

## QRS-Card<sup>™</sup> Cardiology Suite 4.06 Software QRS-Blue<sup>™</sup> ECG Device Operating Instructions





## **Operating Instructions**

## QRS-Card<sup>™</sup> Cardiology Suite Version 4.06 QRS-Blue<sup>™</sup> 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.

Windows<sup>®</sup> and Microsoft<sup>®</sup> are registered trademarks of Microsoft Corporation.

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.

Copyright © 2013 Pulse Biomedical, Inc. All Rights Reserved

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

Pulse Biomedical, Inc. 112 Ivy Lane King of Prussia, PA, USA (610) 666-5510 <u>info@qrscard.com</u> <u>www.qrscard.com</u>



Pulse Biomedical GmbH Wilhelm-Bihler-Str. 4





72474 Winterlingen, Germany



## **Table of Contents**

1.	Safety	9
1.1	Safety Conventions	. 10
1.2	User Responsibility	. 11
1.3	Warnings and Cautions	. 12
1.4	Symbols and Markings	. 15
2	Introduction & Walcoma	16
2.		10
3.	Installing QRS-Card <sup>™</sup> Cardiology Suite Software	17
3.1	Hardware and Software Requirements	. 17
3.2	Software Installation	. 18
3.2.	1 Upgrading Software	. 18
3.2.	2 Installing New Software	. 21
4	ORS-Blue <sup>TM</sup> Hardware Usage	22
<b>4</b> 1	USB Usage	22
4.2	Bluetooth Wireless Usage	22
4.3	Maintenance and Cleaning of ORS-Blue <sup><math>TM</math></sup> .	. 22
_		
5.	Getting Started With QRS-Card <sup>™</sup> Cardiology Suite	23
		~ ~
5.1	QRS-Card <sup>™</sup> Cardiology Suite Master Screen	. 23
5.1 6.	QRS-Card <sup>™</sup> Cardiology Suite Master Screen Resting ECG Module	. 23 25
5.1 6. 6.1	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP	. 23 25 . 25
5.1 6. 6.1 6.2	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG	. 23 25 . 25 . 28
5.1 6. 6.1 6.2 6.3	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG         Reviewing a Resting ECG Test	. 23 25 . 25 . 28 . 30
5.1 6. 6.2 6.3 6.3.	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab.	. 23 25 . 25 . 28 . 30 . 31
5.1 6. 6.1 6.2 6.3 6.3. 6.3.	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab         2       View	. 23 25 . 25 . 28 . 30 . 31 . 33
5.1 6. 6.1 6.2 6.3 6.3. 6.3. 6.3.	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab         2       View         3       Summary	. 23 25 . 25 . 28 . 30 . 31 . 33 . 38
5.1 6. 6.1 6.2 6.3 6.3. 6.3. 6.3. 6.3.	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab         2       View         3       Summary         4       Report	. 23 25 . 25 . 28 . 30 . 31 . 33 . 38 . 46
5.1 6. 6.1 6.2 6.3 6.3. 6.3. 6.3. 6.3. 7.	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module.         RESTING ECG SETUP.         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab.         2       View         3       Summary         4       Report.         Stress ECG Module.	23 25 25 28 30 31 33 38 46 48
5.1 6. 6.1 6.2 6.3 6.3. 6.3. 6.3. 6.3. 7. 7.	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab         2       View         3       Summary         4       Report         5       Stress ECG Module         Stress ECG Setup       Stress ECG Setup	. 23 25 . 25 . 28 . 30 . 31 . 33 . 38 . 46 48 . 48
5.1 6. 6.1 6.2 6.3 6.3. 6.3. 6.3. 6.3. 7. 7.1 7.2	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab         2       View         3       Summary         4       Report         5       Stress ECG Module         Stress ECG Setup       Recording a Stress ECG	23 25 25 28 30 31 33 38 46 <b>48</b> 48 54
5.1 6. 6.1 6.2 6.3 6.3. 6.3. 6.3. 6.3. 7. 7. 7.2 7.2.	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module.         RESTING ECG SETUP.         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab.         2       View         3       Summary         4       Report.         5       Stress ECG Module.         Stress ECG Setup       Recording a Stress ECG.         1       Phases and Stages	23 25 25 28 30 31 33 38 46 48 48 48 54 54
5.1 6. 6.1 6.2 6.3 6.3. 6.3. 6.3. 6.3. 7. 7. 7.1 7.2 7.2. 7.2.	QRS-Card <sup>™</sup> Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP.         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab.         2       View.         3       Summary.         4       Report.         5       Stress ECG Module.         Stress ECG Setup       Recording a Stress ECG.         1       Phases and Stages         2       Starting a Stress ECG Test.	23 25 25 28 30 31 33 38 46 48 54 54 54
5.1 6. 6.1 6.2 6.3 6.3. 6.3. 6.3. 6.3. 7. 7.1 7.2 7.2. 7.2. 7.2. 7.2.	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab.         2       View         3       Summary         4       Report.         5       Stress ECG Module         Stress ECG Setup       Recording a Stress ECG         1       Phases and Stages         2       Starting a Stress ECG Test.         3       Tasks Performed During a Stress Test:	23 25 25 28 30 31 33 38 46 48 48 48 54 55 55 56
5.1 6. 6.1 6.2 6.3 6.3. 6.3. 6.3. 6.3. 6.3. 7. 7. 7.2. 7.2. 7.2. 7.2. 7.3	QRS-Card™ Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab.         2       View         3       Summary         4       Report.         5       Stress ECG Module         Stress ECG Setup       Recording a Stress ECG         1       Phases and Stages         2       Starting a Stress ECG Test.         3       Tasks Performed During a Stress Test:         Reviewing a Stress Test       Stress Test	23 25 25 28 30 31 33 38 46 48 54 54 55 56 60
5.1 6. 6.1 6.2 6.3 6.3. 6.3. 6.3. 6.3. 6.3. 7. 7.1 7.2 7.2. 7.2. 7.2. 7.2. 7.3 7.3.	QRS-Card <sup>™</sup> Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab.         2       View         3       Summary.         4       Report.         5       Stress ECG Module.         Stress ECG Setup.       Recording a Stress ECG.         1       Phases and Stages         2       Starting a Stress ECG Test.         3       Tasks Performed During a Stress Test:         1       Edit	23 25 28 30 31 33 38 46 48 54 54 54 55 56 60 61
5.1 6. 6.1 6.2 6.3 6.3 6.3 6.3 6.3 6.3 6.3 7. 7.2 7.2 7.2 7.2 7.2 7.2 7.2 7.2 7.3 7.3 7.3 7.3	QRS-Card <sup>™</sup> Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab.         2       View         3       Summary         4       Report.         5       Stress ECG Module         Stress ECG Setup       Recording a Stress ECG.         1       Phases and Stages         2       Starting a Stress ECG Test.         3       Tasks Performed During a Stress Test:         1       Edit.         2       View.	23 25 25 28 30 31 33 38 46 48 48 48 48 55 56 60 61 62
5.1 6. 6.1 6.2 6.3 6.3. 6.3. 6.3. 6.3. 6.3. 7. 7.1 7.2 7.2. 7.2. 7.2. 7.2. 7.3 7.3. 7.3. 7	QRS-Card <sup>™</sup> Cardiology Suite Master Screen         Resting ECG Module         RESTING ECG SETUP         Recording a Resting ECG         Reviewing a Resting ECG Test         1       Edit Tab.         2       View         3       Summary         4       Report.         5       Stress ECG Module         Stress ECG Setup       Recording a Stress ECG         1       Phases and Stages         2       Starting a Stress ECG Test.         3       Tasks Performed During a Stress Test:         1       Edit	<b>25</b> <b>25</b> <b>28</b> <b>30</b> <b>31</b> <b>33</b> <b>38</b> <b>46</b> <b>48</b> <b>54</b> <b>54</b> <b>54</b> <b>54</b> <b>55</b> <b>56</b> <b>60</b> <b>61</b> <b>62</b> <b>67</b>



8.	He	olter ECG Module	
8.1	Но	ter ECG Setup and Download	
8.2	Re	viewing a Holter ECG Test	
8.2	2.1	Edit Tab	
8.2	2.2	View	
8.2	2.3	Summary Tab	
8.2	2.4	Expert	
9.	Ar	nbulatory Blood Pressure Monitoring	
9.1	AB	PM Setup and Download	
9.2	Vie	wing an ABPM Test	
9.2	2.1	Edit	
9.2	2.2	View	
9.2	2.3	Summary	
9.2	2.4	Report	
10	C	• /	100
10.	Sp	irometry	102
11.	Re	mote Server/Cloud Database	103
12.	Ut	ilitios	
12.1	•••	\  L ES	
12.1	To	vics	<b> 104</b>
12.1	Toj .1.1	bics	<b> 104</b> 104 104
12.1	Toj .1.1 .1.2	pics Configuration Physicians	<b>104</b> 
12.1 12. 12. 12.	Toj .1.1 .1.2 .1.3	Dics Configuration Physicians Clinics	
12.1 12. 12. 12. 12.	Toj .1.1 .1.2 .1.3 .1.4	Dics Configuration Physicians Clinics Technicians	
12.1 12. 12. 12. 12. 12. 12.	Toj .1.1 .1.2 .1.3 .1.4 .1.5	Configuration Physicians Clinics Technicians Import Records	<b>104</b> 104 104 104 114 115 115 116 117
12.1 12. 12. 12. 12. 12. 12. 12.	Toj .1.1 .1.2 .1.3 .1.4 .1.5 .1.6	Dics Configuration Physicians Clinics Technicians Import Records Import Reports	<b>104</b> 
12.1 12. 12. 12. 12. 12. 12. 12. 12.	Toj .1.1 .1.2 .1.3 .1.4 .1.5 .1.6 .1.7	Configuration Physicians Clinics Technicians Import Records Queue System	<b>104</b> 
12.1 12. 12. 12. 12. 12. 12. 12. 12. 12.	Toj .1.1 .1.2 .1.3 .1.4 .1.5 .1.6 .1.7 .1.8	Dics Configuration Physicians Clinics Technicians Import Records Import Reports Queue System Rebuild	104           104           104           104           114           115           116           117           118           119           122
12.1 12. 12. 12. 12. 12. 12. 12. 12. 12.	Toj .1.1 .1.2 .1.3 .1.4 .1.5 .1.6 .1.7 .1.8	Dics Configuration Physicians Clinics Technicians Import Records Import Reports Queue System Rebuild	
12.1 12. 12. 12. 12. 12. 12. 12. 12. 12.	Toj .1.1 .1.2 .1.3 .1.4 .1.5 .1.6 .1.7 .1.8	pics Configuration Physicians Clinics Technicians Import Records Import Reports Queue System Rebuild	104         104         104         104         114         115         116         117         118         119         122         123
12.1 12. 12. 12. 12. 12. 12. 12. 12. 12.	Toj .1.1 .1.2 .1.3 .1.4 .1.5 .1.6 .1.7 .1.8 Lo	pics Configuration Physicians Clinics Technicians Import Records Import Reports Queue System Rebuild <b>gs</b>	
12.1 12. 12. 12. 12. 12. 12. 12.	Toj .1.1 .1.2 .1.3 .1.4 .1.5 .1.6 .1.7 .1.8 Lo He Co	Dics Configuration Physicians Clinics Technicians Import Records Queue System Rebuild <b>gs</b> <b>lp</b> Itents	



Append	lix 1: Accessories, Warranty and Repairs	
Append	lix 2: Patient Prenaration	
Acauiri	ing a Good Ouality Resting ECG	
Preppin	ng Patient & Electrode Placement	
Reusab	le Electrodes	
Disposa	able Tab Electrodes	
Append	lix 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	
1210	Standard 12 Lead (12 x 1) Report	
1212	Standard Complex Report	
Append	lix 4: Stress Sample Reports	
1000 St	tress ECG Segment (3 lead)	
1001 St	tress ECG Segment (12 lead)	
1002 St	tress ECG Result Table	
1003 St	tress ECG Summary Report	
1004 St	tress ECG Summary Report (Classic)	
1005 St	tress Stage ECG Complex Summary	
1006 St	tress Stage ECG Rhythm Summary	
1007 St	tress Phase ECG Complex Summary	
1008 St	tress Phase ECG Rhythm Summary	
1009 St	tress ECG Full Disclosure	
1010 St	tress Test Trends	
1011 St	tress Stage ECG Rhythm Summary (3 lead)]	
1012 St	tress Phase ECG Rhythm Summary (3 lead)	
1013 St	tress ECG Selected Segments	
1014 R	eview Screen	
1015 St	tress ECG Summary Report (Europe)	
1016 St	tress Stage ECG Rhythm Summary (Classic 3)	
1017 St	tress Stage ECG Rhythm Summary (Classic 12)	
1018 St	tress ECG Real-Time Report	



Appendix 5: Holter Sample Reports	157
13000. Holter ECG Summary Report	157
13010: Holter ECG Result Summary Report	158
13011: Holter ECG Result Summary Report B	159
13020: Holter ECG Hourly Summary Report	160
13030: Holter ECG Trend Report	161
13040: Holter ECG Selected Segments Report	162
13041: Holter ECG Selected Segments Report	163
13050: Holter ECG Full Disclosure Report	164
13060: Review Screen	165
13070: Holter ECG Result Summary Report (pacemaker)	166
13080: Holter HRV Report	167
13090: QT Report	168
13180 Holter HRV Spectral Report	169
Appendix 6: ABPM Sample Reports	170
12001 Standard ABPM Report	170
12002 ABPM Trend Report	170
12003 ABPM Distribution Report	172
12004 ABPM Pie Report	173
12005 ABPM Hourly Summary Report	174
12006 ABPM Measurement Report	175
Appendix 7: Stress Protocols	176
Appendix 8: Corporate Summary	178
Appendix 9: Glossary	179
Appendix 10: Guidance and Manufacturer's Declarations	180
Appendix 11: QRS-Blue <sup>TM</sup> Specifications	185
Appendix 12: Service Instructions / Technical Description	187



# **ACAUTION** US Federal law restricts this device to sale by or on the order of a physician.

▲ CAUTION Use the QRS-Card<sup>TM</sup> 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.

QRS-Card<sup>TM</sup> Cardiology Suite<sup>TM</sup>, QRS-Card<sup>TM</sup> and QRS-Blue<sup>TMTM</sup> are trademarks of Pulse Biomedical, Inc..

Software is Copyright 2007, Pulse Biomedical, Inc. All rights are reserved. The software is protected by United States of America copyright laws and international treaty provisions applicable worldwide. Under such laws, the licensee is entitled to use the copy of the software provided on the original distribution medium. The software may not be copied, decompiled, reverse-engineered, disassembled or otherwise reduced to human-perceivable form.

This is not a sale of the software or any copy of the software; all right, title and ownership of the software remains with Pulse Biomedical, Inc.

For information about any Pulse Biomedical, Inc. product, call your nearest PBI office: USA +1 610 666-5510 Europe + 49 7434 31603



## 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:

## **A**WARNING

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

## **A**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

**ACAUTION** 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**

## **ACAUTION**

- 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<sup>™</sup> first fully disconnect from computer. Use warm soap and water and surface disinfectant only. Do not immerse the QRS-Card<sup>™</sup> in the cleaning solution as permanent damage to the QRS-Card<sup>™</sup> may occur. [u5]

## **A**WARNING

The QRS-Card<sup>™</sup> 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<sup>™</sup> Cardiology Suite system.[B9]
- 4. If using a Treadmill with QRS-Card<sup>TM</sup>, use only FDA cleared treadmills.[u10]
- 5. If software CD becomes unusable, software can be downloaded from PBI web site (<u>www.qrscard.com</u>).[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<sup>™</sup> Device label or in the QRS-Card<sup>™</sup> Cardiology Suite software.[u14]
- 9. Do not connect the patient cable to anything other than the QRS-Card<sup>TM</sup> Device. Be sure you know how to properly connect the patient cable to the QRS-Card<sup>TM</sup>.[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<sup>TM</sup> 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<sup>™</sup> Cardiology Suite hardware and software does not provide or detect pacemaker pulses. Do not rely on the QRS-Card<sup>™</sup> 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<sup>™</sup> ECG device must be at least 6 feet away from the computer.
- 16. LOW BATTERY: If the QRS-Card<sup>TM</sup> 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<sup>™</sup> Cardiology Suite ECG system software is running.
- 20. Use the QRS-Card<sup>™</sup> software as stand-alone software. Do not run other software applications while running the QRS-Card<sup>™</sup> 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<sup>™</sup>, electromagnetic compatibility with surrounding devices should be considered and evaluated. The QRS-Card<sup>™</sup> 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<sup>™</sup> fails, please refer to the troubleshooting section in the user manual.

### **Medical Device Directive**

The PBI QRS-Card<sup>™</sup> 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
- E Caution, Consult accompanying documents.



= Defibrillation proof type CF applied part



= Serial Number of QRS-Blue<sup>TM</sup>



- = Manufacturers address and date of manufacture.
- EC REP
- = Name and address of European Representative



= Temperature Limitation



= Keep Dry



## 2. Introduction & Welcome

Welcome to the Pulse Biomedical QRS-Card<sup>TM</sup> Cardiology Suite. QRS-Card<sup>TM</sup> 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<sup>™</sup> Cardiology Suite software, for more information on device hardware, please refer to the particular hardware manual.

For stress/exercise ECG testing the QRS-Card<sup>TM</sup> 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<sup>TM</sup> Cardiology Suite can also be interfaced with EMR software, please contact PBI for more information.

We thank you for purchasing QRS-Card<sup>TM</sup> 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 <u>www.QRSCard.com</u> Email: Info@QRSCard.com

**NOTICE** QRS-Card<sup>TM</sup> 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.



## Installing QRS-Card<sup>TM</sup> Cardiology Suite 3. **Software**

## **3.1 Hardware and Software Requirements**

PBI QRS-Card<sup>™</sup> 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<sup>™</sup> 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<sup>TM</sup> Hardware products may have additional requirements. Please refer to the applicable hardware guide for information.

NOTICE QRS-Card<sup>™</sup> 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<sup>™</sup> Cardiology Systems come with a software installation CD (you can also download a full software version from our web site <u>www.QRSCard.com</u>). Before installing QRS-Card<sup>™</sup> 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<sup>™</sup> 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<sup>TM</sup> Cardiology Suite follow the instructions below (Note: these instructions are using Windows 7<sup>TM</sup> operating system, for help with other operating systems, contact PBI):

- 1. Uninstall the earlier QRS-Card<sup>TM</sup> Cardiology Suite.
  - Open your Start Menu and select "Control Panel"
  - -



\_

talk Google Talk	
Microsoft Word 2010	Windows 7
Calculator	Documents
Windows Live Messenger	Pictures
Microsoft Excel 2010	Music
EPSON Scan	Games
Microsoft Publisher 2010	Computer
Snipping Tool	Control Panel
Big Calculator	Devices and Printers
Microsoft Office Word 2003	Help and Support
All Programs	
Search programs and files	Shut down 🕨

- 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."





