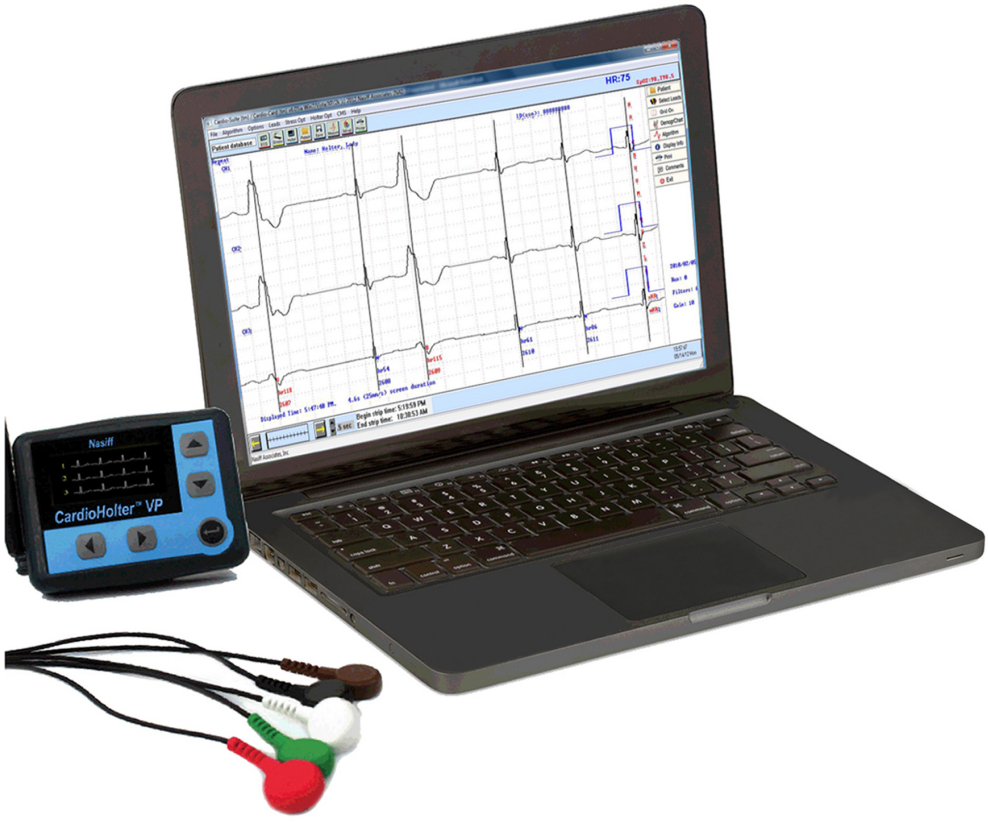
Nasiff Associates CardioCard™

CardioHolter B12™

D2002005_IFU_H_B12_V7_(09/18/2023)

User's Guide

One System does it all: 12-lead interpretive ECG, Stress, Holter, EC G Bluetooth®, Vital Signs, N IBP, Sp O_2, Temperature, W eight, G lucose, Spirometry, S tethoscope, Mobile Device, Patient Record Management, etc.



REV7(09/18/23)

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Brewerton, New York.

FOR CUSTOMER SUPPORT

GO TO CARDIOCARD

CLICK ON HELP

MAIN HELP MENU

CLICK ON THE SECTION YOU NEED

www.nasiff.com

SERVICE & SUPPORT

ONLINE HELP

CALL US

315-676-2346

CUSTOMER SERVICE

IS AVAILABLE

MONDAY - FRIDAY

9:00 AM TO 4:00 PM

EASTERN STANDARD TIME

Nasiff Cardio Holter ECG

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The intended use and relationship of the Cardio Card Products.

Cardio Card is the brand name of the family of Cardio products marketed as Cardio Resting ECG, Cardio Stress, Cardio Holter and Cardio Vitals NIBP. The product has buttons in its user interface that allow all of these tests to be done in a common screen for ease of use. All Cardio Cards come with a small electronics box that acquires the ECGs (and NIBP for units using NIBP), a software CD, patient connection cables, and manual.

In all cases, the system is used to determine the Cardiovascular condition of patients. Medical professionals use this information to determine if a patient has Cardiac disease and if so, the extent. For example, if a resting ECG shows abnormal V5, V6 leads that indicate Left Myocardial Infarction (LMI), the clinician knows to look closer at that part of the heart. This may show also in other leads (e.g. V3, V4) during stressing the patient that will tell the clinician that the anterior part of the heart is also in danger. If the patient is elderly and not a candidate to stress, they may put the Cardio Holter on for the patient to wear all day. The change that came during stress may show then, indicating the same possibility. Cardio Holter is also good for detecting intermittent complaints such as chest pain, palpitations, etc that may occur during the day or at night.

The intended use of the **Cardio Resting ECG System** is to diagnosis ECG medical conditions that are primarily detections of normal and abnormal ECG wave forms during rest. The systems are used to find the cause of chest pain or pressure etc., to diagnose heart attacks and rhythm problems, and to obtain clues about other heart conditions. The main diagnosis categories are blocks, MI's, axis deviations, enlargements, and arrhythmias. A full list of interpretive statements is in the Cardio ECG manual. Typically these tests are only for about 10 seconds, but long term recordings can be used as well to follow rhythm. The patient is first typically attached with tab electrodes to the PC connected Cardio Card device and then Start ECG is selected to view the ECGs. There are buttons to store and print as well.

The intended use of the **Cardio Stress Systems** is to diagnosis ECG medical conditions that are primarily the same detections that didn't appear in a patient resting ECG test, but may show while stressing the patient for a few minutes and after stressing (recovery). It is used for patients who have been experiencing chest pains or other symptoms of coronary heart disease. It also helps to determine if the heart is receiving enough oxygen and has proper blood flow when it needs it the most, such as when the patient is stressed/exercising. The patient is first attached to the PC connected Cardio Card device with snap type electrodes in similar positions to the resting ECG test described above. The test is started with a button being pressed that stores a resting baseline ECG and then a button is pressed to stress the patient. The baseline resting ECG is compared to the stressed ECGs over time. When the patient is done being stressed, the patient is then allowed to go back resting post test (recovery). The ECGs are normally recorded during recovery as well to be sure the patient recovers well or to detect that the heart is not recovering well.

The intended use of the **Cardio Holter System** is to diagnosis medical conditions that are primarily detections of ECG rhythm abnormalities (such as VE beats, Afib, bradycardia, tachycardia, etc) that may

not be caught by shorter tests like the resting or stress ECG testing. A Cardio Holter monitor is a battery-operated portable device that measures and records the heart's activity (ECG) continuously for usually 24 hours or longer while you do daily activities. The main diagnosis categories are Arrhythmias such as VEs (ventricular ectopics), Atrial fibrillation, SVEs (supraventricular ectopics), tachycardias, and bradycardias, etc.

The intended use of the **Cardio Vitals NIBP** is primarily to measure ECG and blood pressure by use of a typical reusable arm cuff. NIBP is typically in millimetres of mercury (mmHg) pressure units and is given as two figures: systolic pressure (the pressure when the heart pushes blood out) and diastolic pressure (the pressure when the heart rests between beats). If the blood pressure is too high, it is putting extra strain on the arteries and on the heart. This may also cause complications such a heart attack, stroke, kidney problems, and vessel damage. If the blood pressure is too low, there is not enough pressure to get blood to all cells of the body and therefore they can die.

These devices can be used multiple times.

The intended users are medical professionals such as physicians, nurses, medical technicians, etc.

The systems are sold as packages and users can buy the supplies locally as they are standard industry wide.

CARDIOCARD® System: USER Interface Manual

WELCOME and thank you for sharing our vision for PC-Based Diagnostics

The CardioCard® System is the most advanced medical instrument available. With this system you can acquire and manage in your databases multiple diagnostic tests for multiple patients over long time periods.

Tests performed and managed by the CardioCard® include:

- Interpretive 12- lead ECG (when running the ECG interpretations, please note the following: no automated analysis is completely reliable and a physician should over read the ECG)
- Stress Testing ECG System
- Holter Monitoring ECG System
- Non-invasive Blood Pressure System (NIBP)

Your interest in our PC-Based ECG Diagnostic Systems indicates that we share the same VISION for ECG Cardiology and for that matter many other Diagnostic Tests.

Namely, by merging the superior ECG Diagnostics of the CardioCard® with the power and flexibility of a PC, Notebook or Tablet, an "unbeatable partnership is formed"!

Nasiff Associates believes that while the innovation of ECG Technology has been significantly enhanced over the years, similar progress has **not** been demonstrated with regard to the "Device" dimensions of the product, and still furthers its ability to integrate into today's medical "System" environment.

Today, it is no longer acceptable for an ECG Recorder "just to take an ECG". Physicians and their Business Administrators want and expect diagnostic equipment to not only compliment the respective medical application, but to successfully integrate into the business aspect of the practice as well.

Nasiff Associates with its CardioCard® System is positioned to offer the Physician USER its **CardioSuite®** PC-Based Devices with FDA 510K and ISO Registrations:
The CardioSuit® with WINDOWS or iOS* "Point and Click" USER Interface includes:*

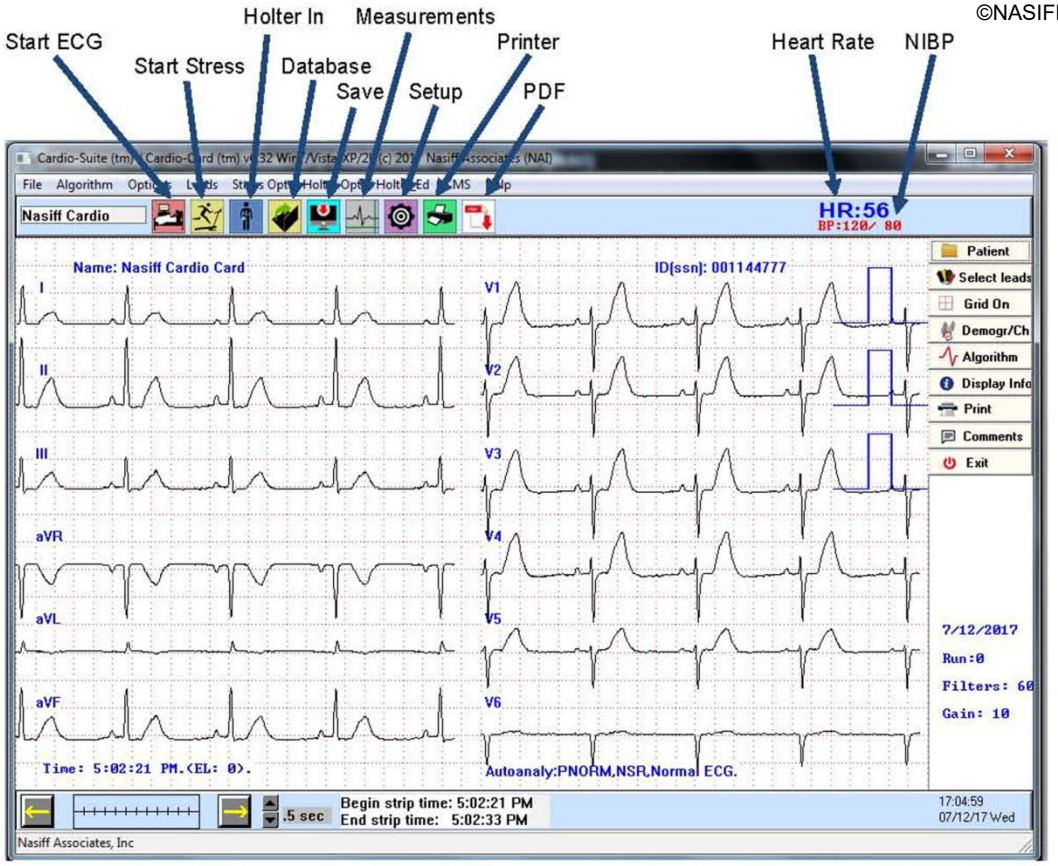
- CardioCard® Software
- Resting ECG Device
- Exercise Stress Testing Device (treadmill can be included upon request)
- Holter Monitoring Diagnostic Device (cassette, digital or BOTH, 3 Lead, Full Disclosure Recorder(s))
- Non-Invasive Blood Pressure and many others...
- **ALL Test Data seamlessly integrates into an inclusive Database and Clinical/Telecommunication Management System**

By merging the diagnostics of the CardioCard® System with the power and low cost of the PC, Nasiff Associates is able to offer **more features at a lower price** than any other ECG System on the market today! Don't forget, **ALL** CardioCard® Diagnostic Modules come with their own "Paperless" **DataBase Clinical Management System** solution, which allows virtually unlimited Patient ECG Record Storage, Networking, Batch ECG Transmission, Electronic Measurement Calipers, Full Complex Measurements, Fax, Modem and **Internet** transmission capability and much more. AND, as you add more CardioCard® Diagnostic Modules, your existing DataBase **seamlessly integrates** the new diagnostic data into your existing DataBase.

Finally a Diagnostic System that your practice can grow into, NOT OUT OF!

~ If your IT Department is going to make changes on your computer make sure they inform you and when they are done please test the Nasiff Cardio Card completely to make sure it is still working fine ~

***** CardioCard® Systems run on **WINDOWS** XP, Vista 32/64 bit, Windows 7, Windows 8, Windows 10 and **iOS** with Boot Camp, Dual Boot, VMware Fusion or Parallels...



<u>During Test:</u>

F8 – Start Acquisition, ECG (1st time)
F1 – Help
F2 – Start / Stop NIBP Cycle
F3 – Store
F4 – Print
F7 – Log time of event
F8 – Read in from Scale (after Acquisition has started)

F9 – Start Stress test

F10 – Change ECG time base
F11 – Change ECG gain
F12 – Change leads viewed

<u>During Retrieve / Database:</u>

F1 - Help
F2 – Open Holter edit beat box
F3 – Go to next Holter arrhythmia
F4 – Print graph report
F5 – Print / View Summaries
F6 – Store measurements, interps, edits
F7 – Run autoanalysis
F9 – View interps / measurements ECG & Stress
F10 – Change time base

F12 – Change leads viewed
Backspace – toggle measure cursors
Alt-m – set measurement cursor datum

During Holter Retrieve:

Alt-F3 – next patient event.
Alt-v – next ventricular beat
Alt-s – next SVE beat
Alt-r – next RonT beat (or special pause)
Alt-f – next Tachy
Alt-a – next Atrial Fib

Cntl-F3 – next not normal beat.
Alt-t – next VE Run (Triplet)
Alt-w – next SVE Run
Alt-q – next Tachy Run
Space bar – scroll on or off

Alt-k – next Pause
Alt-o – next unknown beat
Alt-l – next Brady
Alt-Z – next Brady Run
Ctrl-F5 – Print list of events

Control-F2 – Scroll / Step through event list on screen
Control-F1 – Start event list at beginning
Home key- brings you to the beginning
Delete beat- click on the beat once then hit the delete key

The Purpose of Holter Testing

is to get the Patient's Arrhythmia Condition

A clinically high count of certain arrhythmias can indicate concern for the patient's heart condition

We are looking for the abnormal significance of the patients results, and conditions

Example: Too many pauses, PVC's, Brady's etc… Would indicate further concerns

Nasiff CardioHolter ECG

Package Contents:

Figure 1
CardioHolter
Digital Holter
ECG Monitor

Figure 2
CardioHolter
ECG
Lead Wires

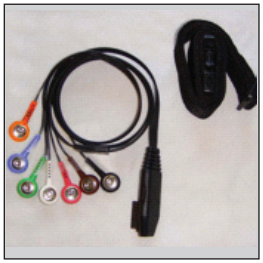


Figure 3
CardioHolter
Pouch
and Belt

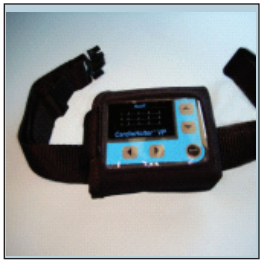


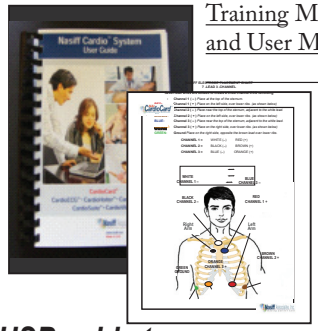
Figure 4
SD Card

Figure 5
USB Flash
Card Reader

Figure 6
USB Security
Key

Figure 7
CardioCard
Software CD

Figure 8
Training Materials
and User Manual



NOTE: ***Do not plug in USB key or USB cable to your computer until installation of software is complete***

Please follow all installation instructions for the Holter ECG Monitor carefully.

Installing CardioCard Software:

To insure an easy installation please closely adhere to the following instructions.

- Place the Nasiff CardioCard software into the DVD drive of your computer. Click on the Windows "Start Button" located at bottom left of your screen, then click on "Computer" with the "CardioCard" software still in the "DVD", RIGHT click on the "DVD drive"
- Click "Open" and scroll down to "Setup" -- double click on "Setup" --if prompted, select "Continue" and "yes" to all. When finished click on "Installed Correct"
- Remember the CardioCard software does not need the internet to install
- When the installation is complete you will see the Nasiff icon appear on your desktop

BEFORE STARTING ALLOW EXCEPTION FOR CARDWIN, CARCOM, AND CAR12WD FOLDERS IN YOUR ANTI VIRUS. ALLOW FULL CONTROL FOR CARDWIN, CARCOM AND CAR12WD.

Installing USB Security Key:

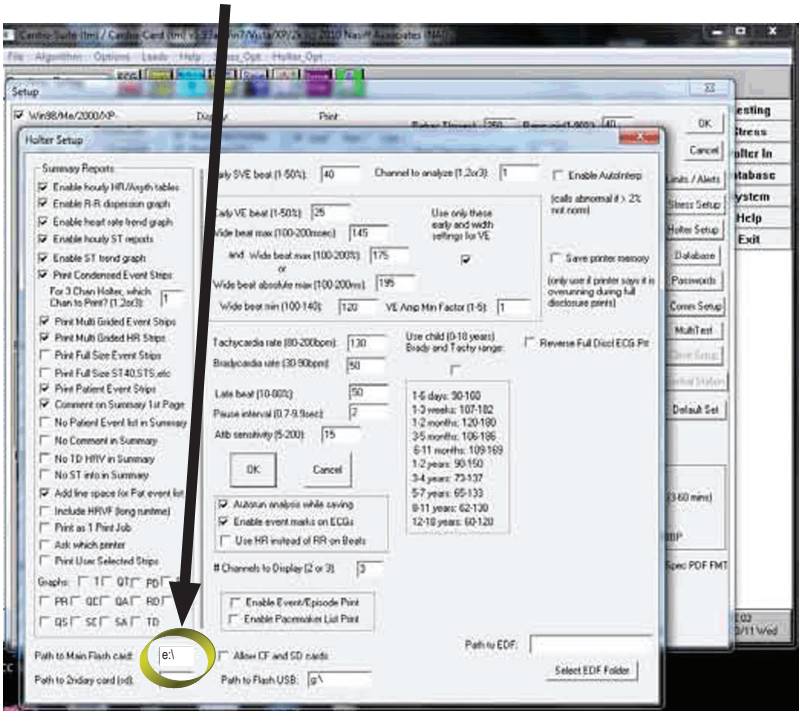
- Click on the Windows "Start Button" located at bottom left of your screen, then click on "Computer" with the "CardioCard" software still in the "DVD", RIGHT click on the "DVD drive"
- This will open a drop down view, click on "Explore" or "Open". Inside the DVD you will see many files in alphabetical order
- Scroll down to the "Sentinel" install. Double click on the "Sentinel" program and let the program install. Click on "I accept", and "Yes" to all, then click "Finish"
- Plug in the USB Security Key wait a few seconds and the tip will light up green. This will ensure that the installation is complete

Installing Holter SD Flash Card Reader:

- Take the Universal External Card Reader/Writer from package
- Insert cable into card reader and plug into the USB of your computer
- We are now going to find the drive letter that your computer will use for reading in Holter ECG data
- Click on the "Start" button located at the lower left of your computer to bring up menu

Installing Holter SD Card Reader: *(continued)*

- Locate and click on “Computer” or “My Computer”
- In this menu locate “Removable Disks”
- With the Universal External Card Reader/Writer there will be several “Removable Disks” , Example “Removable Disk (E:)”
- Please make a note of the first removable disk letter (**NOTE:** *this can vary between computers)*
- Open the CardioCard software application previously installed on your PC and click on the square “System Setup” *(Purple Icon)*
- On the right side of the Setup menu click on “Holter Setup”
- At the bottom left corner locate “Path to Main Flash Card”



- This path has to match the “Removable Disk” letter from your flash card. If the drive letter is the same click “OK”
- If the drive letter does not match proceed to change the letter here **(e:\)** (**NOTE:** *needs to be in this format* ➞ **e:\)**
- To retain your settings please click on “OK” in center of page
- Then click “OK” at the top right of Setup menu
- You are now ready to read in Holter ECG data

Connecting the Holter Recorder to a Patient and Reading ECG Data into PC:

The purpose of this section is to guide you on how to place electrodes for an effective reading and how to begin the reading process with the Holter Monitor device.

Electrode Placement:

Patient Preparation:
Proper preparation of the patient's skin is absolutely essential to obtain a quality ECG recording.

Prep patient's skin well to reduce artifact and assure good results

Get Familiar with Holter ECG Buttons

Buttons used for Holter ECG

To Start Holter ECG click this button

This will bring up the Holter Recorder data in the "Setup" screen.

Be sure to click "OK" to hold settings

Click on the "System Setup" icon. This is the screen where you can enter the name of your Medical Center and customize your settings. *(display, workflow...)*

Click on the "Holter Setup" icon. This is the screen where you can customize your Holter settings for your Medical Center or testing.

Click on the "Open Database" icon to retrieve an existing patient or test from database. Click on "Open Database" highlight patient and click "Open", then highlight test and click "OK"

Click on the "Printer" icon to show your Holter report on the PC display screen.

Note: ***Without good skin preparation, both noise and artifact will degrade the patient's ECG to the point of being unusable by a physician or office***

- Table 1 -

NASIFF CARDIOCARD™ HOLTER ECG ELECTRODE SKIN PREPARATION and PLACEMENT

1. Gently separate lead wires to provide length needed for creating loop and placing electrodes on patient's chest (do not cut wires).
2. Electrodes should not be used if the gel is dried out or in a liquid state (store electrodes in unopened pouches at room temperature – avoid storage in excessive heat or cold).
3. Do not place electrodes over scar tissue, body protuberances, skin lesions, skin folds or established erythema – adhere electrodes exactly as shown on the Placement Chart.
4. Use disposable razor to shave hair from electrode placement sites.
5. Use the scrub pad to gently prep skin sites – avoid injury or abrasion of skin surface.
6. Remove skin oils with alcohol swabs – let dry completely before applying electrodes – skin oils and trapped solvents can cause skin irritation and loss of electrode adhesion.
7. Open electrode pouch, snap wires on the electrodes and then peel electrode from carrier (discard carriers – they are slippery and should not be left on floor) and apply immediately per the Electrode Placement Chart.
8. Hold electrode firmly in both hands and apply to patient's chest skin by gently pressing down around the outer edge in a circular motion to assure firm attachment to the skin at the sites shown on the Electrode Placement Chart.
9. Make sure gel is in firm contact with patient's skin for proper ECG recording.
10. NOTE: Remove an electrode that is not properly positioned per the Electrode Placement Chart and discard it – use a new electrode and position it exactly as shown in the Chart.
11. Long-Term (LT) Monitoring Electrodes typically may be effectively used for several days if properly applied – duration of use is affected by skin conditions and environmental factors.
12. Position lead wires exactly per color coding as shown on the Electrode Placement Chart.
13. Each of the lead wires must be individually restrained using tape strips to prevent excessive motion (motion causes noise and artifacts in the ECG tracing) – loop the wire slightly near the electrode and tape it to the patient's chest skin.
14. Instruct the patient not to touch the lead wires or the electrodes, not to shower or wet the monitor or electrodes, and to return in 24 hours to have the Holter removed. Holter will automatically stop recording after 24 hours; if return is delayed, remove Monitor.
15. To remove electrodes, lift edge and peel back slowly in a continuous motion – properly discard the removed electrodes – rapid removal of an electrode may injure a patient's skin – if necessary, consider using alcohol to moisten the adhesive-skin interface.

- Figure 1 -

NASIFF ELECTRODE PLACEMENT CHART
5 -LEAD 3 -CHANNEL
VX3

Select the sites for electrode application. The electrodes must be applied over bone or cartilage. Refer to the Electrode Placement Chart below.

