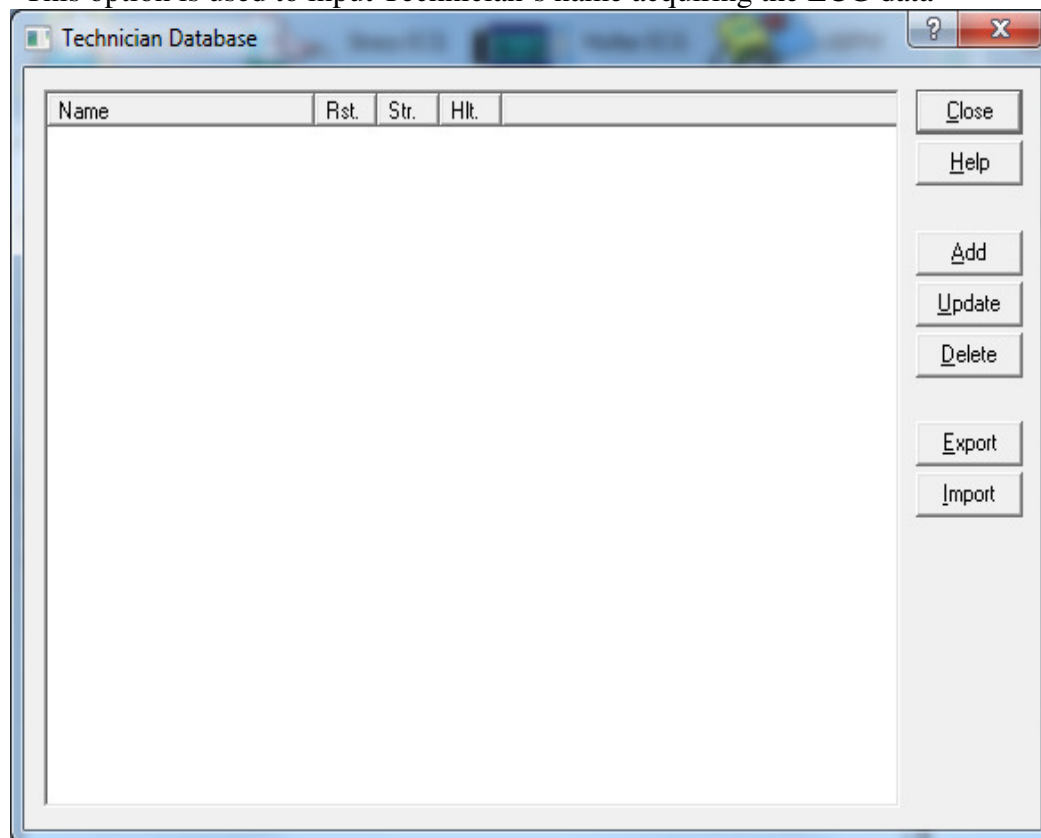
Export: Select to Export an existing Clinic database to text format

Import: Select to Import a text format Clinics names into Clinics database

12.1.4 Technicians

Select “Utility > Technician” then property box will appear

This option is used to input Technician’s name acquiring the ECG data



Add: Select to Add a new Technician Name in the database

Update: Select to Update an existing Technician name in the technician database

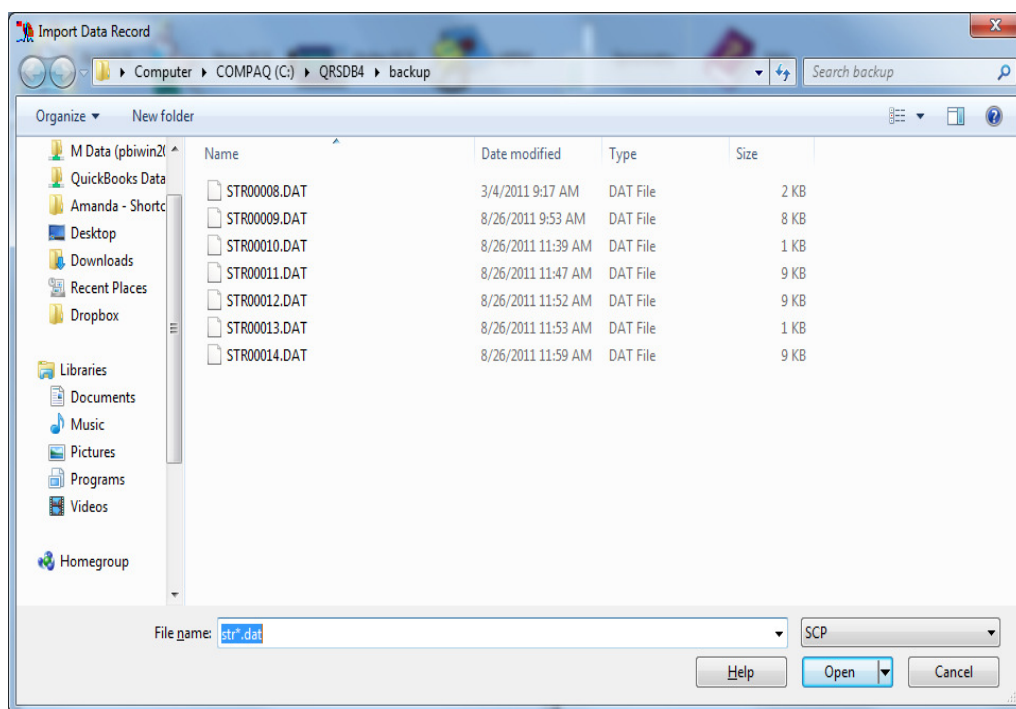
Delete: Select to Delete an existing technician name from the database

Export: Select to Export an existing technician database to text format

Import: Select to Import a text format technician names into technician database

12.1.5 Import Records

Select Utility > Import Records then property box will appear



Cardiology Suite™ will access the 'backup' database. Select the file you would like to import and click 'Open'. Cardiology Suite will import the selected file into your test database.

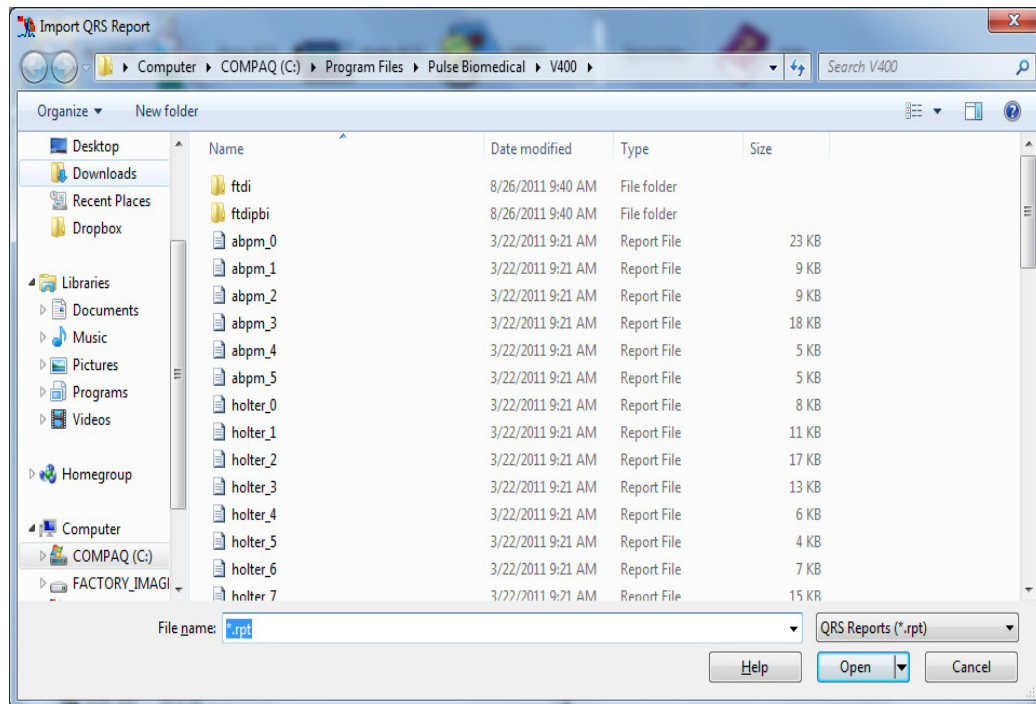
12.1.6 Import Reports

Select Utility > Import Reports

The Import Report option is used to import any new ECG report formats supplied by Pulse Biomedical or to import any changes made to already existing report formats.

To import a report format, highlight the desired report and click Open. The new report will be imported into your report database.

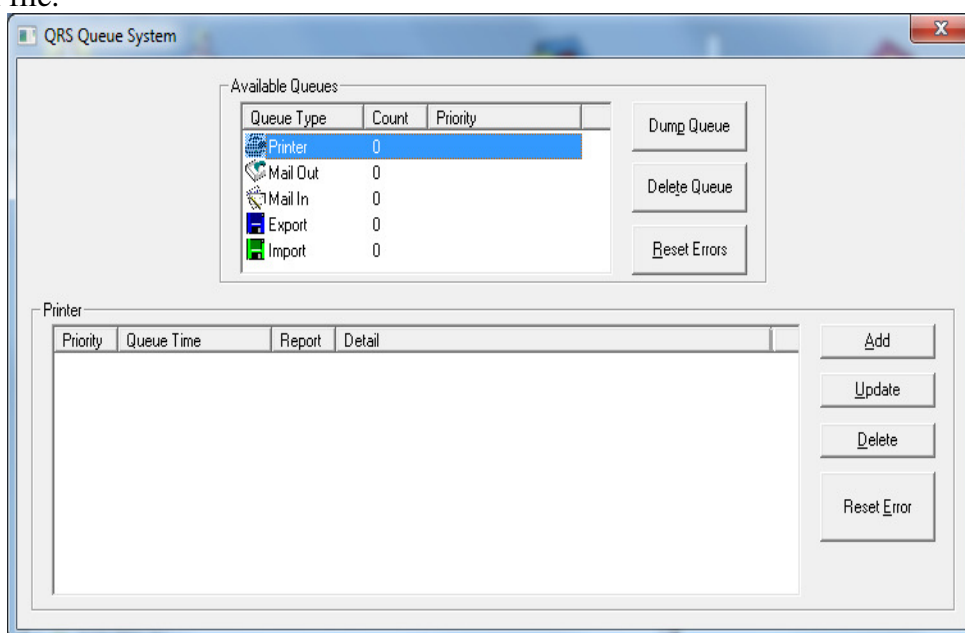
To make changes to the format of an existing report go to Windows Explorer. In the directory containing the QRS-Card™ software, click on the report to be modified with the right mouse button. Select Open. The existing report format will open on the Notepad. Make the desired changes and save them. Return to the QRS-Card™ software and the Import Report option. Highlight the modified report and click on Open. The modified report is now ready for use.



12.1.7 Queue System

Select “Utility > Queue System”

The Queue System places the ECG traces from the patient Tests database in the queue system. At a later time, the user can dump the queue to a printer, E-mail the traces, or export the traces to an external file (one not connected to the QRS databases). Using the Queue system, the user can also receive ECG traces via E-mail or import a trace from an external file.



The system will display the QRS Queue System dialog box.

Dump Queue- Clicking on Dump Queue will dump the entire selected queue to the appropriate output device and the Queue Dump dialog box appears. The Queue Dump dialog box shows the status of the queue dump. Any errors that occurred will be listed.

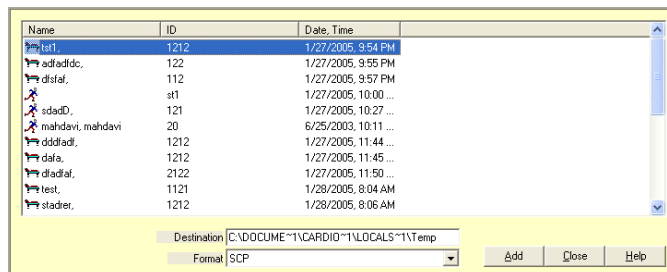
Delete Queue- Clicking on Delete Queue will delete all items in the type of queue selected.

Reset Errors- Clicking on Reset Errors will reset any errors that occurred when dumping a queue.

Add- Clicking on Add will cause the system to display the appropriate Add dialog box for the selected output device. See the Available Queues below for more information.

Update Clicking on Update will bring up the Update QRS Queue Entry dialog box. Details of the selected item can be edited in this dialog box. In particular, the type of report selected for a particular queue item can be edited using this option.

Delete Clicking on Delete in the bottom section of the dialog box allows the user to delete individual items from a particular queue.



Available Queue Options

Print Queue

To add to the Print Queue, double-click on Printer under Available Queues in the Queue Detail Dialog Box or highlight Printer and click on the Add button. The Add Entries to QRS Print Queue Dialog Box will be displayed.

Select the test and the type of report desired, add any comments necessary and click on Add. Click on the Close button to exit this dialog box. The selected traces will be copied to the Print Queue. Select Dump and the traces will be printed.

To aid in finding an encounter, the user may sort the database by name, ID or date/time the encounter was obtained by clicking on the appropriate heading name.

Mail Out

The Mail Out option allows the user to E-mail ECG traces.

Note: For best results, connect to the Internet before entering the Queue System.

To add to the Mail Out Queue, double-click on the Mail Out option under Available Queues or highlight Mail Out and click on the Add button. The Add Entries to QRS Mail Out Box Queue Dialog Box will appear.

Highlight the encounter to be E-mailed and using the directory option, enter the recipient E-mail address. Click on Add to the queue. Click on Close to exit the dialog box. Click on Dump Queue to start the E-mail process.

Mail In

The Mail In option allows the user to receive ECG traces via E-mail.

Note: For best results, connect to the Internet before entering the Queue System.

As the Queue System is accessed, a message "Retrieving message X or X" will appear if E-mail has been sent to you since you last logged onto the Internet. The Mail In option in the Available Queue box will show the number of messages.

Highlight Mail In and click on Dump Queue. The messages will be dumped directly into your database.

Note: Be aware that the time on the encounter is when the test was taken not when it was e-mailed or dumped into the database.

Queue Export

Selecting the Export Queue option will allow the user to export ECG traces to an external file.

To export a file(S) double click on Export under Available Queues or highlight Export and click on the Add button. The Add Entries to QRS Export Queue Dialog Box will be displayed.

Select the file(S) to be exported and click on Add Encounter. Click on the Close button to exit this dialog box. The files will be copied to the Export Queue. Select Dump. The selected files will be exported into the Windows Temporary (TAMP) Directory.

Queue Import

Selecting the Import Queue option will allow the user to import ECG trances from an external file.

To add to the Import Queue, double-click on Import under Available Queues or highlight Import and click on the Add button. The Add Entries to QRS Import Queue Dialog Box will be displayed.

Select the file to be imported and the format to be used and click Apply.

12.1.8 Rebuild

Select Utility > Rebuild

This selection is used to rebuild (Re-Index) a corrupted or bad database.

This selection can also be used if two or more databases needs to be combined together into one database (e.g copy both database *.SCP files into “qrsdb4\files” folder then select Rebuild command)

NOTICE *“Rebuild Database” may take longer with large data files like Holter ECG. Wait times would be comparatively less in case of Resting and Stress ECG files.*

13. Logs

Log files are created each time the STWIN program is run. This file keep track of all operation performed by the user. More importantly this files keep logs of any errors occur during the usage of the program.

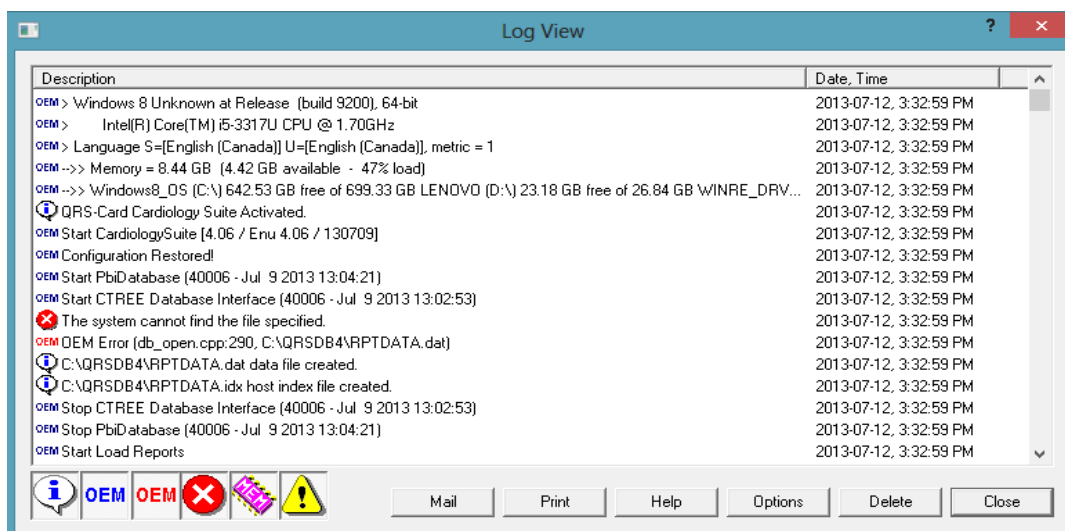
Viewing the file can very helpful in troubleshooting problems with the program.

Status

Use the *Status* command to display the status log. The Status command can be executed by the following method:

- From the “Logs” Menu select “Status”.

When the Status command is executed the system displays the Log View Dialog Box. This log file shows the most recent events the system executed.



Error

Use the *Error* command to display the error log. The Error command can be executed by the following method:

- From the Logs Menu select Error.

Executing the *Error* command causes the system displays the Error Log View Dialog Box. This log file shows the most recent errors that the system encountered.

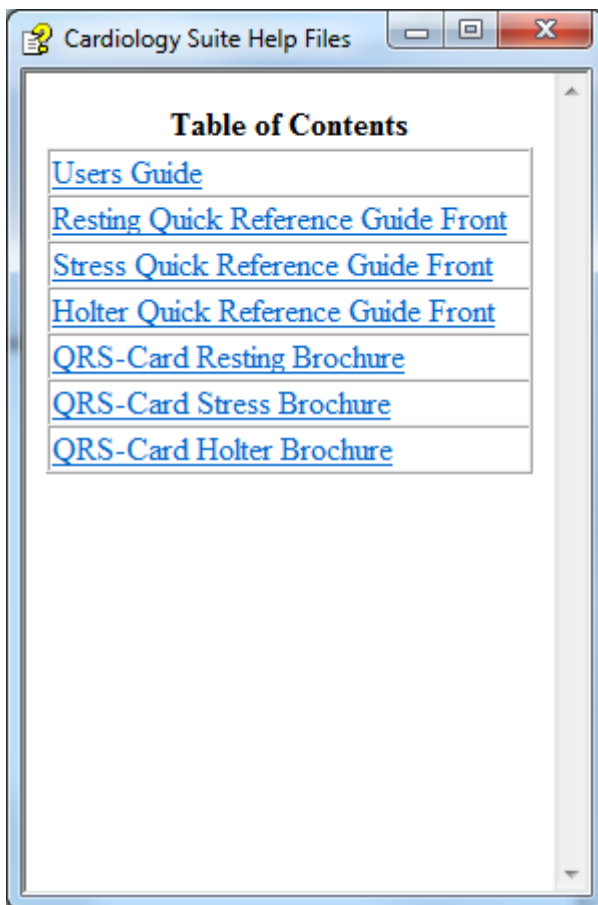
Pressing **MAIL** tab in the Log View will send the log file directly to PBI technical support.