🐻 Add or Re	move Programs		/ . 🗆 🛛
5	Currently installed programs:	ates Sort by: Name	~
Change or Remove	OrderReminder HP LaserJet 1020	Size	0.50MB 🛆
Programs	🔁 PCI SoftV92 Modem	Size	0.55MB
	🚙 pdfsam	Size	14.15MB
Add New	🔁 PL-2303 USB-to-Serial	Size	2.40MB
Programs	PowerDVD	Size	14.42MB
<b>F</b>	Heresto! BizCard 5 SE (English Version)	Size	2.50MB
Add/Remove	🍋 Presto! PageManager 7.16	Size	195.00MB
Windows	PrimoPDF by Nitro PDF Software	Size	11.11MB
components	💯 QB Connection Diagnostic Tool	Size	1.96MB
<b>(</b>	💃 QRS Card for Windows		
Set Program	💃 QRS-Card Cardiology Suite	Size	<u>48.99MB</u>
Defaults	Click here for support information.	Used	frequently
		Last Used On	10/26/2010
	To change this program or remove it from your computer, click Change or Remo	Change	Remove
	🙀 QuickBooks Pro 2007	Size	623.00MB
	🚱 QuickBooks Pro 2010	Size	871.00MB 💻
	🞧 QuickBooks Product Listing Service	Size	17.39MB
	SuickTime	Size	77.55MB 💟

- Once uninstallation is complete, installing QRS-Card<sup>™</sup> 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<sup>™</sup> Cardiology Suite, please see "Upgrading Software" instructions above.

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



## 4. **QRS-Blue<sup>TM</sup> Hardware Usage**

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

**AWARNING** No modification of this equipment is allowed

## 4.1 USB Usage

If the QRS-Blue<sup>TM</sup> is used as a USB device, the device is powered through the computer (you do not need batteries). Once your QRS-Blue<sup>TM</sup> 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<sup>TM</sup> is successfully powered.

### 4.2 Bluetooth Wireless Usage

If the QRS-Blue<sup>TM</sup> 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<sup>TM</sup> is powered on, the status indicator light (next to the on/off button) will display a flashing green light showing that the QRS-Blue<sup>TM</sup> 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<sup>TM</sup>, 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.

**ACAUTION** If you plan on storing your QRS-Blue<sup>TM</sup> for an extended period of time, remove batteries. Leaving battery in QRS-Blue<sup>TM</sup> could cause the battery to leak.

## 4.3 Maintenance and Cleaning of QRS-Blue<sup>TM</sup>

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





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 <sup>TM</sup> Cardiology Suite.
Menu bar	The menu bar contains additional functionality for the QRS-Card <sup>™</sup> Cardiology Suite.



Tool bar	The tool bar contains buttons that give you easy access to the most	
	common tasks in QRS-Card <sup>™</sup> Cardiology Suite, such as testing modules.	
Test Tool	The Test Tool Bar contains buttons that allow you to work easier with	
Bar	saved tests. You can open, print, mail or compare ECG's and add or	
	delete tests.	
Patients'	The Patients' Test Database contains records for all of the tests	
Test	performed. In this area you can find a patient, see which tests were	
Database	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	You can sort the patient database by patient name, id, test date or type of	
Toolbar	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]	
<b>Test Preview</b>	The Test Preview displays a brief overview of the file selected.	
~ ~ ~		
Status &	The Status message contains information about what version of QRS-	
Warning	Card <sup>TM</sup> Cardiology Suite you are running along with licensing	
Messages	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<sup>™</sup> 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

Click on the Rest ECG icon

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



(If the "Show This Window" option in the

Resting Setup has been selected, the Resting Setup screen will automatically be displayed. )

Resting	10-10 10-0 10 10-00 10-00 10 10-10 10-0 10 10-10 10-0 10	<b>x</b>
Resting Procedure Tasks         Show this window         Show electrode position diagram.         Start test when measurements valid         Print ECG report.         View test record         Exit when all tasks complete.         Remote Server.	Default Reports           ID         Name           1200         Standard 12 Lead           1203         Standard 3 Lead           1206         6%2 12 Lead Standard           1208         6%2 2 Page 12 Lead Standard           1210         12%1 12 Lead Standard	<u>Q</u> K <u>C</u> ancel <u>H</u> elp <u>S</u> TAT ECG
ECG Filter Electrical interference 60 Hz Artifact rejection None Baseline Drift Reduction On	ECG Acquisition Recorder QRS Card (Bluetooth  Ity Sample Rate 240 Hz Length 600	<u>D</u> emo
Interpretation PBI	Average Lycies   20	<u>R</u> eset

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	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. 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.	
View Test Record	If selected, the ECG test record will be displayed automatically after the Resting ECG Test is finished. If unselected, after the test is finished, the software will return to the master screen.	
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. ( <b>NOTE:</b> 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	Defines "Default" parameters for Screen display values during ECG acquisition and viewing. E.G. Gain, Speed, Lead Display etc. Configure Acquisition Screen Provide Acquisition Screen	



	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.
	• • • 1 ld     • • • 3 ld     • • • V2     • • • V5     • • • 6 ld
	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"
	Configure Acquisition Screen
	Acquisition       View         Page
	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	
	IT 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.
	<b>NOTICE</b> 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



OR

From the toolbar, click Use the Hot Key <u>F2</u> ٠

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'.

Resting ECG Patient Information       -       ×         Patient       Test       Medication       -       -       ×         Identification       -       Identification       -       -       ×         Identification       -       -       -       ×       -       -       ×         Identification       -       -       -       -       ×       -       -       ×         Identification       -       -       -       -       -       ×       -       -       ×         Last Patient       First 00005       - <td< th=""><th><b>NOTICE</b> 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</th></td<>	<b>NOTICE</b> 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
OK Cancel	

The QRS-Card<sup>™</sup> 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] 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.
Finish Test	Clicking this button will finish the ECG test. Note: If you are using default Resting Test settings, this option is not necessary as the test will automatically terminate after 10 seconds.

After the test is finished, depending on user settings, reports will automatically print or software will return to the QRS-Card<sup>TM</sup> Cardiology Suite Master Screen with test previewed in the Workspace. You 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





Master Screen test database and click **OR** 

Double click on the test to be reviewed.

🗄 📄 1/28/2005 / tesat, / 1121(1)	
🕀 🚞 1/28/2005 / Hz500, / 121(1)	
🖻 📄 1/28/2005 / stadrer, / 1212(1)	
🗝 🎦 Rest ECG 1/28/2005, 8:06 AM	
🗄 🛑 1/28/2005 / test, / 1121(1)	

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).

Edit	Report 🛃 Save 🤣 Help	PR: 146 P axis: 73 QRS: 88 R axis: 74 QT / QTc: 363 / 394 T axis: 72 <b>71</b>	
4 x 3 2 x 6 Complexes Rhythm			
Pa	atent: Michael Money PID: 34345678 Text Date: 7/23/20	0 00, 11:04 AM Location: Pulse Biomedical	
	Height 72in Weight 10010s HR 71 BP 0	Phytecam 1 segmentureLeteLete Original Report inclovereal) - <9RS Card Cardiology Sulle (Enu +.05)-	
in Ga	Res: IRAA Martin III Constantiation III Constantiation Martin III Constantiation III Constantiation Formation III Constantiation III Constantiation Formation IIII Constantiation Formation III Constantiation Formation IIII Constantiatio Formation Fo		
	Sejour 23 nem / 1 Gain: 10 mm mit Plink: Adfaut		
T	avR V1	V4 V4	
-			
-		the set and and a set	
-			
1		V5 V5	
-			
-			
-			
-			
1			
-			
	Cipyliphi @ 2007. Pulse Bioleedical, Inc. All right resented.	120. Center I trad	
	PBI 1305 Catfieh Lane Nomistown PA 194	610 666 5510	
-			
RestingProcedure			

[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  $\checkmark$  or  $\bigcirc K$  to exit interpretation editing.

esting - (8/4/2010, 5:	20:41 PM)			
Edit	Summary	🖕 Report 🔡 Save 🛛 🤣 Help		PR: 154         P axis           QRS: 92         R axis           QT / QTc: 363 / 394         T axis
x3 2x6 Comp	lexes Rhythm			
Patient:		PID:	Test Date: 8/4/2010, 5:20 PM	Location: My Office
Age: NG Height: NG Doctor:	Sex: NA Weight: NG Referred By:	HR 71	BP Physician Confirmation Overread Report (not confirmed)	
Race: NA Alcohol: NA Family: NA Smoking: NA Pacemaker: NA Medication:	ECG Measurer PR: 164m URS: 92 m QT / QTC: 363 P Axis: 76 * CRS Axis: 74 * Sokolow Lyon: 2262 Cornel: 73	ments Interpretation <sup>DS</sup> Borderline ECG, Sinus rhythm. Early repolarization.		
Speet/ 25 nim /s	Gair: 10 mm 9 mV	aVR	vi ka	
37]				

### 2 x 6 Screen

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





### mplex 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

Resting - Artificial Patient	t (8/26/2011, 11:14:	56 AM)	
Edit Andrewski Viev	Summary	Report 🔡 Savi	e 🤣 Help
Table General P Way	/e QKS Wave	T Wave Hypertrophy	Interpretation

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

Edit Address View	I PIVI)											
the state of the s	Sumn	nary ॆ	Report	J Save	🤣 Hel	р					PR: 154 QRS: 92 QT / QTc: 363 / 39	Pa Ra 14 Ta
Table General P Wave	QRS W	ave TW.	ave Hype	rtrophy   I	nterpretation						ur / urc. 505 / 5.	
	1 -		1			1						
					1992							
	Lead	aP1 (uV)	aP2 (uV)	aQ (uV)	aR (uV)	aS (uV)	aR1 (uV)	aS1 (uV)	aT1 (uV)	aT2 (uV)	<u>^</u>	
		90	0	0	1327	0	0	0	400	0		
	a¥R	-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	=	
	Ve	39	0	0	290	-547	0	0	476	0		
	V5	81	0	0	2045	0	0	0	639	0		
	V4	66	0	0	2054	0	0	0	481	0		
	Vé	34	0	-22	1374	0	0	0	251	0	-	
	•	-								+	5 C	



#### **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)		
Edit Andread View Summary Report 🕞 Save 🧶 Help	PR: 154 QRS: 92 QT / QTc: 363 / 394	P axis: 76 R axis: 74 T axis: 71
Table       General       P Wave       QRS Wave       T Wave       Hypertrophy       Interpretation         Solution       Sol	73 0 1 0 1	
in testingProcedure in the second sec		//



#### **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 computergenerated 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.

Resting - (10/21/2010, 11:13:12 AM)							x
Edit Attach	y 🍓 Report 🔡 Save 🤌 Help			PR: 183 QRS: 92 QT / QTc: 350 / 350	P axis: 27 R axis: 53 T axis: 62	60	
Table General P Wave QRS Wave	T Wave Hypertrophy Interpretation	]					
	Physician Interpretation Advance EGG. Sinus rhytm: Anteroseptal myocardial infanction, age undetermined.	1		Statement Library	s or general de pulse formati autial and AN stopic rhythm tedorninant) + acomaker fu ements ents compatible v		
	Computer Interpretation			Gradient ST-T changes compatible     Gradient ST-T changes     Gradient ST-T changes     Gradient ST-T descriptive s     Gradient ST-T descriptive s	ole with suber ges alternativ statements		
	Abnormal ECG. Sinus rhythm. Anteroseptal myocardial infarction, age undetermined.		î 🏿	Attrasticements     Statements related to pe     Statements related to th     III	ediatric ECG e ECG calibr ▼ ▶		
	QRS Card Cardiology Suite (Enu 4.06)           10/21/2010           -	Γ <u>A</u> nølyst 11/ 8/2010 ▼ 11:43:	<b>T</b> 15 AM	☐ Physician 11/ 8/2010 ▼ 11.43	• 3:15 AM •		
RestingProcedure							

[KB45]

**NOTICE** QRS-Card<sup>TM</sup> 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**

ý

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	A COLORADO	X		
Group Normal/Abnorm	al 🔽	<u>O</u> K		
normal ECG	×	Cancel		
normal QRS	X	Help		
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*).

ID Name	Show <u>D</u> etails <u>D</u> K
ID       Name         1200       Standard 12 Lead         1203       Standard 3 Lead         1206       6×2 12 Lead Standard         1208       6×2 2 Page 12 Lead Standard         1210       12×1 12 Lead Standard         1212       Standard QRS Complex         1301       3 Lead Serial Comparison	Show Details       QK         Printer       Cancel         Output       ○         ○ RICOH Aficio 12'.       ○         ○ PCL5 Printer       ○         ○ PDF Eile Viewer       ○         ○ MS Word File Viewe       ○         ✓ Use Color       300 DPI × 300 DPI         ✓ Create and View PDF File       ○         Only 300 DPI resolution supported. Only black and white colors available.

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. <i>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")[B47]



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



# 7. Stress ECG Module

QRS-Card<sup>TM</sup> 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



Stress		X
Protocol       Bruce       Protocol         Controlled Device       Blood Pressure         Simulated Treadmill       Type         Metric       Iest         Display Options       Required         Show this window       Save Strings         Show electrode position diagram.       Terminate         Trend Screen       Strings         View test record       Screens	Demand       1 Page       Protocol         Final:       ID       Name       Image: Name       Image	<u>Q</u> K <u>C</u> ancel <u>H</u> elp
ST Segment Display            • Normal <ul> <li>Maximum STe Elevation or Depression Lead</li> <li>Maximum STe Elevation Lead</li> <li>Maximum STe Depression Lead</li> </ul>	Target Heart Rate            • Calculate ( 220         • age yrs ) × 100         • Assign         180             ECG Acquisition	Demo
ECG Filter Electrical interference 60 Hz Artifact rejection CA Filter Baseline Drift Reduction On	Recorder     QRS Card (USB)     Irv       Sample Rate     240     0     1     2     3       Length     3600     4     5     6     7       Average Cycles     25     25     4     5     6     7	<u>R</u> eset

[KB50]

Protocol	Defines the Stress Test Protocol to be used during the Stress ECG Test.
Protocol Editor	Users can edit and customize protocols using the protocol editer. (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. **Configure Exercise Device** ? × 🏂 Test 🐹 Limits Speed Treadmill Blood Pressure ΟK Help Cancel



	Limits Tab Lists the limits of treadmill or ergometer driver. Automatic Blood Pressure – defines if Blood Pressure measurements will be taken automatically by a BP machine interfaced to the QRS-Card <sup>TM</sup> Cardiology Suite Software or whether the program will prompt the user to enter the BP manually. 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]
	Configure Exercise Device
	🧏 Test 🧏 Limits
	Load Min Max Step
	Elevation (Load) Min. 0.0 Max. 25.0 Step 0.5
	Speed
	Min. 0.0 Max. 12.0 Step 0.1
	Automatic Blood Pressure
	OK Cancel Apply Help
Display Options	
Show This Window	If selected, the Stress setup box will be displayed before the start of each Stress ECG test.
	If it is not selected, the Stress setup box will not appear at the start of each Stress ECG test.
Show Electrode	If selected, the electrode positioning diagram will be displayed



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
	FCG test (BSG)
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 antian allows users to define a Domote Server to remetaly display the ECC test in
	real time. For more information, please contact Pulse Biomedical.
ST Segment	Selects the display lead for the ST Trend Window.
Display	
Normal	Provides the display of ST for the user selected lead.
Maximum ST	Automatically displays the ST values for the lead that has either
Elevation or	the maximum elevation or the maximum depression.
Depression Lead	
Maximum ST	Displays the ST values for the lead that has the maximum ST
Elevation Lead	elevation.
Maximum ST	Displays the ST value for the lead that has the maximum ST
Depression Lead	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	This allows the user to apply a 50Hz or 60Hz filter to the signal.
Interference	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. <b>NOTICE</b> 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<sup>TM</sup> 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 <u>F3</u>

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.

Resting ECG Patient Information -      X Patient Test Medication	
Identification Id DEMO Browse Last Patient First 00005	Patient Age is calculated from the computer date.
Date of Birth 1951-07-16 62 y yyyy-MM-dd Address Street 112 Ivy Lane City King of Prussia State PA Zip 19406	Before running any tests, confirm that the computer's date is correct.
Telephone 610-666-5510	Date of Birth is also required for calculation of Target Heart Rate
WARNING: Devis Acquisition	

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

## 7.2.3 Tasks Performed During a Stress Test:



• 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]



		<u>0</u> K
Patient Request	Equipment Malfunction	Cana
Decreased Systolic Pressure with Increased Work	Moderate Chest Pain	
Severe Chest Pain	Claudication or Marked Dyspnea	<u>H</u> elp
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 Bate Beached, Stress Test Completed	

• 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** 

Equipment Malfunction	Course
Moderate Chest Pain	Lance
Claudication or Marked Dyspnea	Help
Marked ST Segment Elevation	
Marked ST Segment Depression	
Marked Hypertension	
Frequent PVC's	
Supraventricular Tachycardia	
Acute Onset of Bundle Branch Block	
Target Heart Rate Reached, Stress Test Completed	
	Moderate Chest Pain         Claudication or Marked Dyspnea         Marked ST Segment Elevation         Marked ST Segment Depression         Marked Hypertension         Frequent PVC's         Supraventricular Tachycardia         Acute Onset of Bundle Branch Block         Target Heart Rate Reached, Stress Test Completed



## **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.

Select Report			8 x
ID	Name	Show <u>D</u> etails	<u>0</u> K
ID 1000 1001 1002 1003 ✓ 1004 1005 1006 1007 1008 1009 1010 1011 1011 1012 1013 1014	Name           Stress ECG Segment (3 lead)           Stress ECG Segment (12 lead)           Stress ECG Result Table           Stress ECG Summary Report           Stress ECG Summary Report           Stress Stage ECG Complex Summary           Stress Stage ECG Rhythm Summary           Stress Phase ECG Complex Summary           Stress Phase ECG Rhythm Summary           Stress ECG Full Disclosure           Stress Stage ECG Rhythm Summary (3 l           Stress Stage ECG Rhythm Summary (3 l           Stress ECG Selected Segments           Review Screen	Show Details         Printer         Output         C       RICOH Aficio 12:         C       PCL5 Printer         C       PDF File Viewer         C       MS Word File Viewer         ✓       Use Color         300 DPI x 300 DPI	<u>Q</u> K <u>C</u> ancel
1015 1016 1017 1018	Stress EUG Summary Report (Europe) Stress Stage ECG Rhythm Summary (Cla Stress Stage ECG Rhythm Summary (Cla Stress ECG Real-Time Report	Only 300 DPI resolution sup black and white colors avai	oported. Only ilable.

