Nasiff Associates **CardioCard**™

CardioStress/ECG™

D2002005_IFU_S_V6(09/18/2023)

User's Guide



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REV6(09/18/23)

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General Information

Safety of the Cardio systems is discussed in the indications for use section with electrical safety detailed in the Specifications section.

Specifications of the Cardio systems is detailed in the specifications section.

Packaging is discussed in the Returning your system for service in the warranty section. Care should be taken to make sure the devices are protected from physical damage including crushing, immersion, etc.

Storage is discussed in the specifications section. Of note are the temperature and humidity. In general, like all electronic devices, the devices should be kept in low-humidity environments.

Handling and distribution, shipping of the devices should be with packaging mentioned above and with shipping companies that do small packages like the device packages. Shippers such as Fedex, UPS, DHL, Post Office have proven records.

The devices do the measurements and monitoring functions described in this manual. Installation is discussed in the Installation section. There are no user serviceable parts inside the Cardio systems. Refer to the Service section to obtain service.





Safety Warnings

- 1. These devices capture data reflecting a patient's physiological condition that when reviewed by a trained medical professional can be useful in determining a diagnosis. However, the data should not be used as sole means for determining a patient's diagnosis.
- 2. Use of accessories other than those recommended by NAI may compromise product performance.
- 3. To maintain designed operator and patient safety, any peripheral equipment and accessories that can come in direct patient contact must be in compliance with IEC 60601-1.
- 4. Hardware is designed to meet or exceed IEC 60601-1-2, however, some environmental electrical interference may cause an artifact in the ECG. The quality of ECG signals may be adversely affected by electromagnetic interference from environmental sources resulting in non-physiological waveforms with the potential for misinterpretation.
- 5. This device is not intended for use during an MRI.
- 6. Before performing defibrillation or applying any high frequency surgical equipment to a patient, remove leads and electrodes from the chest area. Cable leads or electrodes trapped under defibrillator pads or paddles during defibrillation or electrodes in contact with high frequency electro-surgical equipment can cause patient burns.





Safety Warnings Continued

- 7. Once one or more patient leads are connected to a patient, do not allow patient leads to meet with any grounded or live parts. Contact could cause unacceptable levels of electrical current to flow to the patient.
- 8. The equipment is not intended for infants weighing less than 10 kg.
- 9. Strangulation hazard. Route excess patient cable away from neck area. Avoid having excess cable near machinery where it could be snagged. Select the shortest cable for usable for electrode placement and patient comfort.

Cautions

- 1. Although the plastic enclosures are designed for a clinical environment and can resist moisture, neither the device nor patient cables should be subjected to autoclaving or steam cleaning.
- 2. Recommended cleaning procedure is to wipe the exterior surfaces with a cloth dampened with warm water and mild detergent solution and then dry with a clean soft cloth.
- 3. No serviceable parts are inside. The case cannot be opened without destroying it.
- 4. Do not pull or stretch patient cables, as this could result in mechanical and/or electrical failures. Store patient cables after use by forming them into a loose loop. It's good to keep the patient cables connected to the devices to minimize damaging the connectors to the devices.





Cautions Continued

- 5. Align patient cable connector key and enclosure key before plugging in patient cable. Forcing misaligned connectors can damage connector pins.
- 6. Avoid shock or sudden impact.

Notes

- 1. Excessive patient movement could interfere with the operation of the devices.
- 2. Proper patient preparation is important to successful application of ECG electrodes and operation of the devices.
- 3. Changes or modifications not expressly approved by NAI for compliance could void the users authority to operate the equipment.
- 4. This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in commercial and residential installations. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. This equipment should not cause harmful interference to radio or television reception, and can be tested by turning the wireless transmission off and on. If any interference is detected, the operator is encouraged to consult NAI.



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
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MONDAY - FRIDAY
9:00 AM TO 4:00 PM
EASTERN STANDARD TIME

CARDIO System: User Manual

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The intended use and relationship of the Cardio Card Products.

The Cardio Card System performs the main cardiology tests in one system. The intended use is to acquire, analyze, display and print short term and long term ECGs and non-invasive blood pressure, during resting, stress and holter/ambulatory/mobile conditions. To get a quick diagnostic 12 second ecg strip, to monitor for an extended period, or perform a long term rhythm, the Cardio Resting mode is ideal. Simply click the Cardio Resting Button. Cardio Stress mode is best to monitor during stress/exercising the patient and storing strips at timed intervals for ease of tracking the patient's heart response to stress/exercise. Simply click the Cardio Stress Button. The Cardio Holter is best for recording the patient's ecg over longer periods to catch long term rhythm conditions. Simply click the Cardio Holter Button. Sometimes Medical Professionals want a blood pressure on the patient as well. NIBP is integrated for ease of use. Medical professionals may choose to use any one or any combination of these modes as they see fit.

Cardio Card/Suite 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 integrated 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 indicates 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's 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 ecg 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 a vailable. 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 aut omated 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 A ssociates believ es t hat w hile t he innovation of E CG T echnology has been significantly enhanced over the years, similar progress has **not** been demonstrated with regard to the "Device" dimensions of the product, and s till 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 t heir B usiness A dministrators w ant and ex pect diagnos tic equi pment t o not only compliment t he r espective m edical application, but to successfully int egrate 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 CardioSuite® 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 M onitoring D iagnostic D evice (cassette, digital or B OTH, 3 L ead, F ull Disclosure Recorder(s))
- Non-Invasive Blood Pressure and many others...
- ◆ ALL Test Data seamlessly integrates into an inclusive Database and Clinical/Telecommunication Management System

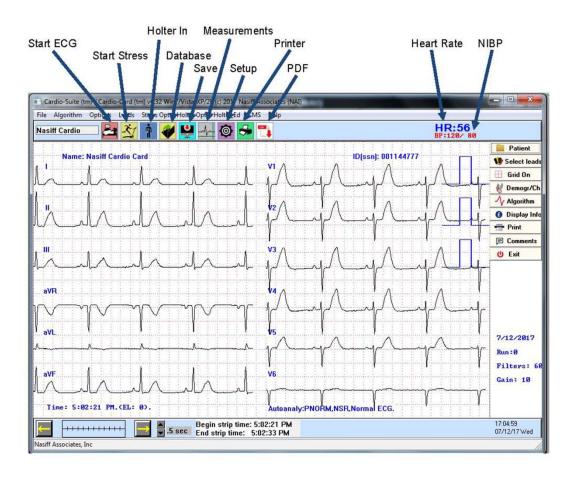
By merging the diagnostics of the CardioCard® System with the power and low cost of the PC, Nasiff Associates is able to offer **more features at a lower price** than any other ECG System on the market today! Don't forget, **ALL** CardioCard® Diagnostic Modules come with their own "Paperless" **DataBase 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 ~

^{***}It is strongly suggested to protect your computer and your Nasiff CardioCard with a Battery back up surge protector.(Such as a APC)***

^{*} 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...



During Test:

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 start

F9 - Start Stress test

F10 – Change ECG time base

F11 – Change ECG gain

F12 - Change leads viewed

During Retrieve / Database:

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. Cntl-F3 – next not normal beat. Alt-k - next Pause

Alt-v – next ventricular beat Alt-t – next VE Run (Triplet) Alt-o – next unknown beat

Alt-w - next SVE Run Alt-s – next SVE beat Alt-I – next Brady

Alt-r – next RonT beat (or special pause)

Alt-Z – next Brady Run Alt-f – next Tachy Alt-q – next Tachy Run Ctrl-F5 - Print list of events

Space bar – scroll on or off Alt-a – next Atrial Fib

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

Nasiff CardioStress Package Contents



Figure 1

CardioCard Resting/Stress ECG Box



Figure 2

Stress ECG Lead Wires



Figure 3

USB cable for CardioCard Resting/Stress ECG Box



Figure 4

CardioCard Software



Figure 5

Serial Port Cable



Figure 6

Stress Belt



Figure 7

USB-to-Serial Converter

Please follow the install instructions for the Stress on the following pages.

Do not plug in USB cable to your computer until installation of software is complete!

