User Guide

Lev El Diagnostics of Heart Diseases Ltd.

HeartTrends Client System

Heart Rate Variability (HRV)
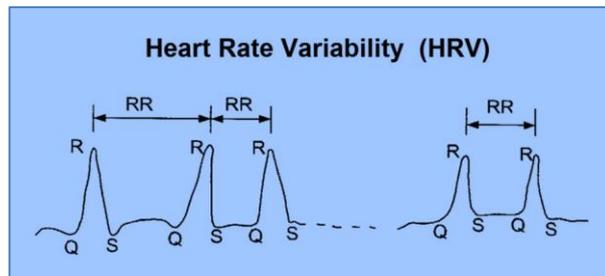
Computerized Analysis of ECG Inter-beat Time Intervals

Lev EL
Diagnostics of Heart Diseases

CE Notice

$$CE_{0344}$$

The symbol CE 0344 indicates compliance of this device with the Medical Device Directives 93/42/ EEC, 2007/47/CE.

EC REP **MedNet GmbH**

MedNet GmbH
Borkstrasse 10
48163 Muenster,
Germany

Lev El Diagnostics of Heart Diseases Ltd.

10 Zarchin Alexander St., P.O.B 4424
Raanana, 4366238
Israel

Document Number UG-C105 Revision 6.0

Text revised January 2016

info@Levhm.com

Table of Contents

1. INTRODUCTION

1.1. THE HEARTTRENDS SYSTEM

The Lev El Diagnostics of Heart Diseases Ltd. HeartTrends™ System is a software application designed for the computerized analysis of RR intervals time series, designed for diagnosis of myocardial ischemia related to coronary artery disease.

The system consists of a Client System and a Server System. This User Guide documents the Client System.

The Client System is used by health professionals to retrieve information recorded by an off-the-shelf certified heart monitoring device (Holter).The Client application strips the confidential patient information (full name and ID) and replaces it with a unique internal Test ID which is used to communicate between the Client and the Server.

The Server system analyzes the RR interval and performs calculations that result in a Dy/Dx indicator value which is communicated back to the Client.

The Client system then further finds/matches the internal Test ID to the patient's real name and ID and generates the result in a PDF report for the user.

1.2. ABOUT THIS USER GUIDE

This User Guide provides the information necessary to operate the HeartTrends Client in a safe and efficient manner. Please read and thoroughly understand this User Guide before operating the system. If any part of this User Guide is not clear, contact customer support.

1.2.1.1. WARNINGS, CAUTIONS AND NOTES

Three types of special messages appear in this User Guide:

A **warning** indicates the possibility of general system failure or hazard to health.

A **caution** indicates a condition that may lead to incorrect or misleading results.

A **note** provides other important information.

1.3.GLOSSARY

Analysis File: The data generated by the HeartTrends Server software and used by the Client software to generate the HeartTrends RR Interval Report.

Billing Id: A unique value that identifies the organization that is using the HeartTrends Client software.

Billing Name: The name of the organization that is using the HeartTrends Client software.

BIT: Built-in Test.

BPM: Beats Per Minute.

Dy/Dx Indicator Value: The proprietary heart disease diagnostic and prognostic value generated by the HeartTrends system.

HeartTrends Client: The software running on the customer's PC, as detailed in this User Guide.

HeartTrends Regular User: The physician, nurse or other healthcare professional who uses the HeartTrends Client.

HeartTrends RR Interval Report: The final result of the HeartTrends system which includes the critical Dy/Dx indicator value.

HeartTrends Server: The software that analyzes the Recorded Data from the HeartTrends Client, and prepares the test result file. Although mentioned briefly in this documentation, a full discussion of the HeartTrends Server is beyond the scope of this User Guide.

HeartTrends Client Administrator User: The person who controls access to the HeartTrends Client software by maintaining a list of users. The Administrator also configures system options, and creates backup data. The System Administrator user is **Admin** and the password must be set on first application launch.

Holter Recording Device: A device that is strapped onto the patient's body and which continuously records heart data. The Holter Recording Device must meet the HeartTrends specifications and be authorized for use with the HeartTrends software. A list of qualifying Holter Recording Devices is provided on page 34. The Holter should be used according to the manufacturer's instructions.

Internal Test Id: A unique value that identifies the patient.

