Nasiff Associates CardioCard™

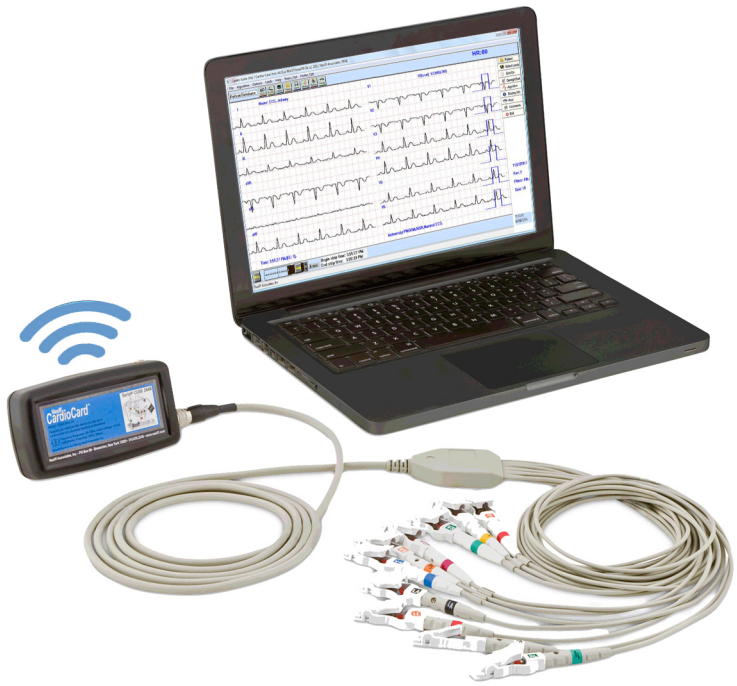
CardioECG™

Bluetooth

D2002005_IFU_BT_V8_(09/18/2023)

User's Guide

One System does it all: 12-lead interpretive ECG, Stress, Holter, ECG Bluetooth®, Vital Signs, NIBP, SpO_2, Weight, Temperature, Glucose, Spirometry, Stethoscope, Mobile Device, Patient Record Management, etc:



REV8 09/18/23

Printed in USA by Nasiff Associates, Inc.

Brewerton, New York.

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 CARDIO CARD

CLICK ON HELP

MAIN HELP MENU

CLICK ON THE SECTION YOU NEED

WWW.NASIFF.COM

SERVICE & SUPPORT

ONLINE HELP

CALL US

315-676-2346

CUSTOMER SERVICE

IS AVAILABLE

MONDAY - FRIDAY

9:00 AM TO 4:30 PM

EASTERN STANDARD TIME

CARDIO System: User Manual

Table of CONTENTS

The intended use and relationship of the Cardio Card Products.

The Cardio Card System performs the main cardiology tests in one system. 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.

~ 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 ~

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 installation

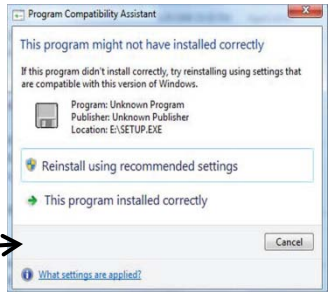
• Place the Nasiff CardioCard software into the DVD drive of your computer

• 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. When finished click on “Installed Correct”

• Remember: the CardioCard software does not need the internet to install

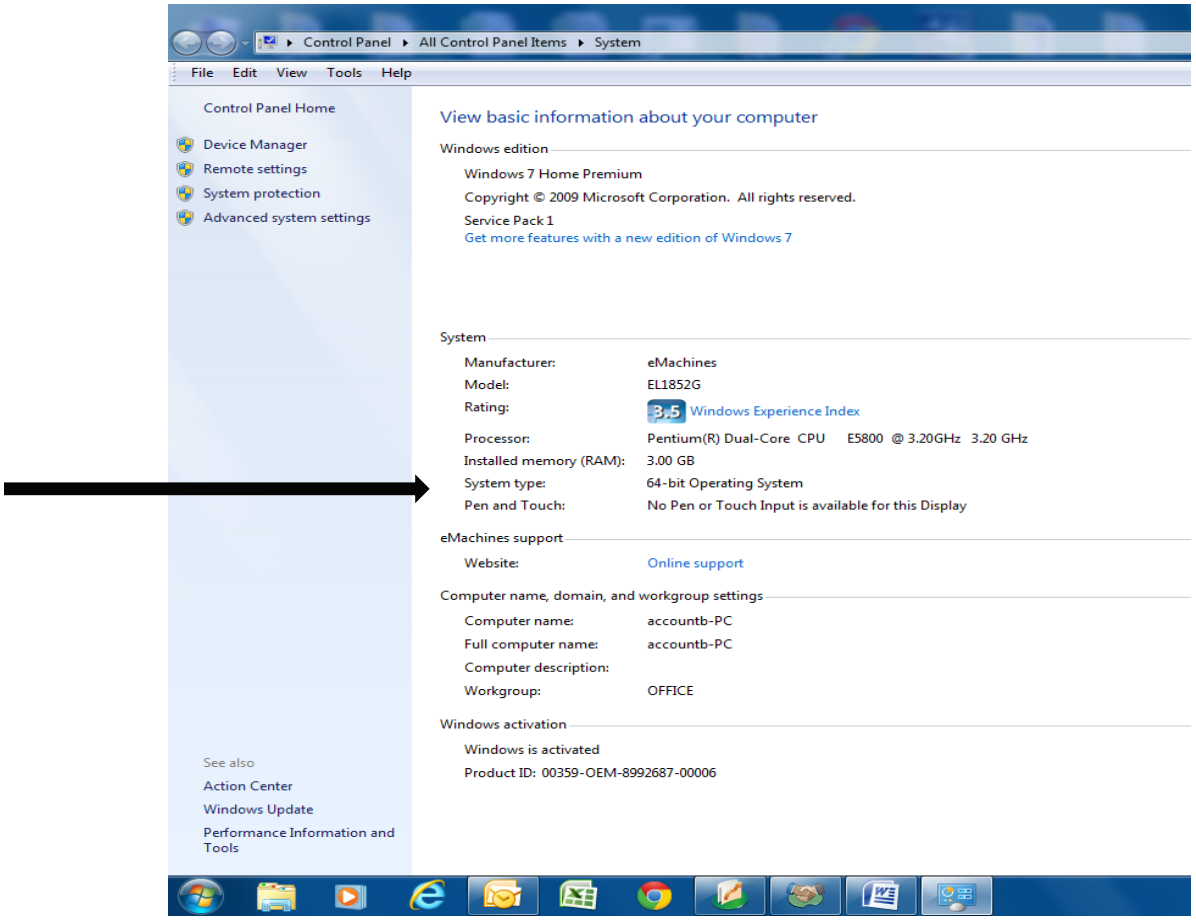
If this message appears, click “This program installed correctly” →



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

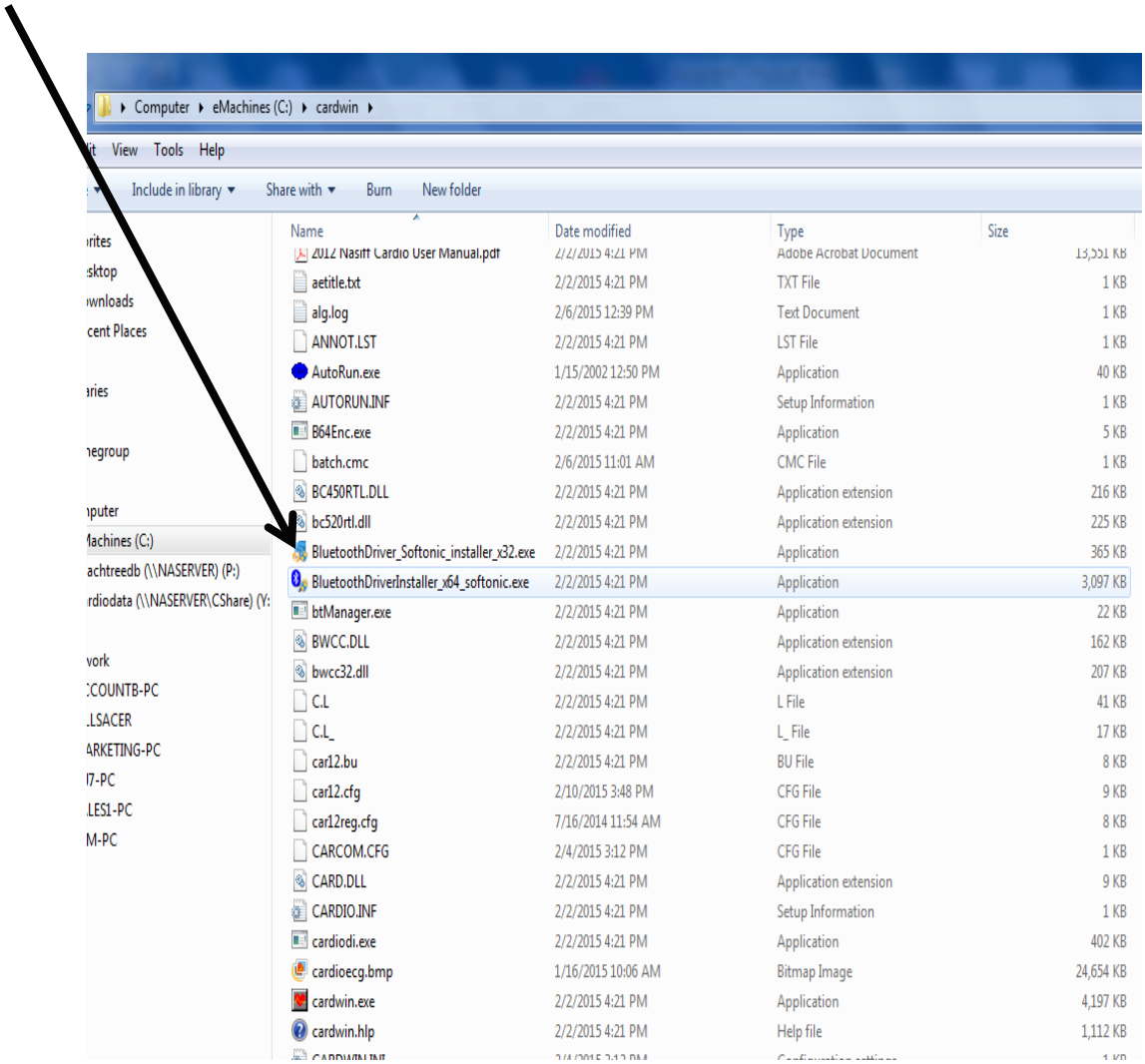
Installing Bluetooth

- If you have an internal Bluetooth installed, you will need to pair you Bluetooth device to run.
- If you need to install Bluetooth Dongle, start with checking you System type on your computer.

