



HEART RHYTHM SCANNER

Special Edition

USER'S MANUAL

Version 1.0

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Call your local dealer for:

- System installation
- Software installation
- System troubleshooting
- Hardware use
- Software use

According to our customer support policy we charge all customers \$60.00 an hour with \$15.00 increments for all incoming calls and \$75.00 an hour when we return calls.

Each new customer has one hour of technical support free. If your computer and peripherals comply with our system requirements and configured properly, there is enough time to get the system up and running within this hour.

Any support related to hardware repair, accessories and supplies replacement is free of charge.

Any reports on possible software bugs found, software comments and suggestions are more than welcome. Please send them to us by fax or e-mail.

1. Introducing Heart Rhythm Scanner SE

This program provides sophisticated, yet easy-to-use tools for assessment of the autonomic nervous system.

The autonomic nervous system is a part of the human nervous system that controls all internal organs and systems, e.g. heart, lungs, kidneys, intestines, glands, etc.

The autonomic nervous system consists of two branches: **sympathetic nervous system** and **parasympathetic nervous system**. Both systems always work together and against each other. This provides a very fine tuned mechanism of regulation of all physiological functions of the organism.

The **sympathetic nervous system** acts as an activation mechanism for most internal organs. For instance, it causes heart to beat faster and stronger, dilates lung airways and prompts adrenal glands to decrease production of their specific substances.

The **parasympathetic nervous system** acts as a calming mechanism for most internal organs. For instance, it causes the heart to beat slower but constricts lung airways.

In a healthy human organism both systems work in very fine tuned balance, providing long-term functional stability, endurance and high adaptation. Depending on various external and internal factors, sometimes the sympathetic system may rapidly increase its activity to concentrate all efforts on coping with those factors. However, once the sympathetic system overcomes these factors, it allows the parasympathetic system to take control of the organism and puts it back in balanced state.

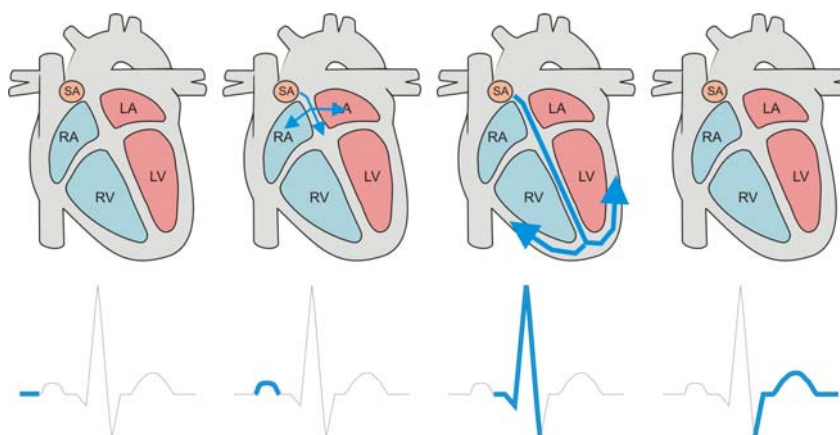
When various pathological processes take place, the autonomic nervous system may have difficulties maintaining its balance, so each branch may substantially increase or decrease its activity, which makes it hard to balance them out and revert back to optimal functioning.

To evaluate primarily parasympathetic branch of the autonomic nervous system, the **Heart Rhythm Scanner SE (Special Edition)** implements standard procedures, which are based on an analysis of heart rate variability caused by specific provocative tests.

2. Scientific Background

2.1. Physiological Basics

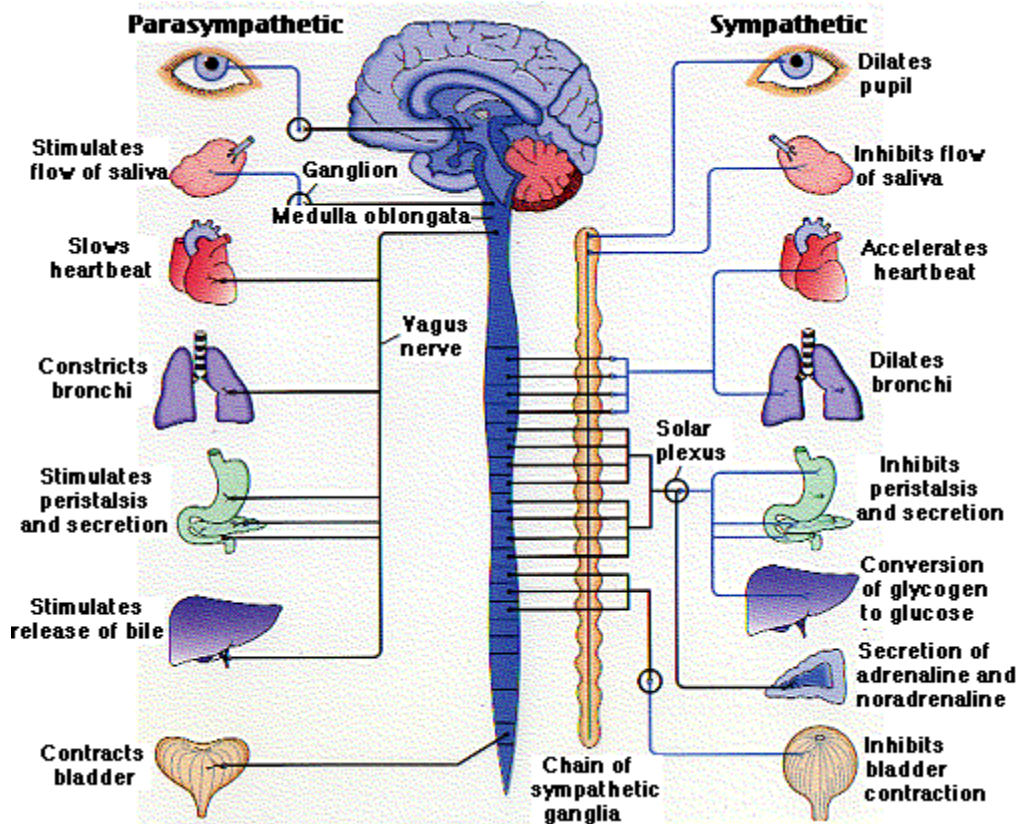
The origin of heartbeat is located in a sino-atrial (SA) node of the heart, where a group of specialized cells continuously generates an electrical impulse spreading all over the heart muscle through specialized pathways and creating process of heart muscle contraction well synchronized between both atriums and ventricles. The SA node generates such impulses about 100 – 120 times per minute at rest. However, in a healthy individual, the resting heart rate (HR) would never be that high. This is due to continuous control of the autonomic nervous system (ANS) over the output of SA node activity. Its net regulatory effect gives real HR. In a healthy subject at rest, it ranges between 60 and 80 beats per minute.



The autonomic nervous system is a part of the nervous system that non-voluntarily controls all organs and systems of the body. As the other part of nervous system ANS has its central (nuclei located in brain stem) and peripheral components (afferent and efferent fibers and peripheral ganglia) accessing all internal organs. There are two branches of the autonomic nervous system - sympathetic and parasympathetic (vagal) nervous systems that always work as antagonists in their effect on target organs.

For most organs including heart, the sympathetic nervous system stimulates organ's functioning. An increase in sympathetic stimulation causes an increase in HR, stroke volume, systemic vasoconstriction, etc.

In contrast, the parasympathetic nervous system inhibits functioning of those organs. An increase in parasympathetic stimulation causes a decrease in HR, stroke volume, systemic vasodilatation, etc.



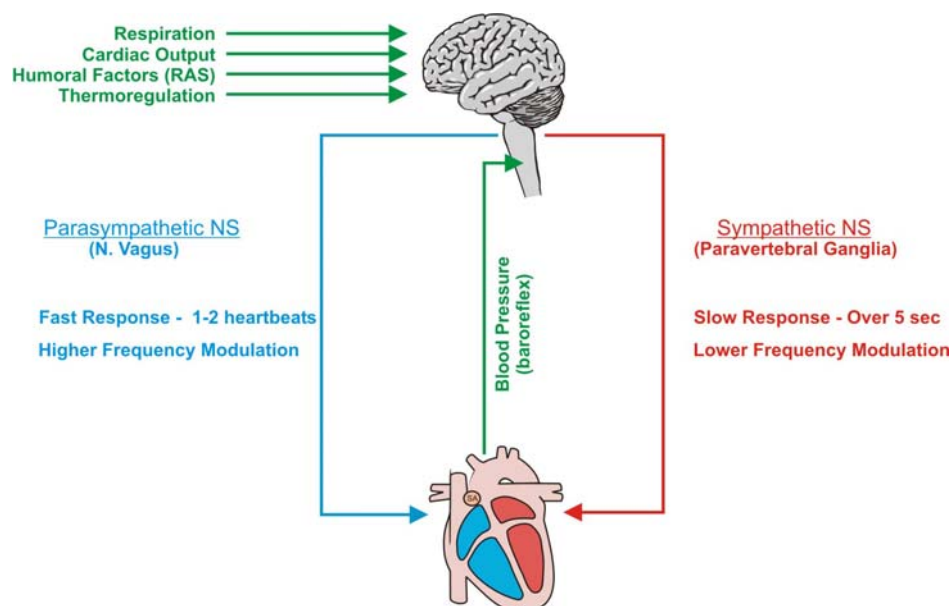
A heart response time to sympathetic stimulation is relatively slow. It takes about 5 seconds to increase HR after actual onset of sympathetic stimulation and almost 30 seconds to reach its peak steady level.