RED: **Channel 1, 2 (–)** *Place at the top of the sternum.*

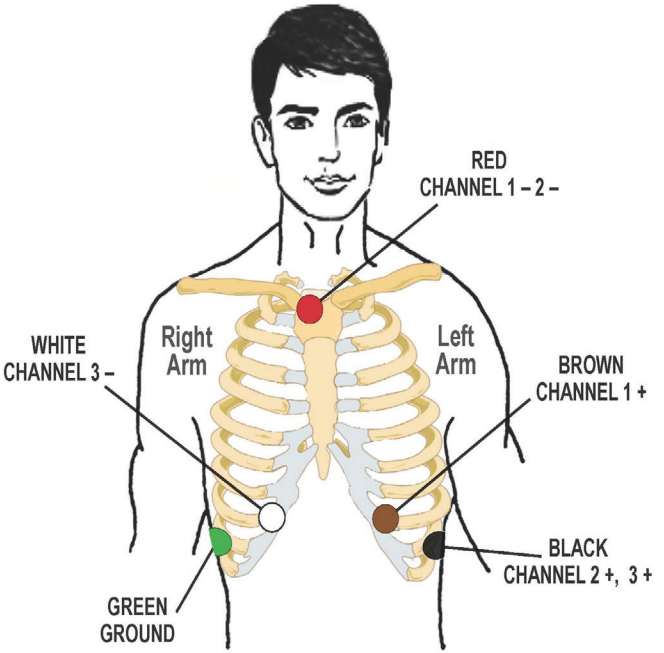
BROWN: **Channel 1 (+)** *Place on the left side, over lower ribs. (as shown below)*

BLACK: **Channel 2, 3 (+)** *Place on the left side, over lower ribs. (as shown below)*

WHITE: **Channel 3 (–)** *Place on the right side, over lower ribs. (as shown below)*

GREEN: **Ground** *Place on the right side, opposite the black lead over lower ribs.*

CHANNEL 1 =	RED (–) ⟷ BROWN (+)
CHANNEL 2 =	RED (–) ⟷ BLACK (+)
CHANNEL 3 =	WHITE (–) ⟷ BLACK (+)



NASIFF ELECTRODE PLACEMENT CHART
7 -LEAD 3 -CHANNEL

Seven lead wires are utilized to create a three channel ECG recording

WHITE: **Channel 1 (–)** *Place at the top of the sternum.*

RED: **Channel 1 (+)** *Place on the left side, over lower ribs. (as shown below)*

BLACK: **Channel 2 (–)** *Place near the top of the sternum, adjacent to the white lead.*

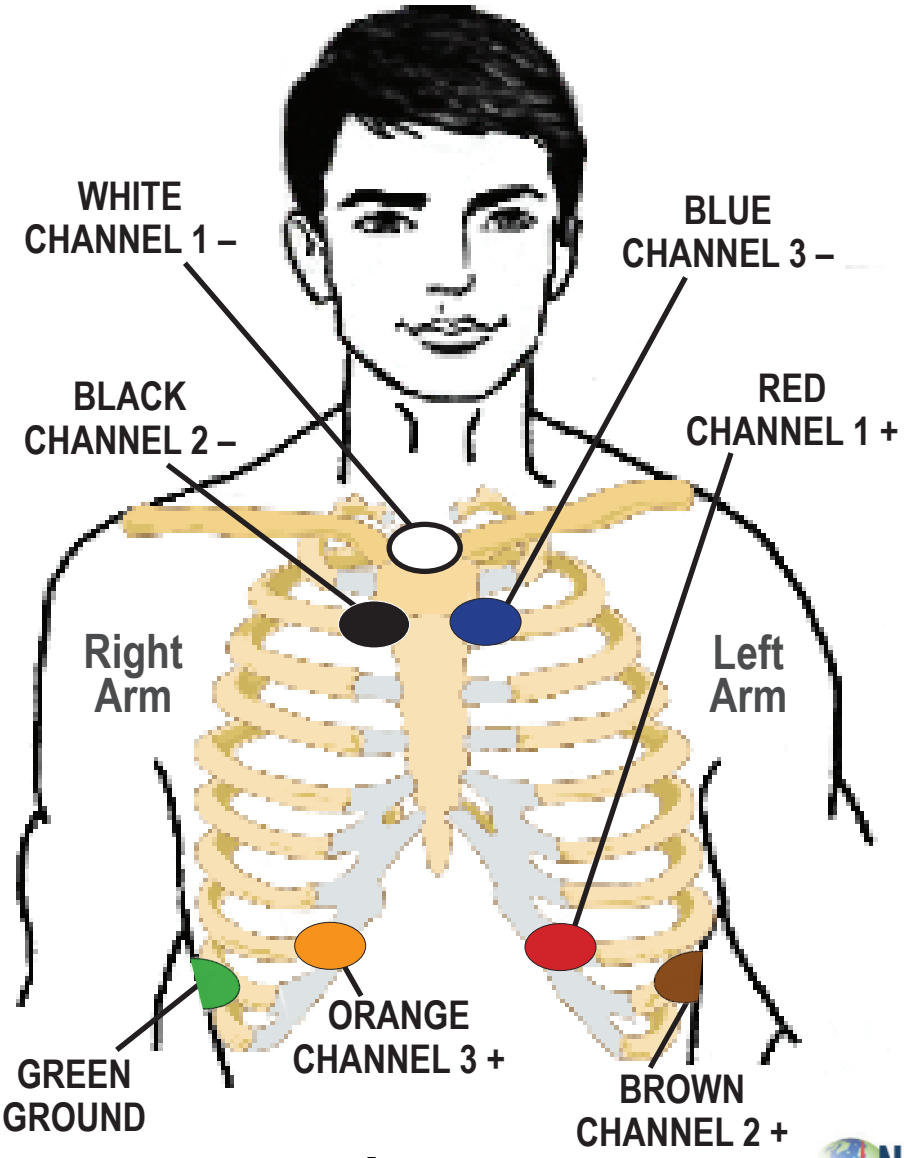
BROWN: **Channel 2 (+)** *Place on the left side, over lower ribs. (as shown below)*

BLUE: **Channel 3 (–)** *Place near the top of the sternum, adjacent to the white lead.*

ORANGE: **Channel 3 (+)** *Place on the right side, over lower ribs. (as shown below)*

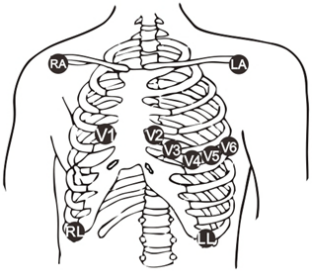
GREEN: **Ground** *Place on the right side, opposite the brown lead over lower ribs.*

CHANNEL 1 =	WHITE (–) ⟷ RED (+)
CHANNEL 2 =	BLACK (–) ⟷ BROWN (+)
CHANNEL 3 =	BLUE (–) ⟷ ORANGE (+)



10 Wire Patient Cable/AHA for B12

10 wire patient cable is utilized by B12 to acquire 12-lead ECG signals. It is recommended to place electrodes as below:

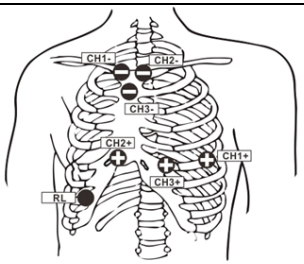


AHA Lead	AHA Color	Electrode Placement
RA	White	On the clavicle, above the infraclavicular fossa, medial to the border of the right deltoid muscle
LA	Black	On the clavicle, above the infraclavicular fossa, medial to the border of the left deltoid muscle
RL	Green	Not critical: any convenient location on the right chest, in the vicinity of V3R or V4R
LL	Red	In the anterior axillary line at the costal margin, over bone
V1	Red	In the fourth intercostal space at the right sternal border
V2	Yellow	In the fourth intercostal space at the left sternal border
V3	Green	Mid-way between V2 and V4
V4	Blue	In the fifth intercostal space in the left mid-clavicular line
V5	Orange	In the left anterior axillary line at the level of V4
V6	Violet	In the left mid-axillary line at the level of V4

Electrode Placement Chart（10A2 /AHA Standard）

7 Wire Patient Cable for 3 channel recordings:

A 7 wire patient cable can be used by B12 to acquire 3-channel ECG signals. It is recommended to place electrodes as below:

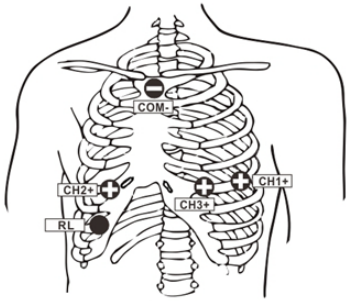


Lead	AHA Color	Electrode Placement
CH1+	Red	Left anterior axillary line 6th rib.
CH1-	White	Right manubrial border of the sternum.
CH2+	Brown	Approximately 1 inch right of xiphoid process on the rib.
CH2-	Black	Left manubrial border of the sternum.
CH3+	Orange	Left mid-clavicular line 6th rib.
CH3-	Blue	Center of the manubrium.
RL	Green	Lower right rib margin over bone.

Electrode Placement Chart (07A2/AHA Standard)

5 Wire P atient Cable for 3 channel re cordings. There ar e 2 accepted electrode placements:

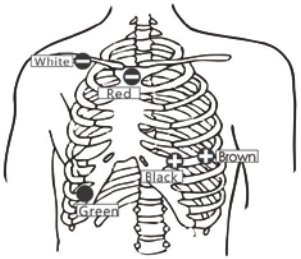
A 5 wire patient cable is utilized by B12 to acquire 3-channel ECG signals. It is recommended to place electrodes as below:



Lead	Color	Electrode Placement
CH1+	Red	Left anterior axillary line 6th rib, equivalent to V5 chest lead;
CH2+	Brown	Right of xiphoid process on the rib, equivalent to V1;
CH3+	Orange	Left mid-clavicular line 6th rib, equivalent to V3;
COM-	White	Right manubrial border of the sternum;
RL	Green	Lower right rib area over bone

Electrode Placement Chart (05S2)

Or A 5 wire patient cable can be utilized by B12 to acquire 3-channel ECG signals a second way. It is recommended to place electrodes as below:



Brown/Red=CH1=CM5

Black/Red=CH2=aVF

Lead	Color	Electrode Placement
CH1+	Brown	Left anterior axillary line 6th rib, equivalent to V5 chest lead;
CH2+ CH3+	Black	Left mid-clavicular line 6th rib, equivalent to V3;
CH1- CH2-	Red	In the manubrium
CH3-	White	Right manubrial border of the sternum;
RL	Green	Lower right rib area over bone

Electrode Placement Chart (05S21)

Do proper prep of the patient's skin as described earlier.

Then attach electrodes and tape down as follows:

Pasting Electrodes

1 Connect the color coded lead wire snaps;

2 Remove protective pad on the surface of disposable electrodes and firmly apply electrodes on prepared skin;

3 In order to prevent the leads from pulling directly on the electrodes, create a strain relief by looping each wire and placing a strip of adhesive tape over the loop and also on the electrode. Please find below picture:

NOTE: ***For Program Capability or Windows Stability it is strongly recommended that all screen savers and power savers are turned off, and that the computer is rebooted at the beginning of each day.***

Prep Kit Contents:

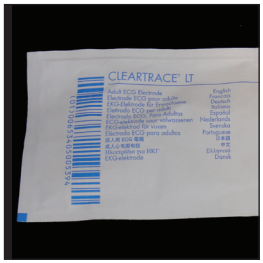


Figure 1
ClearTrace LT
Electrodes

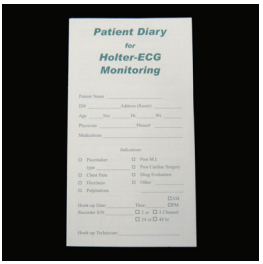


Figure 5
Patient Diary

Figure 2
VX3+-AA Battery
B12- AAABattery

Figure 6
Disposable
Razor

Figure 3
Alcohol Swabs

Figure 7
Wide Tape
Strips

Figure 4
Prep "Scrub" Pad

Recommended Steps:

a) Select the sites for electrode application. The electrodes must be applied over bone or cartilage. ***(See Table 1 for skin preparation and Figure 1 for placement)***

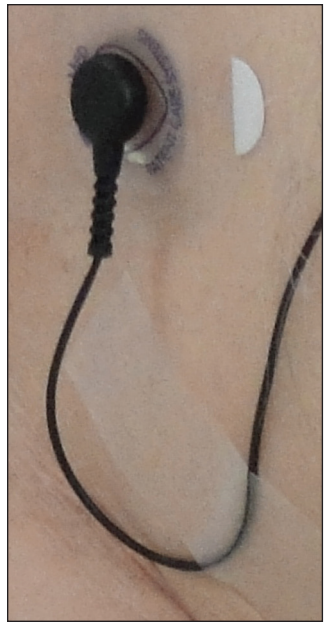
b) If needed, dry shave to remove hair from the electrode sites with the razor provided in the skin preparation kit.

c) Using the scrub pad provided in the skin preparation kit *(or a small square piece of an abrasive material, such as 220 grit sandpaper or equivalent)*, remove the top layer of skin. Use moderate pressure, abrade the skin at the electrode sites by making 3 or 4 crossing strokes. The strokes should cross at the chosen electrode site. Lightly brush the areas with a dry gauze pad to remove any debris.

d) Wipe the skin in the electrode areas with an alcohol prep pad provided in the skin preparation kit.

e) After allowing the skin to dry thoroughly, locate the electrode placement sites by palpation.

f) Connect hook-up connector to Holter Monitor and connect color coded electrode lead cables to electrodes BEFORE applying the electrodes to the patient.



g) Once the backing is removed from each electrode, place it firmly on the prepared skin surface site. Roll it on the patient like a band aid.

h) In order to prevent the lead from tugging directly on the electrodes, make a stress loop with each wire then tape the wire down 1" to 2" from the electrode. You can also loop all the wires at the recorder end and tape them down near the waist.

Electrode Placement

Proved by the clinical practices, correct electrode placement is directly related to signal quality and therefore affects the analysis results and diagnosis conclusions. Please carefully clean skin and place electrodes before each recording.

Caution: It is recommended that only trained medical personnel is required to handle the electrode placement.

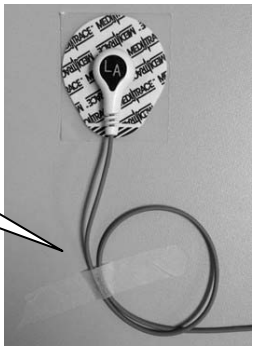
Electrodes

Use high quality silver-silver chloride disposable monitoring electrodes specially used for Holter recordings. It is recommended to choose disposable electrodes complying with ANSI/AAMI EC12-1991 requirements.

Position

It is preferable to place electrodes over ribs or cartilage to avoid interference resulting from movement of soft tissues. Different types of patient cables can be selected as required, the instructions to partial electrode placements are described in the following. Please refer to the appendix A for further information about electrode placements.

Correct Adhesive Operation



Caution: Do not use adhesive tape to stick lead wire snaps during electrode placement, to avoid pull off the color coded label of the lead wire snaps. Please find below picture:

Incorrect Adhesive

Starting the Recording Process:

For CardioHolter Recorder and the SD Flash Cards: Enter the patient's personal data in the patient's diary. Nine digit Unique Data ID Number, Name, Start Date, Start Time, etc.

a) The electrodes and lead wires should be attached to the patient as specified above.

b) For the CardioHolter make sure the wires are going upward when you plug it in. *(It is best to always leave this connected so as not to wear out the connector)*

Make sure the wires are going upward for VX3+

c) For CardioHolter Recorder insert the SD Flash Card into the recorder. To do this remove the cover to the battery compartment. Then insert the card into the slot *(writing or label side up and missing corner in first)*.

1. Remove cover

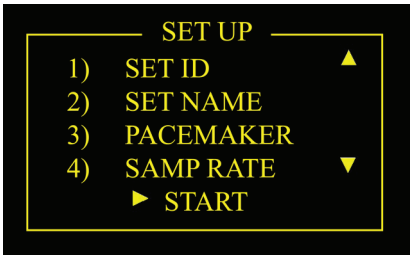
2. This end of card is inserted first

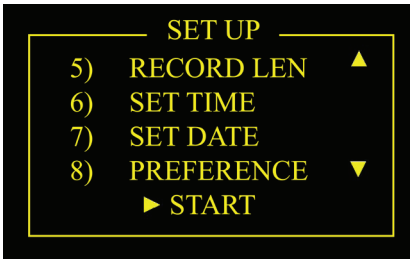
3. Insert the card here and push in as far as it will go until it stays in

4. Insert 1 brand new, previously unused Alkaline AA battery for each test and replace cover

When you flip the recorder over it will be in setup screen mode.
NOTE: You need to make sure that the date and time are correct.

Starting the Recording Process for VX3+: *(continued)*

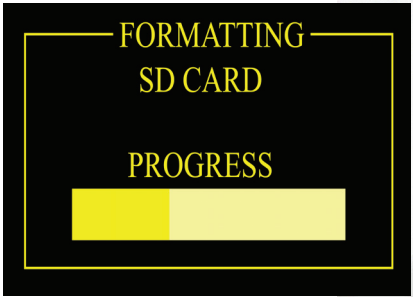




To check time, push down arrow to "**#6**" then hit the black circle with the arrow in it. Use the up and down arrows to adjust the time. Press the black circle with the arrow in it.

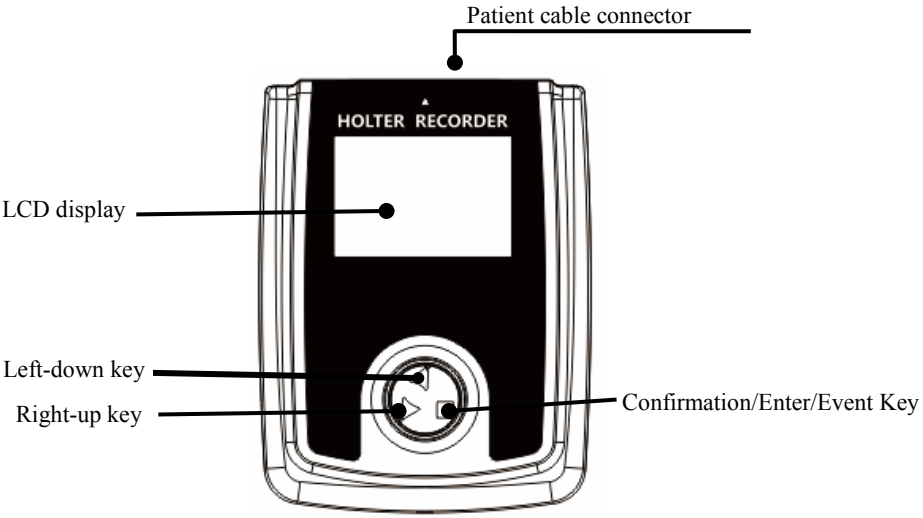
To check date, push down arrow to "**#7**" then hit the black circle with the arrow in it. Use the up and down arrows to adjust the date. Press the black circle with the arrow in it.

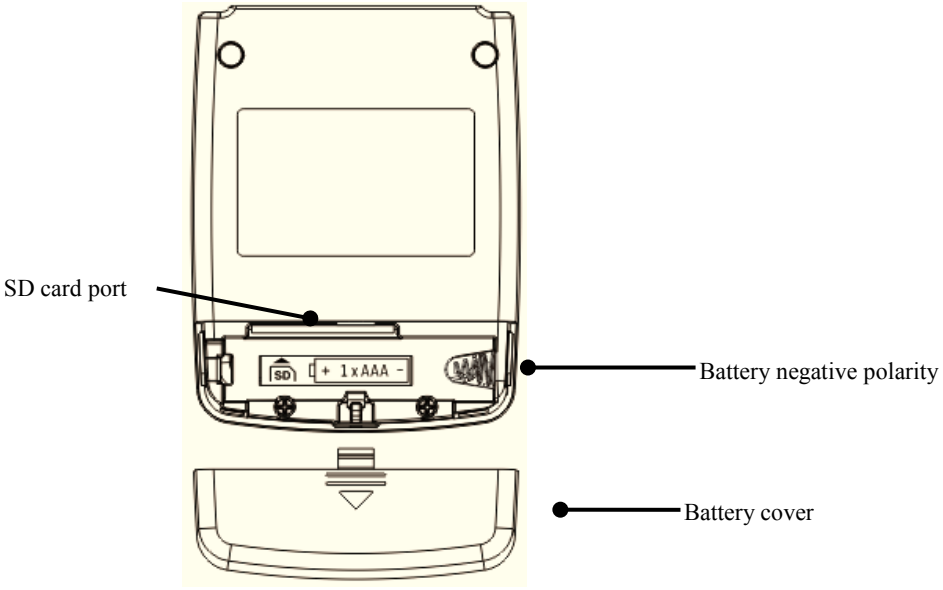
Click the right arrow on the bottom to start the formatting of the SD Flash Card.



12 Lead Holter Manual Additions

The layout of the **B12** Series Holter recorder:



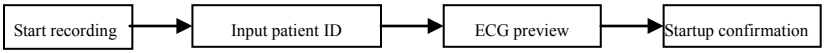


Menu Settings:

The B12 is programmed with a two-level menu. The first level has four menu items. Use the right-up key and left left-down key to move the cursor to select menu items. Use the confirmation key, to enter the second level menu of a selected menu item. Select menu items by right-up key and left-down key in the second-level menu and then enter any changes by pressing the confirmation key. Change parameters of any selected item by the right-up key and the left-down key. Press the confirmation key to exit. Each second level menu has an item "Exit" selection, press the confirmation key to return to upper level menu when the cursor is on the "Exit" item.

Start Recording

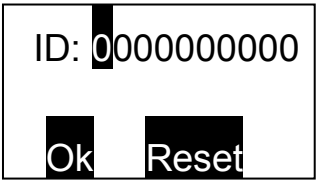
The start menu of recording set-up is process-based. According to different parameters set up in "Advanced Settings", all processes, from simplified to complete, are listed as below:



Move the cursor to "Start Recording" in the first level menu, press the confirmation key to initiate "Start Recording" process:

Input Patient ID

The process will be skipped as the setting of "Input Patient ID" is "off" under the "Advanced Settings" menu.



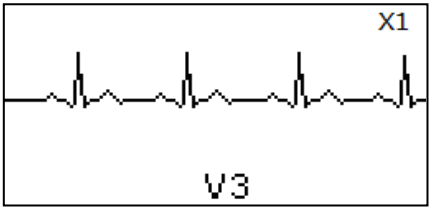
Use the arrow key to change the value of the cursor position, and after pressing the Confirmation key, the cursor will move one digit to the right, until the 10 digits of the patient identification number are input, and move the cursor to the “Ok”, and at this time, the arrow key can be used to switch the cursor between “Ok” and “Reset”, press “Ok” to enter the next process. Press “Reset” to reset the patient information.

ECG Preview

The process will be skipped if the setting of “ECG Preview” is “Off” under “Advanced Settings” menu.

The ECG preview has two modes as 1-channel display and 3-channel display, and the mode selection is set in advanced settings.

1-channel display mode



LCD displays one-channel ECG waveform, the right upper corner displays the current gain setting, while the bottom displays name of the lead (channel) (I, II, III, aVR, aVF, aVL, V1, V2, V3, V4, V5, V6 or CH1, CH2, CH3 under 3-channel mode), Press right-up key or left-down key to change the ECG lead (channel), and press confirmation key to enter the next process.

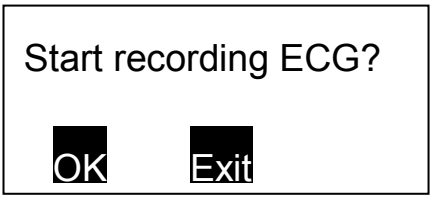
3-channel display mode

The LCD simultaneously displays the ECG waveform of three channels, and the right upper corner displays the current gain setting, and the left side displays the name of the corresponding lead
(channel).（I、II、III、aVR、aVF、aVL、V1、V2、V3、V4、V5、V6，or CH1, CH2, CH3 under 3-channel mode). Press the right-up key or the left-down key to change the ECG lead (channel), and press confirmation key to enter the next process.

During preview, when the lead plug is removed, the ECG waveform will be displayed as a straight line, and the message of "Leads Off" will be shown.

Note: The time axis (paper speed) under waveform display mode is around 1.5cm/s or 3cm/s, which is slightly different from regular ECG with paper speed of 2.5cm/s or 5cm/s. The main purpose is to visually assess signal and basic waveform quality and is not to be used as a basis for quantitative Measurement.

Starting Confirmation



Shift the cursor between "Ok" and "Exit" by pressing right-up key or left-down key. Press "Exit" to return to main menu or press "Ok" to start recording.

Recording Status

Display current date, time, recorded time, patient information and recording parameters. Only one second is needed to shift to real-time waveform display mode by pressing right-up key and confirmation key together.

The recorder will erase the existed data first and wait for two minutes to stabilize the circuit and ECG electrodes.

Information Display

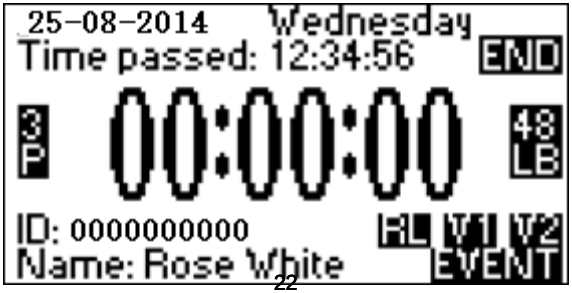
After the recorder is started, it will go into the information display status. Current date, time, recorded time, patient information and recording parameters are displayed in a top-down order.

If recording time is not “1 day”, enter “2 days”, “3 days”, “Cont.” (open end, continuous recording) which will be displayed.

If the recording channels of the B12 are set as 3, a reverse signal of “3” will be displayed;

If the “Pacemaker Detection” setting in the parameters setting menu is “On”, a reverse signal of “P” will be displayed;
If electrodes detach during the recording process, reverse signal of name of the dropped lead name will be displayed;
During recording, if the lead is removed, the message of “Leads Off” will be shown;

The current operation statuses are “ERA” (erase), “WAIT”(wait), and “REC” (record), and after completion of recording, the reverse signal of “END” will appear.



Note: Various status will be specified or explained in other sections of this manual.

Erasing time differs from SD card models and working time. SD card need to be changed in case erasing time is over 2 minutes.

ECG Display

If "ECG Display" is set as "On" in "Advanced Setting" menu, only one second is needed to shift to real-time ECG display mode by pressing right-up key and confirmation key together. Users can observe the validity of recorded ECG waveform.

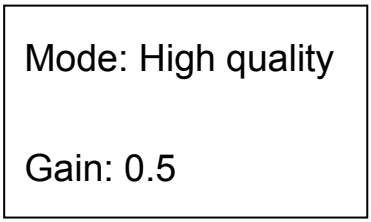
The ECG display interface is the same as the ECG Preview.

In the waveform display status, simultaneously press and hold the Right-up key and the Confirmation key for one second to switch to the information display

Parameters Setting

It's used to set parameters for current recording.

