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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

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EASTERN STANDARD TIME

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CardioCard® System: User Manual

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CardioCard® PC Based ECG

The intended use and relationship of the CardioCard® Products.

The CardioCard® 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 CardioResting™ mode is ideal. Simply click the CardioResting™ Button. CardioStress™ 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 CardioStress™ Button. The CardioHolter™ is best for recording the patient's ecg over longer periods to catch long-term rhythm conditions. Simply click the CardioHolter™ 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 anyone or any combination of these modes as they see fit.

CardioCard® / CardioSuite® is the brand name of the family of Cardio products marketed as CardioResting™ ECG, CardioStress™, CardioHolter™, and CardioVitals™ 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 CardioCard® ECGs come with a small electronics box that acquires the ECGs (and NIBP for units using NIBP), a software CD, patient connection cables, and a 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 CardioHolterTM on for the patient to wear all day. The change that came during stress may show then, indicating the same possibility. CardioHolterTM 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 **CardioResting™ ECG System** is to diagnosis ECG medical conditions that are primarily detections of normal and abnormal ECG waveforms 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 CardioCard® device and then Start ECG is selected to view the ECGs. There are buttons to store and print as well.





CardioCard® PC Based ECG

The intended use of the **CardioStress™ System** 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 CardioCard® 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 **CardioHolter™ 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 CardioHolter™ 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 **CardioVitals™ 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.

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Nasiff CardioResting™ ECG Package Contents

Firgure 1 CardioCard® ECG



Figure 2 Resting ECG Leads



Figure 3 Banana Clips



Figure 4 USB Cable



CardioResting** Bluetooth*
CardioResting** ECG

CardioResting** ECG

CardioResting** ECG

CardioResting** CCArdioResting**

CardioResting** ECG

CardioResting** ECG

CardioResting** ECG

CardioResting** ECG

CardioResting** ECG

Figure 5 CC Software



Please follow the install instructions for the Resting ECG on the following pages.

<u>Do NOT plug-in the USB Cable to your computer until installation</u> <u>of software is complete!</u>

- 1. After installation is complete, please insert banana clips Banana Clips (Figure 3) onto Lead Wires (Figure 2)
- 2. Plug Lead Wires (Figure 2) into digital ECG box (Figure 1)
- 3. Connect USB Cable (Figure 4) into digital ECG box (Figure 1) Then Connect the USB Cable (Figure 4) into the USB Port of your computer
- 4. Store the CardioCard® Software (Figure 5) in a safe place for the event you want to install on another computer. The CardioCard® Software (Figure 5) will install on multiple computers.

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CardioCard® System User Interface

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

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 CardioSuite ® with WINDOWS* or iOS* "Point and Click" USER Interface includes:

- 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!

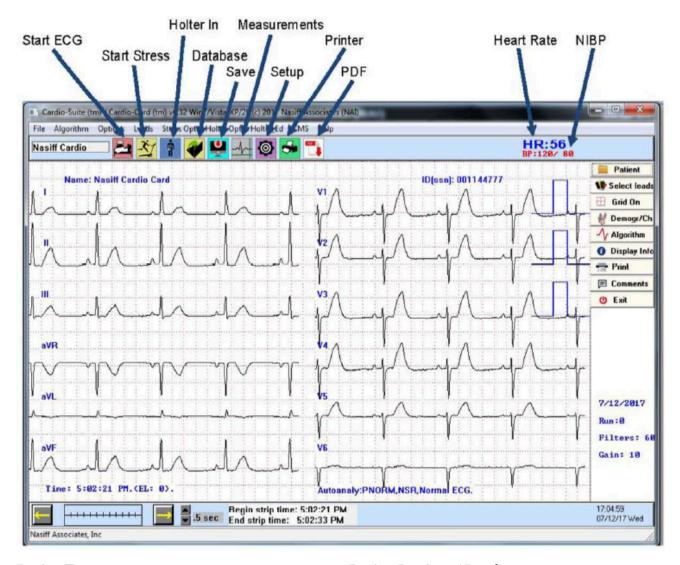
If your IT Department is going to make changes on your computer make sure they inform you and when they are done please test the Nasiff CardioCard® completely to make sure it is still working fine.

It is strongly suggested to protect your computer and your Nasiff CardioCard® with a Battery Back-Up and Surge Protector. (Such as an APC).

CardioCard® Systems run on **WINDOWS** XP, Vista 32/63 bit, Windows 7, Windows 8, Windows 10, and **IOS** with Boot Camp, Dual Boot, VMware, Fusion, or Parallels.

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During Test:

- F8 Start Acquisition, ECG (1st Run)
- F1 Help
- F2 Start / Stop NIBP Cycle
- F3 Store
- F4 Print
- F7 Log time of Event
- F8 Read in from Scale (After Acquisition 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 Editor
- 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

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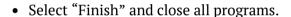




Installing The CardioCard® Software

To insure an easy installation please follow the following instructions:

- Plug in the included USB Drive to your PC
- Open "File Explorer" and find the Nasiff USB Device
- Find "Setup.exe" and run the program as Administrator
- In the Nasiff CardioCard Installation Software:
 Select "Continue" and "Yes" to all questions.