- 1. After installation is complete plug lead wires (figure 2) into digital Stress Box (Figure 1)
- 2. Connect USB cable (Figure 3) into digital Stress Box (Figure 1) then connect into the USB port of your computer
- 3. Take out the Cardio Card software (Figure 4) and store in a safe place in the event you want to install on another PC.
- 4. Connect Serial Port Cable (*Figure 5*) to the Treadmill, then connect the other end to the USB-to-Serial converter (*Figure 7*), then to the USB Port on your computer.

Installing CardioCard™ Software

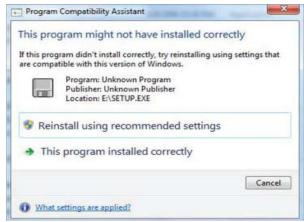
To insure an easy installation please follow the following instructions:

- Make sure that you pause your version of Anti Virus and that you have full administrative rights to your computer prior to the install
 - Place the Nasiff CardioCard software into the DVD drive of your computer it should auto install.

If auto install doesn't work

- Click on the Windows "Icon" or "Start Button" located at bottom left of your screen, then click on "Computer" and locate "Devices with Removable Storage". Highlight the "CardioCard" software in the "DVD" drive and RIGHT click on the "DVD drive"
- This will open a drop down view, click on "Explore" or "Open". You will see many files in alphabetical order. Scroll down to "Setup" double click on "Setup" when prompted, click "Continue" and "Yes" to all questions.
- Remember: the CardioCard software does not need the internet to install.

If this message appears, click "This program installed correctly"



When the installation is complete you will see the Nasiff CardioCard icon on your desktop

ECG & Stress Hardware Install

The purpose of this section is to guide you through the process of installing the ECG & Stress hardware

*** For Program <u>Capability</u> or Windows <u>Stability</u> 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.

IMPORTANT

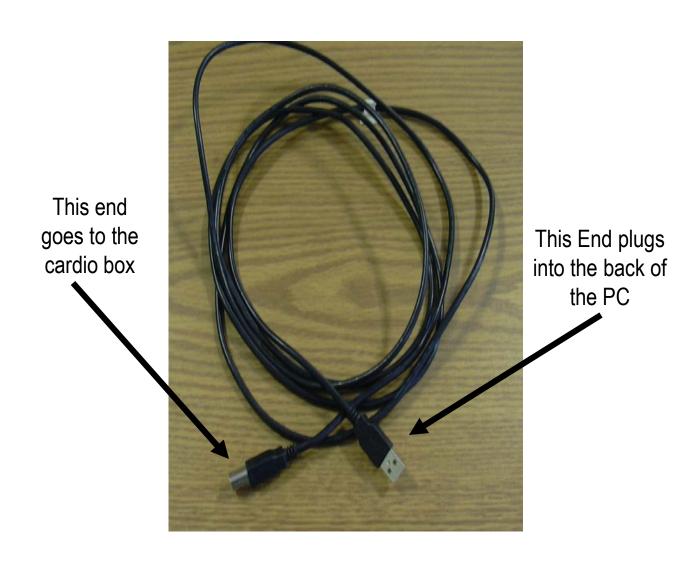
You <u>must</u> have a Windows Operating System installed on your PC

AND

CardioCard software must be installed before installing your hardware.

If your PC isn't medical grade and is plugged into AC power you need to use a isolation transformer/UPS between AC power and the PC

This is the cable that hooks the CUSB box to the PC



This is the ECG/Stress CUSB box which will be hooked up to the patient by a lead set and to the computer by another cable.

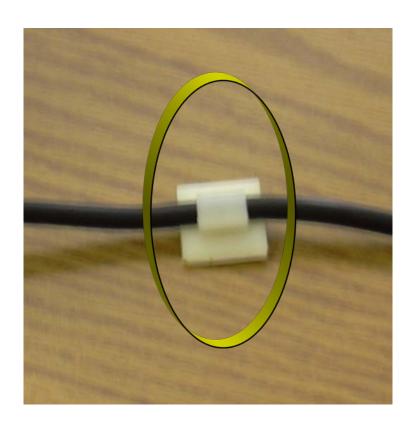


Lead set to the patient plugs in here

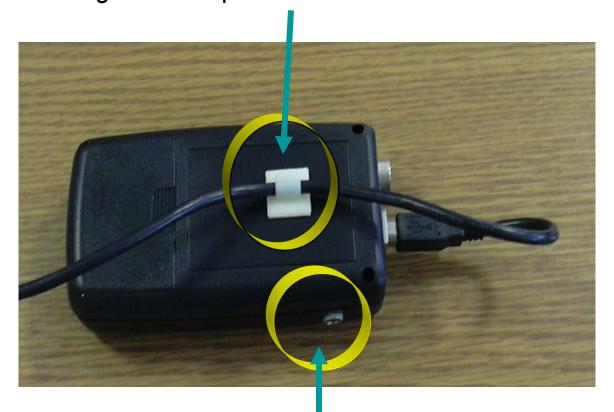
Cable to the PC plugs in here



With ONLY the Stress System your cable should have two adhesive backed clips on it. One is to secure the cable to the PC and the other one is to secure the cable to the CUSB box as detailed in the following pages.

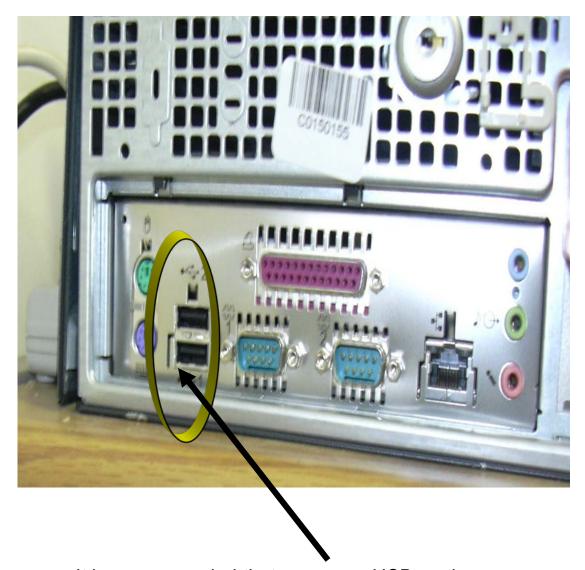


When plugging the cable into the CUSB box, insure that you use the clip provided with the cable to secure the cable to the box so that the cable does not pull loose while doing a stress reading from the patient.



This is the "R" Wave gate for Doppler, Ultra Sound, NIBP etc (signal center conductor and common ground, 1/8" mono phono plug)

Plug device into any USB port on your computer



It is recommended that you use a USB on the **back** of your computer.

Only the cable from the box to the computer should be plugged in, **NOT** any patient lead sets.

To prevent the cable from being yanked out of the USB port during a stress reading, use the second attached clip to secure it to the PC. Be sure to allow some slack in the cable between the USB port and the clip.

To secure the clip which is provided, peel paper backing from the clip and press to a clean spot near the back of the PC



Checking Digital ECG Box Installation

- Plug the USB cable *into the digital ECG* box, then plug into the USB port of your computer make sure to strain relief the USB cable to the ECG box and computer.
- Be sure you have a good connection to the digital ECG box and your computer
- Double click on CardioCard icon on your desktop (square icon with red heart)
- With the CardioCard software open locate the ECG button
- Click once on the ECG button and you should have lines running across the screen (click on ECG button to stop)
- You are now ready to begin!

NIBP

- Slide the NIBP cuff onto the upper arm, just above the elbow. Make sure that the tubes are coming out at the inside of the elbow
- While the ECG is running, press the function key F2 (on your keyboard) to perform the NIBP cycle. The resulting Systolic and Diastolic are reported on the screen and in database when the run is stored

SUNTECH

- Suntech main menu push the 123 setup (setup/enter) button until it goes to the main menu, select monitor setup
 - Select stress system custom
 - Protocol standard
 - ECG trigger digital up arrow

GE E-Bike

To get commands from the Computer the GE E-Bike needs to be set in PC Terminal mode.

HOW TO PERFORM A STRESS TEST

The purpose of this section is to teach you how to perform a stress test.

*** For Program <u>Capability</u> or Windows <u>Stability</u> 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.

Before Performing a Stress Test

- Check the Stress Patient Cable to make sure that the Electrode Connectors have the snap adapters.
- Check that the Treadmill has been properly and securely connected to the host PC.