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.
	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]
MS Word File	Selecting this option will open the report in Microsoft <sup>TM</sup> Word. The save button



Viewer	from Micrsoft work will save the report as a Word file for editing, printing, etc.
	Note: In order to view in Microsoft Word, installation of Microsoft Word on user computer is required.
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<sup>TM</sup> Cardiology Suite Stress Dataview screen.

This screen allows the user to:

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



# 7.3.1 Edit

[	Strue Test - Artificial Patient (8/26/2011, 11:48:12 AM)										
$\left( \left( \right) \right)$	Edit	Allahak Allahak Allahak Allahak Allahak	Summary	Report	🔛 Save	🤣 Help					
	Padorit	Test Medicat	tion Signal								

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 for or buttns, 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.)

Stress Test - (9/9/2010, 4:33:35 PM)							
Edit Andrew Summary	y 🍓 Report 🔡 Sav	e 🤣 Help	3				
		0:00	1 ld	▼ 5 mm/m	V <b>▼</b> 15 m	▼ Rhyth	m Trend R
		<u>║</u> │╀╉╁ <u><u>┞</u>┶╄╃╁╁┶┓</u>	╉╪╪╪╪╪╪╪╪	┕┶╄┺╞╞┟┝╄┺╞╞╞		┟╽╽┑┖╽┟╽┑┖┟╽	╺╅┺╊┼┟╅╄╁┟┟╋┺┟┟╴╺╴
Stress EC G Summary Report				****	++++++++++++	L	*****
1032 Mail Street Novietawr PH 1940	<ul> <li>Product Mentanang, Zeptentere 10, 2010, M2202 Add</li> </ul>	-+++++++++++++		┺╋╋╋╋╋	<b>↓↓↓↓↓↓↓↓↓↓</b>		
Patient: PD: day hit brack hit Parente hit brain hit blanders		uuuuuu	<u>uuuuuuu</u>			uuuuuu	
2m bit. Draph bit. Zindeng bit. Alamid bit. ReferredBy:							
Indications: Test Results:	Banke (Breaded Institut) B (B & of the Q (BB) ( 1917)						
Teat Details: 8002016,4:30 PM Nervor 31 of betain 16 Olive Detaining Data Free (2) Fermion Teams Tea Data of the Details of Data Provided Teams Teams Teams Teams	El mengli SETEN AD rel 16, 322 & genie (333.08.5c) Stati Polenci Connecter						
Bruce Total Place Stage Devotes Spect Note HP DP DP	-	P+++++++++++++++++++++++++++++++++++++	*****	*****	*****	*********	****
Tina Tina Tina (%) mitrr (#475) (#F#) (mm#g) (%) ProTest	nar densitien a 'n anter di (Dre schar)'n anter dij 'na biel anneten ine en An- net de reader nar in publich die policie activement te canter aan 'n de tradie of Hi	********	*****	*****	*******	*****	******
Topine 100 140 1111 11 11 11 11 10 10 10	P. Machina and D. M. Marager providence implement ranks of DE INP 36. In patient two materials may be used for a sust of Dec INP 10, N. B. N. young (D.B. NY 76), The material ranks (D.B. NY 76), The material ranks in the latter state of the state of Dec INP 10, The material ranks in the latter state of Dec INP 10, Neuropean (D.F. NY 76), The material ranks in the latter state of Dec INP 10, Neuropean (D.F. NY 76), The material ranks in the latter state of Dec INP 10, Neuropean (D.F. NY 76), Neuropean (	********	<del>╒╞╒╞╞╞╞╞╞╞╞╞╞╞╞╞</del>	<b>⊦┼╀┞┼┼┼┾┾</b> ╄╄┾┾┾┾	┶┾┾┾┾┾┾┾┾┾┾	*****	*****
Farmer 107 147 148 1410 1410 143 14 14 14 14 14 14 14 14 14 14 14 14 14	a paled in ECD showed I landwidth I'r direaden an tallen ywater Ann 1 m. Tawa erw ' Tae maler aw 27 denallen wr idde men Hit erw (± 147 (†	-++++++++++	╷┼┽┥┽┼┞┞╿┥┕┝┼┝┝┥	<del>╷╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻╻</del>	**********	<b>╘╘╘╘╘</b> ╘ <u></u>	
Levela, 127 127 128 1211, 12 11 27 2013 18	m. Tana ara. Ta u subu un 27 depresato serialme na 27 mm g. 17 (4).	+++++++++++++++++++++++++++++++++++++++	*****	*****		***********	
228 1.8 1.8 1.3 1.7 1.7 8 8 1013 8		~ <del>***********</del>		┟┟┟┟┟┟┟┟┟┟┟┟┟	<b>┟┟┟┟┟┟┟┟┟┟┟</b> ┟	<u>                                     </u>	
328 18 18 1811 17 18 8 1113 8		- uuuuuuuu		աստոր			
100 20 100 102 10 10 10 10 10 10 100 30 100 1011 23 11 8 1113 8							
520 431 132 1231, 23 11 8 1115 16 720 54 540 1231, 23 11 8 1115 16							
100 00 100 100 00 10 10 10 10 10 10 10 1			1.4.4.4.4.4.4.4.4			a hababa hababa h	
444 54 545 545 54 55 54 10118 56 522 54 541 5425 34 52 56 10118 56		40.00					
4 1138 88 148 151 15 15 15 15 15		12:22	10 mm/m 💌	25 mn 💌 🔍	ել 🙏 🦑	🌫 ST	II - ST60 -
4 071 163 103 103 10 10 10 10 10 10 10 10 10 10 10 10 10		450 450		ba ada			
hilbone 0.07 2.4 1.41 2.21 13 13 8 2010 16		120 121	1 120 120 1	20 218			
Boomer 150 34 149 511 51 15 15 50 18 16 Boomer 1513 38 148 511 53 15 16 53 16		╏┢╍╴╋╼╌╋		╊┾┼╊╌╊╼┶	En		
Increase 1070 4.0 100 1170 1171 11 11 10 10 100 10	ny we amin'n seguer une regional Responsitionet overrenandj - «QBER Gand Gandiology nate (Finu 6.66)»				27	_	
Become 1610 6.8 5.80 5.11 5.1 5.8 50.18 10	Comments:				0.0		
Income 20:10 7-8 1-80 1211. 12 13 8 122.8 10 Income 2110 8-8 1-80 8311. 53 13 8 122.8 10		15-V-V		v	0:00	9:00 18:0	0 27:00 36:00
horsey 2010 8.8 161 1310. 13 15 16 123.8 10					Systolic	<ul> <li>Diastoli</li> </ul>	c — Speed 🕁
				4 4 4	205		yst .
		ya ha h	antra	hardenter			E ic
					0.0		8 2
		•		4	0:00	9:00 18:00	27:00 36:00
	-						
StressProcedure							
	J. S. C.						



## **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.)

Stress Test - (9/9/2010, 4:33:35 PM)						- C X
Edit deligitation	iry 🍓 Report 🔡 S	ave 🤣 Help				
Page Complex Strips						1
		1:01	10 mm/m 💌 25 m	m/s 💌 🧱 Rhythr	n Trend 🦉	Report
Stress EC G Summary Rep.	ict .	Pre-Test I Supine 0.4 1.0 METs	-0.1 -0.5 -0.15 -0.30	aVR aVL -0.1 0.4 0.00 0.22	aVF V1 -0.3 0.5 -0.22 0.23	V2 ^ 0.1 0.07 ≡
Tel 20 Jaho Sharov Annovatova AP at Polise: dep 10 rengt hil Promote bid, herey bid Berdendig: Ber	00 Pular Weining, Zysteen (L.201) KD32 Adr	0:50 0.0 0.0 %		~~~~		
Text Decision International In		<b>75</b> 123 / 88				
No.0         UM         Dia Ma         Long         All         No.0         No.0 <thn< th=""><th>Exect functions: The section of the section of the section of the section of the Difference on the section of the section of the section of the Difference on the section of the section of the section of the Difference on the section of the section of the section of the Difference on the section of the section of the section of the Difference on the section of the section of the section of the Difference on the section of the section of the section of the Difference on the section of the Difference of the section of the Difference of the section of the se</th><th>Pre-Test I Hypervent 0.4 1.0 METs 0:05</th><th>II III -0.0 -0.5 -0.10 -0.28</th><th>aVR aVL -0.1 0.4 -0.02 0.20</th><th>aVF V1 -0.2 0.5 -0.18 0.22</th><th>V2 0.0 0.03</th></thn<>	Exect functions: The section of the section of the section of the section of the Difference on the section of the section of the section of the Difference on the section of the section of the section of the Difference on the section of the section of the section of the Difference on the section of the section of the section of the Difference on the section of the section of the section of the Difference on the section of the section of the section of the Difference on the section of the Difference of the section of the Difference of the section of the se	Pre-Test I Hypervent 0.4 1.0 METs 0:05	II III -0.0 -0.5 -0.10 -0.28	aVR aVL -0.1 0.4 -0.02 0.20	aVF V1 -0.2 0.5 -0.18 0.22	V2 0.0 0.03
Lassia 247 147 148 147 17 15 14 14 17 13 14 148 148 148 147 17 14 14 15 17 14 149 148 148 147 17 14 14 14 17 13 16 149 148 148 148 147 147 14 14 14 17 13 16 149 148 148 148 147 147 147 14 17 18 17 18		0.0 % 75 √ 143 / 77	, -hen alfa	-m -p	-h~ ~t	
Aut         SA         Lat         OLV         Aut         T         N         TT         TT         N         TT<		Pre-Test I		aVR aVL	aVE V1	V2 -
4 1038 143 143 143 143 143 143 143 143 143 143		1.01	) mm/m ▼ 25 mn ▼	, 10 mm/m ▼	25 mn_ <b>▼</b>	•  ST60 •
Matern         Dif         Li         U	Rydiains Spanner Digaellingen (or anning) - rold S Can Gordelagy Backford Ada Cammentas				:00 18:00 2	7:00 36:00
howy 210 14 00 111 11 11 11 10 11 11 howy 210 14 18 11 11 11 11 11 11 11			<mark>~</mark>		Diastolic —	Speed Systelic, p
				► 0:00 9:	00 18:00 27	:00 36:00 0iast
StressProcedure						



## **Strips Screen**

Shows:

- a. Automatically Selected Arrhythmia Strips
- b. Stress Event Strip (e.g. every minute save for Bruce protocol)
- c. 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]

Stress Test -	(9/9/2010	0, 4:33:35 PM	1)															J X
Edit	kuk kuk kuk kuk	🚺 Sur	mmary	Repo	ort 📙	Save		Help										
Page Comple	ex Str	rips																
1? Leads	Mark A		ar All				bet sh	ow Marke	a 15 <b>8</b>	Show Un	marked	•	Add Strin	9.0	ndate Strir	×	Delete Str	in
	nd.		2	m			FN						iaa sinp		public bing		Junctice Sta	P
Event	Total	Mark	Time						F	Prematuri	ity (%)					D	uration	
VPB VPB Dair			1:41	2 .67	.67	.67	.67	.67	.67	.67	.67	.66	.67	44%	.66	.67	.67	<u>1s</u>
VTAC				~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~~	~ <b>I</b> ~~~~~							- y						·
Bigeminy																		
Quadrigeminy					V~	v~	-v	~~	-v	~~	V~	V	~	~~~	~~	V	~	v
SYPB	1	1	٨	1	1	١	1	1	1	٨	J.	1	1	١,	1	1	1	1
SVPB Pair	0	0		~f~	-l-	-A	-fr	~l~	-fr	-fr	-l	-fr	-fr	~~~	-fr-	1~	J~	
Aberrant SVPB	0	0	_															
Stress Protocol	26	26																
Selected Strips																		
StressProcedu	ire																	
								_	_				_					//



# 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).

Stress Test - (9/9/2010, 4:33:35 PM)		
Edit Andread View	t 🛃 Save 🧼 Help	
Summary Table Interpretation Protocol Bruce Test Times Pre-Test 1:38 Exercise 10.43 Recovery 2228 Total 34:51	Target HR         180         Device         Treadmill           Resting         HR         0 <t< td=""><td></td></t<>	
Antifact] 0:00 Significant ST change: > 1 mm Maximum STe	Speed 4.2@12.22 Load 16.0@12.22	
<1 mm Minimum STe	0.7 mm @ 1:17 [V4]	
Reason for termination: Protocol Complete		
StressProcedure		1.



#### **Table Screen**

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

🗊 Stress Test - (9/22/2010, 11:16:29 AM)																						
Edit	desktodesk desktode tidesktode tidesktodesk desktodesk desktodesk	Summ	hary	Report		Save	🤣 Help															
Summary	Table In	terpretation																				
Phase	Stage	Start	Durati	METs	Speed	Load	Max.HR	% THR	BP	HRxBP	1	I	Ш	aVR	aVL	aVF	V1	V2	V3	V4	V5	V6
Pre-Test	Supine	0:00 [ 0:00 ]	0:58	1.0	0.0	0.0	73	41	130 / 92	9490	-0.5	-1.0	-0.4	0.7	-0.0	-0.7	1.9	2.7	1.5	0.1	0.4	0.2
Pre-Test	Warm-up	0:59 [ 0:59 ]	0:10	2.1	1.4	0.0	92	51			-0.3	0.0	0.4	0.1	-0.3	0.2	1.1	3.1	2.4	-0.8	0.5	0.1
Exercise	1	1:09 [ 0:00 ]	3:00	4./	2.5	10.0	104	58			-0.0	-0.5	-0.4	2.0	0.2	-0.5	0.6	1.0	2.2	0.0	1.6	0.2
Recovery	Cool-Do	5:09 [ 0:00 ]	0:08	2.2	1.5	0.0	110	61			0.3	-4.7	-5.0	2.2	2.7	-4.9	2.6	2.4	2.5	-1.1	1.4	1.8
Recovery	Cool-Do	5:17 [ 0:08 ]	0:21	1.0	0.0	0.0	110	61			-1.0	13.0	14.1	-6.0	-7.5	13.6	-3.8	-2.9	-4.0	2.1	-4.4	-5.6
Recovery	Imm P.E	5:38 [ 0:29 ]	1:30	1.0	0.0	0.0	121	67	150 / 84	18150	-0.1	-0.2	-0.1	0.2	-0.0	-0.2	0.3	0.7	0.6	-0.0	-0.2	-0.4
Recovery	1.5M P.E	7:08 [1:59]	1:30	1.0	0.0	0.0	125	69 73			-0.2	-0.0	-0.1	0.1	-0.2	-0.3	0.6	0.6	0.2	-0.2	-0.4	-0.5
Recovery	4.5M P.E	10:08 [ 4:59 ]	1:30	1.0	0.0	0.0	131	73			-0.1	-0.4	-0.3	0.2	0.0	-0.3	0.8	1.0	0.5	-0.2	-0.5	-0.5
Recovery	6M P.E	11:38 [ 6:29 ]	0:11	1.0	0.0	0.0	93	52			-0.2	-0.6	-0.3	0.4	0.0	-0.5	0.8	1.2	0.6	-1.8	-0.5	-0.5
				-			2000		1.		-1											
11:50	10 m	m/m ▼ 25 m	nn 🗾 🔪	Leads	. 🖒 Mea	sure 🗧	Print	Select	Grie	а 🧡 н	R HR:	89										
9	2 95	95 97	95	93 9	4 92	92	89	89	90	87 9	0 91	88	89	89	87	87	88	85	86	87	84	85
			U T L'IL	ΪЦÌ											111	III.	L È					
Mmn A	2.0	mound	m	mar	mm	~l~	mon	mart	mal			1	1	Jam	-	MA	1.	1			1~~	m
n Tr		Mal.			1				r - ipr	the second se	m	non	m	rar .			m	Nra		1	~/	- <b>F</b>
- mr	map in	r man	AL.	~ 1				. 1	· 1		10	In	1.					10	has	JAK.	1	
			r	mor	mm	-lr	MA	m	marge	~~~~~ I	mp	- Jm	-pr	- nu	1 Mar	Im	Im	april -	W	Y	Th.	
∀2					, î	1								1	"r	1	1		1	1		5~
											1	1	1		,	1						
									. 1	h.l.h		In	-				.m	1m	when	Nr.		
Vor	m	man	m	map	m h	N	m	m	map	- V	-yr	Υr	m	100	no	- / m	r			12	m	mm
		r y	r r		1	~r								P	r						V	Y
•																						F
						_													_			



#### **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 computergenerated 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.