When the Installation is Complete, you will see the Nasiff CardioCard® icon on your desktop





As well as the Nasiff Reports Folder

<u>Do NOT plug-in the USB Cable to your computer until installation</u> <u>of software is complete!</u>

Checking The Software Installation

- Plug the USB cable or Connect with BT to the digital ECG box
 (Find Bluetooth Pairing in the Next Section)
- Unpack your lead wires and plug wires into the 12 pin round connector located on your ECG CUSB box
- Double click on CardioCard icon on your desktop
 (squareicon with red heart)
- Click once on the ECG button and you should have lines running across the screen (click on ECG button to stop)



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Bluetooth Pairing

• Place the included batteries into your Bluetooth CardioCard Device





- Turn your CardioCard Device on
- The LED will Blink Red when Disconnected
- On the Dual ECG System
- Press the Grey Button In for USB
- And Press the Grey Button Out for BT

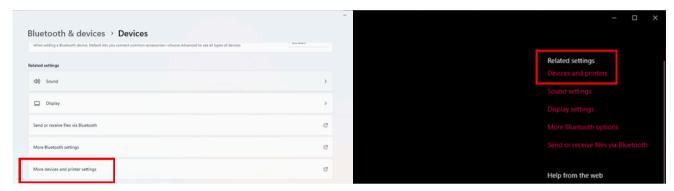




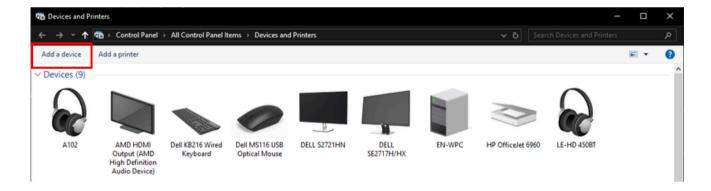


Bluetooth Pairing

- Open Bluetooth Settings
- Select Devices and Printers Win10
- Or More Devices and Printer Settings Win11



• Select Add a Device



• Click the BCD-XXX Device and select Next

Choose a device or printer to add to this PC

Searching for devices



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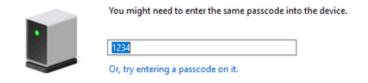




Bluetooth Pairing

Enter 1234 as the Device Passcode and Click Next

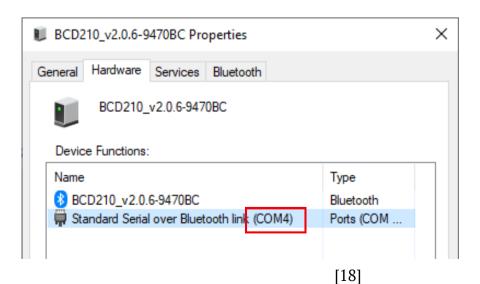
Enter the passcode for your device



- Right Click on the Device in Devices and Printers in "Unspecified"
- And Choose Propreties



• Go to the Hardware Tab and Take not of the COM# Number Example COM4

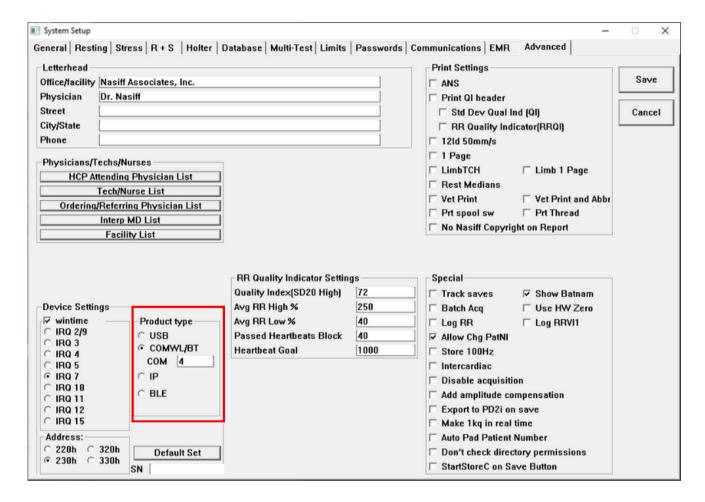




CardioCard® PC Based ECG

Bluetooth Pairing

- Open the CardioCard Software
- Goto System Setup
- And Navigate to the Advanced Tab



- At the Bottom Left in Product Type
- Select COMWL/BTCOM
- And Enter Your COM Number
- Example in this case 4
- And Click Save
 - Running an ECG Test now will use your Bluetooth ECG Device
 - The LED on Your CardioCard Device will Blink Green during the Test

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Nasiff CardioCard® ECG

Getting Familiar with the ECG Buttons

















Buttons Used for ECG Testing



To start an ECG Press this button Be sure to prep the patient well to reduce artifact and assure good results



To start a Stress Test Press this button Be sure to prep the patient well to reduce artifact and assure good results



To Set-Up a Holter Test Press this button
Be sure to prep the patient well to reduce artifact and assure good results



To retrieve patient data at anytime, click on "Patient", then highlight the patient, and click "Open" find the test by date and time and click "OK"



When satisfied with an ECG on-screen click "Save"

Note: You must have a clean ECG on-screen for 12 seconds
You can check "Enter Demographics Before" in settings
to be prompted to enter a patients information before
recording an ECG



To print an ECG report, click on "Printer".

To Print and Retrieve an ECG report within your EMR, make sure to have the send to and read from path filled out in "Set-Up"

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Nasiff CardioCard® ECG

Getting Familiar with the ECG Buttons (Continued)

















Always be sure to click "OK" or "Save" to hold changed settings



Set-Up

Under the "Advanced" tab in "Set-Up" you can fill out the letterhead to appear as wanted on your ECG Reports

Under the "Resting" tab in "Set-Up" you can choose to be prompted to enter demographics before or after acquiring an ECG

Under the "EMR" tab in "Set-Up" you can choose to send your PDF Reports to the "Nasiff Reports" folder on your desktop automatically

Under the "R&S" tab in "Set-Up" you can turn on pacemaker detection

Under the "Advanced" in "Set-Up" tab, click on "Default Settings" to reset all "Set-Up" Settings to factory default

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Preparing a Patient

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

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

Recommended Steps:

a) Select the sites for electrode application.The electrodes must be applied over bone or cartilage.