Before Performing a Stress Test

(Continued)

- Check that all cords are out of Harms way.
- Check to see that the general Treadmill area is CLEAR.
- Check to see that the Treadmill belt is positioned at the center of the running area.
- Never turn the Treadmill Power on with someone standing on the running belt.



Patient Preparation

Proper preparation of the patient's skin is absolutely essential.

Note:

Without good skin preparation, both noise and artifact will frequently degrade the patient's stress test to the point of being unusable by the physician.

Preparation of the Patients Skin

A) Dry shave the electrode areas well.



Preparation of the Patients Skin

(Continued)

B) Take the top layer of skin off by using the scrub pad (or a small square piece of an abrasive material, such as 220 grit sandpaper or equivalent) and moderate préssure, abrade the skin at the electrode sites (at a bony spot) 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. You can also use Nuprep.



C) Wipe the skin in the electrode areas with an alcohol prep pad. Allow the skin to dry thoroughly.

How to Apply Electrodes

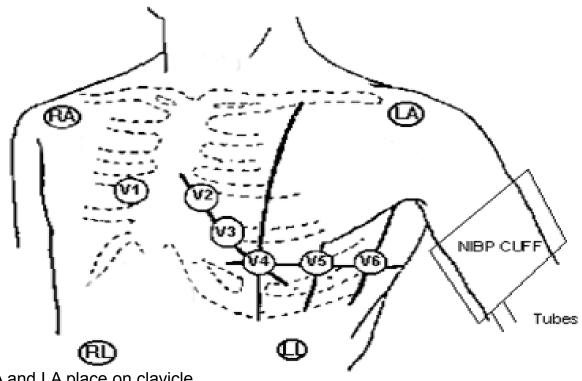
- Placing the electrodes on the patient attach the patient cables to the electrodes then tape the wire down 1" to 2" from the electrode. Tape the electrodes too. You can loop all the wires and tape them down near their waist. You can put the box at the patients lower back.
- Secure all loose lead wires with a close fitting garment or tape. They should not tangle.
- Use the stress belt to hold the junction box in place, or dangle the wire over the handle bars. Make sure the weight does not pull on the Electrodes.



NOTE: You do not want the electrodes to be pulled on or move as you will get artifact. Make sure they are on a bony spot.

Electrode Placement for Stress Hookup Proper prep is Essential

Cardio-Card ECG Lead Placements



RA and LA place on clavicle RI and LL on lower ribs

NOTE: locate a bony spot on patent for better results

V1; 4th intercostals space, right sternal border

V2; 4th intercostals space, left sternal border

V3; midway between V2 and V4 on a line joining these two points

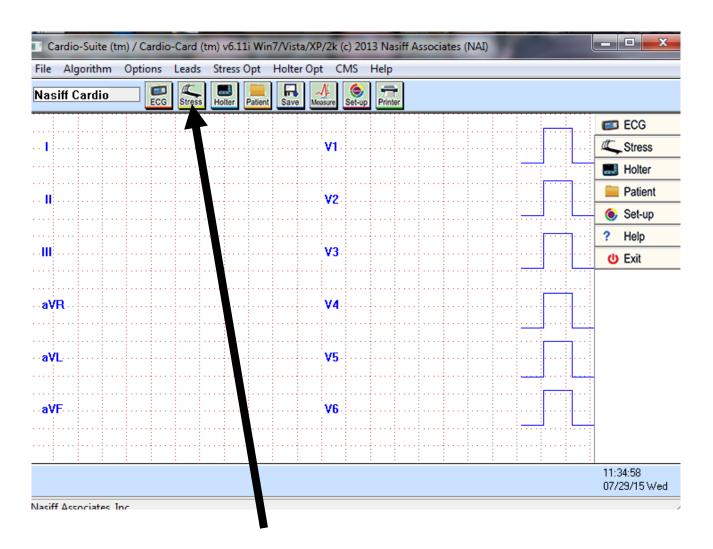
V4; interspace in which apex is located(5th or 6th); mid clavicular line

V5; anterior auxiliary line; on same level with V4

V6; mid auxiliary line; on same level with V4 and V5

**Use a boney spot for improved results

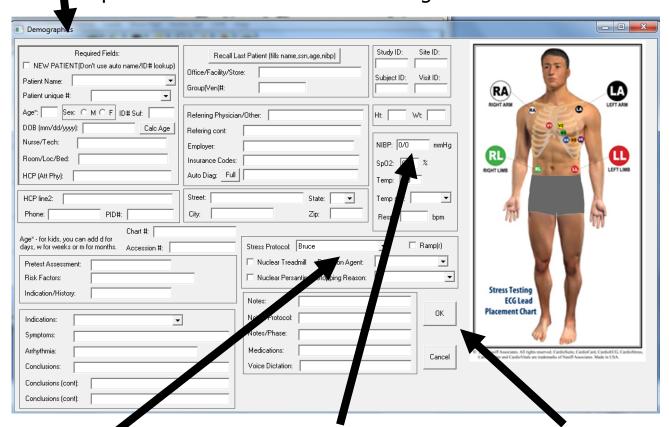
Getting Started with the CardioStress



Click on the "Stress" button at the top of the CardioCard

Patient Demographics Box Appears

- You need to check new Patient, enter Patients Name, (Last, first), Patient unique ID, Age and Sex. These fields are mandatory to continue
 - •Patients ID number is a unique 9 digit number. Most people use SSN or a chart number. It can be padded with zero's to make it 9 digits

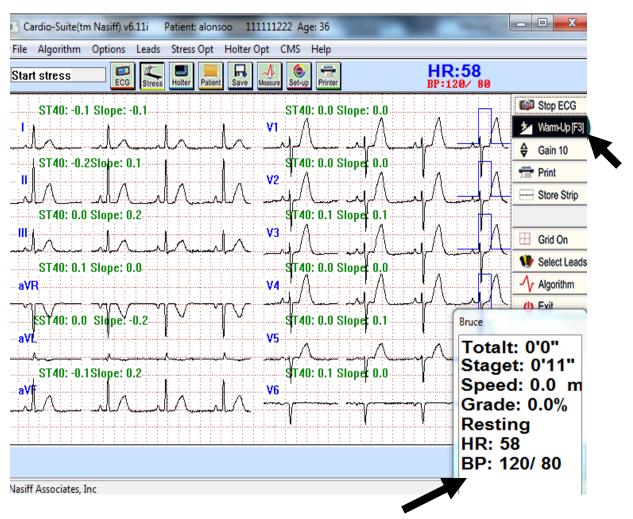


2) Enter the Baseline Blood Pressure.

4) Click "OK"

3) Make sure the stress protocol is set up. In set up you may what to have the most common used be your default. It can be changed here.

Stress Resting Screen



This is the Stage Information Box. It can be moved to another part of the screen. This box gives: Total Time, Stage Time, Speed/Grade of treadmill, Stage, HR & BP

Click on "Warm Up" at the upper right and run until HR is established (approx 15 seconds)

Quality Check

- While the ECG leads are displayed on the monitor lightly TAP each electrode to see if Artifact can be induced. If it can you need to check electrode contact and possible prep the site again and replace the electrode. (Tap an Electrode Test).
- Once satisfied with the quality of the ECG Complex you are ready to start the test.

