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Appendix A – CPT Codes and ICD 9 Codes
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1. Introduction

The Caird Technology Inc. Heart Rate Variability System (HRVS) is the result of over 100 man-years of Holter engineering experience. The system is the latest of the Windows based products designed to be fully compatible with all the Windows family of operating systems (95, 98, ME, NT, 2000 and Vista).

This manual describes the HRV test operation and also provides several tutorials for the user.

Heart Rate Variability Overview:

Heart rate signals show spontaneous fluctuations that mainly represent interactions between the cardiac pacemaker cells and the Heart Rate Variability (HRV). The HRV consists of two components:

- The sympathetic increases the heart rate.
- The parasympathetic (or vagal) system reduces the heart rate.

The heart rate value is a result of the balance between both components.

Clinical Implications:

Assessment of HRV function is clinically important because studies have demonstrated that heart rate variability expressed as diminished variability of an evoked end-organ (i.e. heart) response to a stimulus is associated with increased morbidity and mortality in the diabetic patient.

A decrease in cardiac heart rate variability activity (and especially in vagal activity) occurs usually after acute myocardial infarction. Patients at risk of sudden cardiac death display persistent reduction of heart rate variability. Studies have shown diminished HRV to be a powerful predictor of long-term mortality in survivors of myocardial infarction. This predictor has been shown to be independent of other indices (such as frequency and complexity of ventricular ectopic beats or left ventricular ejection fraction). Autonomic neuropathy is also a recognized complication of HIV infection.

Test:

The HRV Test is broken into 2 parts:

- The Patient Hookup and Exercise.
- The Data Analysis and Report Printing.

Both the above are described in detail below:
2. Patient Hookup and Exercise

2.1 Patient Hookup.

Prepare the Sites by shaving and alcohol rub. Connect the electrodes to the Patient per the diagram. Connect the electrodes to the Lead Wires.

Insert Flash Card into Recorder and Insert a Battery into Recorder. The Recorder will Erase and Format the Card. After formatting the flash card, the recorder will display the patient’s ECG waveform. Use the LCD display to verify a good patient hookup. Switch between channel displays by pressing the event button. (Channels 2 and 3 will be Flat Lines as they are not connected) After a good patient hookup is confirmed. Press and hold the event button for 4 seconds to start the recording. This will be the start time for the Holter recording.

The exercise portion of the test can now be started
2.2 Patient Exercise on the PC.

The three tests used in our standard cardiovascular Heart Rate Variability assessment are:

- R-R Variation (Paced Breathing – maximum / minimum heart rate).
- The heart rate response to the Valsalva maneuver.
- The heart rate response to standing up after lying down (30:15 ratio).

The test operator can hold the ECG Recorder while performing the exercises.

The test operator MUST monitor the patient compliance and insure the patient event button is pressed at the correct times. The Patient Event Button is pressed at the START of each exercise and at the END of the TEST.

**Failure to press the Patient Event Button when prompted will invalidate the test and the entire test will have to be redone.**
2.2.1 R-R Variation Test (Paced Breathing).

The Patient sits quietly while his heart rate is recorded in the ECG recorder. The patient is then asked to breathe deeply and regularly at a rate of six breaths per minute (5 seconds in, 5 seconds out) for one minute, while the ECG record is recorded. The computer monitor provides visual and audio queues to assist the patient in this exercise. The longest and shortest R-R intervals during each breathing cycle are measured from the ECG and converted to beats per minute.

Press the Test Start Button

The following message will appear:

Insure the patient is seated comfortable and is ready to perform the paced breathing exercise.

Press OK

The operator MUST monitor the patient compliance and insure the patient event button is pressed at the start of the test.

Failure to press the Patient Event Button when prompted will invalidate the test and the entire test will have to be redone.
The following screen will appear:

At 5 second intervals the Computer display will change from Green to RED. The patient should INHALE when Green and EXHALE when Red.

The test operator MUST press the Recorder Patient Event button at the start of the first Inhale.