The heart's response to parasympathetic stimulation is almost instantaneous. Depending on actual phase of heart cycle, it takes just 1 or 2 heartbeats before heart slows down to its minimum proportional to the level of stimulation.

At rest, both sympathetic and parasympathetic systems are active with parasympathetic dominance. The actual balance between them is constantly changing in attempt to achieve optimum considering all internal and external stimuli.

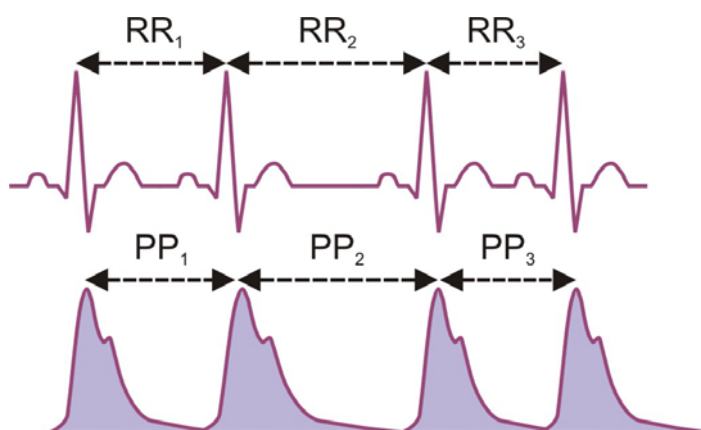
There are various factors affecting autonomic regulation of the heart, including but not limited to respiration, thermoregulation, humoral regulation (rennin-angiotensin system), blood pressure, cardiac output, etc. One of the most important factors is blood pressure. There are special baroreceptive cells in the heart and large blood vessels that sense blood pressure level and send afferent stimulation to central structures of the ANS that control HR and blood vessel tonus primarily through sympathetic and somewhat parasympathetic systems forming continuous feedback dedicated to maintain systemic blood pressure.

This mechanism is also called baroreflex, which increases HR when blood pressure decreases and vice versa. This mechanism is also targeted to maintain optimal cardiac output.



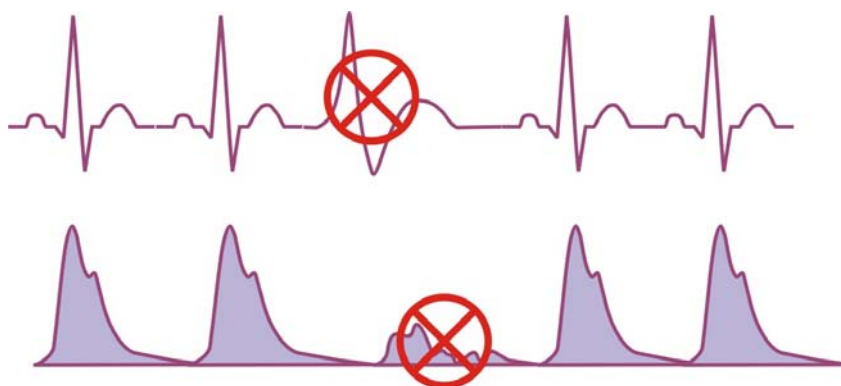
2.2. HRV Analysis

The heart rate variability analysis is a powerful tool in assessment of the autonomic function. It is an accurate, reliable, reproducible, yet simple to measure and process. The source information for HRV is a continuous beat-by-beat measurement of interbeat intervals. The electrocardiograph (ECG or EKG) is considered as the best way to measure interbeat intervals. ECG is an electrical signal measured with special conductive electrodes placed on chest around heart area or limbs. It reflects minute changes in electrical field generated by heart muscle cells originating from its SA node. ECG signal has a very specific and robust waveform simple to detect and analyze. Because of that cardiac rhythm derived from ECG is the best way to detect not only true sinus rhythm but all types of ectopic heartbeats, which must be excluded from consideration of HRV analysis.



The other approach to measuring cardiac intervals is a measurement of pulse wave. It is a less invasive and simple method of measurement based on photoplethysmograph. PPG is a signal reflecting changes in a blood flow detected when infrared light is emitted towards microcirculatory blood vessels. Depending on blood flow volume certain portion of that light is absorbed letting other part to pass or be reflected. An optical sensor detects a quantity of light passed (or reflected from) the blood flow producing a waveform identifying pulse wave. Such waveform can also be processed to derive beat-by-beat interbeat intervals. Although PPG gives the summary information reflecting both cardiac and blood vessel components of HRV, some research studies showed a significantly high correlation between interbeat interval data measured by both ECG and PPG in short-term steady-state recordings.

One of the important issues when measuring either ECG or PPG is the absence of abnormal heartbeat used in interval detection. Only heartbeats originated in SA node can be processed to obtain HRV data. Whether there are ectopic heartbeats (PVCs or other types of extrasystolic heartbeats) or various movement artifacts on ECG (or PPG) considered as heartbeats, they must be excluded from consideration. There are various statistically-based algorithms of detection of such abnormal heartbeats that minimize chances to get contaminated HR recordings. Nevertheless, for the sake of accuracy in HRV analysis it is important to be able to visually verify all heartbeats automatically found, remove abnormal ones and include missing.



2.3. Clinical Significance of HRV

It is found that lowered HRV is associated with aging, decreased autonomic activity, hormonal tonus, specific types of autonomic neuropathies (e.g. diabetic neuropathy) and increased risk of sudden cardiac death after acute MI.

Other research indicated that depression, panic disorders and anxiety have negative impact on autonomic function, typically causing depletion of parasympathetic tonus. On the other hand an increased sympathetic tonus is associated with lowered threshold of ventricular fibrillation. These two factors could explain why such autonomic imbalance caused by significant mental and emotional stress increases risk of acute MI followed by sudden cardiac death.

Aside from that, there are multiple studies indicating that HRV is quite useful as a way to quantitatively measure physiological changes caused by various interventions both pharmacological and non-pharmacological during treatment of many pathological conditions having significant manifestation of lowered HRV.

However it is important to realize that clinical implication of HRV analysis has been clearly recognized in only two medical conditions:

1. Predictor of risk of arrhythmic events or sudden cardiac death after acute MI.
2. Clinical marker of diabetic neuropathy evolution.

Nevertheless, as the number of clinical studies involving HRV in various clinical aspects and conditions grows, HRV remains one of the most promising methods of investigating general health in the future.

2.4. Methods of HRV Analysis

Short-term HRV analysis requires much shorter recordings – typically 5-min long. However such recordings are assumed to be done at steady-state physiological condition and should be properly standardized to produce comparable data. Typically, such measurements should be done in either supine or comfortably sitting relaxed position, limiting body movements, conversations, any mental activities.

According to the standards set forth by the Task Force of the European Society of Cardiology and North American Society of Pacing and Electrophysiology in 1996, there are two methods of analysis of HRV data: time- and frequency-

domain analysis. In either method, the interbeat intervals should be properly calculated and any abnormal heartbeats found.

2.4.1. Time-Domain HRV

Time-domain measures are the simplest parameters to be calculated. Before such calculation, all abnormal heartbeats and artifacts must be removed from consideration. The following time-domain parameters can be calculated for both long-term and short-term recordings: Mean HR, SDNN and RMS-SD. Some extra parameters can be calculated specifically for long-term recordings. The time-domain parameters are associated mostly with overall variability of HR over the time of recording, except RMS-SD, which is associated with fast (parasympathetic) variability.

2.4.2. Frequency-domain HRV

A standard spectral analysis routine is applied to such modified recording and the following parameters evaluated on 5-min time interval: Total Power (TP), High Frequency (HF), Low Frequency (LF) and Very Low Frequency (VLF). When long-term data is evaluated an additional frequency band is derived – Ultra Low Frequency.

The HF power spectrum is evaluated in the range from 0.15 to 0.4 Hz. This band reflects parasympathetic (vagal) tone and fluctuations caused by spontaneous respiration known as respiratory sinus arrhythmia.

The LF power spectrum is evaluated in the range from 0.04 to 0.15 Hz. This band can reflect both sympathetic and parasympathetic tone.

The VLF power spectrum is evaluated in the range from 0.0033 to 0.04 Hz. The physiological meaning of this band is most disputable. With longer recordings, it is considered to represent sympathetic tone as well as slower humoral and thermoregulatory effects. There are some findings that in shorter recordings VLF has fair representation of various negative emotions, worries, rumination etc.

The TP is a net effect of all possible physiological mechanisms contributing in HR variability that can be detected in 5-min recordings, however sympathetic tone is considered as a primary contributor.