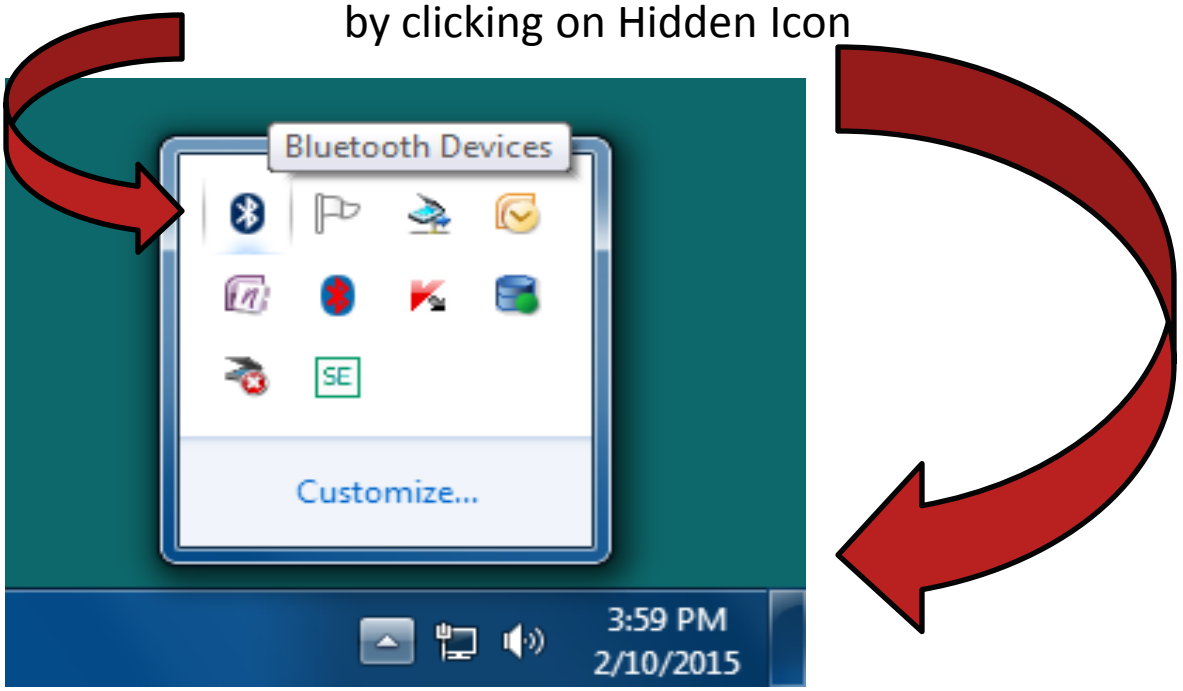


When installing the Bluetooth Driver, check the System Type. See if 32-bit or 64-bit Operating System.

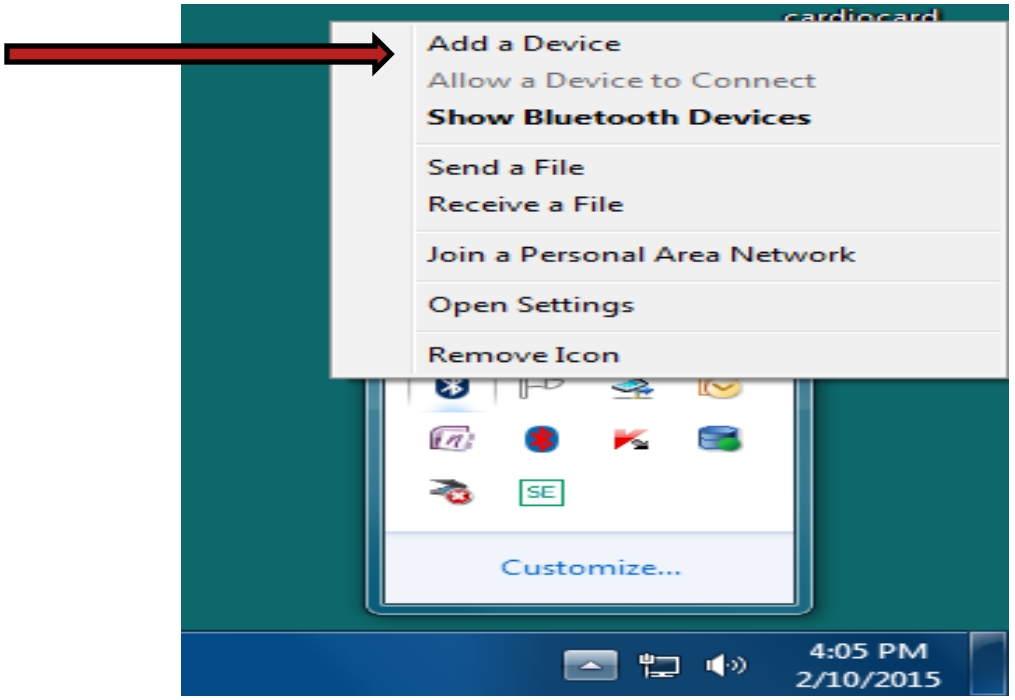
Then go to Cardwin on your computer, open and go down the **Bluetooth Driver Installer**, pick the one that fits your computer, Softonic_installer_x32.exe **<u>or</u>** _x64_softonic.exe, then Install.

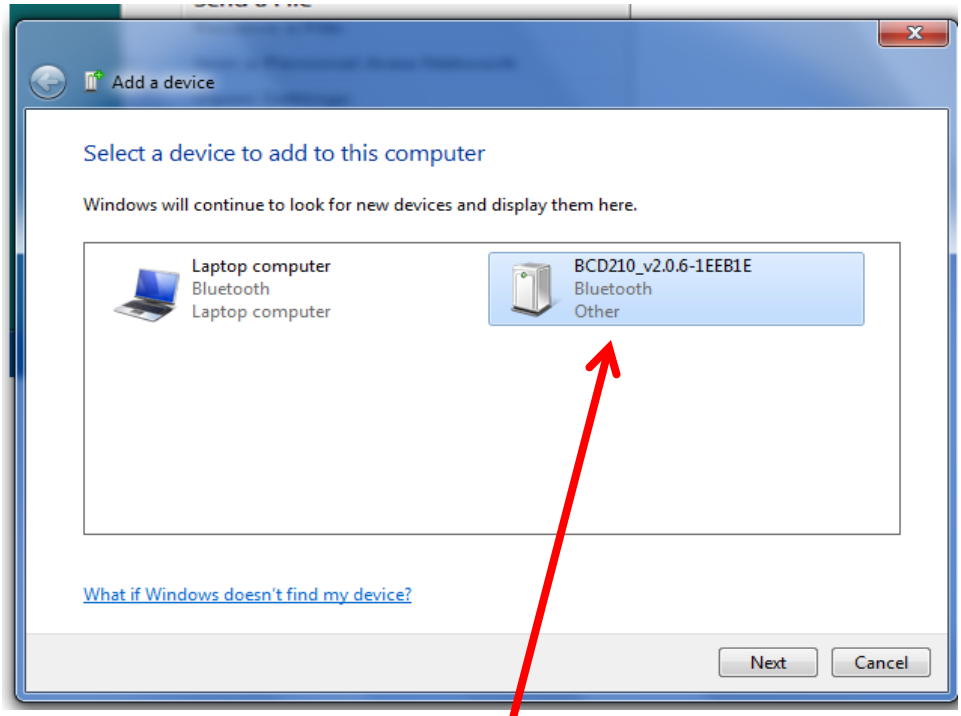


Plug in the Bluetooth Dongle, you should see the Bluetooth Icon by clicking on Hidden Icon

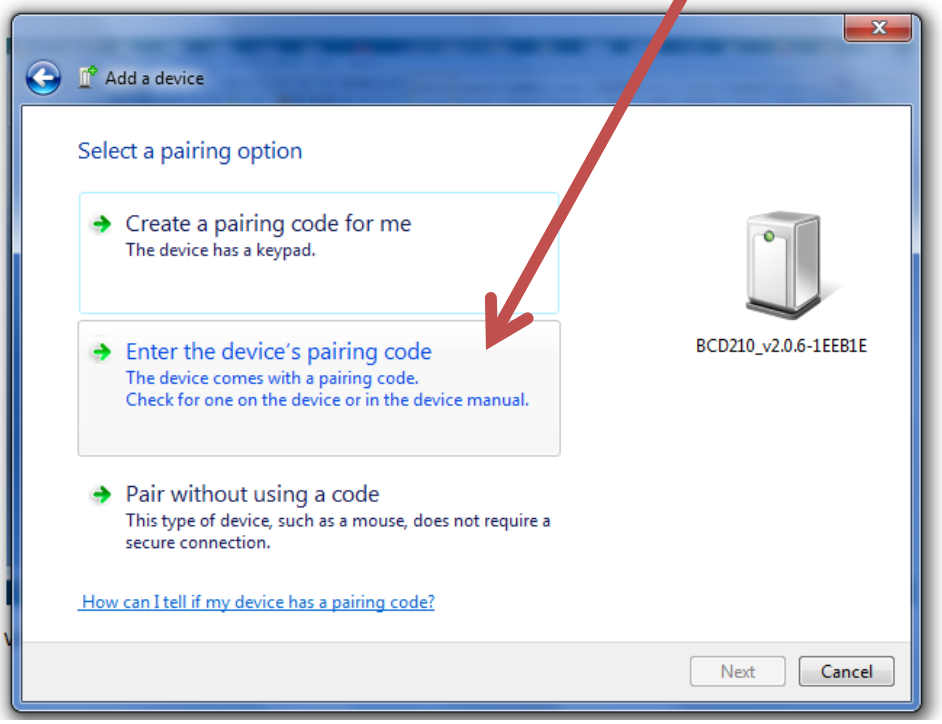


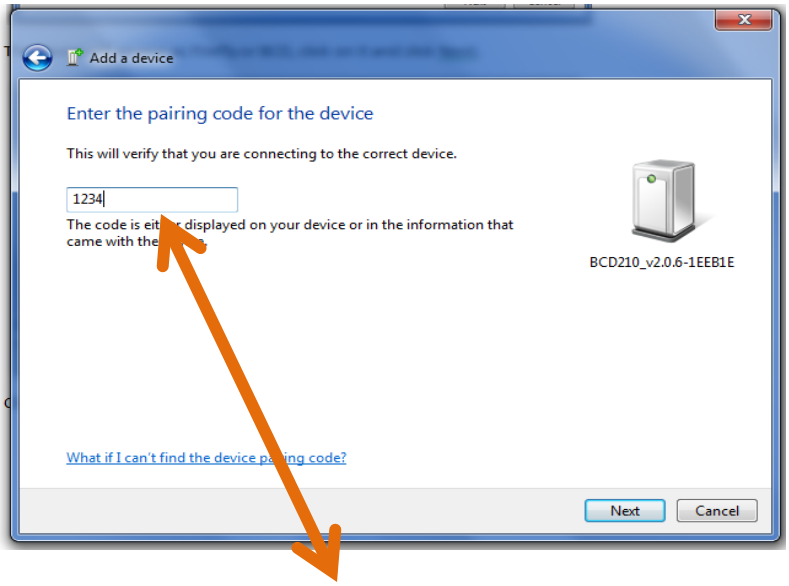
Install batteries in CardioCard Bluetooth Device and turn on.
Click on Add a Device



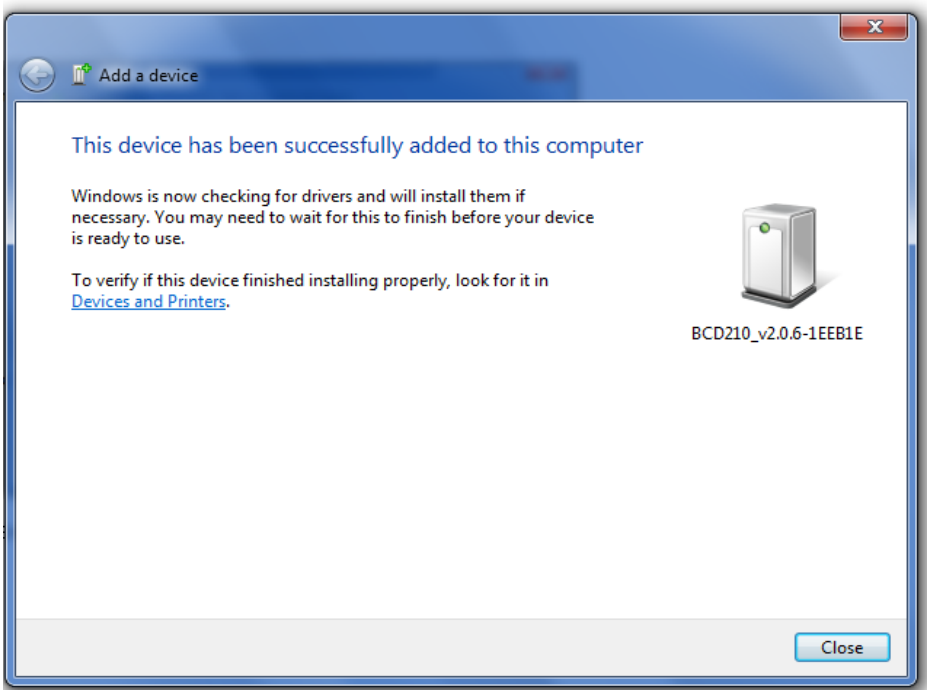


The device will appear as Firefly or BCD, click on it and click Next.
Click on the device's pairing code.