View Field       View Field       View Field         Summary       Table       Interpretation         Physician Interpretation       Statement Library         Het exercised on a Treadmill (Simulated Treadmill for 1.49 minutes. The total exercise time was 39 % of the age predicted target heart rate of 100 BPM. Which was 39 % of the age predicted target heart rate of 100 BPM.         The patient test: maximum exercise effort was 0.0 mi / hr. 0.0 % grade [1.0 METS]. The maximum bloch pressure was 178 / 67. The maximum obloch pressure was 178 / 67. The maximum soft algo product was 12460.         The patient test: ECG showed 8 leads with ST elevation variation greater than 1 mm. These are a/R. The maximum ST depression variation was 2.4 mm @ 0.17 [V3].         The patient test: ECG showed 1 leads with ST depression variation was 2.10 mm @ 0.17 [aVR].         View Statements related to (compute on a non-specific ST-f changes admennts dements the statements test is the patient was 1.0 mm @ 0.17 [aVR].	Stress Test - Miller, Kevin (3/14/2005, 7:25:04 AM)	
Summary       Fable       Attriputed attriputed         Physician       Interpretation         Eet exercised on a Treadmill (Simulated Treadmill for 1:49 minutes: The total exercise time was 0.00 minutes during which the patient acheived a maximum heat rate of 70 BPM, which was 33 % of the age predicted larget heart rate of 70 BPM, which maximum blood pressure was 178 / 67. The maximum double product was 12460.         The patient test's action was 0.0 mi / hr, 0.0 % grade [1.0 METS]. The maximum blood pressure was 178 / 67. The maximum of uble product was 12460.         The patient test's ECG showed 0 leads with ST elevation variation greater than 1 mm. These are 4VR. The maximum ST elevation variation less than 1 mm. These are 4VR. The maximum ST depression variation less than 1 mm. These are 4VR. The maximum ST depression variation was 1.0 mm @ 0.17 [4/V].         Image: Statements related to (predominant) con trained on the struct and the present elevation was statements the elevent to pression variation was 1.0 mm @ 0.17 [4/V].         Image: Statements related to (predominant) con the statements on the maximum ST depression variation was 1.0 mm @ 0.17 [4/V].         Image: Statement related to pression variation was 1.0 mm @ 0.17 [4/V].         Image: Statement related to pression variation was 1.0 mm @ 0.17 [4/V].         Image: Statement related to compatible with subpice         Image: Statement related to pression variation was 1.0 mm @ 0.17 [4/V].         Image: Statement related to pression variation was 1.0 mm @ 0.17 [4/V].         Image: Statement related to the statements         Image: Statement related to	Help	
Physician Interpretation       Statement Lbbsg         Itest exercised on a Treadmill (Simulated Treadmill) for 1.49 minutes. The total exercise time was 30 % of the age predicted larget heart racherized a maximum heart rate of 70 BPM, which was 33 % of the age predicted larget heart racherized a maximum founde product was 12460.       Image the stream exercise effort was 0.0 mi / Nr. 0.0 % grade [1.0 METS]. The maximum blood pressure was 178 / 67. The maximum double product was 12460.       Image the stream exercise effort was 0.0 mi / Nr. 0.0 % grade [1.0 METS]. The maximum blood pressure was 178 / 67. The maximum ST elevation variation grater than 1 mm. These are II, III, AFV, V2, V3, V4, V5. V6. The maximum ST elevation variation less than -1 mm. These are aver. The maximum ST depression variation was 2.4 mm @ 0.17 [V3].       Image the stream treated to grade formation 1 to Sinue node dytunction, attial and AV co statements related to ceptoric rightm abd to grade statements.         Image to the stream to the stream the stream to the stream the stream the stream the stream to the stream the stream the stream to the stream		
Was 39 & of the age predicted digger nearline fail of 10 bPh.       Image: Constraint of the other interval of th	Physician Interpretation test exercised on a Treadmill (Simulated Treadmill) for 1:49 minutes. The total exercise time was 0.00 minutes during which the patient acheived a maximum heart rate of 70 BPM, which	Statement Library
IV 9J.       Image: Statements related to (predominant) con the patient test's ECG showed 1 leads with ST depression variation less than -1 mm. These are aVR. The maximum ST depression variation was -1.0 mm @ 0.17 [aVR].         Image: Statement selected to the patient selected to the	was 33 % of the age predicted target heart rate of 180 BPM. The patient test's maximum exercise effort was 0.0 m i / hr. 0.0 % grade [1.0 METS]. The maximum blood pressure was 178 / 67. The maximum double product was 12460. The patient test'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 2.4 mm @ 0.17	⊕ ↓ Myocardial Infarction     ⊕ ↓ Conduction disturbances     ⊕ ↓ Conduction disturbances     ⊕ ↓ Dher DRS morphology or general descr     ⊕ ↓ Statements related to cimpulse formation       ⊕ ↓ Statements related to cimpulse disturbances     ↓ ↓ ↓ Statements related to cimpulse disturbances
the statements	[r3]. The patient test's ECG showed 1 leads with ST depression variation less than -1 mm. These are aVR. The maximum ST depression variation was -1.0 mm @ 0.17 [aVR].	Statements related to (predominant) con     Statements related to (predominant) con     Statements rupes and pacemaker (runci)     So other rightm related statements     Statements
Computer Interpretation Computer Interpretation Kevin Miller exercised on a Treadmill (Simulated Treadmill) for 1:49 minutes. The total exercise time was 0.00 minutes during which the patient acheived a maximum heat rate of 70 BFM, which was 39 % of the age predicted target heart rate of 180 BFM.	Computer Interpretation Kevin Miller exercised on a Treadmill (Simulated Treadmill) (or 1:49 minutes. The total exercise time was 0:00 minutes during which the patient achieved a maximum heat rate of 70 BPM, which was 33 % of the age predicted target heat rate of 190 BPM.	
Original Report (not overread)       Overread Report (not confirmed)       Confirmed Report         [QRS Card Cardiology Suite (Enu 4.00)       Analyst       Physician       Physician         [3/14/2005       3/14/2005       8.45/40 PM       3/14/2005       8.45/40 PM	Original Report (not overread)         Overread Report (not confirmed)           QRS Card Cardiology Suite (Enu 4.00)         Analyst           3/14/2005         3/14/2005	Confirmed Report Physician 3/14/2005 8:45:40 PM

**NOTICE** QRS-Card<sup>™</sup> 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	And and a second second	×					
Group Normal/Abnor	mal	пк					
normal ECG	X	<u> </u>					
normal QRS X Help							
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							
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).

Select Report						
ID Name	Show <u>D</u> etails <u>O</u> K					
1000       Stress ECG Segment (3 lead)         1001       Stress ECG Segment (12 lead)         1002       Stress ECG Result Table         1003       Stress ECG Summary Report         1004       Stress ECG Complex Summary         1005       Stress Stage ECG Complex Summary         1006       Stress Phase ECG Complex Summary         1007       Stress Phase ECG Rhythm Summary         1008       Stress Phase ECG Rhythm Summary         1009       Stress Test Trends         1011       Stress Phase ECG Rhythm Summary (3 l         1012       Stress Phase ECG Rhythm Summary (3 l         1011       Stress ECG Selected Segments         1013       Stress ECG Summary Report (Europe)         1014       Review Screen         1015       Stress Stage ECG Rhythm Summary (Cla         1016       Stress Stage ECG Rhythm Summary (Cla         1017       Stress Stage ECG Rhythm Summary (Cla         1018       Stress ECG Real-Time Report	Printer       Cancel         Output       • Kyocera EP C320DN         • PCL5 Printer       • PDF File Viewer         • PDF File Viewer       • MS Word File Viewer         • Use Color       300 DPI x 300 DPI         300 DPI x 300 DPI       •         Print Using Kyocera EP C320DN       [ 32 PPM, 262144 KB, HPGL2. ]         Printer has color printing cabability. Printer permits 1 resolutions: 600 DPI x 600 DPI.					

(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.


	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: 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]
MS Word File Viewer	Selecting this option will open the report in Microsoft <sup>TM</sup> 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</i> <i>on user computer is required.</i>
Use Color	Selecting this button will allow user to print ECG reports in color depending on printer options.

#### Save Button

Reports can be saved if modifications are made.



# 8. Holter ECG Module

The QRS-Card<sup>™</sup> Cardiology Suite offers advanced Holter ECG technology with many standard features in one package. By using advanced analysis techniques QRS-Card<sup>™</sup> 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 +  $\underline{F5}$



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. )

OR

nfigure Holter		Artificial Patient		
Device	Braemar DXI	91000	-	<u>O</u> K
Record	e:\braemar.	res	Browse	Cancel
r [	✓ Show this After Read	window	grahics	
Default Report		Episodes		<u>I</u> nitialize Recorder
Default Report	□ 13000 □ 13010 ☑ 13011 □ 13020 □ 13030	Holter ECG Summary Report Holter ECG Result Summary Report Holter ECG Result Summary Report B Holter ECG Hourly Summary Report Holter ECG Trend Report	E	
	13040 13041 13050	Holter ECG Selected Segments Report Holter ECG Selected Segments Report Holter ECG Full Disclosure Report		<u>D</u> emo
	13070	Holter ECG Result Summary Report (pa	···· +	<u>R</u> eset



Device	Select the device you have recorded Holter ECG data with. Options
	include:
	- Braemar DXP1000 (also used for Braemar DL800 and Braemar
	DL900)[B80]
	- Cardioline File Importer
	- Datrix DR512 VX3 (128 $H_7$ )
	- Datrix DR512 VX3 (120 Hz)
	Cardia Demota Holtan
	- Rozin File Importer
<b>N</b> 1	
Record	Use this option to select file you are downloading from. To select a
	different file, click the 'Browse' button.[B81]
Character 41a	If calcuted the Holton Seture window will display each time you and
Snow this	In selected, the Holter Setup window will display each time you are
window	downloading Holler ECG tests.
Enter Patient	If selected the Holter ECG Patient Information dialog box will
Demographics	appear during Holter FCG download
Demographics	uppear during Holter Lees download.
After Reading D	ata from the Recorder:
Exit	If selected, the QRS-Card <sup>TM</sup> 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	Patient data can be uploaded to the recorder. (Note: Only if recorder
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.

Read Data from Holter Recorder	
Downloading user events from	device.
Read Data from Holter Recorder	
Press 'OK' when data entry co	mplete.
Patient Test Medication	
dentification	
Id DEMO	Browse
Last Artificial Patient First	
Date of Birth	NG
M/d/yyyy	
Address	
Street	
City State	Zip
Telephone	
	<u>O</u> K

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<sup>™</sup> Cardiology Suite Holter ECG Dataview screen.



# 8.2.1 Edit Tab

Holter FCG - (Wednesd	day, August 31, 2011, 5:2	27:00 PM)		
Edit	Summary	Expert 🍓 Re	eport 🔡 Save	🤣 Help
Patient Test Diary	Medication Sign	nal		

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**

Holter ECG - Artificial Patient (Sunday, June 13, 2010, 8:37:13 AM)	te Pres der Con The State State	
Fdit 👬 Edit View 🚮 Summary 🔨 Tools 🍓 Report 🚦	🛃 Save 🤌 Help	
🗸 Beats 🚧 Episodes   3四 Page   講 Strips		
N 8249 V 112 S 82 B 0 PA 0 PV 0 A 2	Full Screen	
82/82		
And I I	Bins	
		I
10:35:42 AM (1) HR: 82 10 m V S B PA	$\mathbb{P}_{V} \mathbb{R}_{V} \mathbb{A} \mathbb{X} \mid \mathfrak{s} \simeq  ext{ Print } \mathbb{A}_{V}$ Insert $ ext{ Insert } \mathbb{S}$ Select $ ext{ $($)}$	Scan 🔛 View 📩 Measure 🔠 Grid 🤎 HR
	Rhythm Edit Screen	
ll		hrahrahrahrah
<u>د</u>		
G HolterProcedure		

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

- N = Normal
- $\mathbf{V}$  = Ventricular Ectopic Beats
- Supreventricular Ectopic Beats
- **B** = Aberrant
- **P**<sub>A</sub> = Atrial Paced
- $\mathbf{P}$  = Ventricular Paced
- **LAV** = Atrio-Ventricular Paced
- 🖾 = 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.
- 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**

to Manager Have Line Line	
ile measure view Logs Help	
Summary 1 Tools Summary 1 Tools A Report	
🦞 Beats 😾 Episodes   淺 Page   講 Strips	
Estiveres 0 A 1054 Events	_
VP8 Pair 656 D D D Intorvol	
VTAC 537	
bigenny 1 U U U U U U U U U U U U U U U U U U	
Quadrigeniny 25 0 600 1200 1300 2400	3000
SVPB 133	•
SVPB Par 34	
Episodés 9:19 PM (1), 1 Event	-
V. Paced List 0 b	
Trend Screen	
Increase of the second se	
	du .
Inhibition 0 7:49 PM (1) 11:49 PM (1) 3:49 AM (2) 7:49 AM (2) 11:49 AM (2) 3:49 PM (2) 7:49 PM (2)	2) -
Patient Event 0 V V	•
	_
920532 PM(1) HB:10 m $$ 7.5 s $$ N V S B PA PA RAX $\omega \sim $ Measure Print $\frac{2}{3}$ Ansart $\overline{\Box}$ Select	View
94 94 95 95 94 142 71 93 95 95 95	
94 94 95 95 94 142 71 93 95 95 95	
94 94 95 95 94 142 71 93 95 95 95 95 95 mm	
94 94 95 95 94 142 71 93 95 95 95 95 95 95 95 95 95 95 95 95 95	
94         94         95         95         94         142         71         93         95         95         95	
94         94         95         95         94         142         71         93         95         95         95	
94 94 95 95 94 142 71 93 95 95 95 95 95 95 95 95 95 95 95 95 95	
94     94     95     95     94     142     71     93     95     95     95       1     1     1     1     1     1     1     1     1     1       1     1     1     1     1     1     1     1     1     1     1       1     1     1     1     1     1     1     1     1     1       1     1     1     1     1     1     1     1     1     1       1     1     1     1     1     1     1     1     1     1       1     1     1     1     1     1     1     1     1     1       1     1     1     1     1     1     1     1     1       1     1     1     1     1     1     1     1     1       1     1     1     1     1     1     1     1     1       1     1     1     1     1     1     1     1     1       1     1     1     1     1     1     1     1     1	
94 94 95 95 94 142 71 93 95 95 95 95 <b>Rhythm Edit Screen</b>	
94 94 95 95 94 142 71 93 95 95 95 95 95 95 95 95 95 95 95 95 95	
94 94 95 95 94 142 71 93 95 95 95 95 95 95 95 95 95 95 95 95 95	

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:



#### **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.

 Image: Add Strip
 Image: Show All
 Image: Show Marked
 Image: Show Unmarked
 Image: Show All
 Image: Show Marked
 Image: Show Unmarked
 Image: Show All
 Image: Show Marked
 Image: Show Unmarked
 Image: Show Unmarked</td

## 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

📕 Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)	
Edit View 🗹 Summary 🔨 Expert 🈓 Report 🛃 Save 🤣 Help	
ϟ Beats 🙏 Episodes   路 Page   曲 Strips	
exect Alle Channel 1 v 5 mm/mV 1 m v JA Recalculate Properties	
	~
-hala hala hala hala hala ha	
Indrahandr	-l_
and have a stand have the stand have	$\wedge$
841225 AM (1) 110 min 225 min N V S B PA PV PAV A X 🕫 🗠 🕰 Print 🖏 Insert 🚟 Select 👁 Scan 📩 Measure 🏢 Grid 🎔 HR	
841225 AM (1) HR 65         10 mi          25 mi          N         V         S         B         PA         PV         PA         X         ∞	69
84 125 AM (1)         10 mi y         25 mi y         N         V         S         B         PA         PA         A         X         P         PA	69
84123 AM(1)       10 m···       25 m···       N       V       S       B       PA       PV       A       X       P       P       Punt       Punt       Select       Select       Select       Select       Select       Measure       III of idea       Pint         67       68       67       108       55       66       67       90       50       64       135       53       67       65       67       68       68       67         10       10       10       10       55       66       67       90       50       64       135       53       67       65       67       68       68       67         10	69
84123 AM(1)       10 m····       25 m···       N       V       S       B       PA       PV       A       X       1       10 m····       Select       Select       Select       Select       Measure       If of a baser       If of a baaaa       If of a baaa <t< td=""><td>69</td></t<>	69

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.

8×2 • 10 m • 7.5 s • N	V S B	PA PV PAV	A X N O	Mark Row	Mark Page	Mark All	Ħ
	man man	the	1 mm	Wyon Horsen	The	~~~~	-
4:09 AM (2) 4:10 AM (2)	1:28 PM (2)	9:27 AM (2)	4:48 AM (2)	7:59 AM (2)	4:22 AM (2)	3:05 AM (2)	
the way	1	1 mg	2 dame	hat	bund	-	
-hand -hand	1-1	fr	5	fundam	han	Fr-	
11:53 AM (2) 4:45 AM (2)	11:06 AM (2)	5:58 AM (2)	4:22 AM (2)	9:04 AM (2)	1:19 PM (2)	4:04 AM (2)	-
HolterProcedure							



#### **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**

Biller ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)											
Edit de la constant de la constant d	🚺 Sun	nmary 🏷	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 Pa	atient (Tuesda	ıy, April 13, 200	04, 8:37:13 AM)	4						
Edit Andrewski View	Sumi	mary 🔨	Expert	Report	Save	🤣 Help				
General Supraventricula	ar Ventric	ular Supr	aventricular Rur	ns Venti	ricular Runs	Bigeminy	Tachy / Bra	dy Atrial Fibrillation	Paced ST	Interpretation
					Sup	raventricula	r Interval Ta	ble		
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		
<ul> <li>9:59 AM (1)</li> </ul>	2683	0	0	0	0	0	0	37:36		

#### Ventricular Screen

Holter ECG	- Artificial	Patient (Tue:	day, April 1	3, 2004, 8:37:1	.3 AM)								
Edit 🛔	kolochok kolochok kolochok kolochok kolochok kolochok kolochok	🗹 Su	mmary 🖋	Expert	Rep	ort 🔡	Save						
General 9	Supraventricu	llar Ven	tricular	Supraventric	ular Runs	Ventricula	ar Runs	Bigeminy T	achy / Brady	Atrial Fibrillation	Paced	ST	Interpretation
							Ven	tricular Interv	val Table				
Start Time	Total Beat	Total VPB	Paired V	VT Beats	Bi Beats	Tri Beats	Qua Beats	Time Analyz					
9 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 ECC	3 - Artificial I	Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)												
Edit	Andread Andrea	Sur	mmary 🦨	Expert	Rep	ort 📙	Save	🦻 Help						
General	Supraventricu	lar Vent	ricular	Supraventricu	ilar Runs	Ventricula	ar Runs	Bigeminy	Tachy / Bra	dy Atrial	Fibrillation	Paced 9	GT Interpretation	
							Supraver	tricular Ru	ns 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			
9 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 (Tue	esday, April 1	13, 2004, 8:37:1	L3 AM)								
Edit	Autority Autority Autority Autority	S 🖸	ummary #	Expert	Rep	ort 🔡	Save	🤣 Help					
General	Supraventricu	ular 🛛 Ver	ntricular	Supraventricu	ular Runs	Ventricul	ar Runs	Bigeminy	Tachy / Bra	dy Atrial	Fibrillation	Paced ST	Interpretation
							Venti	ricular Runs	Interval Tal	ole			
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		
9 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**

d ST Interpretation

#### Tachy / Brady Screen

Holter ECG	3 - Artifi	cial Patient (Tuesday, A	April 13, 2004, 8:37:13	AM)					
Edit		iew 🚺 Summar	y 🔨 Expert	Report 🔡	Save 🤣 Help				
General	Supraven	tricular Ventricula	r Supraventricula	r Runs 🔋 Ventricula	ar Runs   Bigeminy	Tachy / Brady	Atrial Fibrillation	Paced ST	Interpretation
				T	achycardia / Brady	vcardia Interval Ta	ble		
Start Time		Total Beat	Brady Beats	Time in Brady	Tachy Beats	Time in Tachy	Time Analyzed		
9 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 EC	G - Artifi	icial Patien	it (Tuesday, A	pril 13, 2004, 8:37:13	AM)								
Edit		'iew	Summar	Expert	Rep	ort 🔡	Save	🤣 Help					
General	Supraver	ntricular	Ventricular	Supraventricul	ar Runs	Ventricula	ar Runs	Bigeminy	Tachy / Brady	Atrial Fibrillation	Paced	ST	Interpretation
							Atri	al Fibrillatio	n Interval Table				
Start Time		Total Bea	at	AFIB Beats	Time in	AFIB	Time A	Analyzed					
9 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 I	Patient (Tue	sday, April 1	3, 2004, 8:37	:13 AM)										
Edit	Hedit View Summary CExpert Save Report Save														
General 9	Supraventricu	lar Ven	tricular	Supraventri	cular Runs	Ventric	ular Runs	Bigeminy	Tachy /	Brady	Atrial Fibril	ation	Paced	ST	Interpretation
							Pa	iced Beats	Interval T	able					
Start Time	Total Beat	Total Pa	A Paced	V Paced	AV Paced	Sense Fail	Capture	Inhib. Fail	% A	% V	% AV	% Paced			
9 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

III He	olter ECG	- Artificial	Patient (Tue	sday, April 1	3, 2004, 8:37:	13 AM)								
8	Edit	kolobolok kolobolok kolobolok kolobolok kolobolok kolobolok	🗹 Su	ummary	Expert	Re	port F	Save	🤣 Help					
Ger	neral 🤅	Supraventricu	ular 🛛 Ven	tricular	Supraventric	ular Runs	Ventric	ular Runs	Bigeminy	Tachy / Brady	Atrial Fibrillation	Paced	ST	Interpretation
									ST T	able				
Sta	irt Time	Total Beat	Avg.HR	ST Episo	ST Durat	Max.STe	Max.STd	Analyze						
0	8:37 AM	1561	69	0	0:00	0.0 mm	0.0 mm	22:46						
0	8:59 AM	4201	70	0	0:00	0.0 mm	0.0 mm	59:58						
0	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 computergenerated 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.