Press "Exit" to return to the upper level menu. Different parameters have to be set up in different versions of recording formats



Recording Mode

Modify the recording mode of the recorder: The user can make selections in accordance with the actual requirements, and the ECG data recorded with the "Long" recording mode can meet the requirements of most analysis functions of Holter software, and it is suitable for recording for a longer time and reading the analysis data at a faster speed. The data recorded with the "High quality" recording mode will have higher sampling rate and sampling accuracy to acquire more accurate ECG waveform, and can meet advanced functional requirements as for P wave analysis and late potential("SAECG"), but the time for continuous recording is short, and it takes more time to read and analyze the data. The "Normal" recording balances the quality and speed.

B12 can be set to High quality/Long, and the default value when powered on is the value set last time. B12 in 3 channel mode can be set to High quality/Normal/Long, and the default value when powered on is the previous setting.

Gain

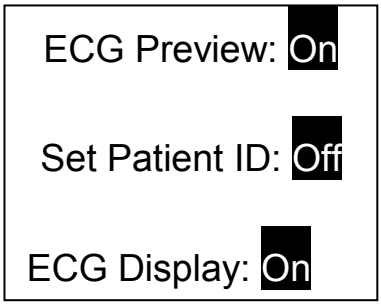
Gain can be adjusted to be 0.5, 1, or 2. The default start-up setting is the previously adjusted value.

Recording Time

Recording time (day) can be set to be 1 day, 2 days, 3 days, 4 days or Cont., the default value is 1 day. Cont.(Open end) is for continuous recording with no specified time, and the recorder will work continuously until the battery is used up. The continuous recording time will be connected to the recording mode and the recording channel, for example, for 12 leads, when "High quality" mode is selected, the recording time will be limited to 1 day.

Note: Not every recorder supports the long-term recording.

Advanced Settings



Operation interface, procedure and time are set up in this menu.

ECG Preview

ECG Preview can be set to be “On” or “Off”. The default value is the previous setting. If set as “Off”, ECG Preview will be skipped.

Patient ID Entry

In the E-label registration detection setting, “On” or “Off” may be selected. The default value is the previous setting. Use Off as On is a special reserved setting.

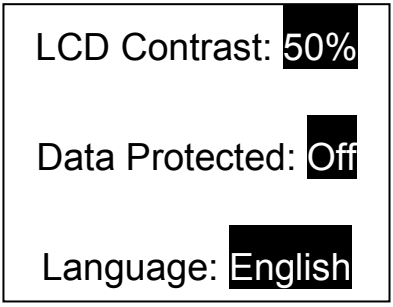
ECG Display

ECG Display during recording process can be set as “On” or “Off”. The default value is the previous setting.

Note: Set the value as “On” and enter ECG display mode by pressing right-up key and confirmation key for 1 second during recording process and observe ECG waveforms. It is unable to enter ECG display mode by pressing confirmation key during recording process if the value is set as “Off”. This helps to prevent undue effect on the patients. Entering or otherwise the ECG display mode will not have any effect on the recorded signals.

LCD Contrast

LCD contrast can be adjusted in the range of 10%～100%， with 10%of gradations. The default value is the previous setting. The item is adjusted according to light environment and users habits. No need to modify it under normal situation.



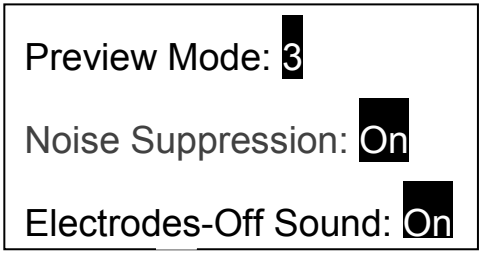
Data Protection

Data protection is used to detect if the recorded data has been analyzed. Use Off as On is a special reserved setting.

Languages

The B12 is provided with multiple languages, including English, Germany, French, Italian, Spanish, Portugal, Polish, Turkish, Russian etc.. Language in the menu prompting message can be set as 5 of 10 languages as above-mentioned before leaving the factory. The default value is the previous setting. **Preview Mode**

Set the channel display mode of the recorder during preview or during recording, and the value that can be set is 1/3, and the default value when powered on is the previous setting.



When it is set to 1, ECG display is for 1-channel mode, and the ECG waveform of only one channel is displayed, and by switching the channels, the other channels can be shown. As only one channel is shown, there is no interference between the waveform of channels, for clear observation.

When it is set to 3, ECG display is for 3-channel mode, and the ECG waveform of three channels is simultaneously displayed, and by switching the channels, the other channels can be shown. The simultaneous display of three channels can be for fast observation.

Noise Suppression

It's used to check whether the data is filtered during recording, and whether the noise interference is suppressed. The value which can be set is "On/Off"; and the default value is the previous setting.

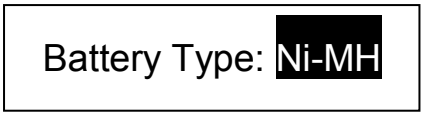
Electrode Off Warning

The detection and warning for electrode detachment during recording can be set as "On" or "Off". The default value is the previous setting

Battery Type

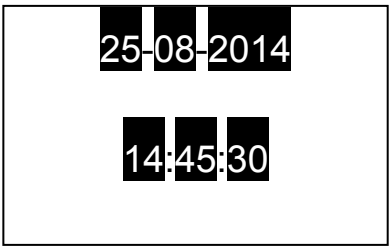
Battery type used for the recorder can be set as "alkaline" or "Ni-MH". The default value is the previous setting.

Note: There is a great difference between initial and final voltage of alkaline and NI-MH batteries. Set real battery type in use so as to ensure more accurate warning for battery depletion. One single AA lithium battery is required for continuous 7 days' recording to ensure the sufficient power supply.



Date and Time

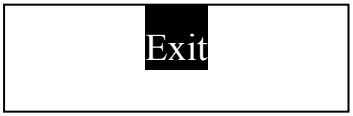
Adjust day-month-year and hour-minute-second of the real time clock. Weeks will be adjusted automatically.



Note: There is a backup battery for built-in clock inside the recorder. Even if the battery of the recorder is taken out for an extended time, the clock circuit will still function normally. If the recorder is unused for an extended time or the time zone is not changed for over one month, the clock will need to be adjusted. It is recommended to calibrate the clock time once a month during daily use. The life of the backup battery for the clock is 5 years, and when exceeding the life, the time to maintain the normal operation of the clock will be reduced, and it shall be replaced.

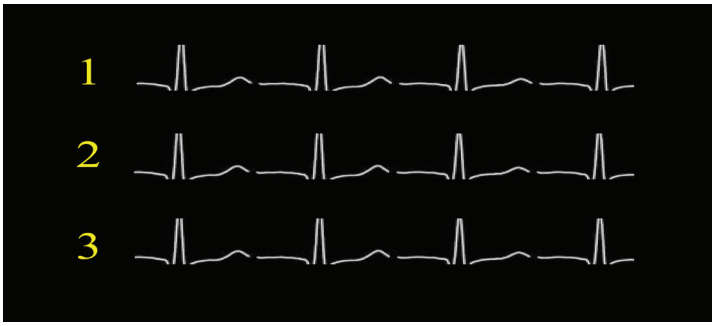
Exit

Press confirmation key to return to the upper level menu.



Checking Holter Hookup:

- When formatting is finished the Holter screen will automatically display all 3 ECG Channels and will stay there for 15 minutes *(It will only flash the time after this initial 15 minute display of ECG tracings)*
- Make sure the "R" waves are going upward and are tall and strong *(indicates proper connections and strong signal)*
- Have patient move around to see that the ECG doesn't change *(i.e., no artifact or noise)*
- Tap gently on all of the electrodes to make sure there isn't a lot of artifact
- If it does change go to ***Figure 1*** and fix the hook up until your hook up is good – use **new** electrodes *(there are extras in the kit)*



Importance of Holter Hookup:

The most important part of the Holter Hookup is seeing that the ECG tracings remain good with patient movement.

Have patient walk in place and move around like they normally would. Tap gently on all of the electrodes. The ECG should not get a lot of artifact. If there is a lot of motion artifact look at the hook up diagram and change the electrode that appears to be bad. Make certain that wires are well taped to the patient's chest.

Once you are sure you are getting an accurate and artifact free reading you may allow the patient to leave the Medical Center after providing instructions presented hereinafter.

Patient Instructions:

Instruct the patient to **avoid** :

- **Getting the recorder wet** *(no showers, baths or swimming. Be careful not to drop the recorder in the toilet, etc.)*
- **Getting too much electrical interference** *(avoid electric blankets, heating pads, waterbed heaters, etc.)*
- **Artifact** *(don't push or pull or touch the electrodes)*

When a patient returns with the Holter recorder you will need to stop the recording process. *(by removing the battery).*

Advise the patient on how to fill out the patient diary.

Also instruct the patient on how and when to use the "event" button on the Holter recorder.

(e.g., Chest pains they need to use the "event" button and make note in the diary.)

Stopping the Recording Process:

a) To stop recording after 24 hours, or sooner if desired, simply remove the battery completely and discard properly.

WARNING:

DO NOT RE-INSERT BATTERIES after removal, this will erase the ECG data on the Flash Memory Card.

Recording

Give appropriate guidance to patients before their leaving:

1. Show them how to use the event button;
2. Explain to the patients or nursing staff the importance of registering patient logs timely and completely. Introduce writing format, contents, what to record, recording time, location, activities and other details;
3. Warn patients as follows:

- Do not get the recorder wet. No bathing, showering or shampooing;
- Do not touch electrodes and disconnect patient cables;
- Do not open the recorder. Do not take out the battery and SD card;
- Do not place mobile, TV or other electrical appliances one meter around the recorder.
- Do not place heat source like heater close to the recorder.

4. Inform them to stop recording when there is a severe discomfort and how they can stop the recording;
5. Let them revisit 24 (48 or longer) hours later.

Caution: Please stop using the recorder and contact the authorized distributor or Nasiff when the recorder is damaged by water or other liquid.

Caution: The recorded ECG signal may have noise due to an interference signal, so please do not use mobile phone or other mobile devices.

Stop Recording

Normally the recorder will automatically terminate the recording when patients revisit the second day or 48 hours later. If the recorder terminates the recording after 30 minutes, its power supply will automatically shut down. If the recording time is less than the preset time, press the confirmation key, the right-up key and the left-down key simultaneously for one second. Then move the cursor on the LCD with right-up key or and left-down key. to “Yes”. Press the confirmation key to terminate recording.

Remove the SD card and insert it into the Nasiff analysis system card reader or connect USB cable with the recorder to prepare for analysis;

Remove the patient cable and electrodes from the patient and clean electrode site for them.

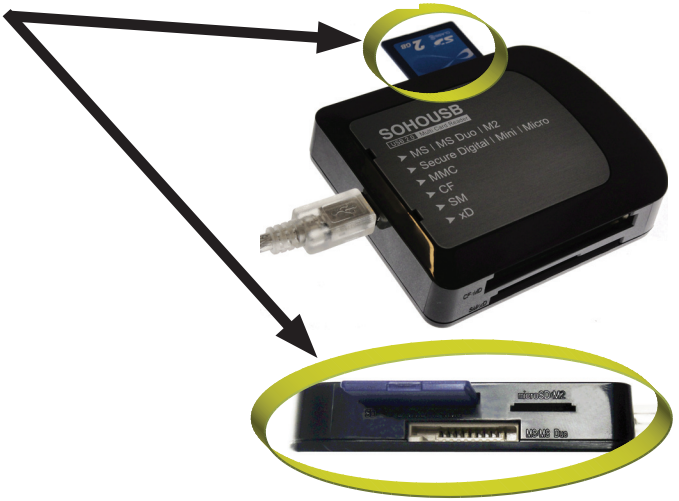
Caution: The skins contacted by the electrodes may appear the symptom of rubefaction, macula or pruritus etc.. Please remove the electrodes right after recording.

Caution: Electrodes are for single use only as they may cause cross infection between different patients. Repeated use is forbidden! For the disposal of abandoned electrodes, follow local laws and regulations. Do not discard carelessly.

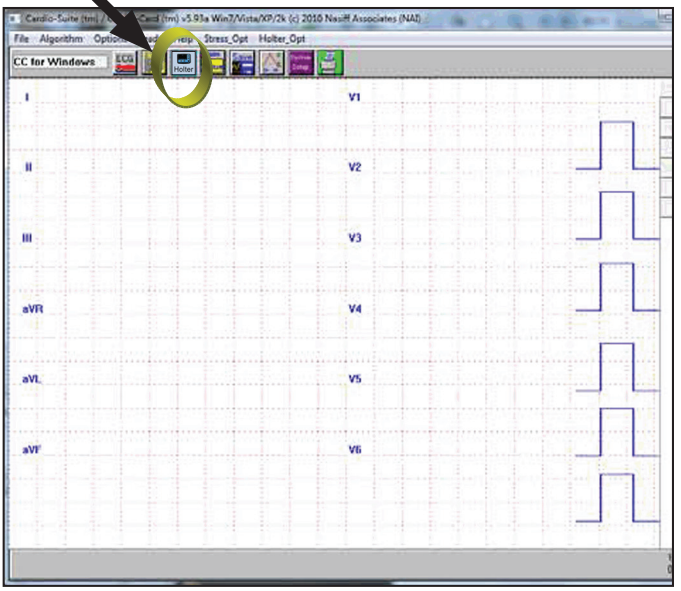
After necessary cleaning and disinfection of the recorder and patient cable, it is well prepared for the next patient. If no need to use the recorder temporarily, please put the recorder into the plastic packing box and place it in a ventilated dry place without direct sunlight

Reading the Holter Recorder ECG Data into the CardioCard™ System:

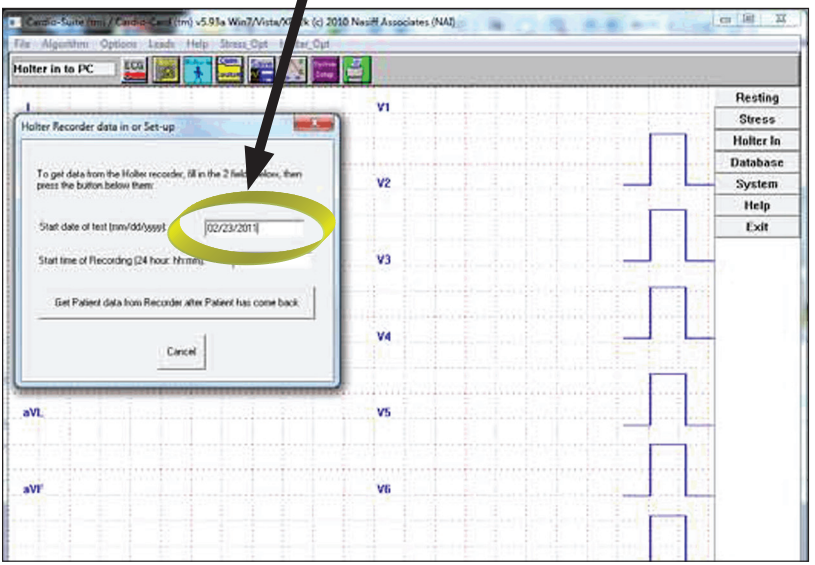
a) Insert the SD Flash Card into the SD Universal External Card Reader/Writer that is plugged into your Computer.



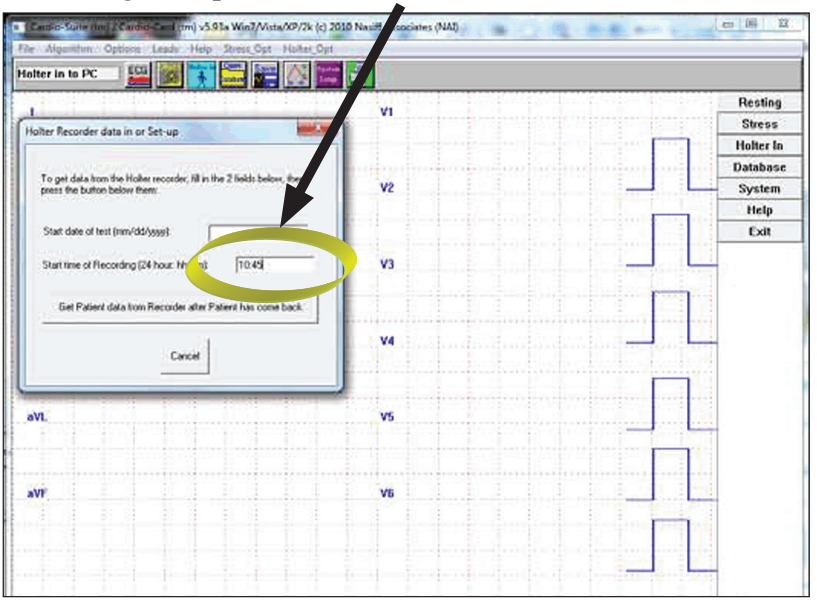
b) In the CardioCard software, click the blue "**HOLTER IN**" butKFEU



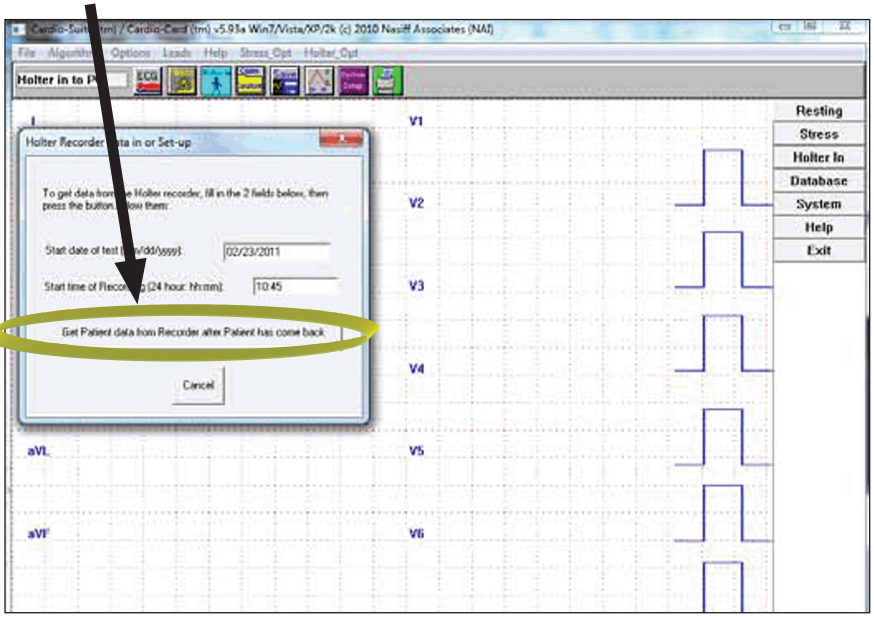
c) Type in the start date for the Holter monitoring of the patient. Use 2 digits for month, 2 digits for day, and 4 digits for year. *(e.g., January 4, 2011 would be 01/04/2011)*



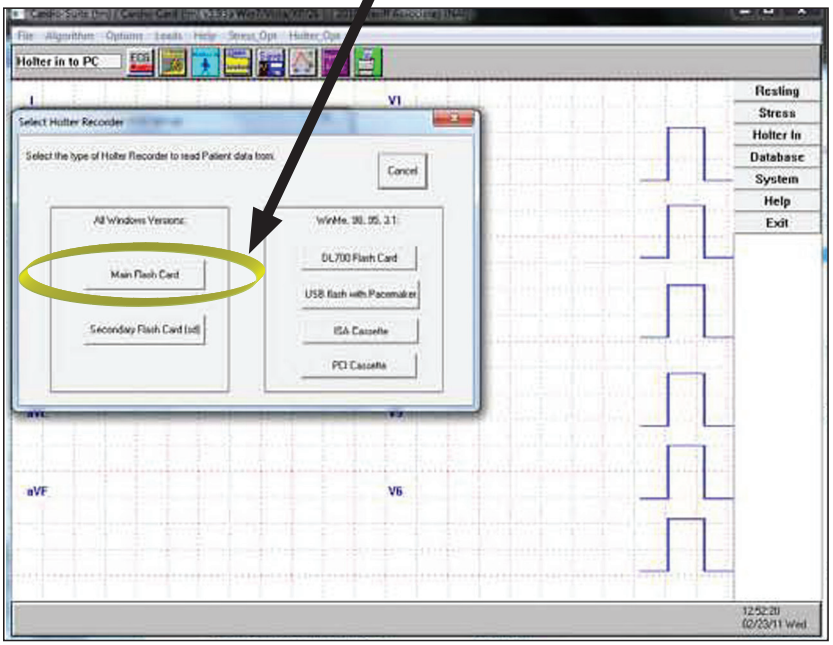
d) Type in the start time of the patient's monitoring using hh:mm format, where hh is hour and mm is minutes – i.e., 2 digit 24 hour format. *(e.g., 1:30 pm would be 13:30`*



e) Click “Get Patient data from Recorder after Patient has come back”



f) Click "Main Flash Card" for Type of Recorder

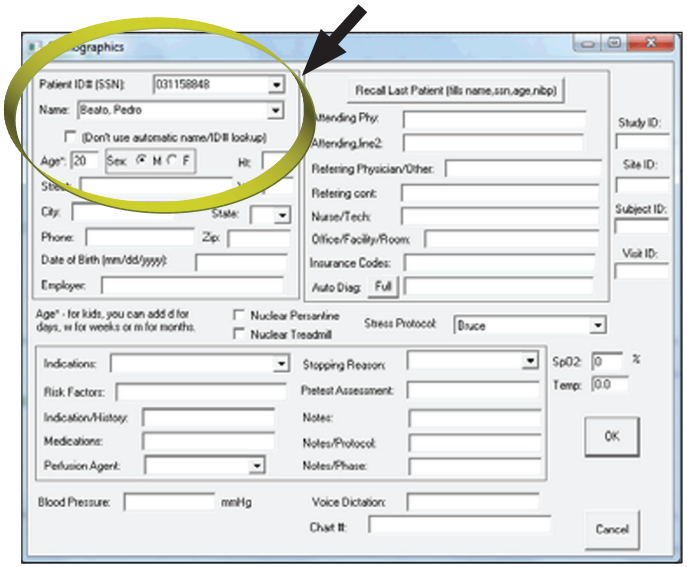


A message will come on the screen "Please Wait". If an error message comes up instead, there are three possible reasons:

1. **USB cable or SD Flash Card may be disengaged and need to be reinserted**. Unplug USB *(SD card reader)* and reinsert. Remove SD Flash Card and reinsert. Now try to read it again.
2. **Go to "Holter Setup" settings to ensure correct drive letter for "path to flash card"**. Correct as needed.
3. **SD Flash Card may be empty or Corrupted** *(unreadable)*. Card contents can be read in "My Computer". Double click on removable disk drive *(letter)*. If you don't see files on NASVP. DAT file, no data exists. It means the card was erased. The patient needs to be hooked back up and make sure they don't take the battery out or put battery back in.

   If there is data on the card, you can go to the following location for additional help: **www.nasiff.com/bsci.html** and click on "troubleshooting".

g) When asked "Store to Database?" answer "Yes". In order to store the Holter ECG data in the database, you must enter an Unique Data ID Number, Name *(last, first)*, Age and Gender of patient *(this must be entered)* and then Click "OK". Most people use SSN or Chart number. If the Chart number is not a nine digit number. *(it can be padded with zeros to make it 9 digits)*



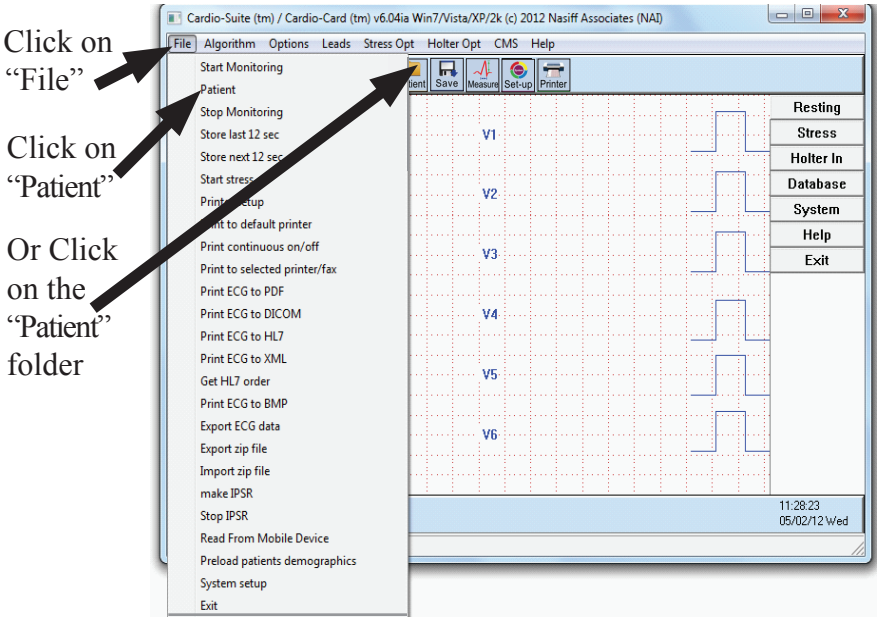
How to do Reports and Editing for CardioHolter

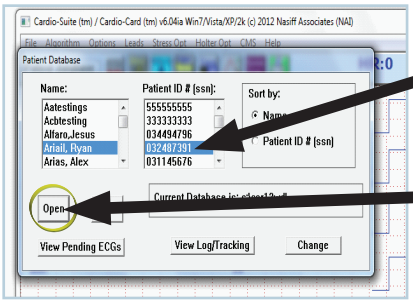
The purpose of this section is to teach you how to do Reports and Editing.

For Program Capability or Windows

Stability it is strongly recommended that all screen savers and power savers are turned off, and that the computer is rebooted at the beginning of each day.