- b) Dry shave the electrode areas well.
- c) Using the scribe pad (or a small square piece of abrasive material, such as 220 grit sandpaper or equivalent) to 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 gauzepad to remove any debris.

You can also use Nuprep.

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



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Nasiff Electrode Placement

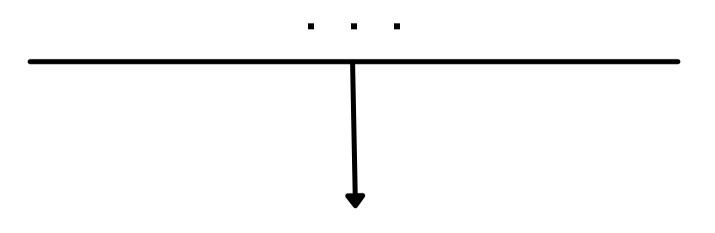
CardioCard® Resting and Stress ECG Lead Placement

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

Proper prep is Essential

| V1 | 4th intercostals space, right sternal border |
|----|--|
| V1 | 4th intercostals space, right sternal border |

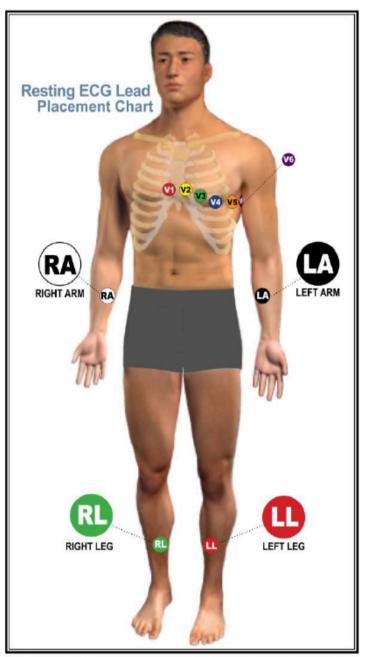
- V2 4th intercostals space, left sternal border
- V3 Midway between V2 and V4 on a line joining these two points
- V4 Interspace in which apex is located(5th or 6th); mid clavicular line
- V5 Anterior auxiliary line; on same level with V4
- V6 Mid auxiliary line; on same level with V4 and V5





Nasiff Electrode Placement Chart CardioCard® Resting and Stress ECG Lead Placement

Proper prep is Essential



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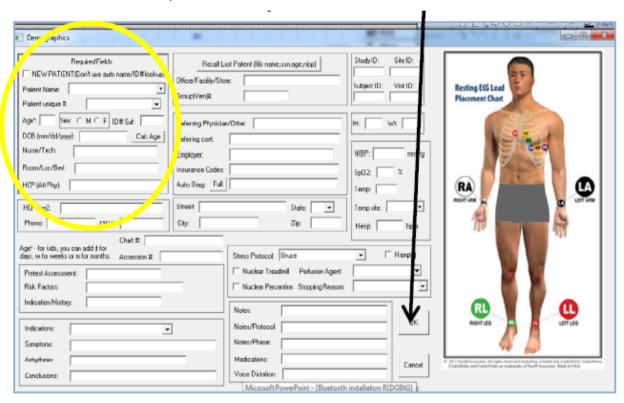


Performing an ECG

Within the demographics page, it is required to fill the following:

- 1. Patient Name, Last Name, First Name. No special characters.
- 2. Patient ID, only number and letters
- 3. Age
- 4. Gender "M" or "F" then press "OK"

These four fields are required to start an ECG



1. When you get a clean ECG tracing click "Save".

This is the Aqua color icon with the Monitor and Red Arrow

- 2. You will be prompted to print, you can set this to create a PDF and auto-save in folder.
- 3. Comments can be added by clicking on "Comments" located on the right of the CardioCard® program while you are in the Patient Test.
- 4. After Comments are saved you can set up auto save and PDF reports will automatically be saved to the "Nasiff Reports Folder and can be uploaded to your EMR when ready. (The PDF will be sent to the "Nasiff Reports" folder on the desktop)







CardioResting™ ECG Extras

- F12 on your keyboard allows you to view different lead options
- F10 on your keyboard will view condensed leads
- To store multiple ECG strips click on "Options" located at the top of the CardioCard® and scroll down to "12-second strips during store". This will allow you to store multiple ECG strips.
- To view measurements: go to "Options" and scroll down to "Display Measurements"
- To change the patient's name: go to "Options" and scroll down to "Display Measurements"
- To Increase or Decrease Gain: go to "Options" and scrolls down to "Gain" then adjust
- To View selected leads: click on "Leads" at the top of the CardioCard® and scroll down to preference.
- To Print-Red grid lines: click on "Leads" at the top of the CardioCard ® and scroll down to preference.
- To Send Report by Fax: click on "File" located at the top left of the CardioCard® screen, scroll down to "Print to a Selected Printer/Fax" (Your PC needs to be connected to a Fax Machine).
- What do the abbreviations for interpretations mean? Click on "Help at the top of the CardioCard® then click on "Main Help Menu" then locate and click on "Appendix and Examples".
- For networking go to your C: Drive and find your (Patient Database" which is the car12wd folder, and move it to your network. Make sure you make a backup of the original "car12wd" folder.
- Pacemaker Detection: turn on in "Set-Up"
- Calipers (Measurement Cursors) can be used by pressing "Backspace" using arrow keys to move the cursor, or by pressing "ALT + M to mark. Arrows over measurements will appear on the screen.







