



DMS ECG Database System

Holter Software - CardioScan 79a

Operator's Manual

Table of Contents

	<u>Page</u>
I. Preface	3
II. The Seven (7) Major Functions of CardioScan 79a	4
III. Getting Started with CardioScan 79a	7
a. Facility Information and Initial Server Settings	7
b. Login	9
c. Interface Overview	10
d. The Patient List – Case Status Indicator	10
e. User/Account Set-up	11
f. System Settings	13
IV. Conducting the Test	16
a. Lead Placement	16
b. Patient Enroll	20
c. Holter Download	21
V. Pre-Analysis Set-Up Menu (Setting ST and QT)	23
VI. Holter Analysis Functions – The Data Access Choices Menu.....	27
a. Overview	27
b. Page Scan	29
c. Poincare	36
d. Template	38
e. Event	44
f. Histogram	47
g. Mega Scan	49
h. Hourly	51
i. ECG Strip	52
j. Report	54
k. ECG	56
l. Tools	59
m. Advanced Tools	70
n. Re-Analysis	81
o. Exit	82
p. Note on Multi-Day Reporting Functionality	83
VII. Recommended Editing Process – General Observations	85
a. Quick A-Fib Review	85
b. Editing “Rules of Thumb”	86
VIII. Navigating the Database	89

I. Preface

Introduction

This manual will provide an overview of the main features of the DMS CardioScan 79a Holter software.

The DMS CardioScan 79a software is one of several DMS ECG analysis programs designed to work with the DMS ECG Database System and DMS Satellite Internet System.

The DMS ECG Database System is a comprehensive system that allows multiple users within the same network to enroll patients (either through direct input or by sourcing patient demographic information from a hospital EMR system); and allows these users to acquire, edit, verify, report, and manage patient ECG test results by means of a centralized database that can be linked to an EMR system.

The DMS ECG Database System can be used in conjunction with the DMS Satellite Internet System which allows for ECG tests to be collected in various remote locations, transmitted via a secure Internet connection to the DMS ECG Database System, and analyzed within the hospital network by a user with the requisite permissions.

It should be noted that the DMS CardioScan 79a software can be used independently of the DMS ECG Database System and DMS Satellite Internet System as a standalone, single-computer system.

Furthermore, it should be noted that the DMS CardioScan 79a software can also be used together with the DMS CardioVision telemetry system to provide Holter analysis while performing beat-by-beat, real-time ECG monitoring.

Note for existing CardioScan 78a users: The CardioScan 79a software package can be installed onto a PC with 78a software. Both software packages use the same USB Security Key. 78a users will find it easy to work with 79a, as it adds functions that are the natural outgrowth of 78a in order to enhance the processing of Holter ECG files.

Note on DMS device compatibility: CardioScan 79a is a 3-lead, 6-lead, and 12-lead system. The 3- and 6-lead capabilities are compatible with DMS 300-2 (cellular), 300-2W (Wi-Fi), 300-3A, 300-4A, and 300-4L Holter recorders. The 12-Lead capabilities are compatible with DMS 300-4A and 300-4L recorders.

How to contact us?

Thank you for purchasing and using DMS products. If you have any questions, please contact us as follows:

Company: Diagnostic Monitoring Software
Address: P.O. Box 3109
290 Kingsbury Grade, #3
Stateline, NV 89449
United States of America

Tel (Main): +1 (775) 589-6049
Tel (Support): +1 (714) 953-2653
Email: info@holterdms.com

II. The Seven (7) Major Functions of CardioScan 79a

One-Day Holter ECG

One-day Holter ECG has been the traditional operational usage of Holter since 1964. Holter ECG has been the gold-standard technique for detecting ECG abnormalities due to its access and review of 100% of the ECG data during the 24-hour monitoring period.

Hundreds of published studies have established that both 24-hour Holter ECG and the up-to-30 day Cardiac Event test have diagnostic yields of detecting a patient's significant ECG abnormality in the 20% to 25% range. This is good news for the 20% to 25% of patients, but what about the rest who may be labelled as normal simply because a potentially serious ECG abnormality did not occur on the day of the Holter ECG monitoring?

Multi-Day Holter ECG

Each additional day of Holter ECG monitoring increases the opportunity for capturing the significant ECG event for a patient that does not fall in the 20-25%.

CardioScan 79a is the premier Holter system for processing multi-day Holter recordings. Our software can process up-to-a-30 day Holter file.

The processing and editing time for a 5-day Holter is approximately 20% greater than a 1-day Holter. Since no physician can predict when a patient will experience a random significant ECG abnormality, it is impossible to predetermine the precise length of a multi-day Holter. That being said, observations of thousands of patients per month suggest that very few new significant ECG abnormalities occur after ten (10) days of Holter monitoring. However, one potential inconvenience with selecting a default 7- or 10-day Holter test is that the patient can experience a significant ECG abnormality on the 2nd or 3rd day of monitoring, rendering the additional 5 to 8 days of monitoring as an unwanted and unnecessary burden on the patient. If desired by the medical professional (and with the requisite DMS equipment), our system can also perform a real-time function (see below).

Holter Review of Real-Time ECG Monitoring of Hospital and Nursing Care Facility Wi-Fi Inpatients

In a hospital setting, with traditional Holter, a hypothetical test is ordered for an inpatient at 9:00 AM on Monday morning. The patient experiences a Sustained V-Tach at 11:00 AM that morning. The test concludes at 9:00 AM on Tuesday, and the Holter report is completed by Wednesday morning. Nearly 48 hours have elapsed since the Sustained V-Tach.

The DMS system offers advancements in monitoring technology for hospitals that perform traditional Holter monitoring for inpatients. While the DMS 300-2W recorder is performing the Holter test, it is also providing a beat-by-beat, real-time, Wi-Fi output (6-Lead ECG from only 3-electrodes). This real-time monitoring system is more sophisticated than a step-down ECG telemetry system.

In the above example, the Sustained V-Tach would have been known and acted upon at 11:00 AM Monday, rather than Wednesday morning. Any physician office in the hospital's network would have had immediate access to the Sustained V-Tach data on their office computer.

Holter Review of Real-Time ECG Monitoring of Cellular Telemetry Outpatients

A small device combines the technology of a 30-day Holter with a mobile phone module. A 3-electrode placement allows for a 6-Lead ECG, which provides the diagnostic data for advanced presentation of P-Waves for A-Fib and Wide Complex Tachycardia patients, and adjacent contiguous leads for valid ST Depressions. The recorder's mobile phone module transmits the real-time ECG from the outpatient to the hospital. A single receiving station (PC) can accommodate up to 48 patients simultaneously with monitoring and processing power that is substantially advanced relative to hospital inpatient step-down telemetry ECG systems.

All patient data is processed independently with real-time ECG viewing and analysis, along with the best Holter technology available. If a patient has a significant problem on 2nd, 4th, 7th day, etc.; the ECG event is captured, known, and the test is terminated. True 100% Full Disclosure for 6-Lead ECG is present with all real-time and Holter monitoring modes of operation.

This will soon become the dominant worldwide technology for outpatient Holter ECG testing.

Holter Satellite Scan Services

While the above-described outpatient cellular telemetry Holter will become the go-to technology for Holter Scan Services in the future; current DMS customers continue to use very large quantities of DMS 300-3A, 300-4A, and 300-4L recorders that require traditional Holter processing methods. Furthermore, many current DMS customers deploy their extensive Holter systems across a wide array of locations (departments and facilities). CardioScan 79a offers advanced database management capabilities (SQL) designed to aggregate, capture, and analyze ECG recordings which may simultaneously originate from many remote hospital and private practice facilities.

Sleep Apnea with Nighttime Respiration, Body Position, and ECG Recording

Sleep Apnea patients often become cardiac disease patients. As a result, cardiologists are showing more interest in detecting the early stages of Sleep Apnea.

Combining Respiration with ECG signals can provide a strong indication of Sleep Apnea. The DMS 300-4L recorder combines these. At 10:00 PM (22:00), respiration monitoring initiates. It continues until 6:00 AM. The respiration signal will tend to flat-line when the patient ceases to breathe. The combination of respiration signal flat-lining with the heart rate slowing down is a strong indication of Sleep Apnea.

CardioScan 79a has an independent program in the Advanced Tools menu that generates a report for potential Sleep Apnea patients who are undergoing a Holter ECG test. A Sleep Apnea report can be printed when desired.

Baroflex Sensitivity

The Autonomic Nervous System (ANS) initiates each beat of the heart. The Autonomic Function Test is closely associated with the ANS and provides data to determine if patient parasympathetic and sympathetic responses are in balance. This general information is referred to as Baroflex Sensitivity.

Baroflex Sensitivity is influenced by heart rate responses to (a) deep breathing for 1-minute, followed by (b) valsalva maneuver during a 1-minute time period, and (c) sitting / standing during a 1-minute time period. A one-page report is then generated.

Only 3-electrodes are required for Baroflex Sensitivity testing; the same as for most DMS Holter recordings. Prior to assigning a Holter recorder to the patient, the testing hospital or private practice can connect a DMS 300-2W Wi-Fi recorder to the patient's electrode cable. The ECG data is displayed on the PC, and the 1-minute monitoring begins for deep breathing, valsalva, and sitting versus standing. When the Baroflex Sensitivity is complete, the ECG cable is disconnected from the 300-2W recorder, and the cable is connected to the designated Holter recorder to begin the Holter testing.

III. Getting Started with CardioScan 79a

A. Facility Information and Initial Server Settings

In this section, we will review the initial facility and server setup process. This is a one-time step. Note: Please consult with your IT department, as well as your DMS representative, before completing this initial setup.

1. Upon initial software installation, launch the CardioScan 79a software by clicking on the shortcut icon found on your computer's desktop



2. A prompt "Input Hospital Information" will appear as shown below:

A screenshot of the "Input Hospital Information" dialog box. The dialog has a title bar with a close button. Inside, it says "Please input your hospital information!". There are input fields for "Hospital Name", "Code", "Tel", "Address", and "Fax". Below these, it says "Please input your department information!". There are input fields for "Department Name" and "Code". At the bottom is a "Save and Exit" button.

3. Input the required hospital and department information. In addition to being stored in the system, this information will appear on patient reports
4. Press "Save and Exit"
5. Double-click on the desktop icon again. The login dialog box shown below will appear:

A screenshot of the "CardioScan Holter Software" login dialog box. The dialog has a title bar. The header area includes the text "INNOVATION and EXPERIENCE" and "DMS DMS DMS" with a globe icon. Below the header, there are input fields for "Server" (with a "Setup Server" button), "Hospital Name" (a dropdown menu), "Test Department" (a dropdown menu), "User Name" (a dropdown menu), and "Password". There is an "UnLock" button and a "Save Password" checkbox. At the bottom are "Login" and "Close" buttons. On the right side, there is an illustration of a human torso with a heart and a stethoscope.

6. Prior to initial user login, you will be required to setup the server. Click on the “Setup Server” button shown above. The following popup window will appear:

Server Setting

Database Username: sa

Password: [masked]

Server:

Server Type	Server Path	Test Status	Default Username and Pass	Action
Main Server	(Server IP or PC name)\dms	Not Test		SaveTest
Backup Server	(Backup Server IP or PC name)\dms	Not Test	<input type="checkbox"/>	SaveTest
Local Database	(Local database IP or PC name)\dms	Not Test	<input type="checkbox"/>	SaveTest

7. Input the corresponding Server Setting information
- Database Username: sa (system default)
 - Password: dmsdms (system default)
 - Main Server: (Server IP or PC name) \ dms (location of all saved patient information and data)
 - Backup Server: (Backup Server IP or PC name) \ dms
 - Local Database: (Local database IP or PC name) \ dms (used to store information locally in case of main or backup server failure; if the facility network is unavailable; or if the user wants to use CardioScan 79a as a standalone system)
8. Once the information has been entered, click “Save Test” on the right side of the popup window. When the server connections have been confirmed, “Pass” will appear:

Server Setting

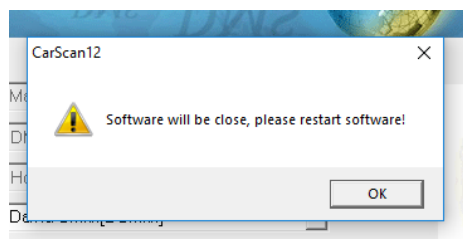
Database Username: sa

Password: [masked]

Server:

Server Type	Server Path	Test Status	Default Username and Pass	Action
Main Server	GIL-ASUS\dms	Pass		SaveTest
Backup Server	GIL-ASUS\dms	Pass	<input type="checkbox"/>	SaveTest
Local Database	GIL-ASUS\dms	Pass	<input type="checkbox"/>	SaveTest

9. When the window is closed, the prompt below will appear. Click “OK”



B. Login

In this section, we will review the user login process. CardioScan 79a is designed to allow for various distinct users, each with a unique username and password, to access the program from the same computer.

Note: For information on setting up new users or modifying existing accounts, please refer to Section D – User / Account Set-up.

1. Launch the CardioScan 79a software by clicking on the shortcut icon found on your computer's desktop (see below)



2. The login screen will appear:

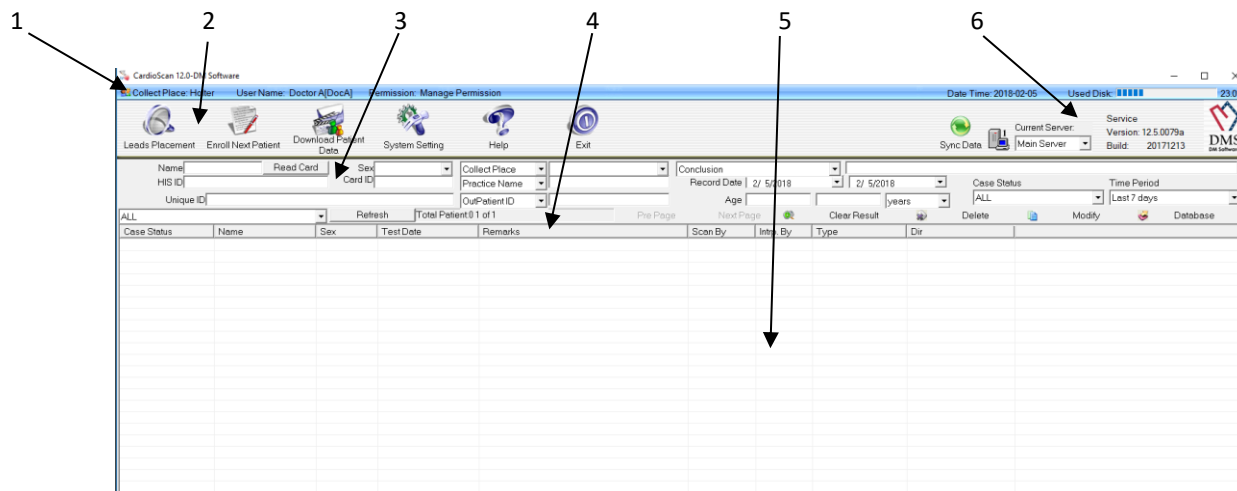
The login screen for CardioScan Holter Software. The window title is 'CardioScan Holter Software'. The header features a banner with the text 'INNOVATION and EXPERIENCE' and the DMS logo. Below the banner, there are several input fields: 'Server' (set to 'Main Server'), 'Hospital Name' (set to 'DM Software[DMS]'), 'Test Department' (set to 'Holter[ECG]'), 'User Name' (set to 'Doctor A[DocA]'), and 'Password'. There is a 'Setup Server' button next to the 'Server' field and an 'UnLock' button next to the 'Test Department' field. A 'Save Password' checkbox is checked. At the bottom, there are 'Login' and 'Close' buttons. On the right side of the login form, there is an illustration of a human torso with a heart rate monitor and electrodes.

3. You will notice that the first two fields ("Server" and "Hospital Name") are greyed out. These are only accessible to a System Administrator. The "Server" refers to the main server hosting the database. The "Hospital Name" refers to the name of the actual facility where the computer is located. While the "Setup Server" button is not greyed out; it is password restricted and, similarly, can only be accessed by a System Administrator
4. From the drop-down menu, select the "Test Department" corresponding to the user who will log in
5. Once the appropriate "Test Department" is selected, the program automatically identifies all users associated with that department (within the specific facility under "Hospital Name"). From the "User Name" drop-down menu, select the appropriate user
6. The user will now enter their password and click "Login". You will now be directed to the main screen

7. All CardioScan 79a test activity will now be recorded in the database under the user name

C. Interface Overview

The main user interface is shown below:



The following is a brief overview of the general interface sections:

1. Displays login information including facility/department name, username, and permission type
2. Function buttons including lead placement, patient enroll, patient download, system settings, help menu, and exit program
3. General search/sort categories, modify patient demographic information, import/export patients, access satellite explorer (for satellite clients)
4. Default displayed patient information fields. This can be adjusted in System Settings.
5. Patient List (see below "Section D: Patient List – Case Status Indicator")
6. Server indicator, software version and build

D. The Patient List – Case Status Indicator

All CardioScan 79a patients can be accessed through the patient list found in the general interface. Double click on any name to access that patient's Holter file (see Section VI).

Each patient on the list will have a case status indicator (with corresponding color icon) immediately to the left of the patient name depending on their stage of analysis/reporting. Please refer to "Section E:

User/Account Set-up” below for instructions on how to set up user permission levels. Only users with the appropriate permissions will be able to perform the functions described in this section. The system maintains a log of which user has performed each function for every patient.

Below are the various case status stages:

Case Status	Name	Sex	Test Date	Remarks
Printed	Printed Patient		27/02/2018 12:00:00	
Verified	Verified Patient		27/02/2018 11:00:00	
Concluded	Concluded Patient		27/02/2018 10:00:00	
Playbacked	Downloaded Patient		27/02/2018 00:01:00	
Reserved	Enrolled Patient		27/02/2018 16:13:00	

- Reserved (Gray) – Indicates the patient has been enrolled in the system
- Playbacked (Black) – Indicates the patient Holter recording has been downloaded for analysis
- Concluded (Yellow) – Indicates the file has been edited and comments/conclusions included
- Verified (Green) – Indicates the physician has clicked “Verify” in the Report section of the Data Access Choices menu. This applies the physician signature to the report and transfers the file to the facility’s Electronic Medical Records (EMR) or Hospital Information System (HIS)
- Printed (Red) – Indicates the report has been printed

E. User/Account Set-up

In this section, we will outline the process of setting up new “Hospital”, “Department”, and “User” Accounts. The software allows for various operational permission levels.

Note: Setting up accounts requires a user with Manager (i.e., Administrator) permissions.

1. The illustration below displays the main interface. You will always see this screen when you first log in. In the upper left portion of the screen, there are several icons (i.e. Leads Placement, Enroll Next Patient, Download Patient Data, System Settings, Exit)

- Click on the “System Settings.” The following will appear:

The screenshot shows the 'System Settings' window. On the left, a tree view under 'Category' includes 'General Information' (selected), 'Basic Settings', 'Report Settings', 'Custom settings', and 'Account Manager'. The main area is divided into several sections:

- Facility Information:** Fields for Facility Name (DM Software), Facility Address, Facility Phone, and Facility Fax.
- Physician Information:** Fields for Physician Name (Doctor A[DocA]), Physician Email, Physician Phone (555-1212), and buttons for 'Modify Password' and 'Electronic Signature'.
- HIS Interface Settings:** Includes 'Interface Option' (None), 'XML Output Path' (C:\), 'Report Format' (PDF), 'PDF Quality' (Middle), and checkboxes for 'FTP Transfer' and 'SFTP PASV'.
- DMS Information System:** Fields for IP (127.0.0.1) and a 'Test' button.
- GDT Settings:** Fields for 'GDT Path In' and 'GDT Path Out', and a button for 'Open GDT File'.
- HL7(Web Php) Settings:** A button for 'Open Settings File'.
- Satellite Holter Server Settings:** Fields for Remote Server IP (127.0.0.1), Port (21), and checkboxes for 'Send Report to Satellite Client', 'Transfer report back to HIS Server', 'Export Local PDF Report', and 'ICD Code Required'.
- DEVICES:** Fields for DEVICE ID (DMSECGMHYKFMMSF) and Unlock Code.

 At the bottom are 'System Manager', 'OK', and 'Cancel' buttons.

- Under “General Information”, select “Account Manager”. You will now see a screen as shown below

The screenshot shows the 'System Settings' window with the 'Account Manager' section selected in the left tree view. The main area displays three account management sections:

- Hospital Account:** A list on the left shows 'DM Software' selected. To the right are fields for Hospital Name, Code, Tel, Address, and Fax, along with 'Delete', 'Modify', and 'Add' buttons.
- Department Account:** A list on the left shows 'ALL', 'Emergency Room', and 'Holter' (selected). To the right are fields for Department Name, Code, and a 'Department Limit' field, with 'Delete', 'Modify', and 'Add' buttons.
- Doctor Account:** A list on the left shows 'James Jones, M.D.' selected, along with other names like 'Doctor A', 'David Smith', 'Technician A', 'Nurse A', and 'Technician B'. To the right are fields for Doctor Name, Password, Tel, Email, Work ID, Satellite User Name, and Satellite Password, along with checkboxes for 'Collect ECG', 'Write Report', 'Verify Report', 'Manage Database', 'Report and Verify Local Hospital', 'Report and Verify Local Department', 'Disable Account', and 'Login In Any Place'. There are also 'Delete', 'Modify', and 'Add' buttons.

 At the bottom are 'System Manager', 'OK', and 'Cancel' buttons.

- In the upper portion of the screen is the Hospital Account Manager menu. To set up a new facility, simply click on the “Add” button, type in the requisite information, and select “Save”. Here, we have set up a facility named “DM Software”. Modifying information or deleting facilities altogether involves selecting the corresponding buttons.
- Once a facility is set up, you can proceed to add corresponding departments in the Department Account Manager menu. In the example above, you can see that under the highlighted facility “DM Software”, there are two departments (“Emergency Room” and “Holter”), as well as an

“All” category. To add new departments, simply click on “Add”, type in the department name and your desired department code. Select “Save”. Click “Modify” to change any information. Click “Delete” to remove a department from the database.

6. Once the department set up is complete, you can proceed to Doctor Account Manager to set up individual user accounts, each with their own level of access/permissions. Each user account is associated with a specific department. In the example above, the highlighted Holter Department has six users. (Please note that the “Satellite User Name” and “Satellite Password” input fields are only to be completed if the user will connect to the DMS Satellite Internet System – refer to the Satellite Internet manual for instructions). Click OK when finished.
7. Each user must select (or be assigned) their own username and password. Additionally, the administrator can assign different types of permissions:
 - a. CollectECG: Limits the user to only enrolling the test / downloading ECG data.
 - b. Write Report: The user can edit the test, analyze results, and provide a summary/conclusion. If this is selected, “CollectECG” is also checked by default.
 - c. Verify Report: Allows the user to review and approve the test report. This will apply the physician signature to the report. If this is selected, “CollectECG” and “Write Report” are also checked by default.
 - d. Manage Database: Allows the user to act as a database administrator and manage other user accounts (can set up facilities, departments, and users). By default, this also grants the user all previously mentioned permissions.
 - e. Report and Verify Local Hospital: Checking this box restricts the user to only accessing tests conducted in the local facility. The user can access patients from any department within this local facility.
 - f. Report and Verify Local Department: Checking this box restricts the user to only accessing tests conducted in their specific department within a local facility.
 - g. Disable Account: Suspends access to a selected user account.
 - h. Login in Any Place: In addition to their assigned department, allows the user to log in from any other department within the local hospital.

8. Once the user account is set up, click “OK”. This will take you back to the main patient screen.

F. System Settings

In this section, we will provide an overview of the remainder of the system settings interface.

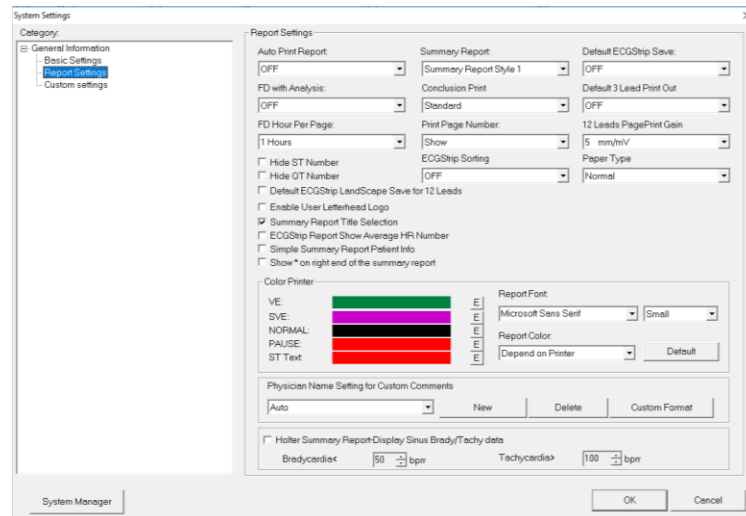
1. Click on “System Settings”. You will be presented with the following screen. Note that most users will not have access to the Account Manager category, as it is restricted to users with Administrative privileges.

The screenshot shows the 'System Settings' dialog box with the 'General Information' tab selected. The left sidebar lists categories: General Information, Basic Settings, Report Settings, Custom settings, and Account Manager. The main area contains several sections: Facility Information (Facility Name, Facility Phone, Facility Address, Facility Fax), Physician Information (Physician Name, Physician Email, Physician Phone, Modify Password, Electronic Signature), HIS Interface Settings (Interface Option, DMS Information System, GOT Settings, HL7/Web Pkg Settings), and Satellite Holter Server Settings (Remote Server IP, Port, Send Report to Satellite Client, Transfer report back to HIS Server, Export Local PDF Report, ICD Code Required). At the bottom, there is a 'System Manager' button and 'OK'/'Cancel' buttons.

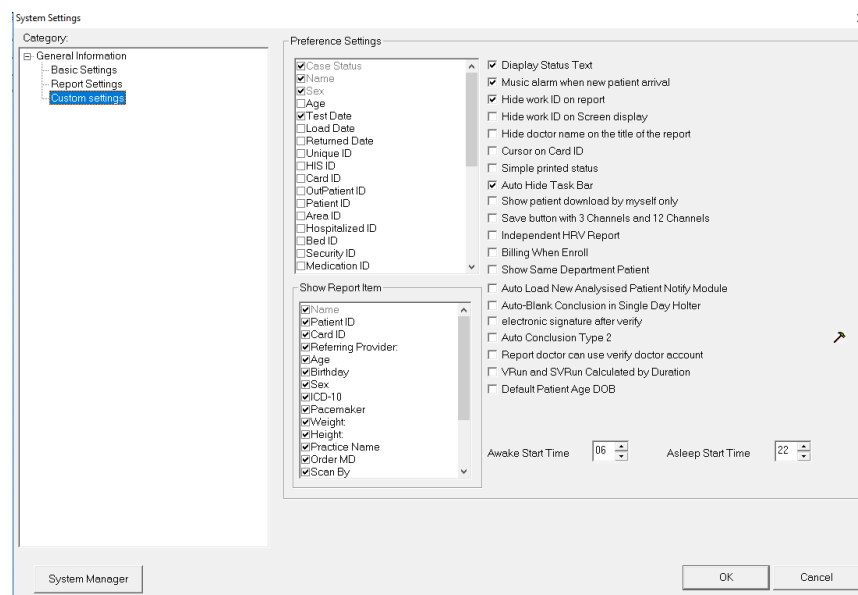
2. With the requisite permissions, the General Information tab allows the user to enter or modify the address, phone number, and fax number for each facility. You can also enter or modify the email address, phone number, and password for the physician/user that is currently logged in. The software allows for a physician’s electronic signature to be stored and used.
3. While the HIS Interface Settings can be adjusted, this is typically set during the initial software installation. The Satellite Holter Server Settings appear only if the user has Administrative privileges. These are relevant if the facility intends to use the DMS Satellite Internet System (please refer to the Satellite Internet manual for instructions).
4. The Basic Settings tab allows the user to set general, analysis, and interface settings. Click OK to save preferences.

The screenshot shows the 'System Settings' dialog box with the 'Basic Settings' tab selected. The left sidebar lists categories: General Information, Basic Settings, Report Settings, Custom settings, and Account Manager. The main area contains several sections: Basic Settings (Raw Data Directory, Filter, Anti Baseline Wander, Monitor Port, CV Server IP Address, CV Server List), Region Settings (Language, Date Style, Weight, Height), Analysis Settings (SVE Premature%, Minimum HR, ST Mode, Auto Gain Adjust, Manual Set ST, Maximum HR, ST Analysis, Pause Time), Interface Settings (ECG Strip Display, ECG Strip Color Mode, ECG Strip HR Display, ECG Antialiasing, 12 Leads ECGSTRIP Gain, Template Protect, Template/Event Auto Update), and Edit Custom Item (Custom Item1, Custom Item2, Custom Item3, Custom Item4). At the bottom, there is a 'System Manager' button and 'OK'/'Cancel' buttons.

- In the Report Settings tab, you can select from several options that will customize the appearance of each printed report.



- The Custom Settings tab allows the user to select the default data fields that will be displayed for every patient in the main interface screen and reports. In this section, the user will also be able to choose from a select number of default actions. When finished, click OK.



IV. Conducting the Test

A. Lead Placement

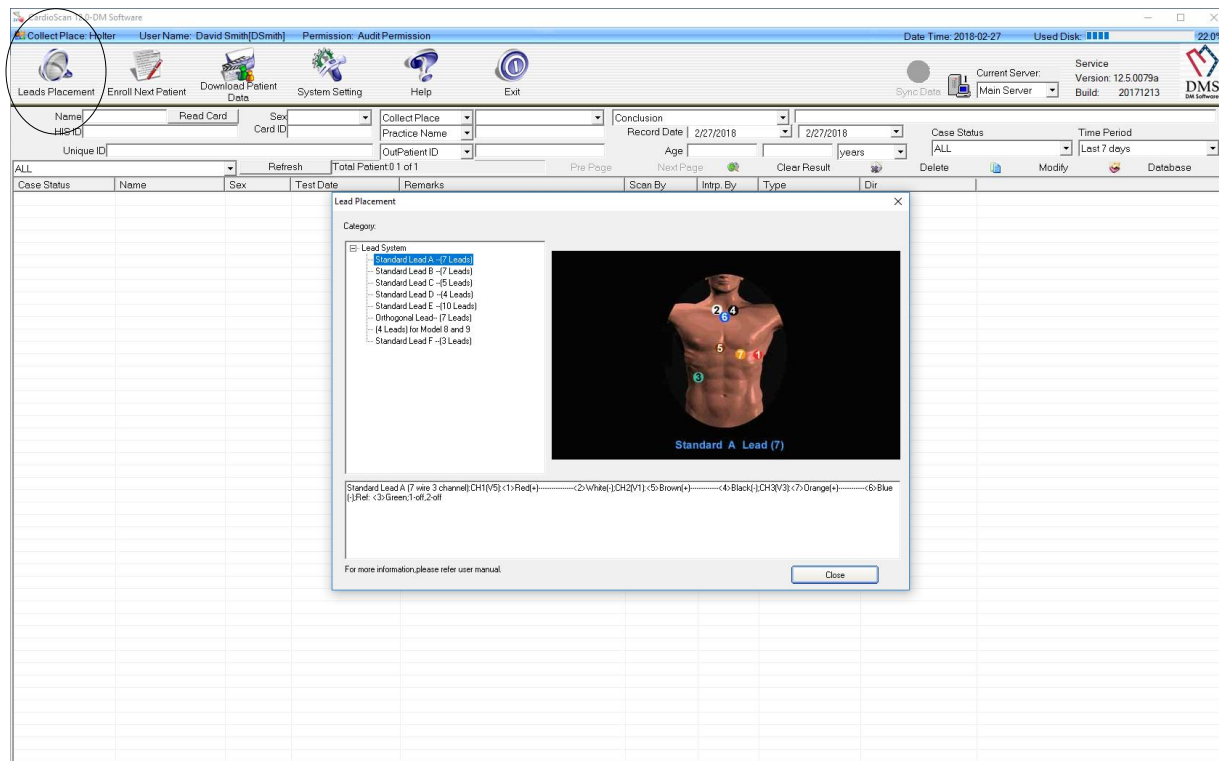
CardioScan 79a is compatible with DMS 300-2 (cellular), 300-2W (Wi-Fi), 300-3A, 300-4A, and 300-4L Holter recorders.