Opening the Database:

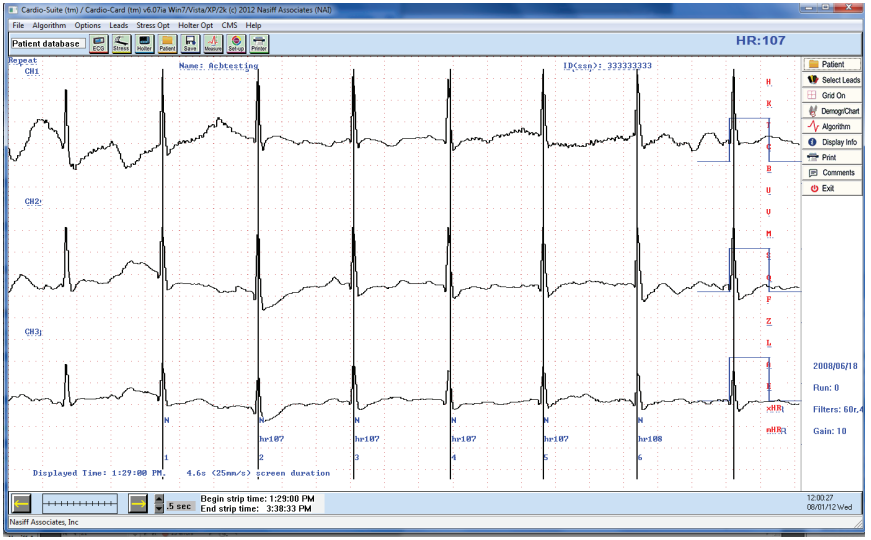




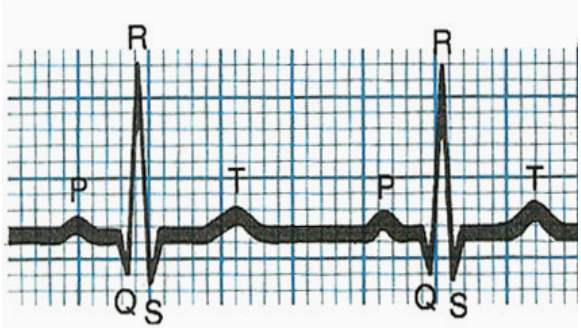
Highlight the "Patient's" Name

Click "Open"

Patient's Holter ECG Data/Report



Example of a Normal ECG



Example of Normal Wave *(Labeled).* The normal wave is labeled with different parts p, q, r, s, and t. The "r" is the primary part used for beat detection. The "t" can cause beat detection problems if too "tall"

12 lead holter you can select leads to view by going to leads select leads

Review the Test

- Review the automatic analysis done by the System and check quality
- Review the report
- Do auto analysis if necessary
- Do editing manually, if necessary

REMEMBER

The purpose of holter testing

is to get the Patient's Arrhythmia Condition

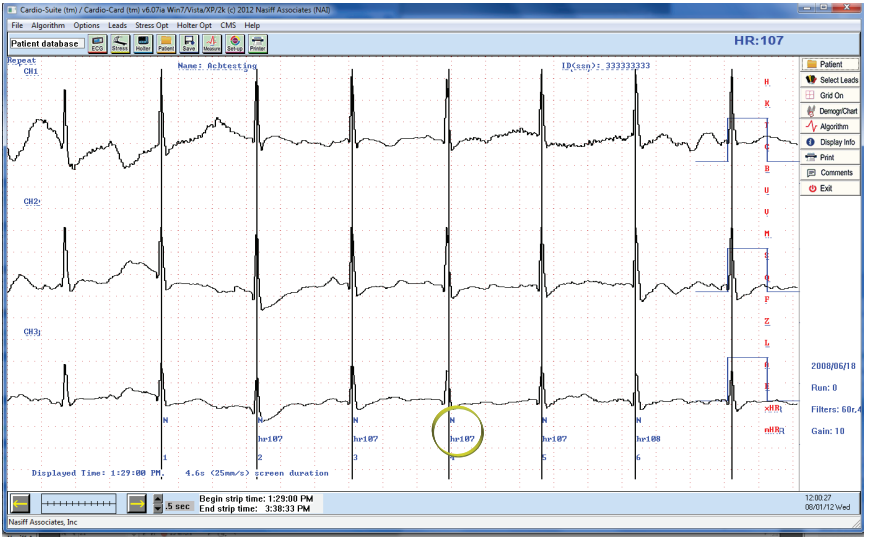
A clinically high count of certain arrhythmias can indicate concern for the patient's heart condition

We are looking for the abnormal significance of the patients results, and conditions

Example: Too many pauses, PVC's, Brady's etc... Would indicate further concerns.

There are two ways to review and edit the report. One is using common UI and the second one is Condensed Method. Both can be used on the same Holter test.

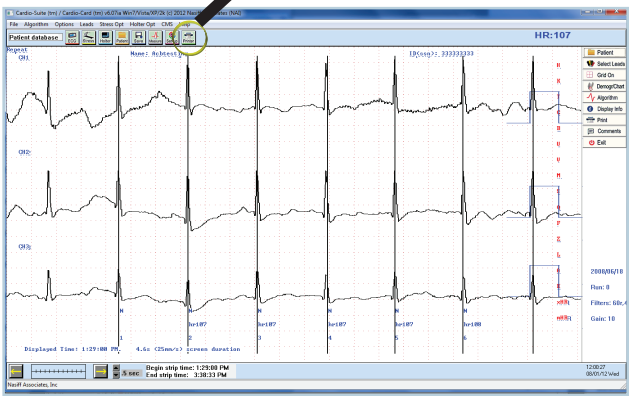
Review the Automatic Analysis done by the System



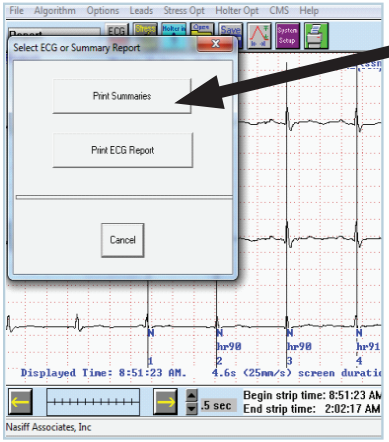
Review the R wave quality and detection accuracy. The rule of thumb for good R wave detection is for the R wave amplitude to be positive (upward) and greater than 1.5 divisions (which is 1.5 large squares or 0.75 mV). There needs to be vertical white lines going through every R wave on the right side of the screen with "Beat Codes" and "Beat Numbers" at the bottom of the beats. Then Pick the best Channel

Review The Report

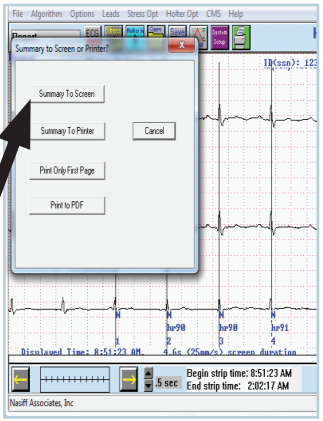
Review the first page of the summary report to determine if there was an excessive number of "pauses" or “abnormalities“ and see what channel the system analyzed. To see the report, click on the “Printer Icon”



Review The Report *(continued)*

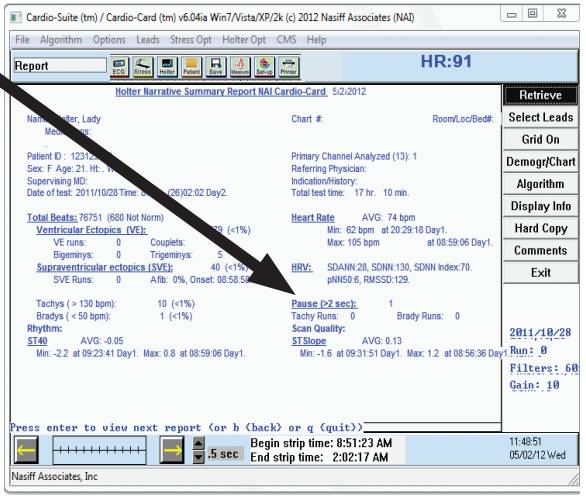


Click on "Print Summaries"



Then click on "Summary to Screen"

Look at "Primary Channel Analyzed" and the number of pauses, etc... To exit the first page of the report, press the "q" key on the keyboard
For 12 Lead it will show the leads it used



Reasons for Analysis

- Reanalyze if there is a better channel to use
- If the R wave amplitudes are too small or there are missing lines, it is usually caused by an amplitude problem
- If too small, the amplitude of the "Primary Channel Analyzed"

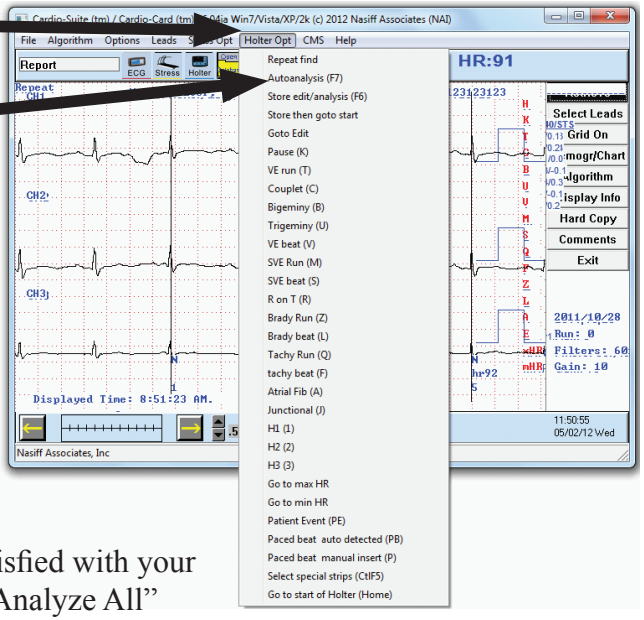
is likely too low. The remedy is to either increase the gain or select a different “Primary Channel”

- If there are beat marking white lines going through T waves, the T wave of the “Primary Channel” is likely too high

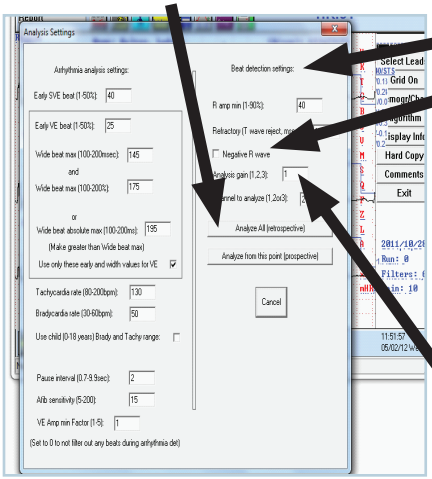
Auto Analysis

Go to “Holter_Opt”

Click on “Autoanalysis” (F7)”



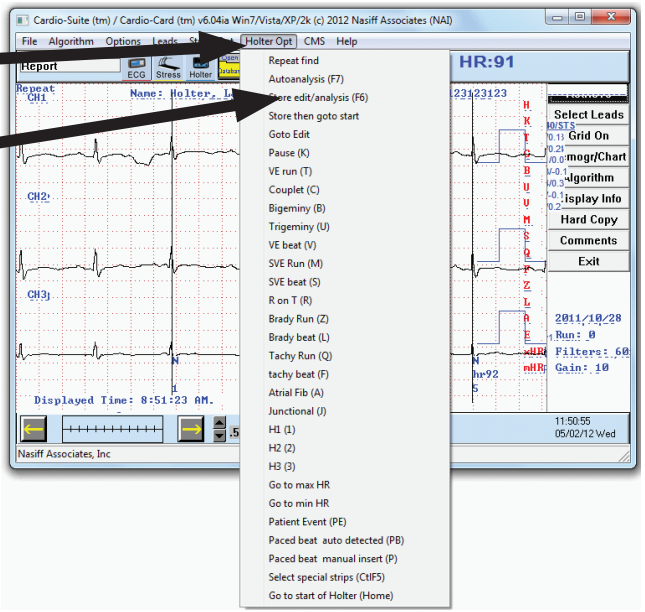
When you are satisfied with your setting click on “Analyze All”

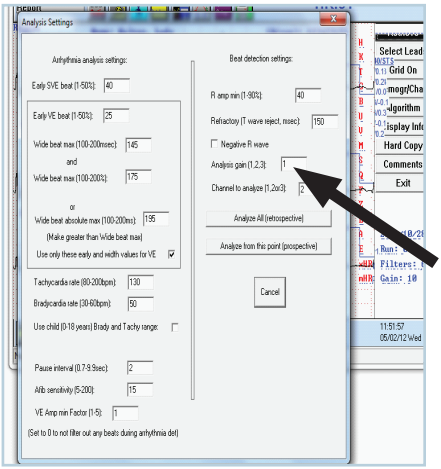


In "Auto Analysis" under "Beat Detection Settings" choose negative R wave *(if primary channel is going negative)* you can change the primary channel analyzed *t*o a better channel, increase analysis gain, and If there are beat marking lines going through T waves, the T wave of the Primary Channel is likely too high. The remedy is to increase the "R Wave Amplitude Minimum". *(The R amplitude minimum rejects any wave part smaller than the percentage set of the last known good R wave)*

Auto Analysis *(continued)*

If satisfied with results click "Holter_Opt" then "Store Edit/ Analysis"

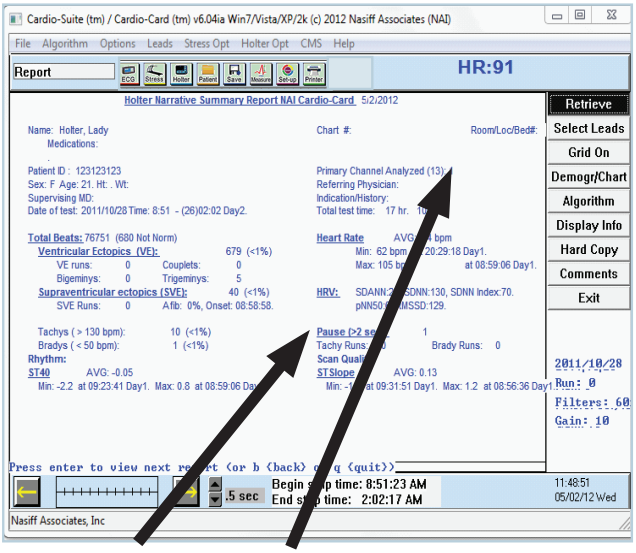




If there are beat marking white lines going through T waves, the T wave of the Primary Channel is likely too high. The remedy is to go to "Auto Analysis" and increase the "R Wave Amplitude Minimum". *(The R amplitude minimum rejects any wave part smaller than the percentage set of the last known good R wave)*

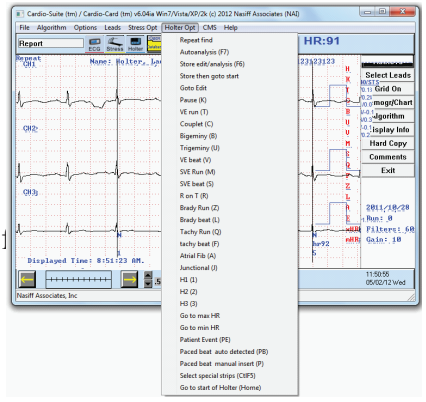
Make the appropriate selections and click "Analyze All". Say "Yes" to "Analyze Beats". When "Percent Complete" reaches 100% say "Yes" to "Analyze Arrhythmias". Repeat this step as necessary to achieve good R wave detection.

Review Test after Auto Analysis



Look at "Primary Channel Analyzed" and the number of pauses. If number of pauses is excessive review of the beats can be done as shown on next page. If a different channel appears to be better, run "Auto Analysis" as described below. To leave the first page of the report, press the "**q**" key on the keyboard."Auto Analysis" also allows Arrhythmia setting changes. Do not run "Beat Detection" when making Arrhythmia changes only

Reviewing Beats and Editing Functions *(complete "Auto Analysis" for all prior work before manually editing)*. All reviewing functions are under the "Holter Opt" menu.

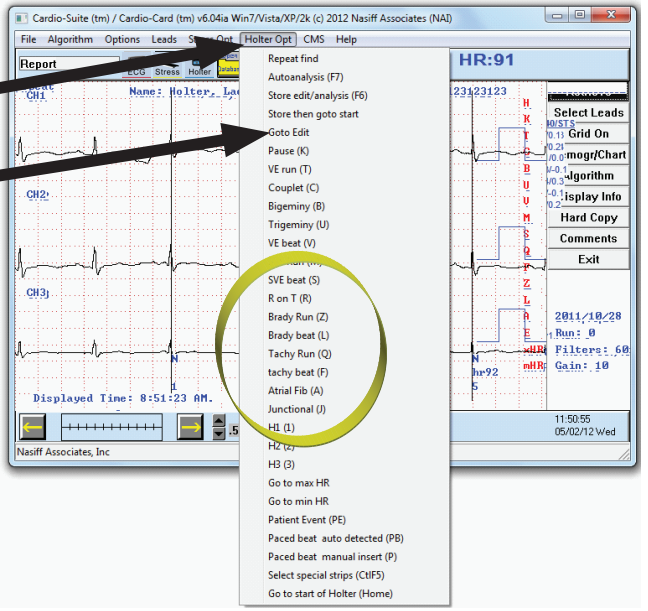


For example: to search for "VE Beats", click on "VE Beat(V)" and the screen will scroll *(to the right)* to the next VE Beat. Clicking "Repeat Find" repeats the process. To search a different type, example "SVE Beat(S)", click on "Go To Start of Holter" then click on "SVE Beat(S)". Note that the beat code isunder the beat searched.

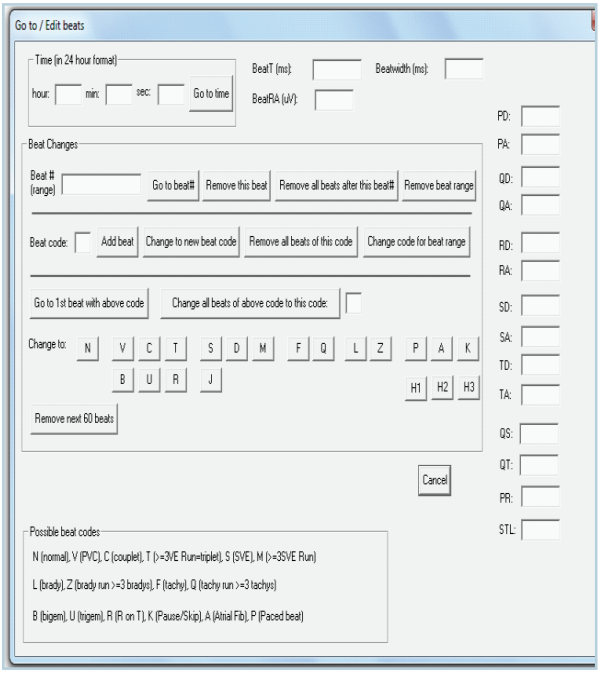
For example, when we searched for the VE Beat,the beat was labeled with a "V"

Editing Beats

To edit a beat or series of beats, go to “Holter Opt” then “Edit Screen” or you can double click on the beat code to display the "Go to Edit Dialog"



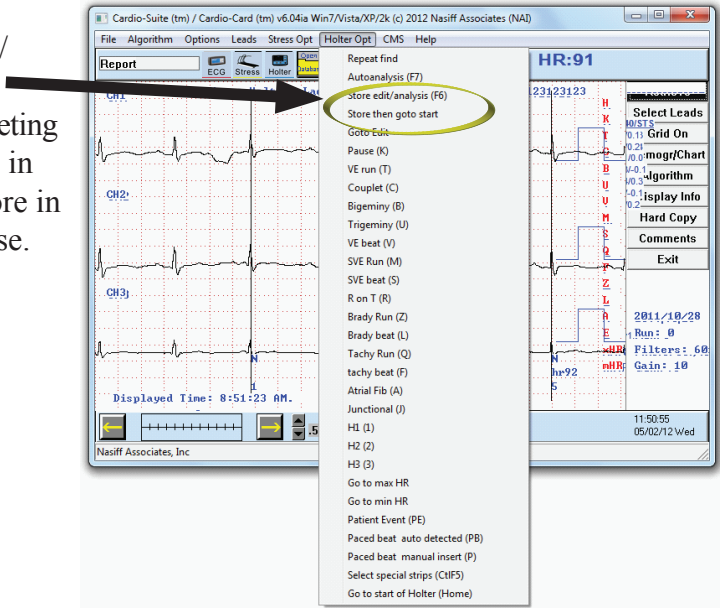
“The Edit Screen” has three sections: the top section allows you to go to any "time" and shows measurement information about the beat; the lower section gives a key to beat codes; and the middle section is where editing takes place.

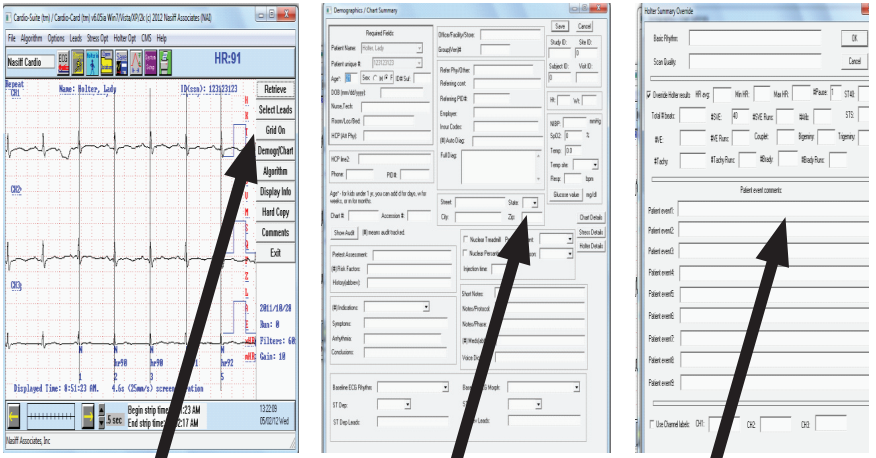


After double clicking on a beat code, the edit dialog gives the beat number and beat code on the left hand side of the screen. Numerous buttons are available for editing. The "Remove Beat" button will remove the beat upon which we just clicked *(this actually removes the beat mark and leaves the ECG in tact)*. The "Remove All Beats After this Beat" will remove all beats after this one. The "Remove All beats of This Code" button will remove all beats of this code. The "Remove Beat Range" removes the beat range typed in the "Beat Number" field (for example, to remove beats 52 through 75, the field must contain 52-75)

To change the current beat code to another beat code, change the code in the "Beat Code" field to the new code and click the "Change to New Beat Code" button. To change a beat range to a new code, change the code in the "Beat Code" field to the new code, put the beat range *(as done previously)* in the "Beat Number" field and click the "Change Beat Code for Range" button. The "Change All Beats of Above Code to This Code" button changes all the beats of the above code to the code entered in the box to the right of this button.

Be sure to "Store Edit/ Analysis" after completing any editing in order to store in the database.

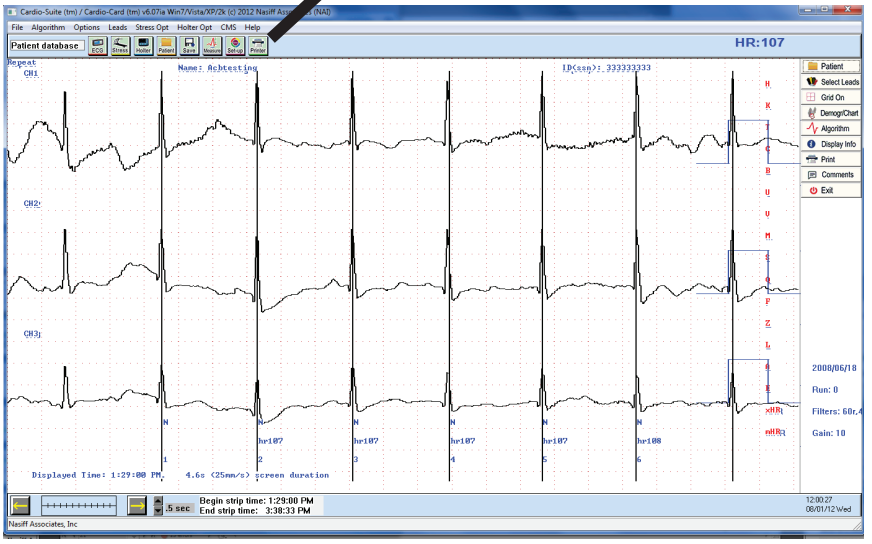




Inside "Demographic/Chart" Click on “Holter Details” this allows the entry of certain overrides and patient event comments.