ECG Interpretive Abbreviation 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 CardioCard® Measurements program and outputs the codes in a character string to be read as is.

 On the ECG report and screen following statement is made: "No automated analysis is completely reliable and a physician should over-read the results"

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Code/STMT Meaning

Normal ECG Normal ECG

Measurement data not available Measurement Data not Available

Susp Arm Lead Reversal Suspected Arm Lead Reversal

RS RSR/QR pattern in V1 suggests possible

Right Ventricular Conduction Delay

IRB Probable IRBBB

(Incomplete Right Bundle Branch Block)

RB Probable RBBB

RBV Probable RBBB + RVE

ILB Probable ILBBB (Incomplete Left BBB)

LB Probable LBBB

LA Probable Left Anterior Fascicular Block

LP Probable Left Posterior Block (LPFB)

BA Probable Bifascicular Block (RBBB & LAFB)

BP Probable Bifascicular Block (RBBB & LPFB)

ID Nonspecific Intraventricular Delay

IB Nonspecific Intraventricular Block

PA Probable Anterior MI, Age Undetermined

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Code/STMT Meaning

OA Possible Anterior MI, Age Undetermined

SDSE Possible ST Depression

TA Possible Nonspecific T wave abnormality

TAA T Wave Abnormality

(Possible Anterior Ischemia)

MAA Marked T Wave Abnormality

(Possible Anterior Ischemia)

TAL T Wave Abnormality

(Possible Lateral Ischemia)

MAL Marked T Wave Abnormality

(Possible Lateral Ischemia)

TAAL T Wave Abnormality

(Possible 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

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Code/STMT Meaning

SBV Suspected Biventricular Hypertrophy

SE Nonspecific ST Elevation Abnomality

SEP ST Elevation (Possible Early Repol or Pericard)

PAP Possible Acute Pericarditis

AP Acute Pericarditis

SI Septal Injury

AI Anterior Injury

LI Lateral Injury

ASI Antero Septal Injury

ALI Antero Lateral Injury

II Inferior Injury

JSD Junctional ST Depression (Probably Normal)

JSDA Junctional ST Depression (Probably Abnormal)

SAD ST Abnormality (Possible Digitalis)

NSD Nonspecific ST Depression (Possibly Normal)

MSDS Marked T Depression

(Possible Septal Subendocardial Injury)

[30]





Code/STMT Meaning

MSDA Marked ST Depression

(Possible Anterior Subendocardial Injury)

MSDL Marked ST Depression

(Possible Lateral Subendocardial Injury)

MSDI Marked ST Depression

(Possible Inferior Subendocardial Injury)

QRSA Abnormal QRS-T Angle

(Consider Primary T Wave)

RAE Probable Right Atrial Enlargement

PLAE Possible Left Atrial Enlargement

LAE Probable Left Atrial Enlargement

BAE Probable Biatrial Enlargement

RSAD Abnormal Right Superior Axis Deviation

IA Indeterminate Axis

LVA Low Voltage QRS (Consider Pulmonary Disease)

S1, S2, S3 pattern (Consider Pulmonary Disease, RVH, or Normal Variant)

PD Probable Pulmonary Disease

CAI Cannot Rule Out Septal Infarction

(Age Undetermined)

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| Code/STMT | <u>Meaning</u> |
|-----------|---|
| CSI | Cannot Rule Out Septal Infarction (Age Undetermined) |
| SIF | Probably Septal Infarction (Injury or Ischemia, Age Undetermined) |
| PLI | Possible Lateral Infarction (Injury or Ischemia, Age Undetermined) |
| LIF | Probable Lateral Infarction (Injury or Ischemia, Age Undetermined) |
| ASIF | Probable Anteroseptal Infarction (Injury or Ischemia, Age Undetermined) |
| ALIF | Probable Pos Anterolateral Infarction (Age Undetermined) |
| CI | Cannot Rule Out Inferior Infarction (Masked by Left Anterior Fascicular Block) |
| PPAC | Possible PAC |
| PRWP | Low Voltage in Limbs |

CardioCard® PC Based ECG

ECG Interpretations

There are FOUR 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 repolarization, 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 an 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.





CardioCard® PC Based ECG

Office/Facility:
Physician
Patient Name:
Patient unique number:
Age: 76, Sex: M, Ht: , Wt: , DOB:
Nurse/Tech: , Room:
Medications:
Meds (cont):
Blood pressure: na. Chart: .

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

3:09:27 PM,2015_07_15,Run:0 HR (bpm): 85 (lead II) R-R (ms): 705 P dur (ms): 116 PR int (ms): 206 QRS dur (ms): 117 P/R/T axis: 0/0/53. QT:360. QTcb:428.QTcf:404.QTch:403.QTcfr:360. Referring Physician:

*** Confirmed by:
*** DIAG: ABN,Sinus,LAD,1stDegBlk,

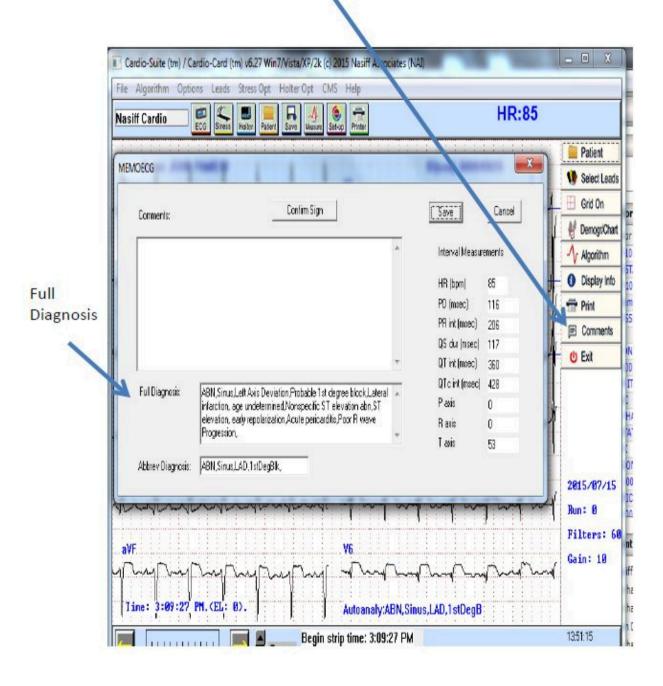
Interp/Comments/Annot:



[34]



To review Full Diagnosis click on the comments



[35]



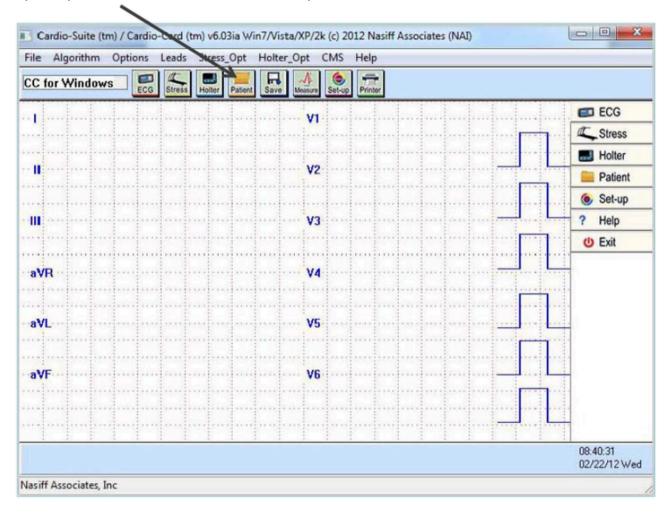


Database Operations

There are FOUR main classes of classical 12 lead ECG

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

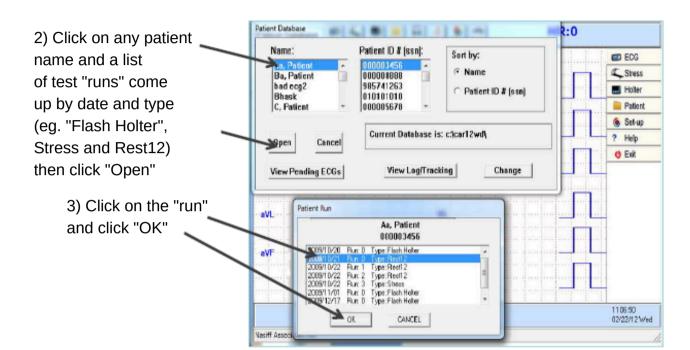
1) To open database click on Patient to open the database





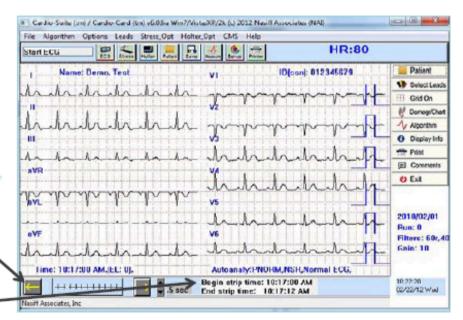


Database Operations



3) **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.

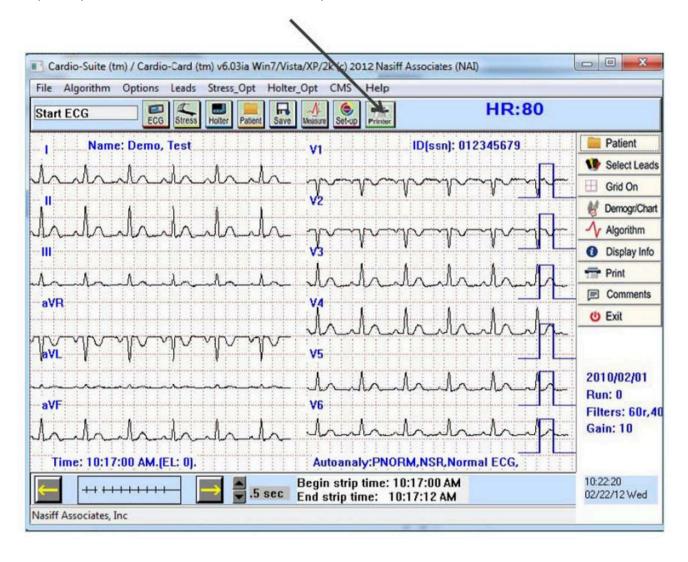


[37]