Below is a list of device leadwire compatibility:

- 300-3A (3-electrode, 5-electrode, 7-electrode (a), 7-electrode (b), Orthogonal)
- 300-4A (3-electrode, 4-electrode, 7-electrode, 10-electrode)
- 300-4L (3-electrode, 5-electrode, 7-electrode, 10-electrode)
- 300-2 (3-electrode, 4-electrode)
- 300-2W (3-electrode, 4-electrode)

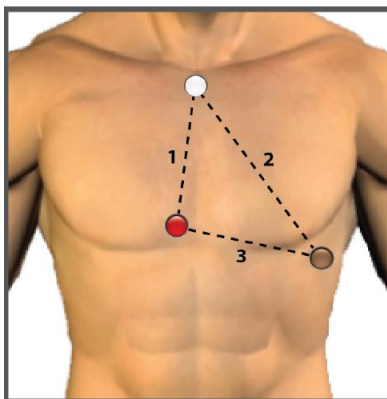
Please note that DMS leadwires are exclusive to DMS Holter recorders. NEVER attempt to use any third-party leadwires, as patient safety and data integrity may be compromised. Also, DMS leadwires are designed to help prevent damage to DMS Holter recorders arising from the discharge of automated external defibrillators (AED).

To review the placement of leadwires, click “Lead Placement” on the main patient screen.

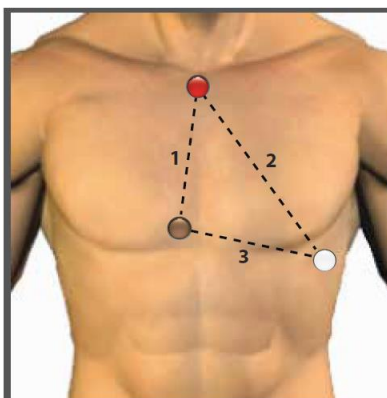


Refer to the detailed lead placement diagrams below:

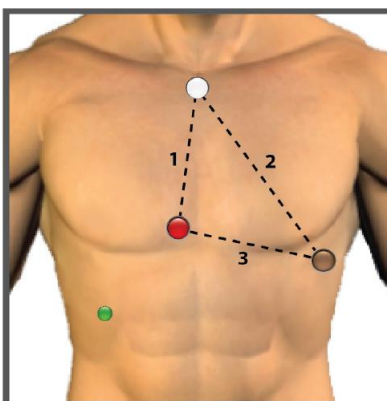
3-Electrode Placement (300-3A, 300-4L, 300-2, 300-2W)



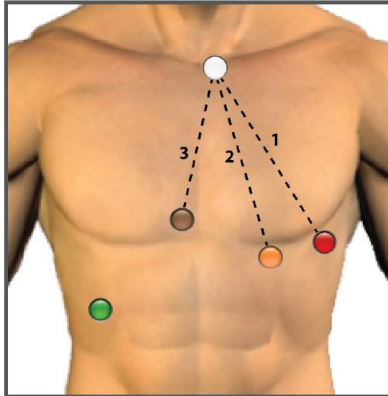
3-Electrode Placement (300-4A)



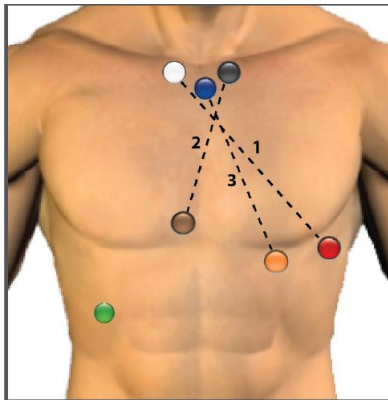
4-Electrode Placement (300-4A, 300-2, 300-2W)



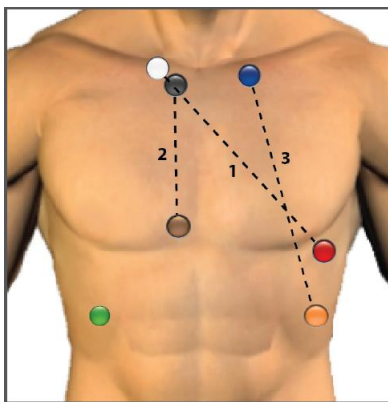
5-Electrode Placement (300-3A, 300-4L)



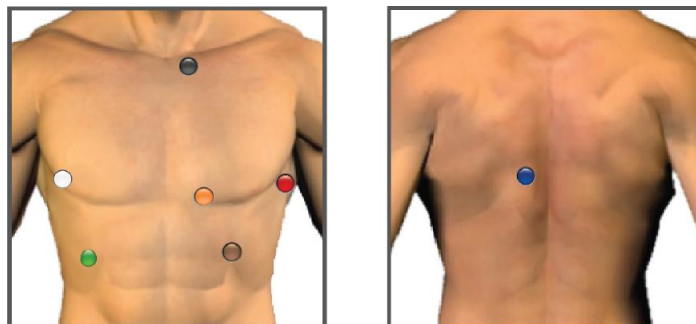
7-Electrode Placement (a) (300-3A, 300-4A, 300-4L)



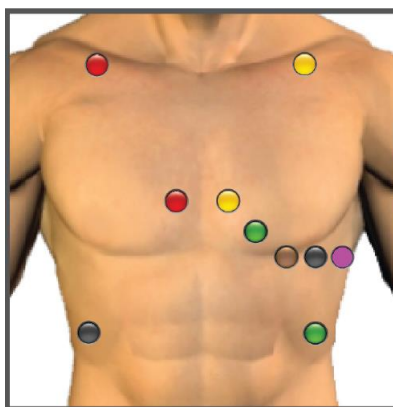
7-Electrode Placement (b) (300-3A)



7-Electrode Placement (Orthogonal) (300-3A)

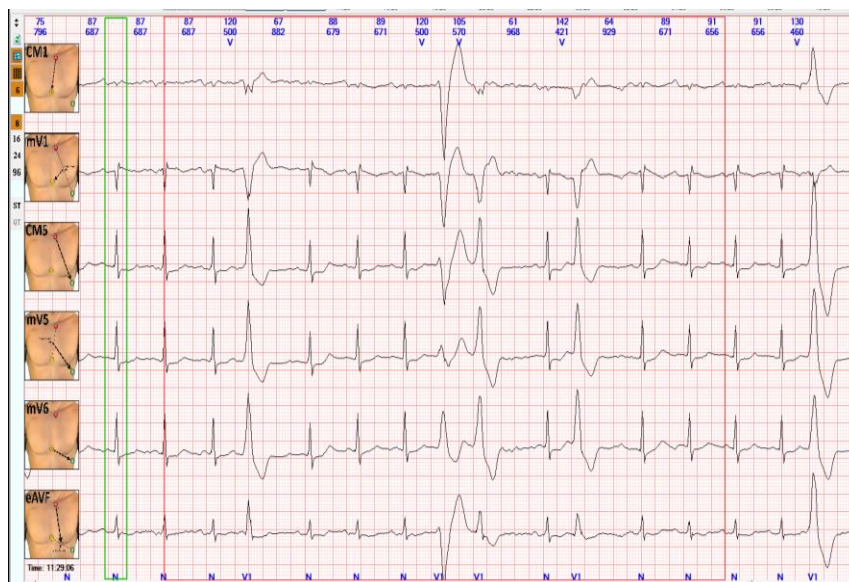


10-Electrode Placement (300-4A, 300-4L)



Discussion on 6-Lead ECG with 3-Electrodes

CardioScan 79a is a 3-Lead, 6-Lead, and 12-Lead system. The 3- and 6-Lead capabilities can be accomplished with a 3-electrode ECG cable. A display of these 6-Leads is shown below:



- Chest picture at beginning of each ECG Lead provides a vector presentation for each ECG lead
- New digital filter for enhanced presentation for ST Segment, QTc, T-Wave Alternans, and HRV
- 6-Lead ECG removes the diagnostic dilemma as to whether or not there is a P-Wave for A-Fib and Wide Complex Tachycardia
- 6-Lead ECG allows presentation of 2-contiguous Leads for ST Depressions
- 6-Lead ECG removes false positives for V-Tach that were, in fact, artifact
- 6-Lead ECG removes false positives for long Pauses that were, in fact, artifact
- 6-Lead ECG allows for better diagnostic decision-making

B. Patient Enroll

1. Connect the Holter recorder to the computer using the provided USB download cable.
 - a. If you are using a DMS 300-3A, 300-4A, or 300-4L device, make sure the battery is removed before connecting the download cable.
 - b. If you are using a DMS 300-2 or 300-2W device, leave the battery in the recorder. Turn it on after connecting the download cable.
2. On the main patient screen, click “Enroll Next Patient”.

The screenshot shows the CardioScan 12.0-DM Software interface. The top menu bar includes options like Leads Placement, Enroll Next Patient (circled), Download Patient Data, System Setting, Help, and Exit. Below the menu bar are various input fields for patient information, including Name, HIS ID, Unique ID, Sex, Card ID, Collect Place, Practice Name, OutPatient ID, Conclusion, Record Date, Age, Case Status, and Time Period. A table at the bottom displays patient data with columns for Case Status, Name, Sex, Test Date, Remarks, Scan By, Intp. By, Type, and Dir.

3. Fill in any patient information you wish to store on the recorder. Keep in mind that the information entered will appear on the Holter report. Please note that Last Name is a required field. Confirm that the scan date and time, which should populate automatically, are correct. Click “Next Step” to write the data to the recorder.

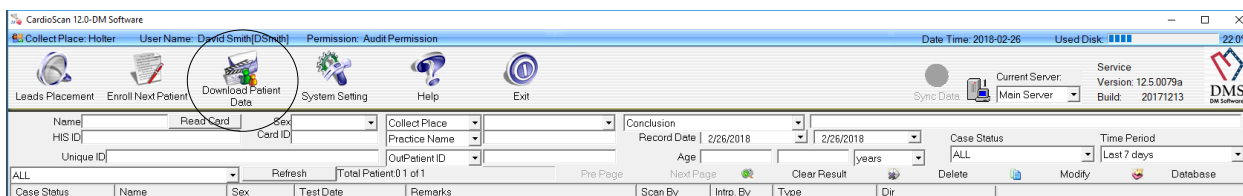
4. Upon clicking “Next Step”, the main patient list screen will appear with the case status indicator for the newly enrolled patient as “Reserved/Enrolled”.
5. Note: If the DMS ECG Database System is connected to your facility’s Electronic Medical Records (EMR) or Hospital Information System (HIS), and the patient has already been entered into that system, you can enter the patient’s unique hospital ID number (“HIS ID”) in the appropriate location, and the patient’s demographic information will automatically populate. The DMS ECG Database System will also work with a select group of barcode scanners. This functionality can be accessed by way of the “Read Card” button in the upper right.

Selected Additional Settings Before Clicking on “Next Step”

1. **Enroll to Server:** This stores the patient enroll information on the CardioScan server without actually writing it to the recorder. This allows the user to enroll a patient for a future test even if a recorder is not available. This is also useful if the user enrolling patients is not logged in at the same location as the user connecting patients to the recorders. Once “Enrolled to Server”, the patient name will be displayed on the main patient screen. When the user is ready to enroll the recorder, simply click on the desired patient name and select “Next Step.”
2. **Enroll to Server and Recorder:** Transmits the enroll data to both the server and recorder.
3. **USB Recorder Setup:** Allows the user to change the sample rate of the 300-3A/4A recorders (at the expense of battery life). By default, this should be left at “Depend on Pacemaker Selection”.
4. **SD Card Recorder Setup:** Allows the user to toggle ON the Pacemaker Channel, Respiration, and Patient ID for the 300-4L device.
5. **Delete Data on Recorder:** Allows the user to delete all of the information on the current recorder even if a new patient is not enrolled to the device.

C. Holter Download

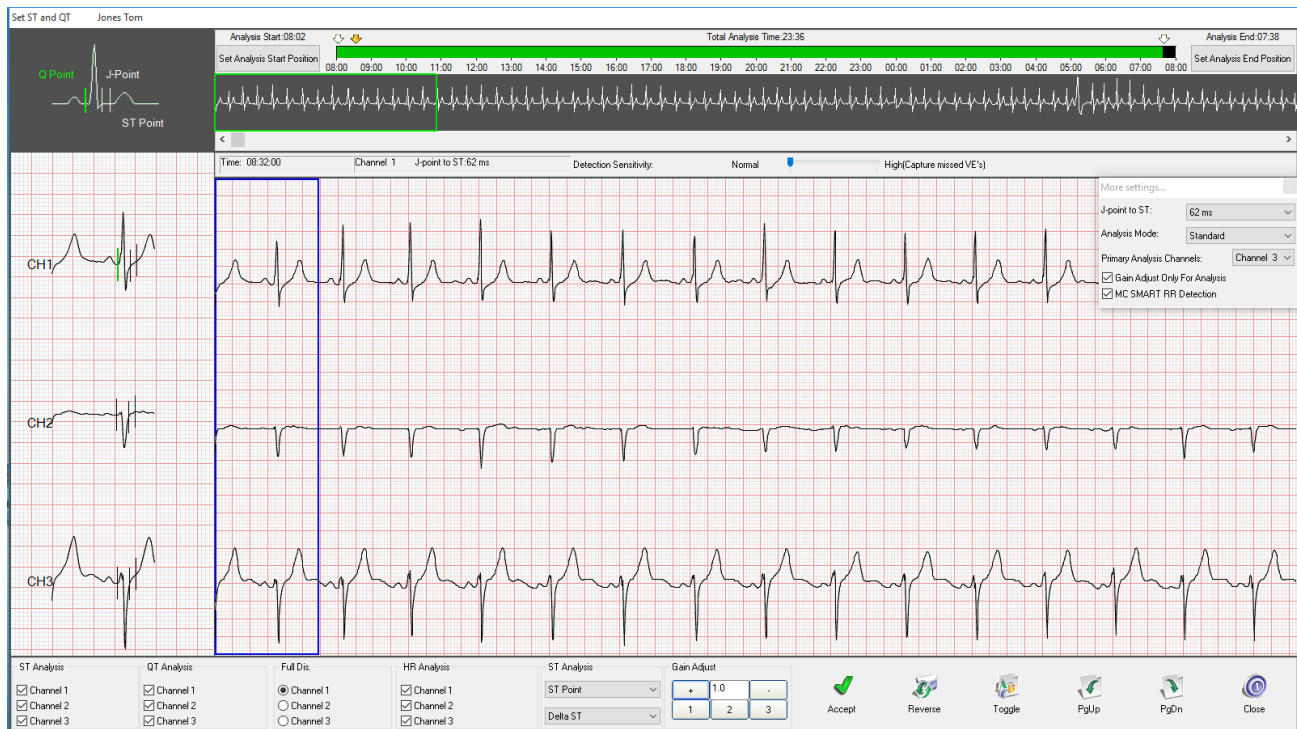
1. Connect the Holter recorder to the computer using the provided USB download cable.
 - a. If you are using a DMS 300-3A, 300-4A, or 300-4L device, make sure the battery is removed before connecting the download cable.
 - b. If you are using a DMS 300-2 or 300-2W device, leave the battery in the recorder. Turn it on after connecting the download cable.
2. On the main patient screen, click “Download Patient Data”.



3. If the device was previously enrolled, all the stored patient information will automatically populate the window shown below. If no previous enrollment occurred, fill in any patient information you wish to save to the patient file. Click “Next Step” to begin the download.

4. Upon completing the download, the **Set ST and QT** screen display will appear (see Section V). Please note that users with only a collect/download permission level, will not have access to any editing and reporting functions. These users will be directed back to the main patient list.
5. The case status indicator for the patient on the main patient list screen will change to “Played/Downloaded”.

V. Pre-Analysis Set-Up Menu (Setting ST and QT)



If you have selected “Manual Set ST – ON” in Basic Settings (we highly recommend this), the **Set ST and QT** screen display will appear immediately after the ECG data has been completely transferred from the Holter recorder to the computer. Otherwise, the Data Access Choices menu will appear (see Section VI).

On the Set ST and QT screen display, the user should adjust the ST orientation cursor manually to identify the three vertical lines (the short lines on the electrograph at the left of the screen) to be set to the correct position. The first vertical line represents the position prior to the Q point located at the beginning of the QRS wave. The second vertical line represents the position of the J point. The third vertical line should be set prior to the beginning of the T wave.

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

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

Below is an overview of the icons and check-boxes found at the bottom of the screen display:

1. The “ST Analysis” and “QT Analysis” boxes on the bottom left of the screen shows you which channels are being analyzed. To remove a channel, move your mouse to the desired box and click. A check mark next to a channel indicates that ST & QT Analysis will be done for that channel. In many cases, physicians will not want to analyze the ST for a negative going QRS.
2. The “HR Analysis” box at the bottom of the screen allows you to select which channels will be analyzed. To remove a channel, simply click on a corresponding box. Sometimes it is desirable to not analyze a channel that has too much artifact.
3. The “ST Analysis” box at the bottom middle of the screen contains two drop-down menus. The first drop-down menu indicates which type of Point (J Point or ST Point) is to be used for ST analysis. The second drop-down menu indicates which type of ST analysis is being performed. Delta ST is the standard method for ST measurements. Delta ST measures the difference in ST changes. Absolute ST always measures from the 0-reference baseline and does not consider the patient’s normal ST level for each individual ECG lead.
4. The “Gain Adjust” box at the bottom of the screen allows you to adjust the gain for each channel individually. Click on the number corresponding to the channel you wish to adjust. Then click on + to increase the gain. Clicking on – decreases the gain. As you increase the gain, you will notice the beats of the channel you are adjusting get larger. If you decrease the gain, the beats on the screen for the channel you are adjusting will become smaller.
5. The “Full Disclosure” box allows you to select the channel that will be printed out in the Full Disclosure.
6. If any of the ECG channels has a reversed polarity because of improper electrode placement, click on the “Reverse” icon at the bottom of the screen before setting the markers on the beat. The polarity of the beat will be reversed.

To set ST and QT, first use the ↑/↓, Page Up/Page Down, or hold the mouse to move the blue area and choose a suitable QRS wave (see below). The QRS selected will be located at the left side of the screen. Select the beat you wish use for ST and QT measurements. To do this, point and click your mouse on the beat in the 1-minute strip at the top of your screen. The enlarged eight-second strip appears on the screen. If you desire another beat within this strip, point and click your mouse within the blue box on the enlarged eight-second strip. Drag and center the box over the beat you desire.



The green vertical marker is the active marker.

The first vertical marker is for placement between the P wave and R wave. It should be set at the beginning of the Q wave, and then press the left arrow key one time to move the green vertical marker to the left of where you think the beginning of the Q wave would be. Use your right and left arrow keys on the keyboard to set this marker in place.

Once in place, press the TAB key on your keyboard or mouse click on the “Toggle” icon at the bottom right of the screen.

If the marker is not at the beginning of the Q wave, then all QT measurements will be inaccurate. The computer program uses the first marker at the beginning of the Q wave to search prior to the first marker for a baseline PR location for the ST measurements.

The second vertical marker is for setting the J Point. Find a spot where the QRS ends and then press the right arrow key once. Once in place, press the TAB key on your keyboard or mouse click on the “Toggle” icon at the bottom of the screen.

The third vertical marker is for setting the ST Point. Using your right and left arrow keys on your keyboard, move the marker to the right to set the sample point. Do not allow this marker to be at the beginning or the up slope of the T-wave. If necessary, keep moving left to avoid the T-wave, especially on the negative going QRS complexes.

After all the markers are placed in their desired locations, click on the “Accept” icon at the bottom of the screen or press the F10 key on the keyboard. This will take you to the next Channel. Repeat the

above process for other channels. After pressing the F10 key for the last channel or clicking on the “Accept” icon for the last channel, this display screen will disappear, and analysis will begin. The analysis may require 1-3 minutes, depending on the computer and the patient ECG.

Note: If you make an error on your ST setup of a 3-Lead ECG, and would like to go back and reset the markers, simply click on the “1, 2, or 3” in the Gain Adjust box. This will move the cursor to the appropriate channel. If you want to reset the markers of a 12-Lead ECG, you will need to select the “Re-Analysis” button found on the Data Access Choices screen display (see Section VI).

Lastly, there is an additional box for more settings at the top right area. The “Analysis Mode” should be on Standard. “Gain Adjust” and “MC SMART” should remain at the default settings. The only setting that may need to be adjusted is the “Primary Analysis Channels”. This should be set to the ECG channel that is the cleanest ECG with a positive-going R-wave.

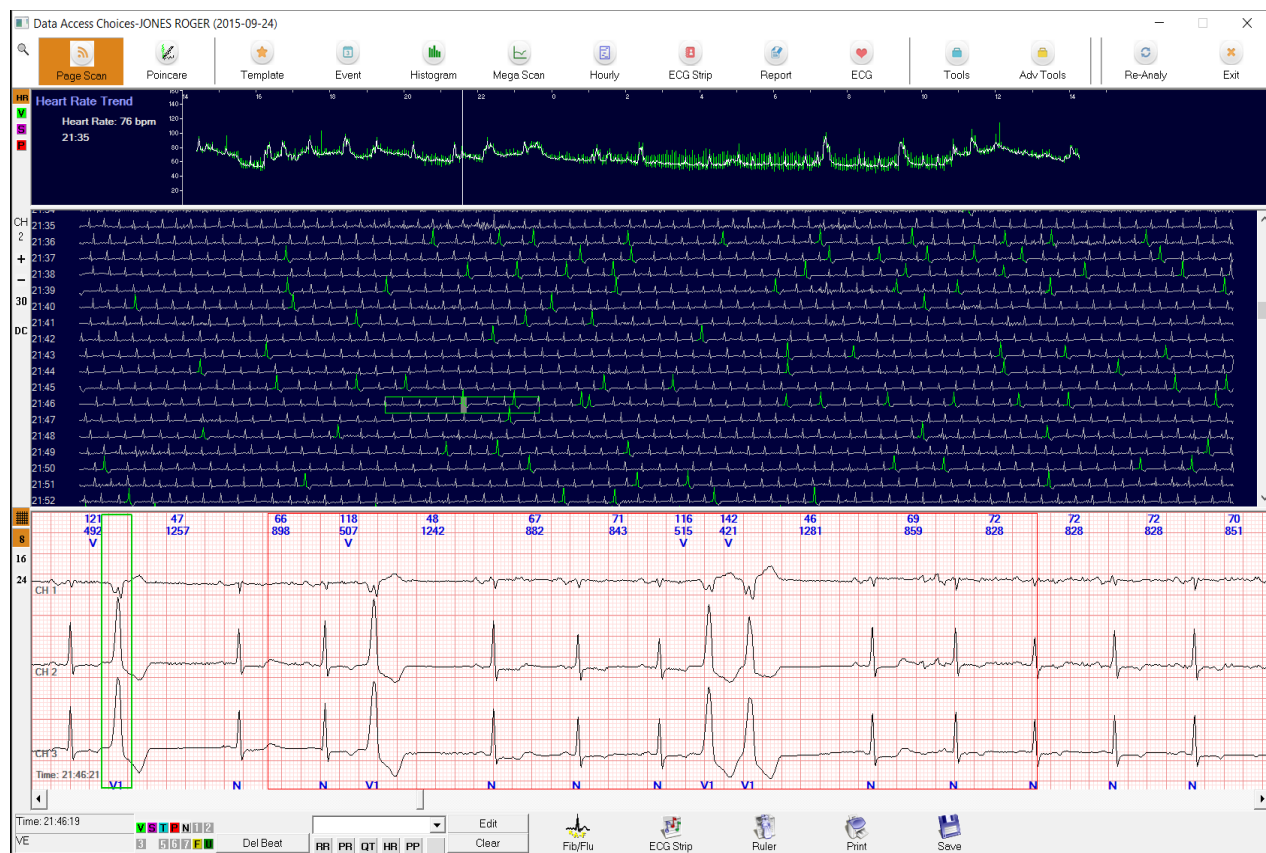
VI. Holter Analysis Functions – The Data Access Choices Menu

A. Overview

The **Data Access Choices** menu can be accessed two (2) ways:

- Automatically after exiting Pre-Analysis (Setting ST and QT) for a downloaded Holter file
- Double clicking on any patient name in the main patient list

This menu displays tabs for all functions at the top of the screen for quick and easy access to data.



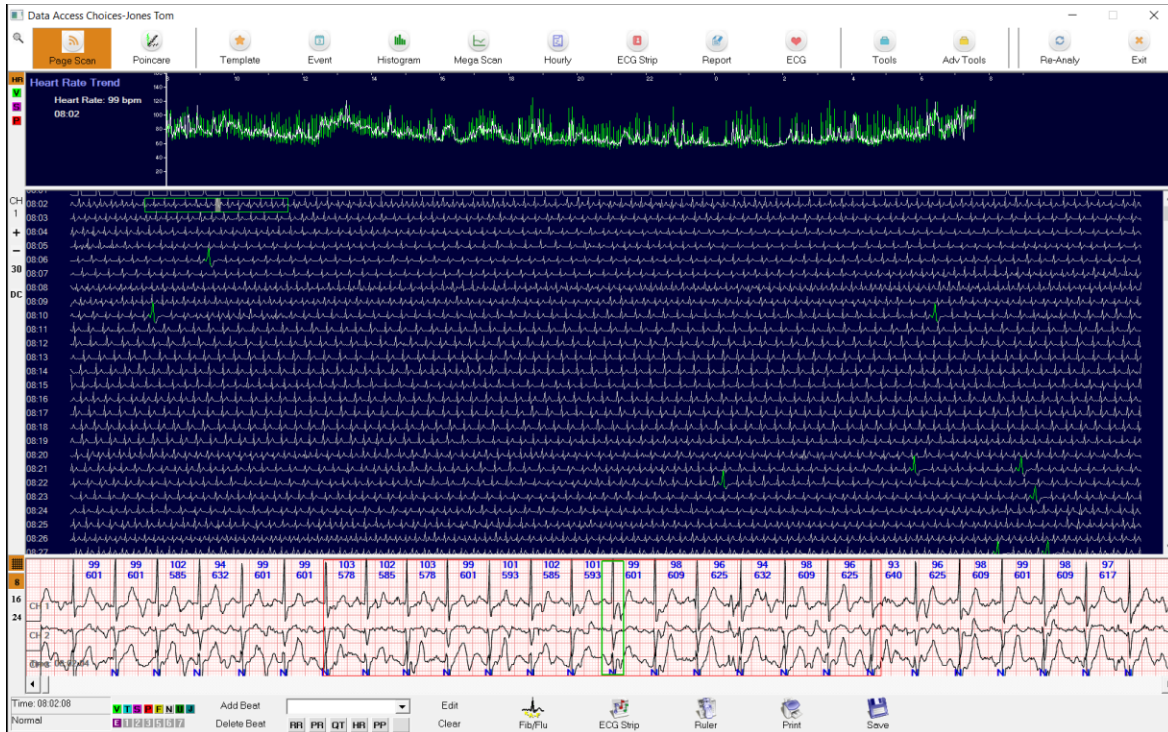
The Data Access Choices tabs include:

- Page Scan (with A-Fib detection and editing)
- Poincare (plots)
- Template (for arrhythmia editing)
- Event (for ECG review prior to printing significant ECG events)

- Histogram
- Mega Scan (novel presentation of arrhythmia groupings)
- Hourly (numerical quantities for ECG data)
- ECG Strip (patient-activated symptomatic events and ECG strip previews)
- Report (menu for selecting various report items for preview and print)
- ECG (ECG beat editing and ECG print selections)
- Tools (access to HRV, ST, QTc, and SAEKG)
- Adv. Tools (HR Turbulence, Deceleration Capacity, Sleep Apnea, T Wave Alternans, FCG)
- Re-Analysis (reset file for pre-analysis; set ST and QT)
- Exit (return to the main patient list)

B. Page Scan

Page Scan automatically opens after Pre-Analysis is complete. You can also access Page Scan by double clicking on any patient name in the main patient list of the general interface.