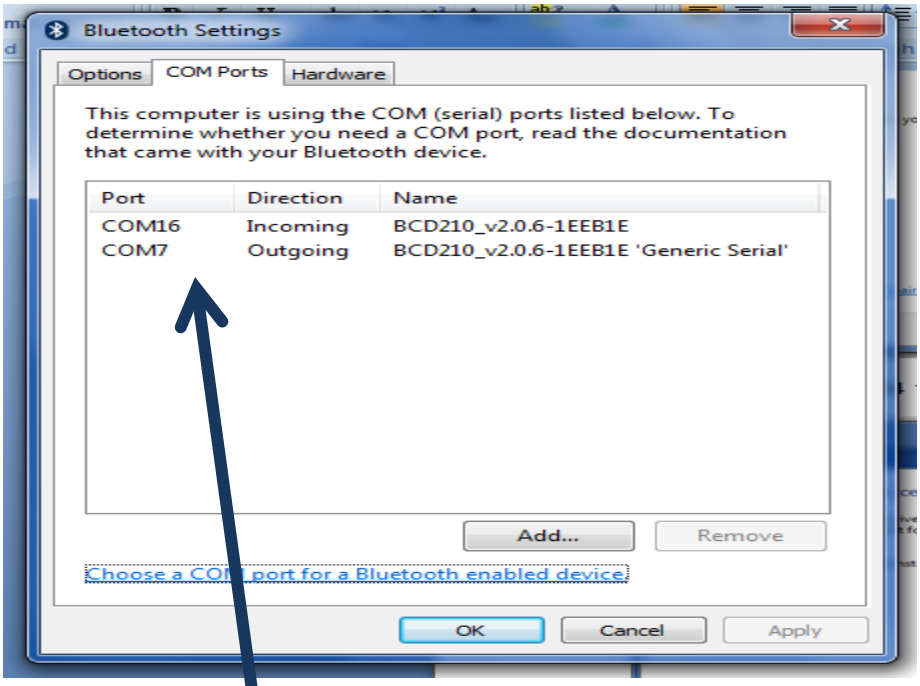


Enter pairing code 1234 for you Nasiff CardioCard Device then click Next.

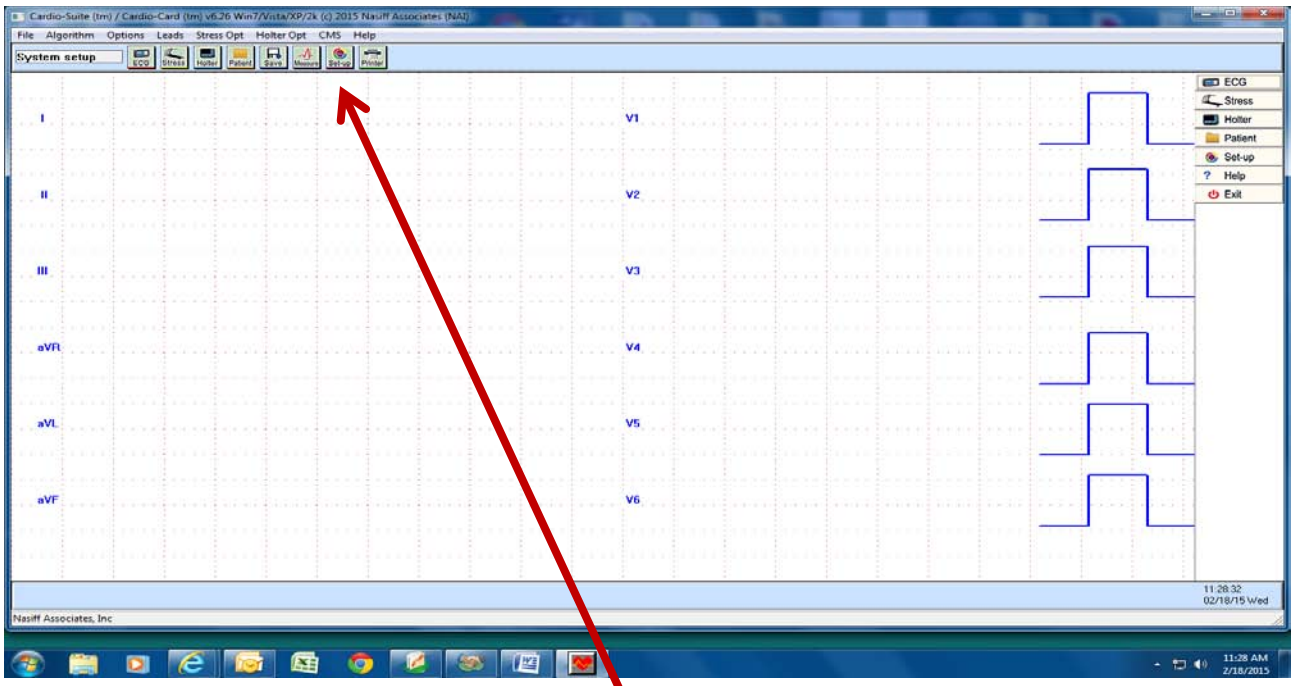


You will get the message: This device has been successfully added to this computer, then click Close.

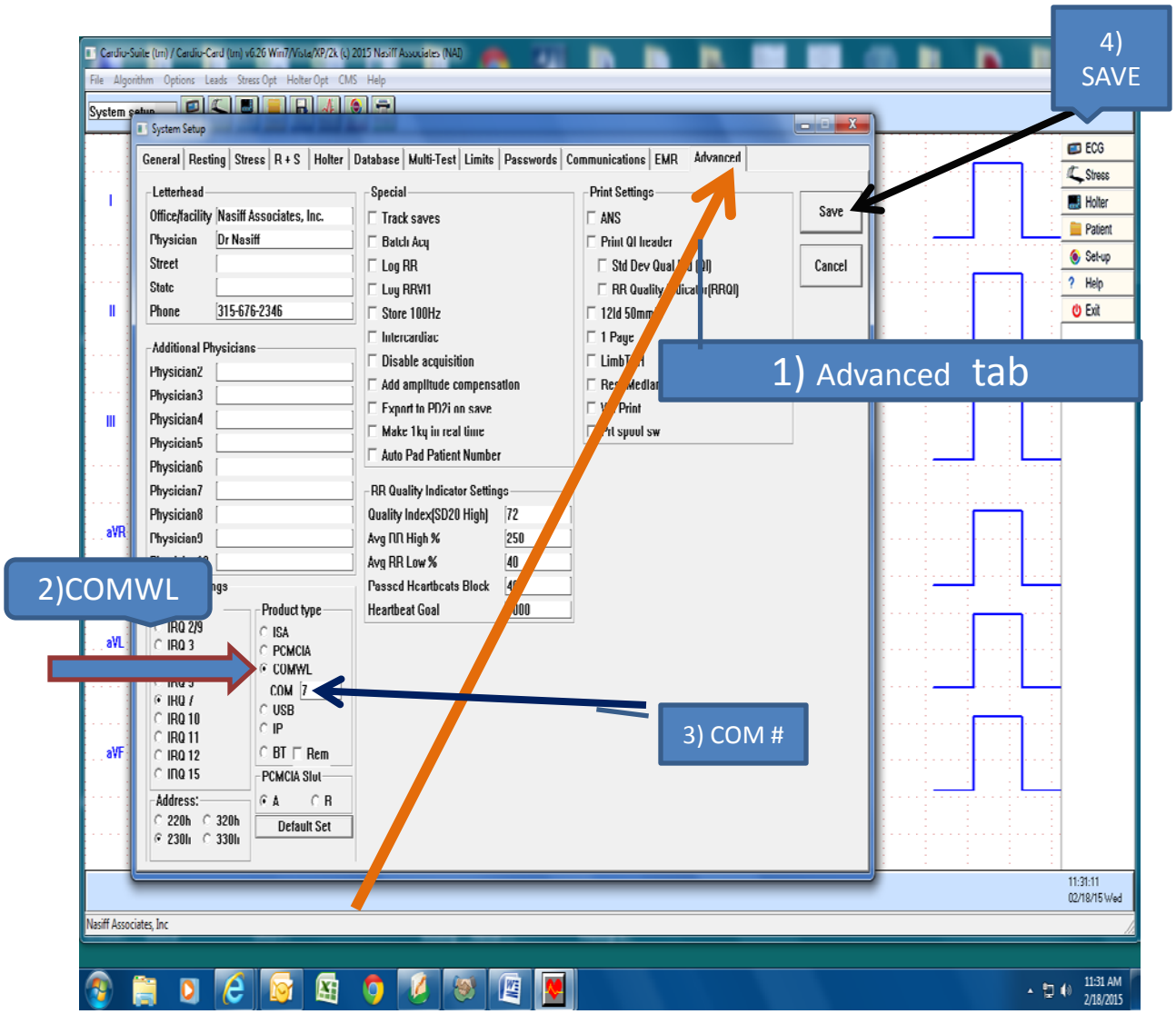
Go back to the hidden Icons and click Bluetooth Icon and click on open settings, Check the outgoing **COM Port**.



Example: COM 7



Open CardioCard, Click on **Setup** Icon at the top.



Click on 1) **Advanced** tab at the top Right, under Product type mark 2)**COMWL**, in the box next to 3**)COM** enter your **COM PORT number**, then click **Save**. Ready to start testing.