NOTICE Error Log file is the ***MOST IMPORTANT*** file for trouble shooting the **QRS-Card™** Hardware and software. During technical support call to PBI the information contains in this file will assist PBI the most information to solve or diagnose the problem over telephone.

14. Help

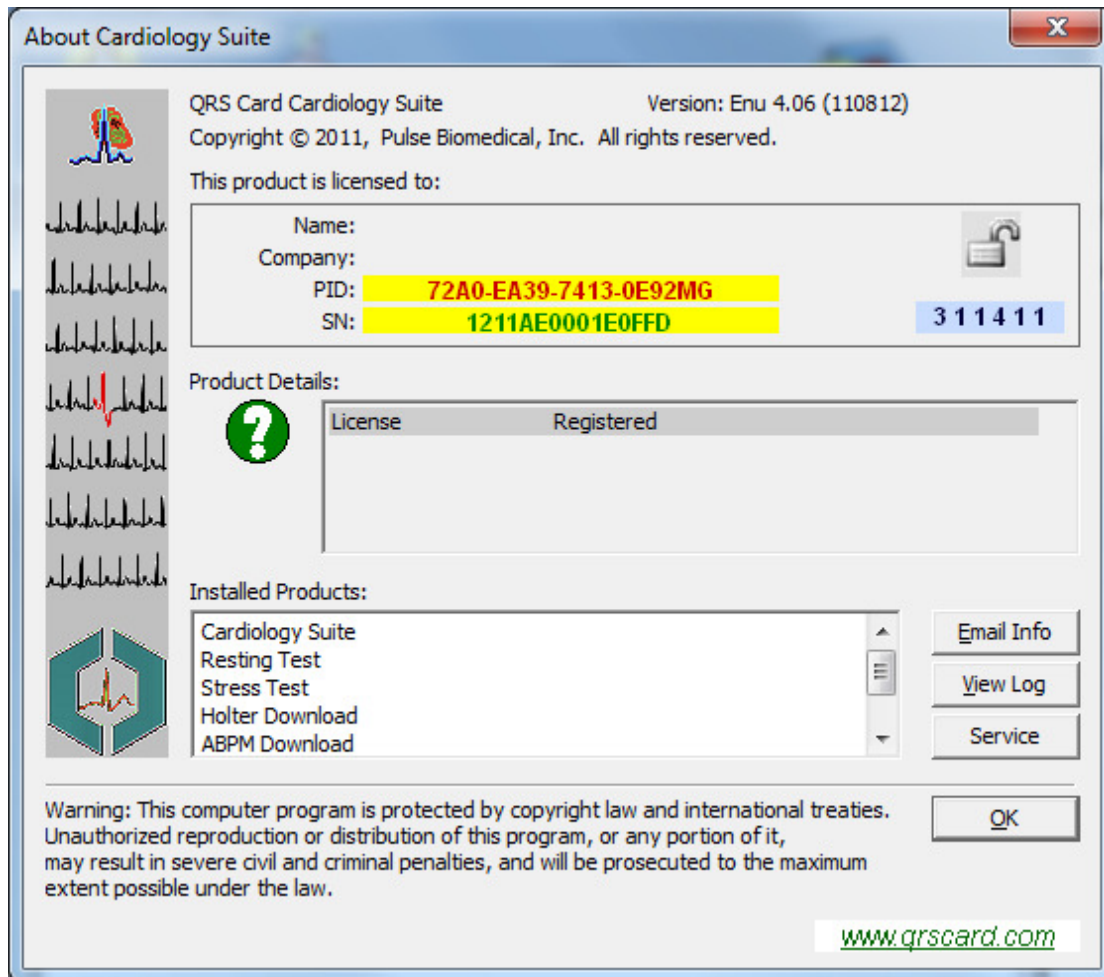
14.1 Contents

The Help → Contents screen allows users to explore the Cardiology Suite user guide, Quick Reference Guides and Brochures





14.2 About

The Help → About screen displays various information about licensing and software versions.



License/Unlock Code:

- Click  to enter the PID available on the “USB Dongle” received with the device
-  **311411** Numbers below the “Lock” represent your licensed products and features in the software

Appendix 1: Accessories, Warranty and Repairs

Accessories

The Pulse Biomedical, Inc. warranty can only be honored if you use Pulse Biomedical, Inc. approved accessories and replacement parts.



Use of accessories other than those recommended by Pulse Biomedical, Inc. may compromise product performance.

Warranty, Service, and Spare Parts

Warranty

All repairs on products under warranty must be performed or approved by Pulse Biomedical, Inc. Unauthorized repairs will void the warranty. In addition, whether or not covered under warranty, any product repair shall exclusively be performed by Pulse Biomedical, Inc certified service personnel.

Assistance and Parts

If the product fails to function properly or if assistance, service, or spare parts are required, contact the nearest Pulse Biomedical, Inc Technical Support Center.

USA + 610-666-5510

Europe + 49-7434-316038

Before contacting Pulse Biomedical, Inc it is helpful to attempt to duplicate the problem and to check all accessories to ensure that they are not the cause of the problem.

When calling, please be prepared to provide:

- The serial number of the device
- Complete description of the problem
- The serial number of your product (if applicable)
- The complete name, address and phone number of your facility
- For out-of-warranty repairs or spare parts orders, a purchase order (or credit card) number
- For parts order, the required spare or replacement part number(s)

Repairs

If your product requires warranty, extended warranty, or non-warranty repair service, please call first the nearest Pulse Biomedical, Inc Technical Support Center. A representative will assist you troubleshooting the problem and will make every effort to solve it over the phone, avoiding potential unnecessary return.

In case the return cannot be avoided, the representative will record all necessary information and will provide a Return Authorization (RA) number, as well as the appropriate return address. A Return Authorization (RA) number must be obtained prior to any return.

NOTICE

Pulse Biomedical, Inc does not accept returned products without an RA.

Packing Instructions

If you have to return goods for service, follow these recommended packing instructions:

- Remove all cables before packing, unless you suspect they are associated with the problem.
- Pack the device safely and include a packing list and the Pulse Biomedical, Inc Return Authorization (RA) number.

It is recommended that all returned goods be insured. Claims for loss or damage to the product must be initiated by the sender.

Limited Warranty Statement

Pulse Biomedical, Inc, Inc. warrants that the Pulse Biomedical, Inc Cardiology Suite computer based product you have purchased meets the labeled specifications of the Product and will be free from defects in materials and workmanship that occur within 1 year after the date of purchase.

Accessories used with the Product are warranted for 90 days after the date of purchase.

The date of purchase is: 1) the date specified in our records, if you purchased the Product directly from us, 2) the date specified in the warranty registration card that we ask you to send to us, or 3) if you don't return the warranty registration card, 120 days after the date on which the Product was sold to the dealer from whom you bought the Product, as documented in our records.

This warranty does not cover damage caused by: 1) handling during shipping, 2) use or maintenance contrary to labeled instructions, 3) alteration or repair by anyone not authorized by Pulse Biomedical, Inc, and 4) accidents.

If a Product or accessory covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period described above, Pulse Biomedical, Inc will, at its discretion, repair or replace the defective Product or accessory free of charge.

You must obtain a return authorization from Pulse Biomedical, Inc to return your Product before you send it to Pulse Biomedical, Inc's designated service center for repair.

Pulse Biomedical Inc. makes no warranties, either expressed or implied, regarding the QRS-Card™ Cardiology Suite 4.06, its merchantability or its fitness for any particular purpose, with the exception of any limited warranties which are disclosed in this manual. The exclusion of implied warranties is not permitted by some states. The above exclusion may not apply to you. This warranty provides you with specific legal rights. There may be other rights that you may have which vary from state to state.

THIS WARRANTY IS IN LIEU OF ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. PULSE BIOMEDICAL, INC'S OBLIGATION UNDER THIS WARRANTY IS LIMITED TO REPAIR OR REPLACEMENT OF PRODUCTS CONTAINING A DEFECT. Pulse Biomedical IS NOT RESPONSIBLE FOR ANY INDIRECT OR CONSEQUENTIAL DAMAGES RESULTING FROM A PRODUCT DEFECT COVERED BY THE WARRANTY.

Appendix 2: Patient Preparation_[B89]

Acquiring a Good Quality Resting ECG

Acquiring a good quality ECG depends upon:

1. ECG technician (operator experience)
2. Patient (patient electrode preparation)
3. Environment (low electrical interference)

PBI has provided you with a high quality QRS-Card™ Cardiology Suite device. When the QRS-Card™ Cardiology Suite is used in conjunction with a computer to acquire ECG data from a patient:

- It is important that the computer you are using with the QRS-Card™ Cardiology Suite be of high quality with low electrical noise generation. If you have not purchased your computer system from PBI or do not have the list of approved low-noise computers in the marketplace, please call us for assistance.
- It is important that the Electrical Ground to the AC mains be properly grounded and in good working order.
- It is important that no electrical noise be generated by any equipment in the vicinity of the QRS-Card™ Cardiology Suite ECG machine.

PBI has tested your QRS-Card™ Cardiology Suite for the best ECG performance.

If you find electrical noise in the signal during a patient ECG, please check the following before calling PBI's technical support line:

- Check that the patient is properly prepared and the lead connections are tightly installed.
- Check the ECG environment to see if there is other electrical equipment present that may be creating the electrical noise.
- Check your computer brand and model to make sure they are from an approved manufacturer.

Electrical noise can be controlled if the above noise detection steps are investigated and corrected.

For any further help, please call Pulse Biomedical Inc. at 610-666-5510.

Before calling PBI please note the serial number of your QRS-Card™ Device.

Prepping Patient & Electrode Placement

Important: Because QRS-Card™ Cardiology Suite is a 12 lead electrocardiograph all electrodes must be correctly connected. Proper skin preparation (abrasion if necessary) and proper electrodes are very important for a good signal quality.

Important: When you connect the electrodes to the patient, make sure that the electrodes and their connectors (also the RL/N electrode) do not contact other conducting parts (including earth).

Extremity electrodes The electrodes may be placed on any part of the arms (as long as they are below the shoulders) or the legs (as long as they are below the inguinal fold anteriorly and the gluteal fold posteriorly). Any other placement necessary by deformed or missing extremities must be noted on the record.

Limb Leads/Extremity Electrodes (RA, LA, RL, LL) [B90]

The electrodes may be placed on any part of the arms (as long as they are below the shoulders) or the legs (as long as they are below the inguinal fold anteriorly and the gluteal fold posteriorly). Any other placement necessary by deformed or missing extremities must be noted on the record.

Electrode Placement: attach electrodes to the patient in the following positions:

AHA	Position	IEC
V1	4 th intercostal space at the right border of the sternum	C1
V2	4 th intercostal space at the left border of the sternum	C2
V3	Midway between locations V2 and V4	C3
V4	At the mid-clavicular line in the 5 th intercostal space.	C4
V5	At the anterior axillary line on the same horizontal level as V4.	C5
V6	At the midaxillary line on the same horizontal level as V4 and V5.	C6
RA	Right arm.	R
LA	Left arm.	L
RL	Right leg.	N
LL	Left leg.	F

[B91]

Reusable Electrodes

Each electrode must be attached securely. The electrode paste, gel, or cream must cover an area the size of the electrode, but must not extend beyond it, especially on the chest.

[129]

Disposable Tab Electrodes

Disposable electrodes have conductive material on the adhesive side only. The electrode tab must be placed between (clip) or on (banana or pushbutton) the electrode adapter, and remain flat. Do not attempt to place the electrode adapter so close to the circular part of the electrode that the tab of the electrode is bent, or contact is made with the conductive gel. Gently tug on the electrode adapter to ensure that the electrode adapter is properly placed on the electrode. Good and accurate placement of each electrode on the first attempt is important. Each time an electrode is lifted off the skin and reattached, the adhesive gel becomes less effective.

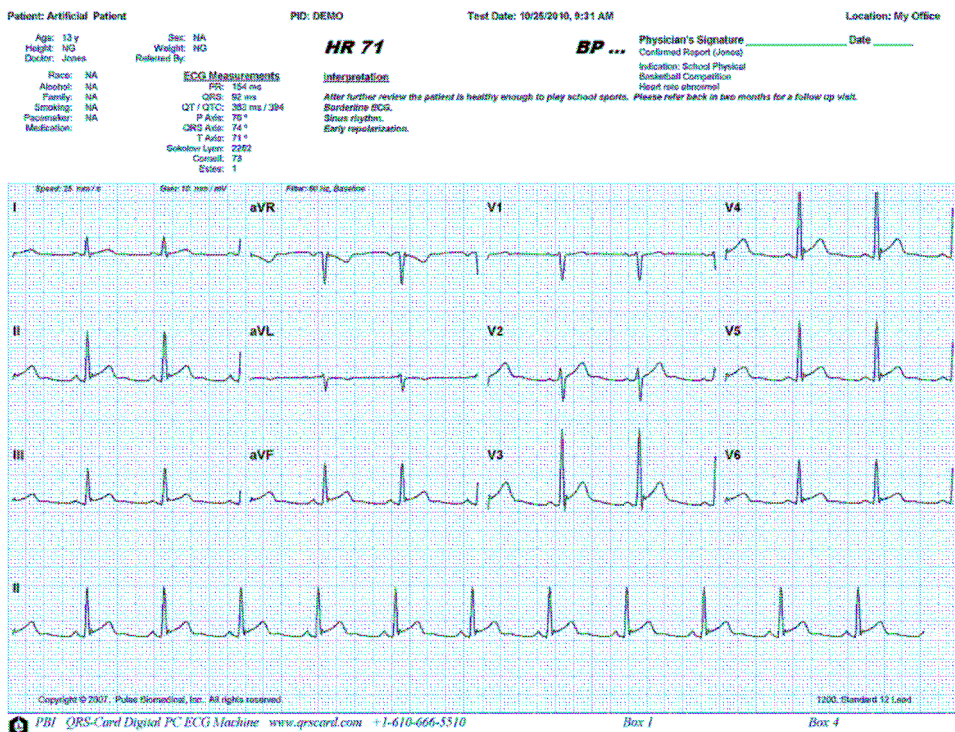
⚠ CAUTION Never mix reusable and disposable electrodes on the same patient.

NOTICE Because QRS-Card™ Cardiology suite is a diagnostic 12 lead system, all electrodes must be connected. Proper patient prep is necessary for a good quality signal.

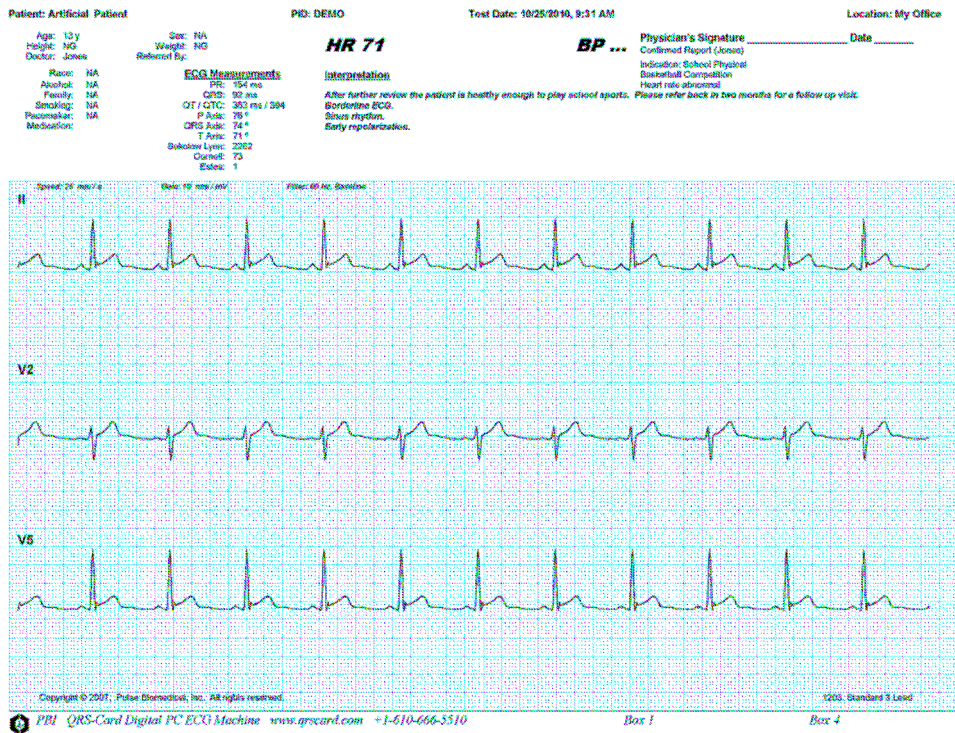
NOTICE When you connect the electrodes to the patient, make sure that the electrodes and their connectors do not contact other conducting parts (including earth).