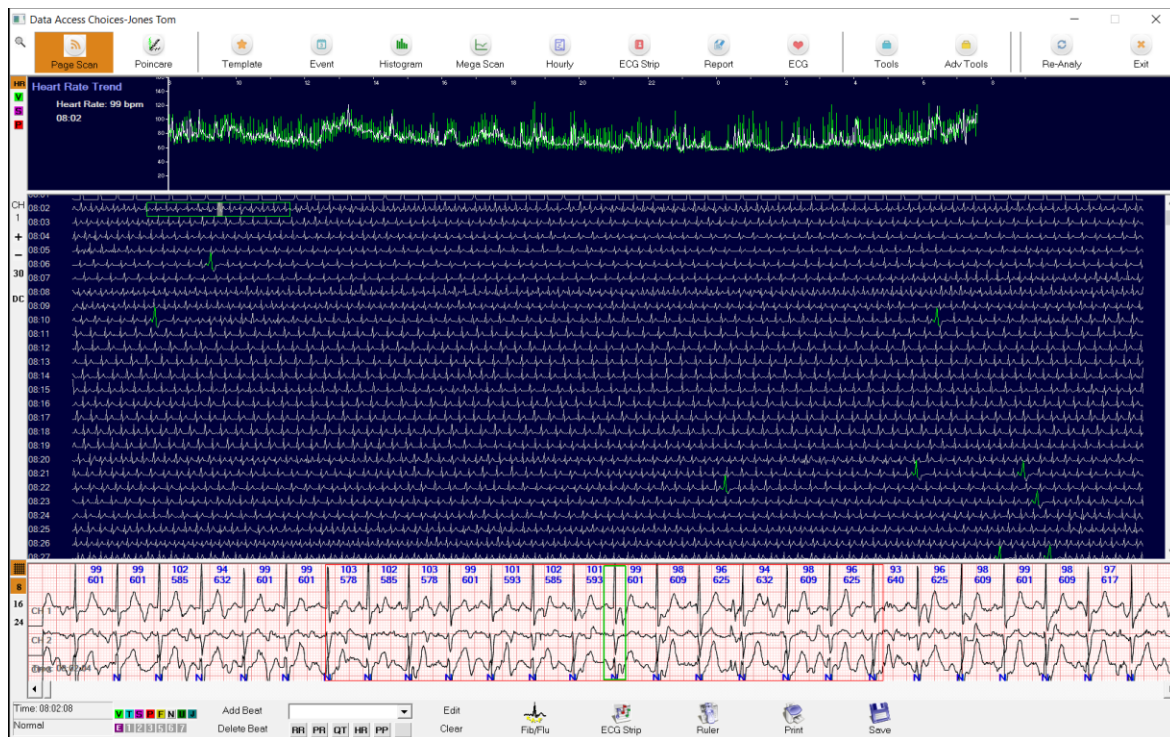


Quick Overview

- Trends are shown at top of the display. You can select Heart Rate, VE/Hour, SVE/Hour, or Pauses/Hour
- Channel display selection: On the left sidebar, click on “CH” and select the desired channel
- Gain selection: On the left sidebar, click on “+” or “-” to increase or decrease gain display
- ECG data can be changed from 60 seconds per line to 30 seconds per line by clicking on “30”
- “DC” is for Deceleration Capacity
- Use the mouse and a single-click on the patient ECG trends to see data on the bottom two-thirds of the display. To enlarge the ECG data, double-click or press the ENTER key. This takes you to the ECG tab of the Data Access Choices menu (refer to Section VI – K)
- A scroll-bar at bottom of the window allows you to slide through the ECG data in either direction

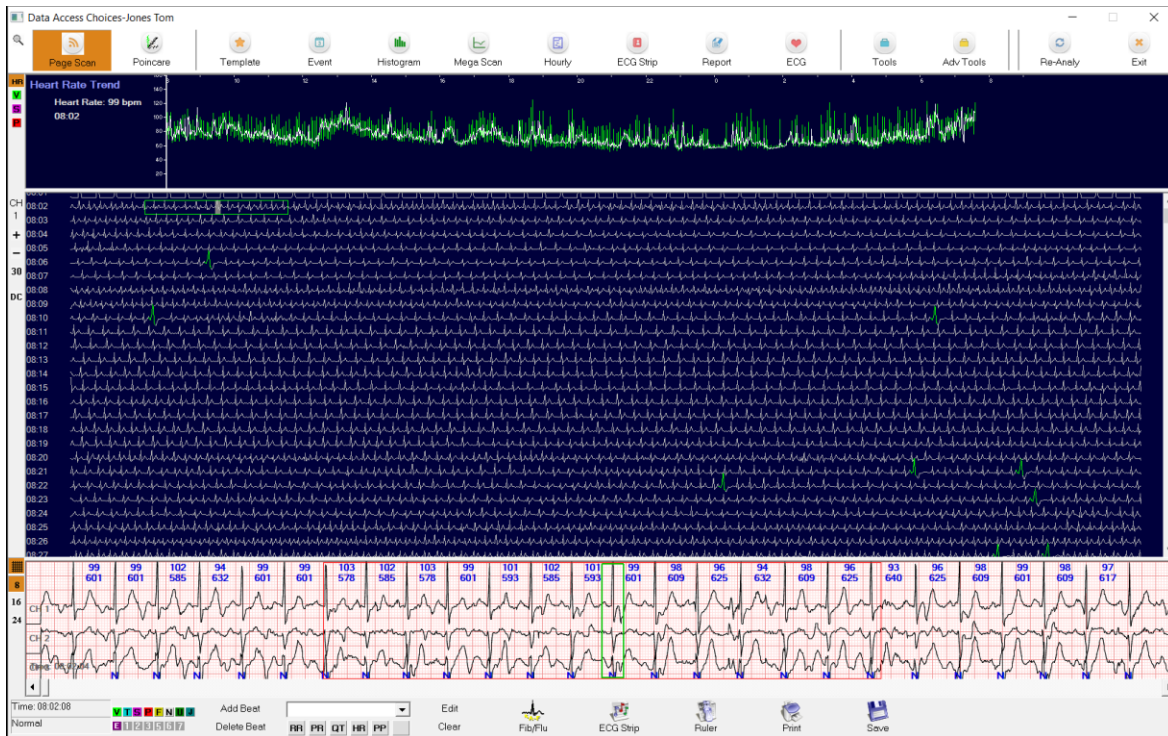
- You can edit beats by pointing your mouse on the beat and selecting VE, SVE, Normal, or Artifact (F). A “point and drag” can edit a V-Run, SV-Run, etc.
- The A-Fib editing tool is at the bottom center
- After any updating of ECG data in Page Scan, click to “Save” your changes.

Detail

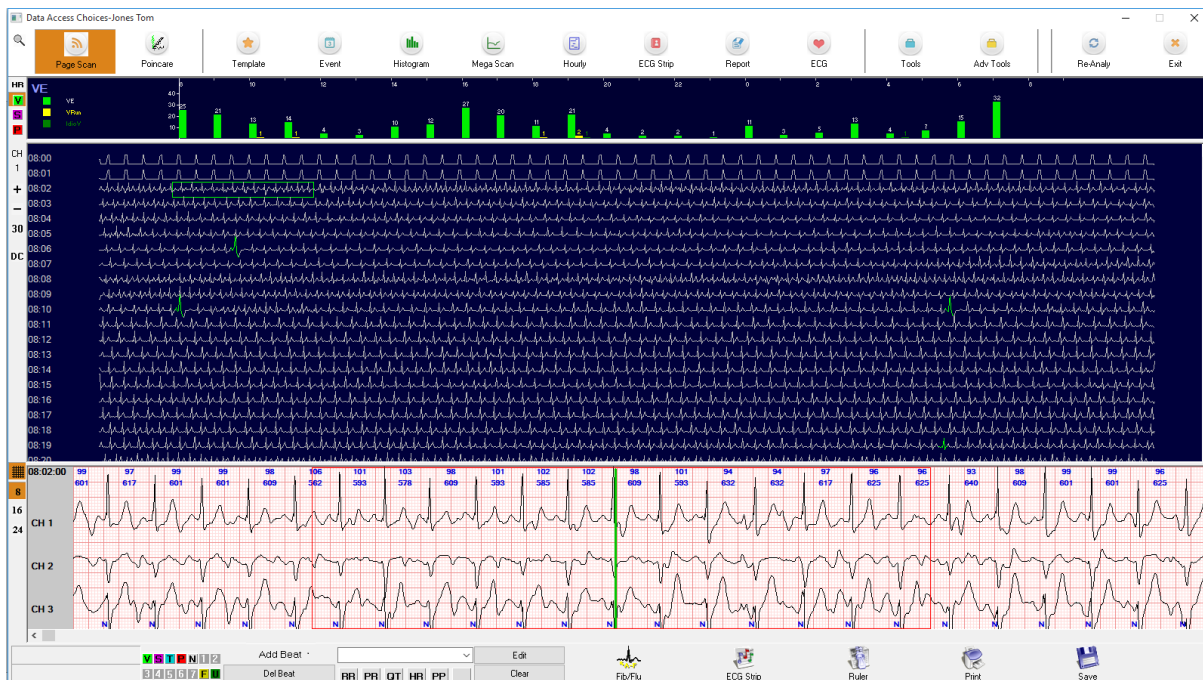


A comprehensive view of Heart Rate (HR) Trend during the recording period is shown in the top third of the display. In the middle third, Heart Rate Trend is displayed by minute (approximately 30 minutes increments). The bottom graph shows 3 different channel ECG (about 20 seconds long).

On the far left you can adjust the size by using the + (for larger view) and - (for smaller view) The channel you are reviewing can be changed by clicking on “CH”. Click on “30” to change the display of the middle third of the screen (see below).

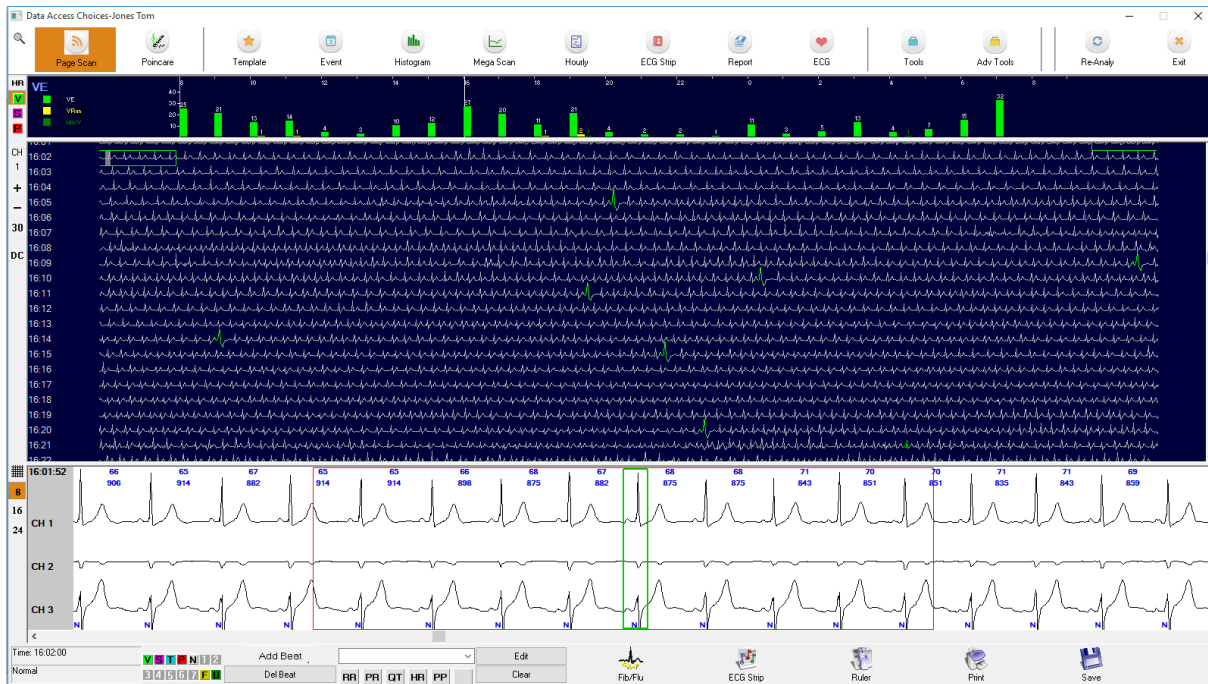


In addition to **HR**, **V**, **S**, and **P** can also be selected in the top left. Selecting **V** will display VE's (green) and VRuns (yellow) found. This is shown in graphical format (rectangles) at the top.



By clicking on the **S**, you can see the SVE's. **P** shows pauses. Note that at the far top left corner of the screen, a magnifying symbol can be selected to magnify any area you wish.

Clicking on any portion of the Trends display at the top will show the associated 30-minute ECG in the middle part of the screen. Furthermore, clicking on any beat in this 30-minute section will place a green highlight rectangle on that portion of the ECG (with the actual selected beat highlighted in white). The green highlight rectangle corresponds to the 3-channels of ECG displayed in the bottom third of the screen. You will notice a narrow vertical green rectangle in the 3-channel ECG display. This corresponds to the beat highlighted in white. (Note that at the bottom of the left sidebar are the numbers “8, 16, 24.” Clicking on these will change the size of this green highlight rectangle in the 30-minute section)



Below the 3-channels of ECG displayed, you will find squares of various colors: green (V) is for VE beats, reddish/purple (S) SVE, blue (T) aberrant, red (P) pause, gray (N) normal, yellow (F) artifact, and dark green (U) for IdioV. Clicking on these will change the color and labeling of the beat in the narrow vertical green rectangle in the 3-channel ECG display.

Clicking on “Add/Del Beat” (to the right of the color squares) will add/delete the beat completely.

After updating of any ECG data on Page Scan, you will need to save your changes.

The A-Fib Function (Fib/Flu)

The recommended first step in editing a Holter file is to determine whether the patient had an A-Fib episode. While the main Page Scan screen allows the user to get a quick indication if the patient experienced A-Fib – refer to Section VII (Recommended Editing Process): A (Quick A-Fib Review) – below you will find a detailed description of the principal Fib/Flu analysis function.

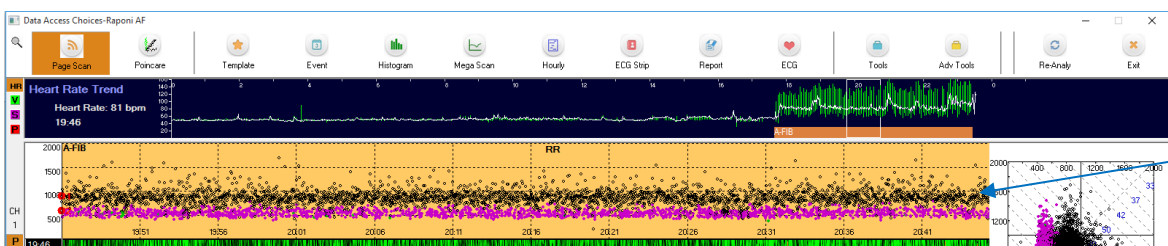
Click on Fib/Flu at the bottom of the display to bring up the A-Fib edit interface (clicking on Fib/Flu again will return you to the main Page Scan screen).



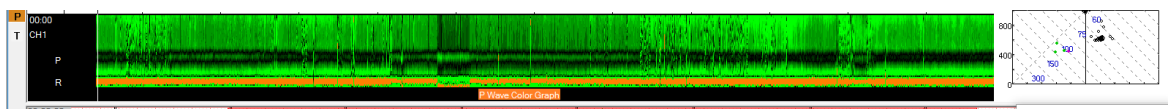
The Heart Rate Trend in the top portion of the above screenshot (circled section only) shows how A-Fib can look. The heart rate is erratic, so you will see long, thin, vertical green lines corresponding to max/min heart rate ranges for each minute.

You will also notice, in the 2nd graph above, a display of individual R-R intervals. For Normal beats you will see dark dots showing the sinus heart rate of the patient. When there is a VE or SVE, you will see color-coded dots above and below the Normal heart rate. These show premature and compensatory pause intervals. The 2nd graph above does not show A-Fib since it is not displaying the circled section.

If there is A-Fib, then the dots on the 2nd graph would be shown in chaotic locations (see below).



The 3rd graph (see below) shows each PQRST complex for a 1-hour period. A good way to think about this graph is to visualize each beat flowing in your direction. Picture that the R-wave is coming at you.

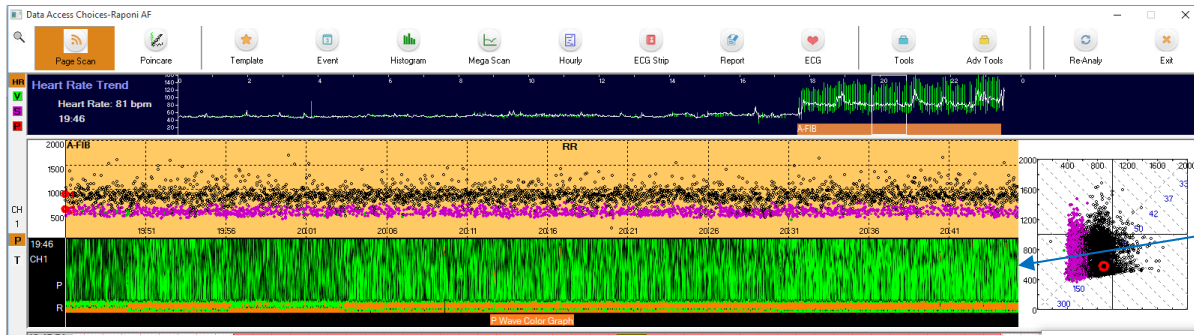


Each PQRST complex is placed side-by-side. Each ECG beat is a straight vertical line. The top of each straight line is the ECG baseline before the P-Wave. The dark black area is the small amplitude of the

P-wave. The green area below the black P-wave is the P-R baseline. The orange area is the tall R-wave. The green area below the orange R-wave is the baseline ST Segment.

The purpose of this display is to show P-wave activity for a 1-hour period. There is no A-Fib here.

If there was an A-Fib episode (see below), then there would be chaotic P-wave activity in the 3rd graph, and you would no longer see the consistent P-wave (black) locations previously shown.



There is also a **Fib/Flu Tool Bar** on the right (see below). If there is actual A-Fib, SVE's will be converted to normal beats by clicking "Remove SVE," and convert VE beats to aberrant beats by clicking "Convert VE to Aberrant."

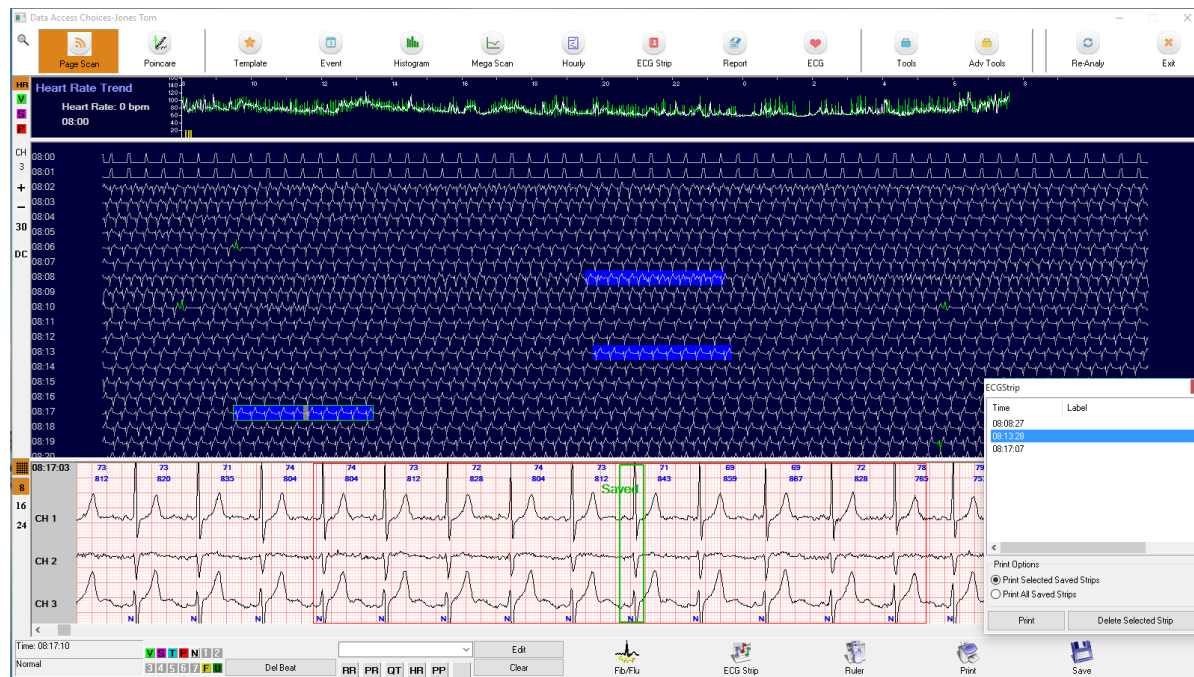


If analysis of the graphs indicates normal sinus rhythm (NSR), but A-Fib is mistakenly labeled, highlight the area labeled incorrectly by left-clicking on the mouse, hold down and drag until the last beat you want to change is highlighted, and then click on "Clear All" in the Fib/Flu Tool Bar. This will change all highlighted beats to NSR. If labeled NSR and you want to change to AFIB, then highlight and click "Add". Click on "Print Fib/Flu Report" to add to the report.

Click on “Fib/Flu” button at the bottom of the display to return to the main Page Scan display.

ECG Strip Function

Click on “ECG Strip” at the bottom of the display to bring up the box on the lower right (see below). You can save strips here by clicking on the strip you want to save.



Saved strips can be printed and shown on the final report. Saved strips can always be reviewed when you double click on the times saved (as seen above highlighted blue). The strip being reviewed appears on the bottom 3-channel graph.

Other

Clicking “Print” will bring up choices for the size of the ECG strip you want to print.



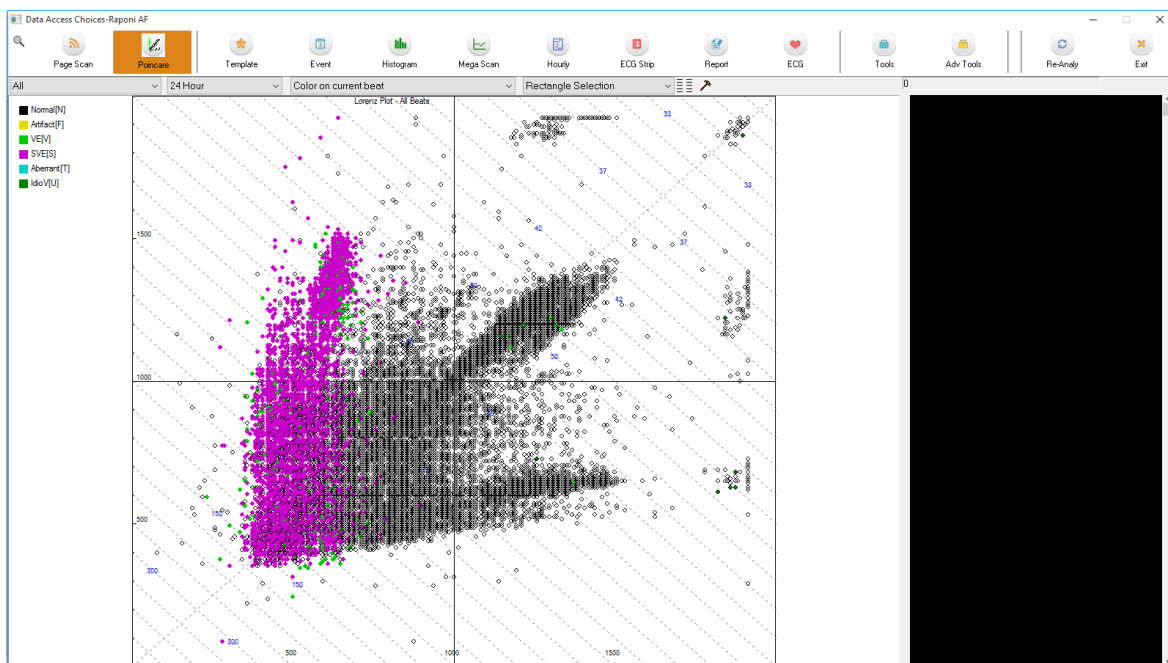
Clicking “Save” will save ECG selections for the final report.

C. Poincare

Poincare plots, in the context of ECG, show the location of successive R-R intervals. Specifically, a Poincare plot is a graph of $RR(n)$ on the x-axis versus $RR(n + 1)$ (the succeeding RR interval) on the y-axis.

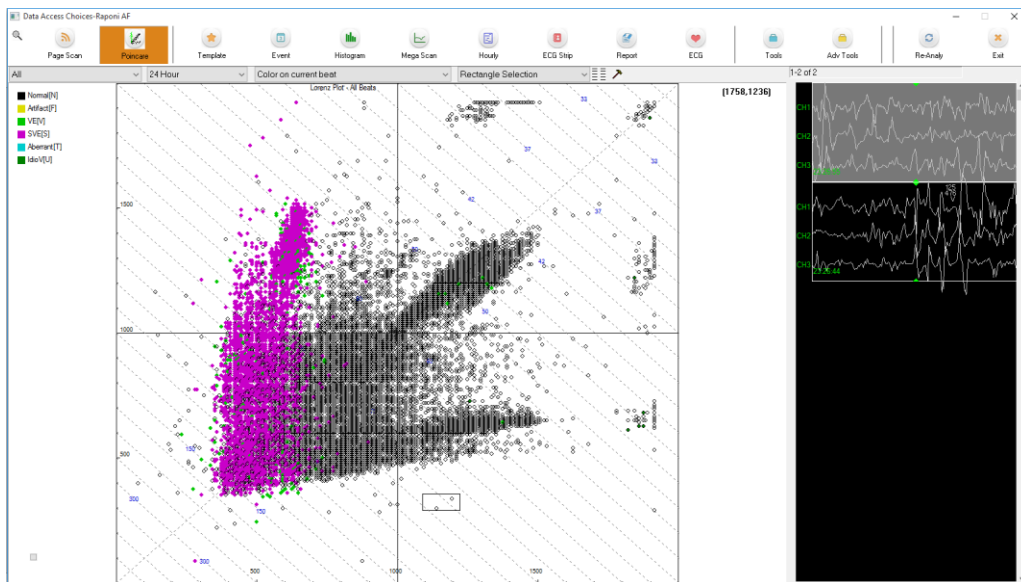
Some literature suggests that as the main group of R-R intervals moves to the lower-left of a Poincare plot quadrant, the higher the risk assessment for the patient. However, scattered beats at the lower left of any quadrant are most often artifacts.

To access these plots, click **Poincare** in Data Access Choices.



The drop-down menus near the top of the screen reflect display options. The plot above is for a 24-hour period.

Editing can take place within the plot by clicking on any point, or group of points, and dragging a rectangle around them. The selected beats will appear on the right of the plot (see below).



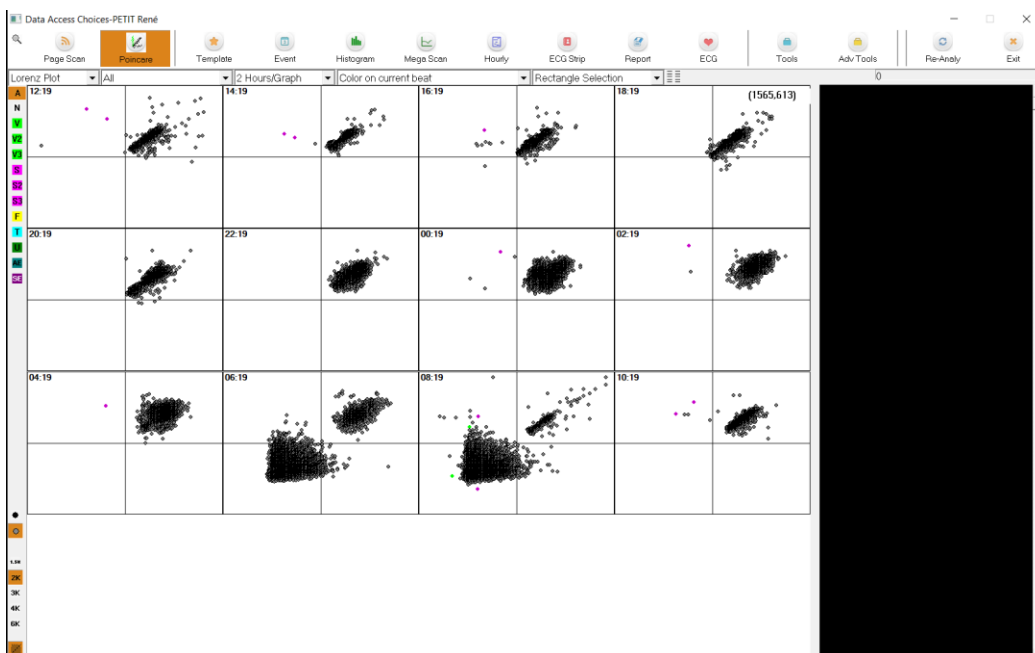
Right click over the rectangle to change the beat type (VE, SVE, Normal, Artifact, etc.).

VE beats are shown in green, and SVE beats are shown in purple.

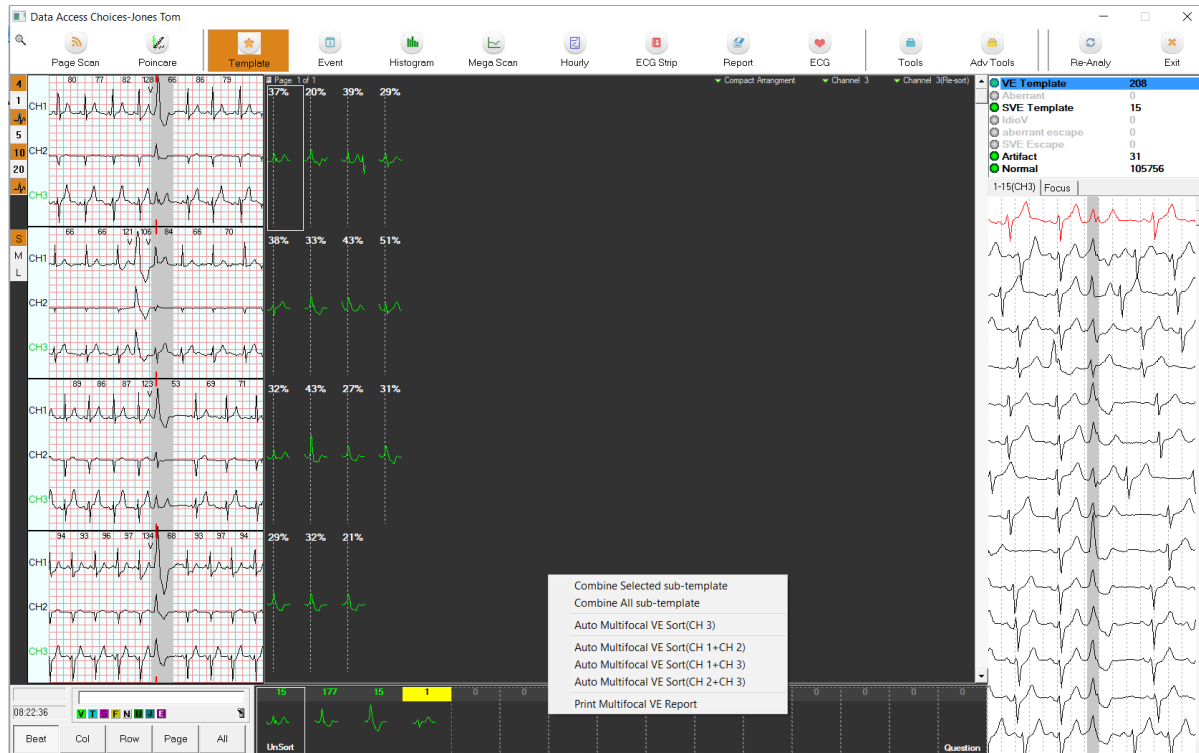
You can remove large quantities of artifact beats by doing a point-and-drag around such dots.

Among the several display options, the drop-down menus near the top of the screen allow you to display only one type of beat if you choose.

For your reference, the plot below shows twelve 2-hour quadrants. The 10th (06:19) and 11th (08:19) quadrants show a distribution of R-R intervals that is associated with an A-Fib episode.