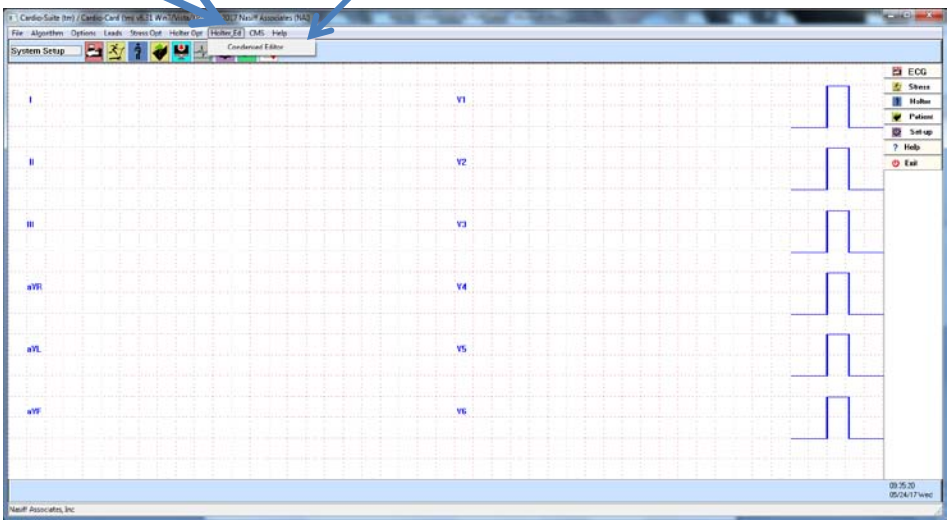
Printing

Clicking the printer icon allows printing of summary and ECG Reports
(for example, full disclosure)

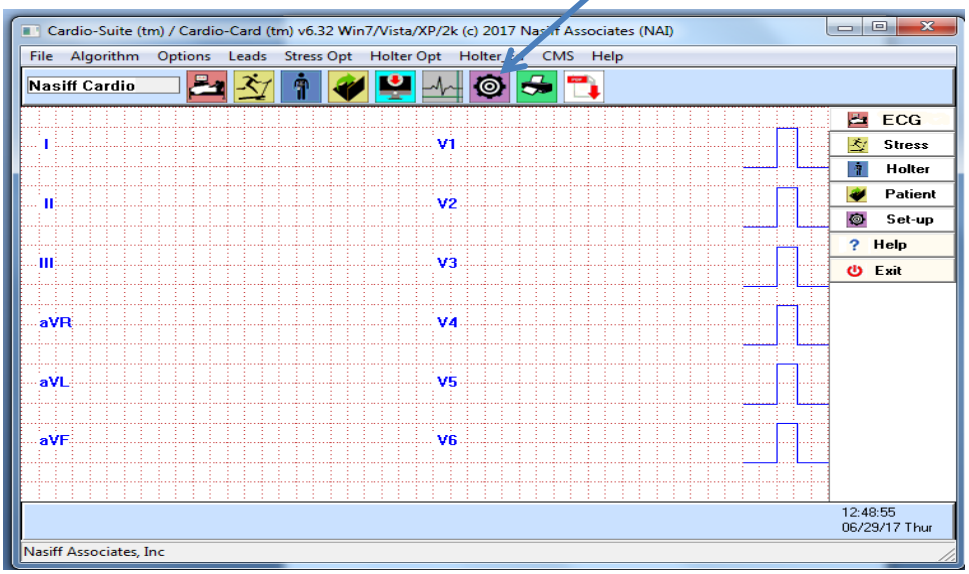


How to use Condensed Editor

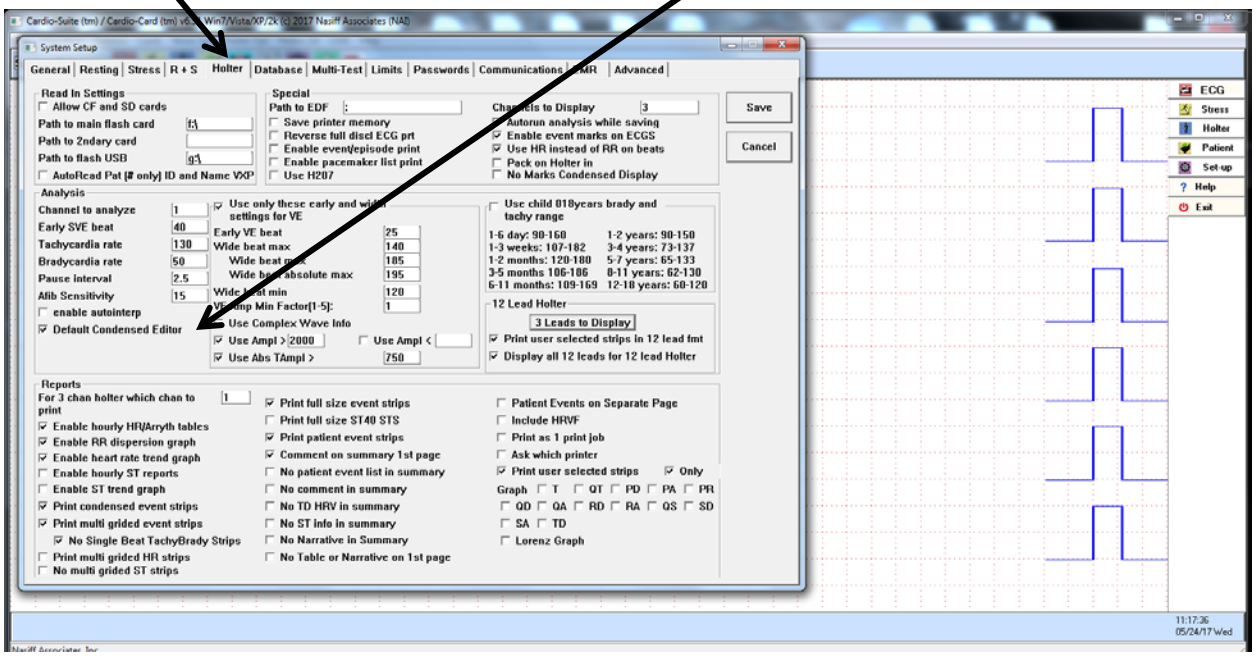
Click on Holter ED then Condensed Editor



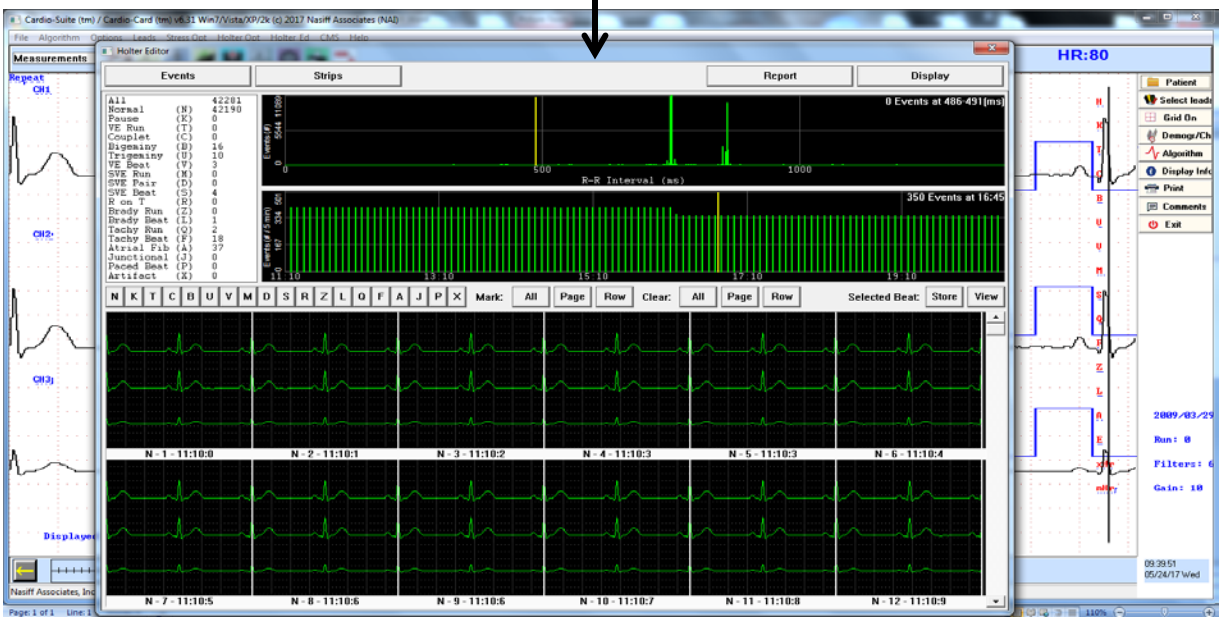
You can set the Condensed Editor to open when you select a holter test. To do this go to setup



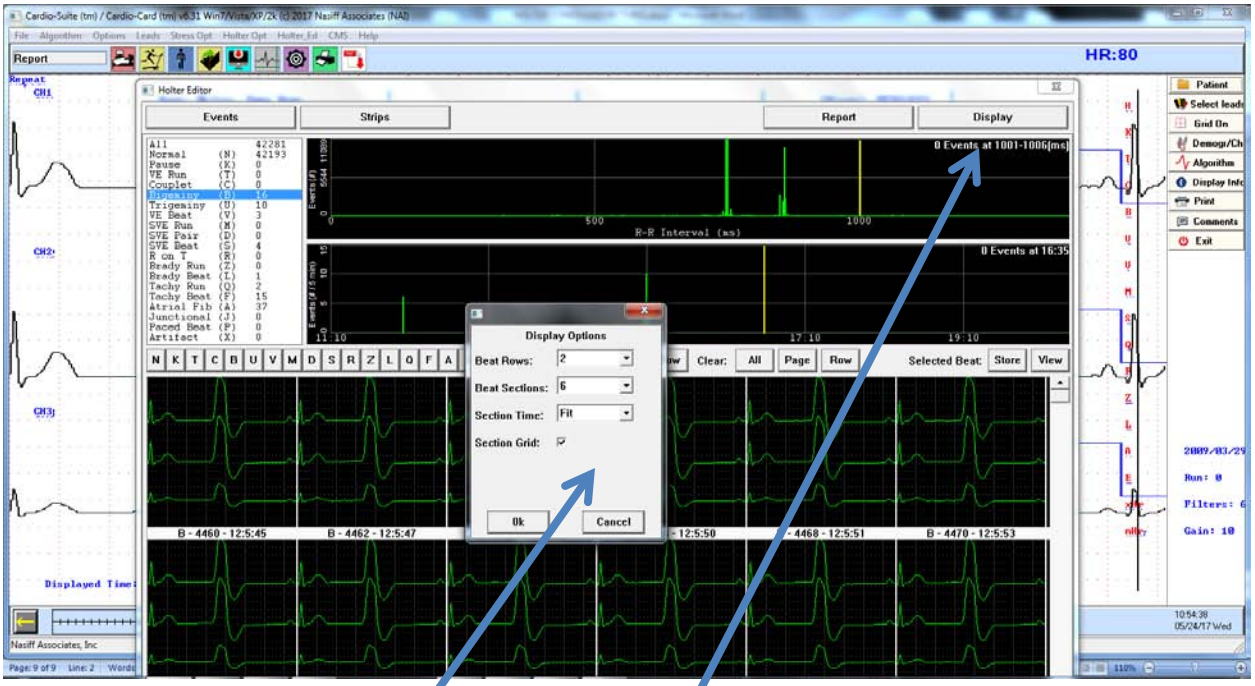
Holter tab then under Analysis check “Default Condensed Editor”



This is the Condensed Editor Screen



Display Options

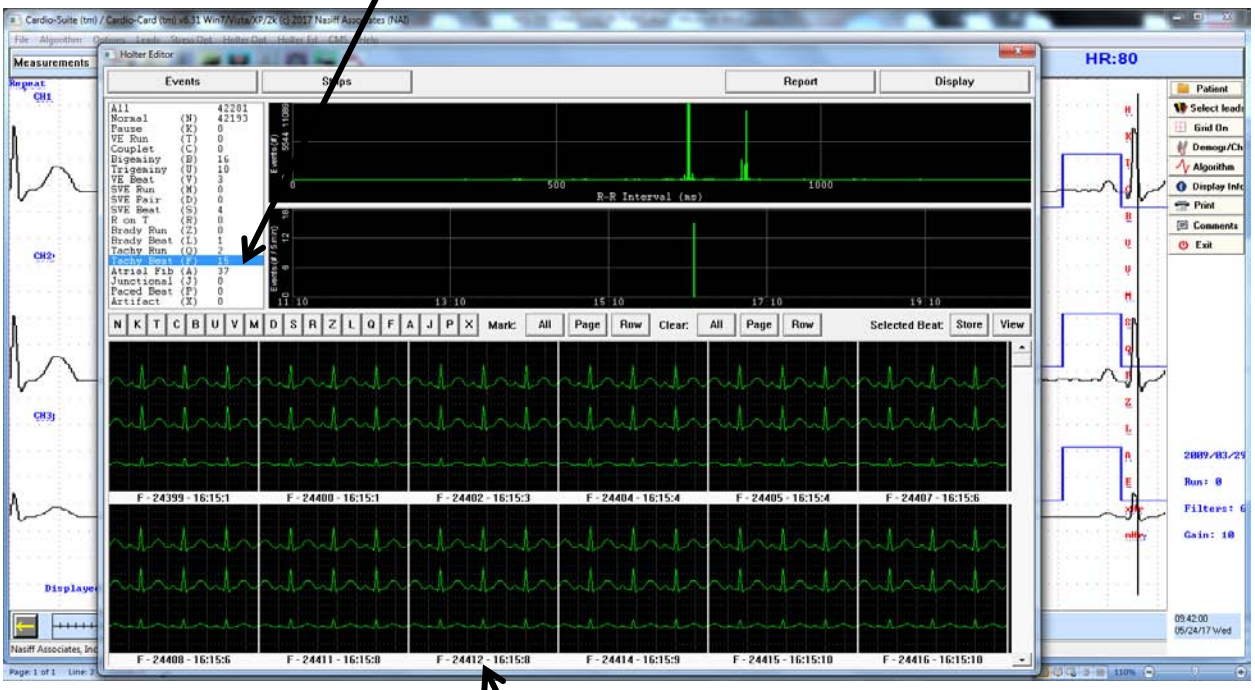


To select Display Options click on “Display”

Beat Rows 1 – 4 Rows
Beat Section 1-8 beats per Row
Section Time: Fit, 1-3 sec
Section Grid: checked on no check is off
After making selection click “OK”

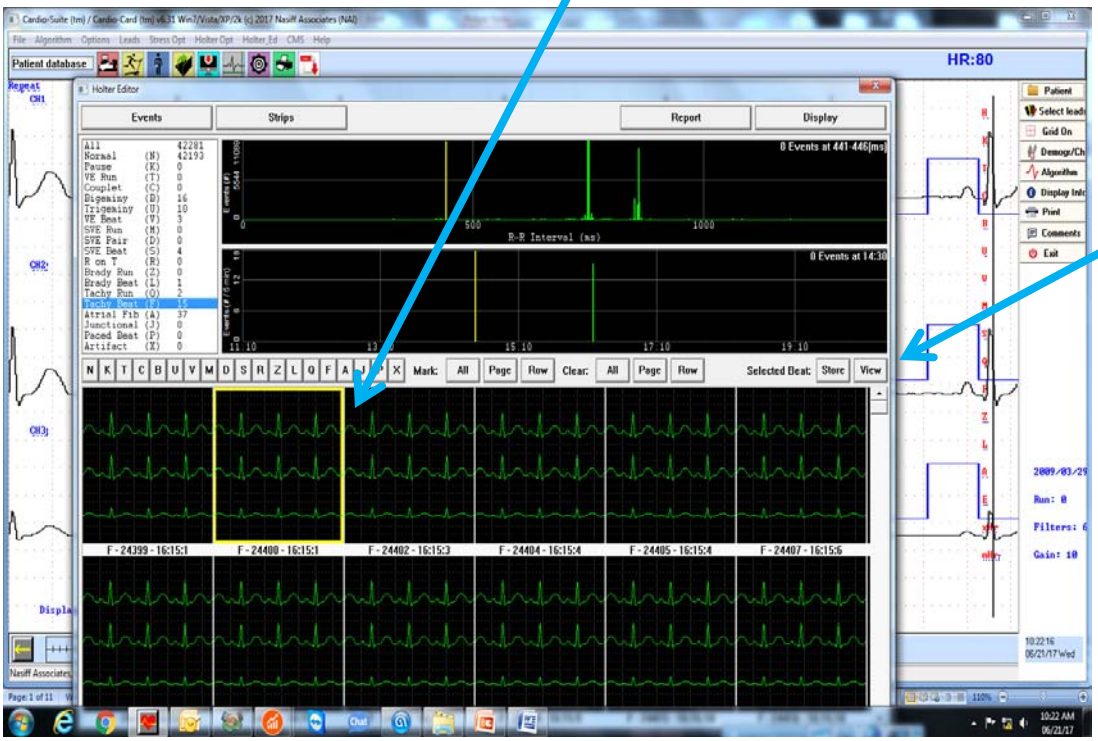
Selecting Events

Select Event by clicking on it



You will see the Event Letter, Beat Number, and Time

Select a Event that you want to view by single click. It will outline it in yellow



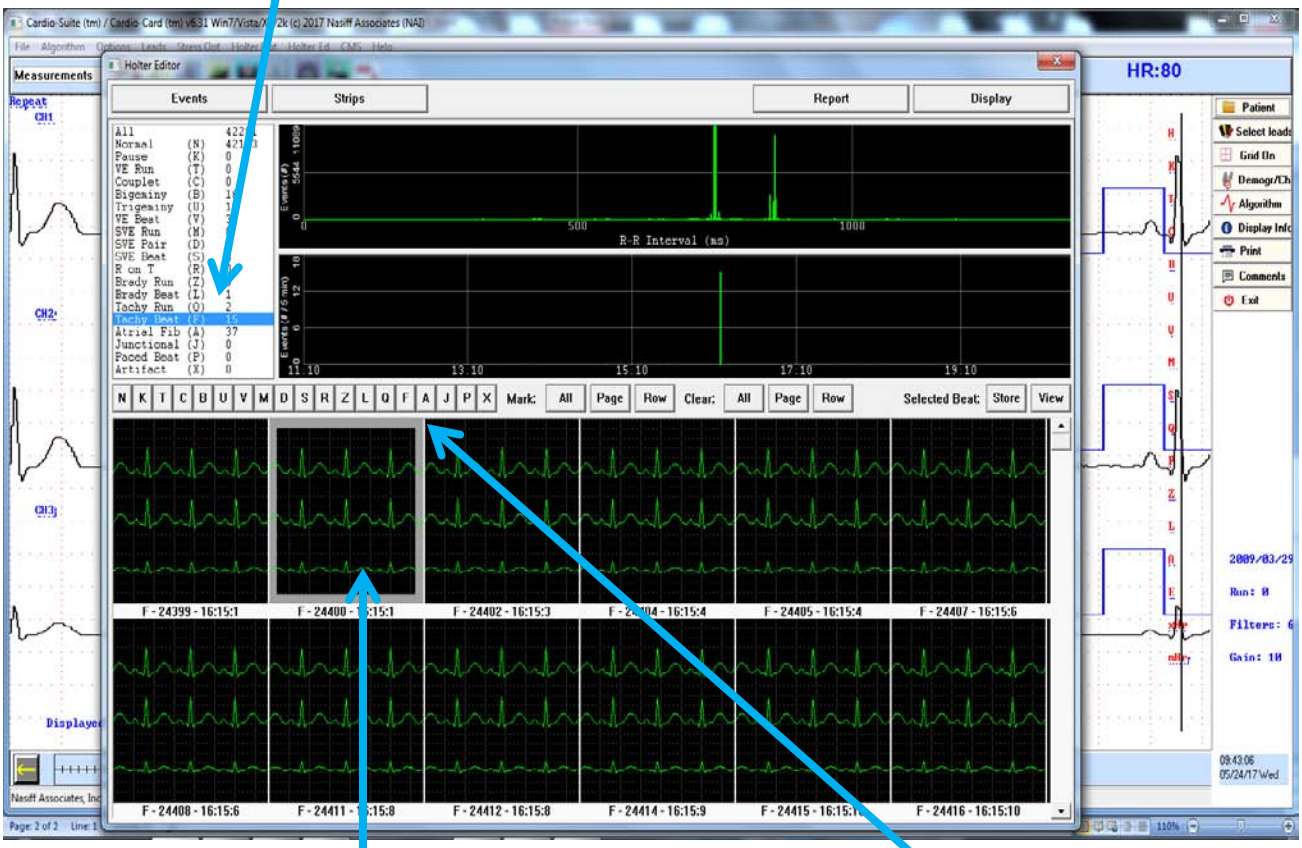
Click“View”

It labels with HR and Beat Number

Click view again to go back to the condensed screen

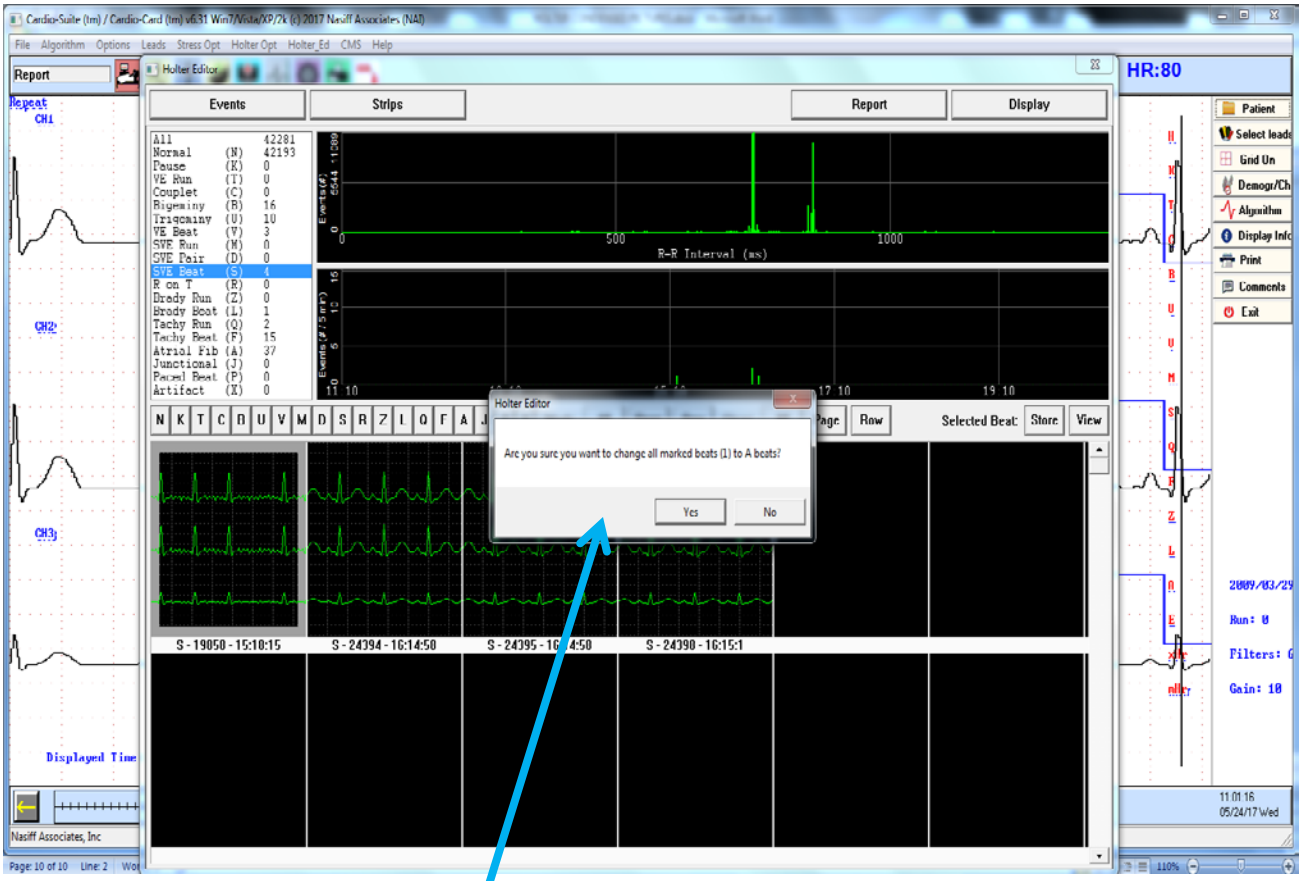
How to Edit Beats

Select the beat you want to view

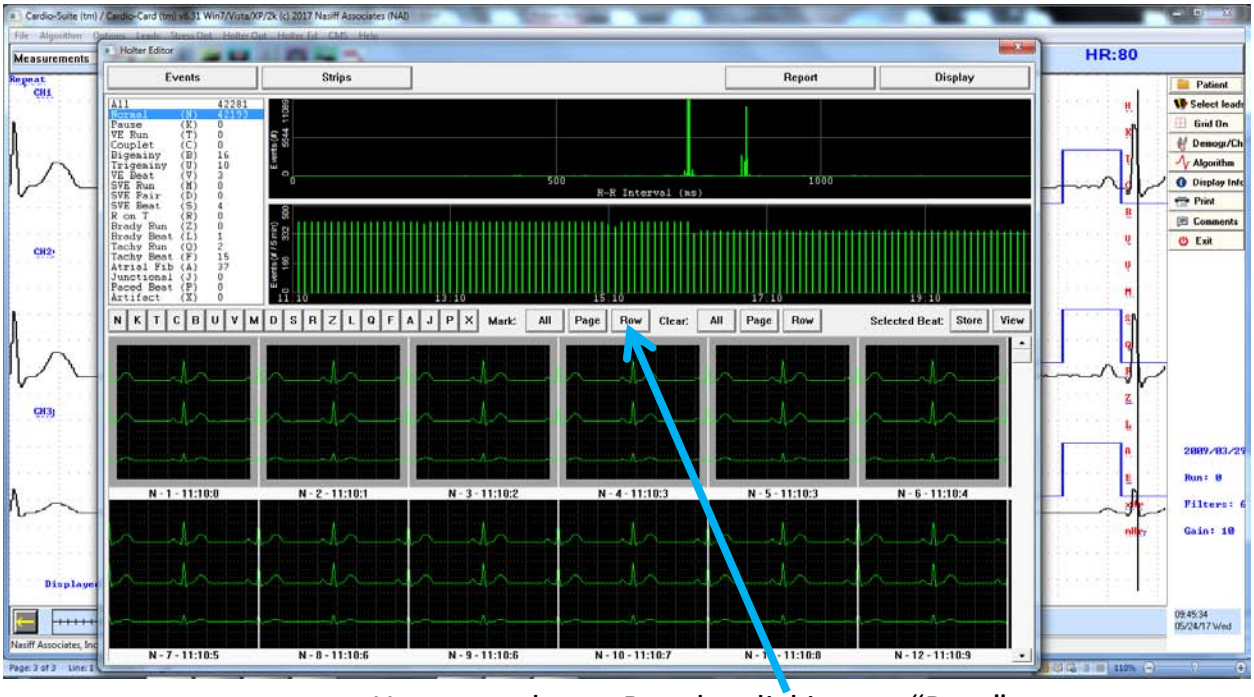


Double click on the beat you want to change. It will be outlined in Gray

Select the beat you want to change it to



You will be asked if you want the change



You can select a Row by clicking on “Row”