Appendix 3: Sample Resting Reports

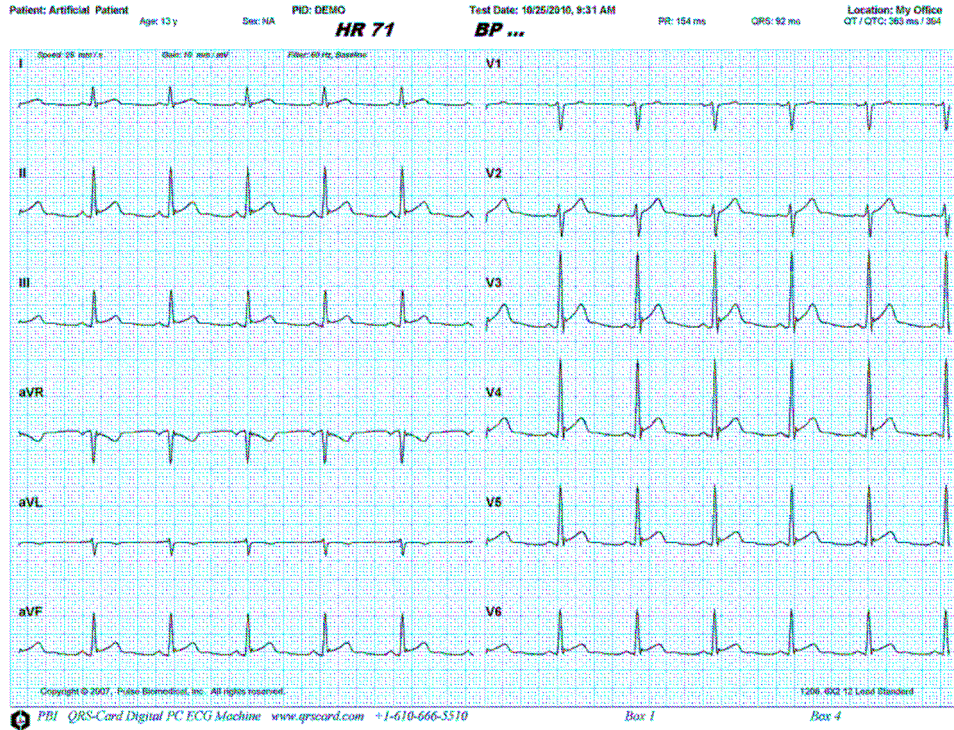
1200 Standard 12 Lead



1203 Standard 3 Lead

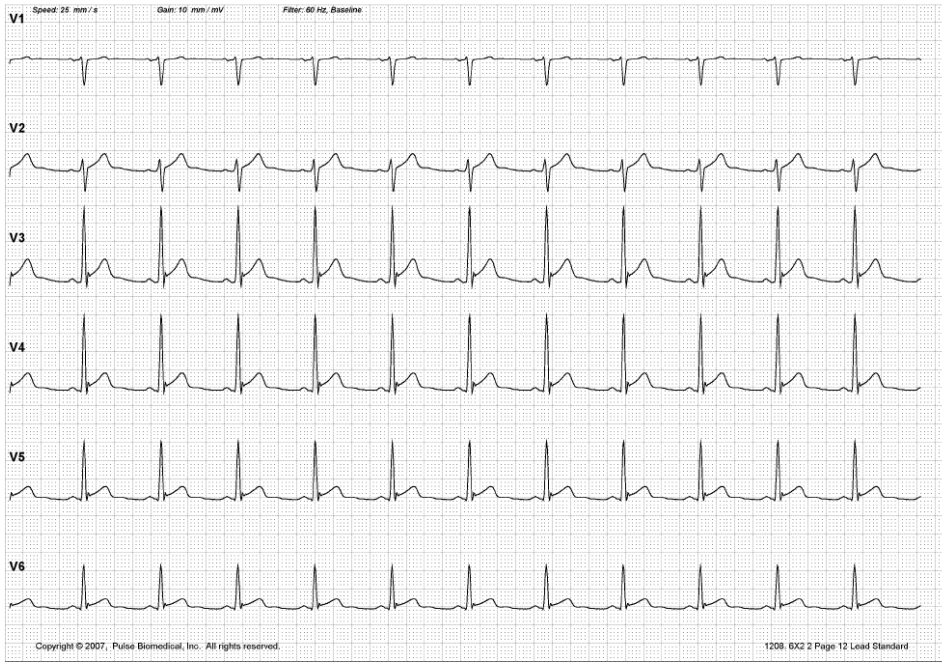



1206 6 x 2 12 Lead Standard



1208 6 x 2 2 Page 12 Lead Standard

Patient: Artificial Patient Age: 13 y Sex: NA PID: DEMO Test Date: 10/25/2010, 9:31 AM PR: 154 ms QRS: 92 ms Location: My Office
HR 71 **BP ...** QT / QTC: 363 ms / 394

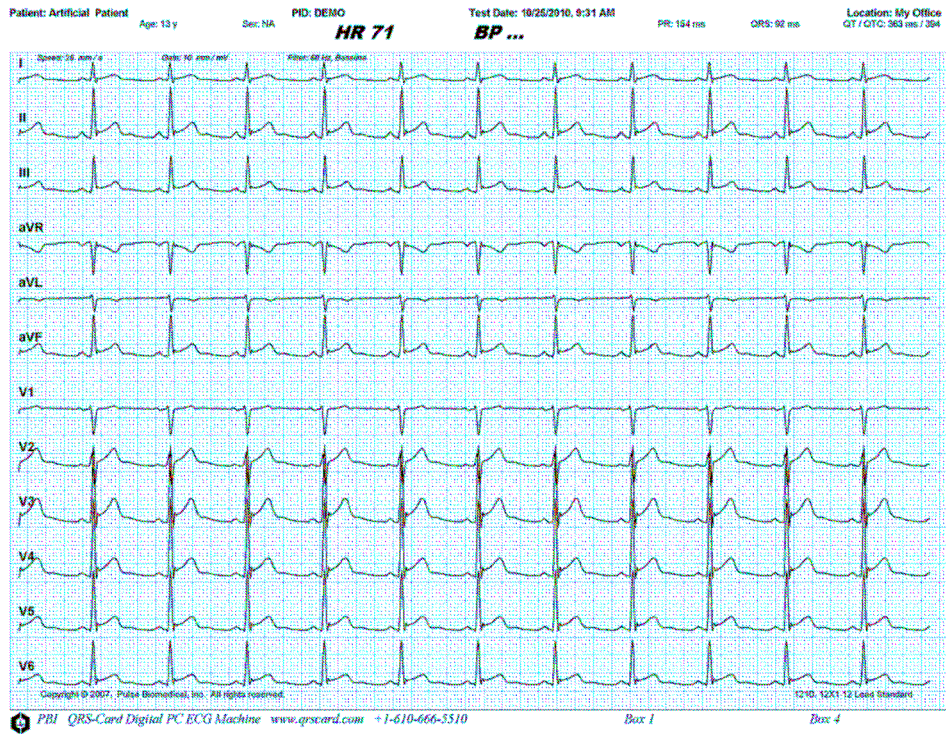


 PBI QRS-Card Digital PC ECG Machine www.qrscard.com 1-610-666-5510

Box 1

Box 4

1210 Standard 12 Lead (12 x 1) Report



1212 Standard Complex Report

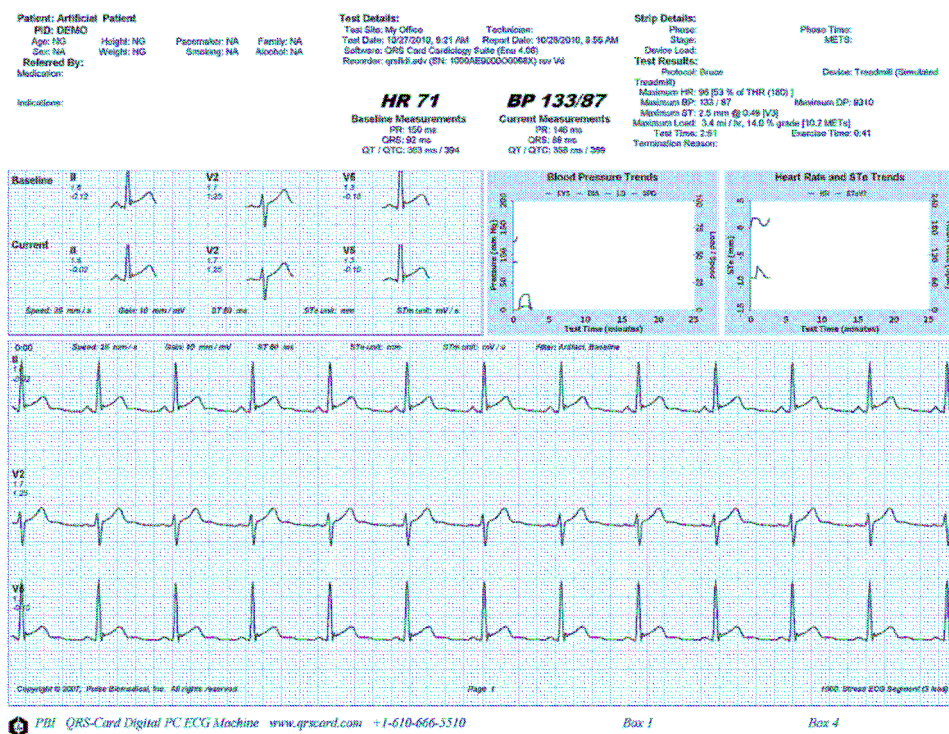
Patient: Artificial Patient PID: DEMO Test Date: 10/28/2010, 9:31 AM Location: My Office

Age: 13 y Sex: NA Physician's Signature _____ Date _____
Height: NG Weight: NG Confirmed Report (Yes/No)
Doctor: Jones Referred By: **HR 71** **BP ...** Indication: School Physical
Race: NA ECG Measurements Interpretation Basketball Competition
Alcohol: NA PR: 154 ms *After further review the patient is healthy enough to play school sports. Please refer back in two months for a follow up visit.*
Family: NA QRS: 82 ms *Borderline ECG.*
Smoking: NA QT / QTc: 383 ms / 394 *Sinus rhythm.*
Pacemaker: NA P Axis: 76 ° *Early repolarization.*
Medication: NA QRS Axis: 74 °
T Axis: 71 °
Sokolow Lysell: 2.82
Cornell: 73
Echoc: 1

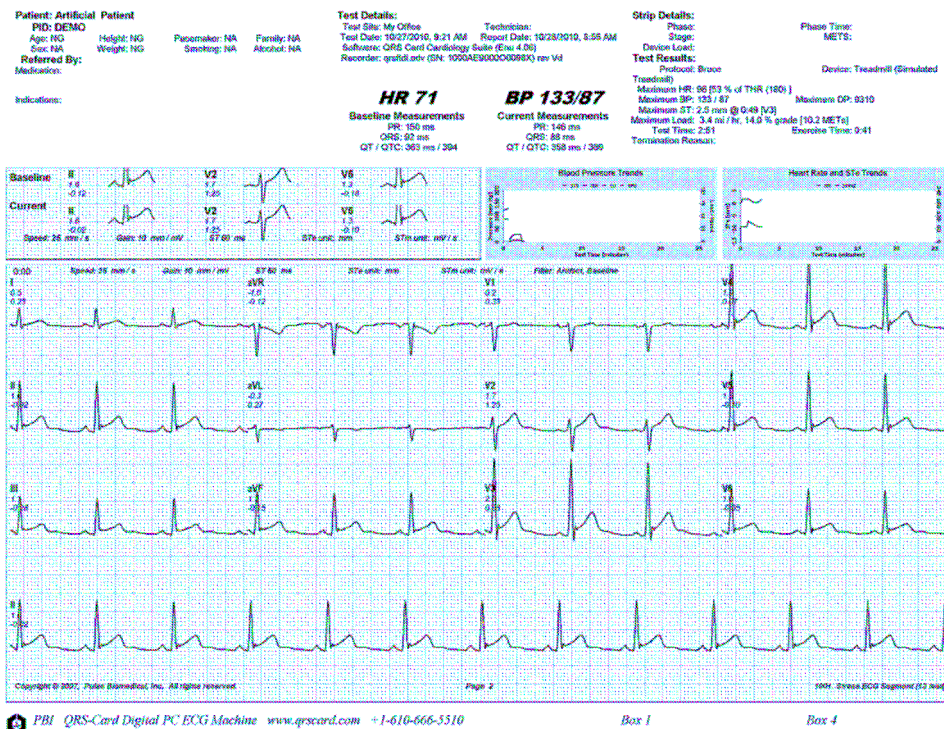


Appendix 4: Stress Sample Reports


1000 Stress ECG Segment (3 lead)



1001 Stress ECG Segment (12 lead)



1002 Stress ECG Result Table

1002. Stress ECG Result Table													Artificial Patient								
 My Office 1052 Main Street Norristown PA 19403 610 666 5510 610 666 5508													Printed: Thursday, October 28, 2010, 8:59:56 AM								
Patient: Artificial Patient PID: DEMO Age: NG Height: NG Pacemaker: NA Family: NA Medication: Sex: NA Weight: NG Smoking: NA Alcohol: NA					Referred By: _____ Indications: _____																
Test Details: 10/27/2010, 9:21 AM Test Site: My Office Technician: Software: QRS Card Cardiology Suite (Env 4.06) Recorder: qrskfif.adv (SN: 1002AES90000958X) rev Vtd					Test Results: Bruce Device: Treadmill (Simulated Treadmill) Maximum HR: 96 (53 % of THR (180)) Maximum BP: 133 / 87 Maximum ST: 2.5 mm @ 0:49 [V3] Maximum Load: 3.4 ml / hr, 14.0 % grade [10.2 METs] Exercise Time: 0:41 Termination Reason:																
Stage	Total Time	Phase Time	Stage Time	Elevation (%)	Speed mi / hr	Work (METS)	HR (BPM)	BP (mmHg)	RPP (/100)	STc: mm	STm: mV / s				ST 60 ms						
										I	II	III	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
# Pre-Test																					
#1 Supine	0:10	0:01	0:01	0.0%	0.0	0.0	71	--	--	0.5	1.6	1.1	-1.0	-0.3	1.3	0.2	1.7	2.5	1.9	1.3	1.0
										0.22	-0.08	0.32	-0.07	0.27	-0.20	0.37	1.29	0.30	-0.09	-0.15	-0.12
Pre-Test																					
Hypervent	0:24	0:02	0:02	0.0%	0.0	1.0	71	105/88	8875	0.5	1.6	1.1	-1.0	-0.2	1.3	0.2	1.7	2.5	1.9	1.3	1.0
										0.20	-0.12	0.33	-0.05	0.27	-0.23	0.40	1.29	0.28	-0.07	-0.18	-0.17
Warm-Up	0:39	0:16	0:03	0.0%	1.4	2.1	76	130/87	9443	0.4	1.5	1.1	-1.0	-0.3	1.3	0.1	1.7	2.4	1.8	1.3	1.0
										0.22	-0.12	-0.33	-0.09	0.25	-0.22	0.37	1.23	0.29	-0.08	-0.18	-0.15
Exercise																					
1	0:49	0:00	0:00	10.0%	1.7	4.6	106	--	--	0.2	0.6	0.3	-0.4	-0.0	0.5	0.5	1.5	2.1	1.6	0.9	0.7
										0.20	-0.55	0.75	0.17	0.48	-0.65	0.66	1.30	0.62	0.20	-0.18	-0.27
2	1:01	0:12	0:01	12.0%	2.5	7.1	106	--	--	0.2	0.6	0.3	-0.4	-0.0	0.5	0.5	1.5	2.1	1.6	0.9	0.7
										0.20	-0.55	-0.75	0.17	0.48	-0.65	0.66	1.32	0.62	0.20	-0.18	-0.27
# Exercise																					
#13	1:50	0:28	0:28	0.0%	0.0	0.0	169	--	--	0.5	1.3	0.7	-0.9	-0.0	1.0	0.5	0.4	0.4	0.4	0.6	0.7
										0.70	1.48	0.77	-1.10	-0.02	1.15	-0.40	0.99	0.62	0.57	0.83	1.07

1003 Stress ECG Summary Report



1003. Stress ECG Summary Report

Artificial Patient

My Office
 1052 Main Street Norristown PA 19403
 610 686 5510 610 686 5508

Printed: Thursday, October 28, 2010, 8:55:57 AM

Patient: Artificial Patient		ID: DEMO
Age: NG	Sex: NA	Address:
Height: NG	Weight: NG	
Pancreases: NA	Family: NA	
Smoking: NA	Alcohol: NA	Telephone:
Medication:		

Indications:

Referring Physician:	ID:
Address:	
Telephone:	

Test Details:

Test Date: 10/27/2010, 8:21 AM	Hookup:
Report Date: 10/28/2010, 8:55 AM	Scanned:
Software: QRS Card Cardiology Suite (Ecu 4.06)	
Recorder: qrsfilt.adv (SN: 1000AE900C00960X) rev V4	

Conclusions: Artificial Patient exercised on a Treadmill (Simulated Treadmill). The total exercise time was 0:41 minutes during which the patient achieved a maximum heart rate of 96 BPM, which was 53 % of the age predicted target heart rate of 180 BPM. The patient Patient's resting heart rate was 71. The resting blood pressure was 133/87. The patient Patient's maximum exercise effort was 3.4 ml / hr, 14.0 % grade [10.2 METs]. The maximum blood pressure was 133 / 87. The maximum double product was 9310 (Maximum HR x Maximum BP = 12768). The patient Patient's ECG showed 8 leads with ST elevation variation greater than 1 mm. These are II, III, aVF, V2, V3, V4, V5, V6. The maximum ST elevation variation was 2.5 mm @ 0:40 [V3]. The patient Patient's ECG showed 1 leads with ST depression variation less than -1 mm. These are aVR. The maximum ST depression variation was -1.1 mm @ 0:15 [aVR].

Physician's Signature _____ Date _____

1004 Stress ECG Summary Report (Classic)



1004. Stress ECG Summary Report

 1305 Cadfish Lane, Nantassat, PA 19403
 Tel: 610-666-6610 Fax: 610-666-6630

Patient Assembly, December 10, 2016, 11:31 AM

Patient:		PID:	
Age: NC	Height: NC	Tenodesis: NA	Family: NA
Sex: NA	Weight: NC	Smoking: NA	Alcohol: NA
Referred By:		Test Results:	
Indications:		Bruce	
Test Details:		Test Results:	
Test Date: 11/2/2016, 11:39 AM		Code: Treadmill (Staircase) Treadmill	
Test Site: QRS Cardiology Suite (F4 - 4.05)		Max HR: 76 (50% of THR (83))	
Referral: QRS Cardiology Suite (F4 - 4.05)		Max HR DP: 63 (50)	
Referral ID: 1004AP0000000002		Max HR ST: 2.5 mm @ 1.0 (5)	
		Maximum Load: 6.0 w 3hr 6.0 to grade 1.0 (1.1)	
		Termination: 0:00	
		Termination Reason:	

Bruce	Total Time	Phase Time	Stage Time	Elevation (%)	Speed (mi/hr)	Work (METs)	HR (BPM)	BP (mmHg)	RPP (100)
Pre-Test									
Supine	0:50	0:50	0:50	0.0%	0.0	1.0	75	160/80	112

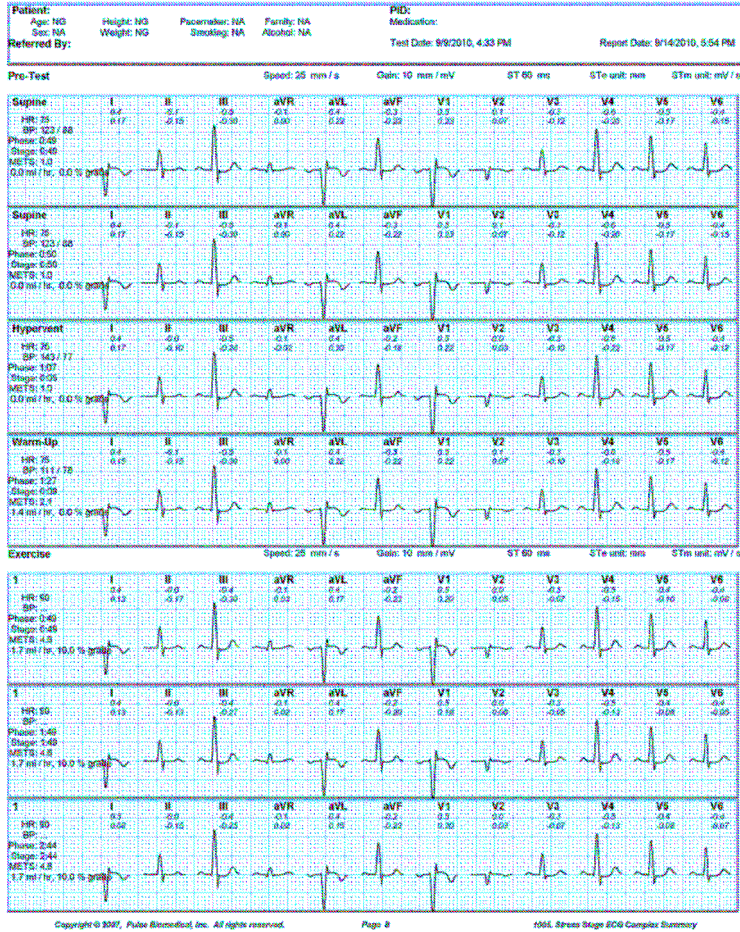
Conclusions:
 Classic test on a Treadmill (Staircase) Treadmill for 5:01 minutes. The total exercise time was 3:00 minutes during which the patient achieved a maximum heart rate of 76 BPM, which was 50% of the age predicted target heart rate of 150 BPM. The patient's maximum exercise effort was 6.0 mi/hr, 0.0% grade (1.0 METs). The maximum blood pressure was 160/80. The maximum stroke product was 11200 (Maximum HR x Maximum BP = 11200).
 The patient's ECG showed 8 leads with ST elevation variation greater than 1 mm. These are II, III, aVF, V2, V3, V4, V5, V6. The maximum ST elevation variation was 2.5 mm @ 1.0 (5).
 The patient's ECG showed 1 leads with ST depression variation less than 1 mm. These are aVR. The maximum ST depression variation was -1 mm @ 1.00 (10%).