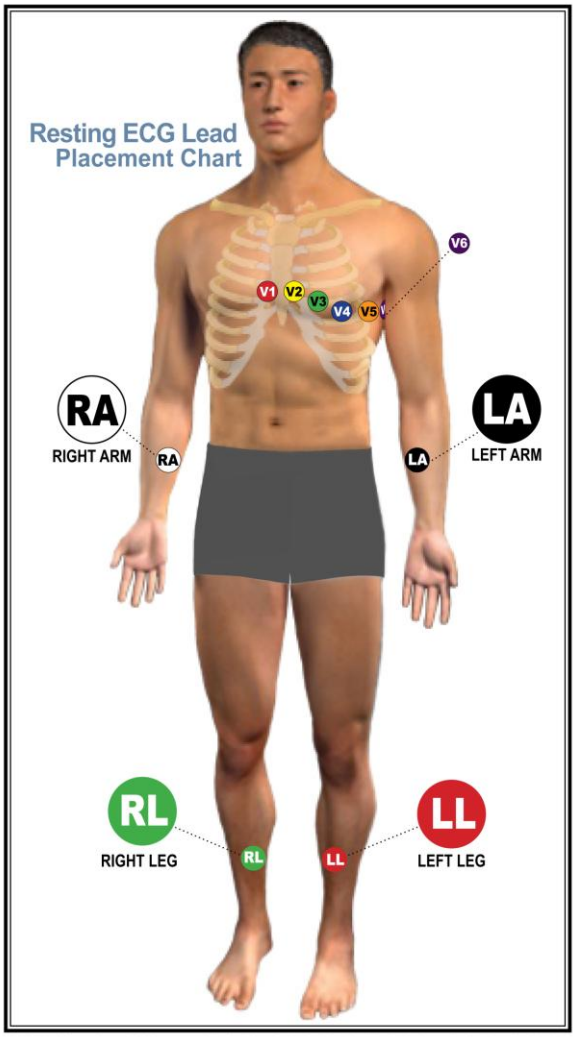
NASIFF ELECTRODE PLACEMENT CHART

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**
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 CardioResting ECG

Getting Familiar with ECG buttons

Buttons used for ECG

To start ECG press this button

Prep patient well to reduce artifact and assure good results

1. With patient hooked up; click on “ECG” button. --This will start the ECG--Pressing the “ECG” button again will only **stop** the ECG**, not store /save** it

2. 

When satisfied with ECG on screen click “Save”
Note: you must have clean ECG for 12 seconds *(In “Set-up” you can check “Enter Demogr Before” to enter patient’s demographics before acquiring ECG)*

3. 

Saving the ECG will allow you to retrieve your patient’s ECG at anytime. Click on “Patient” - then highlight patient and click “Open” - next highlight test and click “OK”

This is your printer icon. Click on the printer icon to print your ECG report. If you would like to print your report to PDF click on “File” at the top left of the CardioCard software then scroll down to print ECG to PDF *(can be set up automatically)*

5. If you would like to print to PDF and retrieve this ECG report in an EMR folder make sure you have set up your path as mentioned in “Set-up”

Nasiff CardioResting ECG

Getting Familiar with ECG buttons

Be sure to click “OK” or “Save” to hold settings

- “Set-up”: Filling out the letter head which is located ¾ of the way down the page will show up on your reports once saved
- Under the “Print:” options column in “setup” you can choose to enter demographics before or after acquiring ECG
- The software automatically creates a PDF folder in your “C Drive” and sends a shortcut to your desktop. By checking the “Print PDF on Save” box in “Set-up” located on the lower left side near the bottom of the setup screen, will send your final PDF report to your “nasiff_reports” folder on your desktop automatically
- To “Enhanced Pacemaker Mark” turn on pacemaker detection
- If desired click “Default Settings” to reset back to factory settings

Preparing a Patient

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

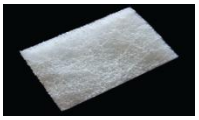
Note: ***Without good skin preparation, both noise and artifact will frequently degrade the patient's ECG to the point of being unusable by the physician.***

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 scrub pad *(or a small square piece of an 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 gauze pad to remove any debris



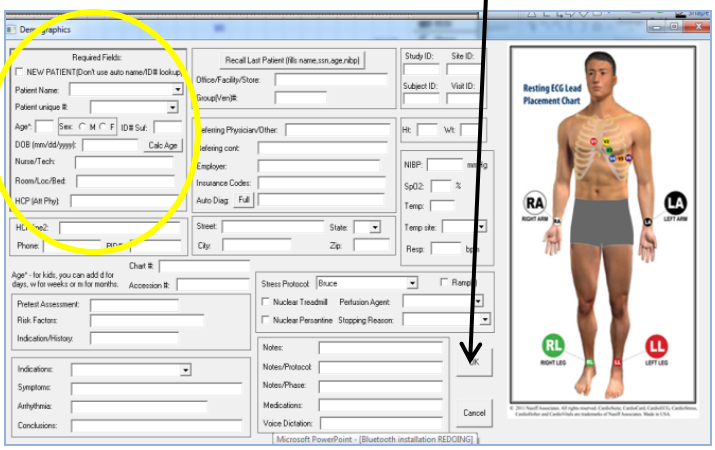
You can also use Nuprep

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

Performing an ECG

The demographics page will appear; you must complete the following:

1. Patient ID number, this must be unique to this patient, *(if less than 9 digits, the program will auto fill with zeros)*
2. Last name, First name
3. Age
4. Gender “M” or “F” Then press “ OK”



- When you get a clean ECG tracing click “Save”
- You will be prompted to print “yes or no” If you press “yes” the report will print to your default printer
- Comments can be added by clicking on “Comments” located on the right of the CardioCard program
- Send final report to EMR click “File”-”Print ECG to a PDF”
  (the PDF is sent to the “nasiff_reports” folder on your 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 sec strips during store” will allow you to store multiple ECG strips
- To view measurements: go to “Options” and scroll down to “Display Measurements”
- Change patient’s name: go to “Options” scroll down to “Change Patient Name” and change name
- Increase or Decrease Gain: go to “Options” and scroll down to “Gain” then adjust
- View selected leads: click on “Leads” at the top of the CardioCard and scroll down to preference
- Print-Red grid lines: click on “Set-up” under “Print” check the box “Lines” *(located top of box) and click on* “Save” to hold your settings. This is for print only and not meant for PDF
- Send report by fax: click on “File” located top left of the CardioCard, scroll down to “Print to a Selected Printer/Fax” *(Your PC needs to be connected to 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!” *“Figure 04”*
- 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 “car12wd” before
- Pacemaker Detection: turn on in “Set-up”
- Calipers (measurement Cursors) can be used by pressing “Backspace” use arrow keys to move cursor, press “ATL and M” to mark, arrow over and measurements will appear on screen

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	Meaning
Normal ECG	Same
Measurements data not available	Same
Susp arm lead reversal	Suspect 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 plus RVE
ILB	Probable ILBBB (Incomplete Left BBB)
LB	Probable LBBB
LA	Probable Left anterior fascicular block
LP	Probable Left posterior fascicular block. LPFB
BA	Probable Bifascicular block. = RBBB & LAFB
BP	Probable Bifascicular block. = RBBB & LPFB
ID	Nonspecific intraventricular delay
IB	Nonspecific intraventricular block
PA	Probably anterior MI, age undetermined
OA	Possibly anterior MI, age undetermined
SDSE	Marked st depression, possible subendocardial injury or digitalis effect
TA	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
MAL	Marked T wave abnormality, consider lateral ischemia
TAAL	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
SBV	Suspected biventricular hypertrophy
SE	Nonspecific ST elevation abnormality
SEP	ST elevation, consider early repol, pericard
SER	ST elevation, early repol
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, probably digitalis
NSD	Nonspecific ST depression, could be normal
MSDS	Marked T depression, possible septal subendocardial injury

ECG Interpretive Abbreviations and Definitions (Continued)

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	S1,S2,S3 pattern consider pulmonary disease, RVH or normal variant
PD	Probably Pulmonary disease
CAI	Cannot rule out anterior infarction, age undetermined
CSI	Cannot rule out septal infarction, age undetermined
SIF	Probably Septal infarction, age undermined, injury or ischemia
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
ALIF	Probable Pos Anterolateral infarct, age undetermined
CI	Cannot rule out inferior infarct masked by left anterior fascicular block
PPAC	Possible PAC.
PRWP	Poor R wave progression
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) .

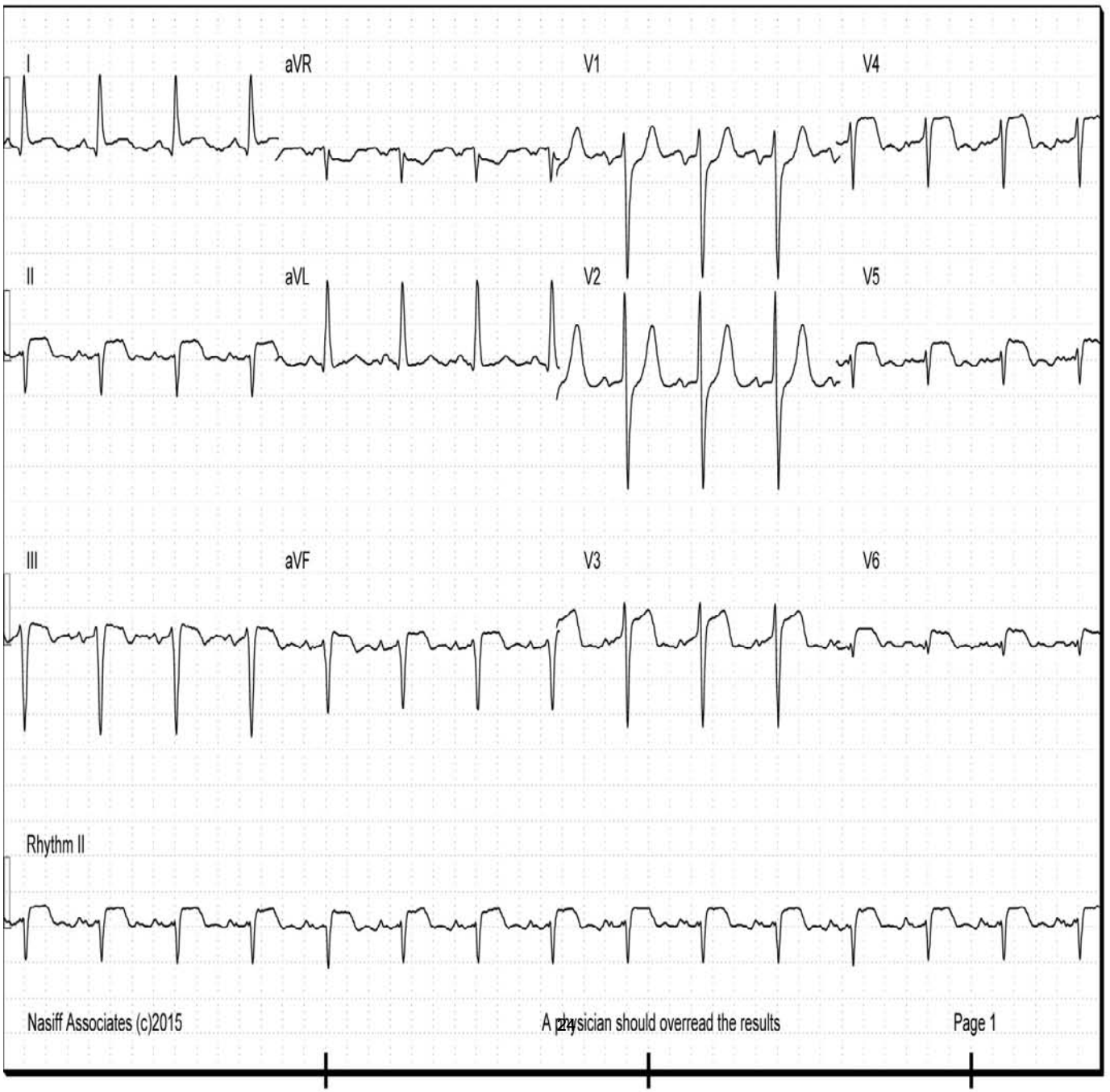
****For example**, the sample on the next page has abbreviated ABN, Sinus, LAD, 1st DegBlk or full interps: ABN, Sinus, Left Axis Deviation, probable 1st degree block, Lateral Infarction, age undetermined, nonspecific ST elevation abn, ST elevation, early replorization, acute pericarditis, poor R wave 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.