The LF/HF Ratio is used to indicate balance between sympathetic and parasympathetic tone. A decrease in this score might indicate either increase in parasympathetic or decrease in sympathetic tone. It must be considered together

with absolute values of both LF and HF to determine what factor contributes in autonomic disbalance.

2.5. HRV Response to Controlled Autonomic Stimulation

There are several techniques that allow for autonomic assessment by means of applying certain stimuli that evoke specific responses of either branch of the autonomic nervous system.

2.5.1. Metronomic Breathing Test

The reflex arc associated with breathing evokes a specific response in heart rate variability. It was first described by Genovely and Pfeifer:

Tidal volume expands the lungs, which activates stretch receptors in the lung, chest wall and heart chambers. The activated sensors stimulate the afferent nerve (vagus nerve). The central processing unit located in the brainstem (the nucleus solitarius) processes information and then decreases parasympathetic tone and/or increases sympathetic tone by sending the appropriate impulses down the efferent vagus and cervical-thoracic-sympathetic nerves, respectively. This information terminates in end-organ (the heart), which responds with an increase in heart rate. Because the reflex arc associated with the R-R variation test is reasonably well known, interpretation of test results is easier to determine than those of the reflex arcs, which are poorly described and understood (such as gastric emptying) or to reflex arcs that are more complicated.

This end-organ response is used in assessment of the autonomic function with the test method described by Wheeler and Watkins in 1973:

With this method, the subject sits quietly while his heart rate is recorded on an ECG. He 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 continued. The longest and shortest R-R intervals during each breathing cycle are measured from the ECG and converted to beats per minute.

The heart rate variability in this test may be presented in the following parameters: Expiratory/Inspiratory Index (E/I), Standard Deviation, Mean Variance of R-R, etc.

2.5.2. Orthostatic Test

The cardiovascular response to the act of changing a posture from supine to standing was used as an indication of the autonomic function in diabetics for a long time. It is one of several tests described by Ewing that have certain clinical value because they are simple, non-invasive, easy-to-use, reproducible and have clear difference between normal and abnormal results.

During the test, the client rises from a supine to a standing position. Normally this causes an immediate increase in heart rate and reaches its maximum level at about 15th heartbeat after beginning to stand. It is followed by a relative bradycardia that reaches its maximum around 30th heartbeat. The phenomena can be quantified as 30:15 ratio, which is the ratio of the longest R-R interval around 30th heartbeat to the shortest interval around 15th heartbeat.

Bennet, Hosking and Hampton et al. have studied the relationship between changes in HR and blood pressure caused by standing to demonstrate its value in assessment of the autonomic effect on cardiovascular system in diabetics. They showed a complex interaction between sympathetic and parasympathetic systems and found that parasympathetic dysfunction is typically more dramatic than damage to sympathetic system. The Orthostatic Test is considered as of highest value when it is performed along with other tests like metronomic breathing and Valsalva maneuver.

2.5.3. Valsalva Maneuver

The Valsalva maneuver was first described by Antonio M. Valsalva in 1707. In 1860 Einbrodt showed that Valsalva maneuver demonstrated “the integrity of the vagus nerves to the heart” – an acceleration of the heart rate during expiratory effort and slowing it down after it. Later Valsalva maneuver has become so well-known that wouldn't require its explanation. The formal Valsalva maneuver definition was described by Hamilton et al. in 1943:

In practice the maneuver can be standardized by asking the seated subject to blow into a mouthpiece attached to a manometer to a pressure of 40 mm Hg for 15 seconds, while a continuous heart rate record is made with ECG. The result can then be simply calculated by measuring with a ruler the longest R-R interval after strain (representing the maximal bradycardia) and dividing it by the shortest R-R interval during strain (representing maximal tachycardia). This gives “Valsalva Ratio”.

3. System Setup

3.1. Package Content

When you receive the Heart Rhythm Scanner SE package, it must include the following items:

Pulse Wave Sensor Version:

1. HRM-02 pulse wave sensor device with an ear-clip probe
2. "Heart Rhythm Scanner SE" software CD
3. Quick Setup Guide

Biocom 3000 ECG Version:

1. Biocom 3000 ECG recorder
2. Y-type ECG electrode cable
3. "Heart Rhythm Scanner SE" software CD
4. Quick Setup Guide

ActiveECG Version:

1. ActiveECG recorder
2. Serial (null-modem) cable to connect ECG unit to PC
3. "Heart Rhythm Scanner SE" software CD
4. Quick Setup Guide

Contact Biocom Technologies or your local dealer if you have any concern regarding content of the product received.

3.2. Minimum System Requirements

The Heart Rhythm Scanner SE has the following hardware requirements to ensure its reliable functioning:

- CPU Pentium III 800 MHz or better
- 256 MB of RAM

- Video card with at least 1024x768, Hi-Color resolution
- At least 500 MB of free hard disk space
- CD ROM drive
- One available USB port (COM port for Active ECG)
- Windows 2000/XP Operating System

If you are not sure about your computer, contact your local computer specialist to verify whether your computer complies with the above requirements.

3.3. Software Installation

To install the Heart Rhythm Scanner SE software:

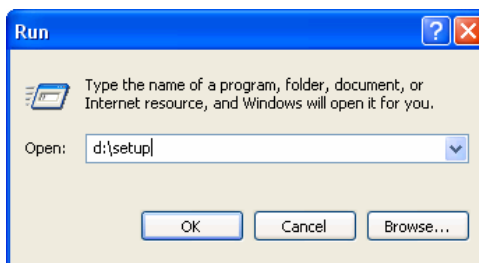
Step 1: Insert the CD-ROM into the drive.

Step 2: Windows will automatically start software installation process.

In some cases the installation process may not start automatically. To install the software do the following:

Click the **Start** button on the taskbar and select **Run** menu option.

In the “Run” dialog box type “D:\setup”



Click **OK**.

Note: The Heart Rhythm Scanner SE software might be bundled with other Biocom software. In this case the following command should be used:

D:\HRSCE\SETUP.EXE

By default CD-ROM device is marked with “D” letter. However sometimes CD-ROM drives could be labeled with a letter other than “D”.

Step 3: If the Heart Rhythm Scanner SE software already exists on this computer, the following window will show up:



Select the **Repair** option, click the **Next** button then proceed to **Step 8**.

If there is no Heart Rhythm Scanner SE software on this computer, the following window will show up:



Step 4: Click the **Next** button. The following window will show up:



Step 5: Select the **I accept the terms of the license agreement** option and click the **Next** button. The following window will show up:

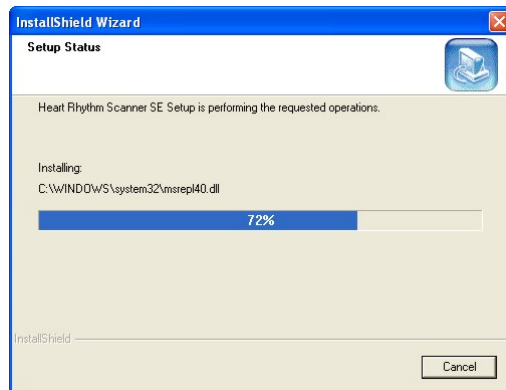


Step 6: Type in the user name and company name then click the **Next** button. If it this software is not for business use, type in anything in the **Company Name** field to continue installation. The following window will show up:

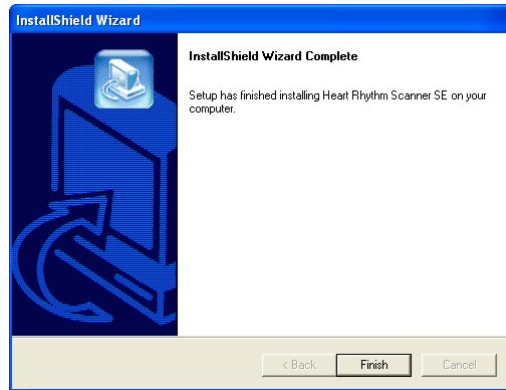


Step 7: Click the **Install** button to continue installation.

Step 8: The following window will show up to indicate the installation progress:



Step 9: After installation is completed the following window will show up:



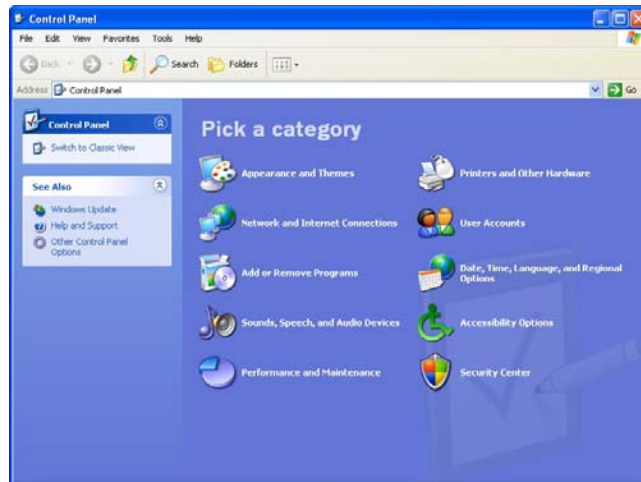
Step 10: Click the **Finish** button to complete the installation process.