Stress Test (Storing Multiple Strips)

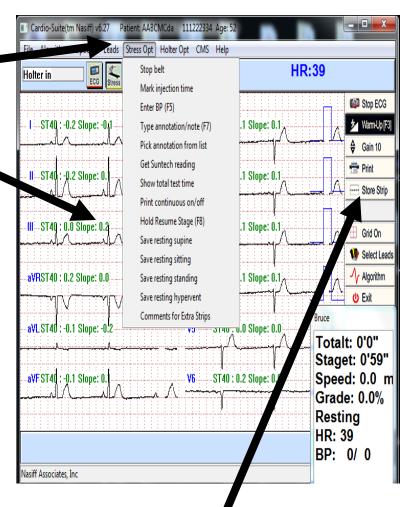
Go to Stress_Opt

You can select

"Save Resting Supine",
"Save Resting Sitting",
"Save Resting Standing"
"Save Resting Hypervent"

It saves multiple strips, the last 12 seconds

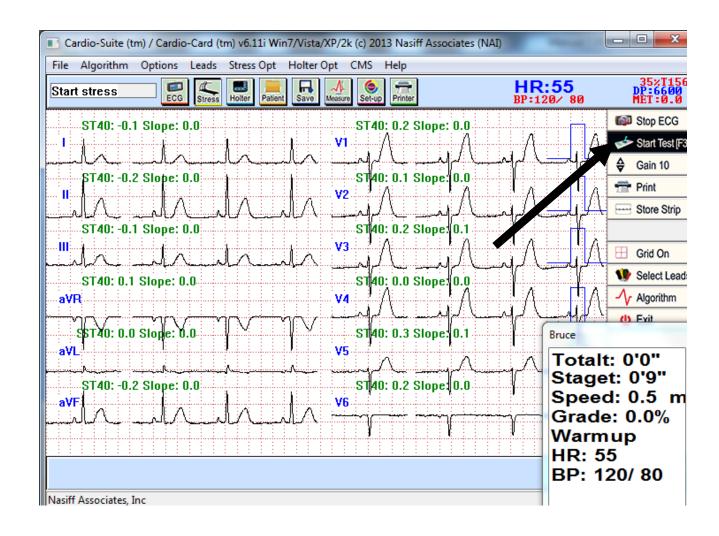
You can also turn on the Auto Scroll to do these test. To do this you will go to System Setup then Stress Setup click on auto scroll and store Supine, Sitting, & Hypervent. After you start monitoring resting click F5, put in the patients Blood pressure and it will ask you if you want to store supine etc...



To store extra strips click on "store strip"

- If the ECG heart rate is significantly lower or higher than you expected, based on the ECG displayed, it is usually caused by an amplitude problem.
- If too low, the amplitude of the "Realtime Analysis Lead" is likely too low. The remedy is to either increase the gain or select a different analysis lead by clicking "Options" then "Realtime Analysis Lead".
- If too high, the "T" wave of the Analysis Lead is likely too high. The remedy is to lower the gain or increase the "R amplitude minimum" under the "options" menu. (The R amplitude minimum rejects any wave part smaller than the percentage set of the last known good R wave.)
- •The rule of thumb for good R wave detection is for the R wave amplitude to be positive and greater than 1.5 divisions (which is 1.5 large squares or 0.75 mV).

Start Test



Click on "Start Test" located at top right and Stress Test will begin

Stage Box and Definitions

Stage Box X

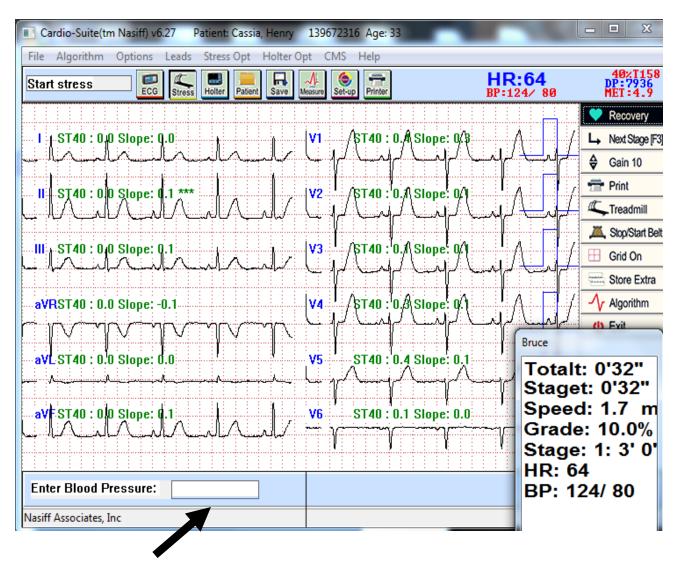
A Totalt: 0'13"
Staget: 0'13" B

C Speed: 1.5
Grade: 0.0% D

E Stage: 0: 0' 0"

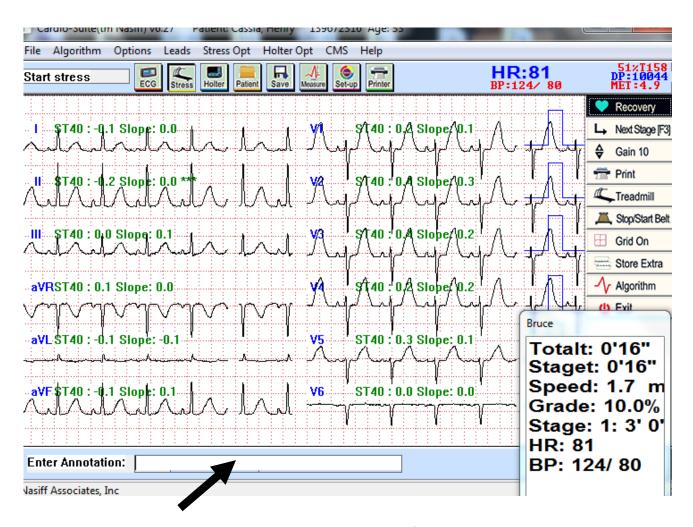
Index	Label	Description		
А	Total Time	When the STRESS Button is CLICKed, this TOTAL Time Clock begins. At this point, these "Times" are only for reference while time is spent acclimating the Patient to the moving TreadMill. Format: XX ' (Minutes) XX " (Seconds)		
В	Stage Time	When the STRESS Button is CLICKed, this STAGE Time Clock begins. At this point, these "Times" are only for reference while time is spent acclimating the Patient to the moving TreadMill. Format: XX ' (Minutes) XX " (Seconds)		
С	Speed	 Present SPEED (mph) of the TreadMill 		
D	Grade %	Present Grade or Elevation of the TreadMill		
Е	Stage	 Stage Status / Time Format: XX Stage: XX' (Minutes) XX" (Seconds) 		

1st Stage of Stress Test



Enter BP in Lower left when prompted during each stage

Enter Annotation



Enter Annotation when prompted for each stage. Notes entered here show on the final report

- •The System will store one strip per Exercise stage by default. In "stress setup" this can be changed to "Full Disclosure" if desired. (Note: This will consume a significant amount of hard drive space.)
- •The Stage Box automatically updates when progressing through the Exercise Protocol.
- If you want to move to Recovery Phase before the test is over, click "Recovery". It will go to the first Recovery interval and continue at that point.

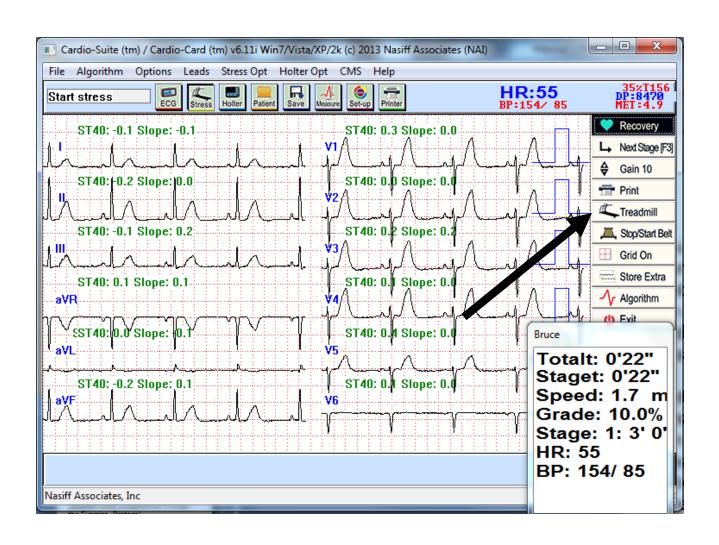
Key options available during Exercise off the general screen (buttons):

- * Recovery button is always available
- * Real time Printing
- * Treadmill speed/grade control
- * Stop and restart belt
- * Next exercise stage
- * Gain settings

Key options available during Exercise under "Stress-opt" menu:

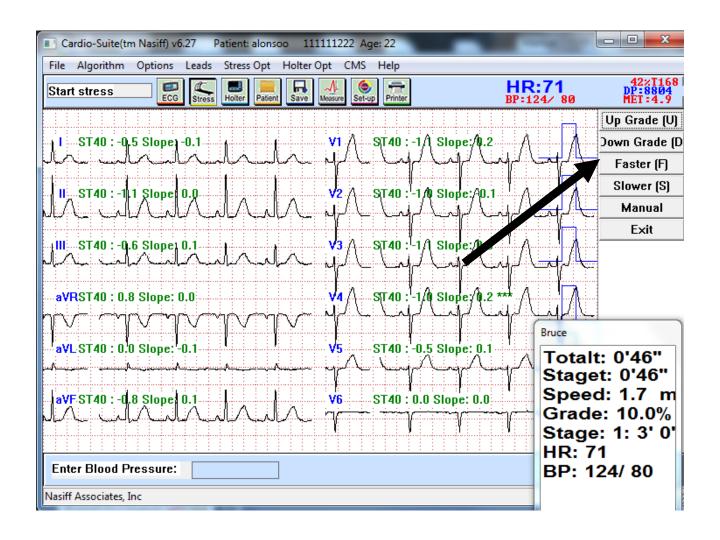
- * Enter blood pressure and annotation notes
- * Hold / Resume current stage
- * Mark injection time

Take Control of Treadmill



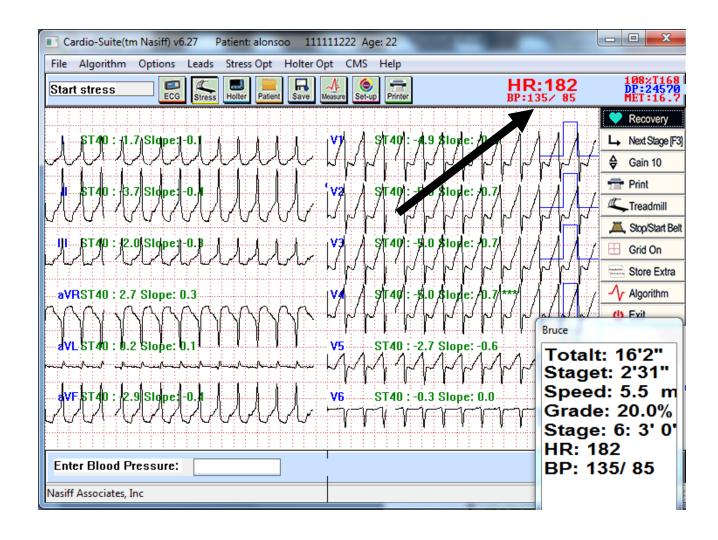
Click on "Treadmill" to manually control treadmill

Manually Controlling the Treadmill



This feature allows you to manually control the speed and grade of the treadmill (you must finish stress test in manual when taking control, click "Exit" to return)

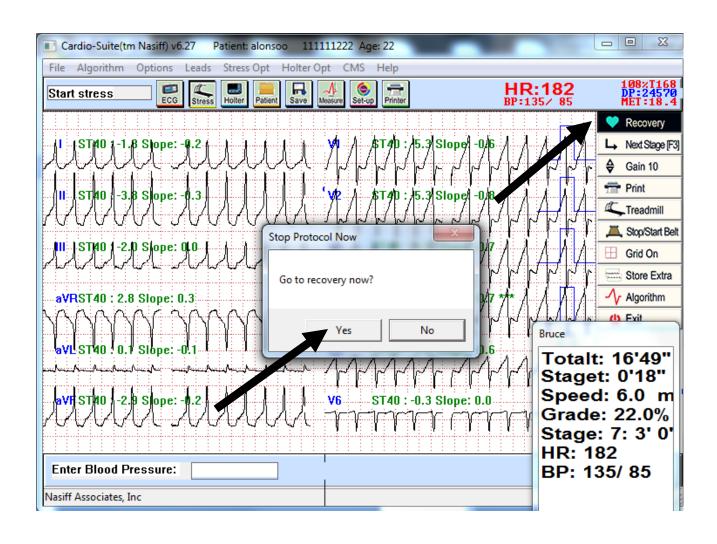
Stress Test



During the test the HR, BP, % of Target HR, DP, and MET % are displayed top right

When target HR is achieved the HR display turns RED

Go To Recovery



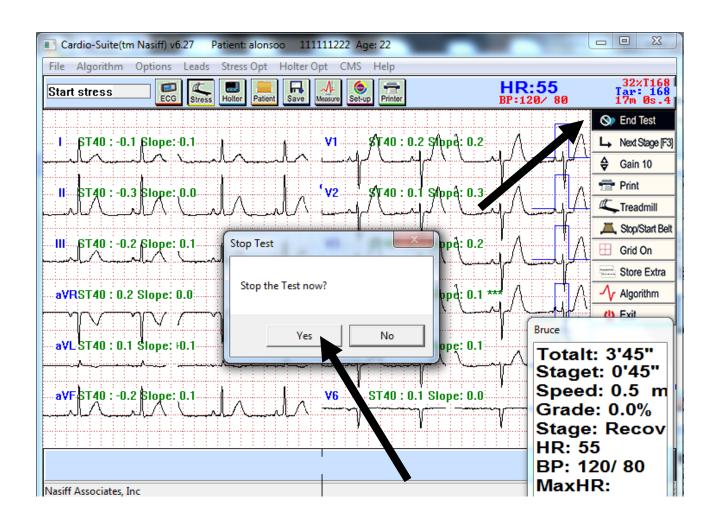
When target HR is achieved click on "Recovery" then click "Yes" to start the recovery stage.

(recommend 3 – 4 minutes in recovery to store and print stage strips) You need to be in recovery for over 1 minute to store the recovery stage.

Recovery Phase (Continued)

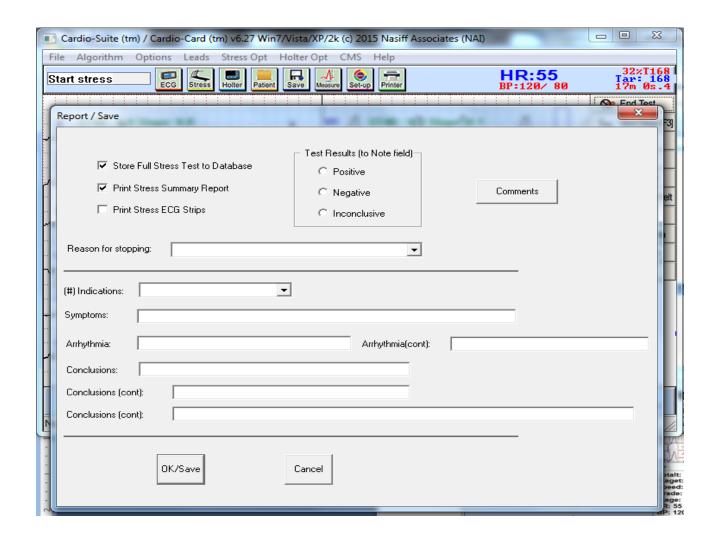
- If you what to conclude the Recovery Phase before the Recovery stages are concluded, click "End Test."
- If the patient runs the full course of the Protocol, Cardio System will automatically move to the Recovery Phase of the test.
- The system will store one 12 second strip every minute during Recovery.
- It is good practice to store at least 3 to 4 minutes of Recovery.
- Active Recoveries are available at this time also.

End Test



Click "End Test" then "Yes"

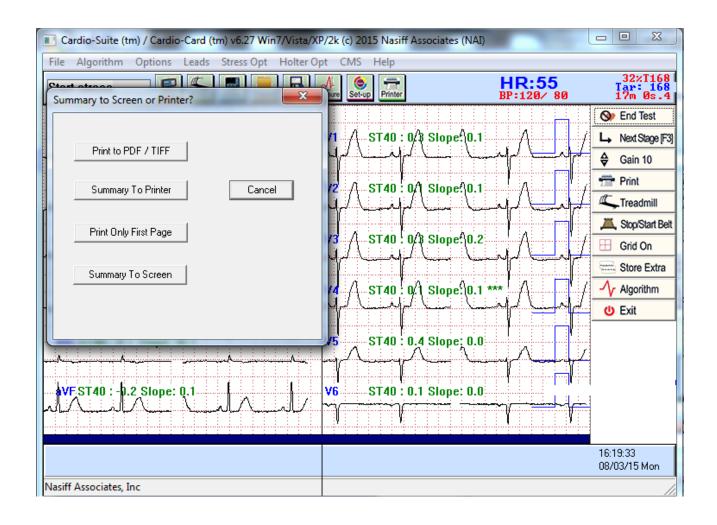
End Test Options



Check test results; "Positive, Negative, or Inconclusive" To enter comments into record, click on "Comments". Select reason for stopping, indications etc... These can be filled in later by clicking on the comments

**ALWAYS Click "OK/Save" to save your test

Print Options



You have four print options

ECG Interpretive Abbreviations and Definitions

- ECG Interpretation Abbreviation Meanings. The meanings of the codes are entered here for easy access. By looking at the codes, they are abbreviations of the typical cardiac diagnostic statement. This format was chosen to make the need for this list almost nonexistent. Obvious meanings are the intent for ease of use.
- Special note:
 Computer ECG analyses are an aid for ECG classification. Unconfirmed computer ECG analysis reports SHOULD NOT be used for prescribing patient treatment or nontreatment without review by a qualified physician. No computerized interpretation is completely reliable and Physicians trained in ECG interpretation should over read the ECG results.
- Actual Reported Code/Statement Meanings:
 The program takes as input the standard output of the Cardio Card measurements program and outputs the codes in a character string to be read as is.
- On the ECG report and screen the following statement is made: "No automated analysis is completely reliable and a physician should over read the results."