Physician's Signature _____ Date _____
 Original Report (not overread) - QRS Card Cardiology Suite (Encl 4.06)

Comments:

1005 Stress Stage ECG Complex Summary

ECG Stage Complex Summary ^{Sleep}



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Page 8

1005 Stress Stage ECG Complex Summary

1006 Stress Stage ECG Rhythm Summary

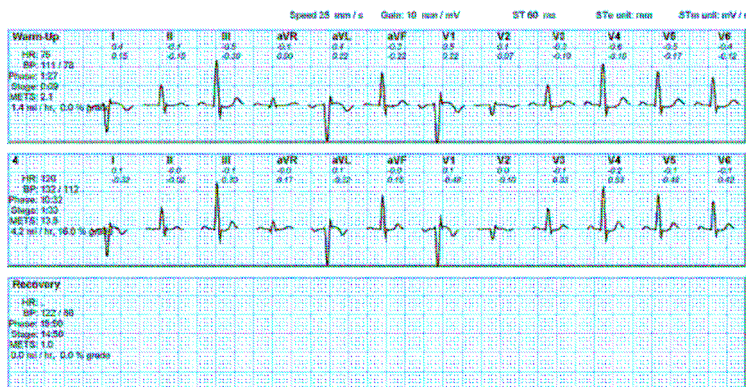


1007 Stress Phase ECG Complex Summary

Stress Phase ECG Complex Summary

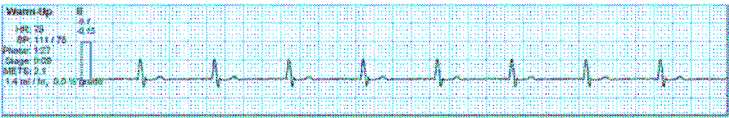

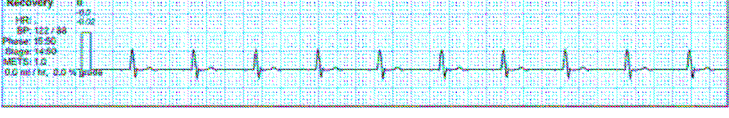
Patient:	Age: NC	Height: NG	Position: NA	Family: NA	PID:
	Sex: NA	Weight: NG	Smoking: NA	Alcohol: NA	Medication:
Referred By:	Test Date: 9/9/2010, 4:33 PM				Report Date: 9/14/2010, 5:54 PM

Indications:	Test Results:
	Protocol: Bruce Maximum HR: 80 (90 % of THR (180)) Maximum BP: 143/77 Maximum DP: 10960 Maximum ST: 0.6 mm @ 1:01 [V1] Maximum Load: 4.2 ml / hr, 16.0 % grade [13.5 METs] Test Time: 34:51 Exercise Time: 10:43 Termination Reason: Protocol Complete
Test Details:	Device: Treadmill (Simulated Treadmill)
Test Site: My Office Technician: Test Date: 9/9/2010, 4:33 PM Report Date: 9/14/2010, 5:54 PM Software: QRS Card Cardiology Suite Hardware: QRS Card Cardiology Suite Revision: 4.05 (10/03/10)	



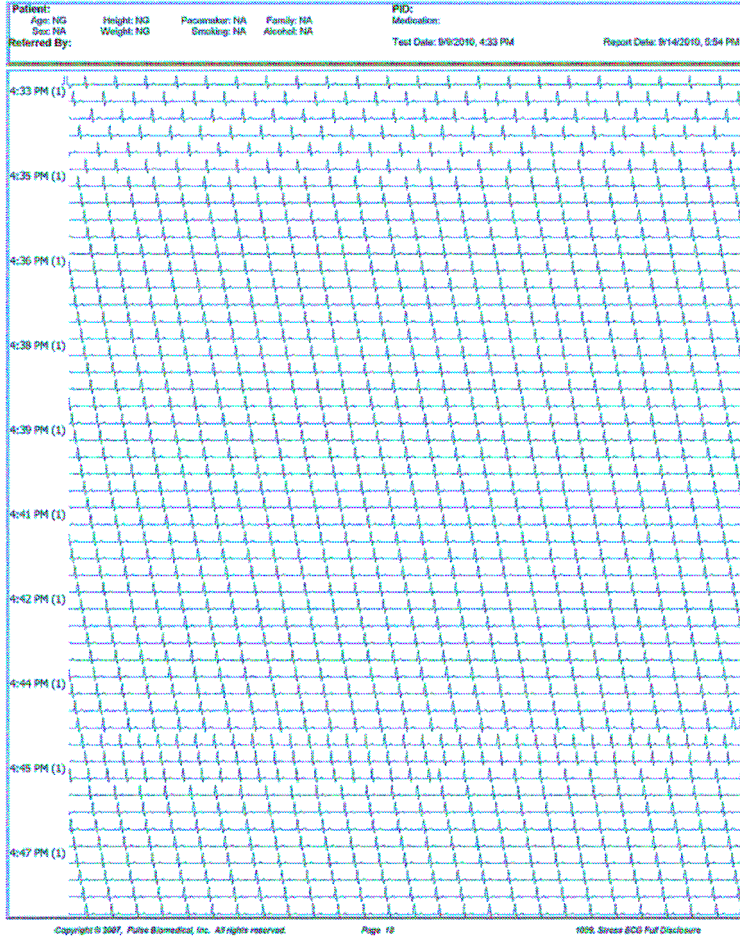
Conclusions:	
exercised on a Treadmill (Simulated Treadmill). The total exercise time was 10:43 minutes during which the patient achieved a maximum heart rate of 90 BPM, which was 50 % of the age predicted target heart rate of 180 BPM. The patient's maximum exercise effort was: 4.2 ml / hr, 16.0 % grade [13.5 METs]. The maximum blood pressure was 143 / 77. The maximum double product was 10960 (Maximum HR x Maximum BP = 12670). The patient's ECG showed 0 leads with ST elevation variation greater than 1 mm. These are . The maximum ST elevation variation was 0.6 mm @ 1:01 [V1]. The patient's ECG showed 0 leads with ST depression variation less than -1 mm. These are . The maximum ST depression variation was -0.7 mm @ 1:17 [V4].	
Physician's Signature	Date

1008 Stress Phase ECG Rhythm Summary

Stress Phase ECG Rhythm Summary					
Patient:		Height: NA		PID:	
Age: NG		Weight: NG		Medication:	
Sex: NA		Pace-maker: NA		Test Date: 9/9/2010, 4:33 PM	
Referred By:		Smoking: NA		Report Date: 9/14/2010, 5:54 PM	
Family: NA		Alcohol: NA			
Indications:		Test Results:			
		Protocol: Stress Device: Treadmill (Simulated Treadmill)			
		Maximum HR: 60 (50 % of THR (180))			
		Maximum BP: 143 / 77 Maximum DP: 10990			
		Maximum ST: 0.6 mm @ 1:01 (N1)			
		Maximum Load: 4.2 ml / hr, 16.0 % grade (13.5 METs)			
		Test Time: 34:51 Exercise Time: 10:43			
		Termination Reason: Protocol Complete			
Test Details:					
Test Site: My Clinic Technician:					
Test Date: 9/9/2010, 4:33 PM Report Date: 9/14/2010, 5:54 PM					
Software: QRS Card Cardiology Suite-Release 4.00/rsbt.adv (SN: 3410A8000100F20) rev. 4.06 (100512)					
Speed: 25 mm / s Gain: 10 mm / mV ST 60 ms STe unit: mm STm unit: mV / s					
Warm-Up					
HR: 78 4.7					
BP: 111 / 78 -0.25					
Phase: 1:23					
Grade: 0.0%					
METs: 2.1					
1.4 ml / hr, 0.0 % grade					
					
4					
HR: 120 -0.0					
BP: 127 / 112 -0.0					
Phase: 30:33					
Grade: 1.3%					
METs: 13.5					
4.2 ml / hr, 16.0 % grade					
					
Recovery					
HR: 122 -0.0					
BP: 122 / 88 -0.0					
Phase: 35:50					
Grade: 0.0%					
METs: 1.0					
0.0 ml / hr, 0.0 % grade					
					
Conclusions:					
The patient exercised on a Treadmill (Simulated Treadmill). The total exercise time was 10:43 minutes during which the patient achieved a maximum heart rate of 90 BPM, which was 50 % of the age predicted target heart rate of 180 BPM.					
The patient's maximum exercise effort was 4.2 ml / hr, 16.0 % grade (13.5 METs). The maximum blood pressure was 143 / 77. The maximum double product was 10990 (Maximum HR x Maximum BP = 12970).					
The patient's ECG showed 0 leads with ST elevation variation greater than 1 mm. These are . The maximum ST elevation variation was 0.6 mm @ 1:01 (N1).					
The patient's ECG showed 0 leads with ST depression variation less than -1 mm. These are . The maximum ST depression variation was -0.7 mm @ 1:17 (V4).					
Physician's Signature			Date		
<small>Copyright © 2007, Pulse Biomedical, Inc. All rights reserved. Page 17 1008 Stress Phase ECG Rhythm Summary</small>					

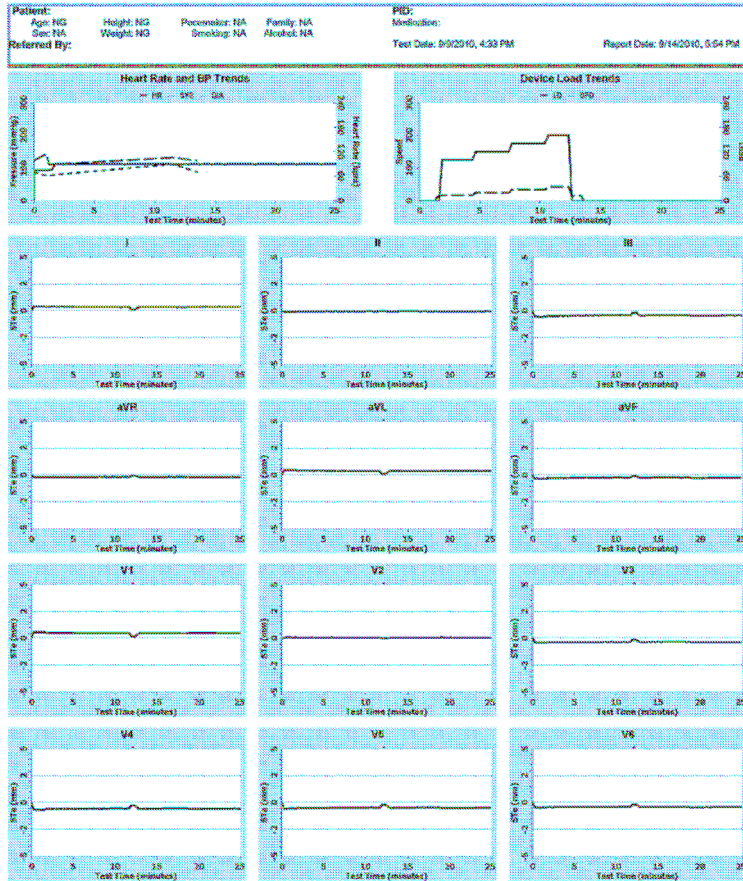
1009 Stress ECG Full Disclosure

Stress ECG Full Disclosure

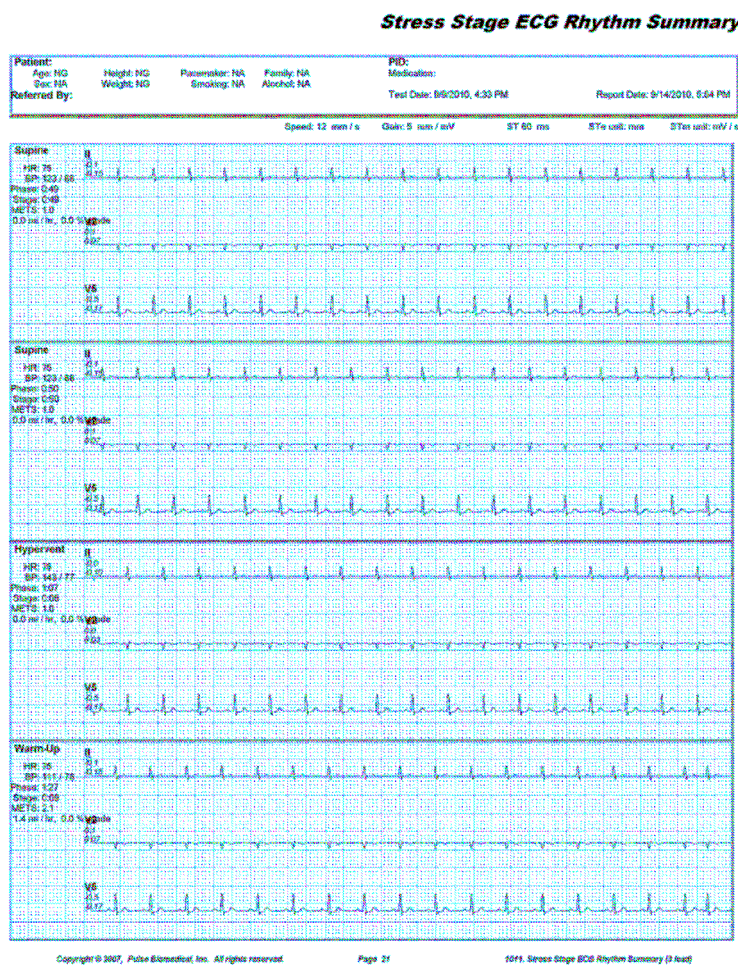


1010 Stress Test Trends

Stress Test Trends



1011 Stress Stage ECG Rhythm Summary (3 lead)]



1012 Stress Phase ECG Rhythm Summary (3 lead)

Stress Stage ECG Rhythm Summary

Patient:	Age: NG	Height: NG	Pacemaker: NA	Family: NA	RID:
	Sex: NA	Weight: NG	Smoking: NA	Alcohol: NA	Medication:
Referred By:				Test Date: 9/9/2010, 4:33 PM	Report Date: 9/14/2010, 5:54 PM

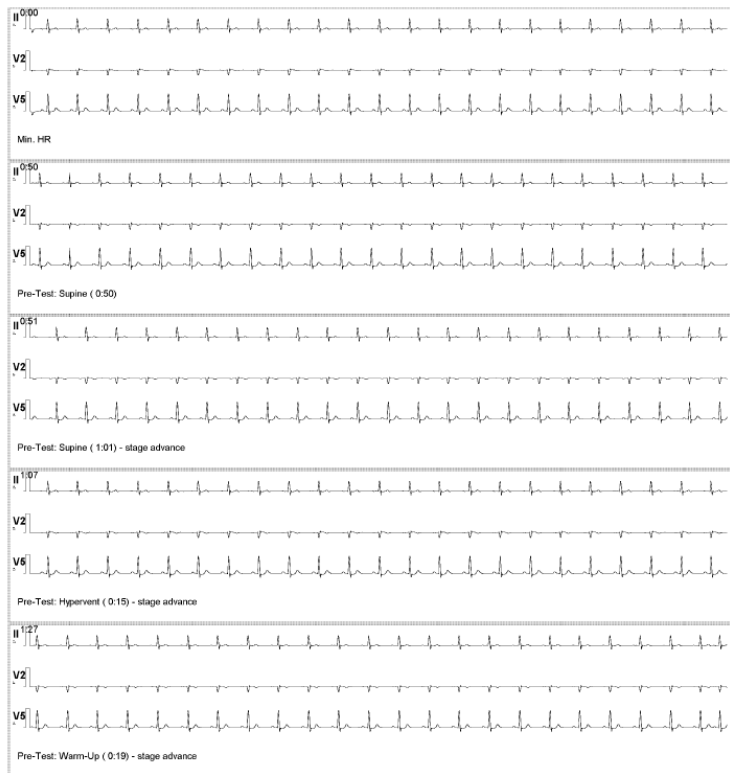
Speed: 12 mm / s Gain: 5 mm / mV ST 60 ms STa cell: mm STm cell: mV / s



1013 Stress ECG Selected Segments

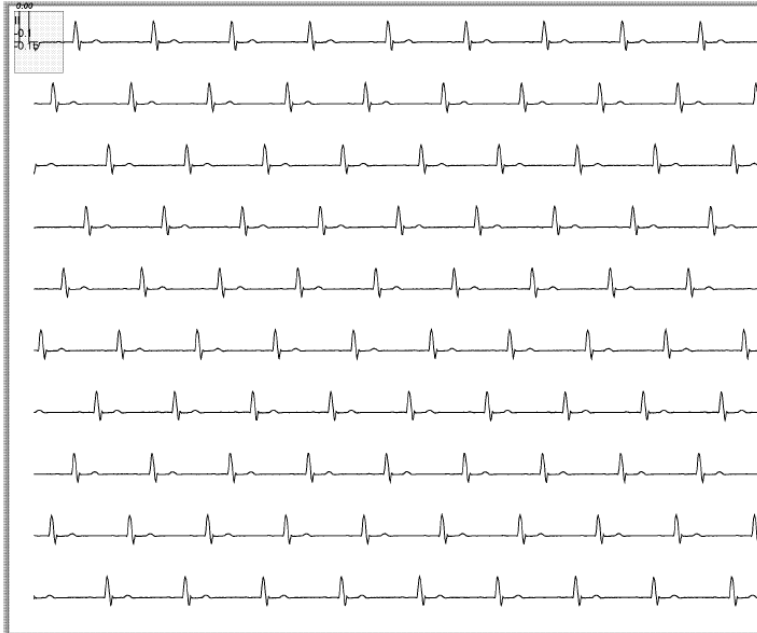
Stress ECG Selected Segments

Patient:		PID:	
Age: NG	Height: NG	Pacemaker: NA	Family: NA
Sex: NA	Weight: NG	Smoking: NA	Alcohol: NA
Referred By:		Medication:	Test Date: 9/9/2010, 4:33 PM
			Report Date: 9/14/2010, 5:54 PM