3.3. Software Uninstallation

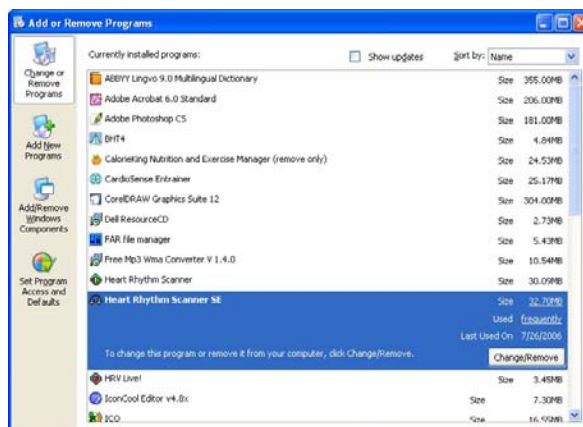
To uninstall the Heart Rhythm Scanner SE software:

Step 1: Click the **Start** button on the taskbar.

Step 2: Select the **Control Panel** option from the **Start** menu. The following window will show up:



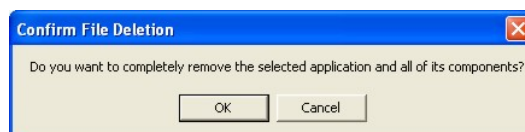
Step 3: Select the **Add or Remove Programs** icon. The following window will show up:



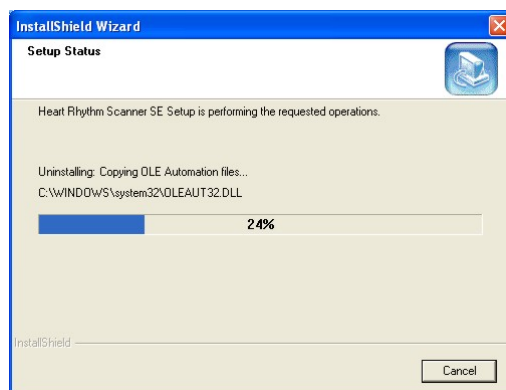
Step 4: Select the **Heart Rhythm Scanner SE** from the list and click the **Change/Remove** button. The following window will show up:



Step 5: Select the **Remove** option then click the **Next** button. The system will prompt you to confirm removing the Heart Rhythm Scanner:



Step 6: Click the **Yes** button to continue uninstallation. The following window will show up to indicate the uninstallation progress.



Step 7: Once the uninstallation process is over the following window will show up:



Step 8: Click the **Finish** button to complete the uninstallation process.

Note: All instructions in this section imply you are using Windows XP operating system. Please look for equivalent options if you have different OS.

3.4. Enabling Signal Acquisition Device

3.4.1. Pulse Wave Sensor

The Biocom pulse wave sensor is connected to your PC through a standard USB port.

Plug its USB connector into any USB slot in your PC and Windows will automatically detect it and enable for further use. Windows will remember this device and quickly enable it every time you plug it in for use by the Heart Rhythm Scanner software.

Plug the ear-clip cable jack into round slot on the side panel of the device box.

If your pulse wave sensor device box is equipped with a belt clip, secure it on your belt or your shirt pocket.

Hook the ear-clip to an earlobe. Make sure it sits securely and does not cause any pain or discomfort.

If the ear-clip is used on different people, it is a good idea to wipe its inner surfaces with an alcohol swab.

If for some reason you cannot hook the ear-clip to you your earlobe, you can put it on your fingertip. This placement should be good enough to acquire clean pulse wave signal.

3.4.2. Biocom 3000 ECG Recorder

The Biocom 3000 ECG recorder is connected to your PC through a standard USB port.

Plug its USB connector into any USB slot in your PC and Windows will automatically detect it and enable for further use. Windows will remember this device and quickly enable it every time you plug it in for use by the Heart Rhythm Scanner software.

3.4.3. ActiveECG Recorder

The ActiveECG recorder is connected to your PC through a standard COM port.

Plug one end of null-modem cable into any COM port in your PC and another end into ECG recorder unit. Windows will automatically detect it and enable for further use.

4. Getting Started

4.1. Pulse Wave Sensor Placement

Pulse wave signal is measured with a pulse wave sensor contained in a small plastic box. The device box has a long USB cable. A separate ear-clip sensor probe is connected to the device box.

Connect the device USB cable to any USB port in the computer. The Heart Rhythm Scanner software will detect it automatically.

Place an ear-clip on the left or right ear lobe. Make sure it is placed so that small glass windows on the inside surfaces of the clip are in good contact with soft tissue of the ear lobe. Be aware that proper placement will affect the quality of pulse wave signal. Small ear lobes or earrings may make placement more difficult.



In some cases when earlobe placement does not give good pulse wave signal the ear-clip can be placed on a finger.



4.2. ECG Placement

The Heart Rhythm Scanner SE supports two types of ECG recorders:

- Biocom 3000 ECG recorder
- ActiveECG recorder

4.2.1. Biocom 3000 ECG Recorder

Biocom 3000 ECG recorder is a portable device connected to your PC with a USB cable.

The device has a standard ECG Y-type cable terminated with two small flat plastic pads (that embed large Ag / AgCl dry ECG electrodes) with two elastic wristbands.

Connect the device USB cable to any USB port in the computer. The Heart Rhythm Scanner software will detect it automatically. Connect a flat RJ-45 connector of the Y-cable to input “B” on the front panel of Biocom 3000 box (opposite side to LED indicator).

Put elastic wristbands on both wrists. Place both sensor pads marked as “Left” and “Right” on respective wrists with electrode disks face down so that wristbands secure those pads firmly.



4.2.2. ActiveECG Recorder

The ActiveECG device has features, which make it exceptional as a portable ECG device. The unit is designed for quick assessment. There are no buttons,

switches, or controls - everything is controlled from the PC. The enclosure itself is designed to hold the ECG lead wires in a compact, easy-to-use platform. Additionally, no latex is used anywhere within the ActiveECG hardware to help avoid allergic reactions from personnel and clients.

The front of the ActiveECG hardware houses a “raceway” which the lead wires are wrapped around. This provides a simple way to manage the lead wires and guarantee that they are always with you. An integrated elastomeric cover surrounds the raceway holding in the lead wire snap connectors. The cover can be replaced by slightly flexing the bottom of the cover and popping out one of the two ends of the cover hinges.

After the lead wires have been unwound from the raceway and attached to electrodes, the elastomeric cover can be closed if you would like to secure it. Leaving the cover open allows you to see that the lead wires stay connected to the raceway connectors.

When you have completed session, disconnect the electrodes, clean the lead wires if necessary, and wrap them around the opened raceway. When there is an inch or so of the lead wires that has not been wound onto the raceway, tuck the remainder of the lead wires into one of the raceway openings and close the cover to secure them. Alternatively, the snap connectors at the end of the lead wires can drape outside the raceway, held in place by the elastomeric cover.

Note that when you connect the lead wires, the colors of the lead wires should match the colors of the connectors.

The components of ActiveECG should be inspected on a regular basis and prior to each use. These inspections are important in order to guarantee the proper working condition of your system.

Perform the following steps to inspect ActiveECG:

1. Inspect the physical condition. Check to ensure that cases and controls are clean and in good condition.
2. Inspect cables, connectors, and electrodes. Make sure that the ECG lead wires are attached inside the raceway. Inspect cables for cracks, breaks, or frayed wires. If any damage is found, replace the cables immediately. Check for adequate supply of ECG electrodes. Make sure the electrodes have not exceeded their expiration date (if available) or that the packages have not been opened or damaged.
3. Make sure that a new spare battery is always available. Check that all batteries being used and the spare battery are not beyond their expiration date.

4.2.2.1. Lead Wire and Electrode Connection

The ActiveECG hardware has three ECG monitoring lead wires that provide the monitoring of lead II only. The lead wires and connectors are all color-coded according to the American Heart Association (AHA) standards. The following table provides a list of AHA color codes for lead II connections:

Lead	Bipolar	Lead and reference	Color
II	RA – right arm	Negative electrode	White
	LA - left arm	Reference	Black
	LL - left leg	Positive electrode	Red

The connection from ActiveECG to each lead wire is an industry standard single .060 pin connector. This allows you to easily replace the lead wires with other compatible lead wire cables. Make sure that the leadwire cables are inserted fully into the ActiveECG hardware. Loose or poor connections can cause intermittent results.

The lead wires provided with ActiveECG utilize standard snap connectors allowing you to use a wide variety of commercially available electrodes. For best ECG monitoring results, silver/silver chloride (Ag/AgCl) electrodes should be used with this equipment. Electrodes of dissimilar metals should not be used.

Take care when attaching or removing the lead wires and electrodes to not damage the wires or connectors.

4.2.2.2. Connection to PC

The ActiveECG hardware connects to a PC with a null-modem serial cable. After connecting the cable to the ActiveECG hardware, make sure to screw in the thumbscrews securely attaching the ActiveECG hardware to the cable.