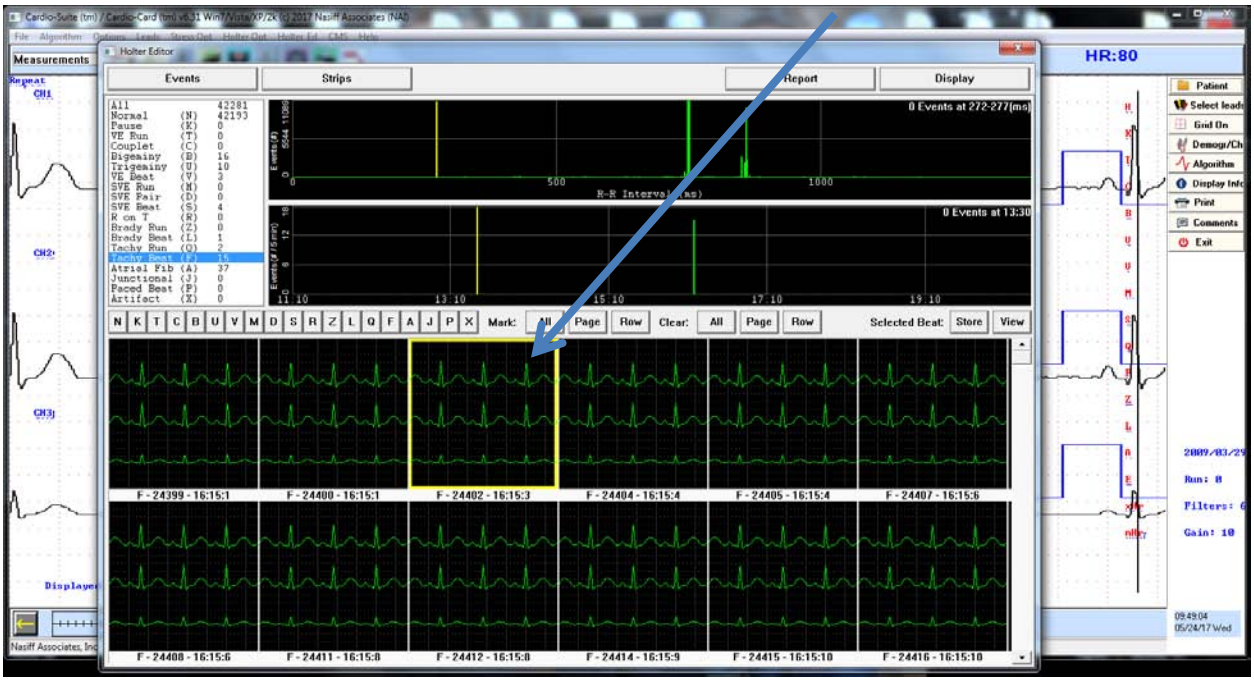
You can also select a “Page”

You can change the row or page to the beat you want

To Clear your selection you can click “All, Page or “Row”

Select Strips

To select a strip single click on the beat



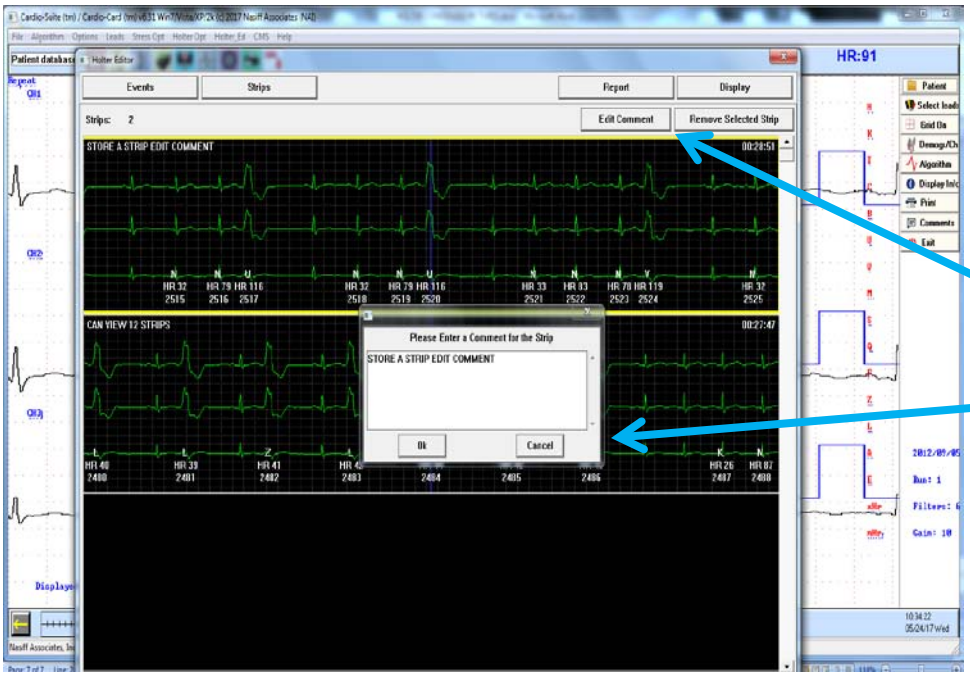
Then click “Store”

Enter your Comment click “OK”

View Selected Strips

Click “Strips” to view

Select the strip that you are editing by single click, a yellow box will outline the one you want to edit

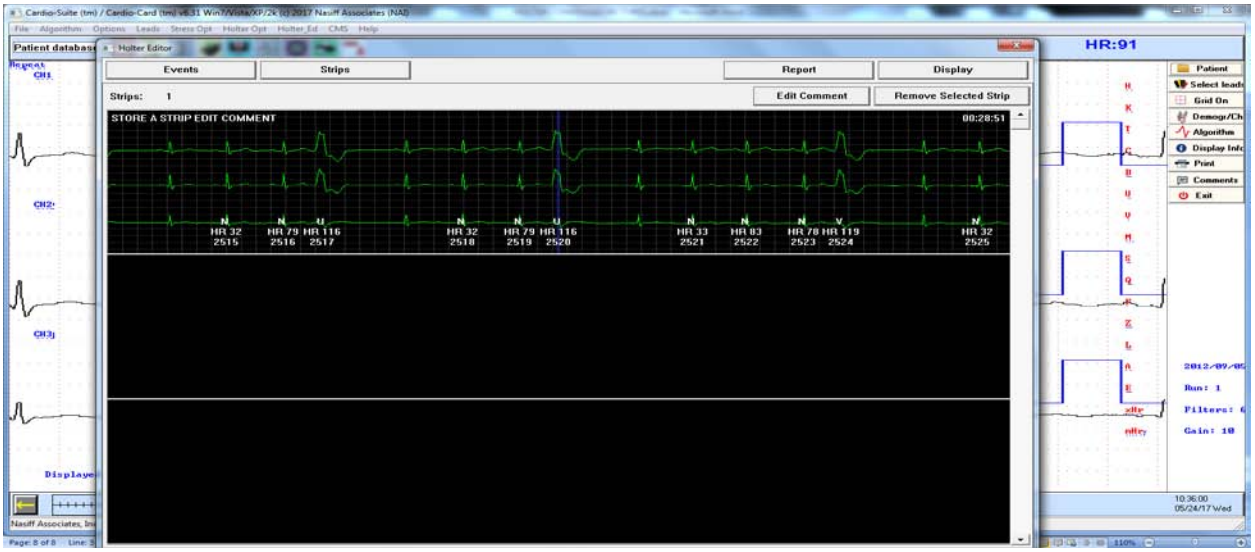


Click “Edit Comment” Make your changes then click “OK”

Remove Selected Strip

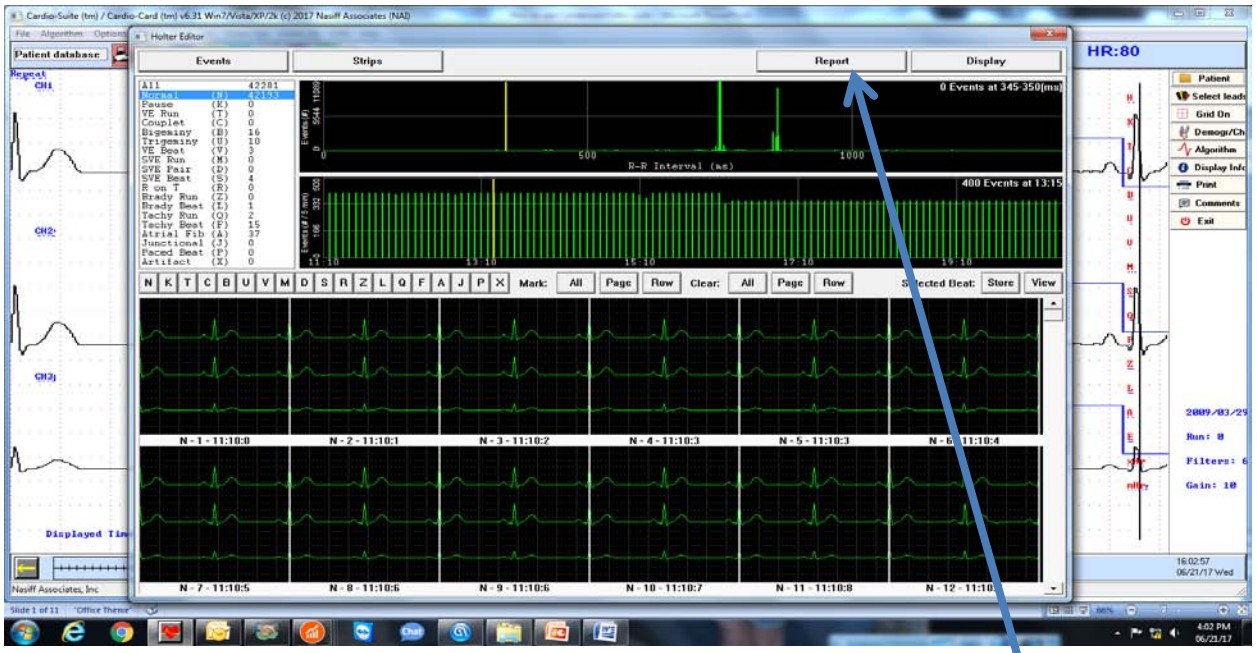
To remove selected Strip, Single click on the strip

Then click on “Remove Selected Strip”

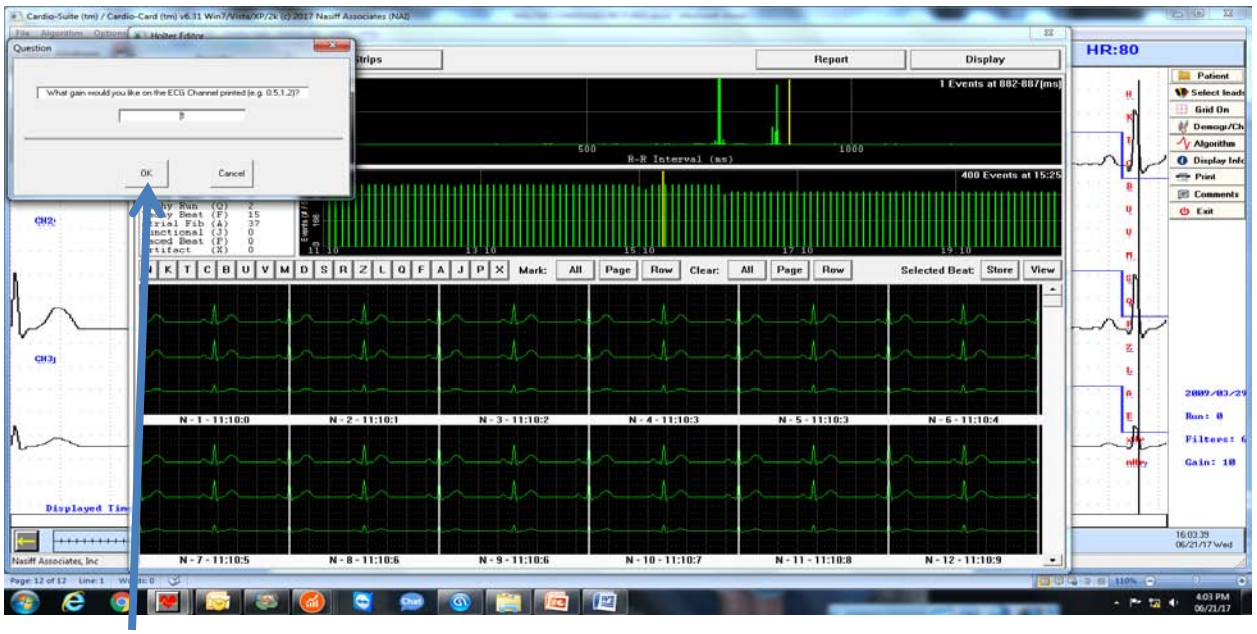


To go back to Events, “Click Events” (May need to Click “View” to go to All Events)

View the PDF Report

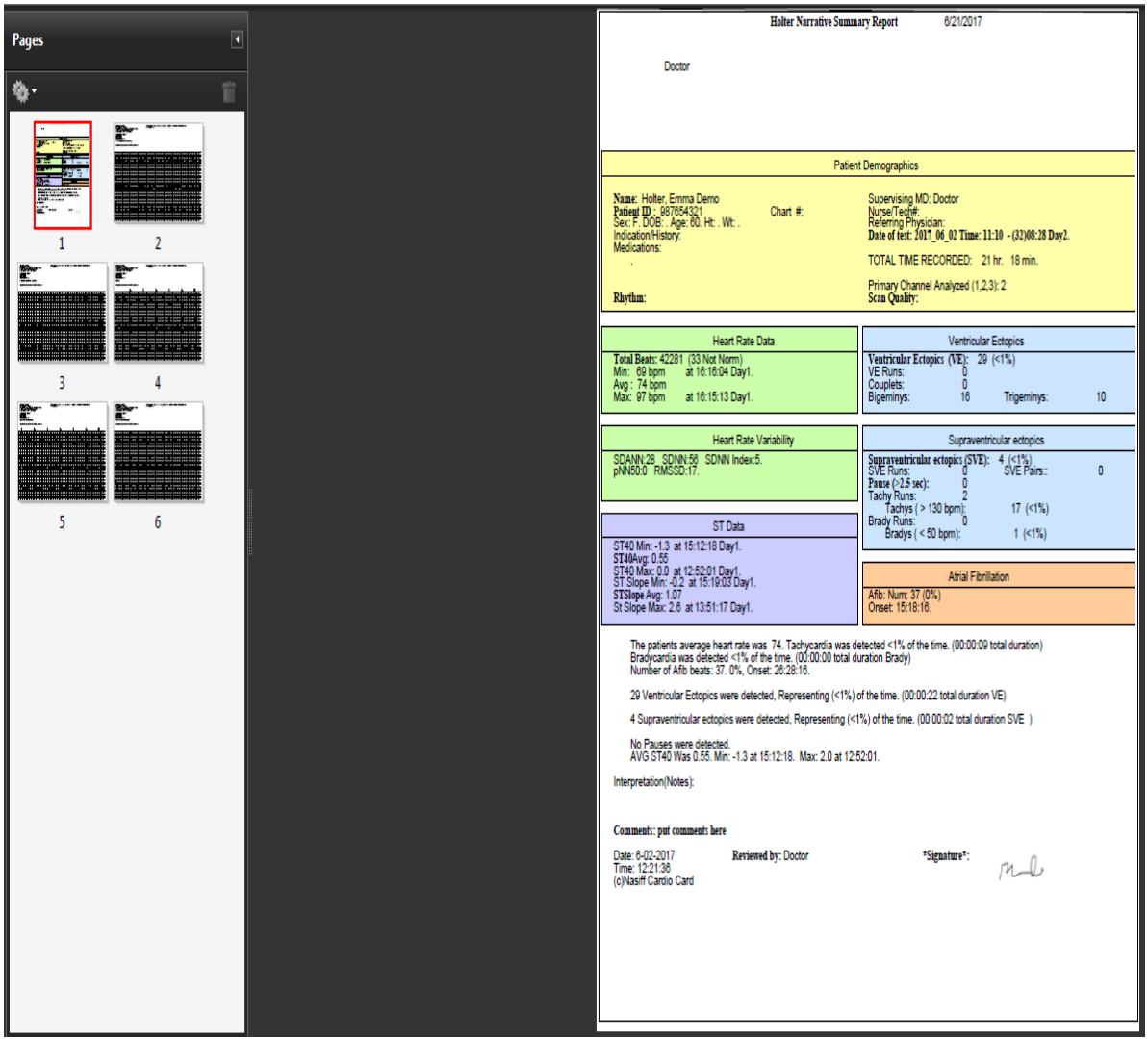


Click on “Report”



Click “OK”

PDF Report

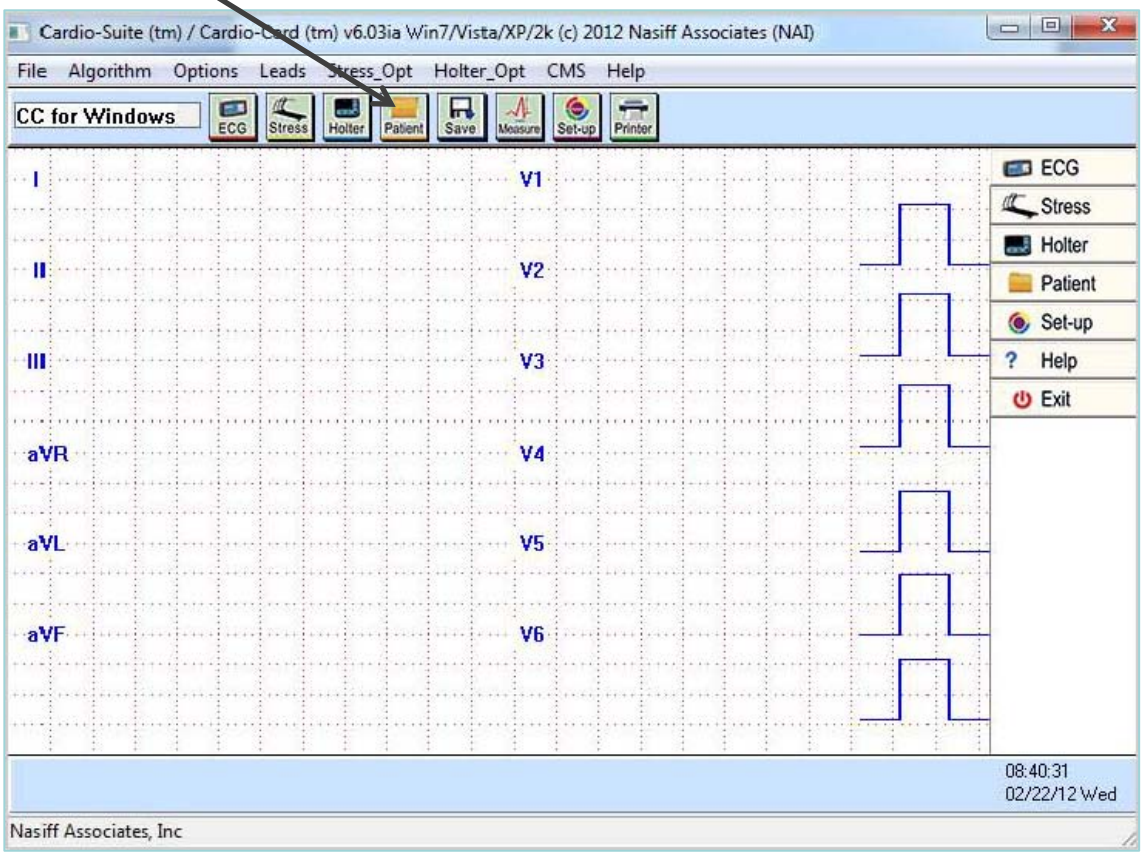


Database Operations

The purpose of this section is to show you the Database Operations

***** For Program Capability or Windows Stability it is strongly recommended that all screen savers and power savers are turned off, and that the computer is rebooted at the beginning of each day**

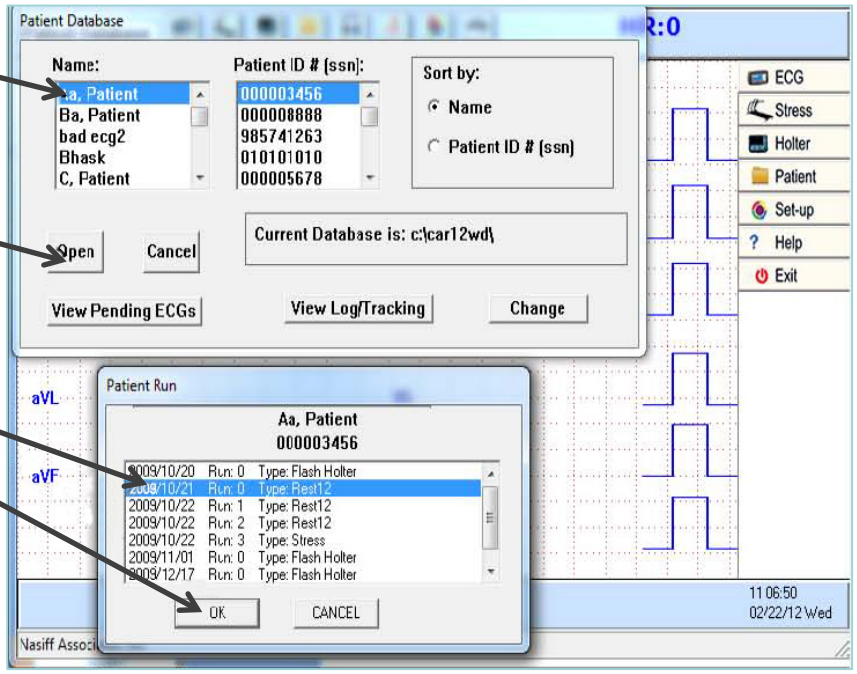
1) To open database click on Patient to open the database



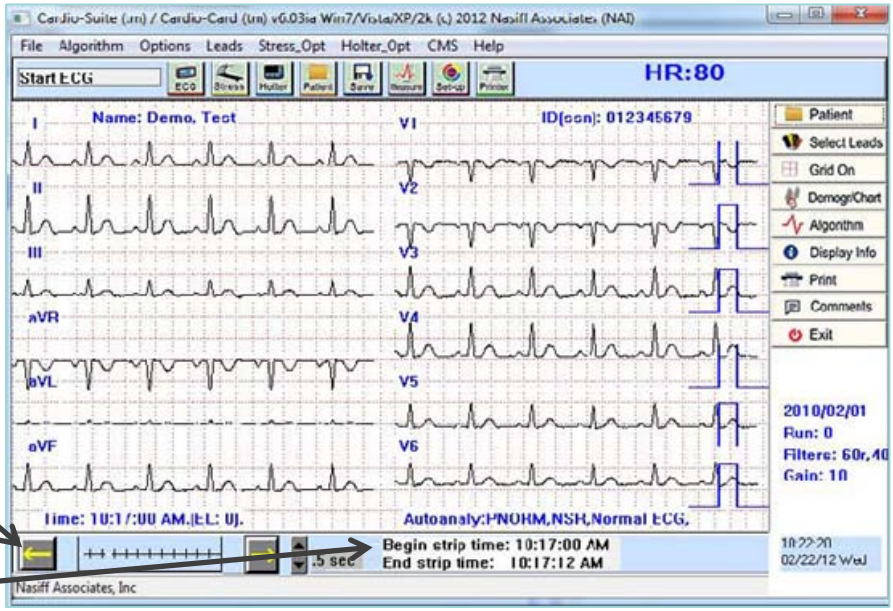
Opening Database

2) Click on any patient name and a list of test "runs" come up by date and type (eg. “Flash Holter”, Stress, and Rest12) then click “Open”

3) Click on the “run” and click “OK”

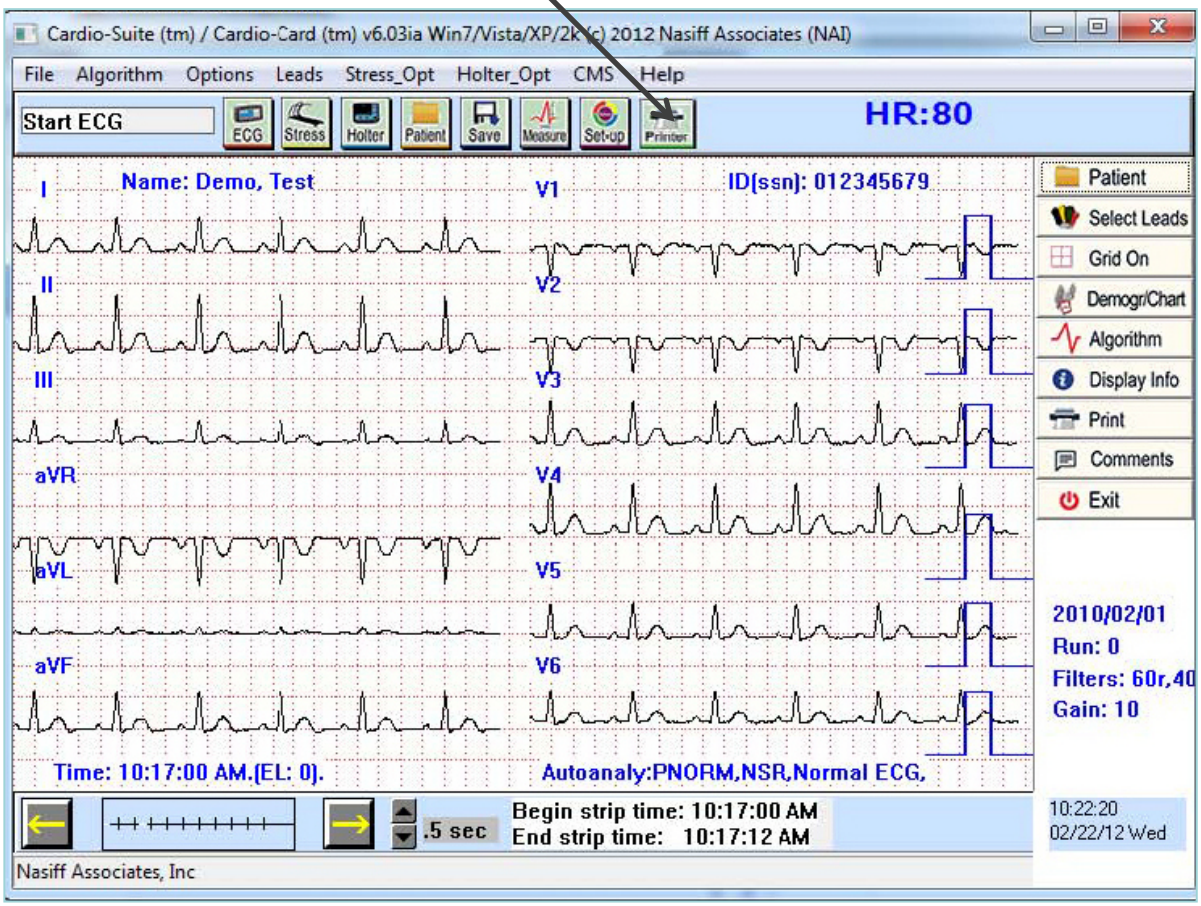


4) ***Note:***
After storing any test (for example: “Rest12", “Stress", “Flash Holter"), the test will appear on the screen. You are in the database when you see the arrows at the bottom of the screen and the begin and end strip time.