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: .

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:

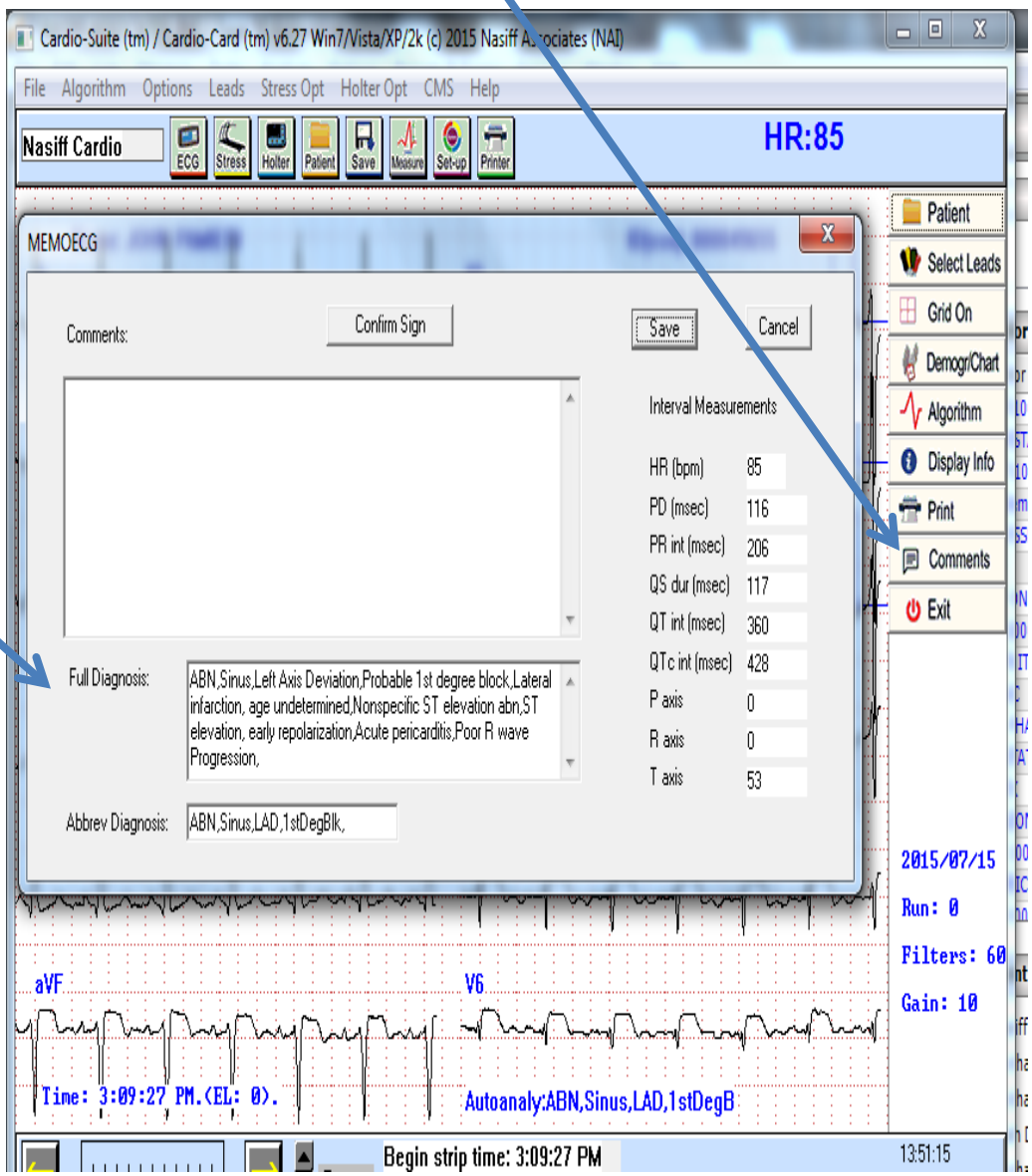
10mm/mV, 0.05-150Hz. 40HzLPF, 25mm/sec
Indications:



A physician should overread the results

To review Full Diagnosis click on the comments

Full Diagnosis

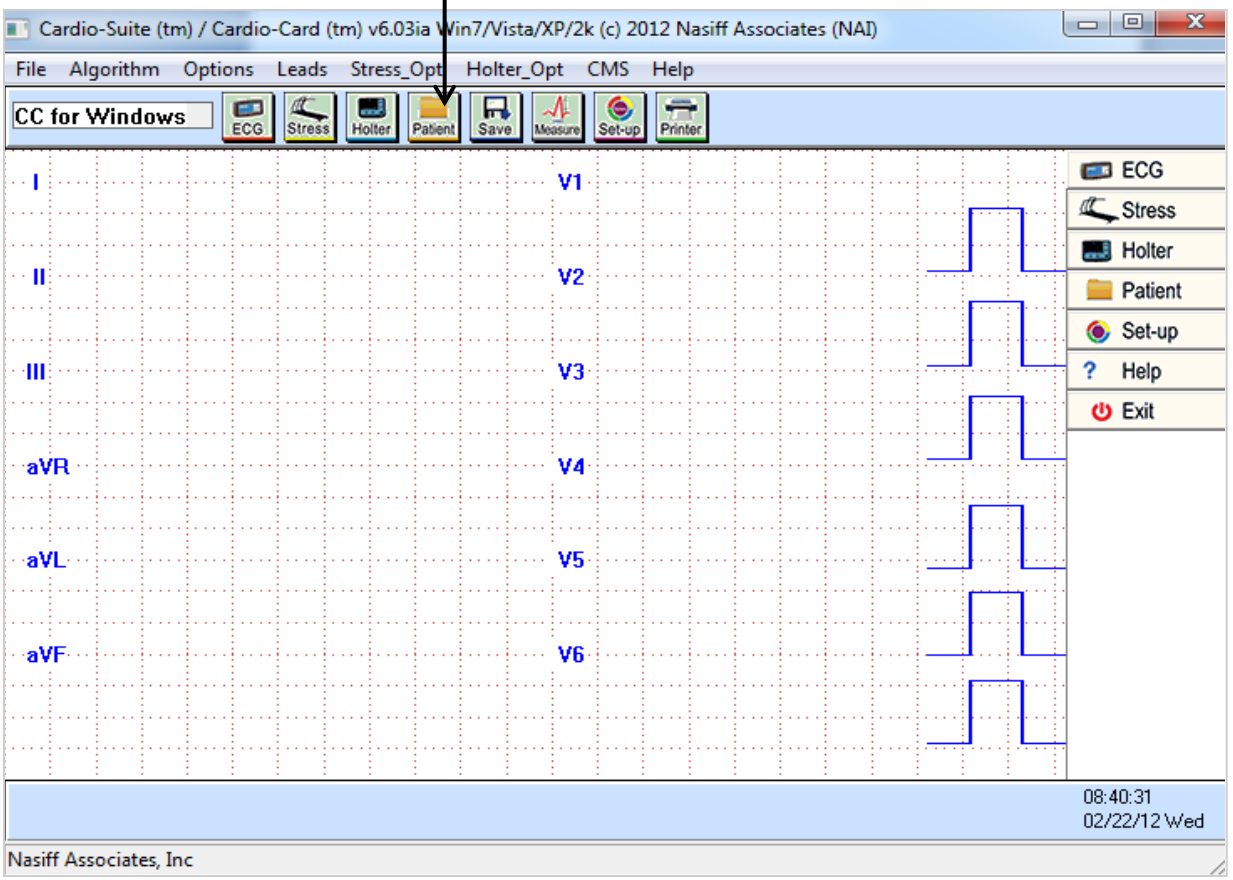


Database Operations

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.

To open database click on Patient to open the database

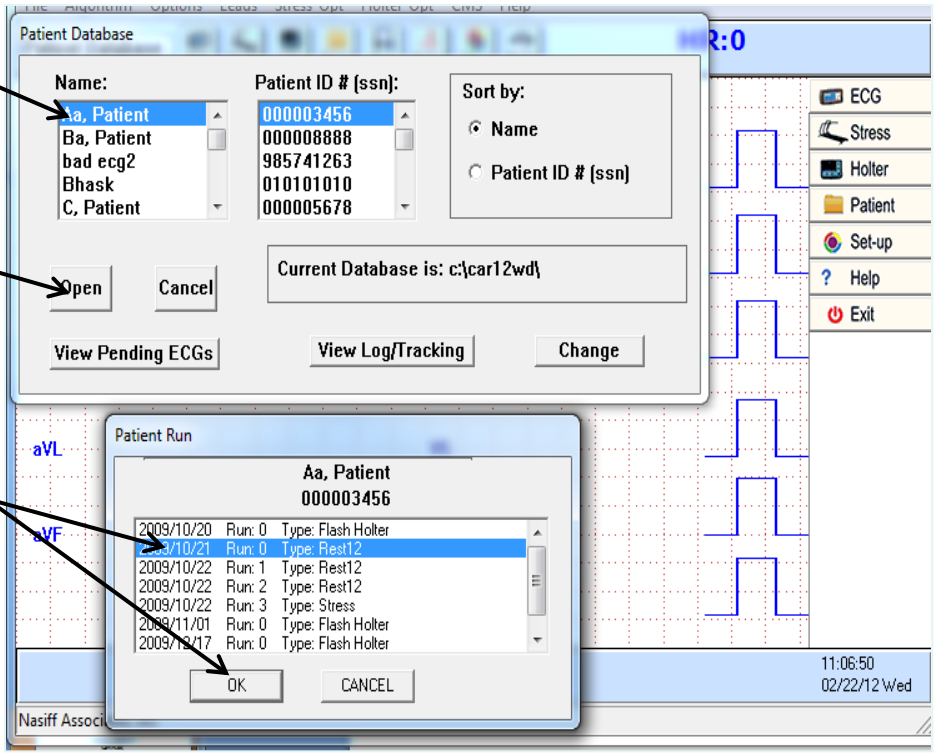


Opening Database

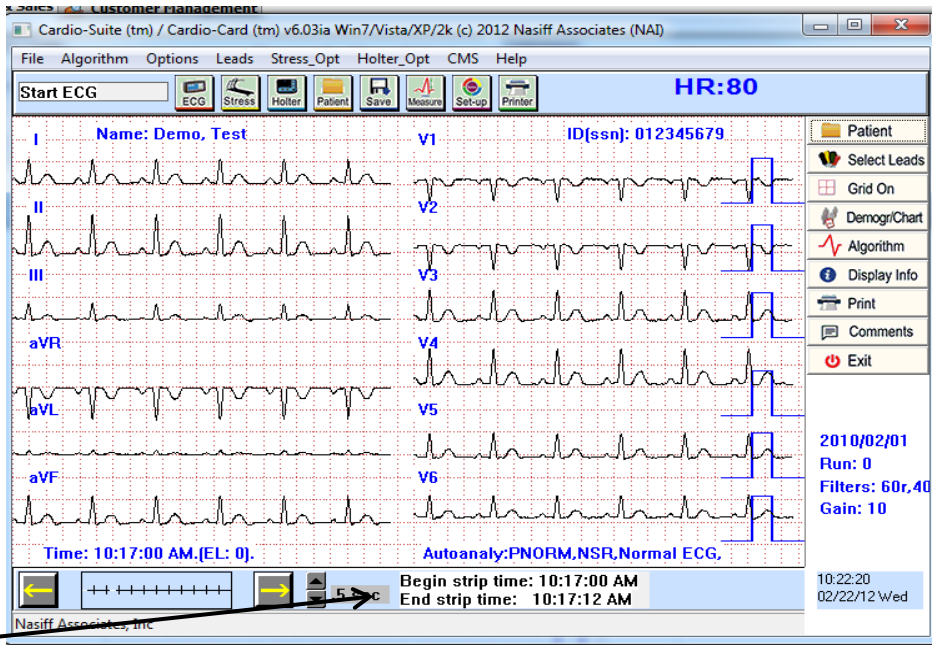
(Continued)