Holter ECG - Artificial Patient (Tuesday, April 13, 2004, 8:37:13 AM)	
Edit det View Summary Kepert 😓 Report 🛃 Save	Nelp
General Supraventricular Ventricular Supraventricular Runs Ventricular Runs	Bigeminy Tachy / Brady Atrial Fib Interpretation
Physician Interpretation Artificial Patient was monitored for 2:00 hours; 2:00 hours were analyzed. During this time the average heat rate was 71, with a minimum heat rate of 64 at @ 941:26 AM (1) and a maximum heat rate of 109 at @ 94:50.90 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 paied ventricular ectopic beats at 00 ventricular ectopic best runs. 0 beats were in ventricular 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). 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).	Statement Library
Computer Interpretation	Statements related to pediatric ELG ana     Constraints related to the ECG calibratio     Constraints related to the ECG calibratio     Constraints related to the ECG calibratio
Original Report (not overread)         Overread Report (not confirmed)           PBI Holter	Confirmed Report           Physician           10/28/2010           9:15:58 AM



# 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<sup>TM</sup> program. This dialog box can be accessed by the following methods:

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



From the toolbar, click on the ABPM icon

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.

Configure Ambulatory Blood Pressure Download	X
Device AND TM-2430 Port COM1 Record	<u>D</u> K <u>C</u> ancel
✓       Show this window       ✓       Enter patient demograhics         After Download       •       •       Egit       ●         Oefault Rept       ID       Name       ●       ●         I 12001       Standard ABPM Report       ●       ●	∐pload Patient Data
C Log Communications	<u>R</u> eset

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.

ABPM Download		🛛 🗖 🗖 🗖
	Press 'Finish' when data entr	ry complete.
Patient Test Med	lication	
dentification		
Īq		Browse
Last	First	
Address	Date of Birth M/d/yyyy	NG
Street		
City	State	Zip
	Telephone	
		Einish



# 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 <u>Patient</u> and <u>Test</u> 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 <u>Signal</u> 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**



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<sup>TM</sup> 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.

Configuration Setup	? ×
Reporting Database Options EMR Real Time Print E-mail Medication	Login
Complex         Gain 20 / mv       Speed. 50 / s         Lead1 II       Lead2 V2         Bhythm         Gain 10 / mv       Speed. 25 / s         Lead1 II       Lead2 V2         Lead1 II       Lead2 V2         Gain 10 / mv       Speed. 25 / s         CoverRead External Program         (If ECG intercretation review performed in Word or an EMP program	Reset Print Grid d Lead1 V2 V Values Sint ST60 V n O mV O uV
	Edit Logo
OK Cancel Apply	Help

## 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.

	Configuration Setup	? ×
Reporting Database Options	EMR Real Time Print E-mail Medication	Login
Root C:\QRSDB4		Reset
Browse	Logging	
	OK Cancel Apply	Help

**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.

	Configuration Setup	? ×
Reporting Database Op	tions EMR Real Time Print E-mail Medication	Login
ST Value Display mm mV C uV	Display Multi-Tasking Warning Message	Reset
PDF Program AcroRd32.e Command C:\Program	xe Files\Adobe\Acrobat 7.0\Reader	Detect
Word Program winword.exe Command C:\Program	e Files\Microsoft Office\OFFICE11	Detect
	OK Cancel Apply	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.

Configurat	tion Setup ? ×
Reporting Database Options EMR Real T	ime Print E-mail Medication Login
Profile Standard (No EMR)	<b>_</b>
Order Options	Demographic Window
File Format None	I Display I Edit
Record Format	Reference Format
DICOM HL7 SCP	GDT HL7 PBI
File c:\qrsdb4\files\rec.scp Template Record File Directory	File Template Record File Name
Report Format	FTP
	Enable 192.168.0.1
TIFF JPEG	Local c:\ftp
File c:\qrsdb4\reports\rpt.fil	Remote c:\vem
Template Record File Directory	User anonymous
Reset	Password guest@unknown
ОК	Cancel Apply Help



#### **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 Setu	ip ? X
Reporting       Database       Options       EMR       Real Time Print       I         Printer       WorkForce 545(Network)       Format       Printer       I         Format       pcl5       Report       Printer       Printer         Scale       Install       Format       Printer         Speed.       25 mm/s       Install       Printer         Install       Report       I       I         Install       Report       I       I         Install       Report       I       I         Install       I       I       I       I         Install       Report       I       I       I         Install       I       I       I       I       I         Install       I<	Jp       r         E-mail       Medication       Login         ▼       Reset         ▼       Reset         ■       ▼         ■       ▼         ■       ▼         ■       ▼         ■       ■         ■
OK Cano	cel 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.

Configuration Setup ? ×
Reporting Database Options EMR Real Time Print E-mail Medication Login
Disable E-mail     O Internet E-mail     O MAPI E-mail     Reset
Server Information
Incoming Mail (POP3)
Outgoing Mail (SMTP)
Incoming Mail Server
Account Name
Password
Outgoing Mail Information
E-Mail address
domain
My outgoing server (SMTP) requires authentication
OK Cancel Apply Help



### 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** 

Configuration Setup	? ×
Reporting Database Options EMR Real Time Print E-mail Medication	Login
System Access	Reset
User User	
Password	
Enable	
Cloud Access	
Confirmation 0 Request Confirmation	
Enable (Provided by email)	
Synchronization	
Update (s) 3600 Now	
Enable	
OK Cancel Apply	Help

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

: Remote/Cloud Server & System Access account username,
chosen by the user.
: Remote/Cloud Server & System Access password, chosen by the
user.
: 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 : Remote/Cloud Server account confirmation code, used to verifyRequestthe 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<br/>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.

Physician Database			1		-		? ×
Name	Att.	Ref.	Rst.	Str.	Hlt.	Specialty	<u>C</u> lose <u>H</u> elp
							Add Update Delete
							<u>E</u> xport Import
							- 2

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

M Import Data Record				1		x
Computer	► COMPAQ (C:) ► QRSDB4 ► backup			✓ 4 Search ±	packup	٩
Organize 🔻 New folder					≡ • 🔳	0
🕌 M Data (pbiwin2( 🔦	Name	Date modified	Туре	Size		
QuickBooks Data	STR00008.DAT	3/4/2011 9:17 AM	DAT File	2 KB		
🎉 Amanda - Shortc	STR00009.DAT	8/26/2011 9:53 AM	DAT File	8 KB		
Desktop	STR00010.DAT	8/26/2011 11:39 AM	DAT File	1 KB		
Uownloads	STR00011.DAT	8/26/2011 11:47 AM	DAT File	9 KB		
Dearbau	STR00012.DAT	8/26/2011 11:52 AM	DAT File	9 KB		
■ Dropbox =	STR00013.DAT	8/26/2011 11:53 AM	DAT File	1 KB		
<ul> <li>i Libraries</li> <li>i Documents</li> <li>i Music</li> <li>i Pictures</li> <li>i Programs</li> <li>i Videos</li> <li>i Homegroup</li> </ul>	STR00014.DAT	8/26/2011 11:59 AM	DAT File	9 KB		
File <u>n</u> ar	me: <mark>str".dat</mark>			✓ SCP Help Open	Cancel	•

Cardiology Suite<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> software and the Import Report option. Highlight the modified report and click on Open. The modified report is now ready for use.

Import QRS Report		Eiles + Dules Piemedical + 1/400 +		a (t) Saamb V///		X
Organize Vew fold	er • COMPAQ(C;) • Program	riles 🖡 Pulse biometrical 🖡 V400 🖡		Jedici V40	i≕ <b>→</b> F1 (	0
E Desktop	Name	Date modified	Туре	Size		
🗼 Downloads	1 A.F.	0.05.0011.0.10.414				
Recent Places	ji ftdi	8/26/2011 9:40 AM	File folder			
Dropbox	🎒 ftdipbi	8/26/2011 9:40 AM	File folder			
- · ·	abpm_0	3/22/2011 9:21 AM	Report File	23 KB		
🔁 Libraries	abpm_1	3/22/2011 9:21 AM	Report File	9 KB		
Documents	abpm_2	3/22/2011 9:21 AM	Report File	9 KB		
Music	📄 abpm_3	3/22/2011 9:21 AM	Report File	18 KB		
	📄 abpm_4	3/22/2011 9:21 AM	Report File	5 KB		
	abpm_5	3/22/2011 9:21 AM	Report File	5 KB		
	holter_0	3/22/2011 9:21 AM	Report File	8 KB		
Videos	holter_1	3/22/2011 9:21 AM	Report File	11 KB		
	holter_2	3/22/2011 9:21 AM	Report File	17 KB		
K Homegroup	holter_3	3/22/2011 9:21 AM	Report File	13 KB		
-	holter_4	3/22/2011 9:21 AM	Report File	6 KB		
Computer	holter_5	3/22/2011 9:21 AM	Report File	4 KB		
COMPAQ (C:)	holter_6	3/22/2011 9:21 AM	Report File	7 KB		
FACTORY_IMAGI	holter 7	3/22/2011 9:21 AM	Report File	15 KB		
File <u>r</u>	ame: .rpt			✓ QRS Reports	; (*.rpt)	,
				Help Open	Cancel	



### 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.

QRS Queue System	×
- Available Queues	
Queue Type Count Pri	ority Dump Queue
Printer 0	
Mail Dur 0	Delete Queue
Export 0	
🔚 Import 0	Reset Errors
- Printer	
Priority Queue Time Report Detail	
	<u>U</u> pdate
	Delete
	Reset <u>E</u> rror

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.

Name	ID	Date, Time				~
🍽 tst1,	1212	1/27/2005, 9:54 PM				
🍽 adfadfdc,	122	1/27/2005, 9:55 PM				
🛏 dísfaf,	112	1/27/2005, 9:57 PM				
*	st1	1/27/2005, 10:00				
📌 sdadD,	121	1/27/2005, 10:27				
养 mahdavi, mahdavi	20	6/25/2003, 10:11				
🛏 dddfadf,	1212	1/27/2005, 11:44				
🛏 dafa,	1212	1/27/2005, 11:45				
🛏 dfadfaf,	2122	1/27/2005, 11:50				
🗖 test,	1121	1/28/2005, 8:04 AM				
🛏 stadrer,	1212	1/28/2005, 8:06 AM				~
	Destination C:\L	DOCUME~1\CARDIO~1\LOCALS~1\Tem	P			
	Format SCF	,	•	Add	Close	Help

### **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 <u>MOST IMPORTANT</u> file for trouble shooting the **QRS**-**Card<sup>TM</sup>** 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  $\rightarrow$  Contents screen allows users to explore the Cardiology Suite user guide, Quick Reference Guides and Brochures





# **14.2** About

The Help  $\rightarrow$  About screen displays various information about licensing and software versions.

About Cardiol	ogy Suite	×
<b>M</b>	QRS Card Cardiology Suite Version: Enu 4.06 (1108 Copyright © 2011, Pulse Biomedical, Inc. All rights reserved.	12)
adadadadada daladadada baladadada	Name:           Company:           PID:         72A0-EA39-7413-0E92MG           SN:         1211AE0001E0FFD	311411
tehelel behele deletatehelel deletatehelet	Product Details: License Registered	
alabelahala	Installed Products:	
	Cardiology Suite Resting Test Stress Test Holter Download ABPM Download	Email Info <u>View Log</u> Service
Warning: This Unauthorized may result in s extent possib	computer program is protected by copyright law and international treaties reproduction or distribution of this program, or any portion of it, severe civil and criminal penalties, and will be prosecuted to the maximum le under the law.	s. <u>Q</u> K
	<u>ww</u>	w.grscard.com

### 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.

# **ACAUTION**

#### 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<sup>TM</sup> 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**<sub>[B89]</sub>

# 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<sup>TM</sup> Cardiology Suite device. When the QRS-Card<sup>TM</sup> 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<sup>™</sup> 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<sup>TM</sup> Cardiology Suite ECG machine.

### PBI has tested your QRS-Card<sup>™</sup> 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<sup>TM</sup> Device.



# **Prepping Patient & Electrode Placement**

**Important:** Because QRS-Card<sup>™</sup> 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/Extremitiy 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 <sup>th</sup> intercostal space at the right border of the sternum	C1
V2	4 <sup>th</sup> 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 $5^{\text{th}}$ 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	C6
	V5.	
RA	Right arm.	R
LA	Left arm.	L
RL	Right leg.	Ν
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.



## **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.

# **ACAUTION** Never mix reusable and disposable electrodes on the same patient.

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

NOTICE

**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















# 1210 Standard 12 Lead (12 x 1) Report





# **1212 Standard Complex Report**





# **Appendix 4: Stress Sample Reports**

# 1000 Stress ECG Segment (3 lead)





# 1001 Stress ECG Segment (12 lead)





# **1002 Stress ECG Result Table**

					1002.	Stres	ss EC My C	G Res	ult T m PA	°ab 1940	le 2							Artit	lcial	Patie	ent
						610 66	6 5510	610 666 (	5508					Printe	of: Thu	raday.	Octobe	er 28, 1	1010, d	55 55	ж
Patient: Artif	icial P	atient						PID: DE	MO												
Age: NG	He	ight: N	G Pa	emaker: NA		amily: N	A	Medication	c												
Sex: NA	We	ight: N	a :	Smoking: NA	A	loohol: N	A.														
Referred By:																					
Indications: Test Details: 10/27/2010, 9:21 AM Test Site: My Office Technician: Software: GRS Card Cardiology Suite (Enu 4.06) Recorder: quisit day (Sit: 10004E900500088); ser Vd							Test Results: Device: Treadmill (Simulated Treadmill) Maximum HP: 36 (53 % of THR (156) ] Maximum 2P: 133 (57 Maximum 2P: 133 (57) Maximum 2P: 133 (57) Maximum Load: 3.4 mil /r, 14.0 % grade [10.2 METs] Exercise Time: 0.4 Formiation Resort:							[s]	Bruce						
Stage	Total	Phase	Stage	Elevation	Speed	Work	HR	BP	RPP		ST	: mm			ST	an: m3	115			IT 60	ms
	same	1 me	ime	699	RM / BT	ពុធន ( ៦)	(88-00)	(mmud)	(1100)			18	avit	341.	ave	**	¥X.	83	94	83	*9
# Pre-Test																					
#1 Supine	Q 19	001	0.01	0.0%	0.0	00	71	***		0.5 0.22	1.6 -0.08	13 -032	-1.0 -0.07	-03 027	13 4 20	0.2 0.37	17 125	2.8 0.30	1.9 -0.03	13 -0.15	10 -0.12
Pre-Test																					
Hypenent	0.24	0.02	0.02	9.0%	0.0	1.0	71	125/88	8875	05	16	11	-10	02 027	13	0.2 6.40	17	25	1.0	13	10
Warm Up	0.38	0.16	0.03	0.0%	14	2.1	76	1307.67	9443	04	15	-033	-1.0	-03 025	12	0.1	17	2.4	1.0	13	10
Exercise																					
1	0.49	0.00	0:00	10.0%	17	4.6	105		~	02 020	0.6 -0.55	03	0.4	0.0	05	0.5 0.65	15	21	1.6	0.9	07
2	101	0.12	0.01	12.0 %	25	7.1	105		**	02	0.6	83 -075	-0.4 0.17	-0.0 0.45	0.5	0.5 0.65	15	21	1.6	0.9	07
# Exercise																				contitio	
#1 3	159	0.28	0.28	0.0%	00	0.0	160			0.5 0.70	13 1.48	07 077	.09 -1.10	00	10 1.15	45 440	84 0.95	0.4 0.62	0.4 0.57	0.6 0.83	07 107
8	~~~~~	***********																			

Begyright © 2007, Pulse Biomedical, Inc. All rights reserved. 1002. Stress ECG Result Table



# 1003 Stress ECG Summary Report

	1003. Stress ECG	Artificial Patient					
-h	1052 Main Street 610 666 5510	Norristown PA 19403 610 660 5508	Printed: Thursday, October .	ber 28, 2010, 8:55:57 AM			
Patient: Artificial Patient Age: NG Height: NG Pacemaker: NA Smoking: NA Medication:	Seic NA Weight: NG Pannly: NA Akochol: NA	ID: DEMO Address: Telephone:					
Indications:							
Referring Ph	<b>ysician:</b> Address: Telephone:	ID:					
Test Details:	Test Date: 10/27/2010, 9:21 AM Report Date: 10/28/2010, 8:55 AM Software: CRS Card Cardiology State ( Recorder: grahtl.adv (SN: 1000AE9000	Hookup: Scenned: (Enu 4.06) )CO096X) rev Vd					
Artilicial Patient e maximum linear rate of 96 IPAL which was 2 he patient Patient's maximum exaction of the patient Patient's maximum exaction of the patient Patient's ECG showed 8 leads wi nm @ 0.49 (V3). The patient Patient's ECG showed 1 leads wi	esrciced on a Treadmill (Simulated Tread 3 % of the age predicted target heat rate of 1 % of the age predicted target heat rate of 1 % as 1.4 m/ hr. 14.5 % grade (10.2 MBT 1 % et al. 14.5 % grade (10.2 MBT 1 % et al. 14.5 % grade (10.2 MBT 1 % et al. 14.5 % grade (10.2 MBT) 1 % of the state of the state of the state of the state 1 % of the state of the state of the state of the state 1 % of the state of the state of the state of the state 1 % of the state of the state of the state of the state 1 % of the state of the state of the state of the state 1 % of the state of the state of the state of the state 1 % of the state of the state of the state of the state of the state 1 % of the state of the sta	nill). The total exercise time was 0.41 of 1 130 BPA. s). The maximum blood pressure was n. These are 8, 81, aVF, V2, V3, V4, V3, h. These are aVR. The maximum ST c	windes during which the patient 133 / 67. The mademen doubl 133 / 67. The maximum ST eleva depression volvation vas -1.1 (	nt achieved a le product was 9310 lice varietion was 2.5 mm @ 0:15 (eVR).			
	Physician's Signatur	e	Date				