1014 Review Screen

Patient: ID: Date: 9/9/2010, 4:33 PM


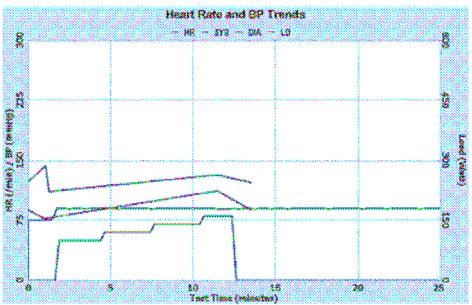


Printed: 9/14/2010, 8:54 PM

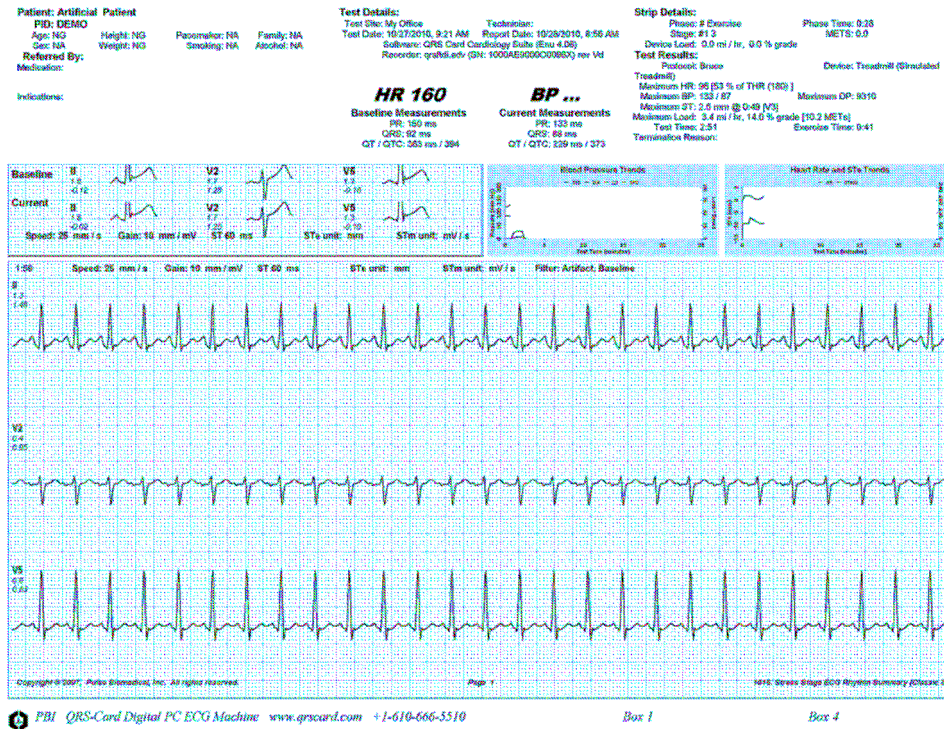
1014_Review_Screen

Page 36

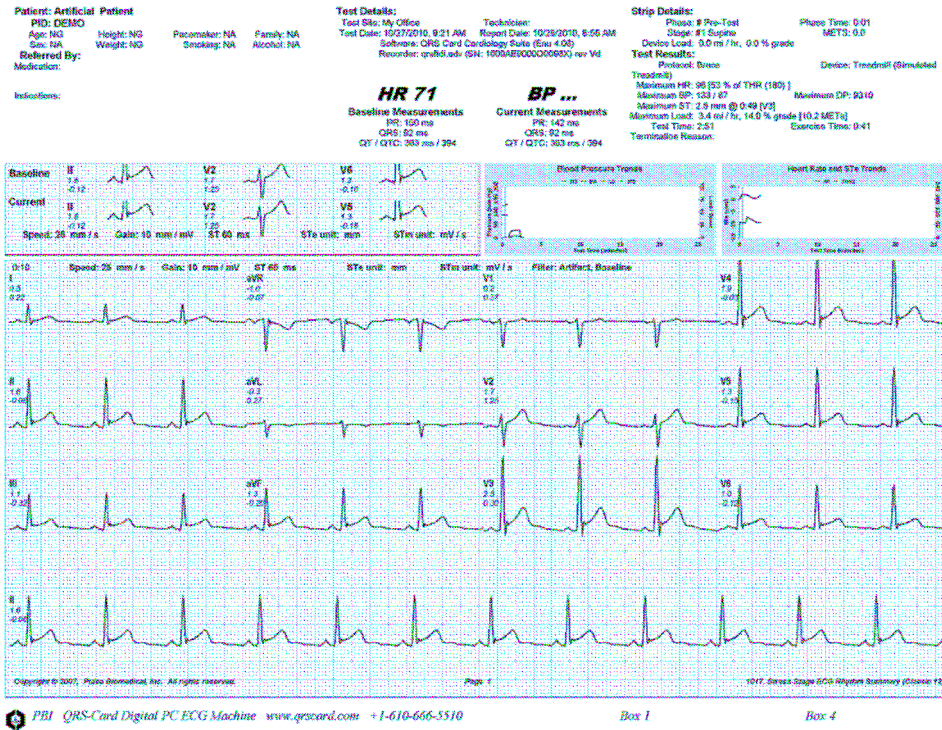
1015 Stress ECG Summary Report (Europe)

														
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Patient														
Name:	Height: NG													
DOB:	Weight: NG													
Sex: NA	Race: NA													
Race: NA	Age: NG													
Referred By:														
Indications	Medication	Test Information Collection Date: 9/9/2010, 4:33 PM												
		Total Time: 34:51 Exercise Time: 10:43 Recovery Time: Maximum Load: 18.0 % Maximum HR: 80 (50 % of THR (150)) Maximum STe: 0.6 mm @ 1:01 [V1] Resting BP: 143 / 77 Maximum BP: 143 / 77 Maximum RPR: 128/80 PWC170: -1 PWC150: -1 PWC130: -1												
Conclusions: exercised on a Treadmill (Simulated Treadmill). The total exercise time was 10:43 minutes during which the patient achieved a maximum heart rate of 80 BPM, which was 50 % of the age predicted target heart rate of 150 BPM. The patient's maximum exercise effort was 4.2 mi / hr, 16.0 % grade [13.5 METS]. The maximum blood pressure was 143 / 77. The maximum double product was 10980 (Maximum HR x Maximum BP = 12870). The patient's ECG showed 0 leads with ST elevation variation greater than 1 mm. These are . The maximum ST elevation variation was 0.6 mm @ 1:01 [V1]. The patient's ECG showed 0 leads with ST depression variation less than -1 mm. These are . The maximum ST depression variation was -0.7 mm @ 1:17 [V4].														
Copyright © 2007, Pulse Biomedical, Inc. All rights reserved. Page 36 1015 Stress ECG Summary Report (Europe)														

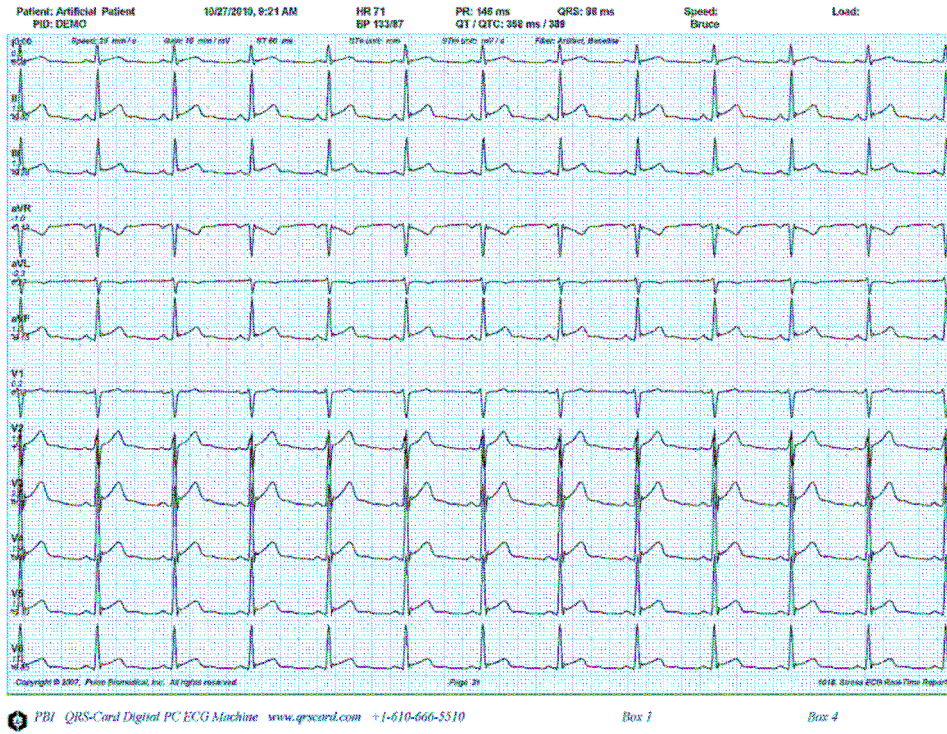
1016 Stress Stage ECG Rhythm Summary (Classic 3)



1017 Stress Stage ECG Rhythm Summary (Classic 12)



1018 Stress ECG Real-Time Report




Appendix 5: Holter Sample Reports

13000. Holter ECG Summary Report

	13000. Holter ECG Summary Report	Artificial Patient																		
My Office 1052 Main Street Norristown PA 19403 610 668 5519 610 668 4506																				
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Patient: Artificial Patient</td> <td style="width: 33%;">Sex: NA</td> <td style="width: 33%;">ID: DEMO</td> </tr> <tr> <td>Age: NG</td> <td>Weight: NG</td> <td>Address:</td> </tr> <tr> <td>Height: NG</td> <td>Family: NA</td> <td></td> </tr> <tr> <td>Pastemaker: NA</td> <td>Alcohol: NA</td> <td></td> </tr> <tr> <td>Smoking: NA</td> <td></td> <td>Telephone:</td> </tr> <tr> <td>Medication:</td> <td></td> <td></td> </tr> </table>			Patient: Artificial Patient	Sex: NA	ID: DEMO	Age: NG	Weight: NG	Address:	Height: NG	Family: NA		Pastemaker: NA	Alcohol: NA		Smoking: NA		Telephone:	Medication:		
Patient: Artificial Patient	Sex: NA	ID: DEMO																		
Age: NG	Weight: NG	Address:																		
Height: NG	Family: NA																			
Pastemaker: NA	Alcohol: NA																			
Smoking: NA		Telephone:																		
Medication:																				
Indications: 																				
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%;">Referring Physician: DR OMED</td> <td style="width: 50%;">ID:</td> </tr> <tr> <td>Address:</td> <td></td> </tr> <tr> <td>Telephone:</td> <td></td> </tr> </table>			Referring Physician: DR OMED	ID:	Address:		Telephone:													
Referring Physician: DR OMED	ID:																			
Address:																				
Telephone:																				
Test Details: <table style="width: 100%; font-size: x-small;"> <tr> <td>Test Date: 4/13/2014, 8:37 AM</td> <td>Hookup: EDO</td> </tr> <tr> <td>Report Date: 10/29/2010, 8:56 AM</td> <td>Scanner:</td> </tr> <tr> <td>Software: PBI Holter</td> <td>Attending Physician:</td> </tr> <tr> <td>Recorder: PBI DEMO (SN: IMMADEMO) rev V01.00</td> <td></td> </tr> </table>			Test Date: 4/13/2014, 8:37 AM	Hookup: EDO	Report Date: 10/29/2010, 8:56 AM	Scanner:	Software: PBI Holter	Attending Physician:	Recorder: PBI DEMO (SN: IMMADEMO) rev V01.00											
Test Date: 4/13/2014, 8:37 AM	Hookup: EDO																			
Report Date: 10/29/2010, 8:56 AM	Scanner:																			
Software: PBI Holter	Attending Physician:																			
Recorder: PBI DEMO (SN: IMMADEMO) rev V01.00																				
Conclusions: Artificial Patient was monitored for 2:00 hours; 2:00 hours were analyzed. During this time the average heart rate was 71, with a minimum heart rate of 44 at @ 8:11:23 AM (1) and a maximum heart rate of 109 at @ 9:45:00 AM (1). The patient had 0 pauses greater than 3.0 seconds. The patient Artificial Patient's test showed 0 (0.0 %) ventricular ectopic beats. The patient had 0 isolated ventricular ectopic beats, 0 paired ventricular ectopic beats and 0 ventricular ectopic beat runs. 0 beats were in ventricular ectopic beat runs. The longest run had 0 beats at @ 8:37:13 AM (1) and the fastest run had a rate of 0 at @ 8:37:13 AM (1). The patient Artificial Patient's test showed 0 supraventricular ectopic beats (25 % premature). 0 beats were in supraventricular ectopic beat runs. The longest run had 0 beats at @ 8:37:13 AM (1) and the fastest run had a rate of 0 at @ 8:37:13 AM (1).																				
Physician's Signature _____		Date _____																		
Printed: 10/29/2010, 8:56 AM	13000. Holter ECG Summary Report	Page 1																		

13010: Holter ECG Result Summary Report


13010. Holter ECG Result Summary Report		Artificial Patient																																														
 <div style="display: flex; justify-content: space-between; font-size: small;"> <div> <p>1052 Main Street 610 666 5310</p> </div> <div> <p>My Office Warrington PA 19433 610 666 5310 610 666 5508</p> </div> </div>																																																
<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 33%;">Patient: Artificial Patient</td> <td style="width: 33%;">Sex: NA</td> <td style="width: 33%;">ID: DEMO</td> </tr> <tr> <td>Age: NG</td> <td>Weight: NG</td> <td>Address:</td> </tr> <tr> <td>Height: NG</td> <td>Family: NA</td> <td></td> </tr> <tr> <td>Pacemaker: NA</td> <td>Alcohol: NA</td> <td></td> </tr> <tr> <td>Smoking: NA</td> <td></td> <td>Telephone:</td> </tr> <tr> <td>Medication:</td> <td></td> <td></td> </tr> </table>			Patient: Artificial Patient	Sex: NA	ID: DEMO	Age: NG	Weight: NG	Address:	Height: NG	Family: NA		Pacemaker: NA	Alcohol: NA		Smoking: NA		Telephone:	Medication:																														
Patient: Artificial Patient	Sex: NA	ID: DEMO																																														
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Medication:																																																
Indications: 																																																
<table style="width: 100%;"> <tr> <td style="width: 50%;">Referring Physician: DR OMED</td> <td style="width: 50%;">ID:</td> </tr> <tr> <td>Address:</td> <td></td> </tr> <tr> <td>Telephone:</td> <td>Fax:</td> </tr> </table>			Referring Physician: DR OMED	ID:	Address:		Telephone:	Fax:																																								
Referring Physician: DR OMED	ID:																																															
Address:																																																
Telephone:	Fax:																																															
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Test Date: 4/13/2004, 8:27 AM	Hookup: EDO																																															
Report Date: 10/28/2010, 8:56 AM	Scanned:																																															
Software: PBI Holter	Duration: 2:00																																															
Recorder: PBI DEMO (SN: IMADEMO) rev V01.00																																																
<table style="width: 100%; font-size: x-small;"> <tr> <th colspan="2" style="text-align: center;">Heart Rate</th> </tr> <tr> <td>Average:</td> <td>Total Beats: 0</td> </tr> <tr> <td>Minimum:</td> <td>8:37:13 AM (1)</td> </tr> <tr> <td>Maximum:</td> <td>8:37:13 AM (1)</td> </tr> <tr> <th colspan="2" style="text-align: center;">Pause</th> </tr> <tr> <td>Total: 0</td> <td></td> </tr> <tr> <td>Maximum (ms): 0</td> <td></td> </tr> </table>	Heart Rate		Average:	Total Beats: 0	Minimum:	8:37:13 AM (1)	Maximum:	8:37:13 AM (1)	Pause		Total: 0		Maximum (ms): 0		<table style="width: 100%; font-size: x-small;"> <tr> <th colspan="2" style="text-align: center;">Ventricular Ectopy</th> </tr> <tr> <td>Total: 0 (-)</td> <td></td> </tr> <tr> <td>Isolated: 0</td> <td></td> </tr> <tr> <td>Paired: 0</td> <td></td> </tr> <tr> <th colspan="2" style="text-align: center;">Runs</th> </tr> <tr> <td>Total: 0</td> <td>Beats 0</td> </tr> <tr> <td>Longest: 0</td> <td></td> </tr> <tr> <td>Fastest: 0</td> <td></td> </tr> </table>	Ventricular Ectopy		Total: 0 (-)		Isolated: 0		Paired: 0		Runs		Total: 0	Beats 0	Longest: 0		Fastest: 0		<table style="width: 100%; font-size: x-small;"> <tr> <th colspan="2" style="text-align: center;">Supraventricular Ectopy</th> </tr> <tr> <td>Total: 0</td> <td></td> </tr> <tr> <td>Isolated: 0</td> <td></td> </tr> <tr> <td>Paired: 0</td> <td></td> </tr> <tr> <th colspan="2" style="text-align: center;">Runs</th> </tr> <tr> <td>Total: 0</td> <td>Beats 0</td> </tr> <tr> <td>Longest: 0</td> <td></td> </tr> <tr> <td>Fastest: 0</td> <td></td> </tr> </table>	Supraventricular Ectopy		Total: 0		Isolated: 0		Paired: 0		Runs		Total: 0	Beats 0	Longest: 0		Fastest: 0	
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<p>Conclusions: Artificial Patient was monitored for 2:00 hours; 2:00 hours were analyzed. During this time the average heart rate was 71, with a minimum heart rate of 64 at @ 8:41:26 AM (1) and a maximum heart rate of 109 at @ 9:45:09 AM (1). The patient had 0 pauses greater than 2.0 seconds.</p> <p>The patient Artificial Patient's test showed 0 (0.0 %) ventricular ectopic beats. The patient had 0 isolated ventricular ectopic beats, 0 paired ventricular ectopic beats and 0 ventricular ectopic beat runs. 0 beats were in ventricular ectopic beat runs. The longest run had 0 beats at @ 8:37:13 AM (1) and the fastest run had a rate of 0 at @ 8:37:13 AM (1).</p> <p>The patient Artificial Patient's test showed 0 supraventricular ectopic beats (25 % prematurity). 0 beats were in supraventricular ectopic beat runs. The longest run had 0 beats at @ 8:37:13 AM (1) and the fastest run had a rate of 0 at @ 8:37:13 AM (1).</p>																																																
<table style="width: 100%;"> <tr> <td style="width: 60%;">Physician's Signature _____</td> <td style="width: 40%;">Date _____</td> </tr> </table>			Physician's Signature _____	Date _____																																												
Physician's Signature _____	Date _____																																															

Printed: 10/28/2010, 8:56 AM

13010. Holter ECG Result Summary Report

Page 2

13011: Holter ECG Result Summary Report B

13011. Holter ECG Result Summary Report B		Artificial Patient	
 <div style="text-align: center;"> My Office 1052 Main Street Norristown PA 19403 610 666 5510 610 666 5508 </div> <div style="text-align: right; font-size: small;"> Printed: Thursday, October 28, 2010, 8:56:32 AM </div>			
PATIENT INFORMATION			
Name: Artificial Patient	Sex: NA	Telephone:	
ID: DEMO	Height: NG	Address:	
Age: NG	Weight: NG		
MONITORING INFORMATION			
Ref. Phys.: DR OMED	Hookup: 4/13/2004, 8:37 AM	Medication:	
Indications:	Recorder: PBI DEMO (SN:		
V-Run	Total: 0	SV-Run	Total: 0
V-Pair	Total: 0	SVEB	Total: 0
VEB	Total: 0	Pause	Total: 0
HEART RATE		VENTRICULAR ECTOPY	
Average: Beats: 0	Total: 0 (-)	SDNN (ms):	
Minimum: *	Isolated: 0	SDSD (ms):	
Maximum: *	Paired: 0	SDANN (ms):	
Pause	Runs	NN50 Count:	
Total: 0	Total: 0 Beats 0	RMSSD (ms):	
Maximum: *	Longest: *	pNN50 (%):	
	Fastest: *	SDNN Index (ms):	
ST SEGMENT ANALYSIS		SUPRAVENTRICULAR ECTOPY	
Episodes: 0	Total: 0	PACEMAKER	
Duration: 0:00 (0.0 %)	Isolated: 0	Total Paced Beats: 0 (0.-1%)	
Maximum STe: 0.0 mm @ 8:56:32 AM (1)	Paired: 0	Atrial Paced Beats: 0 (0.-1%)	
Maximum STd: 0.0 mm @ 8:56:32 AM (1)	Runs	Ventricular Paced Beats: 0 (0.-1%)	
	Total: 0 Beats 0	Both (AV) Paced Beats: 0 (0.-1%)	
	Longest: *	Capture failures: 0	
	Fastest: *	Sense Failures: 0	
		Inhibition: 0	
CONCLUSIONS			
Artificial Patient was monitored for 2:00 hours; 2:00 hours were analyzed. During this time the average heart rate was 71, with a minimum heart rate of 64 at @ 8:41:26 AM (1) and a maximum heart rate of 109 at @ 9:45:09 AM (1). The patient had 0 pauses greater than 2.0 seconds.			
The patient Artificial Patient's test showed 0 (0.0 %) ventricular ectopic beats. The patient had 0 isolated ventricular ectopic beats, 0 paired ventricular ectopic beats and 0 ventricular ectopic beat runs. 0 beats were in ventricular ectopic beat runs. The longest run had 0 beats at @ 8:37:13 AM (1) and the fastest run had a rate of 0 at @ 8:37:13 AM (1).			
The patient Artificial Patient's test showed 0 supraventricular ectopic beats (25 % prematurity). 0 beats were in supraventricular ectopic beat runs. The longest run had 0 beats at @ 8:37:13 AM (1) and the fastest run had a rate of 0 at @ 8:37:13 AM (1).			
Original Report (not overread) - <PBI Holter Physician		Date	