D. Template



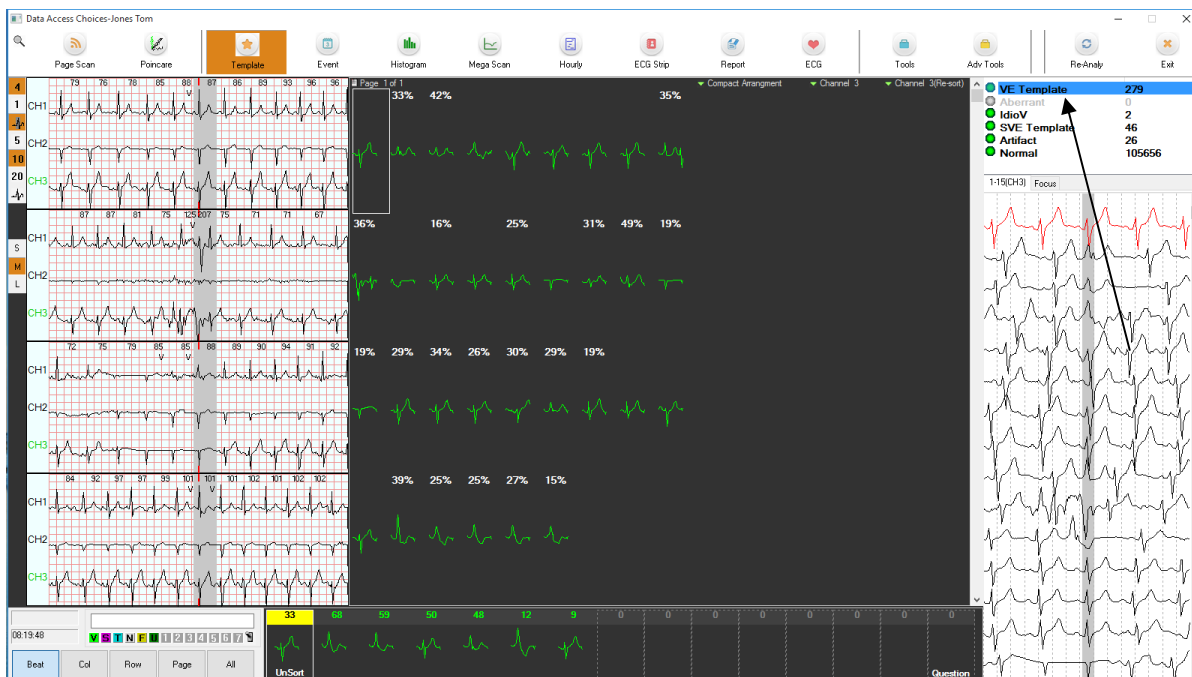
Quick Overview

- Users of CardioScan 78a will be familiar with the basics of Template editing, as CardioScan 79a has the same foundations
- Analysis improvements have been made; especially with SVE Runs of high HR and lengthy time periods
- Before editing with Template, first review the patient for A-Fib episodes. If there is A-Fib, eliminate all SVE counts during the A-Fib episodes by using the Fib/Flu menu within Page Scan (see Section VI: B)
- The right side of the display above shows 15 successive ectopic beats. The beat in red corresponds to the beat highlighted by the white vertical rectangle in the middle of the screen display
- Most of the artifact beats are placed in the first (far left) sub-template at the bottom of the display
- A common editing technique is to artifact all the beats in this first sub-Template; and then:
 - * Right-click on an open sub-template (with a "0" above). It will turn yellow.

- * Identify one or more VE beats above
- * Press and hold the CTRL key and use the mouse to click on the obvious VE Beats
- * Then press the “V” key, and the software will search the Template for like beats and enter them into the new sub-template
- You will typically repeat this process a few times

Detail

Clicking **Template** in the Data Access Choices menu automatically launches “VE Template” (see below). The purpose here is to edit and only keep VE beats, while relabeling beats that need to be relabeled.

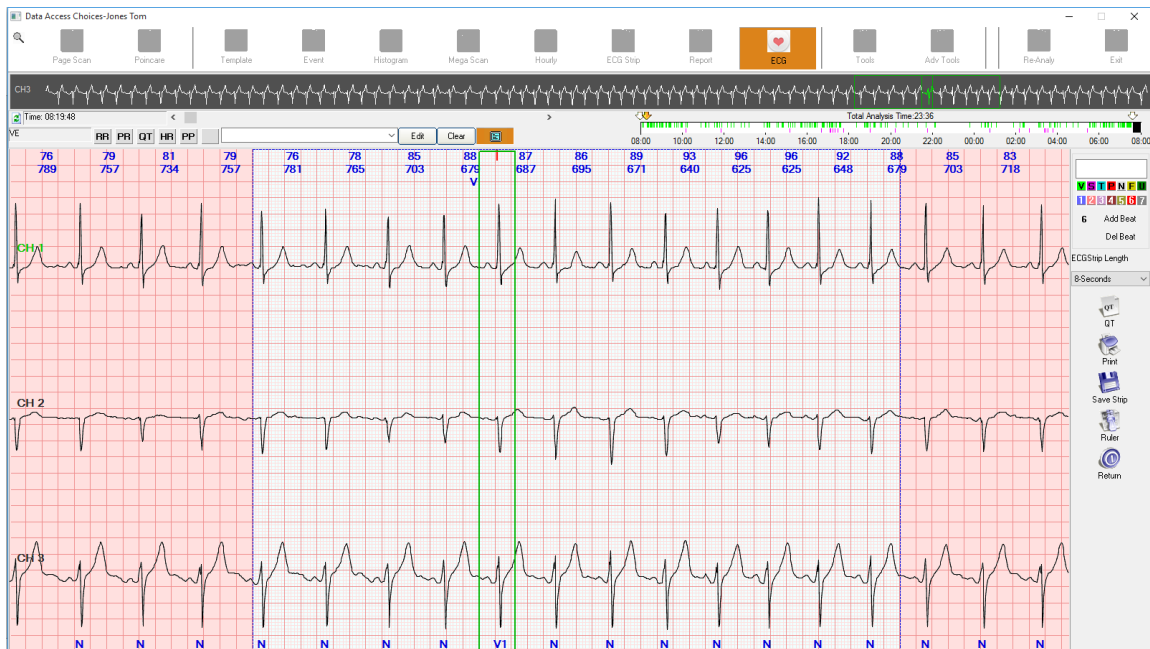


As shown above, click on first template at the bottom of display (highlighted in yellow, with the number “33”). In the middle of the display, you will now see all 33 corresponding beats.

You can begin editing.

Click on any individual beat in the middle of the display and a white vertical rectangle will surround it. The left side of the display will now show the corresponding ECG strips (3-channels shown above). The right side of the display will highlight the selected beat in red and show preceding/successive beats.

You can also double-click on any beat to enlarge it to a full-screen view (see below).

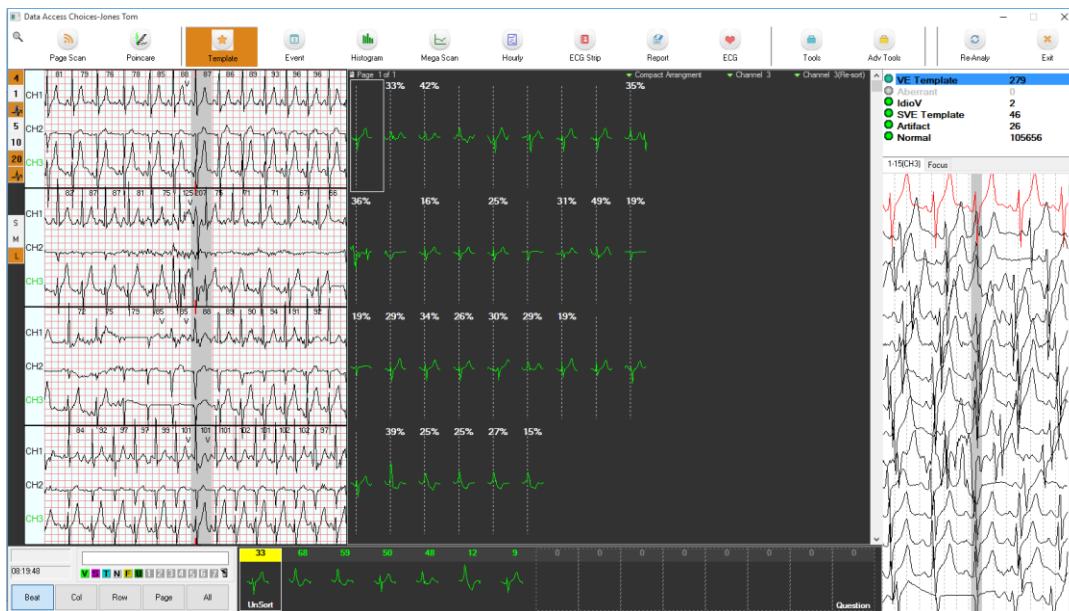


Click on “Return” or hit ESC to go back to the Template menu.

On the top-left corner, you see a “4” and “1”. Clicking on these will change the display on the left side of the screen. Below, “1” has been selected and you can see the highlighted beat in 3 channels.



Clicking on “4” provides 4-strip view (see below).



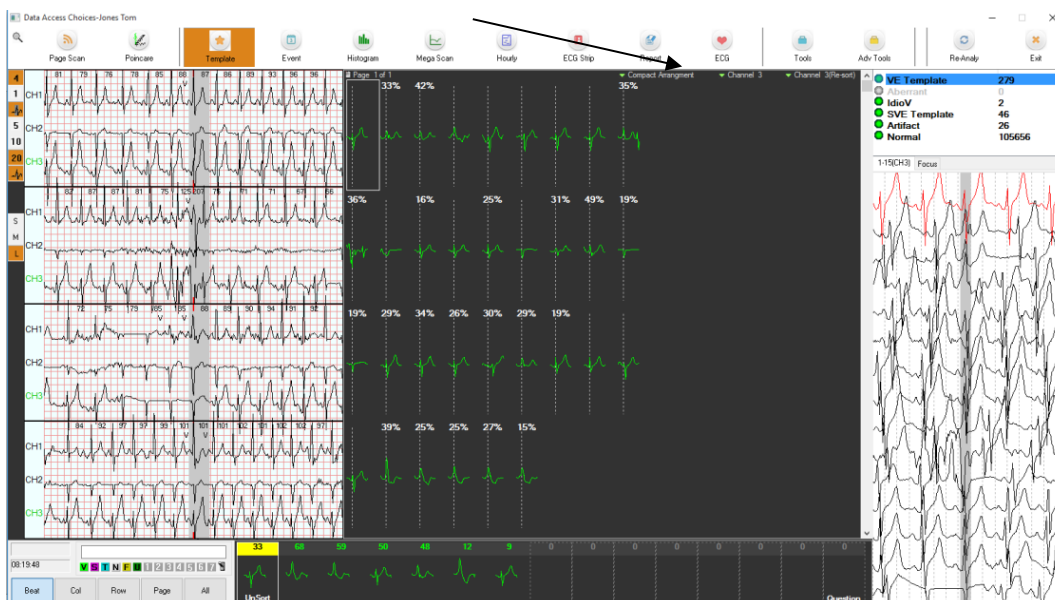
Clicking the icon below the “1” will remove the gray vertical highlight.

Clicking on the “5, 10 or 20” will change the gain on the strip(s).

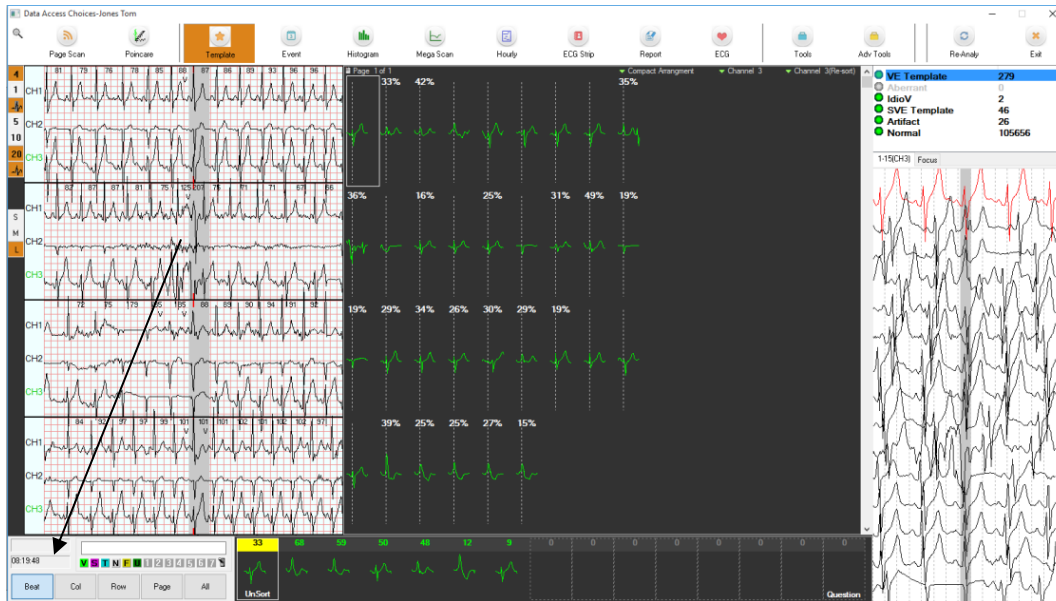
Clicking the icon below the “20” will add dotted vertical lines to the beats in the middle display, as seen above.

Clicking on **S**(small), **M**(medium), or **L**(large) will change the size of the strip(s) on the left of the display.

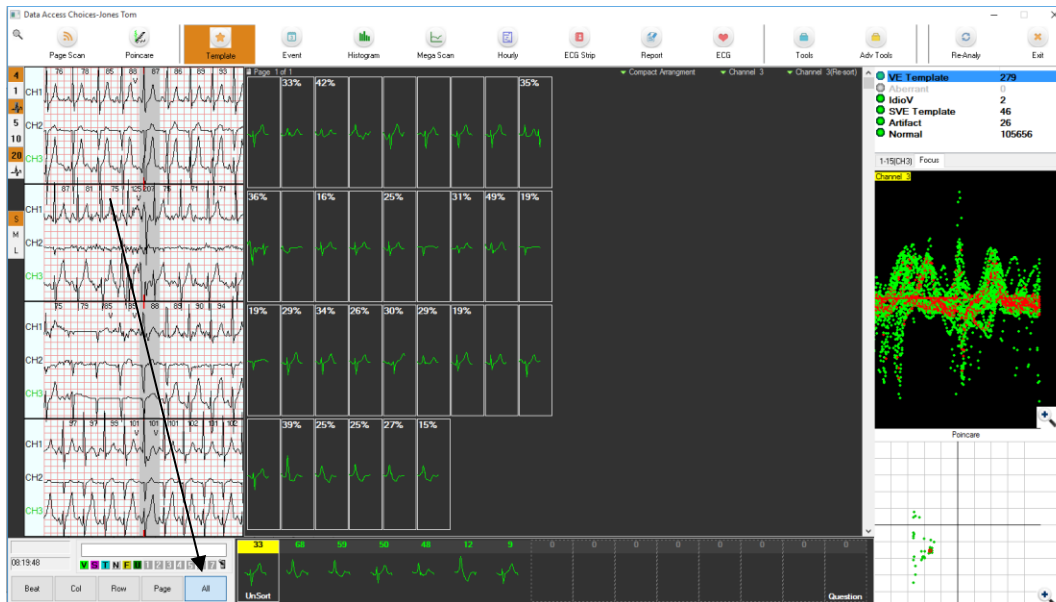
The drop-down green arrows – “Compact Arrangement”, “Channel”, “Channel(Re-Sort)” – found in the top middle of the display change the information/channel shown in the beat grouping display immediately below them (see below).



The time displayed on the bottom left of the screen indicates the time of the beat currently being edited.

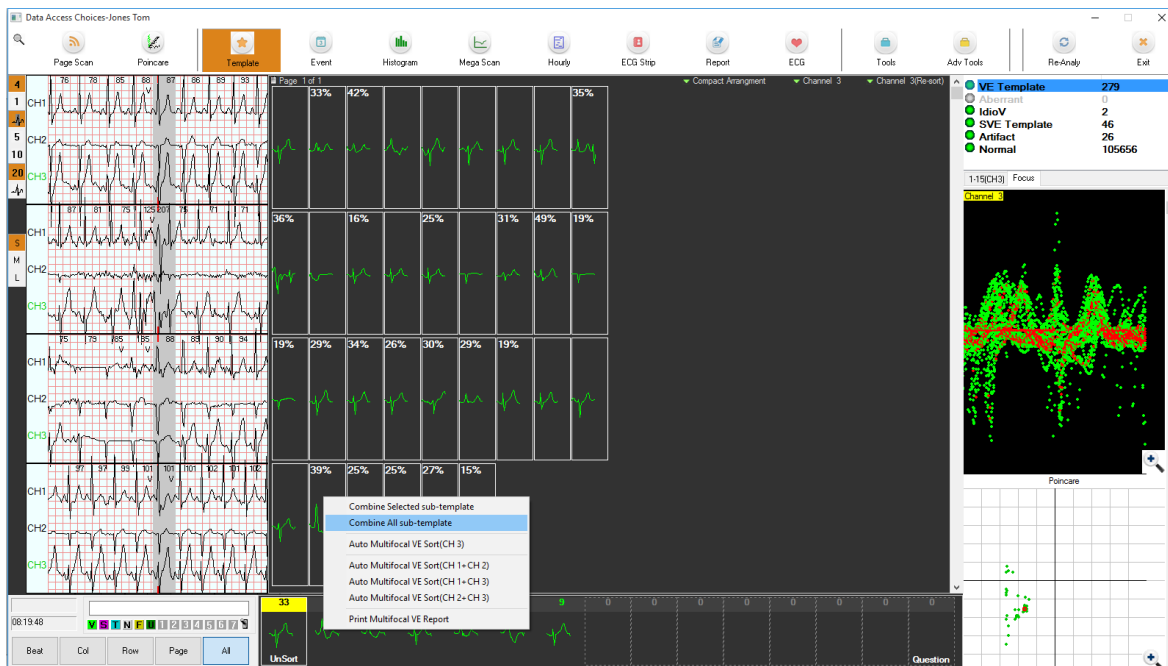


Clicking on “Beat”, “Col”, “Row”, “Page”, or “All” expands the white highlight box (in the middle of the screen) around a single beat, column, row, the entire screen display, or all beats within the template. Below you can see “All” has been selected.



Continue to click on each individual template at the bottom of the screen to repeat the VE edit process.

Please note that you can combine all, or some, of the bottom sub-templates into one template box by right-clicking over the sub-templates and making the corresponding selection (see below).

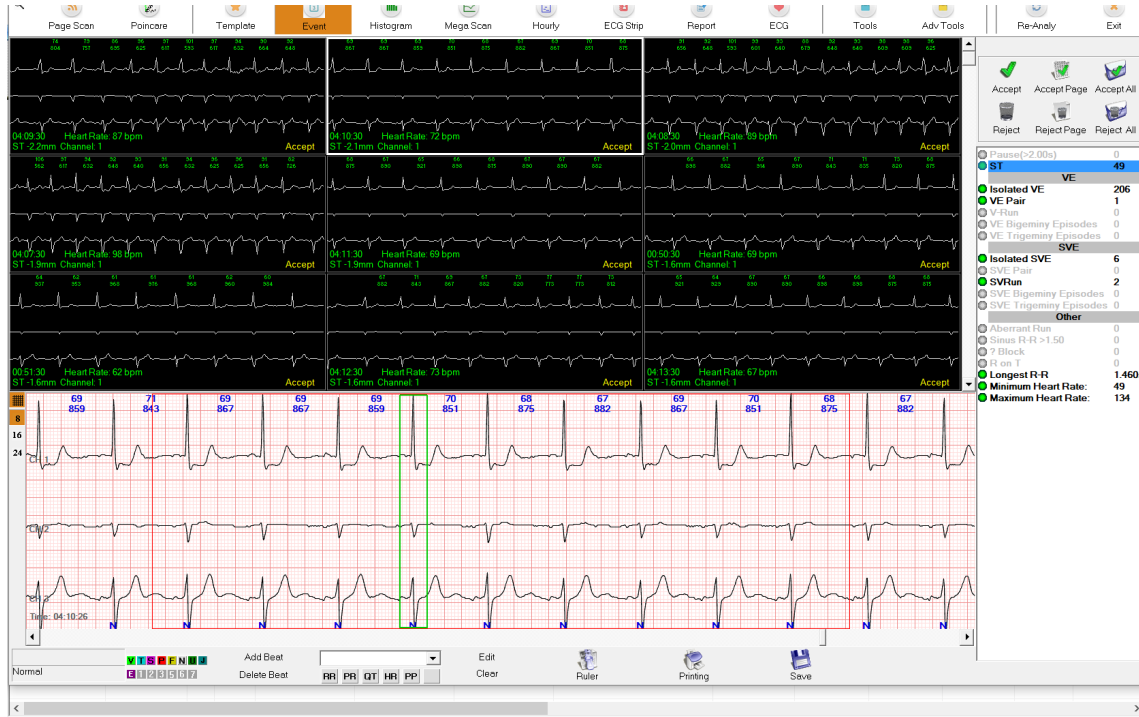


When finished, select the next Beat Type category to edit. In this case, it is “IdioV” (see below).



Repeat the template edit process.

E. Event



Quick Overview

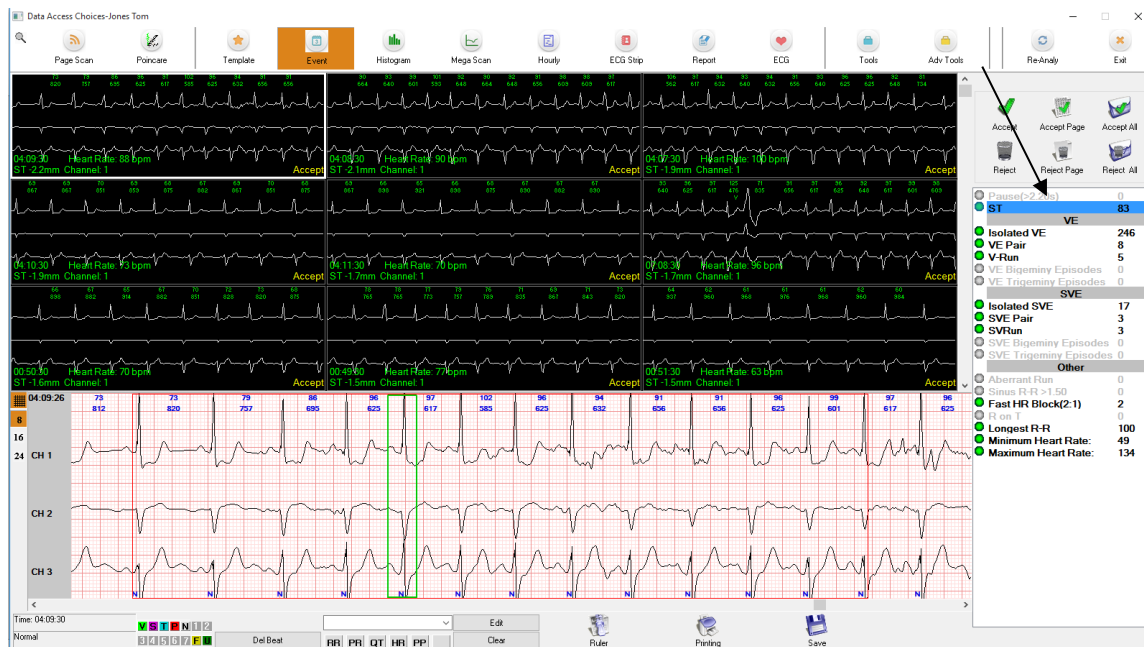
- Users of CardioScan 78a will be familiar with **Event** as they are the same in 79a
- The purpose of Event is to review ECG selections before preparing the final report
- Often, the first three ECG strips for each Event category are printed in the final report
- Thus, it is imperative that the first three ECG strips in each beat category are of good quality
- Any desired ECG strips can be saved for the final report by clicking the “Save” icon at the bottom of the display
- Please note that ECG Strips can be edited during this process
- The ECG strips can be 3-Lead or 6-Lead
- 6-Lead ECG strips are becoming essential in Holter ECG:
 - * Often, a 2- or 3- Lead ECG does not show a P-wave; but a P-wave becomes obvious in 6-Lead. This can be essential in making a valid distinction between A-Fib and Sinus Arrhythmia
 - * 6-Lead ECG is essential for ST Depressions since two contiguous leads are now required for ST Depression detection

- * 6-Lead ECG is beneficial in determining the types of Bundle Branch Blocks
- * An apparent V-Tach may show obvious normal sinus rhythm in Lead 4, 5, or 6
- * The same can occur with 3- or 4-second Pauses that are artifact caused by saturation off-set

Detail

The purpose of **Events** within the Data Access Choices menu is to review ECG selections before preparing the final Holter report, as well as perform further editing as needed.

On the right side of the screen display is a list of beat type categories. The categories in bold correspond the beat types analyzed for the patient. Green dots indicated that the Event categories have not been reviewed. When reviewed, the green dots will change to red. Click on a category in bold to review/re-edit. Please note that clicking on the next beat type category on the list will save changes to the previous beat category.

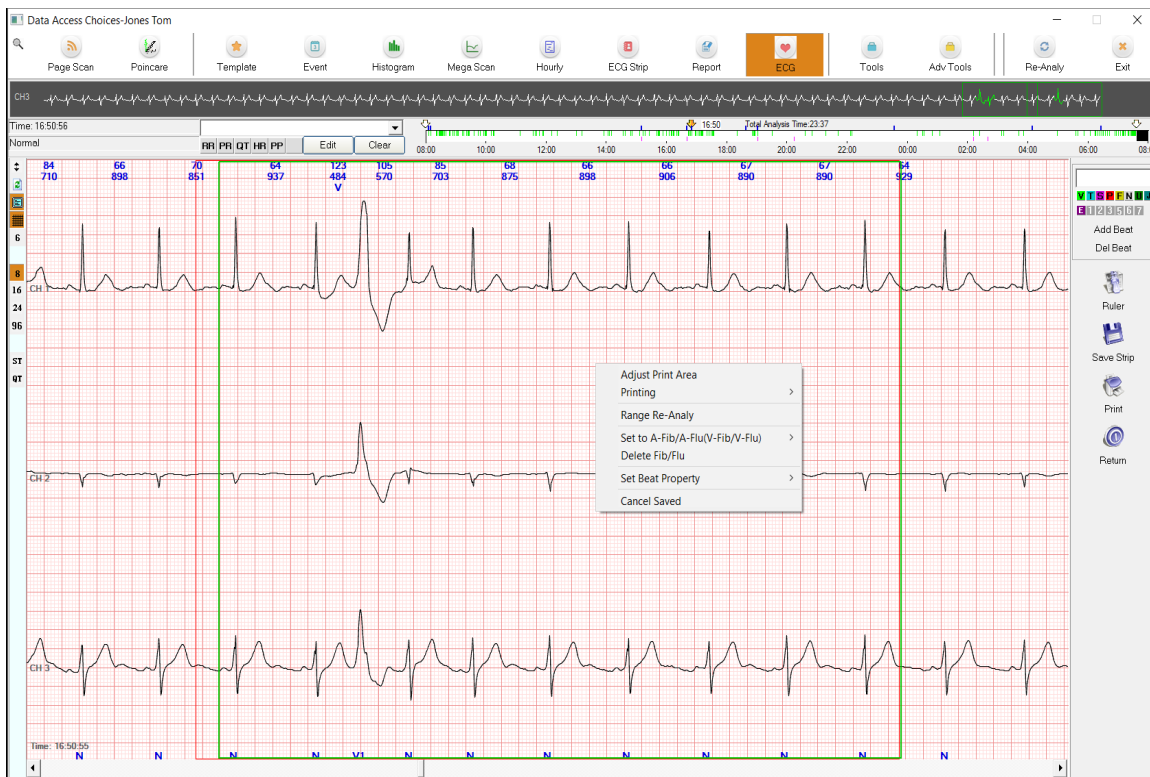


To the left of the beat categories are nine black boxes showing beats in the grouping. Scroll down to view any additional beats. Click on the beat that you wish to review. You will now see a white rectangle highlight (see above). The corresponding ECG strip (for the highlighted beat) will also be shown in the bottom of the display.

If event in the box is incorrect, click "Reject." Otherwise, select "Accept." You can also accept/reject the nine beats displayed at the same time by clicking "Accept Page" or "Reject Page". The same applies to ALL beats in a given category ("Accept All", "Reject All"). Note that, often, only the first three ECG strips for each Event category are printed in the final report.

Also, please note that “Accept” is the only option available for the “Maximum Heart Rate” and “Minimum Heart Rate” beat type categories. Only one event is accepted for each. For max and min HR, confirm that the intervals are being counted correctly. It is preferable to choose the ECG Event strip with the least amount of artifact.

You can double-click on any white highlighted beat for further analysis. This takes you to the ECG section of the Data Access Choices menu (see below).



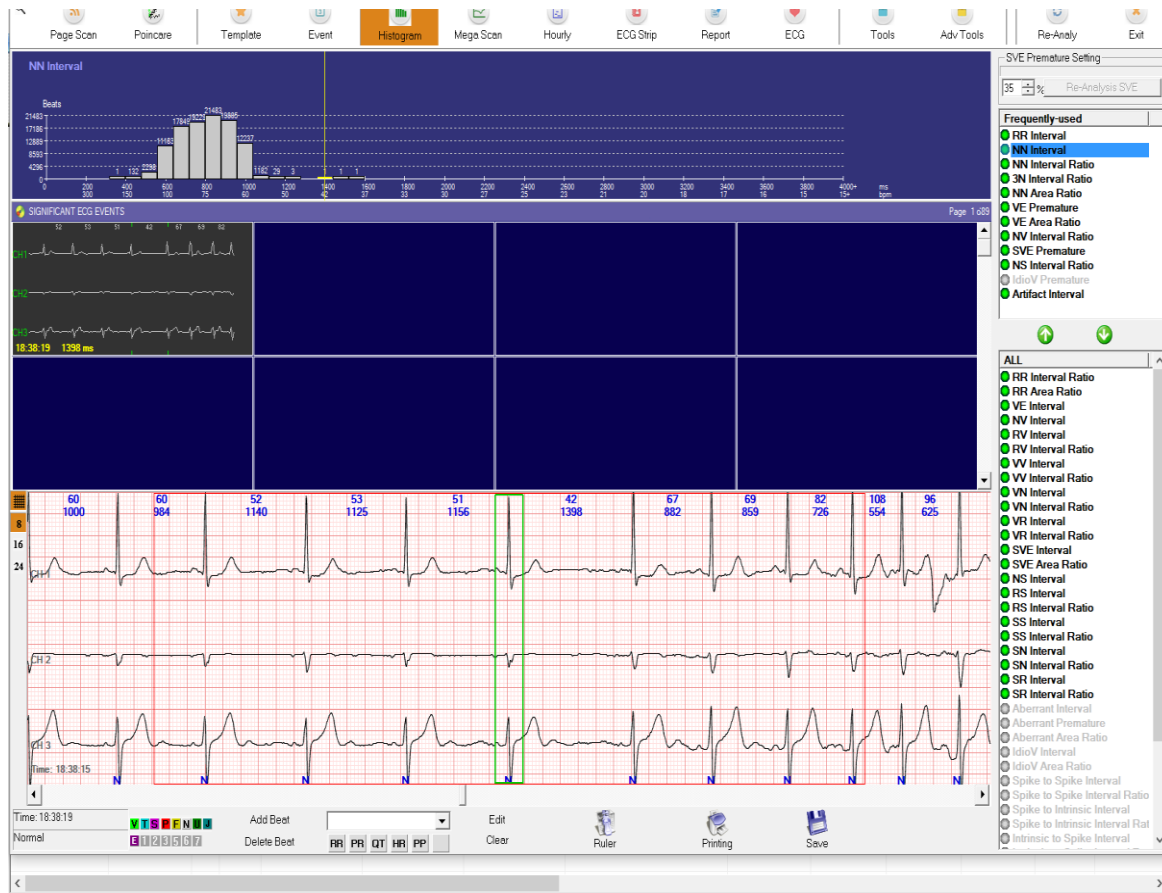
For detailed information on the ECG section, please refer to Section VI – K of this manual.