LED: Light Emitting Diode.

Memory Card: Removable memory storage device (a compact flash or any other flash drive) that is used to copy data between the Holter Recording Device and the Lev El Diagnostics of Heart Diseases Ltd. Client Software PC.

Recorded Data: The RR Interval data recorded by the Holter recording device.

RR Interval: Inter-beat Interval. The time duration between two consecutive R waves of the ECG.

2. SAFETY

2.1. GENERAL SAFETY INSTRUCTIONS

⚠️ **Warning:** Changes or modifications not expressly approved by Lev El Diagnostics of Heart Diseases Ltd. could affect the safety and effectiveness of the system and will void the system's warranty.

⚠️ **Warning:** The system contains no user-serviceable components.

⚠️ **Caution:** Disposal of this device should be performed in accordance with local regulations.

⚠️ **Caution:** Do not use before reading and understanding this User Guide

2.2. INDICATIONS

The HeartTrends™ software is intended for the analysis, summary and reporting of up to three channels of prerecorded ambulatory ECG data. It is also intended to provide measurements of the MPW (Multiple Parameter Weighted) HRV. The Dy/Dx indicator value can be used as a prognostic score to assist in diagnosis of myocardial ischemia related to coronary artery disease for which the physician renders his/her own opinion. HeartTrends does not offer a diagnostic opinion to the user.

Data collection and reporting, using the Holter Recording Device and the Memory Card, can be performed by a nurse, technician, physician, or other authorized medical professional.

The HeartTrends Report that is the final output of the system is used by the physician to evaluate the patient in conjunction with the patient's clinical history, symptoms, and other diagnostic tests, as well as the physician's clinical judgment.

2.3. CONTRAINDICATIONS

HeartTrends is contraindicated in patients with a pacemaker and patients under age 21.

3. INTRODUCTION TO HEARTTRENDS

3.1. DESCRIPTION OF DEVICE

The HeartTrends System is intended to provide detailed analysis of Recorded RR interval Data. The HeartTrends System consists of the **HeartTrends Client** and **Server** Systems and is used in association with the **Holter Recording Device**.

The purpose of the Holter Recording Device is to gather information about the patient's heart. This information is referred to as **Recorded Data**, and is stored in the internal memory of the device for later analysis.

The purpose of the HeartTrends System is to provide detailed analysis of the Recorded Data. The HeartTrends System has two parts:

- The **Client System** is the main focus of this User Guide. It is used by health professionals to download information from the Holter Recording Device, and to prepare data files for processing by the Server System. The **Client System** also receives results files which were prepared by the Server System, and displays the report to the user. The report is referred to as the **Test Results Report**.

- The **Server System** receives data files which were prepared by the Client System, performs the HeartTrends proprietary analysis, and returns results files for the Client System.   A detailed description of the Server System is beyond the scope of this User Guide.

3.2. PRODUCT FUNCTIONS

The HeartTrends Client System has the following user-invoked functions:

- Installation of system on user's computer
- Management of patient information, including personal details and basic medical questionnaire
- Management of a list of physician users and administrator user
- Initialization of Memory Card with patient information, for use on Holter Recording Device
- Acquisition of Recorded Data from Memory Card
- Packaging of data into a proprietary format, for use by HeartTrends Server System
- Unpacking results files from the HeartTrends Server System
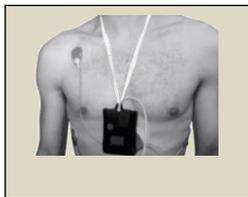- Generation of PDF Report file