13020: Holter ECG Hourly Summary Report

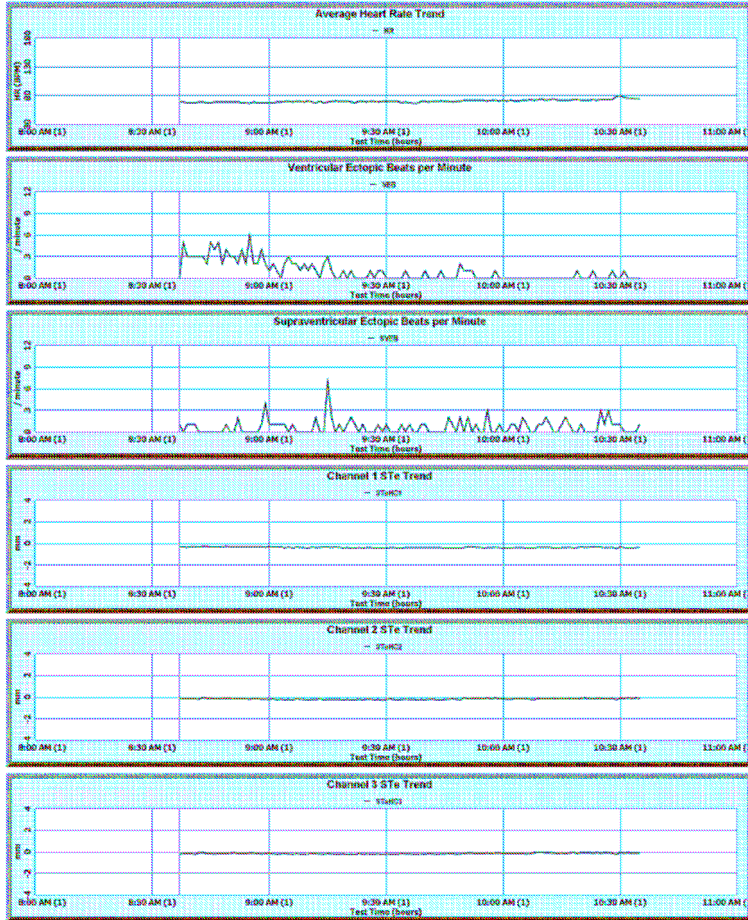
Patient: PATIENT NAME ID: DEMOPAT Date: 4/13/2004, 8:37 AM

Holter ECG General Hourly Summary Report													
Start	Min. HR	Avg. HR	Max. HR	Total Beat	VE Beat	VE Pair	VE Run	SVE Beat	SVE Pair	SVE Run	Pause	Duration	Reject
:13 AM (1)	64	66	71	1583	72	0	0	12	0	1	0	22:47	0:00
:00 AM (1)	64	69	83	4209	40	0	0	41	1	1	0	60:00	0:01
:00 AM (1)	68	73	83	2682	4	0	0	26	0	0	0	37:26	0:00
Total	64	69	83	8445	116	0	0	79	1	2	0		

13030: Holter ECG Trend Report

Patient: PATIENT NAME ID: DEMOPAT Date: 4/13/2004, 8:37 AM

Holter ECG Trend Report

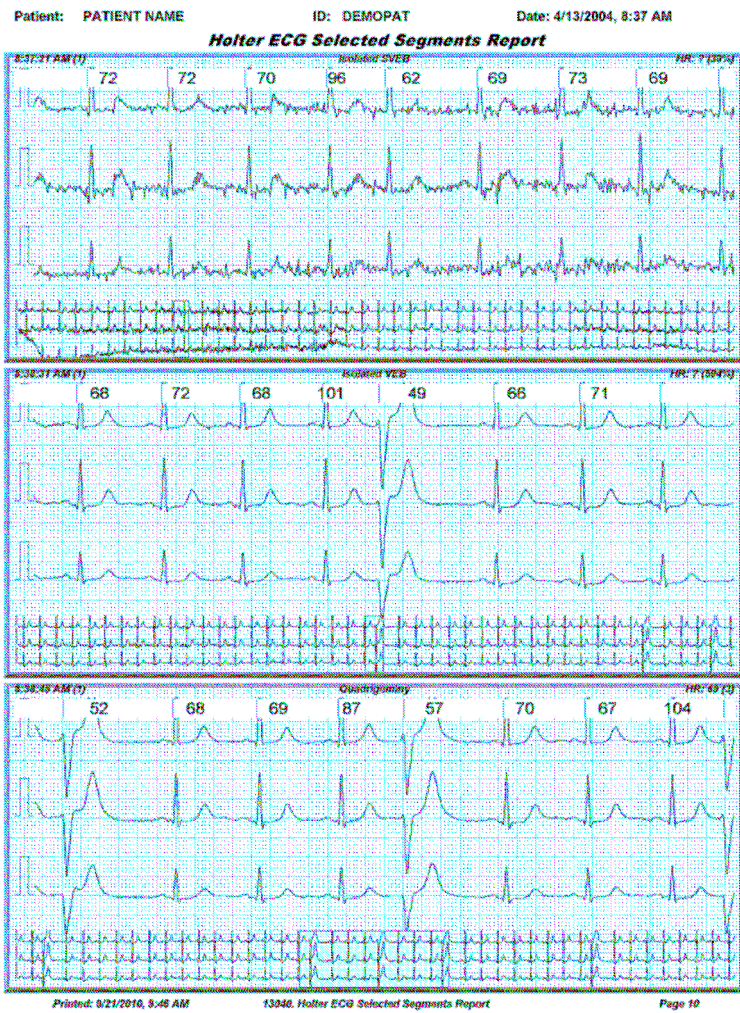


Printed: 8/22/2010, 9:46 AM

13030: Holter ECG Trend Report

Page 8

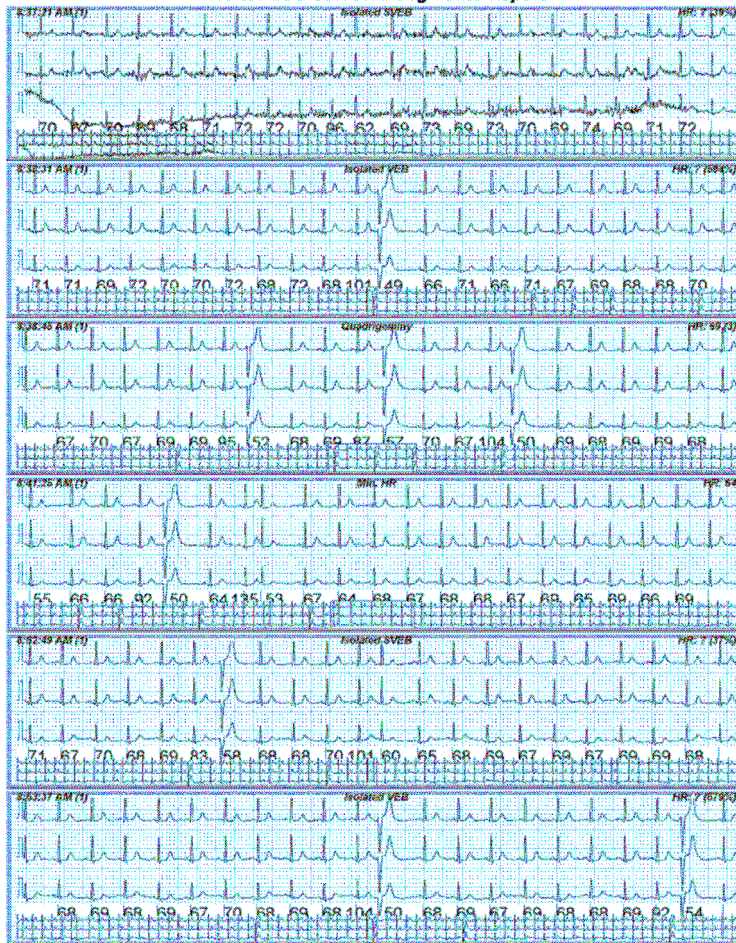
13040: Holter ECG Selected Segments Report



13041: Holter ECG Selected Segments Report

Patient: PATIENT NAME ID: DEMOPAT Date: 4/13/2004, 8:37 AM

Holter ECG Selected Segments Report



Printed: 9/21/2010, 9:46 AM

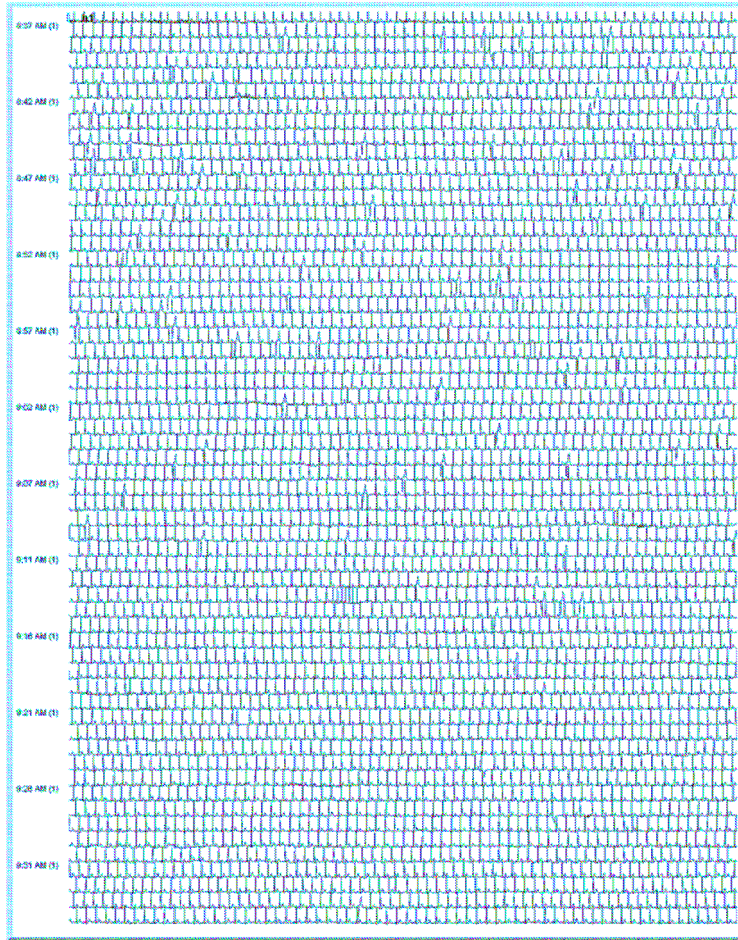
13041: Holter ECG Selected Segments Report

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13050: Holter ECG Full Disclosure Report

Patient: PATIENT NAME ID: DEMOPAT Date: 4/13/2004, 8:37 AM

Holter ECG Full Disclosure Report



Printed: 9/21/2010, 9:46 AM

13050: Holter ECG Full Disclosure Report

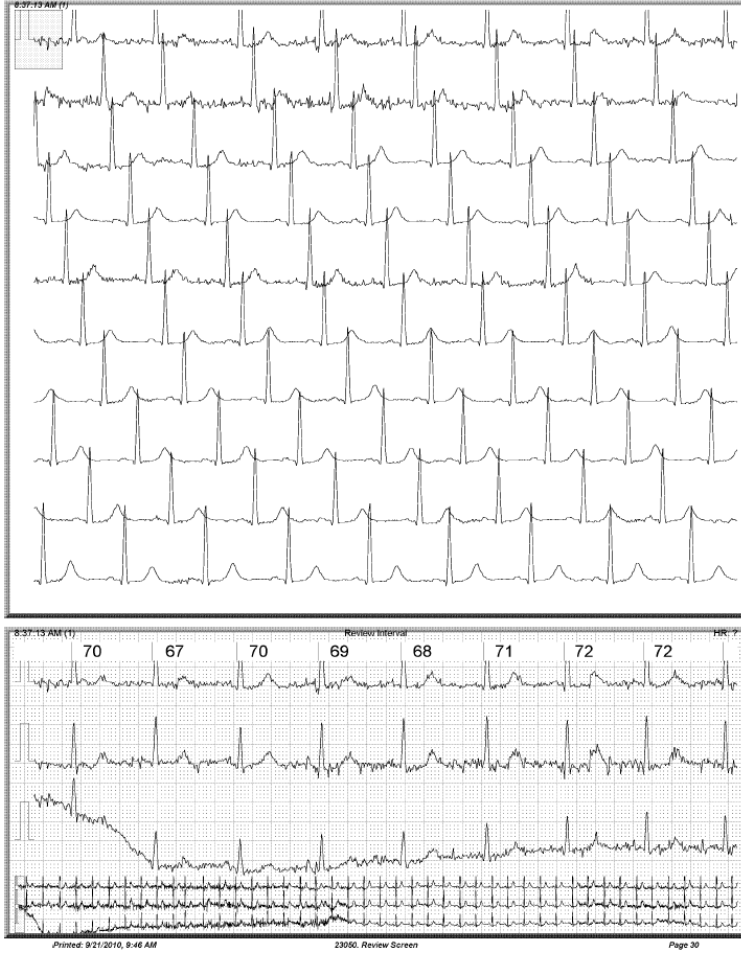
Page 22

13060: Review Screen

Patient: PATIENT NAME

ID: DEMOPAT

Date: 4/13/2004, 8:37 AM



13070: Holter ECG Result Summary Report (pacemaker)

	13070. Holter ECG Result Summary Report (pacemaker)	Artificial Patient
My Office 1052 Main Street - Norristown PA 19403 610 666 5510 610 666 5508		

Patient: Artificial Patient Age: NG Height: NG Pacemaker: NA Smoking: NA Medication:	Sex: NA Weight: NG Family: NA Alcohol: NA	ID: DEMO Address: Telephone:
--	--	---

Indications:

Test Details:

Test Date: 4/13/2004, 8:37 AM	Hookup: EDO
Report Date: 10/28/2010, 8:56 AM	Scanned:
Software: PBI Holter	
Recorder: PBI DEMO (SN: IMADEMO) rev V01.00	

Pacemaker Details:

Total Paced Beats: 0 (0.-1%)	Inhibition: 0
Atrial Paced Beats: 0 (0.-1%)	
Ventricular Paced Beats: 0 (0.-1%)	
Both (AV) Paced Beats: 0 (0.-1%)	
Capture failures: 0	Sense Failures: 0

Heart Rate

Average:	Total Beats: 0
Minimum:	8:37:13 AM (1)
Maximum:	8:37:13 AM (1)

Pause

Total: 0	
Maximum (ms): 0	

Ventricular Ectopy

Total: 0 (-)	
Isolated: 0	
Paired: 0	

Runs

Total: 0	Beats 0
Longest: 0	
Fastest: 0	

Supraventricular Ectopy

Total: 0	
Isolated: 0	
Paired: 0	

Runs

Total: 0	Beats 0
Longest: 0	
Fastest: 0	

Conclusions: Artificial Patient was monitored for 2:00 hours; 2:00 hours were analyzed. During this time the average heart rate was 71, with a minimum heart rate of 64 at @ 8:41:28 AM (1) and a maximum heart rate of 109 at @ 9:45:09 AM (1). The patient had 0 pauses greater than 2.0 seconds. The patient Artificial Patient's test showed 0 (0.0 %) ventricular ectopic beats. The patient had 0 isolated ventricular ectopic beats, 0 paired ventricular ectopic beats and 0 ventricular ectopic beat runs. 0 beats were in ventricular ectopic beat runs. The longest run had 0 beats at @ 8:37:13 AM (1) and the fastest run had a rate of 0 at @ 8:37:13 AM (1). The patient Artificial Patient's test showed 0 supraventricular ectopic beats (25 % prematurity). 0 beats were in supraventricular ectopic beat runs. The longest run had 0 beats at @ 8:37:13 AM (1) and the fastest run had a rate of 0 at @ 8:37:13 AM (1).