Click “Return” to return to the main Event menu.

F. Histogram

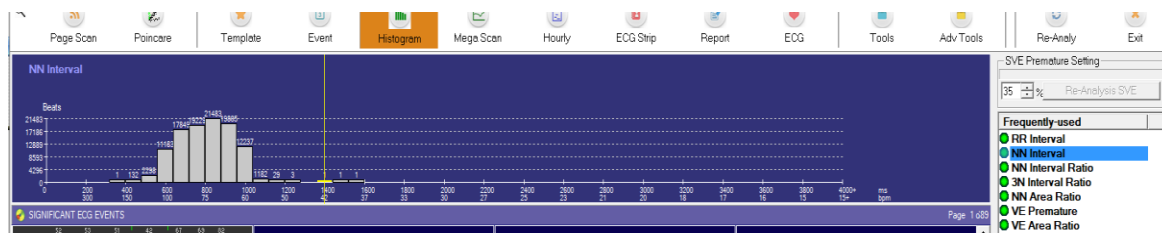
Once you have completed editing Templates or Events, click on **Histogram** in the Data Access Choices menu.

The purpose of the Histogram function is to further review beats, especially those that fall outside of the normal distribution range of VE's, SVE's, and Normal beats.

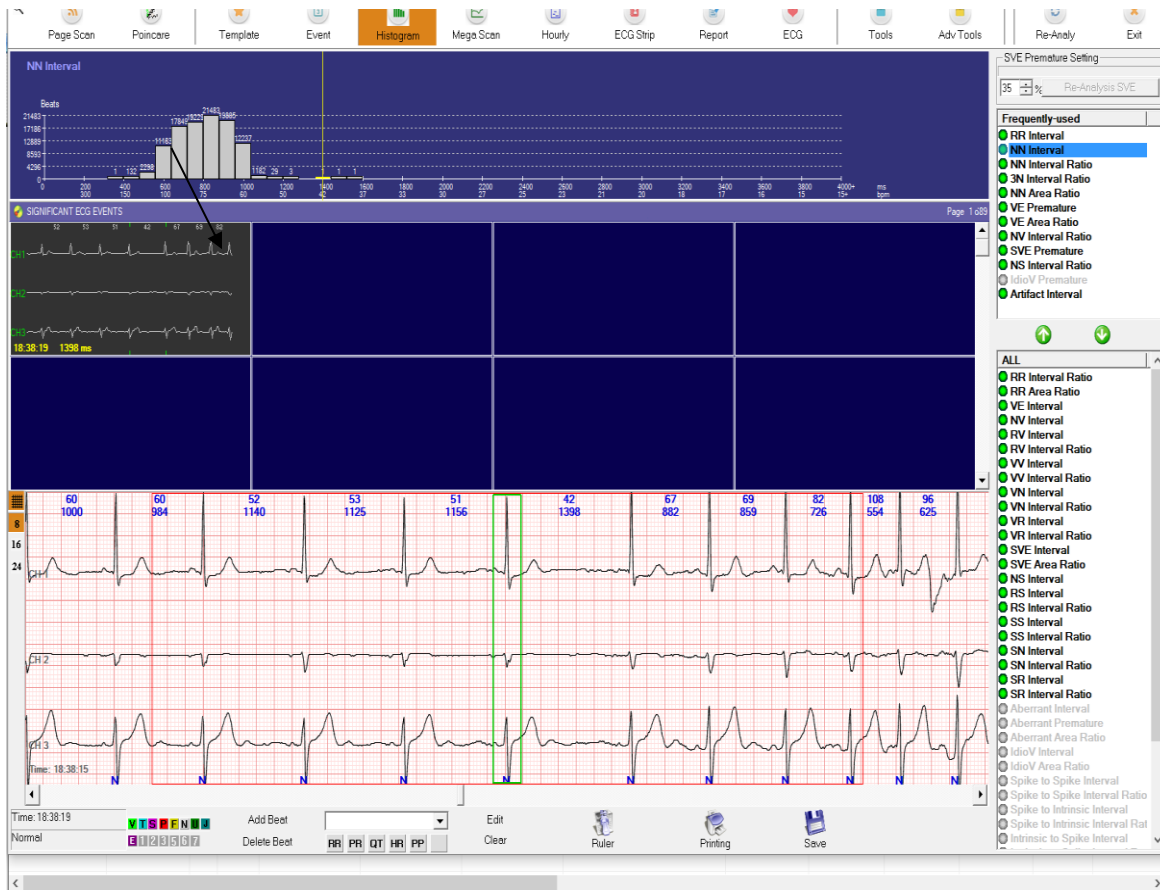


On the right side of the display screen there is a selection menu of over 30 types of histograms. The 10-most frequently used histograms are located in the top section. All other histograms are below.

To view a specific histogram, click on a corresponding category type on the right. The histogram will show on the top of the display screen. The Y-axis of the histogram displays the number of beats in each grouping



Clicking on a specific bar within the histogram will display the associated ECG data underneath (see below). You can scroll down in this section to view additional beats. When selecting the desired histogram, the most interesting data is usually at either of the two far ends of the distribution.



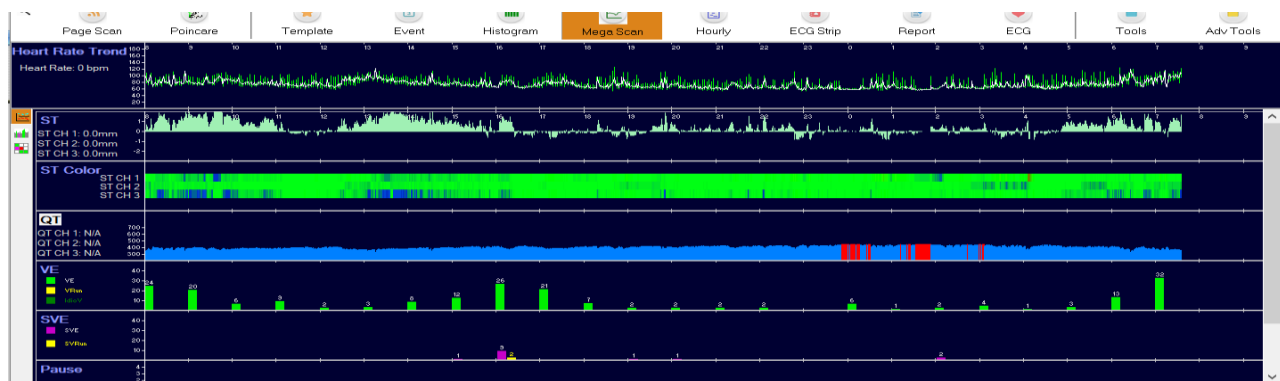
The ECG data can be viewed, edited, saved, or printed as shown in previous sections. Unwanted artifact can also be deleted from the histograms.

G. Mega Scan

The purpose of the **Mega Scan** function is to allow you to view 24-hour trends for HR, ST, QT, VE, SVE, and Pauses, as well as slide your cursor to review areas of interest.



As show below, 24-hour trends of min-average-max heart rate are displayed on a minute-to-minute basis. VE, V-Run, SVE, SV-Run, and Pause trends are shown on an hourly basis. ST Segment trends for all channels are shown on a minute-to-minute basis. QT trends are shown on a one-minute basis.



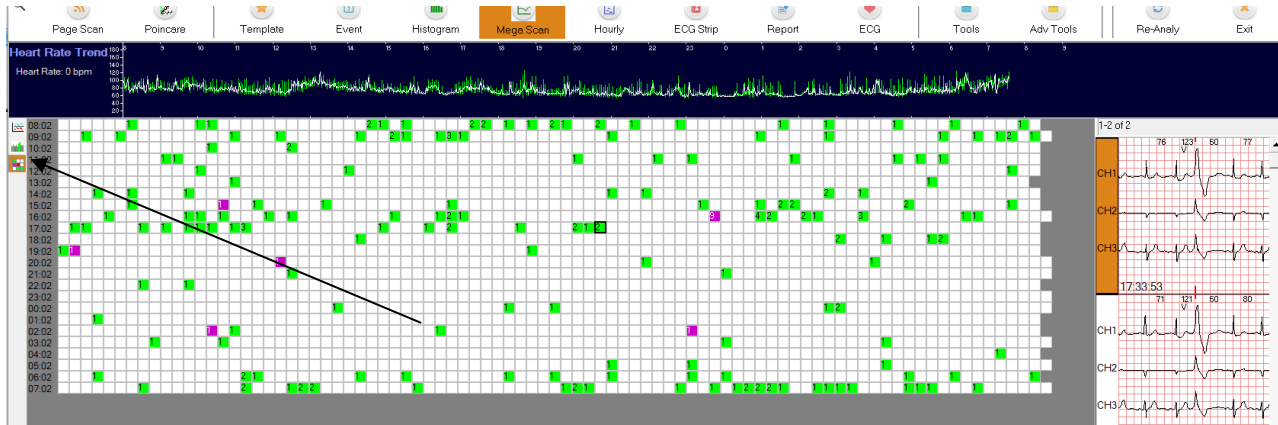
The Mega Scan process can also be useful in locating intermittent events of Atrial Fibrillation and Atrial Flutter. Sudden increases in the vertical range of the min-average-max heart rate could be indications of A-Fib or Flutter.

To activate your cursor, point and click anywhere within any 24-hour graph. This vertical cursor spans across all 24-hour trends. To move the cursor, you may use the arrow keys on the keyboard or point

and click on the location you desire. The ECG strips associated with the selected location will be displayed below the 24-hour trends.

















On the far left of the screen display are three graphs icons (see arrow below).



This is a 24-hour scatter-gram of VE and SVE beats. Each box represents a small period of time during a 24-hour ECG recording. The green boxes represent VE beats and the purple boxes represent SVE beats. There is a number with each box that represents the number of ectopic beats. With a left click on any box, you can see the actual arrhythmias on the right side of this display.

H. Hourly

The **Hourly** function in the Data Access Choices menu is simply an hourly total for each of the categories described in the top rows (Total Beats, Avg. HR, Min HR, Max HR, ST-1, etc.).

																						
Time	Total Beats	Avg HR	Min HR	Max HR	ST-1	ST-2	ST-3	VE	Isolated VE	VE Pair	V-Run	V-Bigeminal	V-Trigeminal	SVE	Single SVE	Pair SVE	SV-Run	SV-Bigeminal	SV-Trigeminal	Pause	IdV	
8:00	4857	83	65	127	2.2	0.0	3.0	24	24	0	0	0	0	0	0	0	0	0	0	0	0	0
9:00	5093	84	66	110	0.2	0.0	2.4	20	20	0	0	0	0	0	0	0	0	0	0	0	0	0
10:00	4773	79	63	107	0.0	-0.1	0.3	6	6	0	0	0	0	0	0	0	0	0	0	0	0	0
11:00	4475	74	61	110	-0.6	-0.1	-0.5	9	9	0	0	0	0	0	0	0	0	0	0	0	0	0
12:00	4865	80	59	119	-0.8	-0.1	-0.3	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0
13:00	5458	90	71	126	-0.6	0.0	2.4	3	3	0	0	0	0	0	0	0	0	0	0	0	0	0
14:00	4772	79	65	127	0.2	0.0	2.0	8	8	0	0	0	0	0	0	0	0	0	0	0	0	0
15:00	4481	74	62	116	-0.4	-0.2	-0.7	12	12	0	0	0	0	0	1	1	0	0	0	0	0	0
16:00	4389	72	59	101	-0.4	-0.3	-0.7	26	24	1	0	0	0	0	9	0	0	2	0	0	0	0
17:00	4699	78	60	109	-0.9	-0.2	-0.8	21	21	0	0	0	0	0	0	0	0	0	0	0	0	0
18:00	4354	72	49	114	-1.1	0.0	-0.8	7	7	0	0	0	0	0	0	0	0	0	0	0	0	0
19:00	4220	69	57	115	-1.2	0.0	-0.6	2	2	0	0	0	0	0	1	1	0	0	0	0	0	0
20:00	4081	67	55	104	-0.4	0.0	-0.3	2	2	0	0	0	0	0	0	1	1	0	0	0	0	0
21:00	4048	66	53	103	-0.8	0.0	-0.2	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0
22:00	4116	68	54	111	-1.2	0.0	-0.9	2	2	0	0	0	0	0	0	0	0	0	0	0	0	0
23:00	3889	64	55	108	-1.2	-0.1	-0.9	0	0	0	0	0	0	0	0	0	0	0	0	0	0	0
0:00	3942	65	50	106	-1.6	0.0	-0.9	6	6	0	0	0	0	0	0	0	0	0	0	0	0	0
1:00	3800	62	54	111	-1.2	0.0	-0.4	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
2:00	4033	66	58	109	-1.0	0.0	-0.4	2	2	0	0	0	0	0	0	2	2	0	0	0	0	0
3:00	4223	69	55	118	-1.5	0.2	-0.8	4	4	0	0	0	0	0	0	0	0	0	0	0	0	0
4:00	4257	70	56	115	-2.2	-0.1	-0.9	1	1	0	0	0	0	0	0	0	0	0	0	0	0	0
5:00	4501	74	61	117	0.0	0.0	0.0	3	3	0	0	0	0	0	0	0	0	0	0	0	0	0
6:00	5107	84	61	134	-0.5	0.0	2.0	13	13	0	0	0	0	0	0	0	0	0	0	0	0	0
7:00	3546	95	64	125	-1.2	0.1	-0.6	32	32	0	0	0	0	0	0	0	0	0	0	0	0	0
Totals	105979	74	49	134	-2.2	-0.3	-0.9	208	206	1	0	0	0	14	5	0	2	0	0	0	0	0

By way of background, some Holter ECG system users prefer the option of processing their Holter recordings by printing out the full disclosure at one-hour of ECG data per page.

In this technique, the user reviews the one-hour full disclosure print-out, and makes an estimate of the number of VE's, SVE's, Pauses, V-Tach, etc. that occurred during that hour.

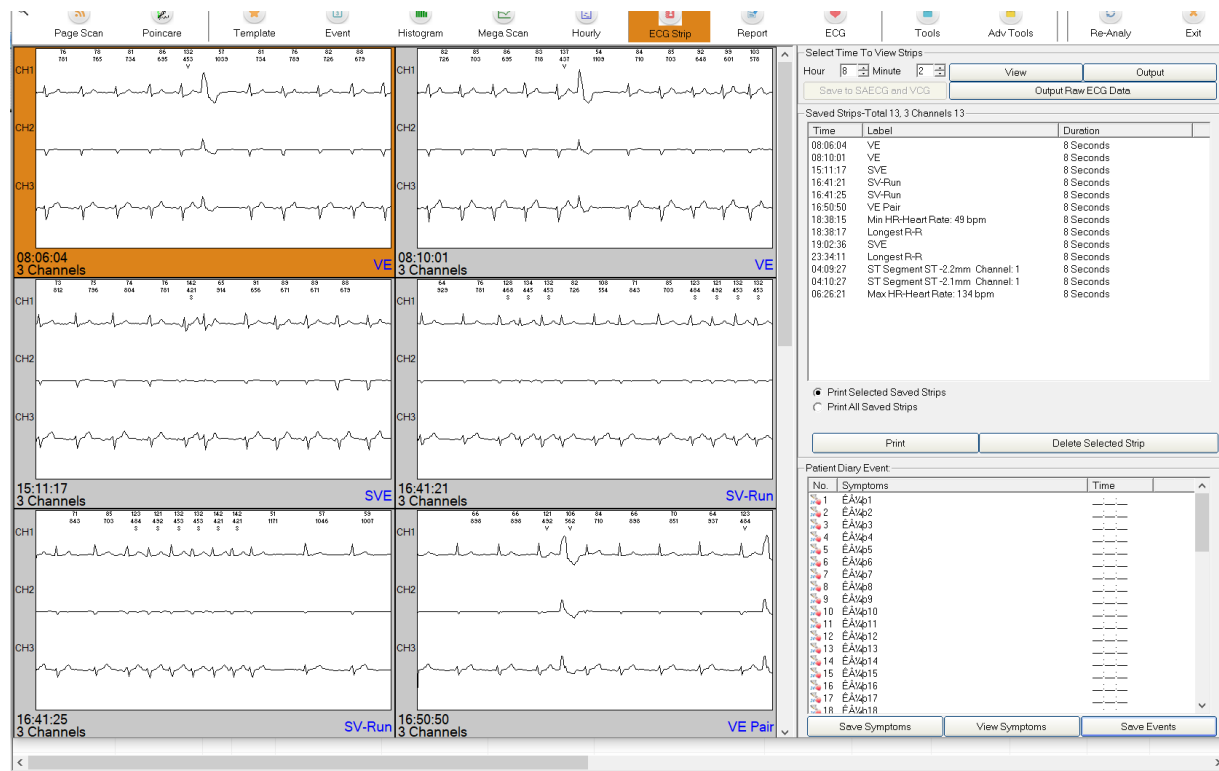
The purpose of the Hourly function is to provide a display that makes it easy for the user to get a summary view of, as well as edit, hourly quantities of abnormal beats. Double-click on any location where you wish to edit or enter data. Using your keyboard, enter the numerical value you desire. This value can be an estimate or the actual count.

I. ECG Strip

Click on **ECG Strip** in the Data Access Choices menu to view all your saved strips.

These are the ECG Strips that you have chosen to include in your final Holter report. Users of CardioScan 78a will be familiar with the ECG Strip menu as it is practically the same in CardioScan 79a.

A list of your saved strips, with corresponding times, will show up on the right (top) side of the screen display (“Saved Strips”). The actual strips will be displayed on the left two-thirds of the screen.



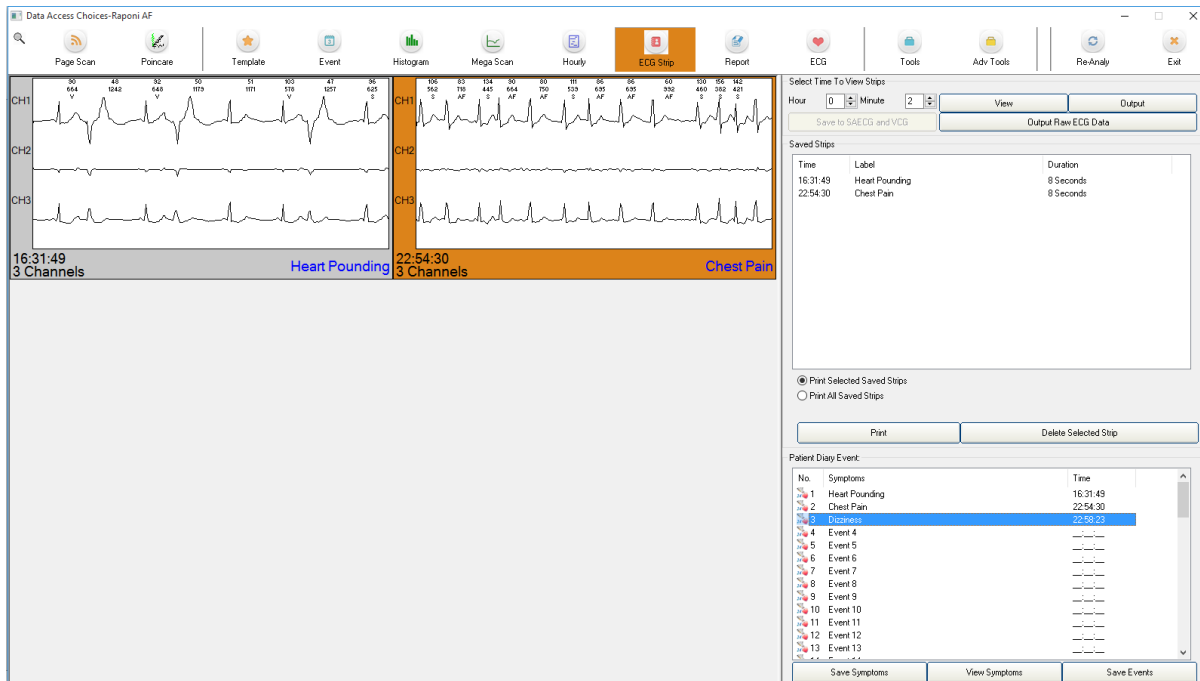
Click on any listed strip from “Saved Strip” to highlight the corresponding strip on the left (orange).

Double-click on the highlighted strip or click the “View” button for further analysis. This will take you to the ECG section of the Data Access Choices menu (refer to Section VI – K). The “Output” button will display a grid tracing of the ECG strip.

If you want to discard a saved strip, highlight that strip and click “Delete Selected Strip.” You can select more than one strip at a time by pressing the CTRL key when clicking.

The “Print” function will allow you to print either a selection or all strips.

A list of patient-triggered events, with corresponding times, will show up on the right (bottom) side of the screen display – “Patient Diary Event” (see below).



Review and save these using the same procedure outlined above. Saved patient-triggered event strips will print out with the final report.

J. Report

Click on **Report** in the Data Access Choices menu to preview your report printing options, add/adjust physician comments, and apply the physician signature.

The Report menu in CardioScan 79a is very similar to that of CardioScan 78a.

The screenshot shows the 'Report' menu in the CardioScan 79a software. The window title is 'Data Access Choices-Jones Tom'. The top toolbar includes icons for Page Scan, Poincare, Template, Event, Histogram, Mega Scan, Hourly, ECG Strip, **Report** (highlighted), ECG, Tools, Adv Tools, Re-Analy, and Exit. The main area is divided into three sections:

- Page Print:** A list of report sections with checkboxes. 'HOLTER ECG REPORT SUMMARY' is selected. Other options include '24 Hour Trends Report', 'ST Analysis', 'QTc and QT Analysis', 'A-FIB', 'Heart Rate Variability Report', 'HRV Poincare and 3D Power', 'ECG Strip' (checked), 'ABP Report', 'SAECG', 'Sleep Apnea 24-Hour Trends', 'Spectral / Multi-Parameter Co', 'Sleep Apnea "At Risk" Form', 'R-R Full Disclosure', 'N-N Full Disclosure', and 'Full Disclosure'. There are also dropdown menus for 'ALL' and 'CH 3'.
- Library:** A list of categories: Arrhythmia, Block, ST, and Other. Each has a zoom icon (Q) to its right.
- Right Panel:** Contains buttons for 'Print', 'Preview', 'Verify' (with a green checkmark), 'Billing(0)', and 'Edit Library'.

At the bottom, there is a 'Physician Comments' section with a 'Remarks' field containing 'ST & TWA ch 3'. Below this is a large text area containing a detailed summary of the Holter ECG report, including heart rate statistics, arrhythmia counts, and ST segment analysis. To the right of this text area are 'Custom Physician Comments' with a dropdown set to 'Auto' and buttons for 'Reset Auto Comments' and 'Save Comment Changes'.

On the left side of the screen display you will find the “Page Print” section. This allows you to select which pages you want printed in the Holter ECG report. You may preview each page of the report by clicking on the zoom icon to the right of each description. Click on the boxes to the left of each page print description that you wish to print. A check mark will appear. The Full Disclosure print functions are in the lower portion of this section.

Report headings can be customized to the appropriate hospital, clinic, physician practice, or other medical facility in System Settings. You can also create individual physician report / conclusion formats. Please refer to “System Settings – Report Settings” and “System Settings – Custom Settings”.

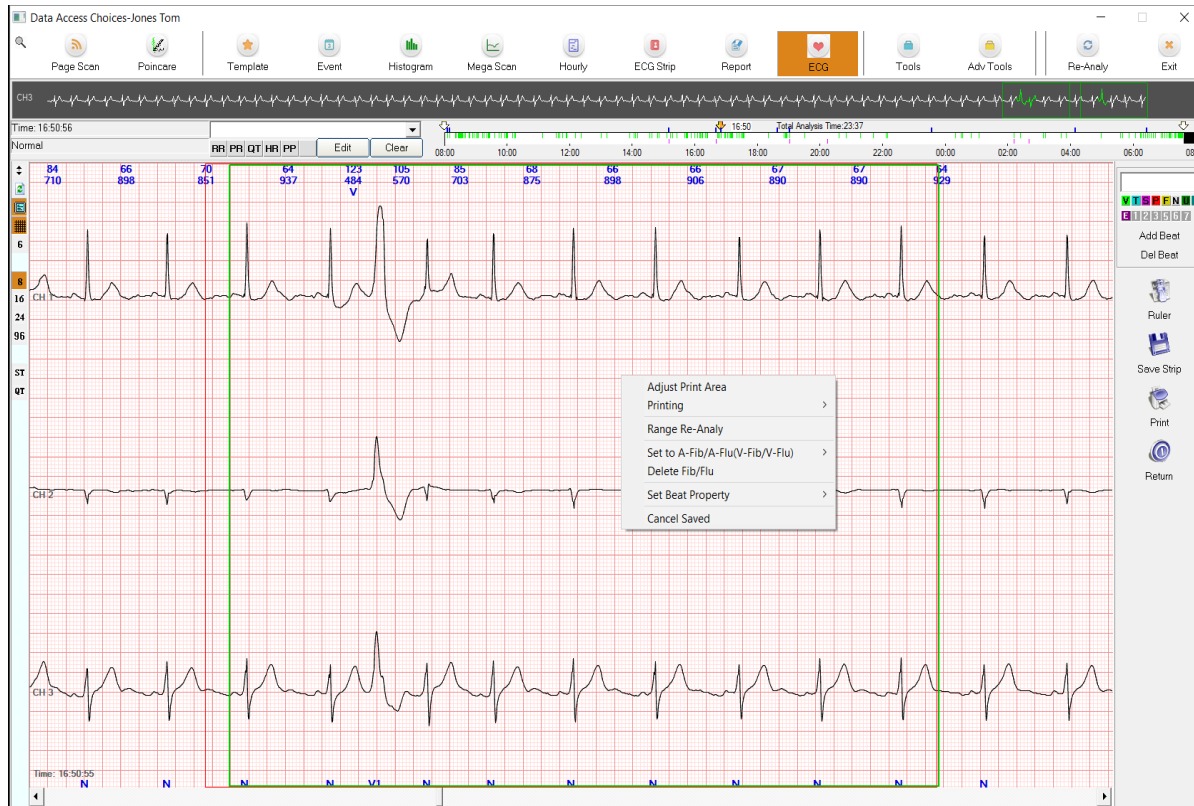
Physician Comments / Conclusions can be found in the lower section of the screen display. Conclusions can be either in a paragraph or line-by-line format. These can be tailored to each individual physician. The physician can override any of the Conclusion formats, and type-in what they feel is appropriate. Always click “Save Comment Changes” prior to report printing.

The “Library” window found on the right side of the screen display provides a menu of choices with which to auto-populate the Physician Comments section, if desired. Simply click on the “+” to the left of each category to expand that selection. Double-click on any desired choices.

On the far right of the screen display, select “Print” to print the report in its entirety. “Preview” allows the user to preview the entire report.

“Verify” applies the physician signature to the report. Only users with a verify permission level will have this option available.