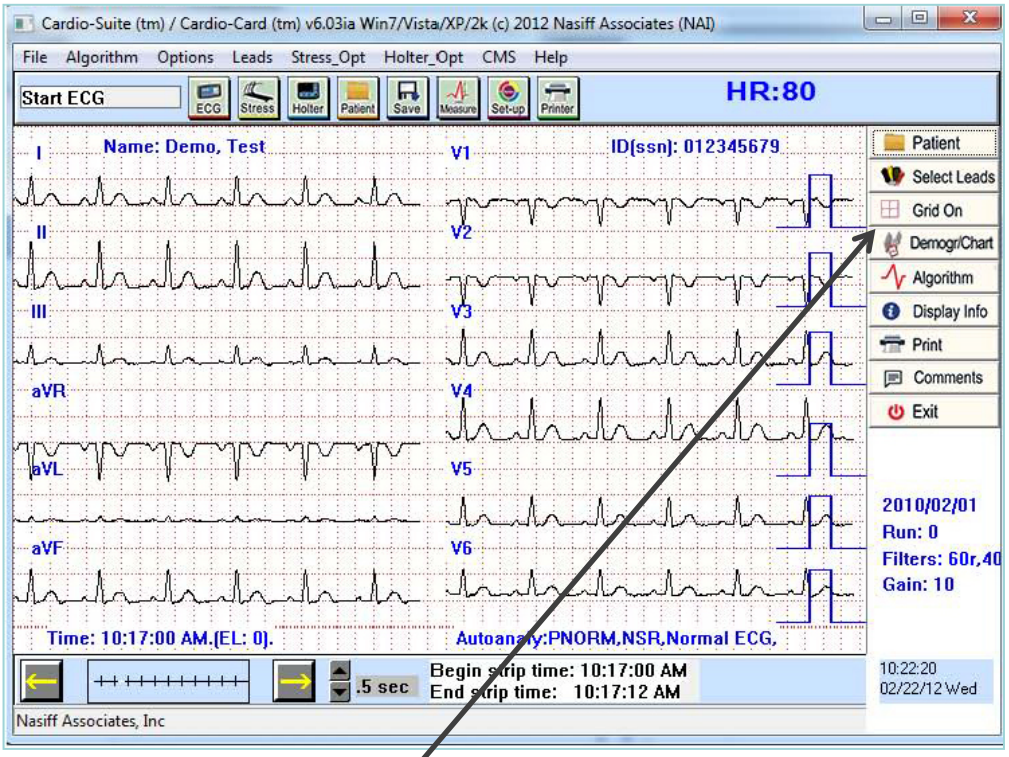


Printing

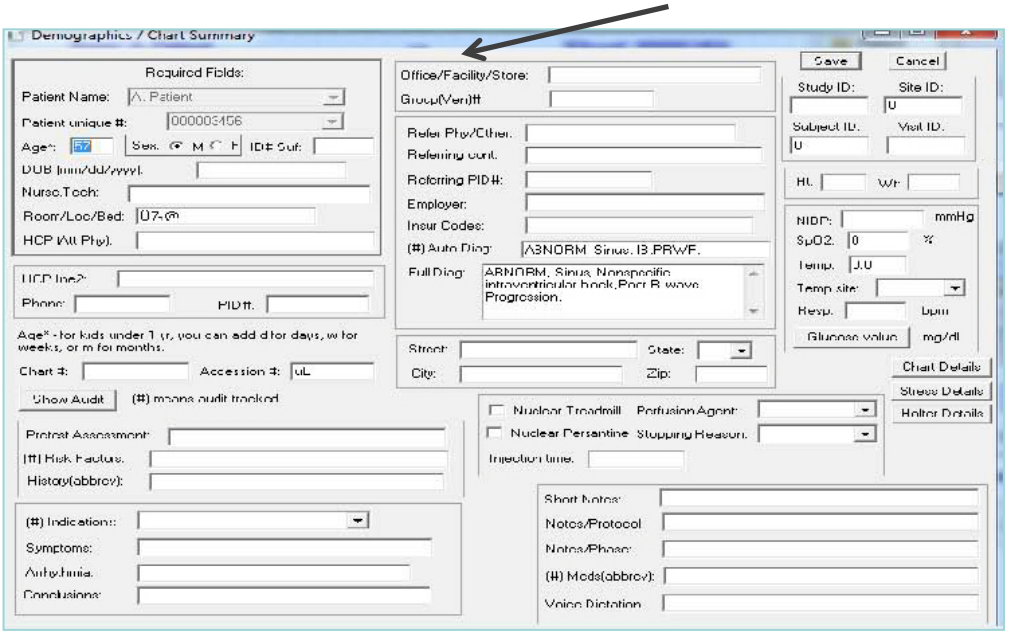
1) Clicking the printer icon prints reports to the default printer



Demographics Chart

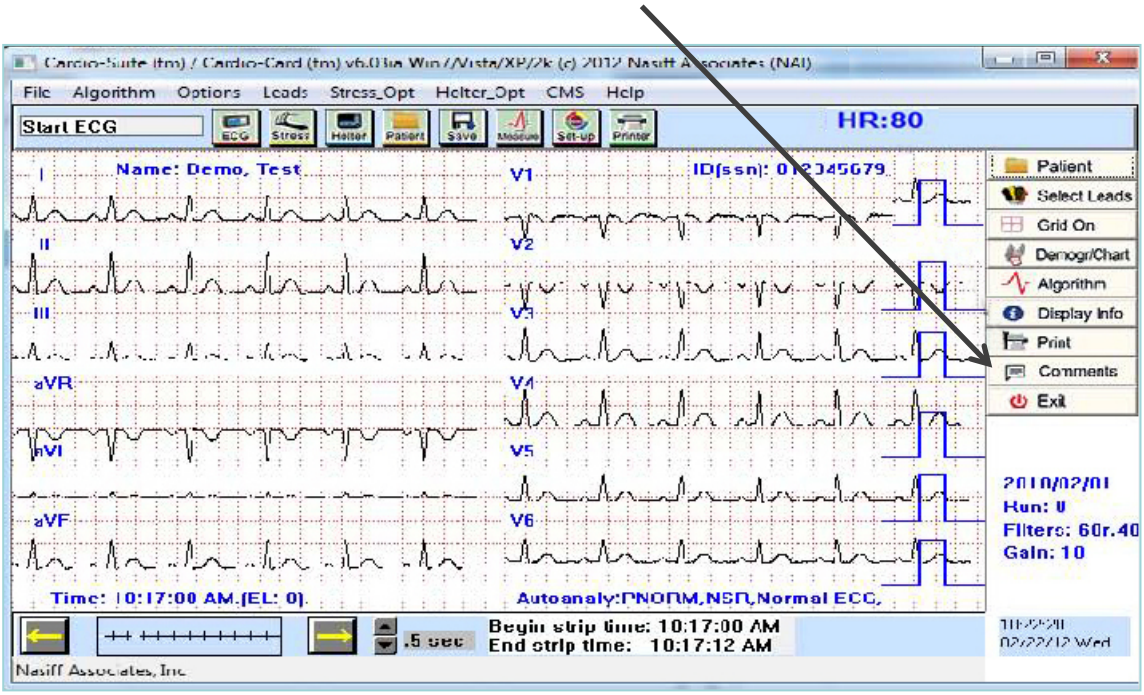


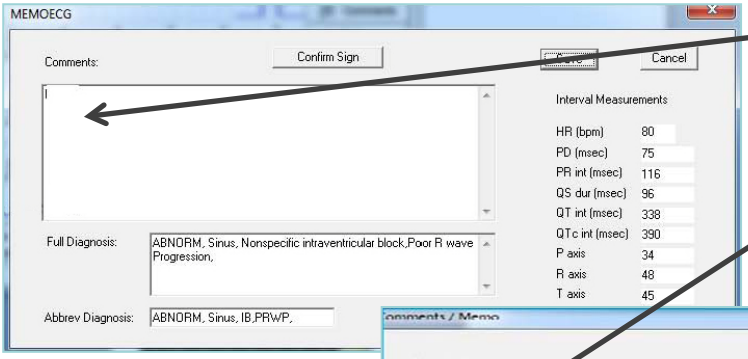
2) Clicking the “Demographics Chart” button displays detailed patient information and provides entry into the Cardio EMR Chart program



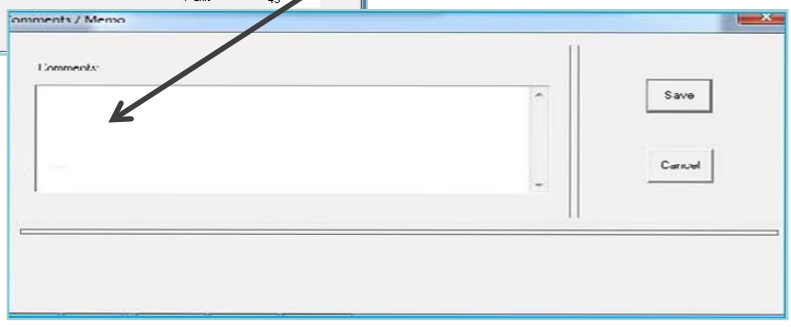
Comments

3) Clicking the "comments" button allows the inputting of unlimited notes, comments, diagnoses, etc. *(Copy and paste from other programs is also permitted in this area)*





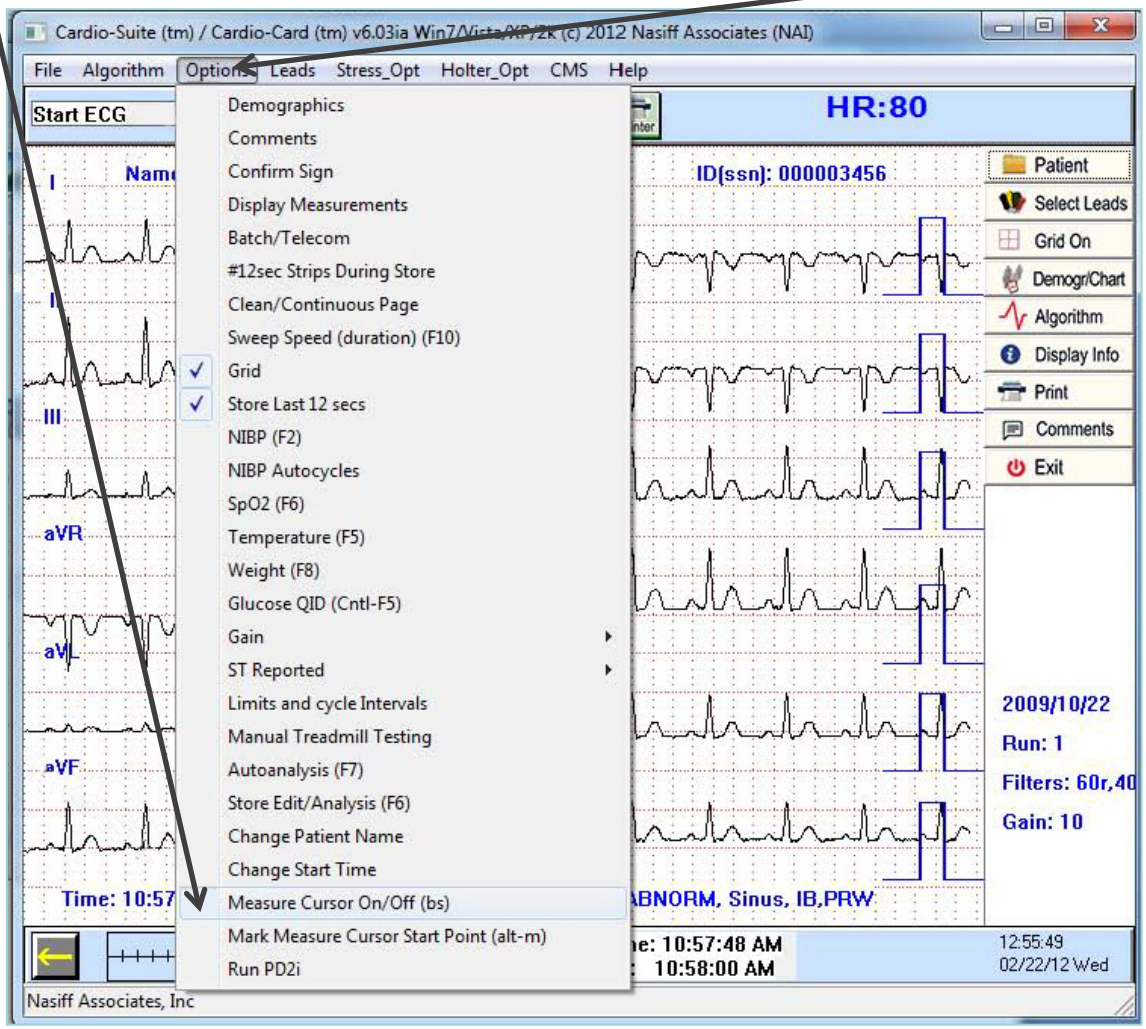
This is the “Comments” field for ECG/EKG



This is the “Comments” field for Stress and Holter

Measurement “Cursors”

4) Measurement "cursors" are available providing wave measuring capability. *(eg. amplitudes, durations, rr values…).* To activate or deactivate click “Options" then "Measure Cursor On/Off". Cursor navigation is accomplished by using the "arrow", "page up" and "page down" keys. Mark cursor start point by clicking “Options" then "Mark Cursor Start Point”



Network & Database Utilities

The purpose of this section is to show you the Network and Database Utilities.

*** For Program Capability or Windows Stability it is strongly recommended that all screen savers and power savers are turned off, and that the computer is rebooted at the beginning of each day.

Database

All patient data and indexes are stored in the CAR12WD folder on the drive where the selected database resides. This folder can be easily copied to any other Windows compatible drive using standard windows "copy" functions.

Procedure

The Cardio Software Suite uses standard windows networking protocols. All users must have windows network access (read and write) in order to use the software in a network environment.

All CAR12WD database folders must be directly off the root database drive. CAR12WD cannot be in a sub directory because the software looks for CAR12WD to be a folder directly off the root of the drive letter.

Transferring Data

To transfer data from one computer to another computer make sure Cardio Card is installed in the other computer. All data goes to “CAR12WD” in your “C” Drive” (**Back this up**) Go to my Computer, Click on the “C: Drive” Right click on “CAR12WD” Highlight “Send To” Pick what function you will use to copy on.

Sharing Cardio Card Data on a Network

- Go to your server and make a folder ex: “Cardiodata”
- Share the folder by right clicking on the folder and go to Share and Security. Under Sharing go to Network Sharing and Security. Make sure both boxes are checked (Share and Allow)
- Click “Apply”
- Click “OK”
- Give the folder a drive letter on the client. To do this go to “My Computer” then “Tools” then “Map Network Drive” then pick a drive letter. You will browse for your folder. Highlight it then click “OK” then “Finish”
- Copy CAR12WD and paste to a New drive letter.
- Change your default in Cardio Card to New drive letter. To do this go to Cardio Card. Open System Setup, then database. This will bring you to a question screen. The question “Which database would you like to change to?” Arrow down to new drive letter. Then click “OK”.
- Close out of everything and reboot your computer.

Batch / Telecom

Entering Batch / Telecom:

(From the opening Cardio Screen) Click on "Options" then "Batch / Telecom" to enter Utilities.

Build a List:

Click “C” button “Clear batch list”. Click “Yes” to question “Are you sure?” Then Click on the “1” button “Edit batch list” to build a batch list of tests. The list can be built by clicking on individual tests and clicking the “add” button. You can also select “like” tests (all Resting, all Stress, all Holter), or the entire database. Once the list is built, there are additional operations that can be formed as noted in subsequent operations.

Serial Compare of resting ECGs:

Click “C” button “Clear batch list”. Click “Yes” to question “Are you sure?” Then Click on the “1” button “Edit batch list”. Click ONLY once on the test you want to compare. Click “Add” you will see the test in the box then click “OK”. Click on the "G" button to compare "like" tests on the screen or "H" to print the comparison of batch tests previously selected.

Delete Batched Files

Click “C” button “Clear batch list”. Click “Yes” to question “Are you sure?” Then Click on the “1” button “Edit batch list”. Click ONLY once on the test you want to delete. Click “Add” you will see it in the box then click “OK” then click “9” “Delete batch files” click “Yes” to the question “Are you sure you want to delete the batch list of runs?”

Pack and ZIP selections:

Click on the "Z" button to create a ZIP file for emailing selected tests.

Rebuild the index:

Click on the "R" button to recreate the database index. This should (theoretically) never be necessary. However, situations like power failures, Windows freeze ups, etc. do occur. If you receive the message "database has become corrupted", you must use this function to rebuild the index.

Trouble Shooting
Before installing Cardio Card

Turn off all virus protections, firewalls; and spy ware.

You need to be a Power user on the network.

Make sure all other applications are closed

If the Cardio application will not start up after installation and shows the error message "cannot load giveio.sys", your network firewall maybe blocking the program.

Contact your network manager.

Common causes are:

The user does not have "kernel mode" rights to run the hardware driver. This can be assured by giving them local administrator rights to their own computer.

OR

Your antivirus or anti spyware software is blocking the service.

OR

The firewall is set so strictly that the CARDWIN.exe program is not being allowed to execute.

This program must be included in your firewall's list of allowed programs or made less strict.

NO REMOVABLE DISK

If there is no Removable Disk listed, try unplugging the card reader from the USB port and plug it in again.

Printing Problems

You need to check to make sure the printer that you are using is the default printer. To check this go to start then click printers and faxes. Make sure the printer that you are using has a check mark. *Or* go to start then Control Panel then click on printer and faxes.

Right click on the printer that is your default printer

To Test Printer

Right click on the printer that you are using as your default printer
then click on properties
click print test page
click “OK”

What Version of Windows

- To check what version of windows you have go to “My Computer”; or “Control Panel”. Then “Help” then “About Windows”. This will tell you the version you are using.

If your computer goes into “Power Save mode” You need to turn this off

- Go to Properties
- Then to Screen Saver
- Click on Power
- Under Power Schemes arrow down to “always on”
- Under Turn off Monitor arrow down to “Never”
- Click “apply”
- Click on Hibernate tab and disable it
- Click “apply”
- Close out of this and reboot your computer

When you have Corrupted Files

- Go to “Start”
- Click “Run”
- Type cmd
- Click “OK”
- Then type CHKDSK /F E:
- The E is where you will type your Drive Letter that your Reader is in.
- Hit Enter
- It may ask you to reboot (if so reboot).
- Type EXIT to get out of this
- Hit Enter

Error Messages

“Database has become Corrupted”.

You need to rebuild the index. Go to Cardio Card Screen Click on "Options" then "Batch / Telecom" Click on the "R" button to recreate the database index. This should (theoretically) never be necessary. However, situations like power failures, Windows freeze ups, etc. do occur. Make sure it is on your drive letter. Then click “OK”.

“No USB Cardio Card devices(s) attached. Please plug in”.

Unplug and plug back in.

“Invalid Flash Recorder Path”.

Make sure card and reader are plugged in. You need to make sure you are in the correct path.

“Cardwin.exe no disk”.

There is no disk in the card reader. You need to take the card out and put it back in making sure it is in all the way.

“Call NAI Support”.

You need to install the Security key (thumb drive).

“Can’t load Giveio.Sys",

Your network firewall maybe blocking the program. You need to turn off the firewall and any security while you are installing.

“There is no disk in the drive. Please insert a disk into drive A. a:\car12wd not found. Please correct the Database letter in System Setup. Data can only be stored to a valid database drive”.

You need to check the Database drive letter. Go to System Setup. Then to Database. Check the current database. If it is wrong change it and click “OK”.

“You must run event detector first”.

Open the database and bring up your patient and the test. If there are flat lines go to the arrows and try to move the screen. If nothing moves you may have a corrupted card. You need to “CHKDSK”. In there are beats then go to holter opt then to auto analysis change channel increase gain and analyze

Troubleshooting For Cardio Holter B12

In case of any problem occurs during use, please refer to the following table to try to find out solutions. In case of any damage or problem, stop using immediately, and contact the distributor or Nasiff, but never make any repair without authorization.

Problems	Possible causes and corrective actions	Solutions
After powering on, the screen has no response or the display is abnormal	1. The battery voltage is too low; 2. The recorder is powered on continuously too fast.	1. Replace with a new battery; 2. Wait for over 5 seconds to power on again.
After powering on, the following message is shown: Warning! Low Battery! Power off in 30 seconds!	The battery voltage is too low.	Replace the battery with a new one.
After powering on, the following message is shown: Low Battery! Continue? Yes No	The battery has been used.	Please replace the battery with a new one.
After powering on, the following message is shown: SD card not found, please insert !	1. The SD card is not inserted into the recorder; 2. Poor contact of the SD card or SD card error.	1. Insert the SD card into the recorder; 2. Replace the SD card.

After powering on, the following message is shown: Warning! SD card access error! Error code: 40h	1. Error in reading and writing the SD card due to occasional factors as unstable voltage when powering on; 2. SD card error.	1. Power on again; 2. Replace the SD card.
After powering on, the following message is shown: No patient cable, please insert !	1. The patient cable is not inserted into the recorder; 2. The patient cable which is not supported has been inserted; 3. The patient cable occurs error.	1. Insert the patient cable 3-channel recorder does not support 10 wire patient cable; 2. Replace the patient cable.
After powering on, the following message is shown: ECG file isn't analyzed Continue ? Yes No	The data recorded last time has not been analyzed.	Please play back the data for analysis and then start the next recording.
During recording, a "beep" sound was heard.	1. The patient had violent movement; 2. The contact of the electrode is poor; 3. Patient cable error.	1. Reduce movement suitably; 2. Re-check and install the electrode; 3. Replace the patient cable.
Recording for 1 day (or the pre-set time) cannot be performed.	1. The battery is poor; 2. Misoperation, incorrect termination in the midway or the battery is removed in the midway.	1. Check the EVT file to confirm the cause of termination, and replace the battery with a good one; 2. Tell the patient not to operate without authorization.
The recording is normal, and when playing back for analysis, the recorder shows message that ECG data cannot be found, and the SD card disk cannot be seen in the operating system.	1. The SD card is not inserted into the card reader or the card reader is wrong (if a card reader is used); 2. The USB cable of the recorder is not connected to the PC (if the cable is used); 3. SD card error.	1. Insert the SD card into the card reader slot or replace the card reader of the SD card; 2. Use the USB cable to connect the recorder and the PC; 3. Replace the SD card.

The recorder shows message that data cannot be found, and the SD card disk can be seen, but no file in the SD card can be seen or file error occurs.	1. Card reader error; 2. Poor contact of the SD card or other errors.	1. Replace the card reader; 2. Replace the SD card.
The quality of the ECG waveform is low, and no QRS waveform can be seen.	1. The electrode position is not good; 2. The electrode is poor; 3. The skin is not clean; 4. There is too much hair in the position for applying the electrode; 5. Patient cable error.	Keep far away from such objects as transformer, electrical blanket and electrical blower.
The ECG waveform has interference from working frequency of stable amplitude and frequency.	During monitoring, there is strong working frequency interference source around the patient.	1. Keep far away from such objects as transformer, electrical blanket and electrical blower; 2. During analysis, the filter switch is enabled.

Technical Support / Service

General

The intention of Technical Support is to assist the USER in solving difficulties which may be encountered while using the CARDIO System.

In the event of an Operational or "How To" Question, the following STEPS are suggested:

1) Reference the USER Manual
2) Fax (315) 676-4711 or Email nasales@nasiff.com
3) Tel # Operational questions: (315) 676-2346
4) Tel # Engineering/Involved Tech questions

CUSTOMER SUPPORT POLICY

Our customer support mission is to provide professional, timely, complete and cost-effective telephone support for resolving problems or questions related to the use of Nasiff Associates products.

OBTAINING CUSTOMER SUPPORT

To obtain support, call into any of the customer support numbers given above. Our *Hours of Operation are* **9:00 am** to **4:30 pm** EST at our National Service Center, Monday through Friday, except holidays. Our Systems department is staffed until 4:30 p.m. The telephone numbers are given above. The Support FAX numbers are also given.