Physician's Signature _____ Date _____

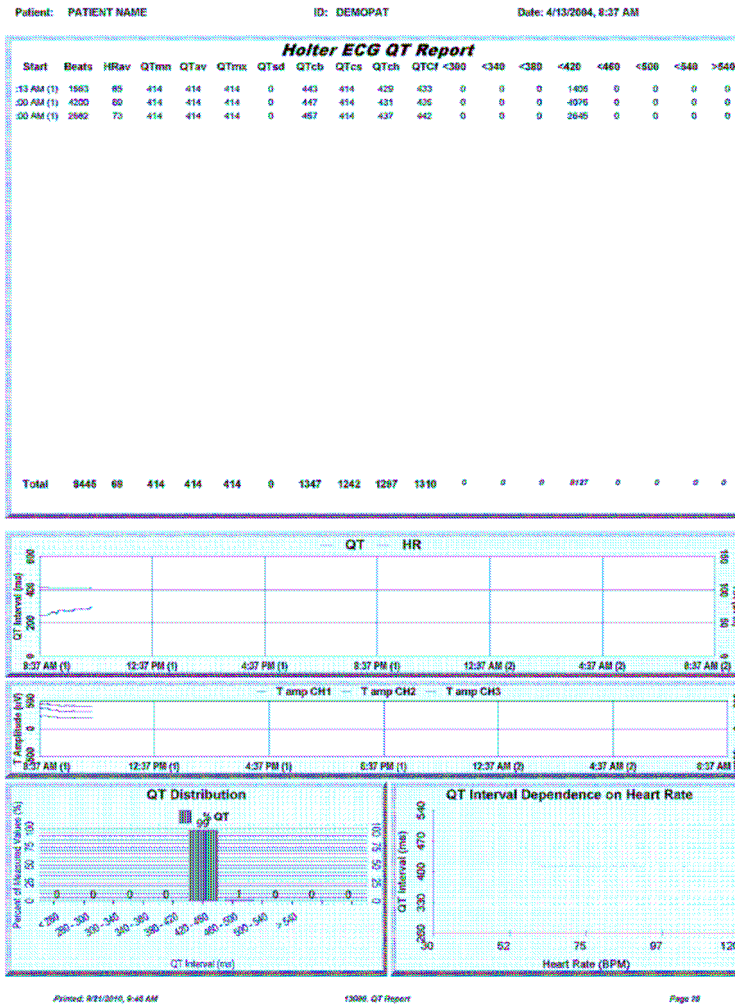
13080: Holter HRV Report

Patient: PATIENT NAME ID: DEMOPAT Date: 4/13/2004, 8:37 AM

HRV Time Domain Summary	
SDNN (ms): 35	SDSD (ms): 33
SDANN (ms): 7	NN50 Count: 293
RMSSD (ms): 33	pNN50 (%): 3.26
SDNN Index (ms): 23	



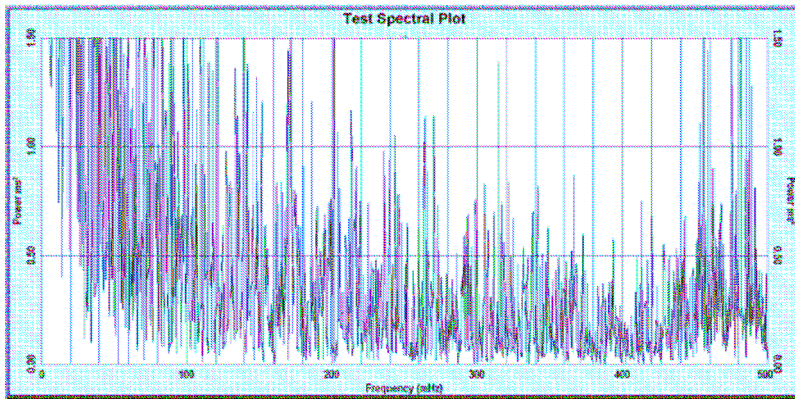
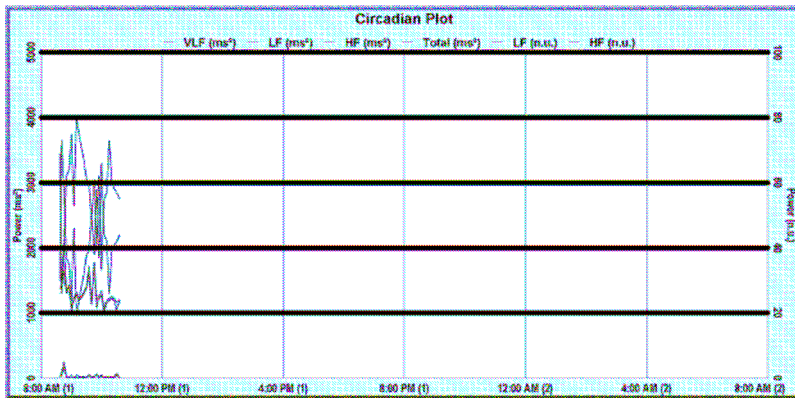
13090: QT Report



13180 Holter HRV Spectral Report

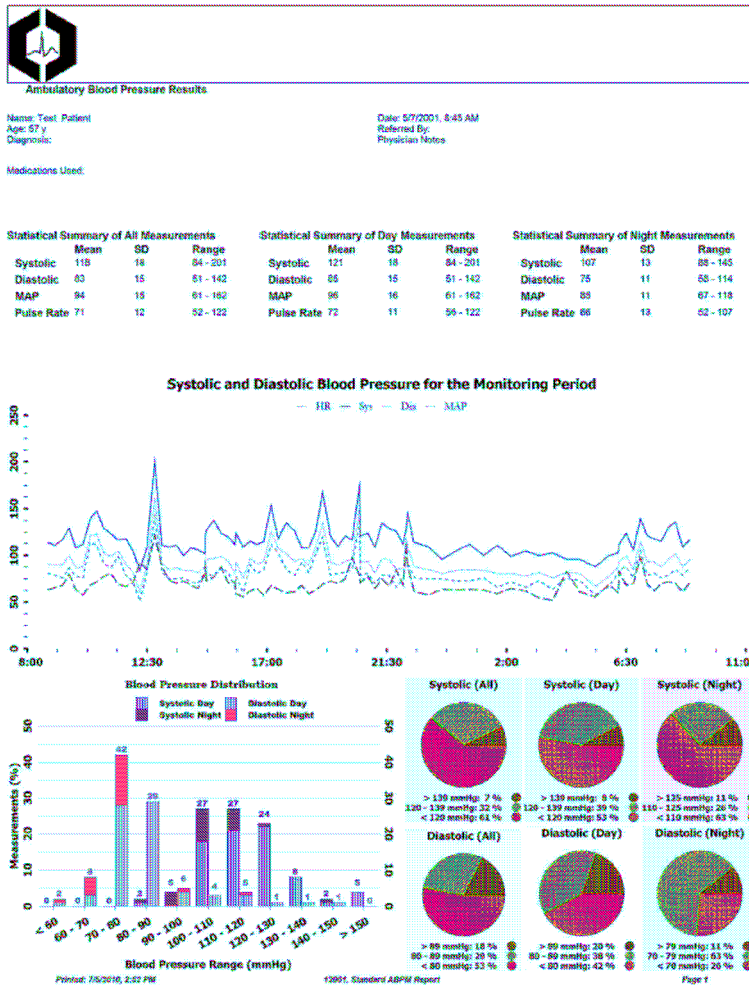
Patient: PATIENT NAME ID: DEMOPAT Date: 4/13/2004, 8:37 AM

HRV Frequency Domain Summary	
Total (ms ²)	1541
VLF (ms ²)	1457
LF (ms ²)	44
HF (ms ²)	39



Appendix 6: ABPM Sample Reports

12001 Standard ABPM Report



12002 ABPM Trend Report


Ambulatory Blood Pressure Results

 Name: Test Patient
 Age: 57 y
 Diagnosis:

 Date: 5/7/2001, 8:45 AM
 Referred By:
 Physician Notes

Medications Used:

Statistical Summary of All Measurements

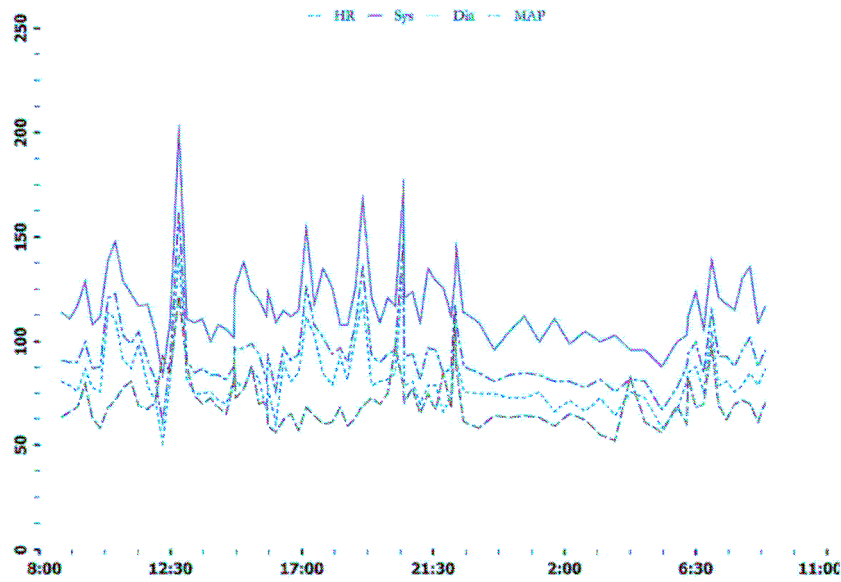
	Mean	SD	Range
Systolic	118	18	84 - 201
Diastolic	83	15	51 - 142
MAP	94	15	61 - 162
Pulse Rate	71	12	52 - 122

Statistical Summary of Day Measurements

	Mean	SD	Range
Systolic	121	18	84 - 201
Diastolic	85	15	51 - 142
MAP	96	16	61 - 162
Pulse Rate	72	11	56 - 122

Statistical Summary of Night Measurements

	Mean	SD	Range
Systolic	107	13	88 - 145
Diastolic	75	11	58 - 114
MAP	85	11	67 - 118
Pulse Rate	66	13	62 - 107

Systolic and Diastolic Blood Pressure for the Monitoring Period


Printed: 7/6/2010, 2:52 PM

19002: ABPM Trend Report

Page 2

12003 ABPM Distribution Report



Ambulatory Blood Pressure Results

Name: Test Patient
 Age: 57 y
 Diagnosis:

Date: 5/7/2011, 8:45 AM
 Referred By:
 Physician Notes

Medications Used:

Statistical Summary of All Measurements

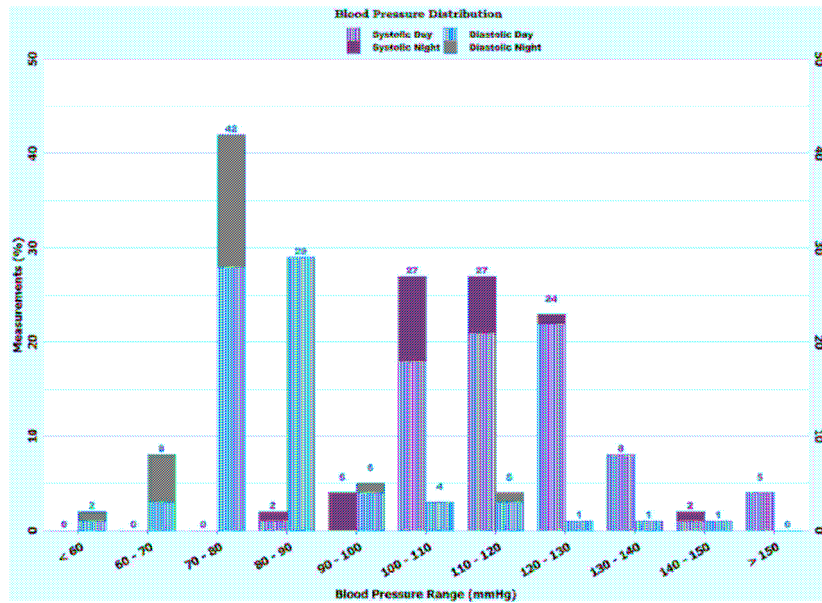
	Mean	SD	Range
Systolic	118	18	84 - 201
Diastolic	83	15	51 - 142
MAP	94	15	61 - 162
Pulse Rate	71	12	52 - 122

Statistical Summary of Day Measurements

	Mean	SD	Range
Systolic	121	18	84 - 201
Diastolic	85	15	51 - 142
MAP	96	16	61 - 162
Pulse Rate	72	11	60 - 122

Statistical Summary of Night Measurements

	Mean	SD	Range
Systolic	107	13	88 - 145
Diastolic	75	11	58 - 114
MAP	85	11	67 - 118
Pulse Rate	66	13	52 - 107



Printed: 7/8/2010, 2:52 PM

12003 ABPM Distribution Report

Page 3

12004 ABPM Pie Report



Ambulatory Blood Pressure Results

Name: Test Patient
 Age: 57 y
 Diagnosis:

Date: 5/7/2001, 9:45 AM
 Referred By:
 Physician Notes

Medications Used:

Statistical Summary of All Measurements

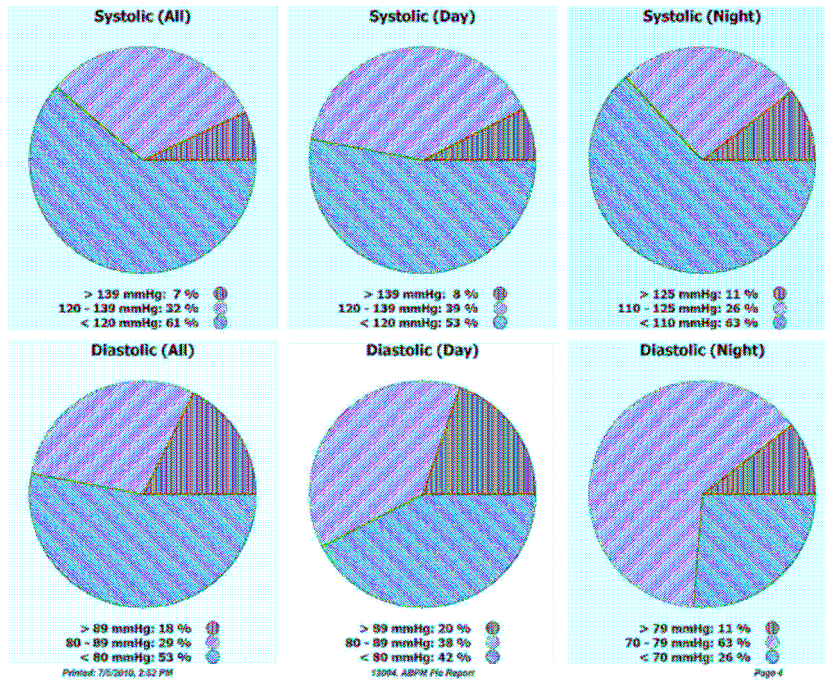
	Mean	SD	Range
Systolic	118	18	84 - 201
Diastolic	83	15	51 - 142
MAP	94	19	61 - 182
Pulse Rate	71	12	52 - 122

Statistical Summary of Day Measurements

	Mean	SD	Range
Systolic	121	18	84 - 201
Diastolic	85	15	51 - 142
MAP	96	16	61 - 182
Pulse Rate	72	11	58 - 122

Statistical Summary of Night Measurements

	Mean	SD	Range
Systolic	107	13	88 - 145
Diastolic	75	11	58 - 114
MAP	85	11	67 - 118
Pulse Rate	66	13	52 - 107



12005 ABPM Hourly Summary Report



Ambulatory Blood Pressure Results

Name: Test Patient
Age: 57 y
Diagnosis:

Date: 5/7/2001, 8:45 AM
Referred By:
Physician Notes

Medications Used:

ABPM Hourly Summary Report							
Start	Systolic	Diastolic	MAP	Pulse Rate	RPP	Number	Duration
:00 AM (1)	117	82	93	62	7254	2	15:00
:00 AM (1)	116	80	91	69	8004	4	60:00
:00 AM (1)	132	98	108	69	9108	4	60:00
:00 AM (1)	119	88	98	72	8568	3	60:00
:00 PM (1)	124	86	99	92	11408	4	60:00
:00 PM (1)	107	77	86	76	8132	4	60:00
:00 PM (1)	112	78	89	75	8400	5	60:00
:00 PM (1)	123	78	92	73	8979	5	60:00
:00 PM (1)	112	79	89	60	6720	4	60:00
:00 PM (1)	135	100	112	64	8640	3	60:00
:00 PM (1)	117	89	97	82	7254	4	60:00
:00 PM (1)	132	93	106	70	9240	3	60:00
:00 PM (1)	131	93	105	80	10480	5	60:00
:00 PM (1)	124	73	90	73	9052	4	60:00
:00 PM (1)	122	86	98	77	9394	5	60:00
:00 PM (1)	102	75	83	61	6222	2	60:00
:00 AM (2)	108	73	84	63	6804	2	60:00
:00 AM (2)	105	71	82	61	6405	2	60:00
:00 AM (2)	102	69	79	63	6426	2	60:00
:00 AM (2)	101	68	79	53	5353	2	60:00
:00 AM (2)	96	74	81	72	6912	2	60:00
:00 AM (2)	94	62	72	62	5828	2	60:00
:00 AM (2)	111	82	91	70	7770	4	60:00
:00 AM (2)	123	85	97	74	9102	4	60:00
:00 AM (2)	125	81	95	67	8375	3	59:00

* - indicates night measurement

Printed: 7/5/2010, 2:52 PM

12005, ABPM Hourly Summary Report

Page 5

12006 ABPM Measurement Report



Ambulatory Blood Pressure Results

Name: Test Patient
 Age: 57 y
 Diagnosis:

Date: 5/7/2001, 9:45 AM
 Referred By:
 Physician Notes:

Medications Used:

ABPM Measurement Report							
Start	Systolic	Diastolic	MAP	Pulse Rate	RPP	Status	Comment
8:47 AM (1)	0	0	0	0	0	X	at desk
8:49 AM (1)	120	84	88	82	74		
8:51 AM (1)	114	81	91	83	72		
9:06 AM (1)	111	79	90	86	73		
9:24 AM (1)	117	76	90	88	80		
9:40 AM (1)	129	87	100	90	103		
9:55 AM (1)	109	78	87	83	68		
10:11 AM (1)	112	76	88	86	65		
10:27 AM (1)	139	114	121	99	95		snack
10:42 AM (1)	148	111	123	72	107		pgm trouble
10:58 AM (1)	129	91	103	78	101		
11:14 AM (1)	123	87	99	81	100		
11:30 AM (1)	117	99	105	89	81		
11:46 AM (1)	118	79	91	87	79		lunch
12:04 PM (1)	106	72	82	71	75		
12:19 PM (1)	84	51	61	93	78		shower
12:35 PM (1)	109	82	91	85	93		walk
12:53 PM (1)	0	0	0	0	0	X	
12:53 PM (1)	201	142	162	122	245		
1:09 PM (1)	111	82	91	88	98		at desk
1:25 PM (1)	109	75	85	74	81		
1:41 PM (1)	111	75	87	70	78		
1:56 PM (1)	100	76	84	73	73		
2:14 PM (1)	109	72	84	98	73		
2:30 PM (1)	108	70	82	85	89		
2:46 PM (1)	102	82	88	81	83		

* - indicates right measurement

Printed: 7/5/2016, 3:05 PM

12006 ABPM Measurement Report

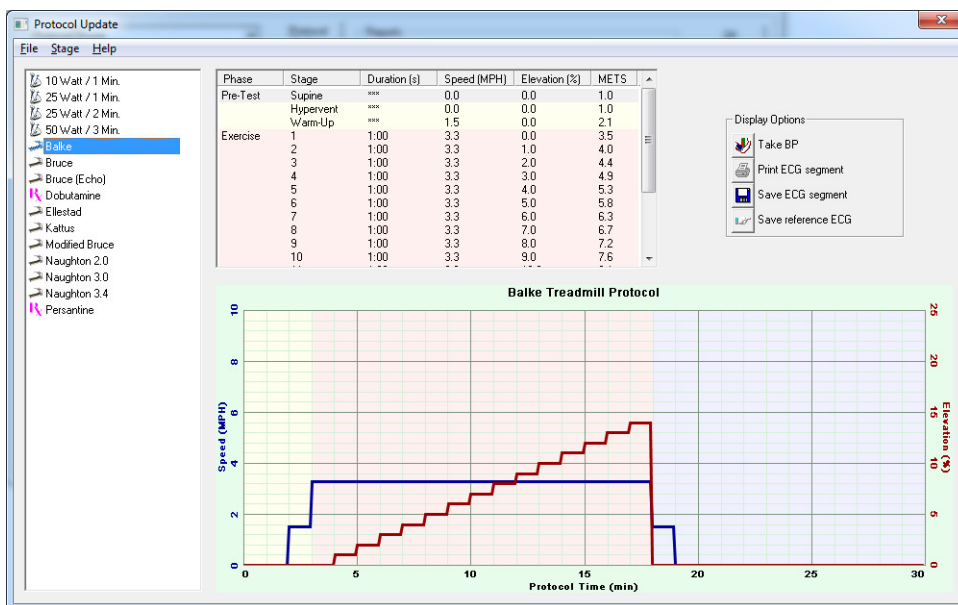
Page 1

Appendix 7: Stress Protocols

PBI has designed its Stress Protocol for maximum flexibility. Users can select a standard, predefined protocol like Bruce, Modified Bruce, etc or they can define their own custom protocol.

Protocols supplied with QRS-Card™ Cardiology Suite consist of three Phases (Pre-Test, Exercise, Recovery). Each Phase is subdivided into stages. Each stage can have a number of events associated with it (Ex: take blood pressure, increase elevation, increase load, print ECG segment).

Note: Within the Pre-phase user intervention is required to move on to the next stage.



Phases and Stages

1. Pre-Test

- **Supine-**
 - ECG monitored/acquired during supine stage.
 - User must click the 'Advance Stage' button to move to next stage.
- **Hyperventilation**
 - ECG monitored/acquired during hyperventilation stage.
 - User must click 'Advance Stage' button to move to next stage.