# 1004 Stress ECG Summary Report (Classic)





# 1005 Stress Stage ECG Complex Summary

ECG Stage Complex Summary

Patient: Age: NG Sex: NA Referred By:	Height: NG Weight: NG	i Pace i Su	radiar: NA xxXing: NA	Family: NA Alcohol: NA		Report Date: 8/14/2010, 5:54 PM						
Pre-Test	***************************************			Speed: 25	nm/s	Gain: 10	nm / mV	ST	50 ms	STe unit: ne	n STo	iun≋:mV/s
Supine Hill: 25 BP: 123 / 88 Phase: 0:49 Stage: 0:49 METS: 1.0 0.0 mi / hr. 0.0 % g	tir eqt∼-	n Zis A		aVR 835		avr 23 232		¥2 ****	v3 81/2 		<b>*</b> ** 1	<b>V6</b> 3,55 
Supine HR: 25 SP: 123 / 88 Phase: 0.50 Clage: 0.50 METS: 10 0.0 mi / ls: 0.0 % g	etr agr-	als A∼∽		aVR 01 0.00	aVL 84 642	avr 22 12 12		V3 2.07 	va siz	J.	vs år If.	<b>ve</b> 315 4
Hypervent HR: 76 8P: 1437 77 Phase: 1:07 Stage: 6:05 METS: 1:0 0.0 mi / hr: 0.0 % g	1 017	в аю Д		avr 652		avr dis A		¥2 6355 √	<b>v3</b> 810 		<b>VS</b> 35 317	<b>vs</b> 40
Warm-Up HR: 75 Phase: 127 Stope 0:09 MET9: 24 1.4 mi/tr, 0.0 % g	er ors	n dis A	н. Д.	aVR 0.00		avr 33 022		¥2 \$ V	V3 85 80 4	J.	<b>V5</b> 357 1/2	<b>V6</b> 3.12 4
Exercise				Speed: 25	nm/s	Gein: 10	nm / mV	ST	50 me	STe unit: m	n STn	unit: mV / s
1 HR: 50 5P Phase: 0:49 Stage: 0:49 METS: 4.5 1.7 mi / ts: 19.0 % (	04 013	в. ал		avr 21 0.03	avi. 817 1			¥2 80 80 80 80 80 80 80 80 80 80 80 80 80	¥2, 		<b>VS</b> 310 410	<b>V6</b> 3000 
1 HR: 50. 37- Phase: 1:49 Shape: 1:49 Shap	*i= *i=	*** 		avr 6.02	avi 8177	avr Sa		¥2 0000 √~~	*** ***		vs Star Star	<b>v</b> 6 3,85 4,85
1 HR 10 BP: Phase: 244 Gloge: 244 METS: 48 1.7 ml / lr, 10.0 % (	is is	и 2016 Д.,		evr See		<b>avr</b> 022 022		¥2 567 V	V3 0.07 	Å.	VS as abs	


# 1006 Stress Stage ECG Rhythm Summary

Patient: Age: NG Sex: NA Referred By:	Height: NG Weight: NG	Pacemaker: 1 Smoking: 1	IA Family. IA Alcohot	; NA t NA	PID: Medical Test D	tion: ale: 9/9/2010, 4:	33 PM	Repor	1 Date: 9/14/	2010, 5:54 PM
Ye-Test			Sp	weed:25 mm/s	Gain: 10 p	son / mV	ST 60 ms	STe unit:	.even S	ITm unit: mV (
Supine 1 BP: 123 / 88 Mase: 049 Glage: 0.49 JETS: 1.0 0.0 mi / hr, 0.0 % gr	eto	,		<u></u>	1	_4_				
Supine II.   HR: 25 0.1   BP: 123 / 88 0.1   Musce: 0.50 3   Stage: 0.50 1   Stage: 0.50 0.0   Stage: 0.50 0.0   Musce: 0.50 0.0   Stage: 0.50 0.0   Stage: 0.50 0.0	e 	<u>_</u>	-1-				4	<b>A</b>	-	
Hypervent II HR: 25 5 SP: M3/77 4 Mars: 107 Diage: COS METS: 1.0 0.0 % gr	e e ede	<b>.</b>		4-		4				4-
Warm-Up II HR 75 1 Page 211/78 1 Page 0:09 J HE 75 2.1 HE 75 2.1 1.4 mir/w, 0.0 % gr	<u>}</u>				4	- <b>\</b> ~		4-		
Exercise		diciticana	Sp	peed:25 mm/s	Gain: 10 r	nm / mV	ST 60 ms	STe unit:	:mm t	iTm unit: mV
1 81 BP - 9 Mase 0.49 Stope 0.49 JETG 4.6 1.7 mir/hr, 10.0 % gr	k nate		+-			<b>_</b>	<u>_</u>	4~-	<b>4</b>	
1 HR:50 5P Those:1.49 15 4.5 1.7 mir/tr, 10.0 % g									4-	
1 N HR 60 0 8P Trasse 244 Clage 2:44 METS 45 1.7 mi / iv, 10.0 % g					<u></u> ,		<b>}_</b>	<b>.</b>		-4-



# 1007 Stress Phase ECG Complex Summary

Stress Phase ECG Complex Summary

8P 1227 88 Phase 3530 Diage 14:30 METS 1.0 D.0 mi / hr, 0.0 % g	rado										
8P: 122 / 88 Phase: 19:50 Show: 14:50	a operation			بهدينا بتوجيب تجاديا							
HR.											
4.2 mi / hr, 16.0 %	ΥY			1Y		1	V		r		
Phase: 1032/312 Phase: 1032 Olego: 103 METS: 135			\$.17		1.		9.59	1.	1.59		1
4	1.	B 81.	avr eo	aVI.	aVF -20	¥!	¥2 00	VS 201	¥4	V5	V6 -01
Stoge: 0:09 METS 2.1 1.4 mi / hr, 0.0 % (	mp~-		~ <b>^</b>	1~-	4~.	15	-v~	4~	~~	~ ~	4~
Warm-Op HR: 75 BP: 111 / 72 Phate: 1:27	04 0.15	210 - 830	3VH 0.90	893. 0.7 0.22	407 -0.22 -0.22	0.5 0.22	44 6.07	43 6.19	0.6 0.10	05 017	0.4 -0.12
			Speed	i25 mm / s	Gain: 10	nan ( mV	ST	30 me	STe unit	rnm 87	m unit: mV / i
Test Details: Test Site: My Offic Test Date: S/IN/201 Software: QFIS Co 3410A/2000100F2/	e 0, 4.33 PM and Cardiology 1 0) rev 4.05 (100	Technician: Report Date: 9/14/20 Suito-(Erw #26grobt.a 312)	10, 5:54 PM dv (SN:		Meximum S oximum Loa Test Tim ormination R	T: 0.6 mm ( d: 4.2 mi / t e: 34.51 hason: Prot	₱ 1:01 [V1] #, 16:0 % grad Ex boot Complete boot Complete	de (13.5 MET ercise Time ;	ej 10:43		
Indications:					Fest Resul Protoco Maximum H Maximum B	ts: # Bruce R: 90 [50 % P: 143 / 77	of THR (180) M	Device: 1 laximum DP:	Treadmill (Si 10980	inulated Tree	dmði)
Referred By:	Weight: NG	Smoking: N/	Alcohol: NA		Tesi Di	de: 9/9/2010	), 4:33 PM	******	Report I	Dete: 9/14/20	10, 5.54 PM
Dok Iov	Height: NG Weight: NG	Patemaker: N/ Smoking: N/	Family: NA Alcohol; NA		PIO: Nedera	lion:	4-22-024			Poster Grid MA	



# 1008 Stress Phase ECG Rhythm Summary

Age: NG Height: NG Pacemakar: NA Pan Gax: NA Weight: NG Smoking: NA Alco eferred By:	niy: NA hol: NA	PID: Medication: Test Date: 9/9/2010, 4:3	3 PM	Report Date: 9/1	42010, 5:54 PM
ndications: fest Details: Trav Bits: My Office Technicise: Proport Due 1920/00.433 PM Proport Due 1920/00.435 PM	244	Test Results; Profaced Sense Maximum HR: 50 [50 % of TH Maximum 2P: 143/ 77 Maximum 2: 10.8 mm @ 1.0 Maximum 2: 0.4 4.2 mi / kr. 16 Test Time 34.51 Termination Reason: Profect O	Device; 1 (R (180) ] Maximum DP; 1 (V1) 3 % grade (13.5 MET) Exercise Time; 1 Complete	freadmill (Simulated 10960 1] 10:43	Treades#)
110AE0001C00F2D) nev 4.06 (100312)	Speed: 25 mm / s	Gain: 10 mm / mV	ST 60 ms	STe unit: mm	STm unit: mV /
Varm-Up II - M1 5 - M2 53 - 4 45 - M2 72	4	<b></b>	- <b>A</b>	4	Ą
не 100, 112 109-120, 112 100-120 10	4.4				4-4
Lecovery II   HT 222   BP-122 / BP 222   BP-125 / BP 222   BP<125 / BP		<u> </u>	4-4		- <b> </b>
Conclusions: exercised on a Transford (Structured PER-violation, 60 % of the app proficient large) from take of a patient is maximum section afford was 4.2 million (4.9 million section HR 4.100mm RP = 12270), a patient is ECG aboved 0 leads with ST depression variation (e platent is ECG aboved 0 leads with ST depression variation (e	Treachnail), The total 100 BPM. doi [13.0 ARE75], Th aber Ihan 4 rom. Th es ahan -1 mm. Th	exercise time van 10.43 minute ne maximum Maxd pressure va sea exe . The maximum ST de sea are . The maximum ST dep	es darling vehich the pa s 143 / 77. The maxim value vehicles was 0, necesion variation was	Bent achlieved a mise am double product v 6 mm @ 1:01 [V1] -0.7 mm @ 1:17 [V4	kown heart rate r was 10980 j.



#### **1009 Stress ECG Full Disclosure**





### **1010 Stress Test Trends**

							Stre	ess Tes	t Trends
Patient: Age: NG Sec: NA Referred By:	Height: NG Weight: NG	Pocemaker: NA Smoking: NA	Family: NA Alcohol: NA		PID: Medication Test Date: 1	99/2010, 4:33 F	w	Report Del	a: 9/14/2010, 5:54 PM
0 200 300 0 200 300 0 200 300 0 200 100	Heart Rai 192	e and BP Trends SYS GA	30 3	No 190 190 190 000	200 200 000 000 000 000 000 000 000 000		Device Los - 10	ki Trends spp 15	
	J 30 35 Test Time (minut	20 5	(un) et al. (100 m) e	H 10 Test Time (J	15 ninutes)	20 25		18 	15 20 25 notes
	aVR 10 15 Teet Time (minute	20 25		aVL	15 ninetes)	20 25		aVF 5 10 Text Time (m	15 20 25 mittai
(mu est of the second s	V1 10 15 Test Time (minist	20 25	2000	V2 Test Time (I	15 ninuter)	28 25	N N N N N N N N N N N N N N N N N N N	V3 5 10 Tast Time (m	15 20 25 Intech
9 N N S 7 S 8 S S S	V4	20 25	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	V5 LO Test Time (r	15 ninutes)	28 25	1000 000 000 000 000 000 000 000 000 00	Vé s 10 Tast Time (m	13 20 25 index)
Copyra	ata © 2007, Pulse Biar	medical inc. All rights re	served.	Page 20				1010. Stree	s Tear Trends

CS406-10 Rev F



# 1011 Stress Stage ECG Rhythm Summary (3 lead)]

Patient: Age: NG Sex: NA beferred By:	Height: NG Weight: NG		P	acemu Smoi	iker: N/ ling: N/		Family Boohc	r na e na				PIE Mo Tes	k licatio t Dete	n: : 8/9/20	)10, ·	4:33 PI				Re	port De	le: 9/1	4/2010	. 5:64 Pt			
											******	5	ipeed	12 /	nm i s	********	Gain	5	n / mV			ST 6	o ms		SYe	unit, m	8
Supine FIR: 75 6P- 123 / 85 hase: 0.49 hase: 0.49 KETS: 1.0 1.0 ns (hr. 0.0	N Ngode		4 <u>;</u>		¥2:			-4 -				4		4						4				3 •	4	4	
	<b>V5</b> 45 807		4.			4.	_1		4.		<u></u>				.fr			<b>1</b>			<b>.</b>	L.					
upine HR 75 BP 123/88 esc 050 bgo: 050 ETS: 1.0	H Artis Altos				_ ,		<b>.</b>			<b>Ļ</b>	-4		4	_4		Ļ.,	4			<b>1</b>				4~	-4		
0 mi / hr, 10.0 *	i <b>yg</b> ude 91 9107 <sub>9</sub>							×			×		×.			(***								,			
	Vis aut	{	~	1.			Ļ	4		Ļ			Ļ		A			•	L	<b>1</b> ~-			~	- <b>k</b>	-4~		
ypervent HR 75 SP 143/77 ass. 107 lags 0:06	я 20 4,12	4.												1	,		<b>1</b>	Å	4			ų.			<b>.</b>		
ETS: 10 0 million, 0,01	102	Y-									c				.,										<u>,</u>		
	<b>VS</b> 4.15.	4.			Į,	4	<b>N</b>			<u>A</u>	ł.			4.			. <b>ц</b> .	4				Į,			<b>.</b>		
Varm-Up HR 35 BP 511/78 esc 127 wps 0:09	8 8 1 8 12	<u>.</u>	4.			4	4		<b>1</b>	Å		1			Ļ			<b>.</b>	4	٩.		4	<u>ц</u>	4	- <u>4</u>		
Sheger C:09 AETS: 2.1 1.4 pm / hr., 0.0 %	s <b>yg</b> ade 912																										
	¥6 435 4.17	(	J.			4~	4		1,			4.						Ļ.	4.	L.		Į	J.	ļ	J.		



#### 1012 Stress Phase ECG Rhythm Summary (3 lead)

Stress Stage ECG Rhythm Summary tient: Age: NG Sex: NA forred By PID: Medication: Height: NG Weight: NG Pacemaker: NA Family: NA Smoking: NA Alcohol: NA 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 STe unit: mm STm unit: mV / s Varm-Ut Man... HR: 75 BP: 111/78 Sec: 127 Platest 1.5 Stage: 9:09 MET3: 2:1 1.4 ms / br, 0.0 % grade V2 V2 V5 877 - 1 нн тос и ян тос и ан т 18 -1.1 HR 60 6P 122/88 602 5 Press: 1550 Stage: 14:50 METS 1.0 O.0 w/hx 0.0 f 1 1 1 V2 V2 A fo V6 (14) I. I. I. I. I. 

Page 28

Copyright © 3007, Pulse Biomedical, Inc. All rights reserved.

1012. Stress Phase ECG Rhythm Summary (2 lead)



## **1013 Stress ECG Selected Segments**

Patient: Age: NG	Height: NG	Pacemaker: NA	Family: NA	PID: Medication:	
Sex: NA Referred By:	Weight: NG	Smoking: NA	Alcohol: NA	Test Date: 9/9/2010, 4:33 PM	Report Date: 9/14/2010, 5:54 PM
		h	4-4-4-	4	-hhhhhhh
V2	-rr	vv	vv	r-r-r-r-r-	-rrrrrr
v5]	hahad	n.h.h.	hala	hahahahah	hahahahahah
Min. HR					
10:50	-hhh	hh			h-h-h-h-h-h-
V2					44444
v5]	hh	hala	-h-h-l	-h-h-h-h-h-	hahahahaha
Pre-Test: Supine	( 0:50)				
11 <sup>0:51</sup>		.h	- J- J f-	-h-h-h-h-h-h-	- for for for for for for
v2	VV	·VVV		-hhhhhhhhhhhhh-	
v5	-h-h	hahah	-h-h-h	hhahahah	-h-h-h-h-h-h-h
Pre-Test: Supine	( 1:01) - stage adva	nce			
"I <sup>1;07</sup>		h	hh	hhhhhh-	-hhhhhh
V2		······	vvr	4	-hhhhhh
v6	hahad	hh	hhh	hhalah	-h-h-h-h-h-h-h-h-h-h-h-h-h-h-h-h-h-h-h
Pre-Test: Hyperve	ent ( 0:15) - stage a	dvance			
"] <sup>1</sup> 4			hh		hhhhhhhhhh-
V2	· · · · · ·				······································
volla	hahah	hhh	hala	-h-h-h-h-h-	h-h-h-h-h-h-h-h-h-h-h-h-h-h-h-h-h-h-h-
Pre-Test: Warm-U	Jp ( 0:19) - stage a	dvance			

Page 29

#### Stress ECG Selected Segments

Copyright © 2007, Pulse Biomedical, Inc. All rights reserved.