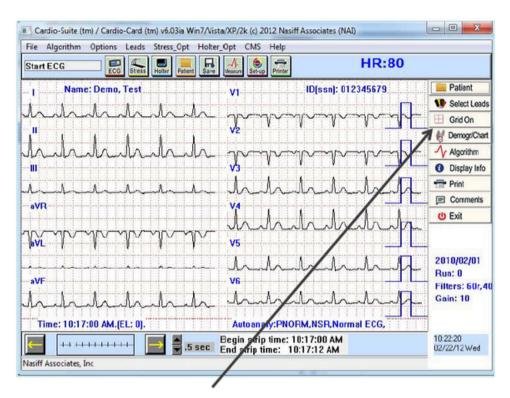
Printing

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

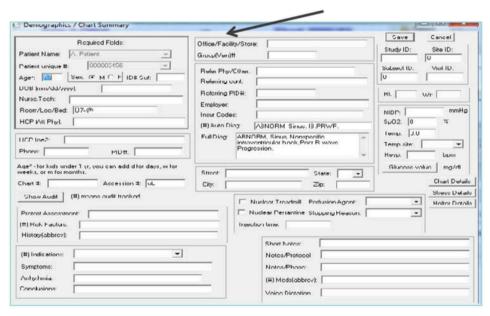




Demographics Chart



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



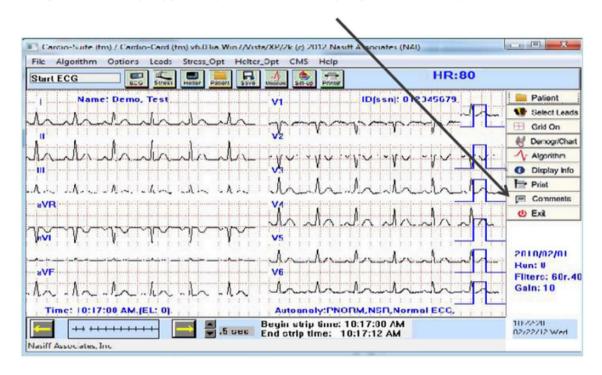


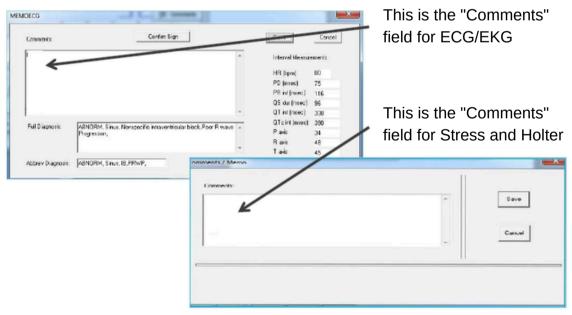




Demographics Chart

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)





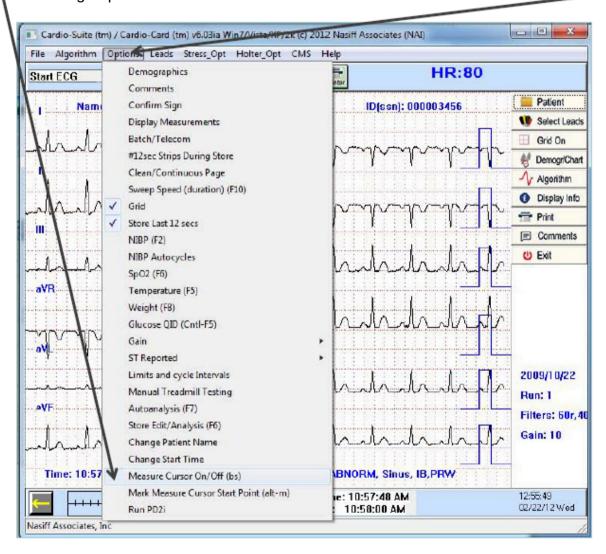
[40]





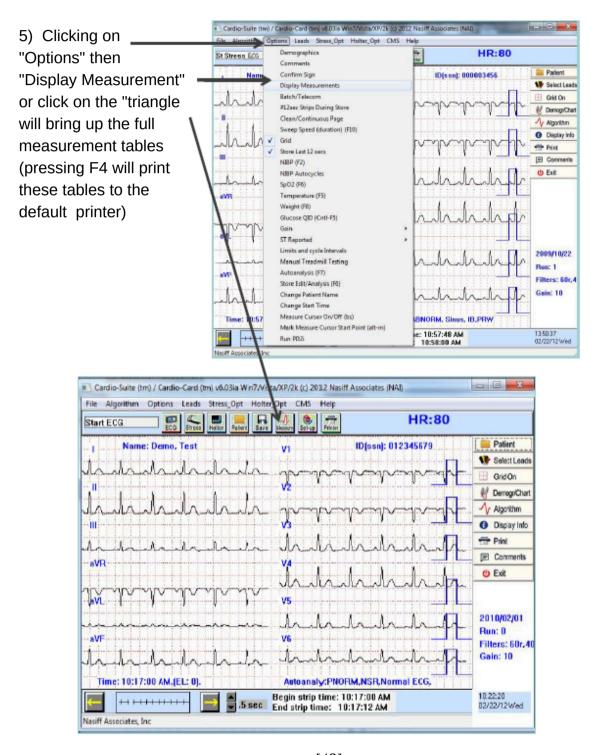
Measurement "Cursors"

4) Measurement "cursors" are available providing wave measuring capability (e.g.amplitudes, duration, 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 the cursor start point by clicking "Options" then "Mark Cursor Start Point".





ECG Database Functions

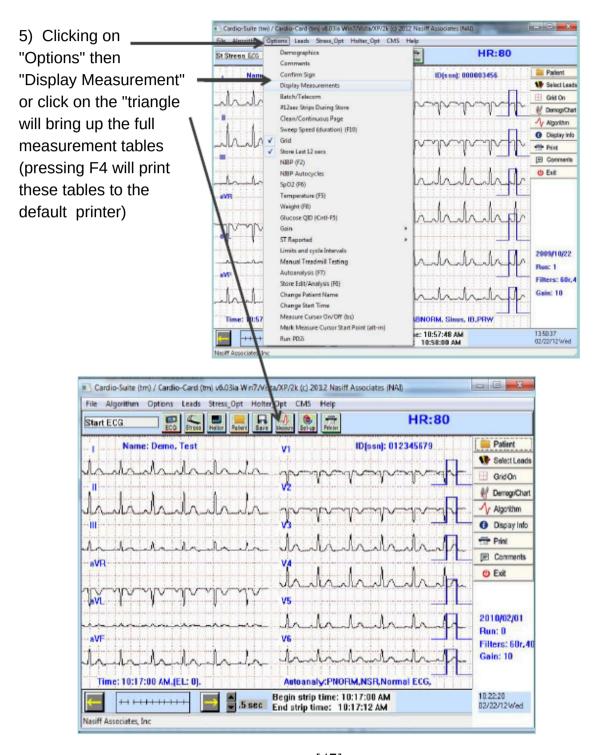


[42]