- **Warm-up**
 - ECG monitored/acquired during warm-up stage to check the quality of the ECG/ lead placement
 - User must click 'Advance Stage' button to move to next stage.

2. Exercise

- ECG monitored/acquired during exercise phase.
- Usually this phase consists of multiple stages (ex: Bruce protocol has 8 stages).

3. Recovery

- ECG monitoring after completing of the exercise phase
- Usually this phase consists of one stage.

Appendix 8: Corporate Summary

Pulse Biomedical Inc. (PBI) manufactures PC-based electrocardiogram (ECG/EKG) products. PBI is located outside Philadelphia, PA, USA and has a European office located in Germany.

PBI designs, manufactures and markets both the hardware and software components of a diagnostic, twelve-lead ECG system for use with a Windows personal computer. PBI QRS-Card™ Cardiology Suite was the first FDA approved PC-based ECG system, receiving approval in 1991.

During the initial years, PBI invested in research and development while establishing a corporate presence in the ECG marketplace through exhibiting at the American Heart Association and American College of Cardiology conferences.

Through research and development Cardiology Suite has progressed from a separate, DOS based insert able PC card to our newest FDA Bluetooth/USB system.

PBI owns all proprietary hardware design and has complete ownership to the source code for Cardiology Suite software, including its own Automatic ECG interpretation algorithm, Automatic ECG measurement algorithm, high-resolution signal averaging algorithms and Holter ECG analysis algorithms.

PBI sells its products through independent dealers worldwide. QRS-Card™ Cardiology Suite is used in over 50 countries worldwide and has sold its products on an OEM basis to a number of companies.

Appendix 9: Glossary

- **ABPM** Ambulatory Blood Pressure Measurement
- **Bluetooth** An open wireless protocol for transmitting data over short distances
- **ECG** (Electrocardiogram) Electrical signals generated by the heart muscles
- **USB** (Universal Serial Bus) Serial communication protocol for exchanging data between a host controller and a peripheral device
- **Hardware** Describes the physical components of a device
- **Software** A general term describing computer programs: applications, libraries, etc.
- **Firmware** Software specifically written for a device.
- **PC** Personal computer. Can be notebook, desktop, etc.
- **MCU** Micro Controller Unit

Appendix 10: Guidance and Manufacturer’s Declarations

⚠ WARNING

QRS-Card™ Cardiology Suite system needs special precautions regarding EMC and needs to be installed and put into service according to EMC information provided in Appendix 10.^[B92]

Portable and mobile RF communications equipment can affect QRS-Card™ Cardiology Suite system.^[B93]

Table 1:

Guidance and manufacturers declaration – electromagnetic emissions^[B94]		
The QRS-Card™ Cardiology Suite system is intended for use in the electromagnetic environment specified below. The customer or the user of the QRS-Card™ Cardiology Suite System should assure that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment- guidance
RF emissions CISPR 11	Group 1	The QRS-Card™ Cardiology Suite system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The QRS-Card™ Cardiology Suite system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions	Not applicable	


⚠ WARNING

The QRS-Card™ Cardiology Suite should not be used adjacent to or stacked on other equipment and that if adjacent or stacked use is necessary, the QRS-Card™ Cardiology Suite system should be observed to verify normal operation in the configuration in which it will be used.

Table 2:

Guidance and manufacturer's declaration – electromagnetic immunity			
The PBI QRS-Card™ Cardiology Suite system is intended for use in the electromagnetic environment specified below. The customer or the user of the PBI QRS-Card™ Cardiology Suite system should assure that it is used in such an environment.			
Immunity Test	IEC 60601 Test level	Compliance level	Electromagnetic environment-guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/output lines	Not applicable Not applicable	No power supply lines Input/output lines < 3M
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable Not applicable	No line(s) to line(s) No line(s) to earth
Voltage dips, short interruptions, and voltage variations on power supply lines IEC 61000-1-11	<5 % U_r (>95 % dip in U_r) 40 % U_r (60 % dip in U_r) for 5 cycles 70 % U_r (30 % dip in U_r) for 25 cycles <5 % U_r (>95 % dip in U_r) for 5 s	Not applicable	No power supply lines
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m		Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_r is the a.c. mains voltage prior to application of the test level			

Table 3:

Guidance and manufacturers's declaration- electromagnetic Immunity			
The PBI QRS-Card™ Cardiology Suite system is intended for use in the electromagnetic environment specified below. The customer or the user of the PBI QRS-Card™ Cardiology Suite system should assure that it is used in such an environment.			
Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic environment- guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2.5 MHz</p>	<p>3 Vrms</p> <p>0.81 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the PBI QRS-Card™ Cardiology Suite system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance $d = 1,2 \sqrt{P}$</p> <p>$d = 4.3 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz</p> <p>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey^a should be less than the compliance level in each frequency range^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> <div style="text-align: center;">  </div> <p>If you experience ECG signal distortion, please contact Pulse Biomedical Inc technical support team for guidance.</p>
NOTE 1	At 80 MHz and 800 MHz, the higher frequency range applies.		
NOTE 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.		
^a	Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the PBI QRS-Card™ ECG is used exceeds the applicable RF compliance level above, the PBI QRS-Card™ ECG should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocation the PBI QRS-Card™ ECG		
^b	Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3V/m		

NOTICE**A Note About Electromagnetic Immunity:**

The PBI QRS-Card™ provides high quality ECG at the expense of RF susceptibility. This position is justified twofold: 1) The morphology of the ECG waveform is maintained at the highest possible quality level. 2) Users of the QRS-Card™ are trained medical professionals that recognize ECG artifacts including RF interference, and thereby make the necessary corrections.

All semiconductors and ICs, whether analog or digital, demodulate RF signals: a process sometimes called audio rectification. Digital circuits exhibit more noise immunity than analog circuits. Highly sensitivity patient coupled analog circuits, such as those used in ECG devices, exhibit the least noise immunity.

It is possible to design analog circuits to demodulate less RF signals, but the problem cannot be eliminated. Shielding and filtering techniques reduce the levels of those RF signals that actually get through to the circuits. Shielding is never 100% effective, which forces the design into analog filtering. Analog filtering of cardiac signals distorts the morphology of the ECG waveform. Analog design requires a tradeoff between maximum signal quality and minimum RF noise. The PBI QRS Card™ uses minimum analog filtering to produce the highest fidelity ECG morphology, the tradeoff permits higher RF signal noise. The improved ECG signal quality justifies the increased RF susceptibility.

Users of the PBI QRS Card™ are trained medical professionals. These experts recognize interference from RF sources and identify interference on the ECG waveform, both during acquisition and when reviewing collected data. In addition, experts adjust electrodes and prepare the patient to minimize RF interference, motion artifact and other external interference for each test. This fact lends credence to the idea that increased sensitivity can be maintained in the device, while maintaining safety and effectiveness.

Hand-held mobile transmitters (such as walkie-talkies, 'handyphones', cellphones, radio-telephones, mobile phones, etc.) use up to 4W of RF power and can be close enough to expose equipment to electric fields in excess of the 3V/m or 10V/m typically required by medical equipment EMC standards. Mobile transmitters used by the emergency services can be up to 10W RF power, whilst (legal) vehicle transmitters can be up to 100W. These facts point out that there is no safe level of EMC immunity, as transmitting device become more powerful and portable.

Due to the ubiquity of hand-portable and vehicle mobile radio transmitters, this is a common problem which very few EMC or safety standards address.

Table 4:

Recommended separation distance between portable and mobile RF communications equipment and the PBI QRS-Card™ Cardiology Suite system			
The PBI QRS-Card™ Cardiology Suite system is intended for use in an electromagnetic environment in which radiated disturbances are controlled. The customer of the user of the PBI QRS-Card™ Cardiology Suite system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PBI QRS-Card™ Cardiology Suite system as recommended below, according to the maximum output power of the communications equipment			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 4.3\sqrt{P}$	800 MHz to 2,5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.43	0.23
0.1	0.37	1.4	0.74
1	1.2	4.3	2.3
10	3.7	14	7.4
100	12	43	23
<p>For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.</p> <p>NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p>			

Appendix 11: QRS-Blue™ Specifications

Addendum 3- Specifications

Resting and Stress Digital ECG Machine:

Channels	: 12
Size	: 4.0" x 2.5" x 1.0" (101.6mm x 63.5mm x 25.4mm)
Weight	: 4.5 ounces (127.6 grams)
Sampling rate	: 240Hz, 500Hz 12 ch.
Digital Resolution	: 5 μ V
Input dynamic range	: 10 mV _{pp}
Input Offset Range	: \pm 300 mV
Frequency Response	: 0.05 to 150 Hz (- 3dB)
CMMR	: -60dB (minimum)
Input Impedance	: > 100 M Ω
Defib protection	: Integrated
Operating Temp	: 0 to 40 °C
Storage Temp	: -10 to 50 °C
Relative Humidity	: 25 to 95 % noncondensing
Atmospheric Pressure	: 70 to 106 KPa
ECG Leads	: Detachable 10 Lead (Banana or Snaps)
Connection	: USB cable or Bluetooth
Power: USB	: Self (Internally) powered via USB port <100mA
Bluetooth	: Internally powered from 2 AA Batteries <100mA, Range up to 10 feet (3 meters) Minimum Operating Time with 2 AA Batteries = 20 continuous hr
Output Port	: TTL or Analog R wave or Non-diagnostic ECGLead selectable Default Gain 1000
ECG Measurements	: Automatic
ECG Interpretation	: Automatic
Data Storage	: PC Hard Drive, Flash Card or SD Card
Printing	: Laser / Inkjet; Color or Black & White
Reports	: Multi-format; user customizable; PDF
Email	: Microsoft® Outlook or MAPI compliant
Screen Format	: 1, 3, 6 or 12 Leads
ECG Speed	: 5, 10, 25 mm/sec
ECG Gain	: 5, 10, 20 mm/mV
ECG Filters	: Digital – 50/60 Line frequency; Muscle tremors 40 Hz Baseline drift

Database : Faircom C-Tree

File Format : Industry Standard SCP (Standard Communication Protocol)
or DICOM, HL7, PDF, TIFF, BMP

EMR Interface : Multiple EMR Software Interfaces

Warranty : 1 year on QRS-Blue™™ Device, 90 days on accessories

Medical Class : Class II

Type of Applied Parts : CF

Minimum System Requirements:

Computer : PC with Windows® XP or Vista (1GB or higher RAM)

Monitor : Color / TFT, Min. Res. 1024 x 768

Printer : Color or Black & White

Connection Type
Needed : USB Port or Bluetooth

Appendix 12: Service Instructions / Technical Description

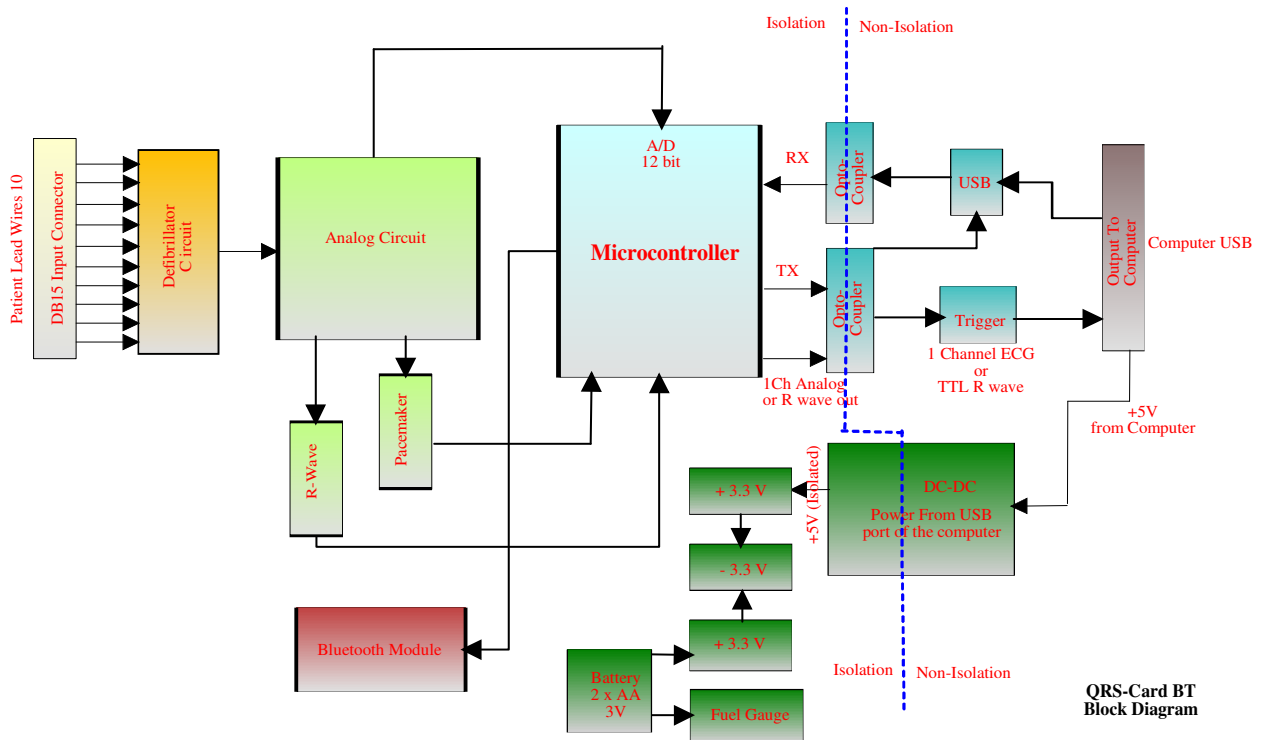
Introduction

PBI QRS-Blue™ ECG device converts a computer (PC) or a handheld device (Mobile Phone) into a 12 lead Resting and Stress Digital ECG machine. Connection between QRS-Blue™ is done via computer USB port or done wirelessly via Bluetooth Interface. ECG's can be viewed in real-time on the computer screen or hand held device. ECG data can be stored on the local memory or can be transmitted via Internet connection. ECG reports are printed via computer attached standard printer.

Theory of Operation

During an ECG, the electrical signals generated by heart on the body are transferred from the electrodes to the electronic circuit (ECG machine)

QRS-Blue™ is designed using sophisticated electronic surface mount component technology. Low voltage heart body potentials (ECG) are amplified by QRS-card BT circuitry and then digitized before sending it to the computer. A low power micro controller digitized the amplified ECG analog signal, formats the ECG data and transfer the data to the host computer via USB or wireless Bluetooth connection.



QRS-Blue™ consists of following:

1. DB15 10 Lead Patient Connector
2. Defibrillator protection
3. Analog Bandwidth .05Hz -150 Hz
4. Input Buffer Amplifiers (x 1)
5. Amplifiers
 - a. Stage 1: Differential Instrumental Amplifiers (x 5)
 - b. Stage 2: Operational Amplifiers (x 16.4)
 - c. Stage 3: Operation Amplifiers (x 2)
6. Hardware R-wave Detection
7. Hardware Pacemaker Detection
8. Micro controller with Analog to Digital Converter
9. Sampling of 240 Hz (8 channels), 500 Hz (8 channeld) or 1000 Hz 4 Channels).
10. TTL R-wave Trigger signal out (Opto-Isolated)
11. One Channel Analog ECG Trigger Out (Pulse width modulation out)
12. Optical Isolation
13. Power Isolation
14. USB data connection
15. Bluetooth data connection
16. Battery Fuel Gauge

Patient Connector:

The QRS-Blue™ uses a DB15 Female connector for connecting a 10 lead patient cable. Pin configuration for this connector is:

Pin #	Signal
1	V2
2	V3
3	V4
4	V5
5	V6
6	Shield
7	N/A
8	N/A
9	RA
10	LA
11	LL
12	V1
13	N/A
14	RL
15	N/A

Defibrillator Protection:

In order to protect the circuit from high voltage generated from Defibrillator total of 10 Metal Oxide Varistors (MOV) used at the input of each lead.

Buffers:

Unity gain Operational Amplifier are used for creating high impedance input before input of the ECG signal to the differential instrumental amplifiers.

Amplifiers:

Stage 1

8 Channels of ECG (lead I, Lead II, V1-V6) are amplified 5 times using Instrument amplifiers and

Stage 2

Operational Amplifiers are used to amplify ECG signal 16.4 times

Stage 3

Operational Amplifiers are used to amplify ECG signal 2 times

Total amplification stage 1 to stage 3 is 164

R-wave Detection Circuit:

Hardware electronic circuit is used to detect R-wave pulses in the patient ECG signal. Output of the R-wave is fed into the microcontroller, which in return provide an optically isolated TTL Rwave signal output to pin 4 of RJ45 output connector.

NOTICE: Pin 4 is software programmable either of TTL – Rave signal or Analog ECG signal

Hardware Pacemaker Detection Circuit:

Hardware electronic circuit is used to detect Pacemaker pulses in the patient ECG signal. Output of the pacemaker circuit is fed into the microcontroller, which in return, provides a marker in the communication data packets.

Microcontroller:

QRS-Blue™ provides a Microcontroller to digitize the ECG signal and control the inputs and outputs of the circuit. Microcontroller supports the digital controlling logic for the circuit. The Microcontroller also supplies the 8 channels of 12 bit analog to digital conversion used for ECG acquisition. Several digital I/O ports are used as inputs and outputs for controlling other logic features. Two UARTS are used to communicate with the USB and Bluetooth connections. The Analog ECG output signal port output requires the pulse width modulation feature of Microcontroller.

Data Format, Resolution and Sampling Rate:

QRS-Blue™ provides digitized data over USB port or Bluetooth wireless connection using proprietary digital data format.

QRS-Blue™ data resolution is 12 bit (4.88uV/Bit).

QRS-Blue™ sampling rate can be adjustable between 240 Hz or 500 Hz via software setup.

Analog ECG Trigger Output:

QRS-Blue™ has an optional signal output (R wave or Analog wave) to provide an optically isolated one channel Analog ECG trigger signal on pin 4 of RJ45 connector. The channel I, II or V1-V6 can be selected via software setup.

NOTICE Pin 4 is software programmable either of TTL – Rave signal or Analog ECG signal

Signal Isolation:

All digital signal isolation between patient and the computer is providing by using low leakage current and high isolation voltage Optocouplers

Power Isolation:

For USB operation of QRS-Blue™ draws power from the computer USB port. Isolation between USB power and patient is provided by medical grade IEC60601-1 approved DC-DC power supply.

Data Communication:

QRS-Blue™ data communication to the computer is done either computer USB port or through wireless Bluetooth connection. When USB interface is used Bluetooth communication is automatically disabled.

Power:

Bluetooth mode of QRS-Blue™ requires 2 AA batteries for its proper operation. During USB mode operation power is drawn from the USB port of the compute. A battery fuel gauge circuit continuously monitors battery voltage and warns the user if the battery is getting low in voltage.

System Maintenance & Service:

QRS-Blue™ is made with high quality electronic parts and has no moveable parts which makes its virtually maintenance free ECG device. Care must be taken for the cables used (Patient lead wires and USB data cable) with the QRS-Blue™ machine so that wires should not be damaged and should always be clean.

QRS-Blue™ is a digital ECG machine with auto calibration built in. QRS-Blue™ ECG does not require any annual calibration of the ECG signals.

Batteries should not be kept inside the QRS-Blue™ device for extended period of time when the device is not in use. Batteries must be replaced when low battery sign is shown on the device LED and on the computer software screen.

QRS-Blue™ does not have any serviceable parts. For repairs or technical support call Pulse Biomedical Inc. for a Return Authorization Number before sending the device for repair to Pulse Biomedical Inc.

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