ECG Interpretive Abbreviations and Definitions (Continued)

Code/Stmt	<u>Meaning</u>
Normal ECG Measurements data not available	Same Same
Susp arm lead reversal	Suspect arm lead reversal
RS	RSR/QR pattern in V1 suggests possible right
IRB	ventricular conduction delay Probable IRBBB (Incomplete Right Bundle Branch Block)
RB RBV ILB	Probable RBBB plus RVE Probable ILBBB (Incomplete Left BBB)
LB LA LP	Probable LBBB Probable Left anterior fascicular block Probable Left posterior fascicular block. LPFB
BA BP ID	Probable Bifascicular block. = RBBB & LAFB Probable Bifascicular block. = RBBB & LPFB
IB	Nonspecific intraventricular delay Nonspecific intraventricular block
PA OA	Probably anterior MI, age undetermined Possibly anterior MI, age undetermined
SDSE	Marked st depression, possible
TA	subendocardial injury or digitalis effect Nonspecific T wave abnormality, could be normal
TAA	T wave abnormality, consider anterior ischemia

ECG Interpretive **Abbreviations and Definitions**

(Continued)

MAA Marked T wave abnormality, consider anterior

ischemia

TAL T wave abnormality, consider lateral ischemia Marked T wave abnormality, consider lateral MAI

ischemia

TAAI T wave abnormality, consider anterolateral

ischemia

LAD Abnormal leftward axis deviation

RAD Right axis deviation

MRD Minor rightward axis deviation

EAD Extreme axis deviation **MLD** Minor left axis deviation

SLV Suspected left ventricular hypertrophy SRV Suspected right ventricular hypertrophy Suspected biventricular hypertrophy **SBV** Nonspecific ST elevation abnormality SE

ŠEP ST elevation, consider early repol, pericard

SER ST elevation, early repol PAP Possible acute pericarditis

Acute pericarditis Septal injury AP

SI ΑI Anterior injury LI Lateral injury

Antero septal injury Antero lateral injury ASI ALI

Ш Inferior injury

JSD Junctional st depression, probably normal Junctional st depression, probably abnormal JSDA

SAD

ST abnormality, probably digitalis
Nonspecific ST depression, could be normal
Marked T depression, possible septal NSD

MSDS

subendocardial injury

ECG Interpretive **Abbreviations and Definitions**

(Continued)

MSDA

MSDL

MSDI

QRSA

Marked ST depression, possible anterior subendocardial injury
Marked ST depression, possible lateral subendocardial injury
Marked ST depression, possible inferior subendocardial injury
Abnormal qrs-t angle, consider primary T wave Probable Right atrial enlargement
Possible left atrial enlargement
Probable Left atrial enlargement
Probable Biatrial enlargement
Abnormal right superior axis deviation
Indeterminate axis
Low voltage QRS, consider pulmonary disease RAE **PLAE** LAE **BAE**

RSAD

IΑ

LVA

Low voltage QRS, consider pulmonary disease S1,S2,S3 pattern consider pulmonary disease, RVH **S1**

or normal variant

PD

Probably Pulmonary disease Cannot rule out anterior infarction, age CAL

undetermined

CSI Cannot rule out septal infarction, age

undetermined

Probably Septal infarction, age undermined, injury or SIF

PLI Possible lateral infarction, age undermined, injury or

ischemia

LIF Probable Lateral infarction, age undermined, injury or

ischemia

ASIF Probable Anteroseptal infarct, age undermined, injury

or ischemia

Probable Pos Anterolateral infarct, age **ALIF**

undetermined

CI Cannot rule out inferior infarct masked by left anterior

fascicular block

Possible PAC. **PPAC**

Poor R wave progression PRWP

LVL Low Voltage in Limbs

ECG Interpretations

Interpretations:

There are 4 main classes of classical 12 lead ECG

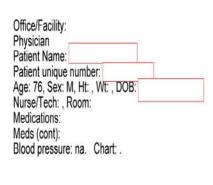
Axis deviations, enlargements, blocks and MIs. Board certified Cardiologists do not always agree on interpretations and machine interpretation programs make mistakes and are not as good as physicians. A physician should over read the results because no machine is correct all of the time. The program calls most of the abnormals it recognizes, but some may not be listed if numerous are found. It tries to list the most significant, and if a statement occurs more than once, it is probably even more significant as more than one set of tests detected it. In any case, always know that a machine interpretation is a tool to assist the medical professional. Actual patient diagnosis and treatment require a medical professional's expert opinion, interpretation. And as we all know, more than one medical professional is needed in many cases to confirm diagnosis and treatment options.

The Cardio ECG systems state first if it thinks the ECG is normal (PNORM = probably normal) or abnormal (ABN, ABNORM). Abnormal occurs when the program detects a significant deviation from normal measurements. If the program states ABN, then it is very important that a physician over read to see what they think is actually happening with the patient. A NORM as the first statement should still be looked at by a physician, but the Cardio ECGs usually are a bit sensitive to try to be sure to flag any possible abnormal for checking.

The next statement is the rhythm. If the program thinks it is normal sinus it'll say NSR, Sinus or normal sinus. It can also state that it thinks it is Afib, Brady or Tachy.

The next statements are details of the analysis when Abnormal (ABN).

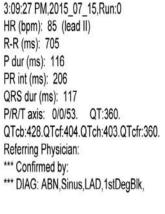
**For example, the sample on the next page has abbreviated ABN, Sinus, LAD, 1st DegBlk or full interps: ABN, Sinus, Left Axis Deviation, probable 1st degree block, Lateral Infarction, age undetermined, nonspecific ST elevation abn, ST elevation, early replorization, acute pericarditis, poor R wave progression. The system states the ECG is ABN abnormal for the reasons given. Note that numerous classes are listed meaning the ECG has numerous conditions that are abnormal. Sinus indicates at least the main heart rate appears regular and somewhat normal. (note that the Cardio systems allow the operator to set the afib sensitivity, Brady and Tachy rates, etc). Note lead II in the sample. It's inversion from normal is causing the system to report left axis deviation. In the sample, note that the PR interval is a bit over 200ms. This indicates the patient is probably in 1st degree block. Note especially how V5 and V6 are very small compared to the rest of the channels. This shape indicates a lateral infarction. ST elevations above 3-4 mm indicate abnormality. Note this is in numerous channels: e.g. II, v3-v6. Poor R wave progression occurs when the R wave is not getting more and more positive from V1-V6.