ECG Database Functions

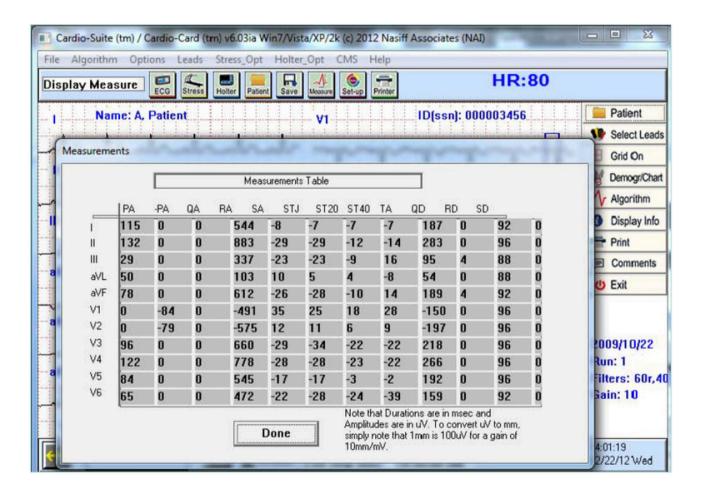


[43]





Measurement Table





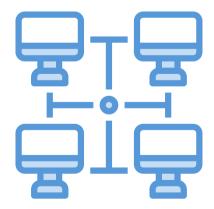
Network & Database Utilities





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,



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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 CardioCard® 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 the CardioCard software is installed on the other computer. All data goes to "CAR12D" in your C: Drive (Make sure to back up the folder). 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 CardioCard® Data on a Network

- Got o 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. To do this go to CardioCard®. 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 the new drive letter. Then click "OK".
- Closeout 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 the 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 the 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.

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Trouble Shooting Before Installing CardioCard®

Turn off all virus protection, firewalls; and spyware. 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 stricly 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.

BEFORE STARTING ALLOW EXCEPTION FOR CARDWIN, CARCOM, AND CAR12WD FOLDERS IN YOUR ANTIVIRUS. ALLOW FUL CONTROL FOR CARDWIN, CARCOM, AND CAR12WD.

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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 checkmark. Or go to Start then Control Panel then click on printer and faxes.

TO TEST PRINTER

Right Click on the printer that you are using as your default printer.

Click on Propreties

Click Print Test Page

Click "OK"

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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
- · Go 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 the Hibernate tab and disable it
- · Click "Apply"
- Close out of this and reboot your computer

When you have Corrupted Files

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- · 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 the CardioCard® 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 plugin":

Unplug and plug back in.

"Invalid Flash Recorder Path":

Make sure the 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 may be 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 CardioCard® System.

In the event of an Operational or "How To" Question, the following STEP 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 3:30 PM** EST at our National Services Center, Monday through Friday, except holidays. Our Systems department is staffed until 4:30 PM. 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 callback. 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 resolved.

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-mails to individual technicians unless specifically requested.

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We prioritize calls based on the urgency of the situation. Unless otherwise informed, we will 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 Online. 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 stand systems 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 inhouse 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
- Invitation 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-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 Newsletters

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; Online 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.



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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 CardioCard® System (See below for CardioCard® 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 that prove to be defective.

The Nasiff CardioCardio® 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 CardioCard® 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 CardioCard® System against defects in materials and workmanship for a period of two years from receipt by the by the end-user (proof of purchase is require). If Nasiff Associates is given notice of such defects during the warranty period, Nasiff Associates will either, at their option, repair or replace products that prove to be defective.

Nasiff Associates, Inc.



GENERAL

Nasiff Associates, Inc. warrants the CardioCard® System against defects in materials and workmanship for a period of two years from receipt by the by the end-user (proof of purchase is require). If Nasiff Associates is given notice of such defects during the warranty period, Nasiff Associates will either, at their option, repair or replace products that 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 the 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 makes no other warranty, either expressed or implied, with respect to this product. Nasiff Associates specifically disclaim the implied warranties of merchantability 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 merchantability 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.

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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 instruction in this manual to make certain the malfunction in your CardioCard® system and not the result of an interference 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, 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 phone number where you may be reached during the bay.
- 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.



Hourly Rate

\$200 Dar Hour

\$185 Per Hour

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

COSTS

| Descripton | Hourly Rate |
|--|----------------------|
| Initial Telephone Customer Traning as part of the initial software purchase. | Included in Purchase |

| Follow-Up Training On-Site requested any | \$200 Per Hour |
|--|----------------|
| time after the purchase of the software. | |

| 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. | |

| Consulting On-Site, In-House or Telephone | \$225 Per Hour |
|---|----------------|
| Consultation requested with senior-level | |
| personnel (5 plus years experience). | |

| Programming Including Software Modification | \$225 Per Hour |
|---|----------------|
| for New Features, Custom Programming, or | |
| Database Repair that requires a Programmer. | |

| Production Includes In-House Preparation | \$225 Per Hour |
|---|----------------|
| of Equipment Prior to On-Site Installation. | |

| Network Engineering. Includes On-Site or | \$225 Per Hour |
|--|----------------|
| In-House, as well as Support of Network | |
| Operating Systems | |

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.