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

3) Click on the “run”and click “Ok”

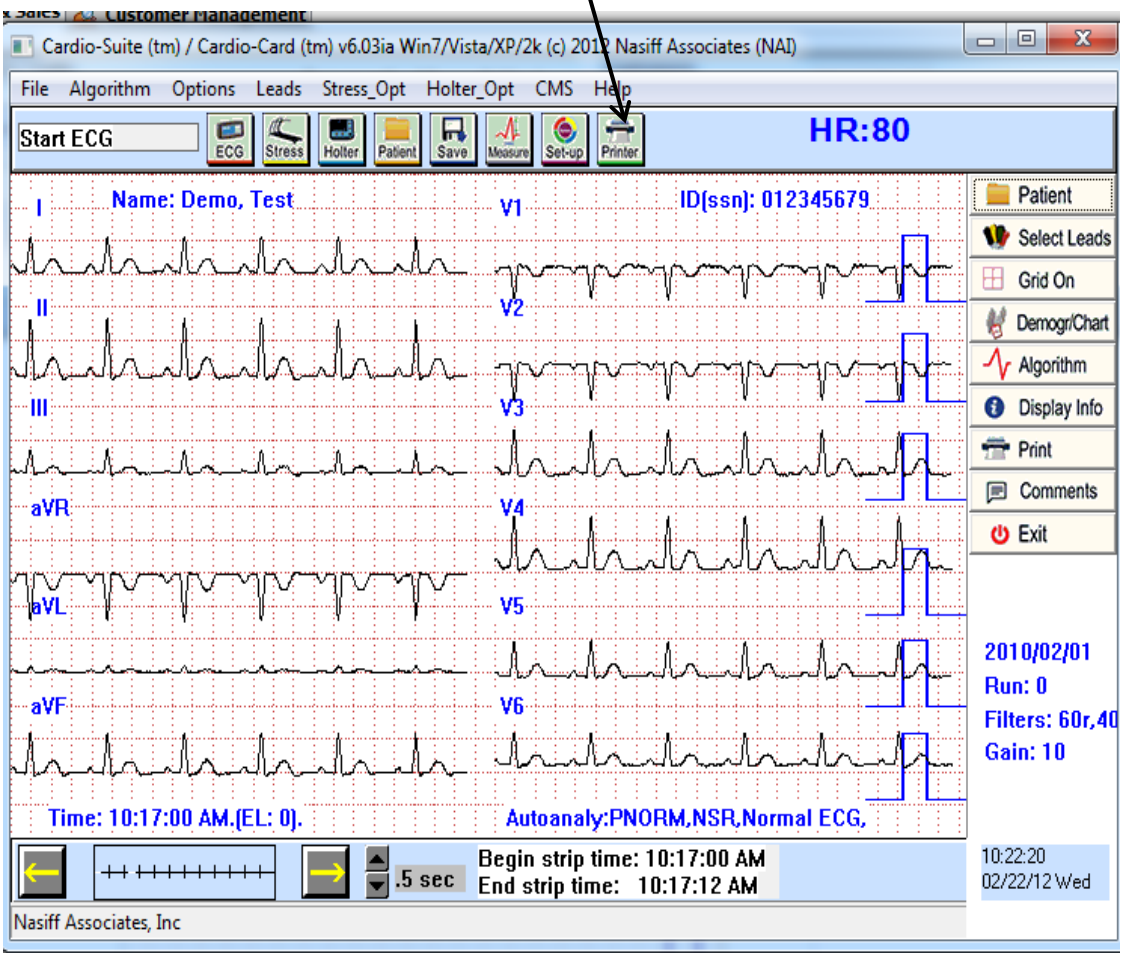


4) *Note:* After storing any test (for example: “Rest12", “Stress", “Flash Holter"), the test will appear on the screen. You are in the database when you see the arrows at the bottom of the screen and the begin and end strip time.

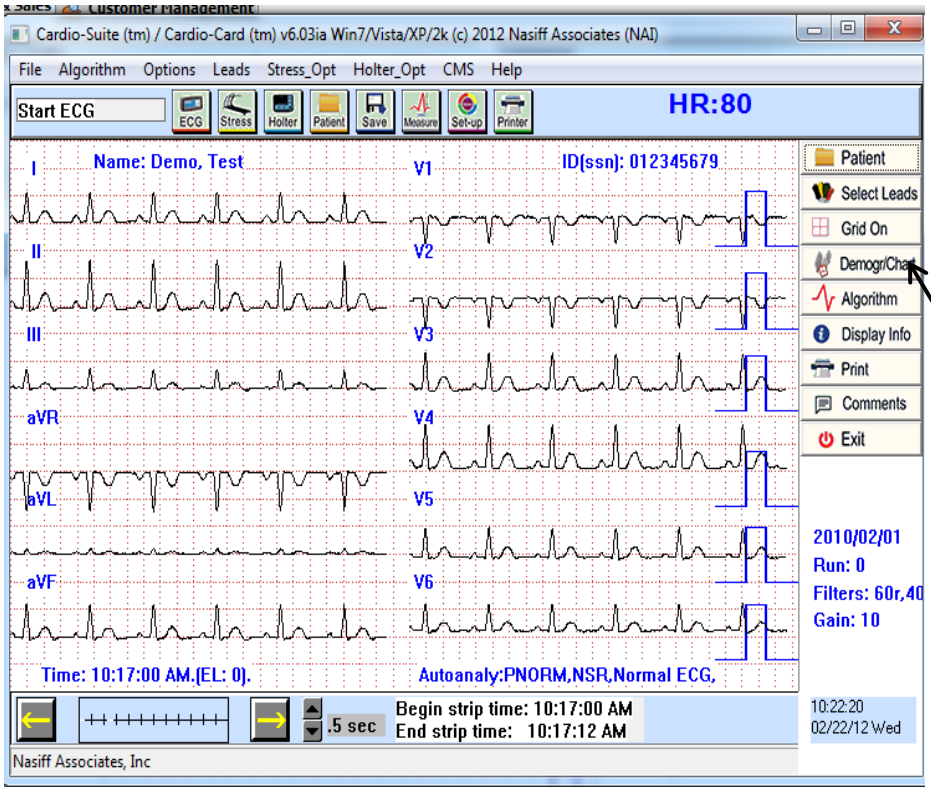


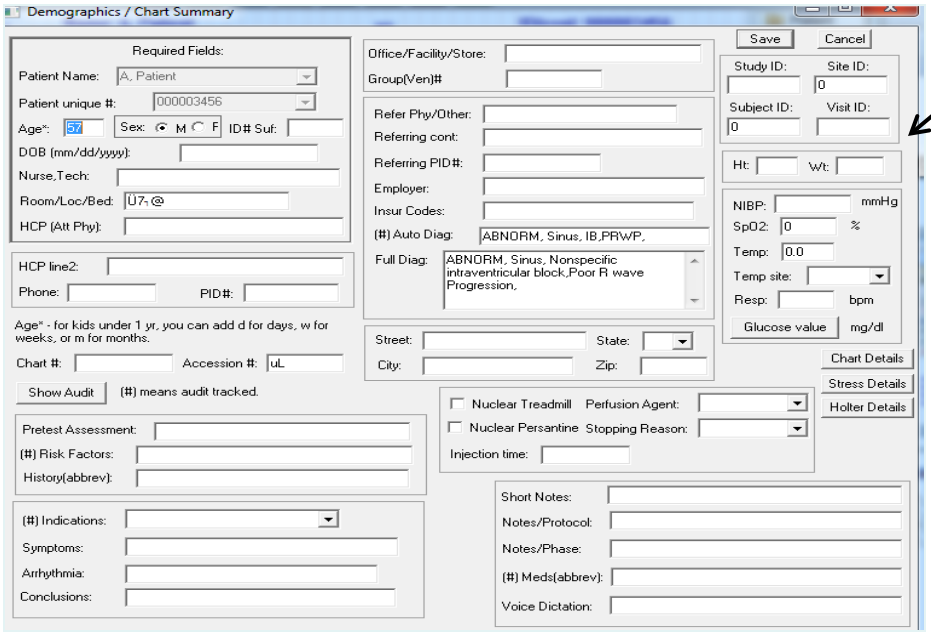
Printing

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



Demographics Chart

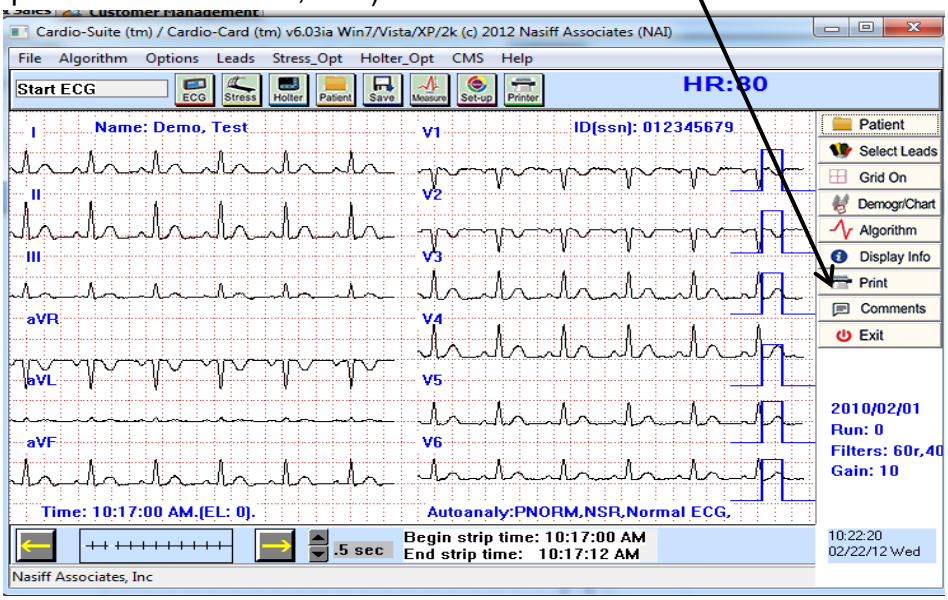




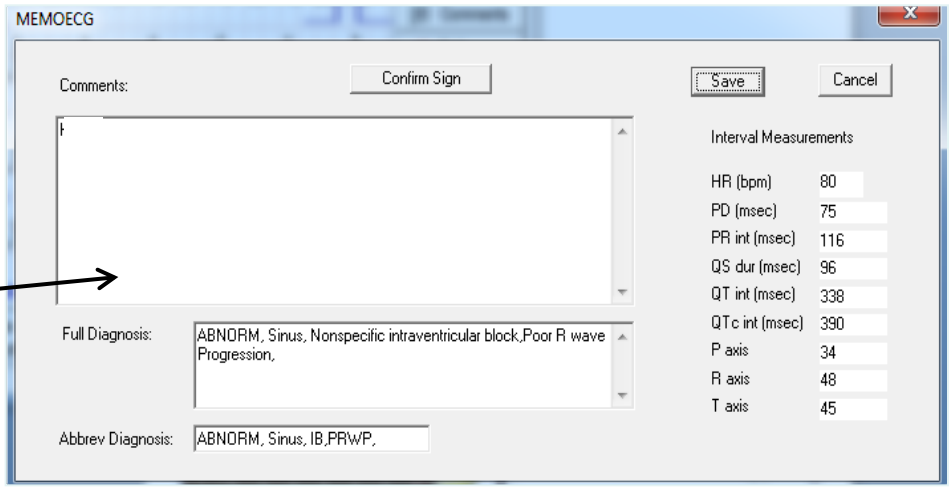
2) Clicking the "demographics chart" button displays detailed patient information and provides entry into the Cardio EMR Chart program.