To ensure accurate ECG recording, it is important that the electrodes be properly attached to the client. Follow the instructions below to prepare the client.

4.2.2.3. Attaching Electrodes to a Client

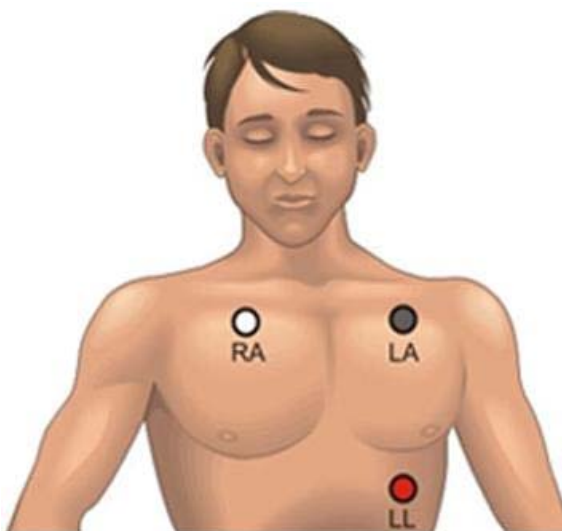
Prepare the client's skin for effective electrode adhesion. Clean and dry the skin. Briskly wipe skin dry with a towel or gauze to mildly abrade the skin and remove oils, dirt, etc. Note that for proper electrode adhesion, never use alcohol, tincture of bezoin or antiperspirant to prepare the skin.

Remove the disposable electrodes from their package. Attach the lead wires to the electrodes and then peel off the protective backing on the electrodes. Inspect the electrodes for any obvious signs of damage. Ensure that the gel on the electrodes has not dried out. If you note damage or dry electrodes, use a new set of electrodes.

Place three electrodes on the client's chest as shown on the diagram below. Apply the electrode flat to the skin and smooth the tape outward in all directions. Do not press the center of the electrode.

Connect lead wires to the electrodes as indicated on the diagram.

Attach the ActiveECG enclosure to the client's clothing, belt, or something in close proximity using the spring-loaded clip on the back. Position the device so as to limit any potential strain put on the lead wires and electrodes.



4.2.2.4. After Each Client Use

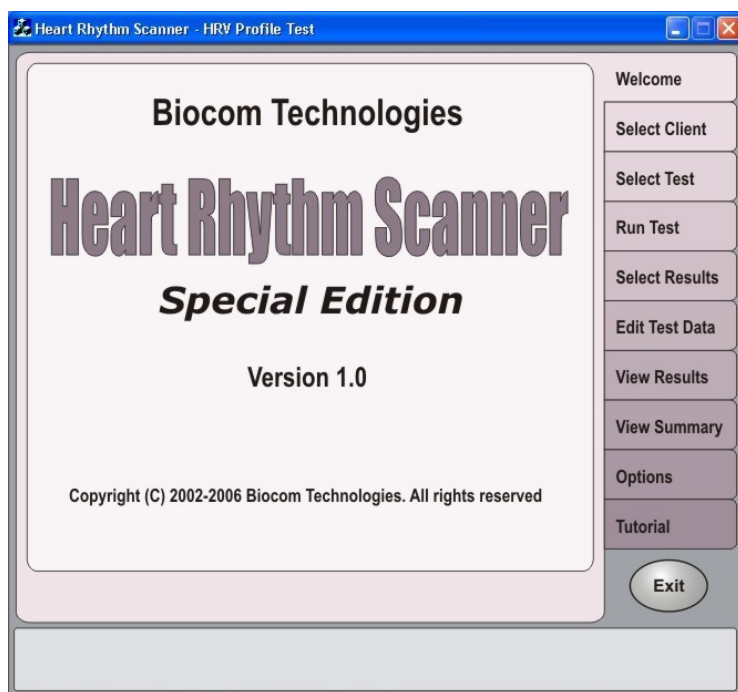
1. Discard used electrodes including electrode sets that were opened and not used. Electrodes dry out in less than 24 hours.

2. Replace the battery in the ActiveECG device if a low battery is indicated in the test program. Make sure you have a spare battery.
3. Clean the device.
4. Inspect the device and cables for damage. Repair or replace damaged items immediately.
5. Check that the leadwires are well connected to the connectors on the ActiveECG device. Wrap the leadwires around the raceway and tuck the snap connector ends inside before closing the elastomeric cover.
6. Recheck disposable supplies and replace whatever is needed.

4.3. Start the Heart Rhythm Scanner SE software



Double-click this shortcut icon on the Windows desktop screen to start Heart Rhythm Scanner SE. Once the program has loaded, the following window appears:



Please wait about a minute until all software components are loaded and the program starts responding.

The program interface is organized as a notepad with a number of tagged pages. Each page represents a certain specialized function. The program always starts with a "Welcome" page, which shows the program title.



Welcome

Click this tab to switch to the “Welcome” page at any time other than when running new test.

5. Conducting Tests

The Heart Rhythm Scanner SE provides the following autonomic assessment tests:

- **Resting HRV Test** Measures standard short-term HRV parameters for subjects at rest.
- **Metronomic Breathing Test** Measures Heart Rate (HR) variations caused by slow, deep metronomic breathing.
- **Orthostatic Test** Measures HR variations caused by change of posture from supine to standing.

Before you start any test, a client name must be selected.

If the “Automatically select last client at startup” option is set (See “Program Options”), then such name selection could be skipped before the test, unless another name should be selected.

Select Client

Click this tab to manually select client's name. The following page will appear in the program window:

Heart Rhythm Scanner - John Smith

Anna Fisher
John Smith

First Name: John Last Name: Smith
Nickname: JSP DOB: 7/ 5/1976 Gender: Male
Street Address: 123 Main Street
City: Seattle State: WA ZIP Code: 98370
Home Phone: 206-123-4567 Work Phone:
E-mail: jsp@gmail.com
Diagnosis:
Medications:
Comments:

New Save Delete Receive Send Exit

Welcome
Select Client
Select Test
Run Test
Select Results
Edit Test Data
View Results
View Summary
Options
Tutorial
Exit

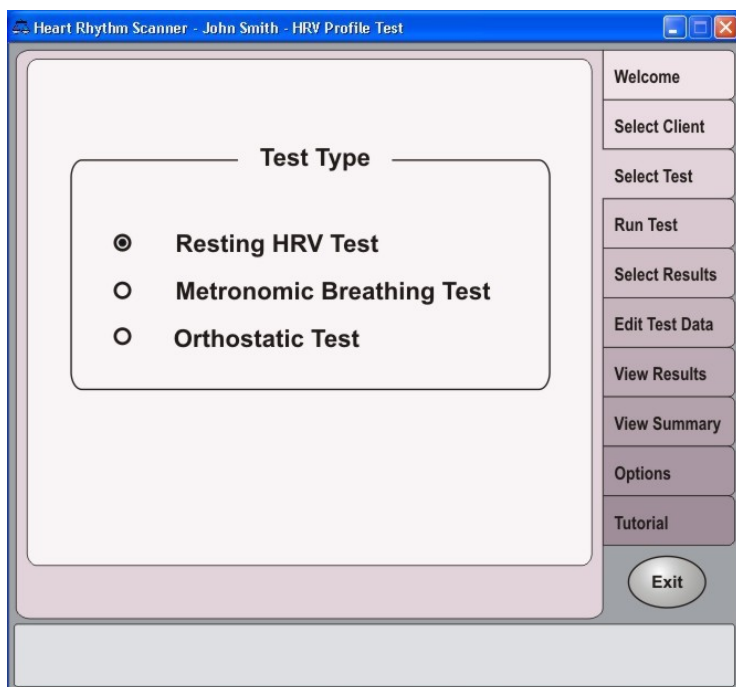
If a client's name is on the list, click it to select.

If a client's name is not on the list, a new record must be created. Refer to "Managing Clients' Records" Section for details.

When a client's name is selected, it appears in the program's caption bar, after the program name.

Select Test

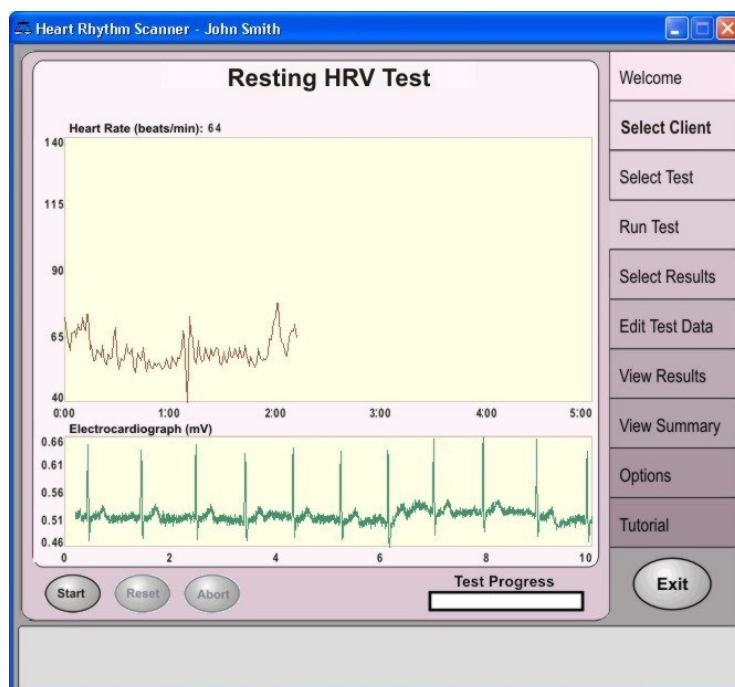
Click this tab to select a new test. The following page will appear in the program window:



Select a test from the list of tests available. The name of the selected test will appear in the program caption bar after program name.