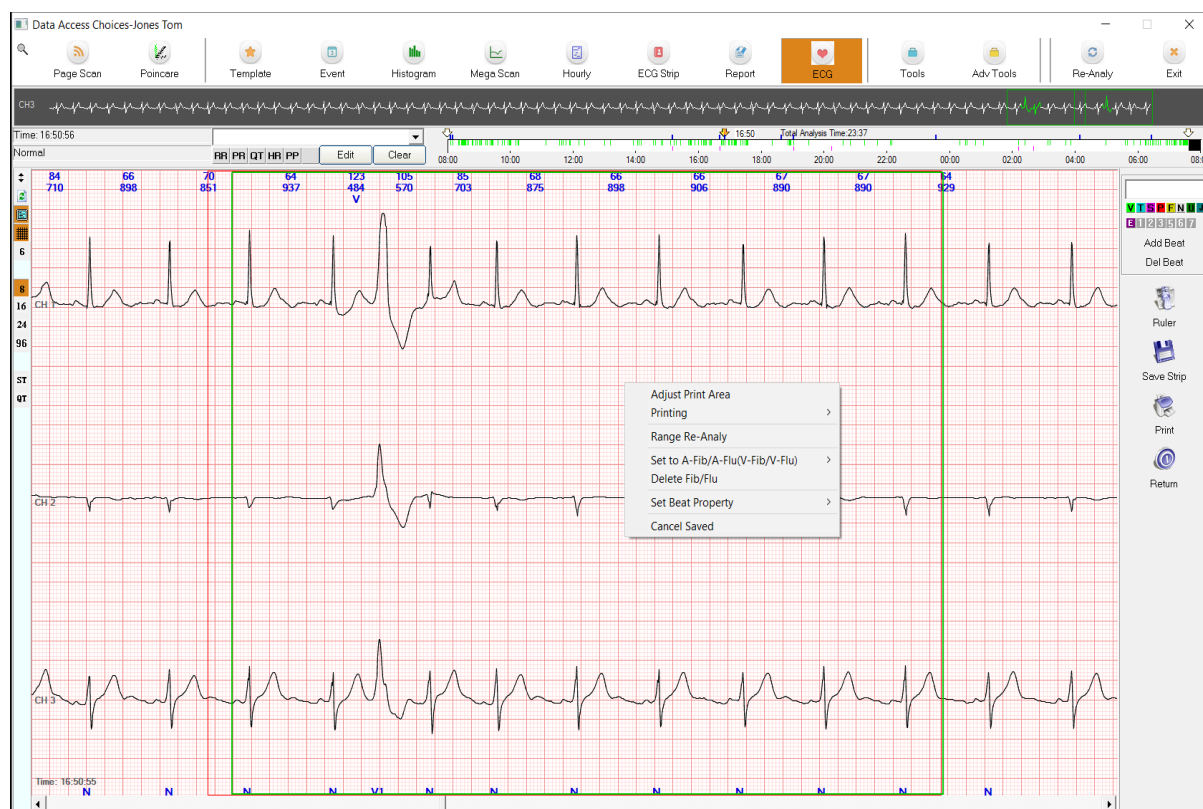
K. ECG



Quick Overview

- Clicking on **ECG** within the Data Access Choices menu allows for re-analysis of ECG events of interest
- The ECG section can also be accessed automatically from “Template”, “Events”, “Histogram”, “Mega Scan”, and “ECG Strip” when the user double clicks on any ECG strip in these sections
- The ECG section can be an excellent tool for labelling the exact beats that represent the on-set and off-set of an A-Fib episode
- Any data that was not previously analyzed can be analyzed here
- The long narrow box above the multi-channel ECG with the label “Total Analysis Time” uses small vertical green and purple markers to show where arrhythmias occurred during the monitoring period. Click on a green or purple marker to bring up an ECG event
- Move the cursor to any QRS on the main screen display, click, and a green rectangular box will surround the beat

- To expand this green box to encompass multiple beats, place the cursor on the left vertical line of the box, click, and drag right (see below)
- Right-click on the box to bring up the option menu. You can also edit/save/print using the buttons on the far right of the screen display (see below)

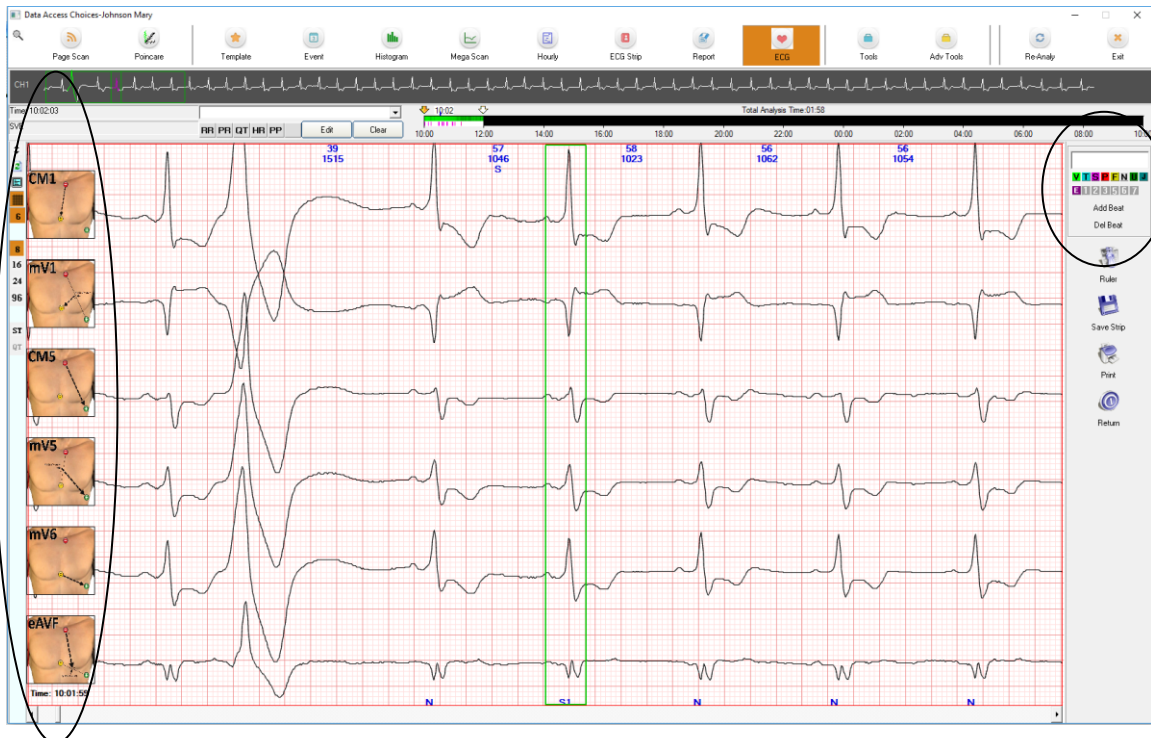


Detail

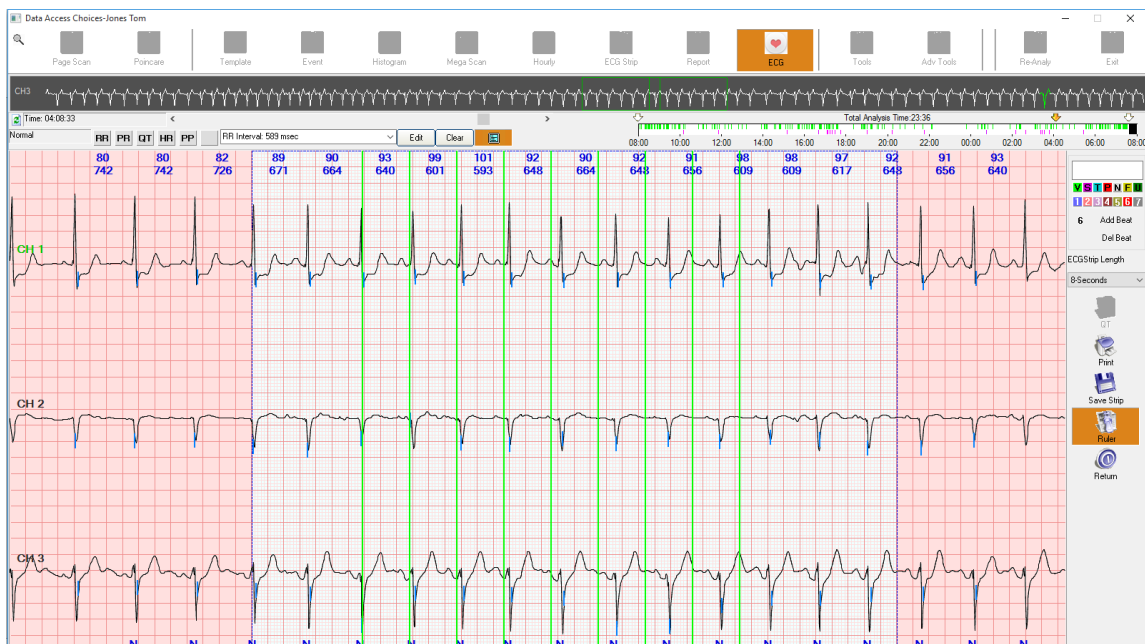
The ECG section allows the user to analyze/re-analyze ECG events of interest.

Incorrectly labelled or previously unanalyzed beats can be edited by clicking on the corresponding color squares on the far right (V, T, S, P, F, N, U, J) of the screen display. The user can also add or delete a beat (“Add Beat”, “Del Beat”). Please refer to the screenshot below.

While the default is a 3-lead display, clicking the “6” on the small left sidebar will change to a 6-lead ECG strip display with ECG vectors shown (see below). The user can also choose to print strips of 8 seconds, 16 seconds, 24 seconds, or 96 seconds (choose by highlighting and click “Print”).



To use the “Ruler” for measuring intervals, first click what you wish to measure (RR, PR, QT, HR, or PP), then click Ruler. Select the first beat to start the measurement and click-drag to the second beat. The ruler will measure out approximately nine beats to provide the interval measurement (as seen below)

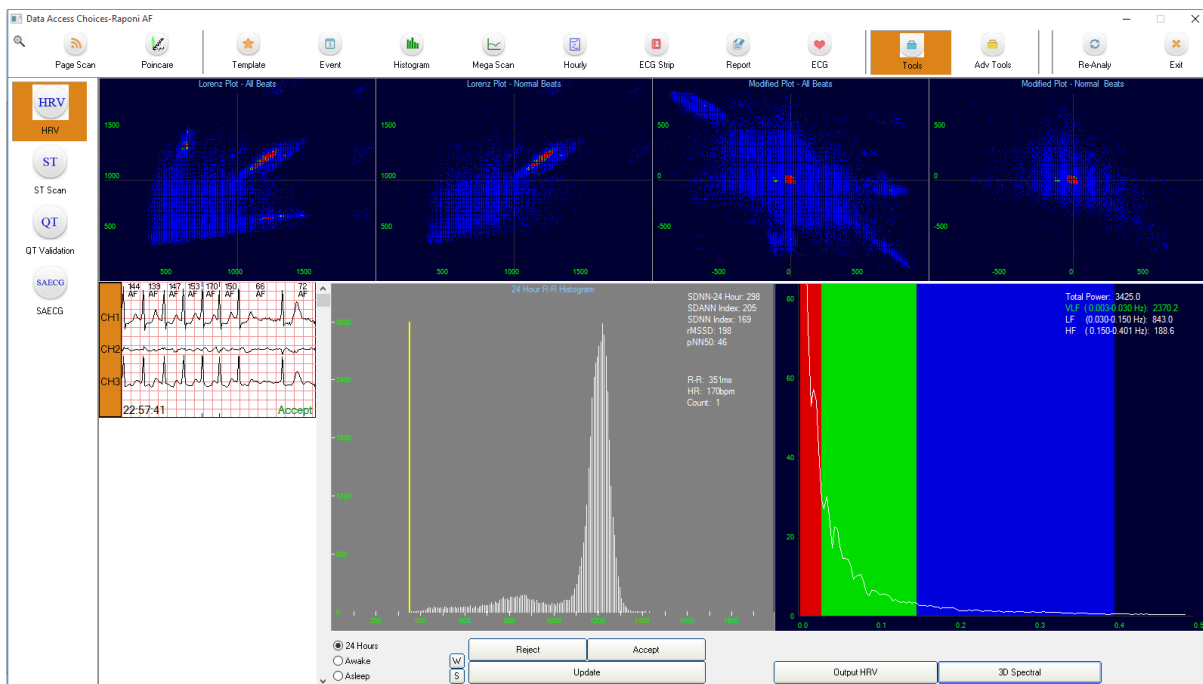


L. Tools

The **Tools** section of the Data Access Choices menu is comprised of four functions:

- HRV (Heart Rate Variability)
- ST Scan
- QT Validation
- SAECG (Signal-Averaged ECG)

Users of CardioScan 78a will be familiar with these features as they are essentially unchanged in CardioScan 79a.

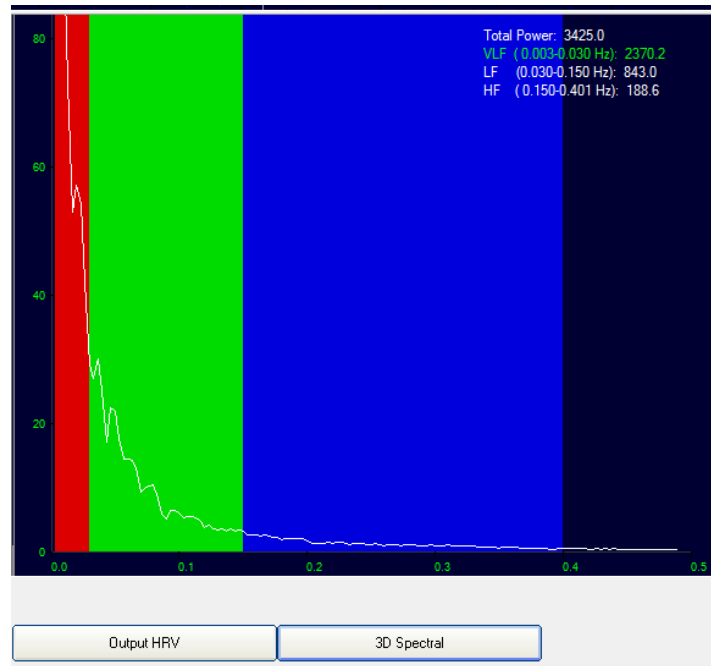


HRV (Heart Rate Variability)

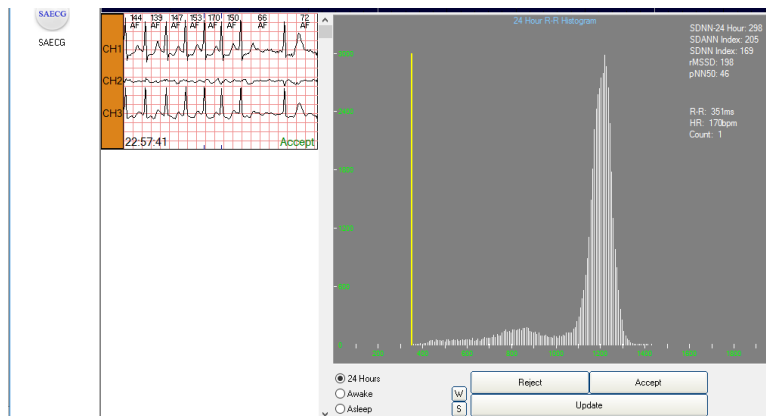
The HRV function shows four Poincare plots across the top of the display. A Spectral Power Graph appears on the lower right quadrant, while a Time Domain R-R Histogram is shown in the middle of the display below the second and third Poincare plots. Immediately to the left of the Histogram, the user will find ECG strips associated with the yellow vertical line marker on the Histogram.

With respect to the Spectral Power Graph (see below), some physicians prefer to customize their own frequency range. In the top right of this graph, you will find “Total Power”, “VLF” (Very Low Frequency), “LF” (Low Frequency), and “HF” (High Frequency). To adjust these ranges, click anywhere on the graph. This will highlight it. “VLF” will be highlighted in green text by default. Use the right and left arrow keys to adjust the ranges as desired. Press the Tab key to toggle between the various

frequencies. Upon completing the adjustments, click on “Accept” located in the middle bottom of the display.



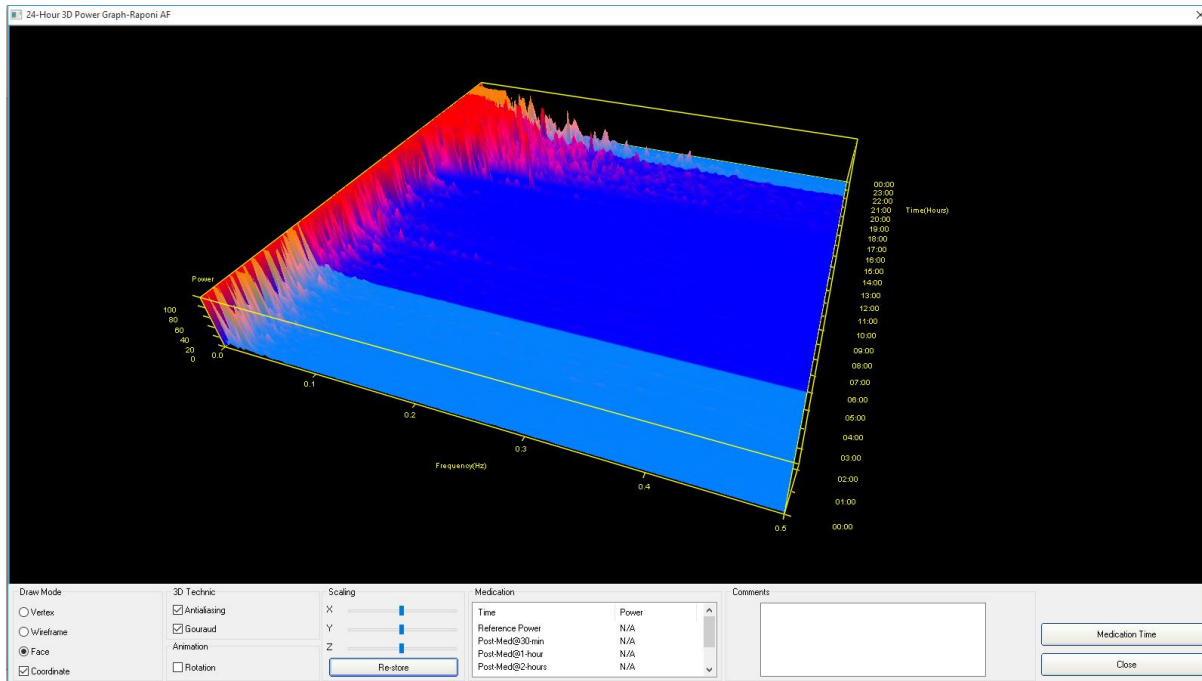
The Time Domain R-R Histogram (see below) is immediately to the left of the Spectral Power Graph. As only normal beats should be included in the HRV count, you can use the histogram to validate that all arrhythmia and artifact beats have been removed from the HRV file of normal R-R intervals.



To review and edit, click anywhere on the graph. It will now be highlighted. A yellow vertical line will appear over the various beat distributions. Corresponding ECG strip data will be displayed to the left of the histogram. Use the right and left arrow keys (or simply click) to view the ECG data at far ends of the distribution. Determine if any of the beats should be rejected from the HRV data file. Any abnormal beats or artifact will cause the HRV data to be incorrect. Click “Reject” as appropriate, and “Update” to save any changes. Double click on any ECG strip that merits further analysis. This will take you to the ECG function within the Data Access Choices menu (please refer to **Section VI – K**). Toggle between “24 Hours”, “Awake”, and “Asleep” to view the histogram, as well as the Spectral Power

Graph, for the corresponding time periods. Click on the “W” and “S” buttons to adjust the default Awake and Asleep times.

Click on “3D Spectral” immediately below the Spectral Power Graph to view a 3D Power Graph (see below).



Use the various choices on the lower left (“Draw Mode”, “3D Technic”, “Animation”, “Scaling”) to adjust the visual effects of the graph. To restore the initial default settings, click on the “Restore” button at the bottom of the Scaling box.

Each 5-minute data period is analyzed using a spectral frequency methodology. A power graph is drawn for each period, and then overlaid. The resulting 3D graph provides a visual representation of the patient’s heart rate variability.

To view the actual totals for each 5-minute period click “Close”, and then click on “Output HRV” on the lower right of screen (see below).

For a 3-lead recording, the individual ECG waves on the left side of the display (CH1, CH2, CH3) are 1-minute averaged waves representing the beats at the position/time indicated by a white vertical marker running down all the trend graphs on the right three-quarters of the screen display. In the above screenshot, the white vertical marker just so happens to be at the y-axis of the graphs.

The average ST value of the 1-minute beats is shown at the left corner above each individual ECG wave. The short red line markers on the individual ECG waves indicate the position of the ST segment.

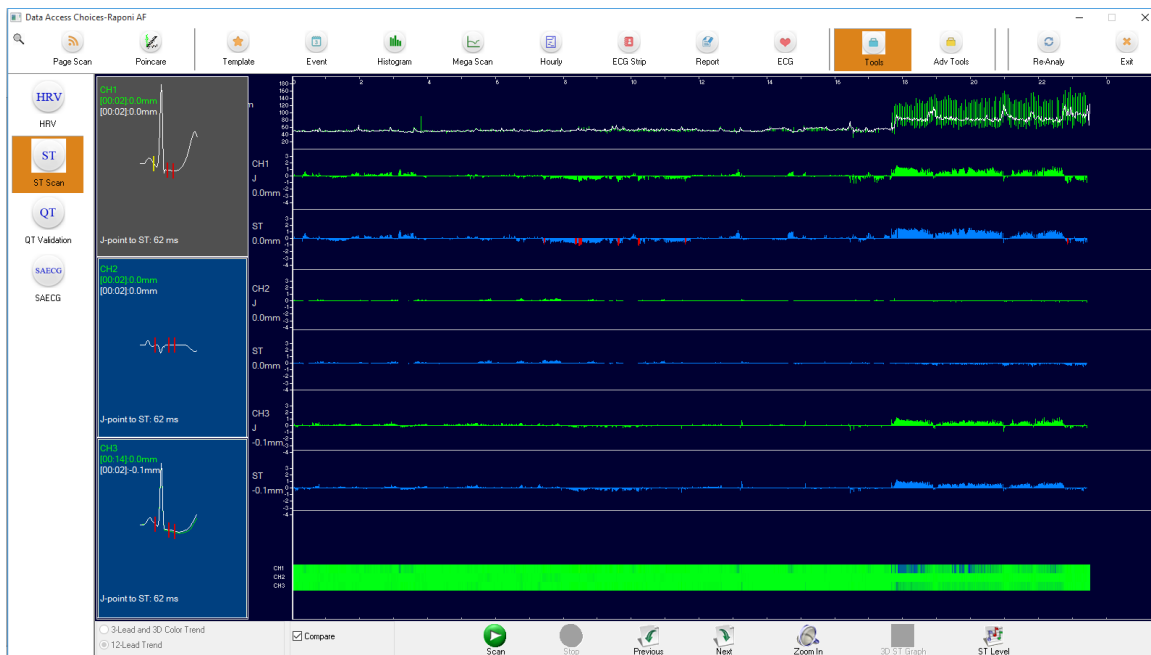
Move the white vertical marker on trend graphs using the arrow keys or the “Previous”/“Next” icons on the bottom of the display. This will change the individual waves and average ST values accordingly.

To see dynamic ST changes, click on the “Scan” icon at the bottom of the screen. The white vertical marker will automatically move from its current position on the trend graphs toward the right along the time (X-) axis. The 1-minute average ECG waves on the left side of the screen change accordingly. Click on the “Stop” icon at the bottom of the display to stop this.

You can compare the ST segment of any point on the trend graph with a standard 1-minute average wave automatically set by the program. To do so, click on the box next to “Compare” at the bottom left of the screen. This will enable Compare mode. The standard ECG wave will be shown in green and its location will be fixed. The white ECG wave that is overlaid represents the 1-minute average for the selected time. As the white vertical marker is moved, the white ECG wave will change accordingly.

If the user wishes to view an enlarged 8-second ECG strip, move the white vertical marker to the desired position. You can then access the ECG function within the Data Access Choices menu (refer to Section VI – K) by double-clicking, pressing Enter, or selecting the “Zoom” icon at the bottom of the screen.

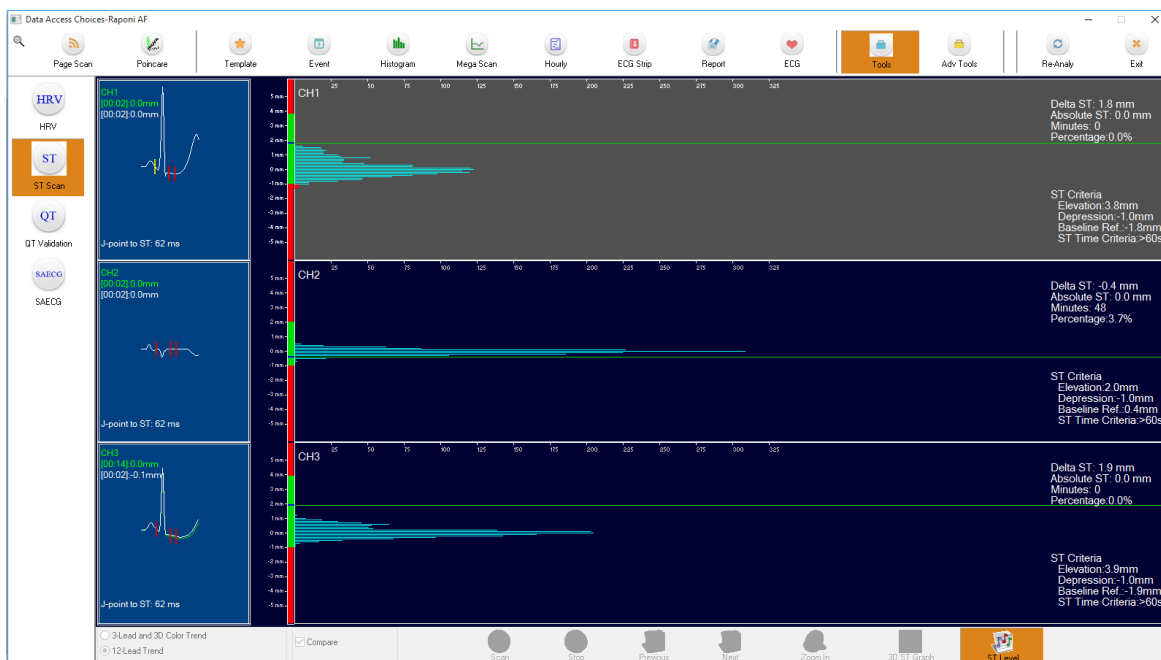
As shown below, the trend graphs found on the right three-quarters of the screen display represent (from top-to-bottom): Heart Rate trend, J-point and ST segment for each of the three channels, and ST spectral graph.



Red bars found anywhere on the ST trend graphs indicate potentially abnormal ST segments; blue bars indicate normal.

Red markers in the ST spectral graph indicate that the ST segment is depressed; deep blue indicates ST segment elevation; green is normal.

At the bottom right of the screen display, locate the “ST Level” icon. Click and the screen below will appear.

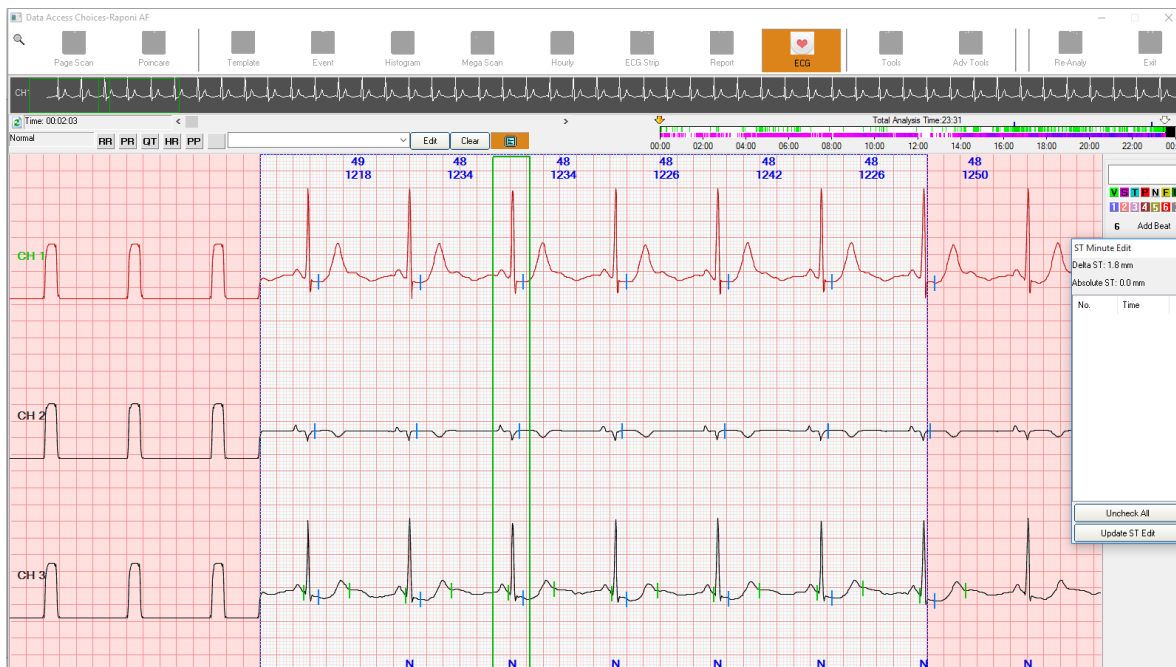


The main display shows the ST distribution of the channels. The Y-coordinate indicates the ST elevation or depression value relative to the horizontal green line. The X-coordinate indicates the time (minute) period occupied by beats with the same ST value.

Click to select any of the channel distributions. The active channel will be highlighted in gray. Move the horizontal green vertical marker with the Up/Down Arrow key to view different ST distributions.

Right click anywhere on the distribution graph to select different ST criteria through the shortcut menu.

To see an enlarged 8-second ECG strip, access the ECG function within the Data Access Choices menu (refer to Section VI – K) by double-clicking or pressing “Enter”. The following screen will appear.



Click on “X” or press the Esc key to exit.

QT Validation

The QT Validation function allows the cardiologist or technician to validate the accuracy of their QT and QTc analysis.

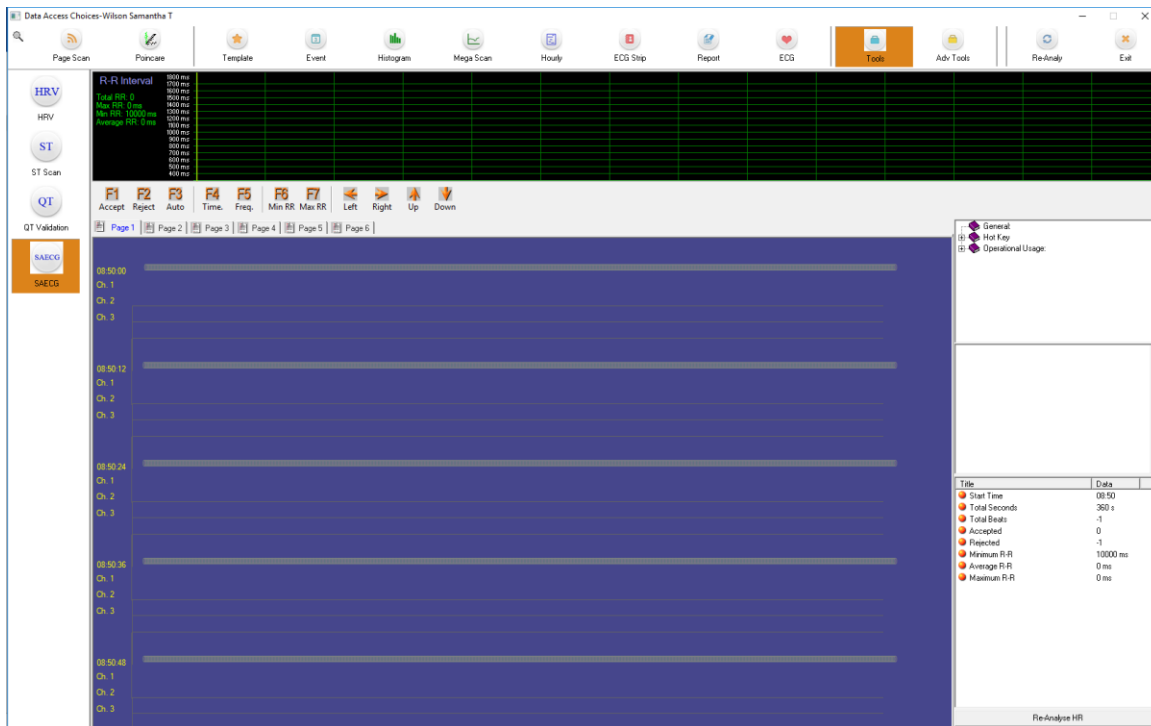
QT is analyzed on a beat-to-beat basis. The heart rate is factored into the QT analysis so that QTc and QT measurements can be made from the same data. A QTc Histogram is then developed (see below).

You have now accessed the ECG function within the Data Access Choices menu (refer to Section VI – K).

Click on “X” or press the Esc key to exit.