We have a dedicated team of “Front Line” technicians that triage all incoming calls. If your call is a simple Application question, our Front Line Team is usually able to provide you with an answer. If your question is more complex, they may have to schedule a call back. If you are experiencing an emergency, they will immediately escalate your call to a “Back Line” technician that will take ownership of your call until the problem is resolve

Generally speaking, calls are returned according to the priority and in the order they are received. We make a best effort to return all calls promptly. Because of the complex and time-consuming nature of some of the calls received, we cannot guarantee a specific turnaround time. If we cannot get to your call immediately, you will normally receive a call within 4 business hours either to support your call or to notify you that we have not had a chance to address the call and the anticipated time frame for resolution.

Non-urgent questions may be e-mailed to support@nasiff.com. Responses will be e-mailed back to the sender (unless otherwise specified) within one business day. We do not check the e-mail in-boxes of support technicians in their absence. Therefore, do not send e-mail to individual technicians unless specifically requested.

We prioritize calls based on the urgency of the situation. Unless otherwise informed, we will use the following protocol to determine the urgency of the call:

1. System is down
2. Employee cannot perform their work
3. Month-end closing
4. Program termination
5. Insurance claim revision
6. Questions or training over the phone
7. Custom form changes

Many times we receive suggestions and requests to make a change to the standard system. To guarantee the integrity of the system, changes to standard programs cannot be made 'on-line'. Also, since changes to standard programs affect all clients, these changes need to be carefully considered. We strongly encourage your suggestions and we track all requests, by product and client, for inclusion in a future release of the software. We will make our best effort to respond to frequently requested or 'urgent' requests as quickly as possible. Revisions to the standard system will be made under the following conditions:

1. The requested change follows standard system conventions
2. The requested change will only be made available as part of a standard software upgrade
3. We reserve the right to make the requesting client(s) a beta site for new releases
4. The time spent on programming, testing and documenting new features may be billed to the requesting client at our standard rates
5. The revision will become available as an option to all clients as part of a future release

As a service to our clients, we can sometimes create customized user reports within the standard system when requested to do so. These customized reports will be developed in-house then supplied to a client via modem, email or diskette. Optionally, a customer may request assistance via telephone in order to customize their own reports; in either event a report noting an estimated cost and time frame will be generated, and upon receipt of authorization, the task will be assigned to a support representative. Custom designed reports may be made available to other clients at our discretion.

Should you decide that your organization wishes to design and utilize a custom form or label not supported by our standard forms utilities, our support staff will provide a cost estimate, and the estimated time-frame for completion of the custom programming, in the form of a Programming Request Response (PRR) or Work Order. Upon approval, the work will be assigned to a support representative. Software modifications will customarily be made via diskette or modem, not on-site.

Your Service Agreement covers the following:

- Problem resolution and answers to quick 'how-to' questions
- Modem toll calls and emails
- Periodic upgrades/enhancements to the applications software
- User documentation updates
- Invitations to company sponsored user meetings
- Access to our most recent technical documentation and guidelines for the covered product
- Assisting a knowledgeable on-site representative (client-designated) in diagnosing problems with the software (including third-party database management systems integrated with Nasiff Software and approved by Nasiff Associates).
- Advice about configuring Nasiff software for maximum performance
- Assisting a knowledgeable on-site representative (client-designated) in installing or configuring Nasiff software (including third-party database management systems integrated with Nasiff software and approved by Nasiff Associates) to our latest specifications.
- Periodic issues of Nasiff company newsletter

The Service Agreement does not cover:

- User training (on-site or extended telephone training)
- Custom software
- Custom form modifications performed via modem or diskette
- Any assistance related to the diagnosis and/or resolution of problems concerning 3rd party hardware, remote communications, operating systems, and cabling or network software.
- Problems caused by misuse of the program or lack of adherence to commonsense standards (improper system shutdown, failure to maintain system backups, etc.)
- On-line database integrity verification; database repair/restoration
- Support for third-party software provided by vendors other than Nasiff
- Equipment relocation
- Assistance with product updates. Routine updates are to be performed by the client. Nasiff will bill at its standard hourly rate if asked to assist with an update.
- Operating system upgrades including Microsoft service packs
- On-site installation of software updates
- Data repair and/or restoration; on-line database integrity verification
- Tape Verification
- Equipment Relocation
- On-site assistance

Note: *The only on-site service covered under the Service Agreement is Nasiff application updates that Nasiff Technical Services chooses to perform on-site*.

A major mission of SERVICE is to promptly assist the customer in solving problems that they may encounter while using the CARDIOCARD.

At this time we have established our main TECHNICAL SUPPORT ADDRESS is at:

NASIFF ASSOCIATES, INC.
CARDIOCARD SYSTEM TECHNICAL SUPPORT
P.O.BOX 88, BREWERTON, N.Y.13029.

Please feel free to call or write anytime for any special questions and projects. We welcome any suggestions you may have.

Nasiff Associates: Two Year Limited Warranty

It is very important to Register your CARDIO System with Nasiff Associates. Not only does it activate the Warranty Benefits of the CARDIO System, BUT it also adds your CARDIO System to the list for FREE Software Product enhancements as they become available during the two year limited warranty.

Nasiff Associates, Inc. warrants the CARDIO System (See below for CARDIO System definition) against defects in materials and workmanship for a period of TWO years from receipt by the end USER (Please retain purchase Records in event of Warranty Claim). If Nasiff Associates is given notice of such defects during the Warranty period, Nasiff Associates will either, at their option, repair or replace products which prove to be defective.

The Nasiff CARDIO System includes:

Product Description	Warranty Conditions
CARDIO System PC Board Electronics	TWO Year Limited Warranty
CARDIO System Digital Holter Recorder	TWO Year Limited Warranty
CARDIO System Diagnostic Software	TWO Year Limited Warranty
CARDIO System Patient Cable and Leads	90 Day Limited Warranty
CARDIO System Holter Electrode Leads	90 Day Limited Warranty
CARDIO System Holter Recorder	See Recorder User Manual

Nasiff shall not be liable for defects or support of any third party devices (e.g. computers, treadmills, printers, other company's Holter recorders, etc) used with a CARDIO System. This includes operating system incompatibilities and hardware incompatibilities (e.g. for PCMCIA systems, the computer has to support PCMCIA I/O standards, etc). Warranty and support for these devices is the responsibility of their Manufacturers.

GENERAL

Nasiff Associates, Inc. warrants the CARDIO system against defects in materials and workmanship for a period of two years from receipt by the end user (proof of purchase is required). If Nasiff Associates is given notice of such defects during the warranty period, Nasiff Associates will either, at their option, repair or replace products which prove to be defective.

EXCLUSIONS

The above warranty shall not apply to defects resulting from: improper or inadequate maintenance by the customer; customer-supplied software or interfacing; unauthorized modification or misuse; operation outside of the environmental specifications for the product; or improper site preparation or maintenance. Only service personnel authorized by Nasiff Associates, Inc. directly are allowed to service Nasiff equipment. If customer desires to have someone other than Nasiff Associates, Inc. service the equipment they must get prior written authorization from Nasiff Associates, Inc., otherwise anyone other than Nasiff Associates, Inc. providing service ***voids*** *the warranty.*

OBTAINING WARRANTY SERVICE

To obtain warranty service, return the product to a service facility designated by Nasiff Associates. Nasiff Associates may repair on-site at the option of the customer. The customer is responsible for travel charges when on-site repair is requested.

Customer shall prepay shipping charges for products returned to Nasiff Associates for warranty service and Nasiff Associates shall pay for return of the products to the customer. However, the customer shall pay all shipping charges, duties, and taxes for products returned to Nasiff Associates from another country.

WARRANTY LIMITATIONS

Nasiff Associates make no other warranty, either expressed or implied, with respect to this product. Nasiff Associates specifically disclaim the implied warranties of merchant ability and fitness for a particular purpose. Some states or provinces do not allow limitations on the duration of an implied warranty, so the above limitation may not apply to you. However, any implied warranty of merchant ability or fitness is limited to the 1-year duration of this written warranty.

This warranty gives you specific legal rights, and you may also have other rights which may vary from state to state, or province to province.

EXCLUSIVE REMEDIES

The remedies provided herein are the customer's sole and exclusive remedies. In no event shall Nasiff Associates be liable for any direct, indirect, special, incidental, or consequential damages, whether based on contract, tort, or any other legal theory. Some states or provinces do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation or exclusion may not apply to you.

OBTAINING SERVICE DURING WARRANTY

If your hardware should fail during the warranty period, follow the service procedures in this manual, then take the failed piece to an Authorized Nasiff Associates Repair Center or send the equipment to one of the Nasiff Associates Field Repair Centers. (Nasiff Associates may repair on-site at your option, in which case you are responsible for travel charges).

OBTAINING SERVICE AFTER WARRANTY PERIOD

If your hardware should fail after the warranty period, follow the service procedures in this manual, then contact an Authorized Nasiff Associates Repair Center or call your Nasiff Associates Sales and Service Office for details of the services available.

DETERMINING IF YOUR CARDIO - CARD SYSTEM NEEDS SERVICE

Your CARDIOCARD system is designed to give you years of reliable service. If you are having a problem with your system, however, follow the service procedures in this manual.

RETURNING YOUR SYSTEM FOR SERVICE

If your system needs service, contact the Nasiff Associates Support Office where you purchased the system for complete service information.

If you need to ship your system, be sure it is packed in a protective carton. We recommend that you save the original shipping container for this purpose. If needed, packaging materials and a carton may be obtained from Nasiff Associates In-transit damage is not covered by the warranty.
We suggest that you always insure shipments.

You can help assure effective servicing of your system by following these guidelines:

1. Follow the instructions in this manual to make certain the malfunction is in your CARDIOCARD system and not the result of an interface error or a malfunction in your computer or software. If possible, identify the defective area or function.

2. If you determine that repair is required, please include the following items when you return your systems for service:

   a. A description of the exact configuration at the time of the malfunction, including interface cable, computer and peripherals, and software (programs) in use.

   b. A brief description of symptoms for service personnel.

   c. Hard copy produced on a printer that might help illustrate the problem area.

   d. The serial numbers for the components in your CardioCard system.

   e. If purchased through a Nasiff Associates dealer, a copy of the sales slip or other proof of purchase to establish the warranty coverage period.

3. Include your name, address, and a phone number where you may be reached during the day.

4. You do not include any operating accessories with the system, unless the problem relates to an accessory. Do include your CARDIOCARD, BOX12 patient connector, ISOTR1 isolation transformer, any other equipment that is part of your CardioCard system (Holter recorders, playback hardware, NIBP modules, etc) and original CardioCard software disks.

Note: A valid RMA Number is REQUIRED for ACCEPTANCE of SHIPMENT

COSTS

Description	Hourly Rate
Initial Training telephone customer training as part of the initial software purchase.	included in purchase price
Follow-up Training On-site training requested any time after the purchase of the software.	$200 per hour
Technical Support In-house phone support or on-site support for Nasiff software, third party software, hardware, training via phone, forms modification, data manipulation/repair or EMC support.	$185 per hour
Consulting On-site, in-house or telephone consultation requested with senior level personnel (5 plus years experience).	$225 per hour
Programming Includes software modification for new features, custom programming or database repair that requires a programmer.	$225 per hour
Production Includes in-house preparation of equipment prior to on-site installation.	$225 per hour
Network Engineering. Includes on-site or in-house and support of network operating systems.	$225 per Installation hour
Travel Includes time necessary to travel to and from customer site. If travel includes multiple customer sites then travel time is equally distributed among customers.	$125 per hour

NOTE: *Minimum charge for any provided service is ¼ hour. Cabling is not provided.*

Unless disputed in writing, customers with support payments 30 days or more past due will have their technical support temporarily suspended pending payment of their past-due balance. Customers without a valid Service Agreement will be provided with assistance at Nasiff's discretion and/or upon the reinstatement of a valid Service Agreement. If your support coverage has lapsed, please contact our Finance and Administration Department for additional information regarding the terms and conditions for reinstating a Service Agreement.

Licensor is Nasiff Associates

Licensee is End User Customer

Licensor End User License Agreement (EULA) terms:

a. LICENSEE AGREES TO BE BOUND BY THE TERMS OF THIS EULA BY INSTALLING, COPYING, OR USING THE SOFTWARE.

b. GRANT OF LICENSE. Licensor grants Licensee the following rights provided that Licensee complies with all terms and conditions of this EULA:

1. Licensee may:

(a) install and use a copy of the Software on one personal computer per Software License Key supplied by Licensor to Licensee

(b) Alternative Rights for Storage/Network Use. As an alternative to (a), Licensee may install a copy of the Software on a network storage device, such as a server computer, and allow one access device, such as a personal computer, to access and use that licensed copy of the Software over a private network. Licensee must obtain a license to the Software for each additional device that accesses and uses the Software installed on the network storage device.

2. License Grant for Media Elements. The Software may include certain photographs, clip art, shapes, animations, sounds, music and video clips that are identified in the Software for Licensee's use (together "Media Elements"). Licensee may copy and modify the Media Elements, and license, display and distribute them, as part of Licensee's software products and services, including Licensee's web sites with credit given to Licensor, but Licensee is not licensed to do any of the following:

- Licensee may not sell, license or distribute copies of the Media Elements by themselves or as part of any collection, product or service if the primary value of the product or service is in the Media Elements.
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Specifications

MINIMUM PC SYSTEM REQUIREMENTS

- IBM compatible Pentium or higher.
- 512MB ram for program for Windows 2000/ XP/ Vista and Mac with boot camp. CD-ROM
- USB Ports
- 5 MB hard drive space for programs and additional for patient data. For standard 12-lead tests only 60kb are needed. For Holter, 33MB are needed per 24 hr patient test.
- 2000/ XP/ Vista Mac with boot camp
- Display: Any Windows compatible display.
- Printers: Any Windows compatible printer.
- Mouse: Any Windows compatible mouse.
- Keyboard: Any Windows compatible keyboard.

MEDICAL SYSTEM (ECG, HOLTER, NIBP) FEATURES

- Leads:
  12-lead systems: 12 (+ XYZ optional) on PCC16. Standard 12 with BOX12.
  Holter systems: 3 to 12 leads.
- Display:
  LCD, Color, Monochrome.
- Monitor quality defib protection.
- ECG storage to any device that appears to the pc as a drive. e.g. hard drives, floppies, optical, etc.
- Data stored:
  ECG waveforms, time and date, and patient information (i.e. demographics).
- ECG transmission by direct connect, modem, fax and internet.
- Measurement's tolerances:
  time: +/- 4msec
  amplitude: +/- 1.22uV at 10mm/mV gain.
- Holter analysis:
  standard arrhythmia classification of all beats detected.

- NIBP's tolerances:
  time: +/- 4msec
  pressures: +/- 2mmHg
  pulse rate: +/- 1bpm
- NIBP limits: 45 - 300 mmHg (system cut-off at 300mmHg)
- NIBP cuff, tubes, and connectors:
  Cuff length: For bandage cuffs:
  The full cuff length extends beyond the end of the inflatable bladder by at least the equivalent of the length of the bladder, The length of the cuff is long enough that when inflated to 300mmHg, it does not slip or become loose.
  For hook and contact closure cuffs:
  The cuff is long enough to completely encircle the largest circumference limb (44cm), and maintains its full width throughout this length.
  Pressure capacity: The cuff completely retains the bladder when the bladder is inflated to a minimum Pressure of 330mmHg. The tubes and connectors remain intact at 330mmHg.
  Cuff closures/construction for non-disposable cuffs: The cuff integrity is maintained after 1000 open-close cycles, and after 10,000 cycles to 300mmHg.
  The cuff bladder length encircles much of the circumference of the limb throughout its length and maintains it's much of its width throughout its length.
  The bladder length is at least 0.80 times the circumference of the limb at the midpoint of the cuff application.
  The cuff bladder width is at least 0.37 (preferably 0.40) times the circumference of the limb at the midpoint of the cuff application.
  System leakage (cuff bladder, tubing and connectors, etc) is less than 1 mmHg per second.
- Cables: all electrical cables have individually insulated wires and a jacket (usually PVC). All cables can withstand a stretch force of up to 5 lbs.
- Connectors: all electrical connectors have at least 0,025" spacing between conductors, have a maximum conductor

contact resistance of 10ohms, and maintain this maximu resistance after 100 connect-disconnect cycles.

- NIBP features:

  Report: Systolic pressure, Diastolic pressure, heart rate, and in full disclosure pulse and pressure waveforms.

  Indications:
  Ages: Infant - Adult
  Arm Circum: 8-44cm
  Contraindications: Open wounds to limb distal to cuff application.

MEDICAL ELECTRICAL PERFORMANCE & SAFETY

- Frequency response: .05 - 120 Hz. upper 3db at 120 Hz. (AAMI & AHA Stds).
- Lead leakage: < 10 uA. (AAMI Standards).
- Chassis leakage: < 100 uA. (AAMI Standards).
- Input impedance: > 100 M. (AAMI Standards).
- Gain sensitivity: 5, 10, 10/5, and 20 mm/mV. (AAMI).
- CMRR: 120 db. (AAMI).
- 12-lead ECG Sampling rate: 250 - 1000 Hz.
- A/D resolution: 13 bits.
- A/D rate: 10 kHz.
- Time base: 25 & 50 mm/sec. (AAMI).

GENERAL SYSTEM

- Power consumption:

  < 300 mA from the pc bus.

  CC-Holter recorder:

  1 AA battery for 24/48 hours of continuous use.

- Dimensions:

  PCC Rev B: 5.5" x 4.5" x 0.6"
  PCC Rev L: 6.5" x 4.5" x 0.6"
  Box12 Rev M: 4.5" x 2.5" x 0.8"
  CCHolter Rev A: 6.25" x 2.75" x 0.75"
  Flash Holter recorder: 4.4" x 2.6" x .95"
  ISOT Rev B: 6" x 5" x 4.25"
  CCNIBP-I: 5.75" x 3.6" x 1.75"

- Weights:
  PCC Rev B: 118g (4.2oz)
  PCC Rev L: 118g (4.2oz)
  Box12 Rev M: 268g (9.5oz)
  ISOT Rev B: 1806g (4lbs)
  CCHolter Rev A: 268g (9.5oz) + 1 AA battery
  Flash Holter Recorder: 5oz with batteries
  CCNIBP-I: 350g (12.5oz)
- Environmental:
  Max temperature range: 10°C (50°F) to 40°C (104°F)
  Recommended range: 15°C (59°F) to 35°C (95°F)
  Storage range: -40°C (-40°F) to 60°C (140°F)
  Humidity: 10-70% RH non-condensing.
  Vibration: < 0.3G over a 10 min period (Holter Recorder and NIBP modules).
  Altitude: -500 to +5000 feet w.r.t. sea level.

  Note: that the instrument's specifications may degrade if operated outside of these environmental specifications

CASSETTE PLAYBACK SPECIFICATIONS

- Signal channels: 2 or 3, software selection
- Clock track: Recorded on channel 3
- Clock track frequency:32Hz
- Scanning speed:480 mm/sec
- Rewind speed:2000 mm/sec
- Sample rate:128 samples/sec nom. (referred to 1mm/sec Record speed)
- Sample signal:Clock track or CD350 tachometer
- Signal range:±2.5 mVPP
- Analog digital conversion:8 bits per channel
- Signal resolution:19.6 uV per bit
- PC board pre-amp gain:X.5, X1 and X2
- PC board amplifier gain:256 levels from X0 to X1.99
- PC board address range:340H - 35FH
- PC board data memory size:1MByte
- Data collection method: Software - no DMA or interrupt levels needed

- Bezel: 3 ½" molded plastic-Apple platinum color.
- +12V current:3 amps
- -12V current:200ma
- +5V current:1 amp
- Operating Temperature:+5◦C to +45◦C
- Trans/Storage Temperature: -40◦C to +70◦C

SpO2 SPECIFICATIONS

- Oxygen saturation range: 0-100%
- Accuracy: +/- 2% for 70-100%. +/- 3% for 50-69%.
- Pulse rate: 30-250.
- Probes: finger, ear, non-disposable

TEMPERATURE SPECIFICATIONS

- Range: 80 F to 115 F (26 C to 45 C)
- Accuracy: +/- 0.2 C
- Self-test between each monitor reading: about 2 sec.
- Probes: oral and rectal

WEIGHT SPECIFICATIONS

- Range: 400 lbs (180kg)
- Accuracy: +/- 0.5 lb (0.2kg)
- Platform size: 12" x 12.25" x 2.25" (30.5x31.1x5.7cm)

HOLTER FLASH RECORDER SPECIFICATIONS

- **Functional**

Channels	:	3
Resolution	:	8-bit (13-bit in the Cardio-Card system)
Recording	:	Full disclosure
Minimum Recording Time	:	24 hours / 48 hours
Storage Medium	:	Removable FLASH memory (Standard PCMCIA-ATA card)
Download Interface	:	PCMCIA card interface
Pace Detection		

- **Physical**

Dimensions	: 4.4" x 2.6" x .95"
Weight	: 5 ounces with batteries
Enclosure	: Molded plastic
Operating Position	: Any orientation
Operating Temperature	: 0 C to 45 C
Non-operating Temperature	: -40 C to 60 C
Operating Humidity	: 10% to 90% (non-condensing)

- **Electrical**

Battery	: One AA Alkaline (disposable)
Connector	: 5 or 7 Lead Wires
Test Jacks	: 3 channels

Special Features

Special File Export Files

When File Export is selected the following files are created from the retrieved Resting ECG run (note that the “ascii” root filename is user defined during export):

ascii.txt - 500hz file exported from File Export selection. Outputs data (4 chars plus sign per sample.) for each lead tab delimited in order:

I\tII\tIII\taVR\taVL\taVF\tV1\tV2\tV3\tV4\tV5\tV6\n

ascii.hed - ascii tab delimited file of patient demographics. Order of fields is:

name //Patient Name
ssn // Social Security Number.
street //Street address
csz //City State Zip
phone //Phone Number
dob //Date of Birth
ashw //Age, Sex, Height, Weight
doc //Doctor
orb //Office Room Bed
empl //Employer
insur //Insurance Codes
med //Medications
notes //Notes
notesp //Notes Protocol
notesph //Notes Phase
bp //Blood Pressure
autodiag //Auto Diagnostics
voicedict //Voice Dictation

ascii.rr – File Export list of R-R times in msec. (limits allowed are entered by user).

ascii.rrv – File Export of R-R average times for user defined intervals (1-1000sec).

ascii.rrs – File Export of R-R limit status. Gives # beats, # outside limits, etc.

ascii.hrv – File Export of HR average bpms for user defined intervals (1- 1000sec).

ascii.evt - File Export list of times of events being hit. (during real-time, pressing F7 causes a log of this time to be saved). Times in ascii.evt are in 2msec sample number (i.e. 500hz sample number).

ascii.ibp - 500hz file exported from File Export selection. outputs data for ibp/cnibp
tab delimited. goes through entire file until done. Puts out 4 chars plus sign per sample. from tempio.t.

ascii.rsp - 500hz file exported from File Export selection. outputs data for respiration tab delimited. Goes through entire file until done. Puts out 4 chars plus sign per sample. from tempio.e.

ascii.sp - ascii tab delimited file of SpO2 values for every 10 sec from tempio.s.

Real time pointer file - ptrf

During the start up of the program a file called ptrf is produced in the running directory (usually c:\cardwin). It has the following 32-bit pointers to the data in the device driver that assist programs that may want access to the real-time sampled data:

```
int * data      //int ptr to where vxd int (the driver) is loading ecg data
                    //tables.
uint * table[0] //lead I data. 4msec apart. 3180 unsigned ints. data is
                    //13-bit to represent +/- 5mV FS rti.
uint * table[1] //lead II data.
uint * nbpil    //uint ptr to where vxd is loading bp pulse data.
uint * nbpbuf   //bp pulses. 4msec apart. loads locations 25-250. Data
          //is 13-bit as in ECG lead data in table[].
uint * SpO2pp   //ptr to where vxd is loading SpO2 pulse data.
uint * SpO2pleth  //sio data. 4msec apart. loads locations 0-99. Data is
          //8 bit and relative in intensity.
```

For example, the pointer data is the first 4 bytes of the ptrf file. The table[0] pointer is the next 4 bytes. The table[1] pointer is the next 4 bytes. And so on.

Note that the first pointer called data gives the position in table[0] and table[1] where the driver is loading the ECG data. Note that the SpO2pleth buffer is loaded with a different pointer (SpO2pp) and the SpO2pleth buffer is only 100 points long and only 8 bits (1 byte per point). While the table[] ECG data is 3180 points long and 13 bits (2 bytes per point).

Calling the Cardio-Card from external programs

File I/O:

A user program can load a file called ccio to have the Cardio-Card do just acquisition, retrieve, use tempios, deleting, etc.

structure:

when calling cardwin.exe (all ascii):

"company code"ab"patient last, first mi name"ccccccccmmddyyyyr

where company code (get from factory).
a is either a,r,t, or d where a is acquisition, r is retrieve,
t is tempio retrieve, and d is delete selected file.
b is the database drive letter.
ccccccccc is the 9 digit patient number (ssn).
mm is month.
dd is day.
yyyy is year.
r is run number (starts with 0 for each patient each day).

on exit from cardwin.exe, ccio contains:

```
char opcode     //0=no store. 1=data saved.
char ecgf      //1=ecg taken
short heartr     //heart rate bpm.
short sysp       //systolic bp mmHg.
short meanp       //mean bp
short diasp      //diastolic bp
short spo2       //SpO2 percent.
short pulser     //pulse rate ppm.
short temp       //temperature * 10 degrees F. (e.g. for 98.6,
                  this would be 986).
```

Message API:
When both the Cardio-Card and another program are running at the same time, the other program can command the Cardio-Card to perform many of its functions. A very fast, easy to use, full featured API has been defined that performs this task. Note that the Cardio-Card program can be run in any standard Windows mode (e.g. normal, hidden, minimized, etc).

Contact Nasiff Associates at 315-676-2346 for a copy of this API document.

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