Run Test

Click this tab to prepare for the selected test. If the Resting HRV Test is selected, the following page will appear in the program window:



Upon opening this page, the program activates an ECG device and starts displaying a live ECG trace in the lower graph. If ECG electrodes are not affixed yet, place them as described above.

Once a real ECG trace is detected, a live heart rate (HR) will start displaying on the upper graph.

Wait until the ECG trace and heart rate start showing real and stable readings; then click "Start" to initiate test.

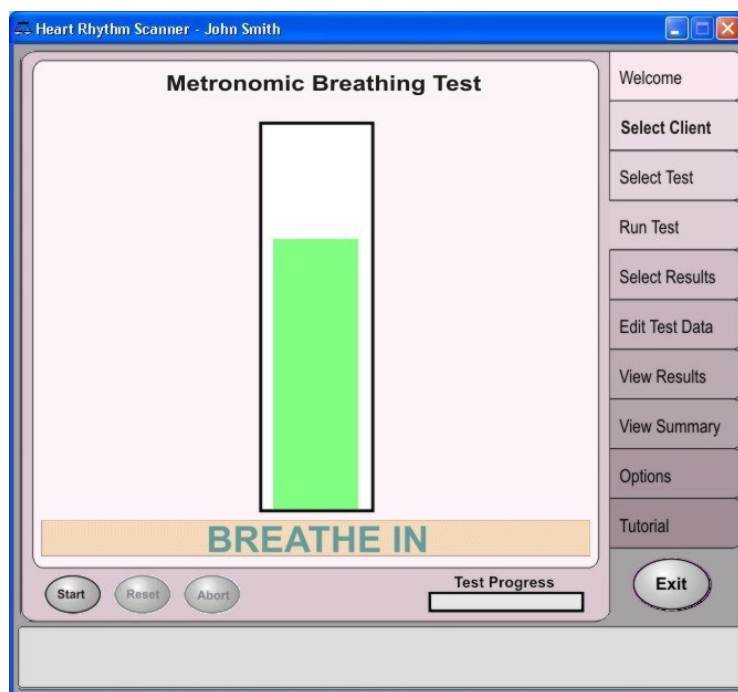
The total duration of this test is 5 minutes. A "Test Progress" indicator will show how the test advances in time.

If any major disturbances in the ECG trace happen that may spoil HR data (for example, an electrode fell off, too many movement artifacts), fix it and click the "Reset" button to reinitiate current test.

If for some reason, the current test cannot be continued, click the "Abort" button to stop it.

The test finishes automatically after 5 minutes, and the program brings you to the "View Results" page to observe your test results.

If Metronomic Breathing Test is selected, the program first performs a baseline recording, which is identical to Resting HRV Test described above. Once baseline recording (5-min HRV Profile) is over, the program automatically displays the following page:

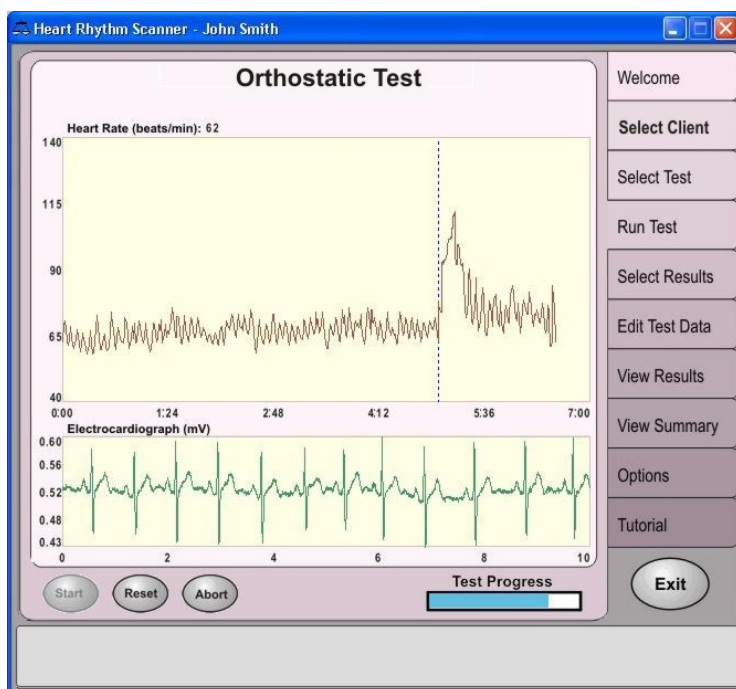


Turn display to the client and instruct him/her how to take deep, slow breaths according to pacer bar displayed on screen.

Allow the client to synchronize breathing with pace; then click the "Start" button.

Once six full breath cycles are completed, the whole test is over and the program brings you to the "View Results" page to observe test results.

If Orthostatic Test is selected, the program first performs a baseline recording, identical to the Resting HRV Test described above. Once the five-minute baseline recording is completed, the program automatically initiates the Orthostatic Test by displaying the following page:



A dashed line now separates the heart rate data collected during the baseline recording from the data which will be collected during the Orthostatic Test.

The test is begun with the click of the “Start” button. Instruct your client to stand up and press “Start” as he/she stands up.

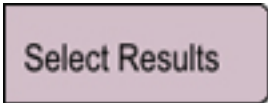
The client should remain standing throughout the duration of the test.

If any major disturbances in the ECG trace happen during the test, that may spoil HR data (for example, an electrode fell off, too many movement artifacts), the test cannot be completed and must be aborted. Click the “Abort” button to stop the test. If you wish to repeat the test, the client should return to a supine position and be allowed sufficient time before the next test is conducted.

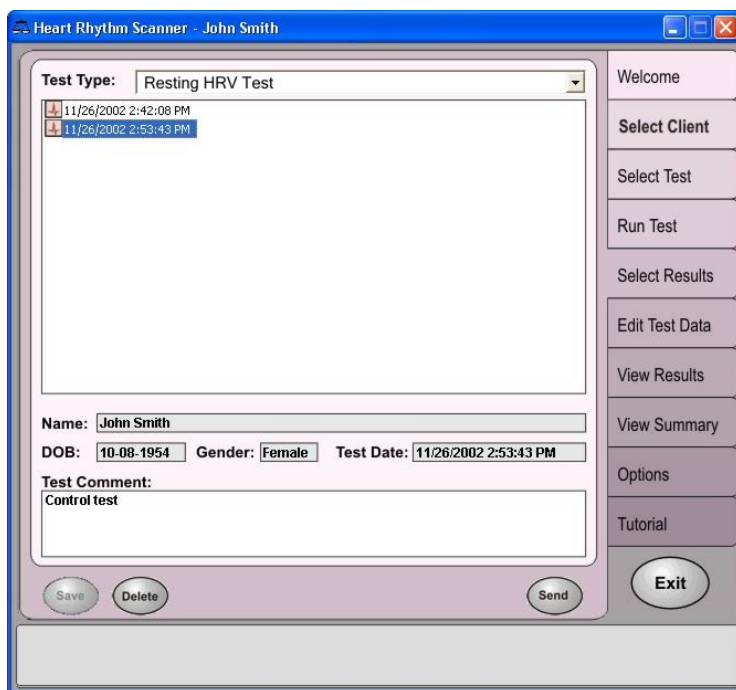
6. Viewing Test Results

This section describes how to review the results of a specific test for a selected client. Before viewing test data, an appropriate client's name and test record should be selected.

If the user's name is already selected, it is displayed on the program caption bar next to program name. If a client's name is not selected or another name must be selected, refer to the previous section to find out how to select a client's name.

A rectangular button with a light purple background and a thin black border. The text "Select Results" is centered in a dark purple, sans-serif font.

Click this tab to display test results. One of the following pages will appear in the program window:



Select the appropriate type of text from the "Text Type" dropdown menu. A list of dates should appear in the window directly below the menu. Click on an appropriate date to select it.

You can add/modify test comments by editing information in the Test Comment box. If you've made any alterations in the test comments, press "Save" to save your changes.