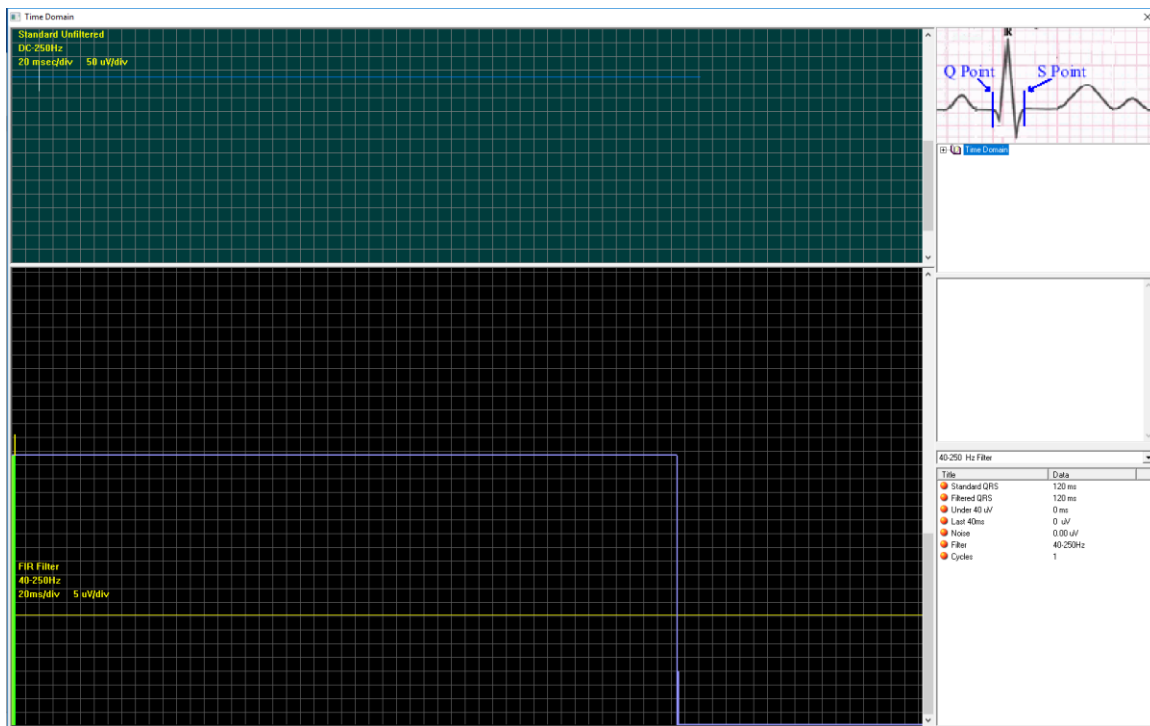
SAECG (Signal-Averaged ECG)

The SAECG function consists of two data displays. The top display is the R-R Interval graph. Each vertical line represents one beat. The longer the line, the slower the heart rate. Individual R-R intervals can be edited by moving the marker with a click or with the Arrow keys to the desired location. Press F1/F2 to accept/reject the R-R interval.



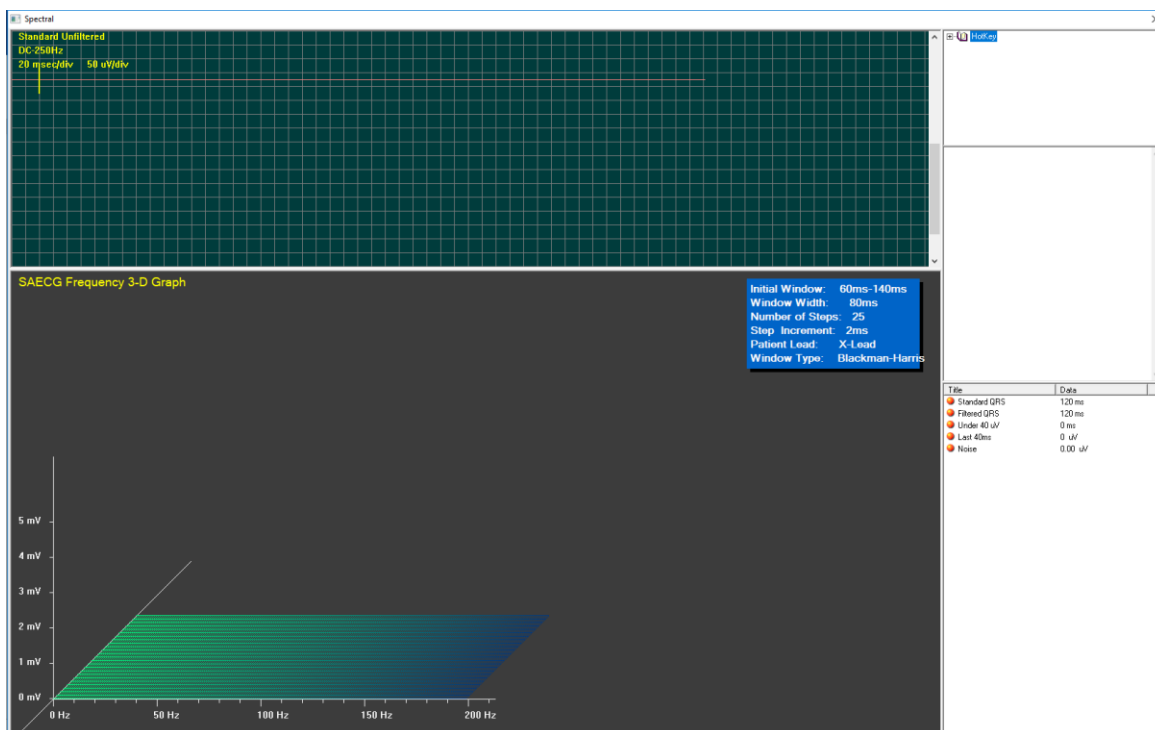
The large data display shows one minute of ECG data (each horizontal sweep represents 12 seconds). Unwanted ECG beats can be eliminated by placing the cursor on the desired location and selecting. It is desirable to remove beats with artifact from the SAECG Late Potential file. You can access Minutes 1 through 6 by clicking the Page 1, Page 2, Page 3, Page 4, Page 5 or Page 6 tabs, or you can change the minutes by pressing the PG UP and PG DN keys.

To access the Time Domain analysis, click Time or press F4. The following display will appear.



The upper portion of the display shows the superimposed ECG waves without filtering. Different leads can be selected. The lower portion shows synthetic, superimposed and filtered ECG waves. The right side lists the analytical parameters for time domain.

To access the Frequency analysis, click Freq or press F5. The following display will appear.



As with the Time Domain analysis, the upper portion of the display shows the superimposed ECG waves without filtering. The lower portion is the 3D frequency-time spectrum for SAEKG, which is called the Haberl method.

View the Frequency Graph for Channel 1. You can move the active yellow marker at the end of the QRS with the Arrow keys. Note that the Initial Window numbers will change in the data box directly above the 3D graph, as well as in the 3D graph.

Right click to change channels. The SAEKG Frequency Graph will change with each channel. You will be able to view the changes in spectral power.

When you are finished, click on "X" at the top right corner of the screen display to close. You will be returned to the main SAEKG screen display.

M. Advanced Tools

The **Advanced Tools** section of the Data Access Choices menu is comprised of five functions:

- HRT (Heart Rate Turbulence)
- DC/DR (Deceleration Capacity)
- Sleep Apnea
- T Wave Alternans
- FCG (Frequency ECG Analysis)

Users of CardioScan 78a will be familiar with these features, although significant analysis enhancements have been made to the Sleep Apnea function.



HRT (Heart Rate Turbulence)

Heart Rate Turbulence is the physiological, bi-phasic response of the sinus node to premature ventricular contractions. It consists of a short initial acceleration followed by a deceleration of the heart rate. HRT can be quantified by two numerical parameters, namely the Turbulence Onset and the Turbulence Slope. The premature ventricular contraction causes a brief disturbance of arterial blood pressure (low amplitude of the premature beat, high amplitude of the ensuing normal beat). When the autonomic nervous system is normal, this fleeting change is registered immediately with an instantaneous response in the form of HRT. If the autonomic nervous system is impaired, this reaction is either weakened or entirely missing.

HRT is suitable for assessing risk following myocardial infarction. After data analysis of more than 3,000 post-infarction patients, it was established that HRT, independent of other predictors, was the most powerful ECG-related risk predictor. The predictive value of HRT is comparable to that of the ejection fraction of the left ventricle.

- Turbulence Onset (TO)

Turbulence Onset (TO) is the percentage difference between the heart rate immediately following VE and the heart rate immediately preceding VE. It is calculated using the following equation:

$$TO = ((RR1 + RR2) - (RR-2 + RR-1)) / (RR-2 + RR-1) * 100$$

With RR-2 and RR-1 being the first two normal intervals preceding the VE and RR1 and RR2 the first two normal intervals following the VE. Initially, TO is determined for each individual VE, followed by the determination of the average value of all individual measurements. Positive values for Turbulence Onset indicate deceleration; negative values indicate acceleration of the sinus rhythm.

- Turbulence Slope (TS)

The Turbulence Slope (TS) corresponds to the steepest slope of the linear regression line for each sequence of five consecutive normal intervals in the local tachogram. The Turbulence Slope calculations are based on the averaged tachogram and is expressed in ms per RR interval.

- Filters

The algorithm for HRT quantification can only provide viable results if the triggering event was a true VE (and not, for example, artifact).

Additionally, it must be ensured that the sinus rhythm immediately preceding and following the VE is free from arrhythmia, artifact, or false classifications.

In order to fulfill these requirements, the software utilizes filters which exclude RR intervals with the following characteristics from the HRT calculation:

- <300 ms
- > 2000 ms
- > 200 ms difference to the preceding sinus interval
- > 20% difference to the reference interval (mean of the 5 last sinus intervals)

In addition, we limit the HRT calculations to VEs with:

- a minimum prematurity of 20%

- a post-extrasystole interval which is at least 20% longer than the normal interval

Click on the “HRT” icon. The following display will appear:



The top half shows the HRT tachogram. You may select to show the “Average Histogram” or “Single Histogram”. The bottom half shows the individual VE. The upper right of the display shows results and risk factors.

Click “Previous” to check the previous VE. Click “Next” to check the following VE.

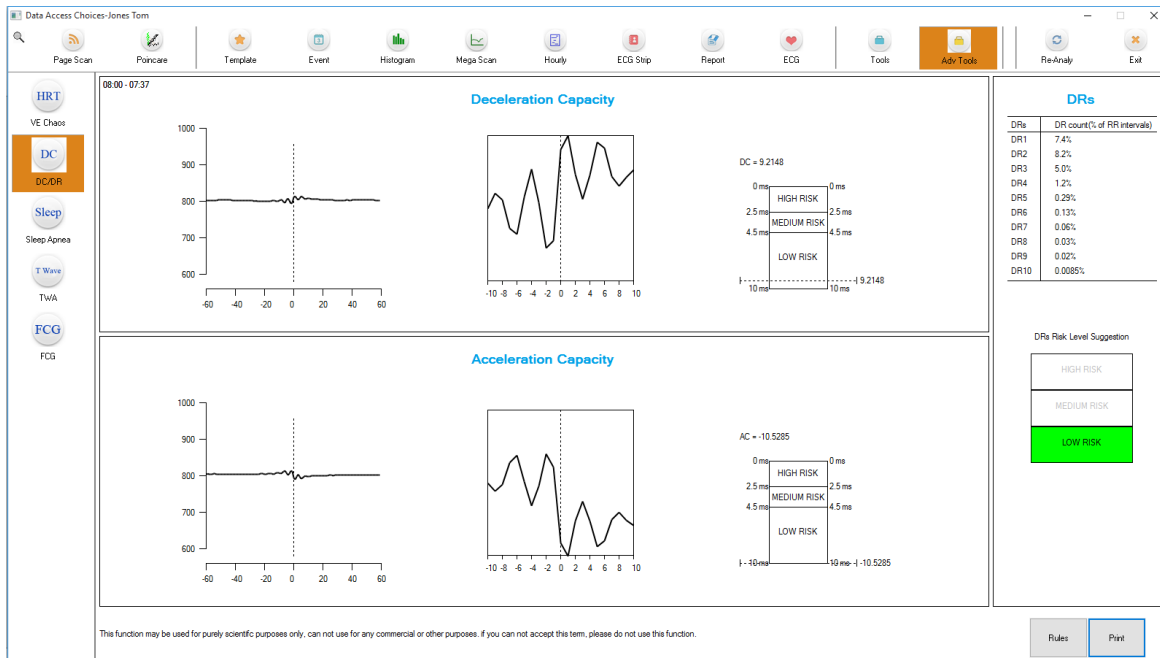
Click “Print” to print HRT report.

Click “Rules” to set the filters. Click “OK” to return to the main HRT screen.

DC/DR (Deceleration Capacity)

Various studies have highlighted the potential of heart rate deceleration capacity (DC) analysis in identifying at-risk patients.

Click on the “DC” icon. The following display will appear:



The top half of the display relates to deceleration capacity, and the bottom half to acceleration capacity. The software will provide a risk assessment for each, as well as an overall assessment.

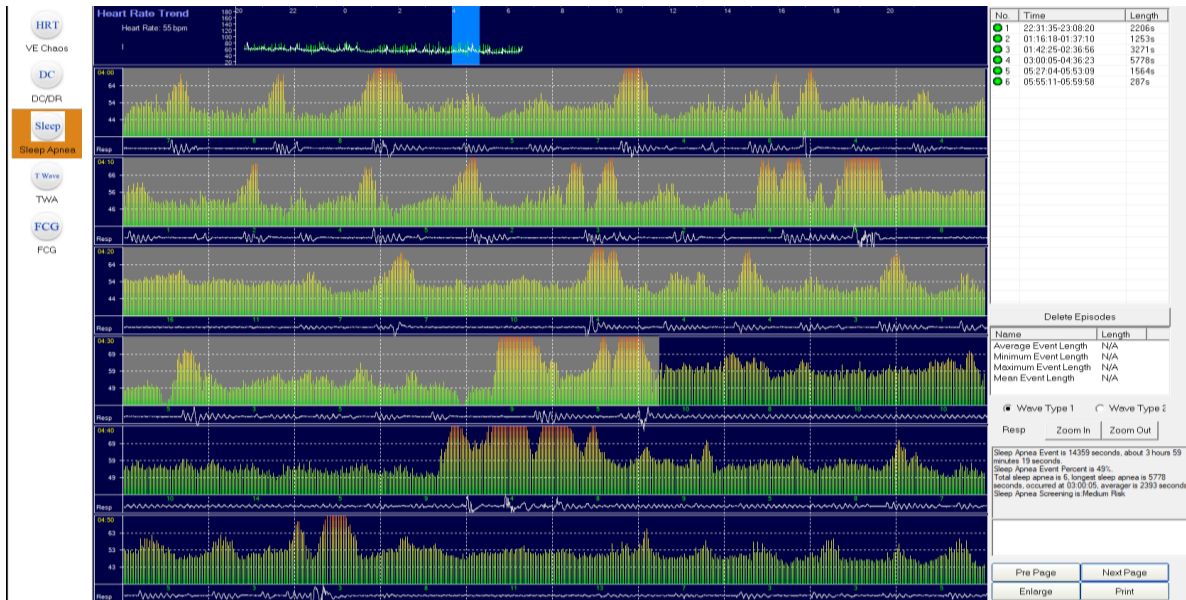
The “Rules” icon (see below) allows for the measurement of selected time periods.



Click “Print” to generate the Deceleration Capacity report.

Sleep Apnea

The Sleep Apnea function analyses the interaction of the respiration signal with the pattern of gradual heart rate increases/decreases together with the sudden reduction in very low frequency HRV power.



The top of the screen display shows the Heart Rate Trend graph during the entire sleep period.

Beneath the Heart Rate Trend graph, each horizontal sweep in the main screen display represents 10 minutes. Given that there are six such horizontal sweeps, this represents one hour of sleep. This 1-hour period corresponds to the section of the Heart Rate Trend graph that is highlighted in blue.

On the main screen display, the patient's heart rate is represented by the green/yellow/red vertical lines. The dotted vertical white lines segment the 10-minute horizontal sweeps into 1-minute periods. The white waveform under each 10-minute horizontal sweep represents the respiration signal.

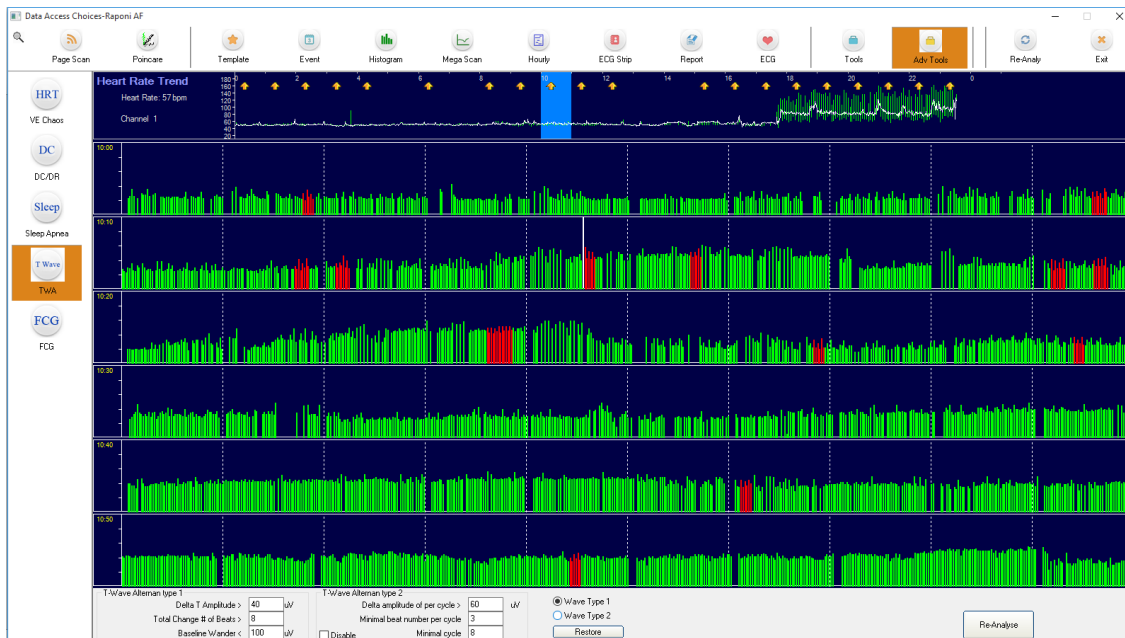
To review any portion in detail, double click on the relevant green/yellow/red vertical line. You will be taken to the ECG function within the Data Access Choices menu (refer to **Section VI – K**).

Upon analysis, right click on any area of the main screen display that represents the onset of a sleep apnea episode and select "Set Sleep Apnea Start Point". Similarly, right click on the area that represents the offset of a sleep apnea episode and select "Set Sleep Apnea End Point". The selected area will now be highlighted in white, and the episode time/duration will be logged on the upper right of the main display.

T Wave Alternans

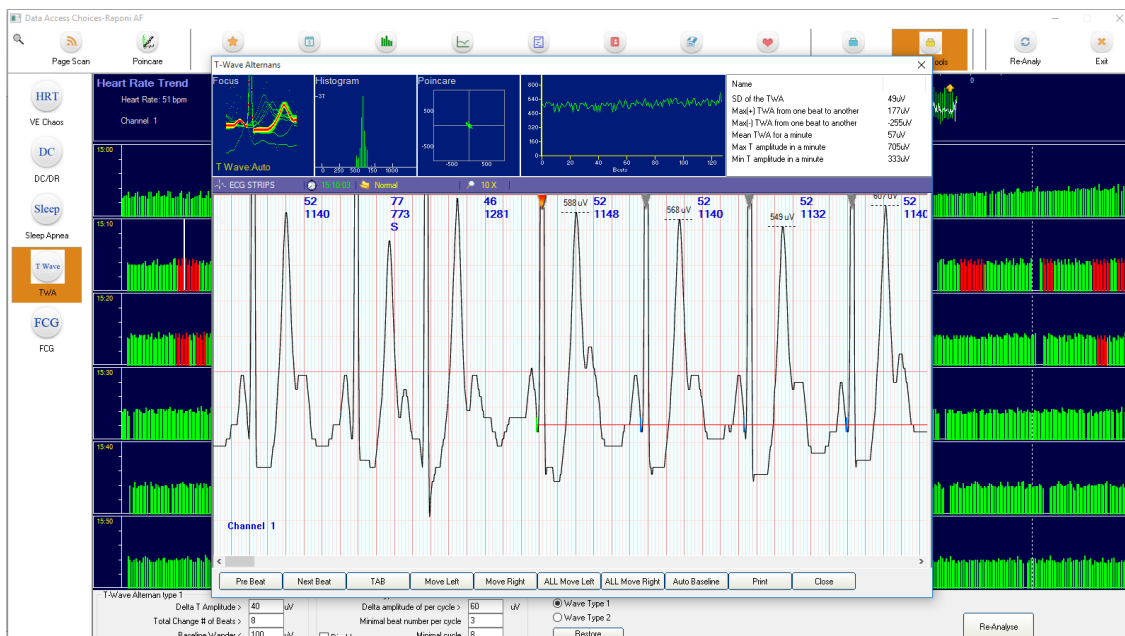
The top of the screen display shows the Heart Rate Trend graph. The blue shade on this graph is for 1-hour of data. This corresponds to the six 10-minute increments on the main screen display beneath the Heart Rate Trend graph. Click on any desired portion of the Heart Rate Trend graph to adjust the

1-hour of data displayed. The yellow arrows above the Heart Rate Trend graph correspond to hours with detected T Wave Alternans. The green vertical lines on the main screen display represent T-wave amplitudes. Any red color for these amplitudes indicates the potential for a T-Wave Alternans abnormality.



At the bottom of the display (middle), you will see toggle buttons for “Wave Type 1” and “Wave Type 2”. Wave Type 1 is the default option and highly recommended.

Double click on any vertical T-wave amplitude lines for further analysis. The following window, displaying data for 128 beats, will appear:



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

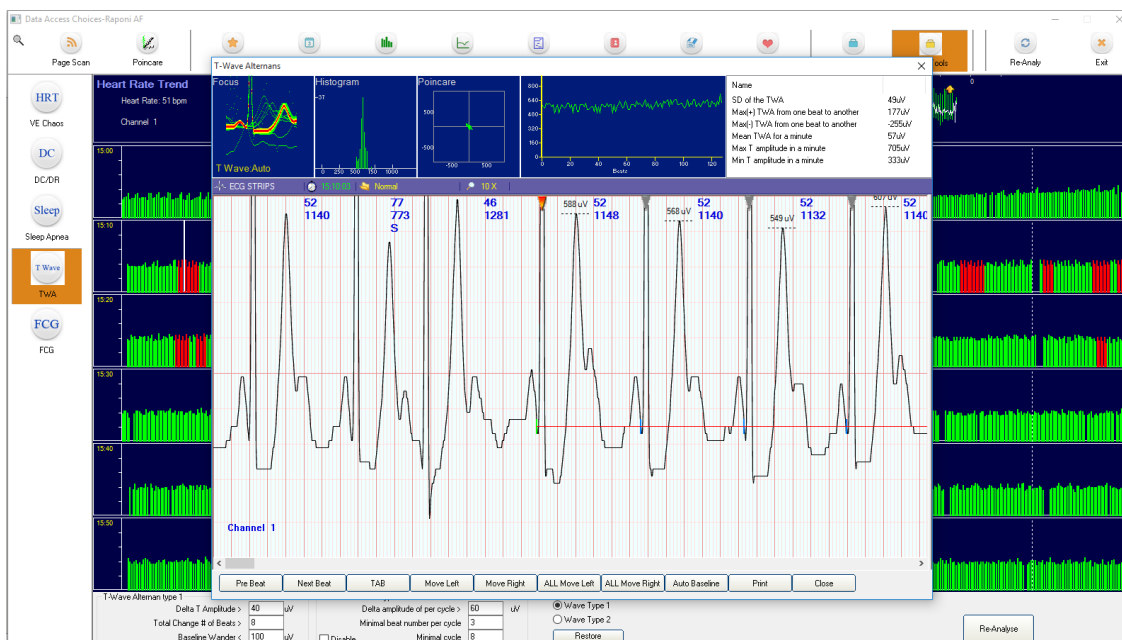
The Histogram Bar Graph next to the ECG superimposition shows the simple distribution of T-Wave height in micro-volt levels. The wider the bar graphs, the more the T-Wave Alternans.

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

The Beat-to-Beat Graph next to the Poincare Plot shows the T-Wave height of each successive T-Wave. This is the key analysis detection feature. The more jagged the graph, the more the T-Wave Alternans. When you see an up-down-up-down trend that looks like 50-60 cycle interference, there is a likely T-Wave Alternans event.

Use the right mouse click on the 8-second ECG strip to select the channel with the largest and cleanest T-Wave.

To expand/reduce the size of the T-wave, press on the +/- keys.



The above screen shows a 10x expansion (the expansion helps us to better visualize changes in T-Wave peaks). The expansion number is noted on the purple bar above the strip in the middle of the screen. Please note that as you expand, the size of the ECG may exceed the size of the window. Just point, click, and drag to move the ECG for better viewing.

Set the green cursor on the beat at either the P-R Baseline, J-Point, or end of the T-Wave. To do this, click on "Move Left"/"Move Right". To move the corresponding blue cursors found on subsequent and

preceding beats, click on “ALL Move Left”/“ALL Move Right”. Next, click on “Auto Baseline” to straighten the baseline.

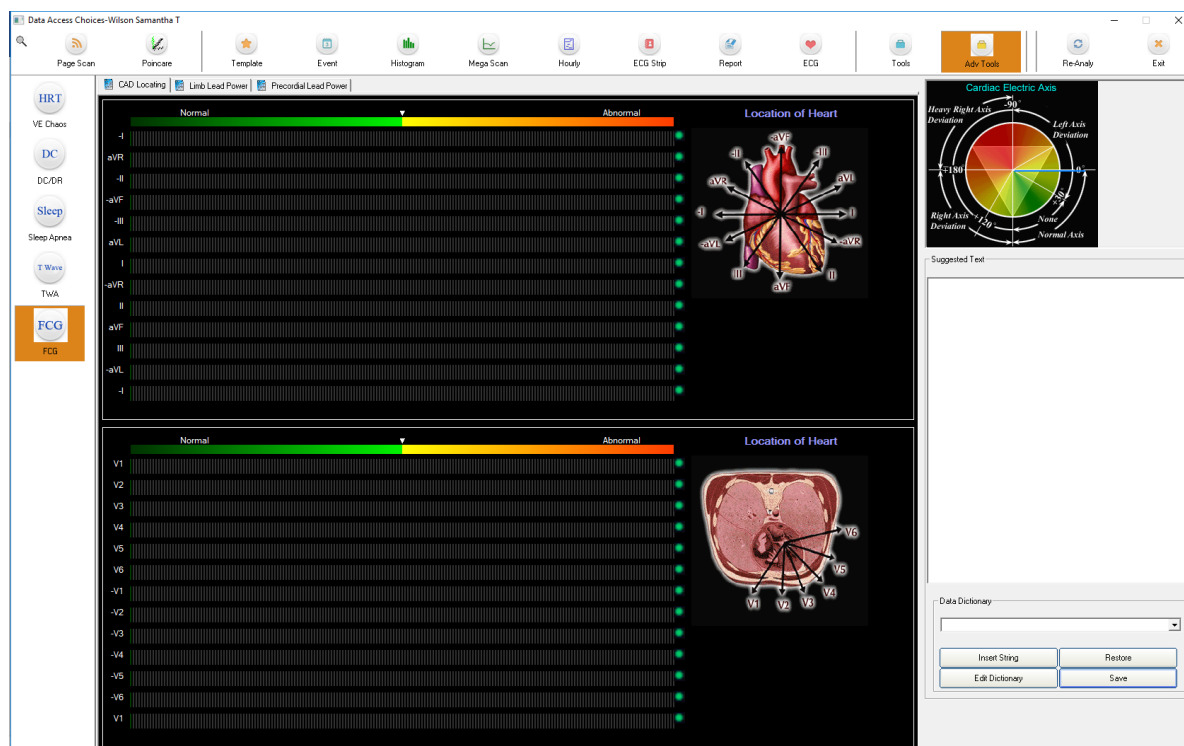
Click on “X” to exit and return to the main TWA screen.

FCG (Frequency ECG Analysis)

The purpose of the FCG test, widely used in China, is to detect and locate blockages in coronary arteries in the absence of a patient exercise component. While traditionally Holter has been limited in detecting CAD (coronary artery disease) in the absence of exercise, the FCG test – combined with 12-lead ST analysis – significantly increases the detection of CAD. Thus, the FCG test must be conducted using only a 10-electrode, 12-Lead Holter recorder such as the DMS 300-4A or DMS 300-4L.

Click on the “FCG” icon and you will see the “CAD Locating” display.

- CAD Locating



The CAD analysis function attempts to identify the location of CAD and myocardial ischemia. The user should review the distributions along the 12-lead ECG power spectrum (positive and negative). If any values exceed the green ranges (beyond the mid-point of the color bar), it indicates the possibility of an abnormality in that lead. A combination of abnormalities in various leads may indicate different ischemia locations.

The following table provides a reference for suggested ischemia locations.

Table: Ischemia Location Description	
Leads	Location
V1+V2+V3+V4	Anteroseptal
V2+V3+V4+V5	Anterior
II +aVF+V1+V2	Inferior Posterior
I +aVL+V3+V4+V5+V6	Anterolateral
I +aVL+V5+V6	Lateral
I +aVR+aVL+V6	I
II +aVR+aVF	II
III+aVL+aVF	III
I + II +aVR+V5	aVR
I + III+aVL	aVL
II + III+aVF	aVF
V1+V2+V6	V1
V1+V2+V3	V2
V2+V3+V4	V3
V3+V4+V5	V4
V4+V5+V6	V5
V5+V6+V1	V6
V1+V2	Septal
II +aVF	Inferior

More than one of above conditions can be met at the same time.

Please note that if more than 10% of patient beats are abnormal, the FCG analysis should not be performed since these abnormal beats will significantly affect the reliability of results.