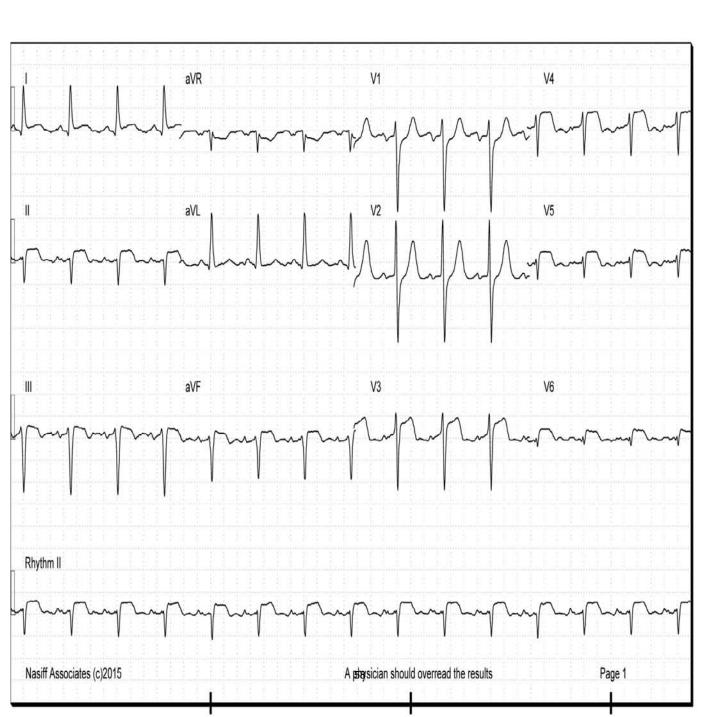


10mm/mV, 0.05-150Hz. 40HzLPF, 25mm/sec Indications:

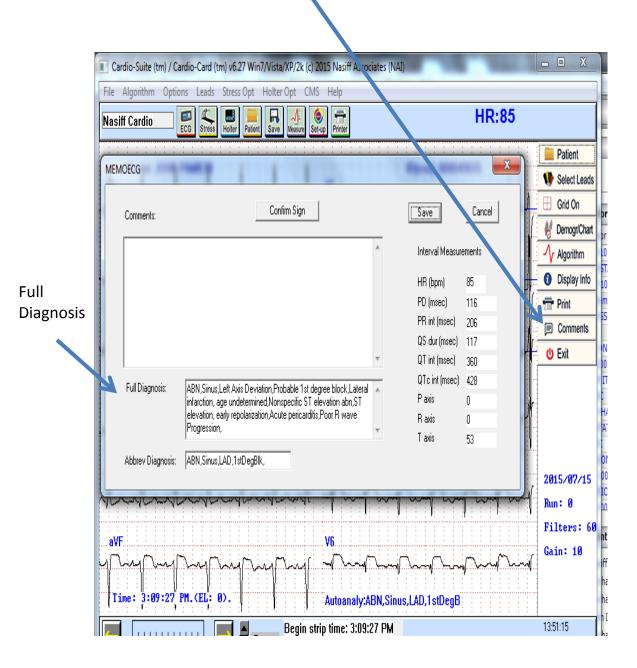
3:09:27 PM,2015_07_15,Run:0

Interp/Comments/Annot:





To review Full Diagnosis click on the comments

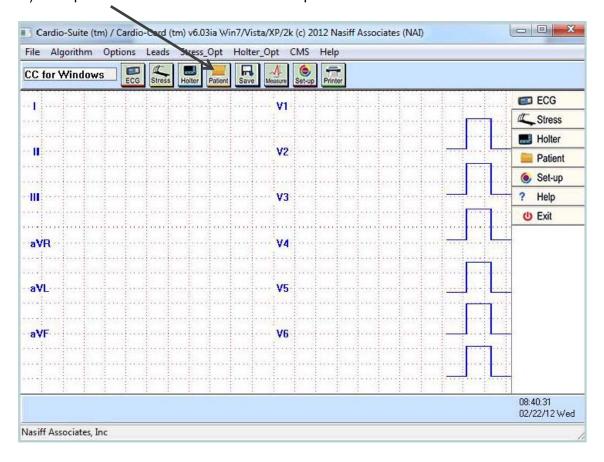


Database Operations

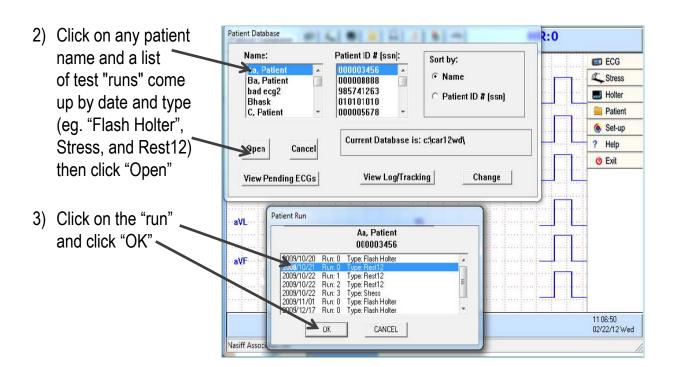
The purpose of this section is to show you the Database Operations

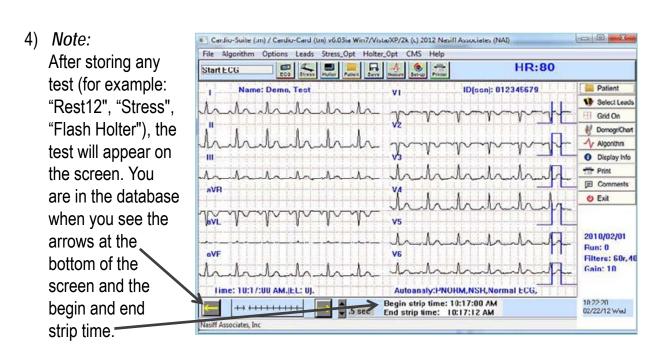
*** For Program Capability or
Windows Stability it is strongly
recommended that all screen
savers and power savers are
turned off, and that the
computer is rebooted
at the beginning of each day

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



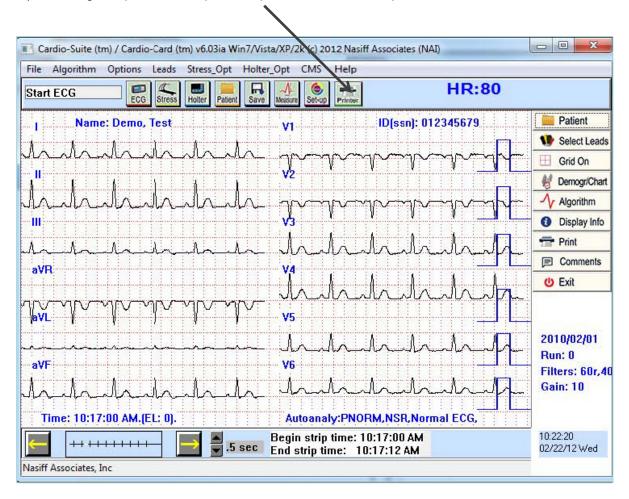
Opening Database



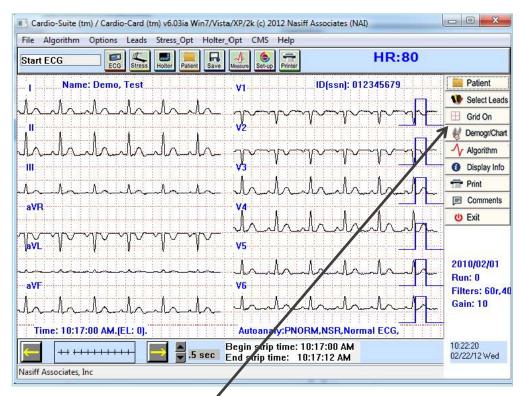


Printing

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



Demographics Chart

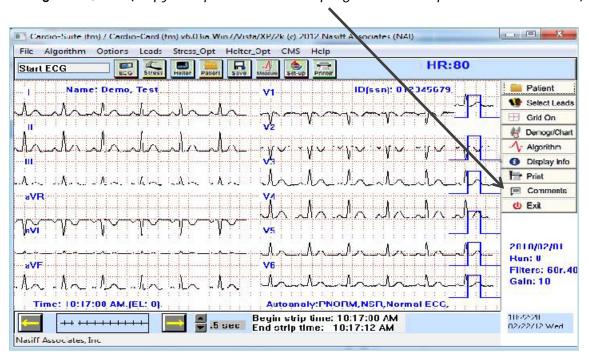


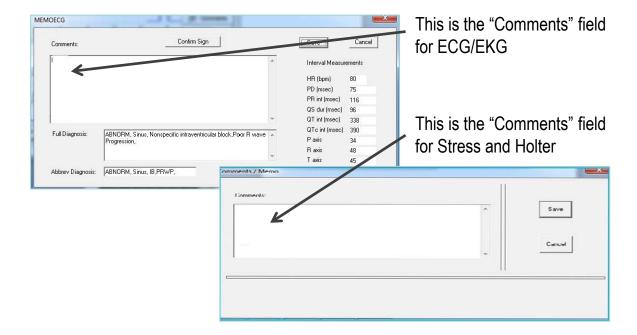
2) Clicking the "Demographics Chart" button displays detailed patient information and provides entry into the Cardio EMR Chart program