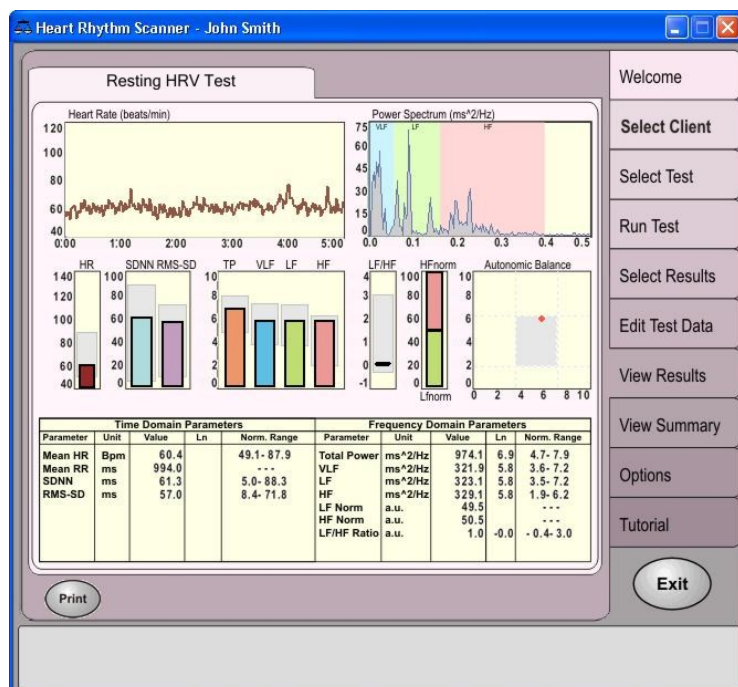
Once you have selected the right test date, you may view the results.

View Results

Click this tab to display test results.

Depending on the type of test you've selected, the results are presented in one of the following modes:

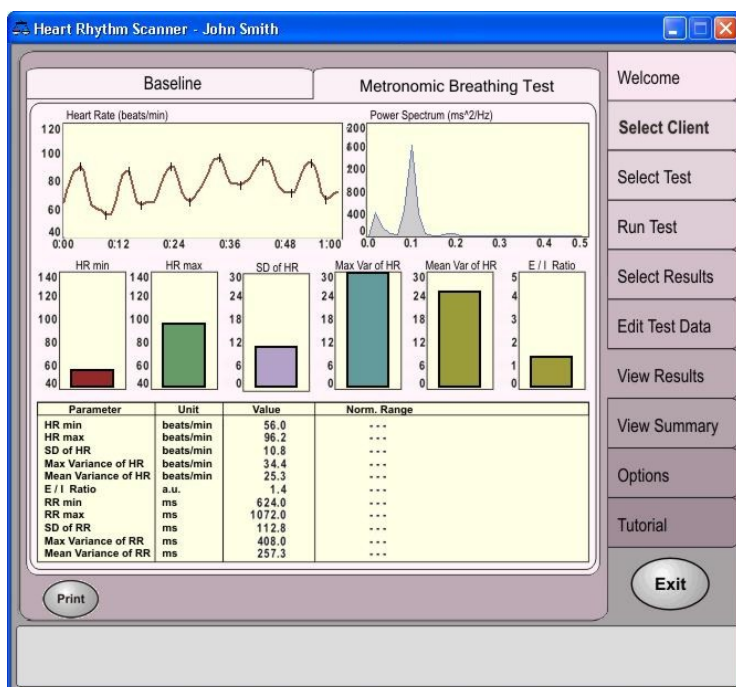
If you've chosen to view the Resting HRV Test, a single screen should appear, displaying all the results of this test.



If you chose to view a Metronomic Breathing Test, the results will be separated into two sections – results of the five-minute Baseline Recording and results of the Metronomic Breathing Test.

To view the Baseline Recording results, click the “Baseline” tab above the main screen.

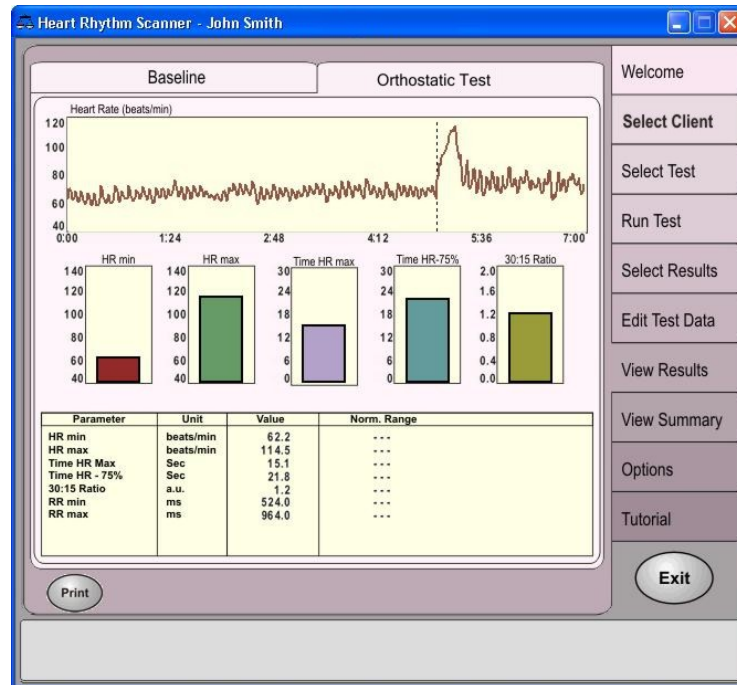
To view the Metronomic Breathing Test results, click the “Metronomic breathing” tab above the main screen.



If you chose to view the results of a Orthostatic Test, the results will also be separated into two sections – results of the five-minute Baseline Recording and the results of the Orthostatic Test.

To view the Baseline Recording results, click the “Baseline” tab above the main screen.

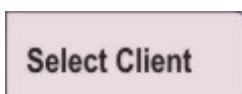
To view the Orthostatic Test results, click the “Orthostatic Test” tab above the main screen.



7. Managing Client Records

This section describes how to do the following operations:

1. Create a new client's record.
2. Edit an existing client's personal information.
3. Delete a selected client's record, along with all test data associated with it.



This tab opens a list of client names in the program window.

Click the client's name on the list to select his/her record. The selected name will appear on the program caption bar.

To create a new client's record:

1. Click the "New" button.
2. Type in the client's name in the appropriate field.
3. Type in the client's date of birth (mm/dd/yy).
4. Select the client's gender from the dropdown menu.
5. Type in appropriate information into remaining fields, if necessary.
6. Click "Save".

To edit an existing client's personal information:

1. Highlight the client's name by clicking on it.
2. Modify data in any field. Make sure the name is entered, and date of birth and gender are selected.
3. Click "Save".

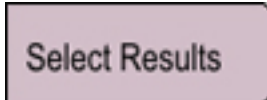
To delete a client's record:

1. Select the client's name from the list by clicking on it.
2. Click "Delete", then confirm deletion when prompted by a message box.

8. Managing Test Records

This section describes how to perform the following operations:

1. Edit test comments.
2. Delete selected test records.



Click this tab to open test record page in the program window.

Select the appropriate type of text from the “Text Type” dropdown menu. A list of dates should appear in the window directly below the menu. Click on an appropriate date to select it.

You can add/modify test comments by editing information in the Test Comment box.

To edit test comments:

1. Select a test data from the list by clicking on it.
2. Modify data in test comment field.

If you've made any alterations in the test comments, press “Save” to save your changes.

To delete test records:

1. Select a test data from the list by clicking on it.
2. Click the “Delete” button, then confirm deletion when a message box will prompt you to.

Once you have selected an appropriate test type and date and are ready to view the results, you can edit the test data.



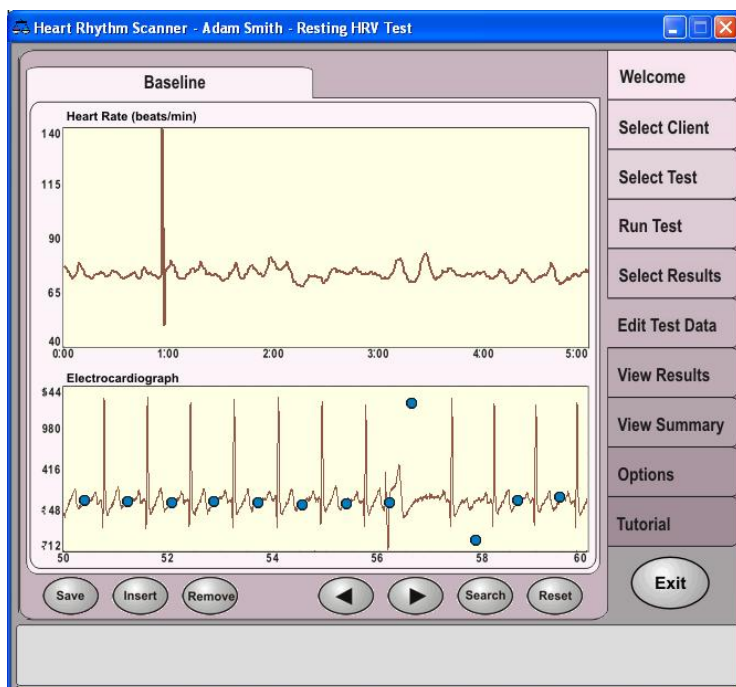
Click this tab to view and edit test data.