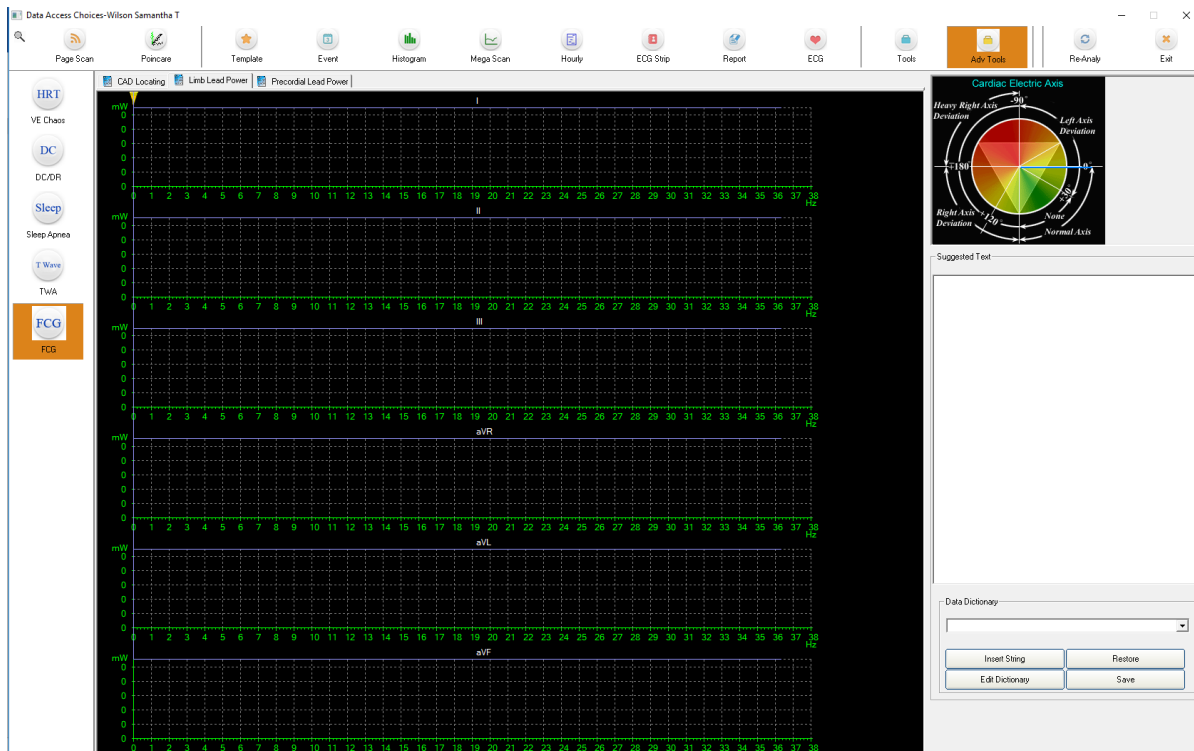
Below is an overview of the various features of the “CAD Locating” screen display.

Table: CAD Locating Diagnosis Screen Description	
Items	Description
A	Cardiac Electric Axis
B	Automatic interpretation. You may also type in your own interpretation. Click “Save” to save changes
C	Data dictionary: Click on the drop-down arrow to select terms from the list. Click “Insert String” to add the selected term to the “Suggested Text” box. Click “Save”

Click “Restore” to return to the previous saved comments.
To add more categories to the data dictionary, click on “Edit Dictionary”

- Limb Lead Power

Click on the “Limb Lead Power” tab at the top of the screen to access the display below.



Power Spectrum is a frequency analysis of ECG power, namely a power distribution of the ECG signal over each frequency. The graph shows Power in mW (vertical axis) versus Frequency in Hz (horizontal axis). The graph is displayed from low frequency to high frequency as peaks.

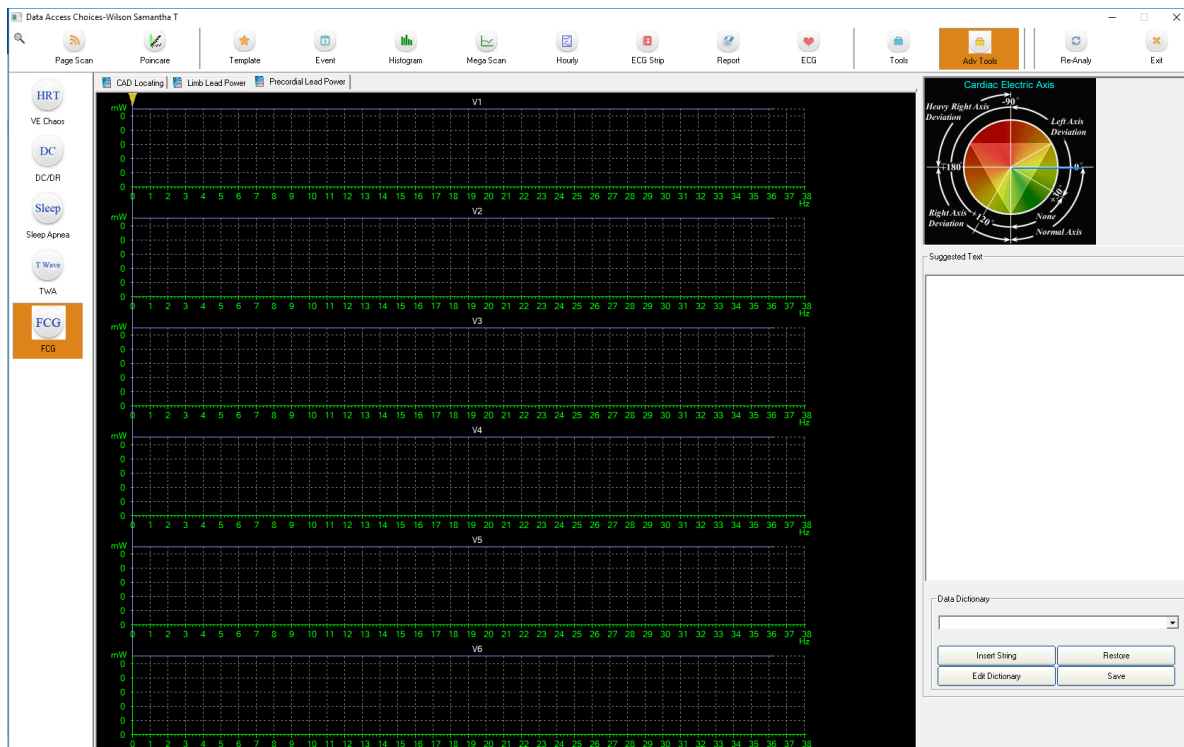
Power Spectrum can provide significant information about arrhythmia, fibrillation, and overall poor myocardial function.

Leads I, II, III, aVR, aVL, and aVF are displayed in six power spectrums. The analysis system automatically provides the first five peak values of the spectrum.

To zoom out, right click anywhere on the graph. Left click to zoom in.

- Precordial Lead Power

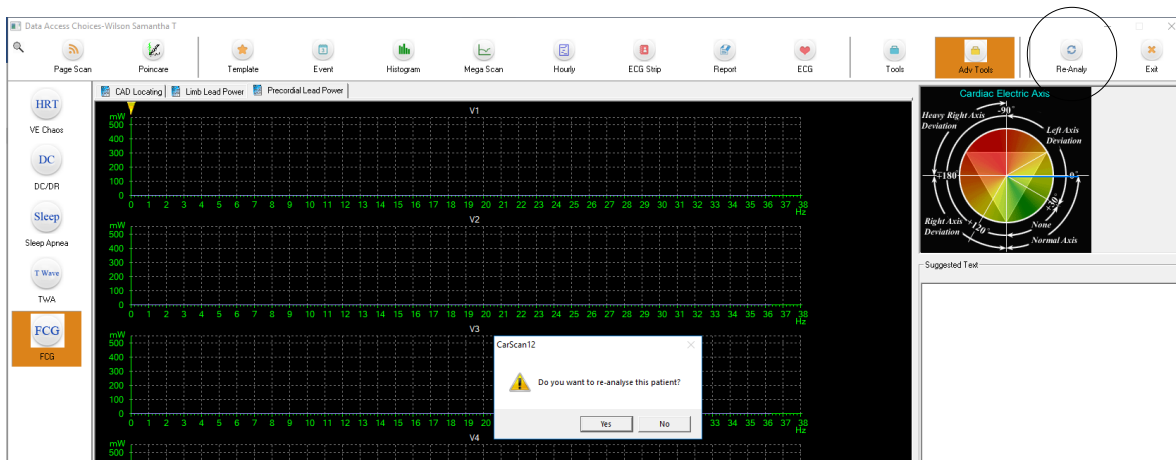
Click on the “Precordial Lead Power” tab at the top of the screen to access the display below.



Leads V1-V6 are displayed in six power spectrums. The analysis system automatically provides the first five peak values of the spectrum.

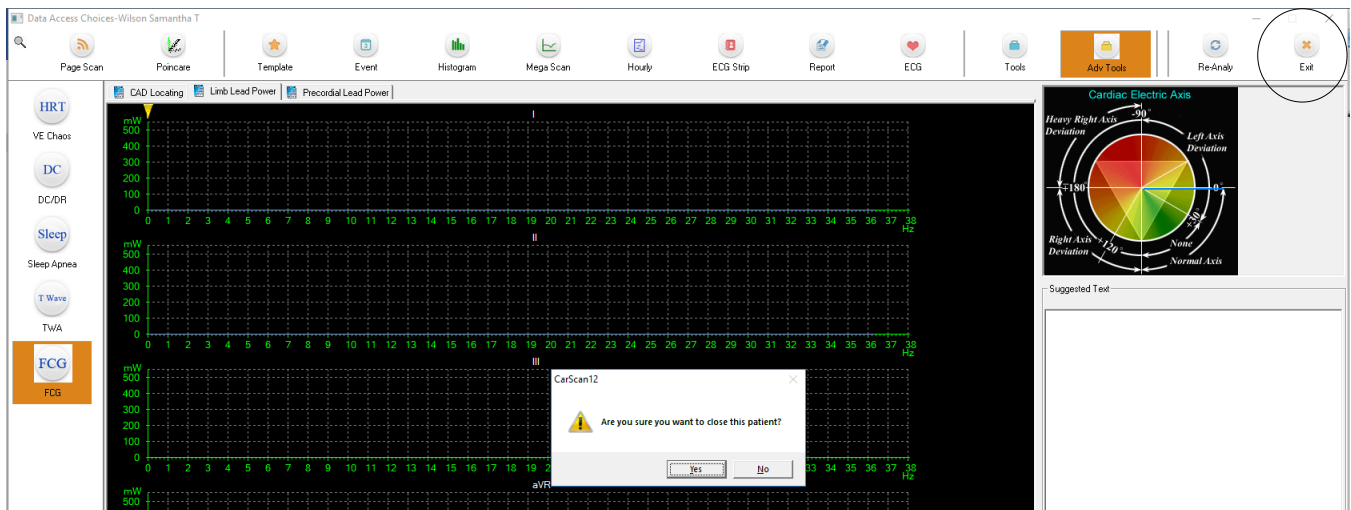
To zoom out, right click anywhere on the graph. Left click to zoom in.

N. Re-Analysis (Refer to Section V and Section VI – B)



- On occasion the user may wish to re-analyze the Holter recording. Reasons for this include selecting different sample points for the ST-QT analysis, or placing the primary analysis focus on different channels, etc.
- To start the re-analysis process, click on the **Re-Analy** icon in the Data Access Choices menu
- A pop-up window will appear confirming the request to re-analyze the patient file. Click “Yes”

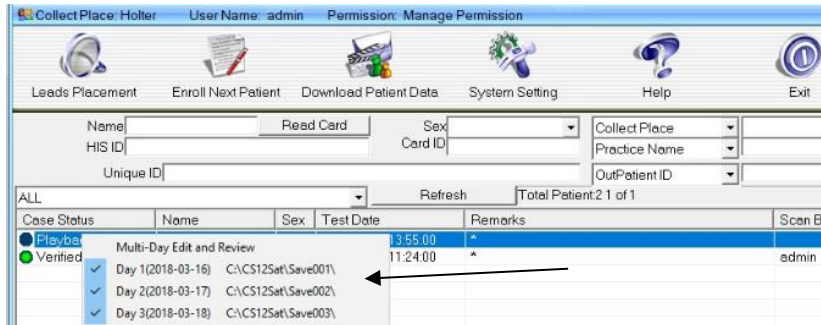
O. Exit



- Click on the **Exit** icon in the Data Access Choices menu to return to the main patient list
- A pop-up window will appear confirming the request to exit. Click “Yes”

P. Note on Multi-Day Reporting Functionality

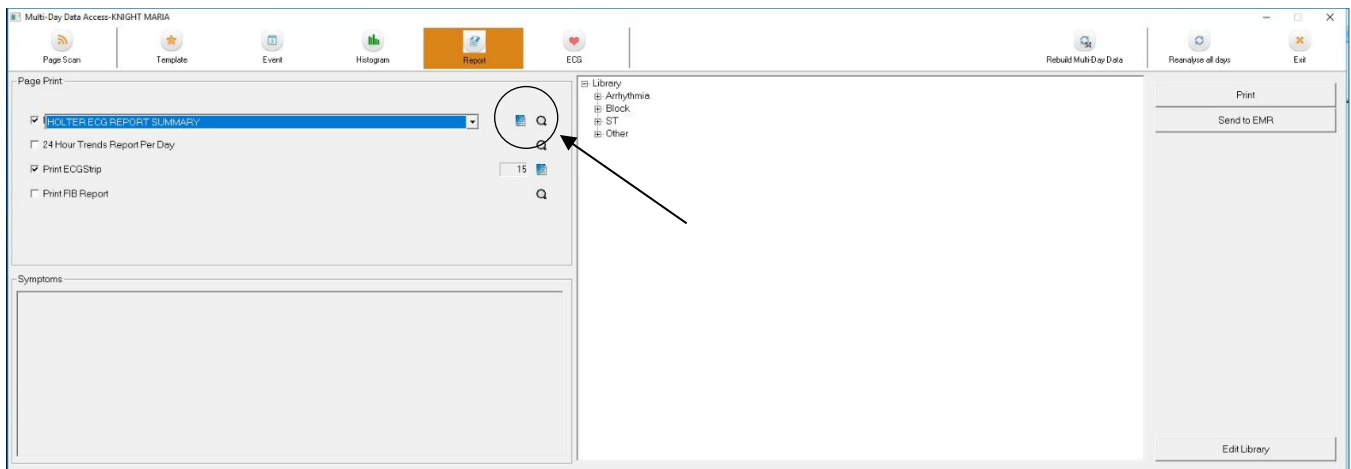
To access multi-day report and edit functions, double-click on a patient name in the main patient list. If there are multiple days of recorded ECG data, the menu below will appear.



Click on “Multi-Day Edit and Review” to enter the **Multi-Day Data Access** menu. As you can see below, this menu is similar to the Data Access Choices menu but with fewer options.



While most features in the Multi-Day Data Access menu work the same way as they do in the Data Access Choices menu, let us focus on some notable differences in the **Report** function.



The first selection in the Page Print menu is “Holter ECG Report Summary”. When first entering the Report function, the edit button circled above will appear gray to indicate that no editing of this report has occurred. Once the user has edited this report, the button will change from gray to blue.

It is important to note that if this button is gray, all edits/changes made to the patient file will be reflected in this report. However if this button is blue, any edits/changes will not automatically update in the report. In order to update, click on the button and you will see the window below:

Summary Page Edit

Heart Rate		Ventricular Ectopy		Heart Rate Variability	
Minimum HR-4 Intervals:	44 bpm at 01:344	VE Total	2	3/16	2021697.3
Maximum HR-4 Intervals:	107 bpm at 01:10:25	V/Run Total	0	3/17	272370.0
Average HR-24 Hours	64 bpm	vVCT Total	0	3/18	1087023.1
Minimum HR-Hourly		Max vVCT Duration	N/A	3/19	N/A/N/A
Maximum HR-Hourly		Max HR in vVCT	N/A	3/20	N/A/N/A
Averaged Beat:	59604	Min HR in vVCT	N/A	3/21	N/A/N/A
Analysed Minutes:	1596	45's per 1000 and per Hour	1.7	3/22	N/A/N/A
ECG Monitoring Period	72 hours 0 minute	VE Burden%	N/A		
		Ventricular Run %	N/A		

ST Segment Analysis		Supraventricular Ectopy		Pauses and QT	
Total ST Minutes CH1:	0	SVE Total	186	Pauses in Excess of 2.50 sec:	0
Total ST Minutes CH2:	0	S/Run Total	0	Max Pause:	N/A
Total ST Minutes CH3:	0	Longest S/Run	N/A	Max QT:	462 ms (Ch. 1)
Max Delta ST Depression	N/A	Max HR in S/Run	N/A	Max QTc:	400 ms
Max Delta ST Elevation	N/A	SVE's per 1000 and per Hour	3.0	Time of Max QTc:	at 01:18:43 HR (6) bpm
Max ST Ectopic	N/A	SVE Burden%	0.0	IdexV	N/A
Max HR in ST Ectopic	0	Total Slowest Beats/Run	0.0		
		AF Burden%	0.0		

Physician Comments:

Edit Library

Restore to Default Value

Save

Close

Once changes have been made, click on “Restore to Default Value” to save.



The second selection in the Page Print menu is “24 Hour Trends Report Per Day”. This allows the user to select individual days for printing daily ECG trend reports.

Multi-Day Data Access-KNIGHT MARIA


Page Scan | Template | Event | Histogram | **Report** | ECG


Rebuild Multi-Day Data | Reanalyse all days | Exit

Page Print

☒ **HOLTER ECG REPORT SUMMARY**  

☐ 24 Hour Trends Report Per Day

☒ Print ECG Strip 15 

☐ Print FIB Report 

Symptoms

Library

- ☒ Arrhythmia
- ☐ Block
- ☐ ST
- ☐ Other

Print

Send to EMR

Edit Library

The last two selections in the Multi-Day Data Access menu Report function – “Print ECGStrip” and “Print FIB Report” – allow the user to print a pre-determined number of saved strips and a summary A-Fib report, respectively.

VII. Recommended Editing Process – General Observations

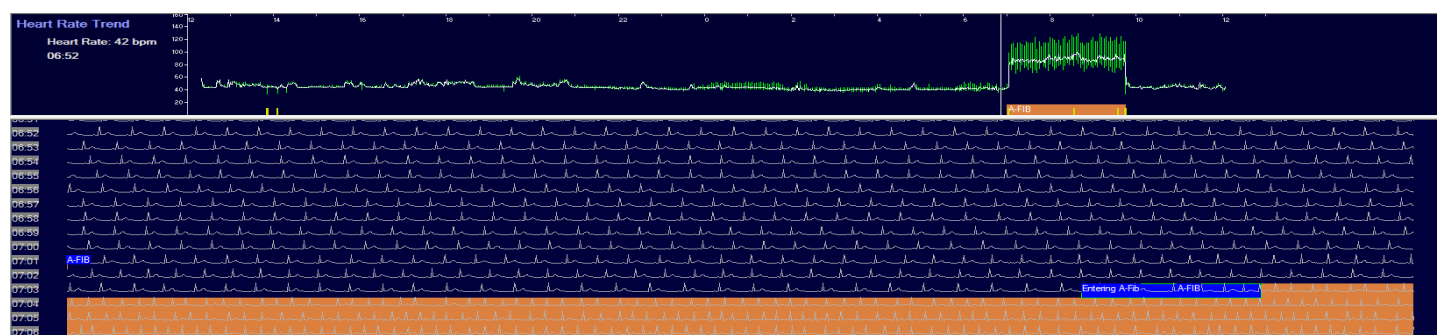
A. Quick A-Fib Review

The recommended first step in editing a Holter file is to determine whether the patient had an A-Fib episode. The vast majority of the time, there is no A-Fib episode during the Holter recording.

Within the Data Access Choices menu, Page Scan allows the user to quickly see if the patient experienced A-Fib (see below):



In contrast to the example above, below is an example of A-Fib.



The top Heart Rate (HR) trend displays classic A-Fib. The average HR shows a sudden and significant increase. The green vertical lines for each minute display the min and max HR in that minute. The Sinus rhythm minutes have very short vertical green lines, but the A-Fib minutes show long green lines indicating substantial changes in min and max HR.

You will see an orange bar underneath the A-Fib event in the HR graph. If the orange bar is not present, then a mouse click and drag will generate an orange bar in the HR graph.

While actual editing and verification of the A-Fib episode is performed elsewhere in the software, it is important to first know the patient's A-Fib status, so as not to waste editing time on SVE beats.

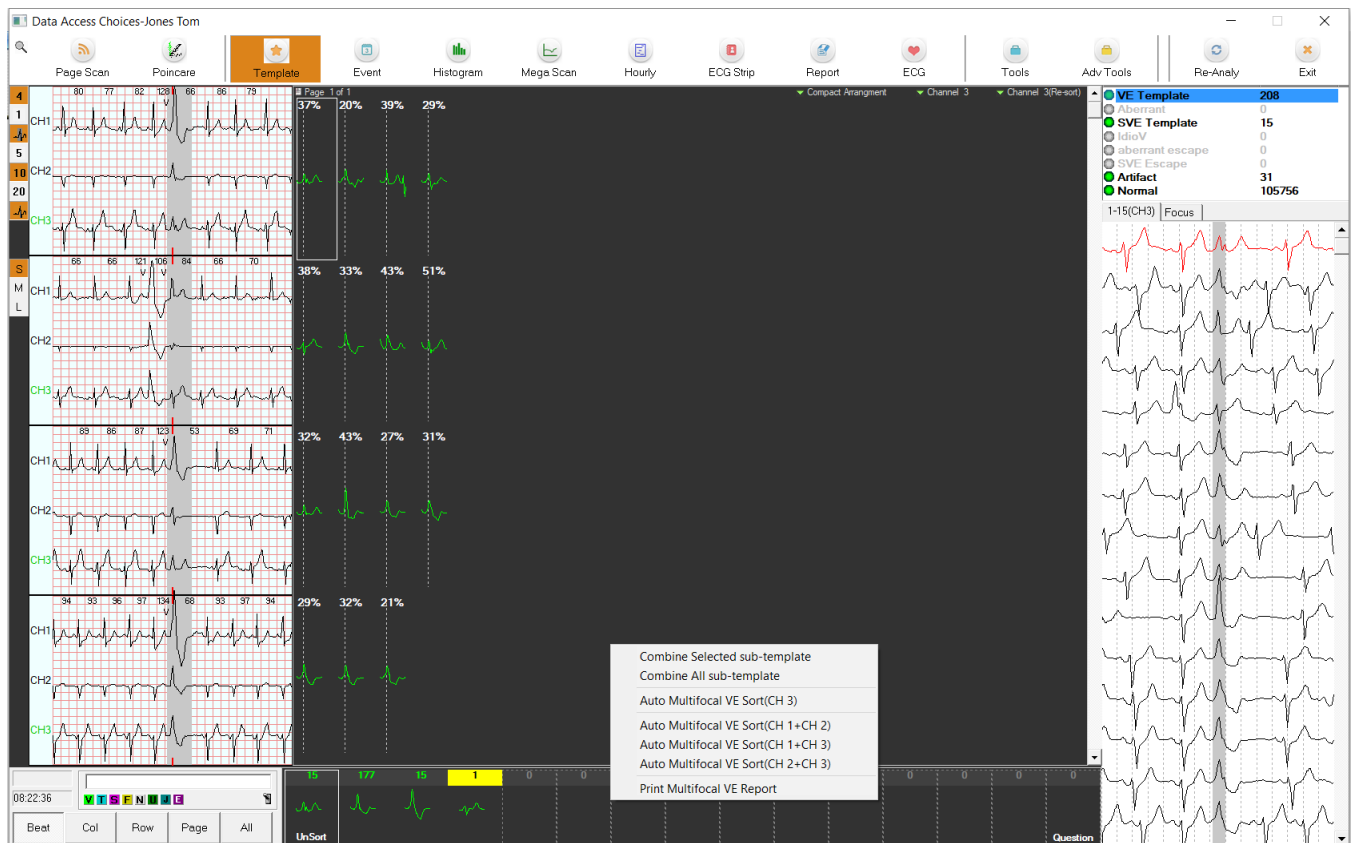
If, indeed, there is A-Fib, click on the "Remove SVE" icon. This will delete the SVE label, and counts, for all such beats during A-Fib episodes.

Assuming there are no A-Fib episodes, the next step is to go to the "Template" tab in the Data Access Choices menu for editing arrhythmias (see Section VI: D).

B. Editing "Rules of Thumb"

Note: This assumes that you have first determined that there were no A-Fib episodes.

1. Click on the "Template" tab (also refer to Section VI: D)



2. Edit the VE, SVE, and IdioV Templates (most of the effort put into editing a Holter file is in the Template editing process)
3. Sometimes significant arrhythmias can be found in the Artifact and Normal Templates

- After completing the Template Editing process, go to the “Event” tab (see Section VI: E)



- Review each Event category
- If you see mistakes in the Event categories, you can either correct the mistakes or label them Artifact.
- After you have completed the Event review, you can direct the program to print the first, or first two or three, ECG Strips for each Event category in the Final Report (except for the Minimum and Maximum Heart Rate)
- Sometimes, the presence of an AV Block will show itself when reviewing the various ECG strips in the Event Category – Minimum Heart Rate
- Sometimes, the presence of A-Fib and ST Depression will show itself when reviewing the various ECG Strips in the Event Category – Maximum Heart Rate. Note that there are separate analysis programs for the detection of A-Fib and ST Depression
- Then, proceed the “Report” tab, and select what you want displayed and printed in the Final Report (see Section VI: J)

11. For significant ECG events, there are various print routines such as: 3-Lead ECG, 6-Lead ECG, 24-second standard-size ECG Strips, 96-second ½-size 3-Lead ECG, 1-Lead 1-minute ECG, and 1-Hour Full Disclosure
12. Note that the editing process is essentially the same, whether it is a 24-Hour Holter ECG or a 30-day Holter ECG
13. Also, the storage and retrieval of Holter ECG files is the same, whether a 24-hour Holter ECG or a 30-day Holter ECG

VIII. Navigating the Database

In this section, we will provide a quick overview of the functionality of the database.

1. The database system allows each user to customize how they view, sort, organize, search, and access patients. The portion of the main patient screen highlighted by the arrow below displays the various data fields that can be used to accomplish this.

Case Status	Name	Sex	Test Date	Remarks	Scan By	Intp. By	Type	Dir
Printed	Printed Patient		27/02/2018 12:00:00		admin	admin	3-Leads[02:00]	C:\CS125a\Save027\
Verified	Verified Patient		27/02/2018 11:00:00		admin	admin	3-Leads[02:00]	C:\CS125a\Save028\
Concluded	Concluded Patient		27/02/2018 18:00:00		admin	admin	3-Leads[02:00]	C:\CS125a\Save029\
Playedback	Downloaded Patient		27/02/2018 00:01:00				3-Leads[02:00]	C:\CS125a\Save024\
Reserved	Enrolled Patient		27/02/2018 16:13:00					C:\CS125a\DMSECG2\

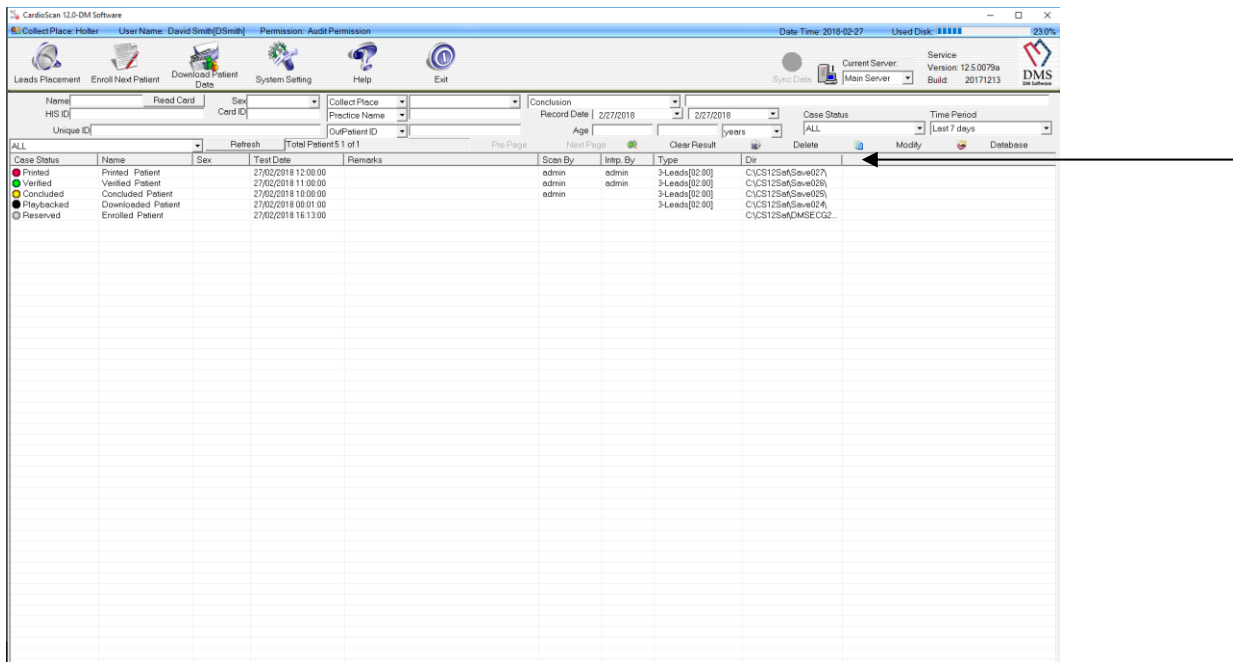
2. The illustration below is a magnified version of these data fields. We will briefly summarize each.

Name	Read Card	Sex	Collect Place	Conclusion	Record Date	Age	Case Status	Time Period
HIS ID	Card ID		Practice Name	Record Date	2/27/2018	2/27/2018	ALL	Last 7 days
Unique ID			OutPatient ID					

- a. Name: Search for a patient by name.
- b. HIS ID: Search for a patient by Hospital Identification number.
- c. Unique ID: Search for a patient by their DMS database-assigned ID number. These are automatically generated, and generally correspond to a “Facility/Department/Year/Date/Time” format.

- d. "All": This toggle button allows the user to view patients from only a selected facility. Use the drop-down box to select the facility.
- e. Sex: Sort patients by gender.
- f. Card ID: Search for a patient by a card identification number.
- g. Refresh: Allows the user to refresh the database to view any new patients or adjustments.
- h. "Collect Place": This is a toggle button. The user can select Collect Place, Collect Doctor, Scan By, or Interpretation By as the condition. The drop-down box immediately to the right of the toggle button will automatically populate with the relevant fields for each condition. The user can sort patients accordingly.
- i. "Practice Name": This is a toggle button. The user can select Practice Name, Order MD, or ICD-10 (US-specific) as the condition. These fields correspond to those entered for each patient in the patient demographic information screen.
- j. "OutPatient ID": This is a toggle button. The user can select OutPatient ID, Area ID, Hospitalized ID, Bed ID, Patient ID, Security ID, or Medication ID. These fields correspond to those entered for each patient in the patient demographic information screen.
- k. Total Patient: This shows the total number of patients currently on the database, as well as the page list number currently being viewed.
- l. "Conclusion": This is a toggle button. The user can select Conclusion or Symptom/Indication, and then search the database for patients with certain keywords in their observations/conclusions.
- m. Record Date: Can search for patients within a specified date range.
- n. Age: Can search for patients of a certain age (or months/weeks for pediatric patients).
- o. Clear Result: Allows the user to reset the database from the current search.
- p. Case Status: Can sort patients based on their case status indicator.
- q. Time Period: Can view patients based on a given time frame (i.e., Today, Yesterday, Last 7 Days, This Week, This Month).
- r. Delete: Allows a user (with appropriate permissions) to delete a highlighted patient.

- s. Modify: Allows a user to modify a patient's demographic information.
 - t. Database: Allows the user to import or export patients from the database. The user can also print a patient list.
3. The arrow below highlights the default data fields displayed for every patient in the database. These can be adjusted as the user sees fit.



4. To adjust, click on the System Settings icon in the upper left of the main patient screen, and select "Custom Settings".
5. You will now be able to select from a variety of Patient List Options. Check on those you wish to display on the main patient screen. When finished, click OK.