After 5 seconds the Computer Display will change to:

An audible tone will also sound to indicate to the patient to inhale or exhale. The patient should continue this exercise until the test is completed.
The test will last for 100 Seconds.
After the patient has completed 10 cycles the following dialog box will appear;

The test operator should now explain the Valsalva test to the patient and prepare them for the test.

When the patient is ready to perform the test the operator should press OK.

The operator **MUST** monitor the patient compliance and insure the patient event button is pressed at the start of the test.

**Failure to press the Patient Event Button when prompted will invalidate the test and the entire test will have to be redone.**
2.2.2 Valsalva Test.

The Valsalva maneuver is performed by attempting to forcibly exhale while keeping the mouth and nose closed. It is used as a diagnostic tool to evaluate the condition of the heart. The Valsalva maneuver is used with patients who have suspected heart abnormalities. The maneuver is based on the fact that when a patient forcibly exhales against a closed nose and mouth while bearing down, as if having a bowel movement (The patient can also blow into a mouthpiece of a manometer at a pressure of 40mmHg for 15 seconds). During this maneuver specific changes occur in the heart rate. The heart rate normally increases during the maneuver, followed by a rebound bradycardia after release. The ratio of the longest R-R interval shortly after the maneuver to the shortest R-R interval during the maneuver is then measured.

After the operator presses OK the following will be displayed:

The operator MUST press the patient event button at the start of this test.

Failure to press the Patient Event Button when prompted will invalidate the test and the entire test will have to be redone.

The Blue Bar will move across the Display for 15 Seconds.
After the 15 second Valsalva test the following Dialog Box will be displayed:
The Valsalva test has been completed.
The operator should lie the patient down for an approximate time of five (5) minutes.
The computer will display the following during this time:

After five minutes have elapsed the computer will display the following Dialog Box:
The operator MUST monitor the patient compliance and insure the patient event button is pressed at the correct time – at the start of this test – When the Patient Stands UP.

**Failure to press the Patient Event Button when prompted will invalidate the test and the entire test will have to be redone.**

**Press OK to have the patient stand up and complete the test.**

**Press the patient Event Button after the Patient has been standing stand for about 1 minute.**

Remove Flash Card from recorder to stop recording.

**Insert the Flash Card into the Flash Card Reader.**

*Note: The operator does not have to immediately proceed to the Data Analysis and Printing phase. The patient information is stored on the Flash Card until it is inserted again into the ECG Recorder AND batteries inserted.*
2.3 Patient Exercise on the Recorder.

Should the operator choose to use the recorder to prompt the patient through the test this procedure is defined in the VX3 Recorder Manual.
3.0 Data Analysis and Printing.

This check is to insure the procedure has been completed prior to analyzing the data.

The Initial Patient Information Dialog Box will appear.
The Initial Patient Information Dialog Box:

All data entry items are text strings except for the Time (Hour and Minute). The time should be entered on a 24-hour basis (i.e. 14:22) This should be the start time of the recording. All ECG Data presentation (ECG Strip Time, Graphs, and Tables) will then be adjusted accordingly.

The only required information is:

1. Patients Last Name
2. Patients Age

The operator can press “OK” or “enter” on the Keyboard to start the data analysis.

After the ECG Data has been loaded and analyzed the user may add additional information or edit the existing patient information.

The operator can now print the report.
4.0 Setup.

When accessed from the **Main Tool Bar** all the Setup entries are written to the Windows System Registry. This means that whenever the Application is started the Windows System Registry is read and the appropriate entries are filled in. Thus the operator need not complete any of this information as the system will automatically fill in the data. These entries will also be stored in the Individual Procedure file for use when the patient record is called up at a later time.

When any of the specific menu items from the **Application Tool Bar** are accessed after the ECG Data is loaded into the system all Setup entries are only used for the current procedure. These entries will be stored with the Procedure File but not in the system registry.

4.1 Physician Information

![Physician Information Dialog Box](image)

The Physician Information Dialog Box appears on both the Main and the Procedure Windows.

All Physician information items are text strings.