1013. Stress ECG Selected Segments



### **1014 Review Screen**





### 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

<b>0</b>	13000. Holter ECG Summary Report My Office 1005 Meth Sector With Sector With A Sector 1005 Meth Sector With Sector With Sector 1006 SECTOR SECTOR SECTOR	Artificial Patient
Patient: Arti Pace Se Medication:	Ificial Patient ID: DEMO Ager NG Gen: NA Address: Height NG Weight NG ansker: NA Family: NA noking: NA Alcohot: NA Telephone:	
	Indications:	
	Referring Physician: DR OMED ID: Address: Telephono:	
	Test Details: Test Dato: 4/13/2004, 8:37 AM Report Date: 1/03/2010, 8:56 AM Software: PBI Helter Reaceder: PBI Helter Reaceder: PBI Helter	
Conclusions at all states AM The pertent Antiforial to entricular actorpic be (1) The patient Artificial f (2) 8.37:13 AM (1) an	Artificial Palient was monitored for 2:00 hours; 2:00 hours were anstyzed. During this time the average (1) and a maximum heat rate of 100 at @ 9.45:00 AW(1). The patient had 9 pauses greater than 2 0 seconds alternist set showed 010 0 significant ectips heat. The patient had 0 subsets effective and 0 seconds alternist best showed of 0.0 significant ectips heat. The patient had 0 subsets at @ 8.21'13 AM(1) and 1 Autors for the showed of 0.0 significant ectips heat. The longest run had 0 beefs at @ 8.21'13 AM(1) and 1 Autors for the showed of 0 superventing ectips heat. Give figure and the statest run had a rate of 0 at @ 8.23'13 AM(1).	nertransmitter between the sensitivity of the sens
	Physician's Signature	Uate



## **13010: Holter ECG Result Summary Report**

13010.	Holter ECG Result Summary F <i>By Office</i> 1983 Main Street Novrisoon PA 19403 610 666 5510 C10 668 5508	Report Artificial Patient
Patient: Artificial Patient Apr: NG t Height: NG WW Pacemaker: NA Par Smoking: NA Act Medication:	Ser: NA Address: ight: KQ nhot: NA Telephone:	C
Indications:		
Referring Physician: 1 Address: Telephone:	DR OMED ID:	
Test Details: Test Details Report Date: Software: Recorder:	413/2004, 8:37 AM Hockup: DO Tor25/2010, 8:56 AM Schnred: Duration: 2:00 PISI DEMO (SN: IMMADEMO) rev V01.00	
Heart Rate Average: S2713 AV (1) Minimum: S2713 AV (1) Maximum: S3713 AV (1) Pause Total: 0 Maximum (ms): 0	Ventricular Ectopy Toat: 0 (- ) Parent: 0 Runs Toat: 0 Beats 0 Longest: 0 -	Supraventricular Ectopy Total: 0 Pairod: 0 Runs Total: 0 Beats 0 Longvet: 0 -
Conclusions: Artificial Patient was heart rate was 71, with a minimum heart (1). The patient had 0 pauses greater th The patient Artificial Patient's test showe beats, 0 paired ventricular ectopic beats The longest run had 0 beats at @ 8:37:1 The patient Artificial Patient's test showe supraventricular ectopic beat runs. The @ 8:37:13 AM (1).	monitored for 2:00 hours; 2:00 hours wern rate of 64 at @ 3:41:26 AM (1) and a ma an 2:0 seconds. d 0 (0.0 %) ventricular ectopic beats. The and 0 ventricular ectopic beat runs. 0 be 3 AM (1) and the fastest run had a rate of d 0 supraventricular ectopic beats (25 % p longest run had 0 beats at @ 8:37:13 AM	e analyzed. During this time the average iximum heart rate of 109 at @ 9:45:09 AM e patient had 0 isolated ventricular ectopic ats were in ventricular ectopic beat runs. I 0 at @ 8:37:13 AM (1). orematurity). 0 beats were in (1) and the fastest run had a rate of 0 at
Printed: 10/26/2010, 8:56 AM	hysician's Signature	Date Rays 2



# 13011: Holter ECG Result Summary Report B

()		13011. H	olter ECG Res My O 1052 Main Street 610 666 5510	ult Summar flice Norristown PA 19 610 666 5508	y Report 403	B Artificial Patient Printed: Thursday, October 28, 2070, 8:56:32 AM
PATHENTEN POR Name: / ID: D Age: N	MARION Artificial Patien EMO G	t	Sex: N Height: N Weight: N	A G G	Telephone: Address:	
Ref. Phys.: Di Indications:	R OMED		Hookup: 4/ AM Recorder: Pl	13/2004, 8:37 31 DEMO (SN:	Medication:	
V-Run	0			SV-Run	0	
V-Pair	Total O			SVEB	Tetal O	**
VEB	Total O	***		Pause	Total O	- 100 - 100
HEART RAFE Average: Minimum: 4 Maximum: 4 Maximum: 4 Pause Total: ( Maximum: 4 ST SEGN Episodes: ( Duration: ( Maximum STd: ( CONCLUSIONS Artificial Patie	Bea (ENTANALISIS ) ) ):00 (0.0 %) ).0 mm @ 8:56:3 0.0 mm @ 8:56:3 :nt was monitor	2 AM (1) 2 AM (1) 2 AM (1) ed for 2:00 h	VENTRUCULAR DETC Total: 0 (- ) Isolated: 0 Paired: 0 Runs Total: 0 Longest: * SUPAAVARTUCULA Total: 0 Isolated: 0 Runs Total: 0 Longest: * Fastest: * SUPAAVARTUCULA Total: 0 Runs Total: 0 Longest: * Fastest: *	Beats 0 RECTOPY Beats 0 analyzed, During	HEAR S S S D N R R R R S D N N I PACEA Ventric Both (	TENTE VARIABILITY DNN (ms): DDN (ms): ANN (ms): 450 Count: ISSD (ms): NN50 (%): index (ms): <b>IAKSR</b> otal Paced Beats: 0 ( 01%) valar Paced Beats: 0 ( 01%) capture failures: 0 Sense Failures: 0 Inhibition: 0 average heart rate was 71, with a
minimum heart greater than 2.0 The patient Ariti paired ventrical 0 beats at @ 8:3 Dhe patient Ariti ectopic beat runs	rate of 64 at @ seconds. Ticial Patient's to ar ectopic beats 7:13 AM (1) at Cicial Patient's to S. The longest	8:41:26 AM ( est showed 0) and 0 ventric di the fastest i est showed 0 ( run had 0 bea	(1) and a maximum h 0.0 %) ventricular eci ular ectopic beat runs run had a rate of 0 at a upraventricular ectop ts at @ 8:37:13 AM (	eart rate of 109 a topic beats. The p. 0 beats were in @ 8:37:13 AM (1 ic beats (25 % pr 1) and the fastest	i @ 9;45;09 A patient had 0 i ventricular ec ). ematurity). 0 run had a rate	M (1) The patient had 0 pauses isolated ventricular ectopic beats, 0 topic beat runs. The longest run had beats were in supraventricular c of 0 at @ 8:37:13 AM (1).



# 13020: Holter ECG Hourly Summary Report

Patient:	PATIENT	NAME			10	: DEMOP	AT		Dat	e: 4/13/2004	, 8:37 AM		
			Hol	ter EC	G Gen	eral H	ourly	Summ:	ary Re	port	_	_	
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	65 e0	71	1663	72	0	•	12	0	1	0	22:47	0.00
00.888 (1)	84	68 70	83	4200	40			41	2			80.00	0.01
Total	64	69	83	\$445	116	0	0	79	1	2	8		



## 13030: Holter ECG Trend Report





### 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 Se	elected Segi	ments Report	
8.37.21 AM	» Indruk	la la la la	holated SVEB	ul la la la la	ululululu
	ملياريل	بململما ما	املسلمه	ما دا دا د	alatalala
×,					
H-79-	o to to ka	71-72-72-70-1	6 62 69 7	3 69 73 70 69	4. 69. 71. 72
ليتراجع					
	Undrie.	h h h h		rhh hh	Intratation
Und	utrtrta.	Internet	rtr All	Matria	hpulit
li	and	hhhl		. I. I. I. I.	in the last
14447	469,73,79+	70, 72, 69, 72, 6	8101 49 6	fr:71:+ff:/7:+f7:	69, 68, 68, 70,
0.00 45 644	adalah kabula kabala kaba				Andrei Steiner auf der Gester Beiter
A A	"Intrah.	rdy lad	~~~~	ala typeta	hirtral
1 A	Internal	ruhtin	LL/LL	ALA L	hindrik
	I. L. L.	uh u	. I. K. I		hilling
11111	170-67-69	9, 95, 52, 68,6		9+67,194 59+169-1	69-69-69-68-11
8.41.25 AM	1. Andrew Provension and Andrew Prov. 1	ule de gelecter de la de la feute de la	Min HR	de de la dedeció de la classica de la dedeció de la control Control de la control de la	FIR 64 1
	itul	In the In	that	Intritute	unhin
L.	ntala	J. H. h	hille	Intertent	children
IL.	hun	1. II. In	the hash	Linker	andread
utte	6 66 92 59	64125 53 67	<u>64 69 67</u>	68,68,67,69,6	
8.52.49 AM	<b>n</b>	Les provide to the base	Isolated SVEB		HR: 7 (37%)
Inda	Indrite.	hAlle	ritita	Andraha	h h h h h
the	. Indruka	h h h h	rdila	mertentanta	Intrintria
Undo	J. J. L.	Mul	rthe	Shellah	mininte
44467	70,68,69	33, 59, 69, 69,	( <u>11169</u> , 6	68,69,67,69	67, 69, 69, 68
8.53.37 AM	"   .   .   .		Isolated VEB		HR: 7 (679-3)
	Interior	rhhh	ALA	Adata	hhill
Inde	Intra	hhi	uhi	- the hard	hund
111168	69,68,69	7,70,68,69,6	8104/59116	8, 69, 67, 69, 68	F8 F9 92 54
Prin	ted: 9/21/2010, 9:46 AM	13041, Holter	ECG Selected Segm	ents Report	Page 18



# 13050: Holter ECG Full Disclosure Report

Patient:	PATIENT NAME	ID: DEMOPAT Date: 4/13/2004, 8:37 AM
		Holter ECG Full Disclosure Report
8:57 AM (1)	╙ <b>┼╄</b> ╇ <sub>╋</sub> ╋╋┝╋╋╋╋╋╋╋	╺┱╅┧╅╅╘┶┇╘╧┶┶┶┶┼┍┶┶┍┶┙╴┢┶┶╘╘┶┶╄┶┶┺╘┶┶┶┶┙┿┵┶┶┙┙┺┙┷┙┺
6:42 AM (1)		
	╘╺╪┥╧╌╧╌╧╧╧╧╧╧╧	$\langle \mathbf{r}_{\mathbf{r}} \rangle_{\mathbf{r}}}}}}}}}}$
8-47 AM (8)		
		╺┶╜╜╸ <sub>╧┍</sub> ┍╪┍┾╸┥┺┲┥┥┝┥╼╋┿╍╗╴┝┫┝╕╗┲╈╗┝╗╗╖╸╗┚╴╗┙┍╖┙┍╋╗╌┝╗╸┝╻┍╄╖╸╻ ╴
	<u>ithiacht</u>	
8.52 AN (1)		┶┍╞┪┙┙┝┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙┙
	hundredenter	
		╊╍╬╗┺╍╬┑╫╗┇┿╋ <b>╣┱╘╕┧╴╪┿╪╕┿╍╪╌╡</b> ┺┥┢┪╕╏┍┪╡┙╞╝┑┑╡╢╖╝╌╝┝╌┩┹┙┝╌┝┙╧┙┙┙╝┙┙╸╝╸┍╸┥┍┿┙╿╸┥╌╝╴╴┨
4.57 AM (1)		
	******	<b>┥┟╈╫┦╴┉┢╢╼╶┝┶┉┶╍┝└┤╎╌╄╷┥┩╷╽╱╎╌</b> ┣╎┲┝╻┝╱┡╷╝╴╄╵╽╴╄╵
9-02 AM (1)		
		╘╶┙┥┺┹┝╊┤╴╊╢╴╄╅╘╋╪╋╘╋┺┥╋┥┹╗┧┇╎╴╘┝╘╔╎╡╘╖┥┷┿╋┿┍╄┥╎┺┿┝┶┝┝┝╎╴
	and the second	
9:07 AM (3)		
		<u>↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓↓</u>
	<b>ATTEND</b>	
9.11 AM (1)		
		╕╫╴╪╌╞┑╪╌╞┙┝╖┙┝┙╪┙┿╢╬╣║╏╴╪┚╞╌╡╴╖╶╛╶╞╴┇╸╞╸╞╸╞╸╞╸┝╸┝┙┝╴╕┙╴╕╴╝╴╕╴╡╴╖╴╴ ┑╴╴╴┝╴┙╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴
9.16 AM (1)	pppppppppppppppppppp	੶ੑੑਲ਼ਲ਼ਖ਼੶ਫ਼੶ਫ਼੶ਫ਼੶ਫ਼੶ਫ਼੶ਫ਼੶ਫ਼੶ਫ਼੶ਫ਼੶ਫ਼ਫ਼੶ਗ਼ਫ਼ੑਗ਼੶੶ਫ਼੶ਫ਼੶ਫ਼੶ਫ਼੶ਫ਼੶ਫ਼੶
		┙╹╅╺┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶┶
	╘┲┺┺┺┡┠┹┺┡╄┹┺┲	<mark>┑┝╶┧╶┪┑┑╴╞╺┝┑┥┑╴╞╺┝╶┥┑┝╸╞╸┥┑╸╞┍╋╶╽┝╋┑</mark> ╎╺┚╽┑┶┑┡┝╽╹╠╍┶╞┷┍┶╵╘╞╍┿┚╗┍┝╩┍╻┝┺┑╵╻╘╶╸╸ ╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴╴
9.21 AM (1)		
	$-\frac{1}{2}$	┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉┉
9.08 48 70		╺┍╴┍┍╶┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍┍
9.44 cm (c)	┶┺╋┶┶╋┷╋╋╋╋	·····································
9.51 AM (1)		┢┹┙┹┥┿┿╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋╋
		ի կարող արդությունը որությունը հարցությունը, որությունը հարցությունը հարցությունը հարցությունը հարցությունը հա Հարցությունը հարցությունը հարցությունը հարցությունը հարցությունը հարցությունը հարցությունը հարցությունը հարցութ
	. A.	ւները արարարությունները արարարարարարարությունները արարարությունները արարարարությունները արարարարարարարարարարարարարարարարարարա
Pt	inted: 9/21/2010, 9:48 AM	13050. Hoher ECG Full Disclorure Report Pege 22



### 13060: Review Screen





# **13070:** Holter ECG Result Summary Report (pacemaker)

	13070. Holter	ECG Result Summar, My Office 1052 Main Street Norristown 810 888 5510 810 868 5500	y Report ( <sup>9</sup> / <sub>9</sub>	pacemaker)	Artificial Patient
Patient: Artifi He Pacem Smo Medication:	<b>cial Patient</b> Age: NG Jght: NG W Aker: NA Fe Aking: NA Ak	Sor: NA eight: NG mily: NA ochol: NA	ID: DEMC Address: Telephone:		
	Indications:				
	Test Details: Test Date Report Date Software Recorder	: 4/13/2004, 8:37 AM 10/28/2010, 8:56 AM PBI Holter PBI DEMO (SN: IAMADEMO) rev V01.00	Hookup: EDO Scanned:		
	Pacemaker Details: Capture failures: 0	Total Paced Beats: 0 (01%) Arial Paced Beats: 0 (01%) Ventricular Paced Beats: 0 (01%) Both (AV) Paced Beats: 0 (01%) Sense Failures: 0		Inhibilior: 0	
H Averngo: Minimum: Waximum: Pause Total: 0 Masimum (ms): 0 Set at @ Sk12 SM M(1) Replatent Artificial Parentificial Parentific	eart Rate Total Beats: 0 8:37:13 AM (1) 8:37:13 AM (1) Artificial Patient was monitor and a maximum heart rate of 109 limits test aboved (0.0 %) vent finals test aboved 0.0 %) vent truns. 0 beats were in ventincular limits test aboved 0.0 suppreventiou he fastest run had a rate of 0 at @	Ventricular Ecto Total: 0 (-) Isolated: 0 Paired: 0 Runs Total: 0 Beats 0 Longest: 0 * Fastest: 0 * end for 2:00 hours: 2:00 hours were analyzed at @ 945:09 AM (1). The patient had 0 po dura ectopic beats. The patient had 0 isol ectopic beat runs. The longest run had 0 b are ectopic beats. The patient had 0 po sets (25 % prematurity). 0 beat 8:37:13 AM (1).	Py . During this time to user groater than ated ventricular ect exists at @ 8:37:13 // tis were in suprave	Supraventricu Total: 0 Isolated: 0 Paired: 0 Runs Total: 0 Beat Longest: 0	a minimum heart rate of topic beats and 0 te of 0 at @ 3.37:13 AM ingest run had 0 beats at
	Ρ	'hysician's Signature		Date	



# 13080: Holter HRV Report

Patient:	PATIENT NAME	ID: DEM	OPAT	Date: 4/13/20	04, 8:37 AM
		HRV Time Dor SOAN (ms): 25 SOAN (ms): 7 RNSSC (ms): 73 SONN Index (ms): 23	Main Summary SDSD (ms): 33 NNSD Count: 263 pNNSD (%): 3.26		
8441 842 0 0 0 0 1 2 0 2 0 0 0 0 0 1 5 0 2 0 0 0 0 0 0 1 5 0 2 0 0 0 0 0 0 1 5 0 0 0 0 0 0 0 0 0 0 0 0	Total Beats	8246 Normal Beats 007 051 001 050 100 1.50 2.00 R-R Current (s)	007 051 001 150 100 1 007 051 001 150 001 007 051 001 150 000 000 0.50 1.00 1 R-R Current	S 007 051 001 050 0010 (\$)\$0004444 44 50 200	79 SVE Beats
8 8 8 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9 9	12:00 PM (1)	SDNN (ms)	SDSD (ms)	arg)	3 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8 8
		NN50 (#)	pNN50 (%)		
2010 AM (1)	12:00 PM (8)	4.00 P8 (1) 8:00	FIR [1] 12:00 AI	* (4) 430	u am (a) 6.00 AM (2)
006 SZ2 005 005 00		Mean RR (ms)	Proc Time (sec)		
000 AM /0	45-00 046 /4	6.00 CM /45	[	8 M S	
Prove	3: \$21:3010, \$.46 4.0	4.00 P30 (N 8.00) 13080. Holic	r HRV Report	- (4)	Page 27