NOTE: Minimum Charge for any provided service is 1/4 hour. Cabling is not Provided. Unless disputed in writing, customer with suppoprt payments 30 days or more past due will have their technical support temporally 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 ters and conditinos for reinstating a Service Agreement.

\$125 Per Hour

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Specifications

MINIMUM PC SYSTEM REQUIREMENTS

- · IBM Compatible Pentium or Higher
- 4GB of RAM for Windows 10/8/7/2000/XP/VISTA and MAC
- USB Parots
- 250GB Hard Drive Space
- · Any Windows Compatible Display
- Any Windows Compatible Printer
- Any Windows Compatible Mouse
- · Any Windows Compatible Keyboard

MEDICAL SYSTEM (ECG, HOLTER, NIBP) FEATURES

- Leads:
 - 12-Lead System: 12 (+ XYZ Optional) On CUSB with Pacemaker Detection
 - Holter Systems: 3 to 12 Leads.
 - 0
- Display
 - · LCD, Color, Monochrome.
 - c
- 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 email, modem, fax, internet, CardioHospital
- Measurement's tolerances
 - Time: +/- 4msec
 - Amplitude: +/- 1.22uV at 10mm/mV gain
- Holter Analysis
 - Standard Arrhythmia Classification of all Beats Detected.

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NIBP Tolerances

Time: +/- 3msec

pressures: +/- 2mmHgPulse 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 (preferable 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 1mmHg 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 5lbs.





- Connectors: all electrical connectors have at least 0.025" spacing between conductors
- NIBP Features:
 - Report: Systolic pressure, Diastolic pressure, Heart Rate, and in full disclosure pulse and pressure waveforms.

Indications:

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

MEDICAL ELECTRICAL PERFORMANCE & SAETY

- 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 > 100M (AAMI Standards)
- Gain Sesitivity: 5,10, 10/5, and 20mm/mV (AAMI)
- CMRR: 120DB (AAMI)
- 12-Lead ECG Sampling Rate: 250-1000 Hz
- · A/D Resolution: 13 bits
- A/D Rate: 1- kHz
- Time Base: 25 & 50 mm/sec (AAMI)

GENERAL SYSTEM

- Power Consumption:
 - < 300 mA from the pc bus</p>

CC-Holter Recorder:

- 1 AA battery for 24/48 hours
- · Dimensions:
 - CUSB: 4.9" x 2.7" x 1.25"
 - CCHolter Rev A: 6.25" x 2.75" x 0.75"
 - Flash Holter Recorder: 4.4" x 2.6" x .95"
 - CCNIBP-I 7" x 5" x 1.5"

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Weights

- CUSB: 120g (0.26lbs)
- CCHolter Rev A: 268g (9.5oz) + 1 AA Battery
- Flash Holter Recorder: 5oz with Batteries
- CCNIBP-I 350g (1lb)

Eviromental:

- 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 +5,000 feet w.r.t sea level.

Note: The instrument's specifications may degrade if operated outside of these environmental specifications.

SpO₂

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°
- Accuracy: +/- 0.2°C
- Self-test between each monitor reading: about 2 sec.
- Probes: oral and rectal

WEIGHT SPECIFICATIONS

- Range: 400lbs (180kb)
- Accuracy: +/- 0.5lb (0.2kg)
- Platform Size: 12" x 12.25" x 2.25" (30.5cm x 31.1cm x 5.7cm)

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HOLTER FLASH RECORDER

HOLTER FLASH RECORDER SPECIFICATIONS

Functional

• Channels: 3

• Resolution: 8-bit (13-bit in the CardioCard® System)

· Recording: Full Disclosure

Minimum Recording Time: 24 hours / 48 hoursStorage Medium: Removable FLASH Memory

· Download Interface: std card interface

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: 50 to 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 retrievedResting 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: \\tII\tII\\taVR\\taVL\\taVF\tV1\\tV2\\tV3\\tV4\\tV5\\to

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ascii.hed - ASCII tab delimited file of patient demographics. The Order of Fields:

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

• insure: Insurance Codes

med: Medications

notes: Notes

notesp: Notes Protocol

• notesph: Notes Phase

• np: Blood Pressure

autodia: Auto Diagnostics

· voicedict: Voice Dictation

ascii.rr - File Export list of R-R times in msec. (limits allowed are entered by the 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 from 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, and puts out 4 chars plus sign per sample from tempio.e.

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

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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 vxt (the driver) is loading ecg data

unit * 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

unit* nbpil - unitptr 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 locations0-99. 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 in 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 the table[0] and table[1] where the driver is loading the ECG data. Notes that the SpO2pleth buffer is loaded with a different pointer (SpO2pp and 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 (2bytes per point).





Calling the CardioCard® from External Programs

File i/o:

A user program can load a file called ccio to have the CardioCard® 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 the factory).

a is either a,r,t, or d where a is the acquisition, r is retrieved,

t is tempio retrieve, and d is delete the selected file.

b is the database drive letter.

ccccccc 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 pulse-pulse rate ppm

short temp - temperature * 10 degrees F (e.g. for 98.6, this would be 986)

Message API: When both the CardioCard® and another program are running at the same time, the other program can command the CardioCard® 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 CardioCard® 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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Product Update Policy

One of the major advantages offered by the CardioCard® System is its ability to incorporate Product Updates, Enhancements, New Features, and Modifications via Software. The CardioCard® 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

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EULA





End Manual

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