The physician information will be printed on the first page of the standard report.
4.2 HRV Analysis Settings

The RR Interval Analysis Parameters Dialog Box appears on both the Main and the Procedure Windows.

If a value is changed in this Dialog box AFTER a patient has been loaded and analyzed the analysis will be repeated.

There are many references (three are included with this manual) about the normal and abnormal limits of the above measurements. They are made available to the user should the user wish to change them.
4.3 Recorder Type

There is only currently only one option available.

Other options will become available in the future.
4.4 Local Language

Using this setting will allow the user to either setup or edit the local language. The system is setup to allow a wide variety of languages to be used by the system.

To enter or edit the local language the user should:

1. Select the Local language from the drop down edit box.
2. Select the text string to change or edit from the text string list.
   The Language text description box will display where the text is used.
3. Enter the desired text in the “Change Text to” box.
4. Select the Update Local Language Button to change the text string.
5. If the user wants to use the local language the Default Language must be changed.

Note: The Local Language updates will not immediately take effect. The system must be restarted in order for these changes to be implemented.
4.5 Select Input Device

This option allows the operator to define the input Drive location.

Because every system is different this must be specified in order for the system to know where to go to retrieve the ECG Data.

The Input Drive should be defined as a letter between A to Z

The Input Drive is specified from the main menu Settings item.

4.6 Automatic Report Print

When this item is checked the report will print automatically after analysis is complete.

4.7 File handling

When the system reads data from an ECG recording device it stores that data into a Windows File. When the system analyzes the ECG data it appends the analysis information to this File.

The name of the file is the following:

Patient Last Name - Date - Time.rkg

For example if the patients last name were Smith the file name might be:

Smith 9 11 1999 12 46 42.rkg

The benefits to the user for this method are:
• Using the windows Explorer Tools | Find function the operator can easily search the entire system for a patient by inputting only the last name. Once the patients with that last name are found the date and time provide a unique identifier.

• Archival storage becomes very easy with this system. The operator simply highlights the files to store and the system (windows or the appropriate storage device) handles it.

4.8 Graphic Review

4.8.1 Paced Breathing RR Interval Histogram.

![Paced Breathing RR Interval Histogram]

4.8.2 Paced Breathing Poincare Graphs.

![Paced Breathing Poincare Graphs]
4.8.2 Paced Breathing Difference Graph.

4.9 Tabular Data Review.
4.10 Full Disclosure ECG Data Review.

The Paced Breathing Procedure ECG will be colored:
- **GREEN** for INHALE
- **RED** for EXHALE

The Valsalva Procedure ECG will be colored:
- **BLUE** During the Procedure

The Posture Procedure ECG will be colored:
- **YELLOW** Starting with the Patient Standing

To view the ECG in the 15 Second Strip with the Grid with the mouse pointed to the area to view in the Full Disclosure “double click”. The 15 second display will automatically be updated.

The Full Disclosure ECG can be reviewed by paging through the ECG. The top - bottom vertical scroll bar can be “grabbed” and moved to any time within the 24 hours.

The Full Scale ECG can be reviewed by paging through the ECG. The left – right horizontal scroll bar can be “grabbed” and moved to any time within the 24 hours.
4.10.1 Editing.

The system will attempt to automatically remove any PVC’s from analysis. Because there is only 1 recorded channel the identification of PVC’s is not as accurate as the three (3) channel Holter. The user can review and edit the information and then reanalyze the information if required.

To edit the recorded data;
1. Turn off the ECG arrows.
2. Select QRS to EDIT – use mouse pointer to “Left Click” on the QRS.
   a. Declare QRS Normal
   b. Declare QRS artifact
   c. Add a QRS
   d. Delete a QRS

Note: the system does not currently use the morphology buttons. These may be used in the future.
4. 
Appendix A

CPT CODE: 95921

Testing of Heart Rate Variability function:
cardiovagal innervation (parasympathetic function)
including two or more of the following:
• heart rate response to deep breathing with recorded R-R interval.
• valsalva ratio.
• 30:15 ratio (posture test).