# 13090: QT Report

Patient:	PATIE	NT NA	ME				ID:	DEMC	PAT				Date: (	4/13/2004	<b>1,</b> 8:37 <i>A</i>	M		
						A	loite	r EC	g an	r Rei	oort							1
Start	Beats	HRav	QTmn	QTav	QTmx	QTsd	QTcb	QTcs	QTch	QTCI	<300	<340	<380	<420	<460	<500	<548	>540
:13 AM (1) :00 AM (1)	1583 4200	85 89	414 414	414 414	414 414	0	443 447	414 414	429 431	433 435	0	9 9	0	1406 -1076	0	0	0	0 0
(1) MA OC:	2582	73	414	414	414	0	457	414	437	642	0	0	9	2645	0	a	0	•
Total	9445	69		414	414		1347	1242	1297	1110	0	0		8127				
1044	4440	40			414	•	1.047		1607	1010								
	*******	******															*******	anna an
8		11110	a par		10.000	<u>ique</u>		QT	06400	HR			tanat n					- #
1																		
24																		- 8 t 6
18																		- 88
8:37 AN	<u>0</u>	1	2:37 PM (1	1	43	17 PM (1)		8:3	7 PM (1)		12:	37 AM (2	0	4:3	7 AM (2)		8:37	ANI (2)
<b>28</b> 🗮						- Ta	mp CH1		amp C	H2	T amp	СНЗ		100 2 6 9 9 9			1001.0900	
1.																		····· 🔿
28																_		8
8:37 AS	<u>0</u>		2:37 PM (	2	4	37 PM (1		8	37 PM [1	<u>.</u>		2:37 AM	<u>(</u> 2)		4:37 A18	2		37 AN (2)
8			QTI	Distrik	ution					<b>ę</b> ,	QT Ir	nterva	d Dep	endene	e on	Heart	Rate	
<b>\$</b> 8				<del>ۆر</del> اللا الاللا					8 .	* • •								
2× ==									24	ę.								
18									0	8								
₹. <b>₽</b>	·, 0	0	<b>, 0</b> ,	, IIII	UL.,L.	, o	•		0	8								
2 0	50-350 SS	-340-	390-68	o to	0.90	90 .49	8			8 -								
										30		52		75		97		120
				21 Interva	H (mis)					******		******		leart Rat	e (8PM			
	vined: 82	1/2010, 9	48 AM					13080	QT Repo	<del></del>							Page 20	



## 13180 Holter HRV Spectral Report





# **Appendix 6: ABPM Sample Reports**

### 12001 Standard ABPM Report



12002 ABPM Trend Report







# 12003 ABPM Distribution Report

Ambulato	ary Blood Pre	essure Results								
me: Test Pa e: 57 y sgnosis:	dent				Date: 5/7/2 Referred B Physician I	001, 8:48 AM y: 4otes				
dications Us	ed:									
stistical Se	immary of Al	i Measurement	s Statistical	Summary	of Day Mea	surements	Statistical Su	smmary of	Night Me	asurements
untolio	Mean :	SD Ras	ge 201 Sustalia	Mean	SD	Range	(Cantalia	Mean	SD	Range
ystoac iastolic	83	16 64 -	142 Diastolic	85	15	51 - 142	Diastolic	75	11	58 - 114
AP	94	15 61 -	162 MAP	96	16	61 - 162	MAP	85	11	67 - 118
ulse Rate	71	12 52 -	122 Puise Ra	te 72	11	<b>56 - 122</b>	Puise Rate	66	13	52 - 107
			в	lood Press	sure Distri 8c Day	bution Diastolic Day				
9				Systol	lic Night	Diastolic Night				g
-'										Ŭ
		4	8							
2										
9			ing in the second s							
8					27	27				6
8					27	27	••••			6
8					27	<b>"</b>	4			
8						27	24			
8					27	27				
R					<b>57</b>					
8					<b>**</b>	**************************************	24			
30			······································			27	24 			5 5 5
30						27	84 			6 
90 90		······································			27	27	84 			6 0 0 5
30	2	· · · · · · · · · · · · · · · · · · ·				27 	24 0			5 5 5
93 93 94 94 94 94 94 94 94 94 94 94 94 94 94	2 0 0 0 0 0	* * *	2 2 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7 7	La Constantino de la Constanti	27 	27 5 6 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	24 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	2 1	5 5 7 <sup>150</sup>
۲۰۰۰ ۲۹۹ ۲۹۹ ۲۹۹ ۲۹۹ ۲۹۹ ۲۹۹ ۲۹۹ ۲۹۹ ۲۹۹	2 6 6 9 7 2	* • •	200 900 GD	u <sup>0</sup> u <sup>0</sup>	27 4 4 - 310 5 5 5 5	27 5 5 0,128 100 100 100 100 100 100	64 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	A 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1		5 7 1 <sup>50</sup>
99 59 59 59 59 59 59 59 59 59 59 59 59 5	z o 69-1 <sup>1</sup>	8 0 70 <sup>+</sup> 50	2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2 2	u <sup>®</sup> u <sup>®</sup>	27 4 - STR SS SSURE Range	27 5 6 0 - 120 100 - 100 (mmHg)	0 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1 1	1 10 140 -	2 1	5 5 7 198



# 12004 ABPM Pie Report

Ambulate	ory Blood I	Pressure I	Results								
Name: Test Ps Age: 57 y Diagnosis:	atierst					Oate: 5/7/20 Referred By Physicien N	201, 8:45 AM c lotes				
Medications Us	ied:										
Statistical St	ummary of	All Measu	irements	Statistical S	ummary o	of Day Meas	urements	Statistical St	ummary ol	f Night Mea	asurements
Systolic	Mean 118	5D 18	Range 84 - 201	Systolic	Mean 121	SD 18	Range 84 - 201	Systolic	Mean 107	SD 13	Range 88 - 145
Diastolic	83	15	61 - 142	Diastolic	85	15	51 - 142	Diastolic	75	11	58 - 114
MAP	94	15	61 - 162	MAP	96	16	61 - 162	MAP	85	11	67 - 118
	Systo	lic (All)			Systo	olic (Day)	)		Systol	ic (Nigh	t)
120	> 139 m ) - 139 mn < 120 mn	mHg: 79 nHg: 329 nHg: 619	/s €0 /s ⊘ /s ⊚	120	> 139 n ) - 139 m < 120 m	nmHg: 8 % imHg: 39 % imHg: 53 %	6 (B) 6 (C) 6 (C)	110	> 125 m ) - 125 m < 110 m	mHg: 11 % mHg: 26 % mHg: 63 %	/6 (1) /6 (2) /6 (3)
	Diasto	olic (All)	)		Diasto	olic (Day	)		Diastol	lic (Nigh	it)
80 Prin	> 89 mmi ) - 89 mmi < 80 mmi sted: 7/6/2010,	Hg: 18 % Hg: 29 % Hg: 53 % 252 PM	8	81	> 89 mn - 89 mn < 80 mn 12094 A	nHg: 20 % nHg: 38 % nHg: 42 % BPM Pic Repor	,	71	> 79 mm ) - 79 mm < 70 mm	Hg: 11 % Hg: 63 % Hg: 26 %	Page 4



## 12005 ABPM Hourly Summary Report

Ambulatory Blood Pressure Results

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

Name: Test Patient Age: 57 y Diagnosis: Medications Used:

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	62	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
100 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
100 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

				Di Ri Ph	der 5/7/20 derred By ysicien N	01, 8:45 AM cites	Ì	
		ABPM	Mea	isure	ment	Repo	rt	1
Start	Systolic	Diastolic	MAP P	uise Rati	RPP	Status	Comment	1
8:47 AM (1)	0	0	0	0	0	x	at desk	1
8:49 AM (1)	120	84	86	82	74			1
8.51 AM (1)	114	81	91	63	72 .			1
9:08 AM (1)	311	79	90	<u>66</u>	73			1
9/24 AM (1)	117	78	90	88	80			1
8:40 AM (1)	129	87	100	80	103			1
9.55 AM (1)	108	78	87	63	68			1
10:11 AM (1)	112	76	88	58	85			1
10:27 AM (1)	139	114	121	58	95		snack	1
10:42 AM (1)	348	111	123	72	107		pgm trouble	
10:58 AM (1)	129	91	103	78	101			
11:14 400 (1)	123	97		51	100			
11:30 800 (1)	***	30	100	.05	01 70		hand	
1040 /00 (1)	110		- 20	.97	19		NUMBER	1
10:00 (0)	100	36 61	04 61		79		abauna	1
12:35 PM (1)	100	82	01		60.		and a second	1
12-53 PM (1)	0		8	0				1
12.53 PM (1)	201	142	162	122	246			1
1.09 PM (1)	111	82	91	88	98		at detk	1
1/25 PM (1)	109	78	85	74	81			
1:41 PM (1)	111	79	87	70	78			
1:58 PM (1)	100	78	84	73	73			
2:14 PM (1)	108	72	84	55	73			
200								
2:30 PM (1)	108	70	82	00	03			

\* - indicates right measurement Primed: 7/6/2010, 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<sup>TM</sup> 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) manufacturers PC-based electrocardiogram (ECG/EKG) products. PBI is located outside Philadelphia, PA, USA and has a European office located in Germany.

PBI designs, manufacturers 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<sup>TM</sup> 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<sup>™</sup> 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
		Timoulatory Blood Tressale medsalement

- 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**

# 

QRS-Card<sup>™</sup> 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<sup>TM</sup> Cardiology Suite system.[B93]

#### Table 1:

Guidance and manufacturers declaration – electromagnetic emissions[B94]		
The QRS-Card <sup>™</sup> Cardiology Suite system is intended for use in the electromagnetic environment		
specified below. The customer or the user of the QRS-Card <sup>™</sup> Cardiology Suite System should assure		
that it is used in such an environment.		
Emissions Test	Compliance	Electromagnetic environment- guidance
RF emissions	Group 1	The QRS-Card <sup>™</sup> Cardiology Suite system uses RF
CISPR 11		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	Class B	The QRS-Card <sup>™</sup> Cardiology Suite system is suitable for
CISPR 11		use in all establishments other than domestic and those
Harmonic emissions	Not applicable	directly connected to the public low-voltage power
IEC 61000-3-2		supply network that supplies buildings used for domestic
Voltage	Not applicable	purposes.
fluctuations/flicker		
emissions		



#### **A**WARNING

The QRS-Card<sup>TM</sup> 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<sup>TM</sup> 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 <sup>™</sup> Cardiology Suite system is intended for use in the electromagnetic environment			in the electromagnetic environment
specified below. The c	customer or the user o	f the PBI QRS-Card <sup>TN</sup>	<sup>4</sup> Cardiology Suite system should assure
that it is used in such as	n environment.		
Immunity Test	IEC 60601	Compliance level	Electromagnetic environment-
	Test level		guidance
Electrostatic	$\pm$ 6 kV contact	$\pm$ 6 kV contact	Floors should be wood, concrete or
discharge (ESD)			ceramic tile. If floors are covered
	$\pm$ 8 kV air	$\pm$ 8 kV air	with synthetic material, the relative
IEC 61000-4-2			humidity should be at least 30%.
Electrical fast	$\pm 2$ kV for power	Not applicable	No power supply lines
transient/burst	supply lines		
IEC 61000-4-4	$\pm 1 \text{ kV for}$	Not applicable	Input/output lines < 3M
	input/output lines		
Surge	$\pm 1$ kV line(s) to	Not applicable	No line(s) to line(s)
	line(s)		
IEC 61000-4-5		Not applicable	No line(s) to earth
	$\pm 2 \text{ kV line(s) to}$		
xx 1. 1. 1	earth		
Voltage dips, short	$<5\% U_{\rm r} (>95\%$	Not applicable	No power supply lines
interruptions, and	$dip in U_r$ )		
voltage variations on	10 07 II (60 07 dim		
power suppry lines	$40 \% U_r (60 \% dlp)$		
IEC 61000 1 11	$\Pi O_r$ 101 5 cycles		
ILC 01000-1-11	70 % U (30 % din		
	in II) for 25		
	cycles		
	eyeres		
	<5 % U <sub>r</sub> (>95 %		
	dip in $U_r$ ) for 5 s		
Power frequency	3 A/m		Power frequency magnetic fields
(50/60Hz) magnetic			should be at levels characteristic of a
field			typical location in a typical
			commercial or hospital environment.
IEC 61000-4-8			
NOTE $U_r$ is the a.c. mains voltage prior to application of the test level			



Table 3:

The PBI QRS-Card <sup>TM</sup> Cardiology Suite system is intended for use in the electromagnetic environment specified below. The customer or the user of the PBI QRS-Card <sup>TM</sup> Cardiology Suite system should assure that it is used in such an environment.ImmunityIEC 60601 test levelCompliance levelElectromagnetic environment- guidanceTestIEC 60601 test levelCompliance levelPortable and mobile RF communications equipment should be used no closer to any part of the PBI QRS- Card <sup>TM</sup> Cardiology Suite system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.Conducted RF IEC 61000-4-63 Vrms3 VrmsRecommended separation distance d = 1,2 $\sqrt{P}$ Radiated RF IEC 61000-4-33 V/m 80 MHz to 2.50.81 V/md = 4.3 $\sqrt{P}$ 80 MHz to 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz to 2.5 MHzMHzNHz0.81 V/mField strengths from fixed RF transmitter, and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya should be uses than the compliance level in each frequency range <sup>b</sup>		
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 TestIEC 60601 test levelCompliance levelElectromagnetic environment- guidanceTestIEC 60601 test levelPortable 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.Conducted RF IEC 61000-4-63 Vrms3 VrmsRecommended separation distance $d = 1,2 \sqrt{P}$ Radiated RF IEC 61000-4-33 V/m 80 MHz to 2.5 MHz0.81 V/m $d = 4.3 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter and <i>d</i> is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup>		
an environment.Immunity TestIEC 60601 test levelCompliance levelElectromagnetic environment- guidanceTestlevelPortable and mobile RF communications equipment should be used no closer to any part of the PBI QRS- CardTM Cardiology Suite system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.Conducted RF IEC 61000-4-63 Vrms3 VrmsRecommended separation distance $d = 1, 2 \sqrt{P}$ Radiated RF IEC 61000-4-33 V/m 80 MHz to 2.5 MHz0.81 V/m $d = 4.3 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup>		
Immunity TestIEC 60601 test levelCompliance levelElectromagnetic environment- guidanceTestlevelPortable and mobile RF communications equipment should be used no closer to any part of the PBI QRS- Card <sup>TM</sup> Cardiology Suite system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.Conducted RF IEC 61000-4-63 Vrms3 VrmsRecommended separation distance $d = 1, 2 \sqrt{P}$ Radiated RF IEC 61000-4-33 V/m 80 MHz to 2.5 MHz0.81 V/m $d = 4.3 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter manufacturer and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya should be less than the compliance level in each frequency range <sup>b</sup>		
TestlevelPortable and mobile RF communications equipment should be used no closer to any part of the PBI QRS- CardTM Cardiology Suite system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.Conducted RF IEC 61000-4-63 Vrms3 VrmsRecommended separation distance d = 1,2 $\sqrt{P}$ Radiated RF IEC 61000-4-33 V/m 80 MHz to 2.50.81 V/m $d = 4.3 \sqrt{P}$ 80 MHz to 800 MHz d = 2.3 $\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya should be less than the compliance level in each frequency range <sup>b</sup>		
Conducted RF IEC 61000-4-63 Vrms3 VrmsRecommended separation distance calculated from the equation applicable to the frequency of the transmitter.Radiated RF IEC 61000-4-63 V/m 80 MHz to 80 MHz0.81 V/m $d = 4.3 \sqrt{P}$ 80 MHz to 800 MHzRadiated RF IEC 61000-4-33 V/m 80 MHz to 2.5 MHz0.81 V/m $d = 4.3 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter in watts (W) according to the transmitter and d is the recommended separation distance in meters (m).Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup>		
Conducted RF IEC 61000-4-63 Vrms 150 kHz to 80 MHz3 Vrms <b>Recommended separation distance</b> $d = 1, 2 \sqrt{P}$ Radiated RF IEC 61000-4-33 V/m 80 MHz to 2.5 MHz0.81 V/m $d = 4.3 \sqrt{P}$ 80 MHz to 800 MHz $d = 2.3 \sqrt{P}$ 800 MHz to 2,5 GHz 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).Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya should be less than the compliance level in each frequency rangeb		
Radiated RF IEC 61000-4-33 V/m 80 MHz to 2.5 MHz $0.81V/m$ $d = 4.3 \sqrt{P} 80 \text{ MHz} to 800 \text{ MHz}$ $d = 2.3 \sqrt{P} 800 \text{ MHz} to 2,5 \text{ GHz}$ 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).Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya should be less than the compliance level in each frequency rangeb		
MHz where <i>P</i> is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and <i>d</i> is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup>		
Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup>		
Interference may ecour in the visibility of		
equipment marked with the following symbol:		
$(((\bullet)))$		
If you experience ECG signal distortion, please contact Pulse Biomedical Inc technical support team for guidance.		
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.		
<sup>a</sup> 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 <sup>TM</sup> ECG is used exceeds the applicable RF compliance level above, the PBI QRS-Card <sup>TM</sup> 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 <sup>™</sup> ECG <sup>b</sup> Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3V/m		



# **NOTICE** A Note About

A Note About Electromagnetic Immunity:

The PBI QRS-Card<sup>TM</sup> 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<sup>TM</sup> are trained medical professionals that recognize ECG artifacts including RF interference, and thereby make the ne ssary 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>™</sup> Cardiology Suite system

The PBI QRS-Card<sup>TM</sup> 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<sup>TM</sup> 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<sup>TM</sup> Cardiology Suite system as recommended below, according to the maximum output power of the communications equipment

Rated maximum	Separation distance according to frequency of transmitter m		
output power of transmitten	150 kHz to 80MHz	80 MHz to 800 MHz	800 MHz to 2,5 GHz
W	$d = 1.2\sqrt{P}$	$d = 4.3\sqrt{P}$	$d = 2.3\sqrt{P}$
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

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.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for 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.



# **Appendix 11: QRS-Blue<sup>TM</sup> 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 μV		
Input dynamic range	$: 10 \text{ mV}_{pp}$		
Input Offset Range	$\pm 300 \text{ mV}$		
Frequency Response	: 0.05 to 150 Hz (- 3dB)		
CMMR	: -60dB (minimum)		
Input Impedance	$: > 100 \text{ M}\Omega$		
Defib protection	: Integrated		
Operating Temp	: 0 to 40 °C		
Storage Temp	: -10 to 50 °C		
Relative Humidity	: 25 to 95 % noncondensing		
Atmospheric Pressure	2:70 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 <sup>TMTM</sup> Device, 90 days on accessories
Medical Class	: Class II
Type of Applied Part	s: 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>™</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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:**

CS406-10 Rev F



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<sup>TM</sup> 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<sup>TM</sup> provides digitized data over USB port or Bluetooth wireless connection using proprietary digital data format.

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

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

### **Analog ECG Trigger Output:**

QRS-Blue<sup>TM</sup> 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<sup>™</sup> 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<sup>TM</sup> 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<sup>TM</sup> 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<sup>™</sup> 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<sup>™</sup> machine so that wires should not be damaged and should always be clean.

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

Batteries should not be kept inside the QRS-Blue<sup>TM</sup> 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<sup>TM</sup> 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.

Pulse Biomedical Inc. Technical Support Department +1-610-666-5510