Required Fields:	Office/Facility/Sto	Save Cancel Study ID: Site ID:	
Patient unique #: 000003456 Age*: Sex. FM C F ID# Suf: DUB Inim/dd/yyyyl. Jursc.Toch: Room/Loc/Bed: 07-M 4CP I/U Phy).	Refer Phy/Cther Referring cont. Referring PID#: Employer: Insur Codes: (#) Auto Ding:	A3NORM Sinus, I3.PRWF.	Subject ID. Viol ID. Ht. Wr MIDP: mmHg Sp02. 0 %
Phone: PIDIT. ge*-tor kids under 1 (r, you can add d for days, w for eeks, or m for months.	intra	IDBM, Sinus, Nonspecific worthing to hook, Port B wave gression.	Temp. J.U Temp site: Hesp. Glucoss value mg/dl
Chart #: Accession #: UL Show Audit (#) moons audit tracked Protest Assassmont:			
(#) Indication:: Symptome: Authyrhmia. Conclusions:		Short Notes: Notes/Protectol Notes/Protection (#) Mods(abbrev): Voice Distation	

Comments

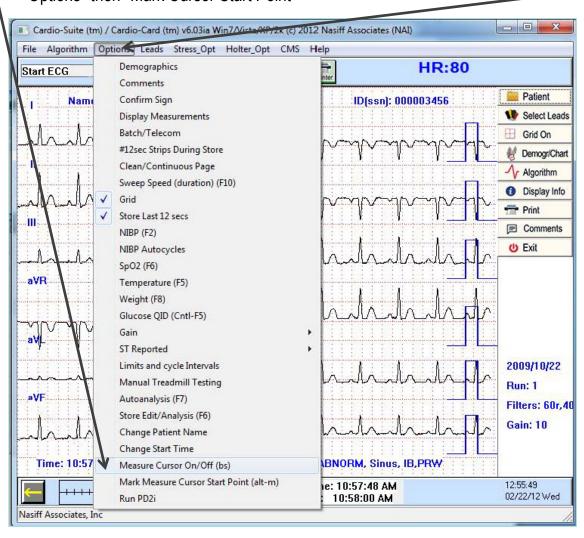
3) Clicking the "comments" button allows the inputting of unlimited notes, comments, diagnoses, etc. (Copy and paste from other programs is also permitted in this area)



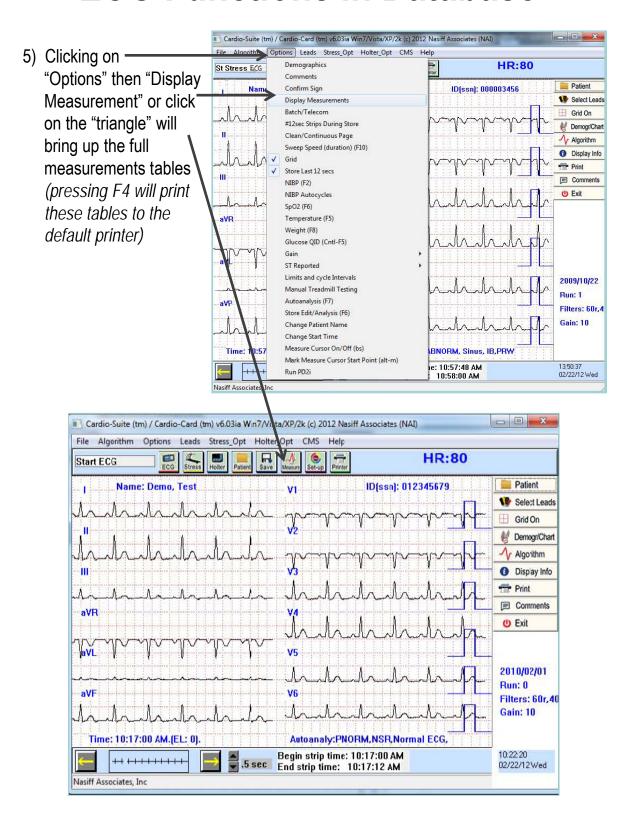


Measurement "Cursors"

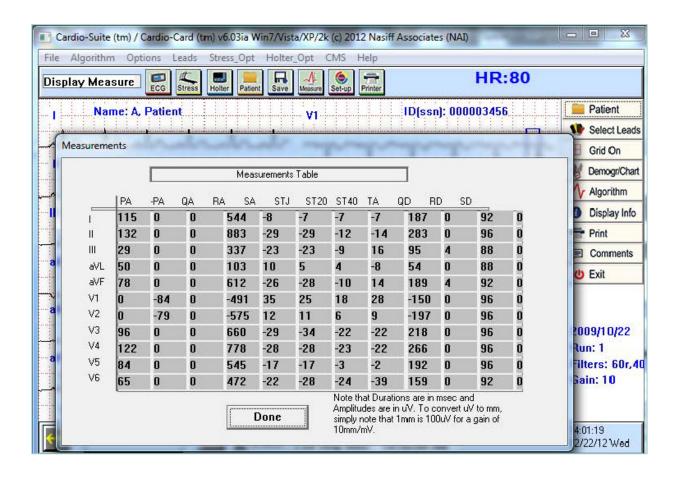
4) Measurement "cursors" are available providing wave measuring capability.
 (eg. amplitudes, durations, rr values...). To activate or deactivate click "Options"
 then "Measure Cursor On/Off". Cursor navigation is accomplished by using the
 "arrow", "page up" and "page down" keys. Mark cursor start point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



ECG Functions in Database



ECG/Stress Measurements Table



Network & Database Utilities





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

*** For Program <u>Capability</u> or Windows <u>Stability</u> 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.

DICOM WORKLIST AND TRANSFER

To allow CardioCard Data to transfer or receive data from your DICOM System, you will need to enter Nasiff's AETitle: NAI_CC. In System Setup go to EMR Tab, Enter a Valid IP address, Port, and AETitle. Check the box for Send DICOM by IP and DICOM Embed PDF, and if needing JPG Check box for DICOM JPG too. After entering the information click Save.

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.

<u>OR</u>

Your antivirus or anti spyware software is blocking the service.

<u>OR</u>

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

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 guestions: (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 <u>FREE Software Product</u> 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:

- 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 include part of the initial software purchase.	uded in purchase price
Follow-up Training On-site training requested any time after the purchase of the software.	\$300 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.	\$385 per hour
Consulting On-site, in-house or telephone consultation requested with senior level personnel (3 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.	\$525 per Installation hour
Travel Includes time necessary to travel to and from customer site. If travel includes multiple customer sites travel time is equally distributed among customers.	\$525 per hour then

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.

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Specifications

MINIMUM PC SYSTEM REQUIREMENTS

- IBM compatible Pentium or higher.
- 8GBB ram for program for Windows 10/8/7/XP/ Vista and Mac with boot camp.
- 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.
- Win10/8/7/2000/ 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.

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.

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:

CUSB box: 4.87" x 2.75" x 1.25" Flash Holter recorder: 4.4" x 2.6" x .95" CCNIBP-I: 5.75" x 3.6" x 1.75" • Weights:

CUSB: 120g (.26lb)

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

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.

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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.

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

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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.

Product UpDate Policy

One of the major advantages offered by the CARDIO System is its ability to incorporate Product Updates, Enhancements, new Features and Modifications via Software. The CARDIO System is Technology Expansive, no longer is your diagnostic Equipment obsolete the day it is purchased.

It is the Policy of Nasiff Associates to extend Software to the Purchaser on a No change basis for the TWO year period of the Warranty.

This Software will include:

- ♦ Product Updates
- Product enhancements
- Product modifications.

All subsequent Software Enhancement and Major Feature additions to the Product will be extended to the USER on a favorable term basis.

It is important for the USER to Register his CARDIO System not only to activate his / her Warranty with Nasiff associates. BUT to also be eligible for the above mentioned Software UpDate