Comments

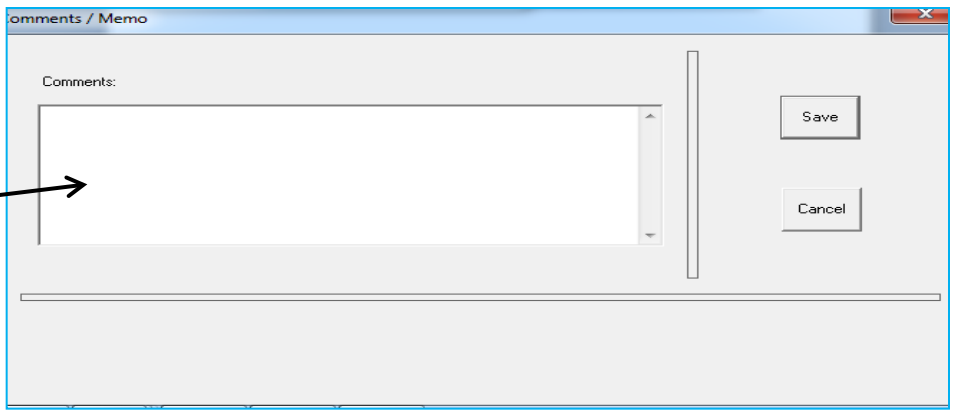
3) Clicking the "comments" button allows the inputting of unlimited notes, comments, diagnoses, etc. (Copy and paste from other programs is permitted in this area, also)



This is the comments for ekg

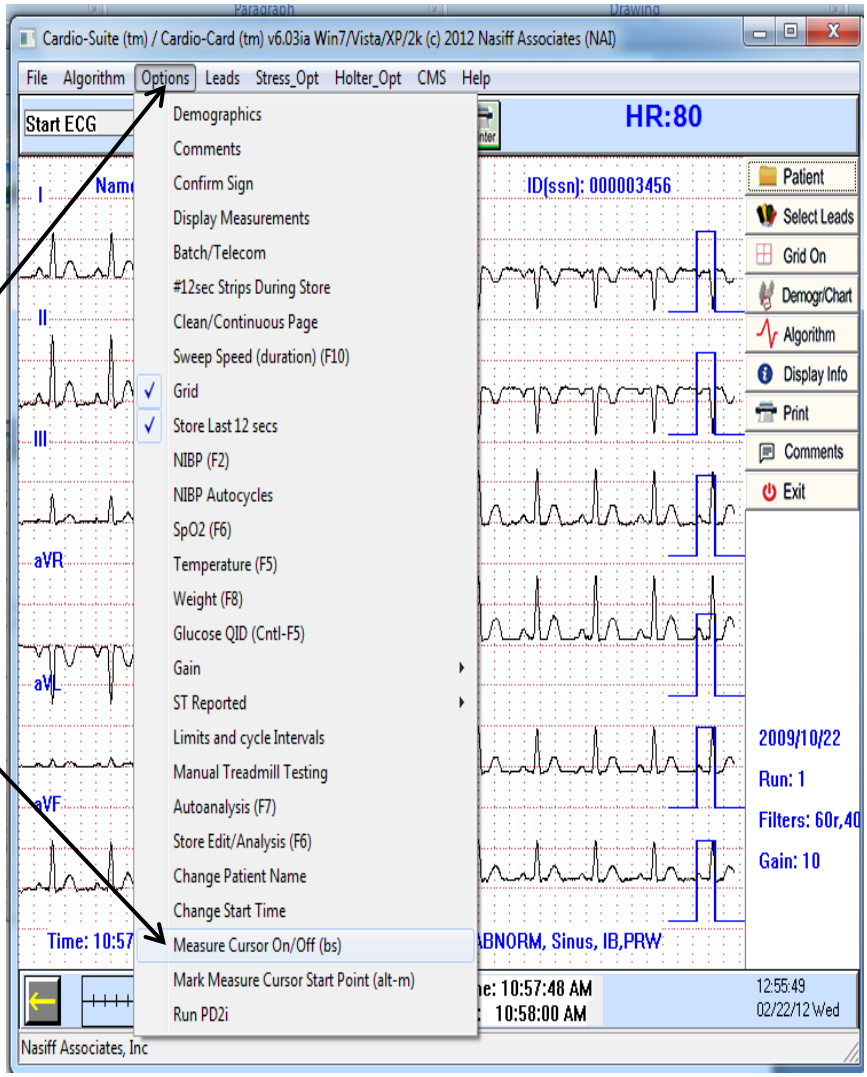


This is the comments for stress and holter



Measurement “Cursors"

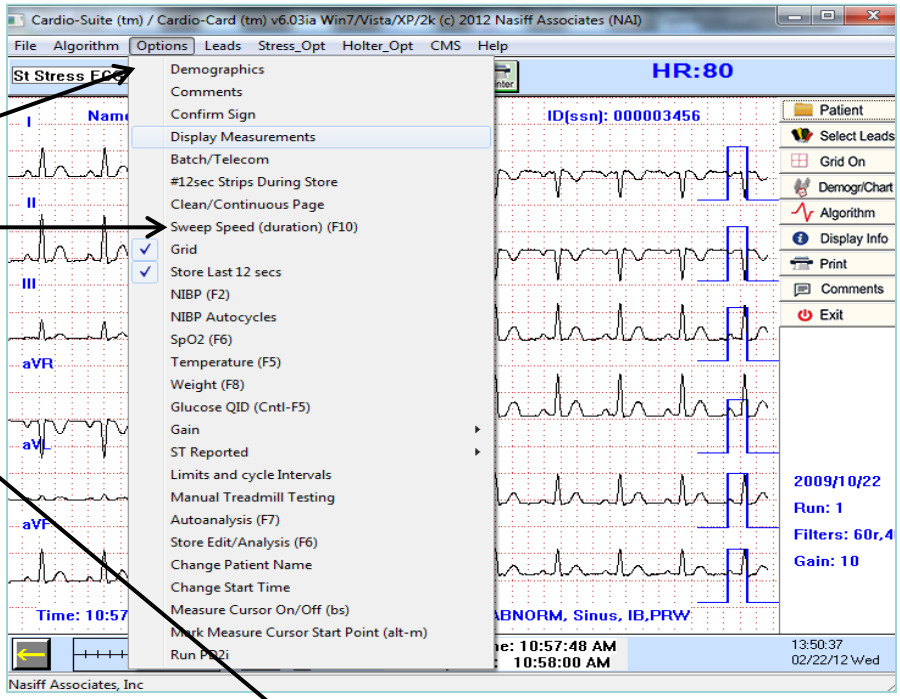
4) Measurement "cursors" are available providing wave measuring capability. (eg. amplitudes, durations, rr values, etc). To activate or deactivate click "options" then "Measure Cursor on/ off". Cursor navigation is accomplished by using the "arrow", "page up" and "page down" keys. Mark cursor start point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

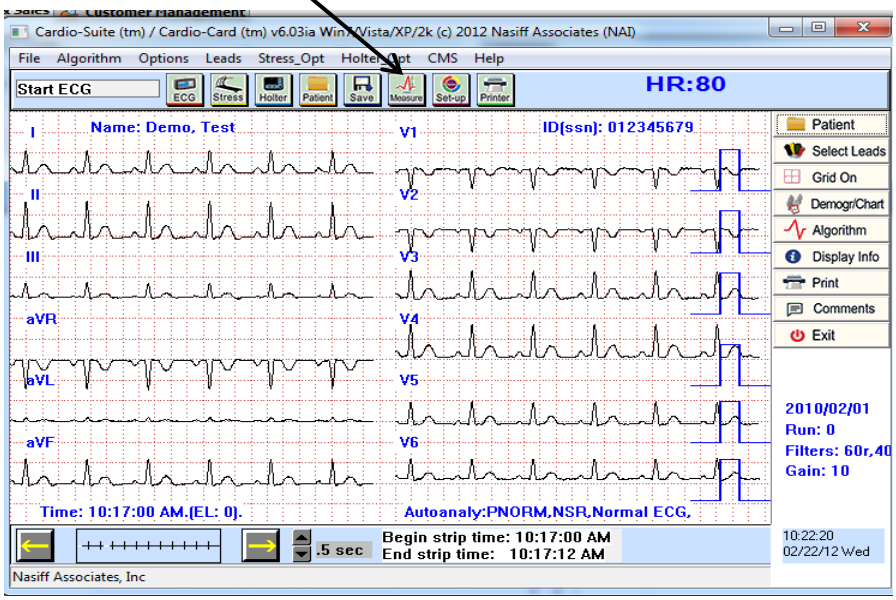


ECG Functions in the Database

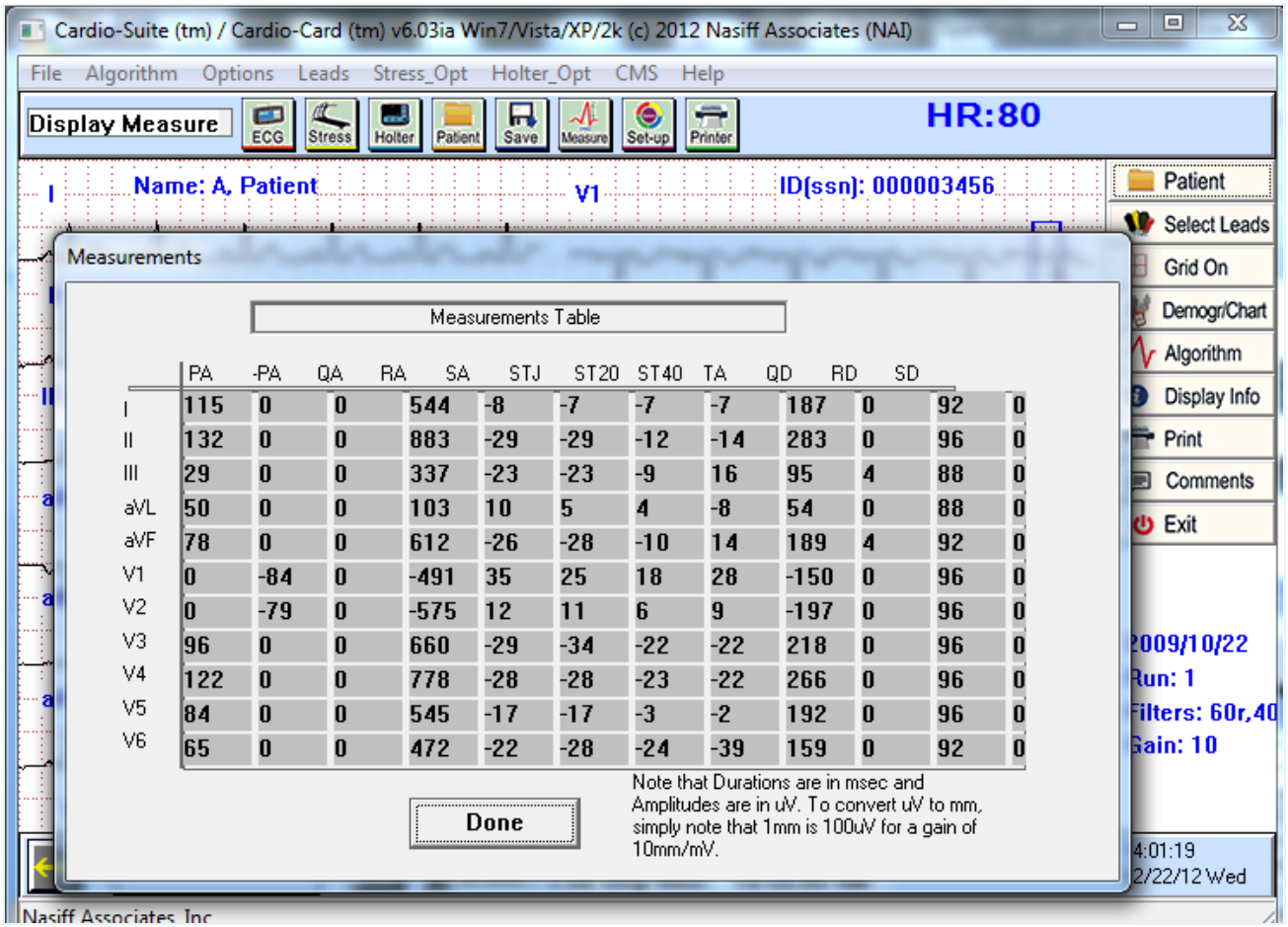
(Continued)