As with viewing test data (see Section 5 – “Viewing Test Data”), you will have different options, depending on the type of text you choose to edit.

- If you have selected an Resting HRV Test, the results appear in a single screen.
- If you have selected a Metronomic Breathing Test, the results are separated into two screens – the five-minute Baseline Recording and the Metronomic Breathing Test.
- If you have selected a Orthostatic Test, the results are also separated into two screens – the five-minute Baseline Recording and the Orthostatic Test.

If the results are separated into two screens, use the tabs at the top of the screen to toggle between the screens.

Once you have selected the appropriate screen, you can edit the results of the test.



The screen is divided to show two sets of data – Heart Rate and ECG data.

You can use the left and right arrow buttons located below the data display to navigate through and review the displayed results.

Here, you may correct the data by inserting valid R-peaks not detected automatically and/or deleting incorrectly detected R-peaks in your ECG data.

Use the “Insert” and “Remove” buttons located below the data display to edit ECG data.

- If you come across an R-peak on the ECG trace that you wish to **include** in the Heart Rate data, press “Insert” and place the “rectangle” cursor over the chosen R-peak. Once the cursor is positioned correctly, click left mouse button to insert.
- If you come across an R-peak on the ECG trace that you wish to **remove** from the Heart Rate data, press “Remove” and place the “rectangle” cursor over the chosen blue dot associated with the R-peak you wish to remove. Once the cursor is positioned correctly, click left mouse button to remove.

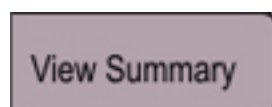
If you need to restore the data to its original state, press “Reset” to restore data and edit again.

Once all necessary changes to the data have been made, press “Save”.

9. Viewing Test Summary

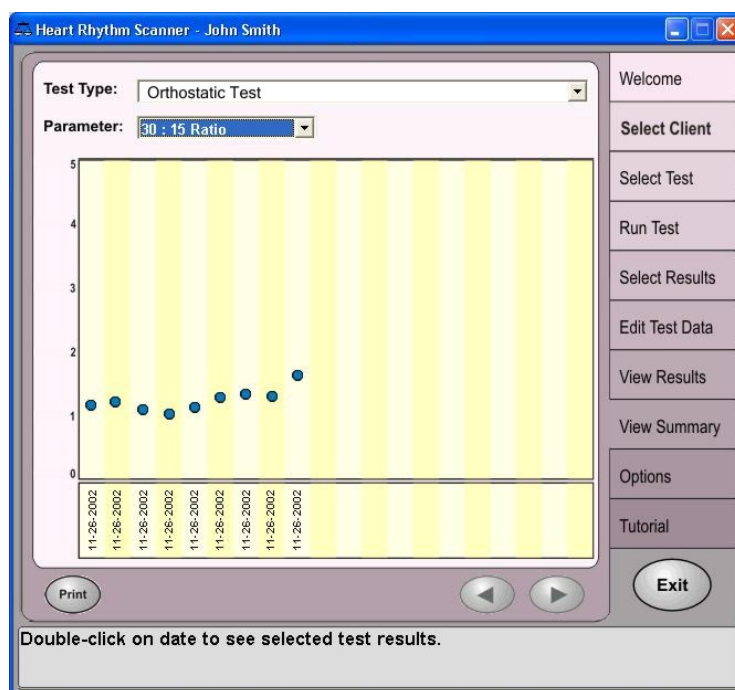
This section describes how to perform the following operations:

1. Format test results
2. View and print your results.



Click this tab to view and edit test summary.

This page will appear in the program window.



To view a summary of a particular test for the given client, you may select an appropriate test type and parameter in which to view the data.

Select the **test type** from the "Test Type" dropdown menu.

Select the **parameter** from the "Parameter" dropdown menu.

Once you have selected the appropriate test type and parameter, every recorded set of data for the selected test type will appear on the graph. These sets of data will be labeled as the date on which the test was taken. To view the detailed results of any test, double-click on its corresponding date.

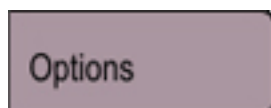
Each test date is represented by a blue dot on the graph. This will allow you to compare sets of data, based on your chosen parameter.

You may use the left and right arrow buttons to scroll through the graph.

To print the results shown in the summary, press "Print".

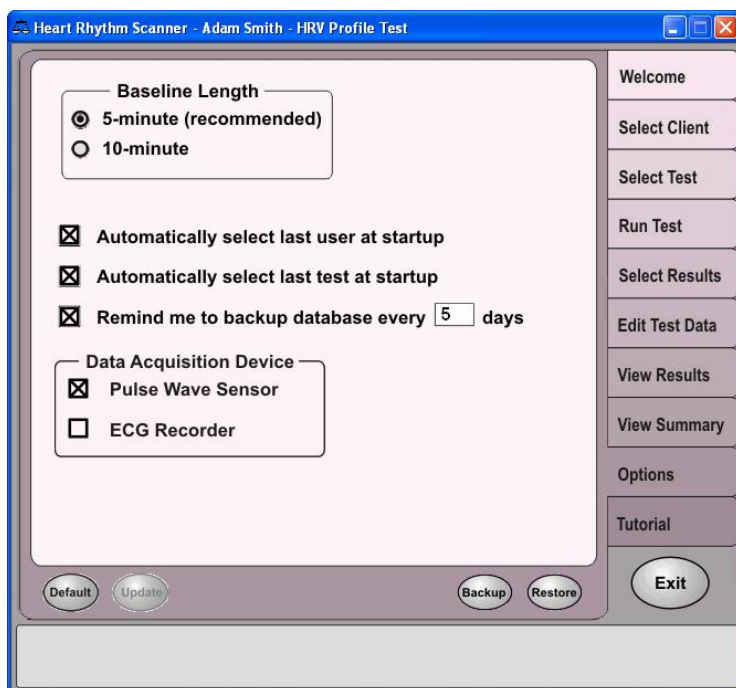
10. Program Options

This section describes how to set or modify various program settings.



Click this tab to open options page and edit your options.

This page will appear in the program window.



You can select the “**Baseline Length**” of the Baseline Recordings (used in the Metronomic Breathing Test and Orthostatic Test, using the provided radio buttons. The baseline recording can be either 5 minutes or 10 minutes.

Select the “**Automatically select last user**” option to automatically select the most recent client’s name at startup.

Select the “**Automatically select last test**” option to automatically select the most recently conducted test at startup.

You may select the “**Remind me to backup database**” option to be reminded to backup your data. Enter a number of days from 1 to 99 to specify how often you wish to be reminded by the program. If you do not wish to receive reminders, deselect this option.

To backup your data, press the "Backup" button on the bottom of the screen. Click "OK" when prompted to confirm. A dialog will then appear where you may enter a filename for the backup data. Enter a filename and click "OK" to save.

To recall backup data, press "Restore". When a dialog appears, select the file you wish to restore and click "OK".

You can specify the type of data acquisition device used to gather physiological signals used to evaluate test results. Choose either of the following options: **"Pulse Wave Sensor"**, **"ECG Recorder"**. If both options are selected, both signals will be displayed on the screens and stored in the test records.

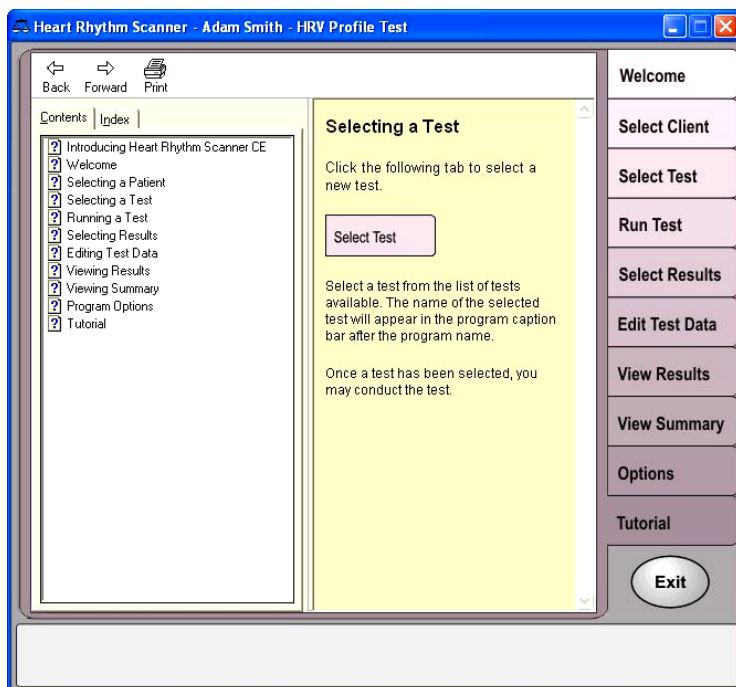
Press the "Default" button on the bottom of the screen to restore default settings.

If you have made any changes to the settings, press "Update" to save your changes.

11. Using the Tutorial

Tutorial

Click this tab to view tutorial page displayed in the program window:



The help menu will automatically display a topic specifically for the program page from which the Tutorial was called.

Use the table of contents to open a specific topic.