2) Clicking on "Options" then "Display measurement" or click on the "triangle" will bring up the full measurements tables (pressing F4 will print these tables to the default printer)





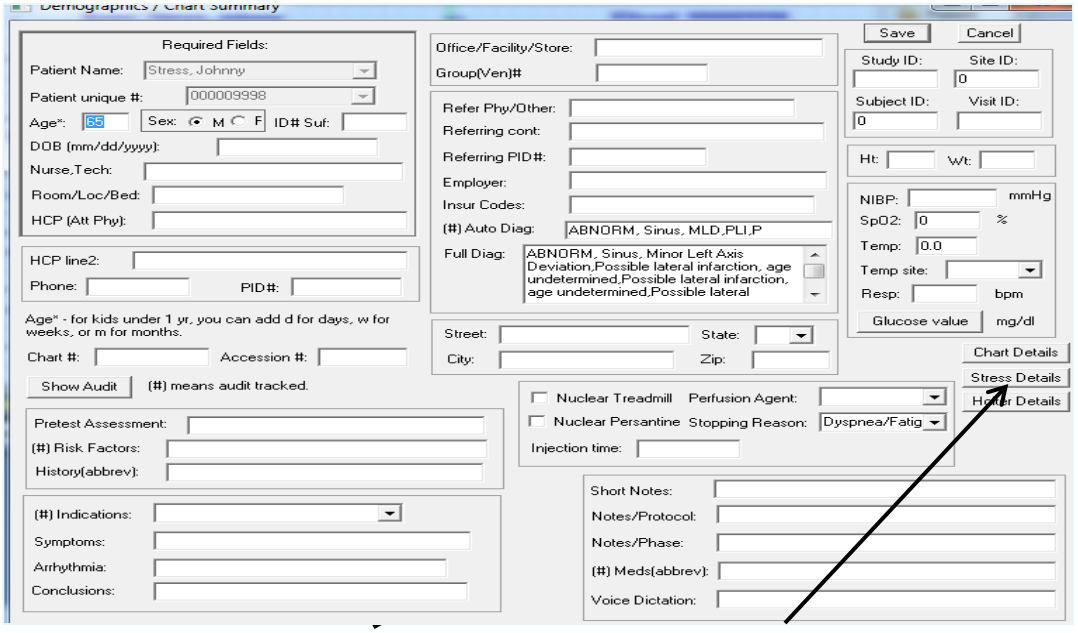
ECG/Stress
Measurements Table



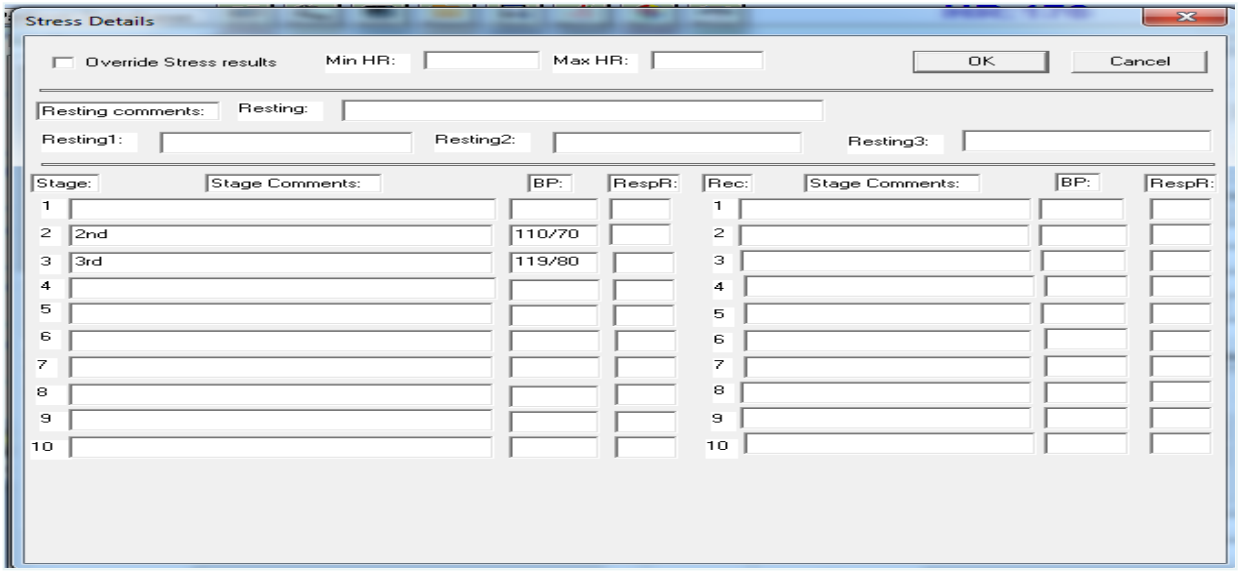
	PA	-PA	QA	RA	SA	STJ	ST20	ST40	TA	QD	RD	SD
I	115	0	0	544	-8	-7	-7	-7	187	0	92	0
II	132	0	0	883	-29	-29	-12	-14	283	0	96	0
III	29	0	0	337	-23	-23	-9	16	95	4	88	0
aVL	50	0	0	103	10	5	4	-8	54	0	88	0
aVF	78	0	0	612	-26	-28	-10	14	189	4	92	0
V1	0	-84	0	-491	35	25	18	28	-150	0	96	0
V2	0	-79	0	-575	12	11	6	9	-197	0	96	0
V3	96	0	0	660	-29	-34	-22	-22	218	0	96	0
V4	122	0	0	778	-28	-28	-23	-22	266	0	96	0
V5	84	0	0	545	-17	-17	-3	-2	192	0	96	0
V6	65	0	0	472	-22	-28	-24	-39	159	0	92	0

Stress ECG Functions

(Continued)



3) Clicking "Stress Details" inside "Demographic/Chart" allows the entry of certain overrides and the editing of stage comments, BP's, etc.



Network & Database Utilities

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

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

Database

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

Procedure

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

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

Transferring Data

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

Sharing Cardio Card Data on a Network

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

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 CardioCard

- Turn off all virus protections, firewalls; and spy ware
- You need to be a Power user
  on the network
- Make sure all other applications are closed

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

Contact your network manager.
Common causes are:

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

OR

Your antivirus or anti spyware software is blocking the service.

OR

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

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

OR

With “Vista” user account control may be on. It needs to be turned off.

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. Make sure the printer that you are using has a check mark

Double click the printer that you want as the default printer Go to Printer Click set as default printer There should be a check mark next to that. It should be the only check mark in the box

To Test Printer

- Right click on the printer that is 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 the “Drive Letter” where your flash card is)
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 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 CardioCard 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 unplug the card and plug it back in. Make sure it is in all the way

- **"Call NAI Support". ** You need to install the Memory Stick.

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. You can try shutting down and rebooting.

"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"
Check to make sure your drive letter is correct. Also check to make sure your database is correct. 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",

Technical Support / Service

General

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

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

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

CUSTOMER SUPPORT POLICY

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

OBTAINING CUSTOMER SUPPORT

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

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

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

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

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

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

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

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

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

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

Your Service Agreement covers the following:

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

The Service Agreement does not cover:

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

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

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

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

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

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

Nasiff Associates: Two Year Limited Warranty

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

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

The Nasiff CARDIO System includes:

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

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

GENERAL

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

EXCLUSIONS

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

OBTAINING WARRANTY SERVICE

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

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

WARRANTY LIMITATIONS

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

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

EXCLUSIVE REMEDIES

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

OBTAINING SERVICE DURING WARRANTY

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

OBTAINING SERVICE AFTER WARRANTY PERIOD

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

DETERMINING IF YOUR CARDIO - CARD SYSTEM NEEDS SERVICE

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

RETURNING YOUR SYSTEM FOR SERVICE

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

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

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

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

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

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

   b. A brief description of symptoms for service personnel.

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

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

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

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

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

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

COSTS

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

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

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

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Specifications

MINIMUM PC SYSTEM REQUIREMENTS

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

MEDICAL SYSTEM (ECG, HOLTER, NIBP) FEATURES

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

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

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

- NIBP features:

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

  Indications:

  Ages: Infant - Adult

  Arm Circum: 8-44cm

  Contraindications: Open wounds to limb distal to cuff application.

MEDICAL ELECTRICAL PERFORMANCE & SAFETY

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

GENERAL SYSTEM

- Power consumption:

  < 300 mA from the pc bus.

  CC-Holter recorder:

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

- Dimensions:

  PCC Rev B: 5.5" x 4.5" x 0.6"

  PCC Rev L: 6.5" x 4.5" x 0.6"

  Box12 Rev M: 4.5" x 2.5" x 0.8"

  CCHolter Rev A: 6.25" x 2.75" x 0.75"

  Flash Holter recorder: 4.4" x 2.6" x .95"

  ISOT Rev B: 6" x 5" x 4.25"

  CCNIBP-I: 5.75" x 3.6" x 1.75"

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

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

CASSETTE PLAYBACK SPECIFICATIONS

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

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

SpO2 SPECIFICATIONS

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

TEMPERATURE SPECIFICATIONS

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

WEIGHT SPECIFICATIONS

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

HOLTER FLASH RECORDER SPECIFICATIONS

- **Functional**

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

- **Physical**

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

- **Electrical**

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

Special Features

Special File Export Files

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

ascii.txt - 500hz file exported from File Export selection. Outputs data (4 chars plus sign per sample.) for each lead tab delimited in order:
I\tII\tIII\taVR\taVL\taVF\tV1\tV2\tV3\tV4\tV5\tV6\n

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

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

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

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

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

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

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

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

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

Real time pointer file - ptrf

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

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

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

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

Calling the Cardio-Card from external programs

File I/O:

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

structure:

when calling cardwin.exe (all ascii):

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

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

on exit from cardwin.exe, ccio contains:

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

Message API:

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

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

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