3.3. PROCESS FLOW DIAGRAM

The overall process flow of the HeartTrends System is shown below.
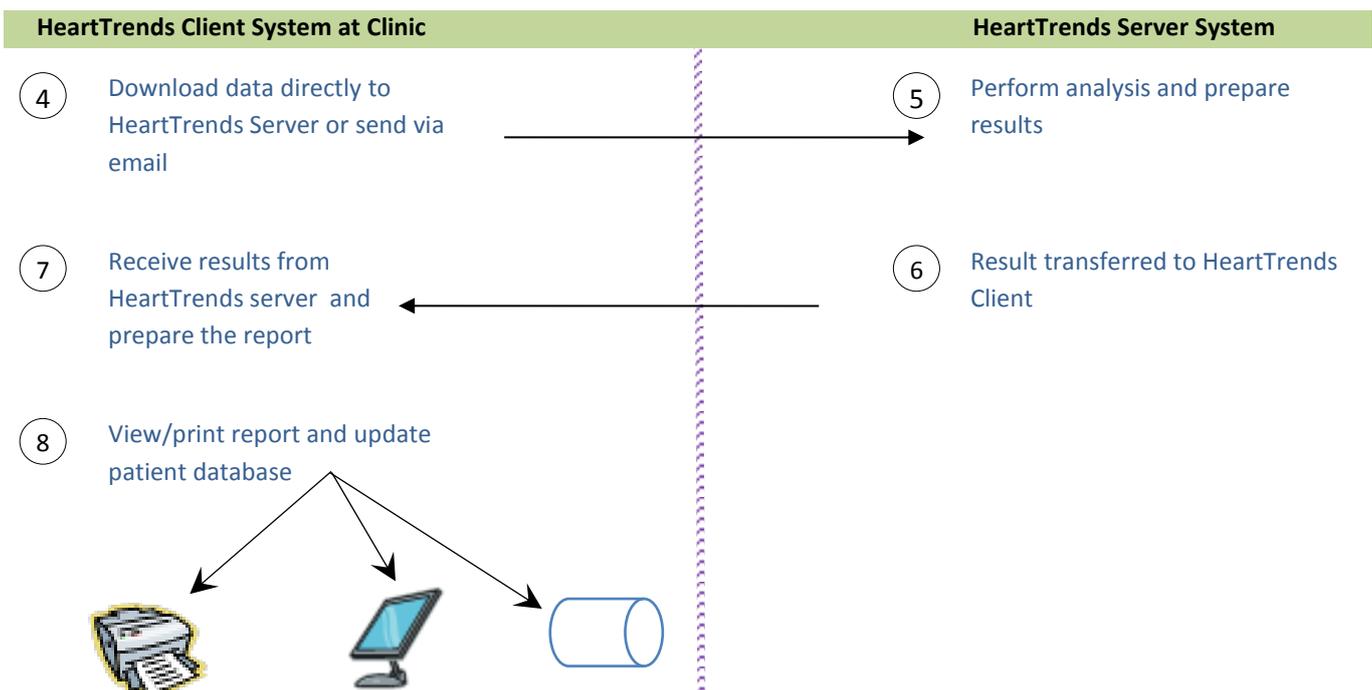
1   Initialize Memory Card using Client PC

2   Patient wears Holter Recording Device (according to Holter manufacturer instructions)

3   Remove Memory Card from Holter Recording Device and import into Client PC.

The remaining steps illustrate the interaction between the **HeartTrends Client System** (the subject of this User Guide) as used at the Clinic, and the **HeartTrends Server System**. The Server system is typically run by a service bureau or host service provider.

HeartTrends Client System at Clinic	HeartTrends Server System
4 Download data directly to HeartTrends Server or send via email	5 Perform analysis and prepare results
7 Receive results from HeartTrends server and prepare the report	6 Result transferred to HeartTrends Client
8 View/print report and update patient database	

3.4. PROCESS DESCRIPTION

The HeartTrends System is designed to allow the gathering and analysis of RR Interval data from a supported Holter Recording Device.

Using the HeartTrends Client System user interface, the user enters patient information such as name and date of birth. This data is stored internally on the PC and on the Memory Card. Additionally, the Client system generates a unique Test ID for the patient. This Test ID is never duplicated, even by other users of the HeartTrends system. It is used to uniquely identify the patient to the HeartTrends Client and Server system.

The user then transfers the Memory Card to the Holter Recording Device, and wears the Holter Recording Device around his chest, according to manufacturer instructions. The Holter Recording Device gathers and saves comprehensive heart data on the Memory Card. At the direction of the customer, the Memory Card is removed from the Holter Recording Device and inserted into the PC that is hosting the HeartTrends Client System.

Using the HeartTrends Client System software, the user imports the raw Holter Recording Device data from the Memory Card to the Client PC. After some internal processing, the HeartTrends Client Software generates a data file that is ready for shipping to the HeartTrends Server System software.

The user ships this raw data, via regular post or electronically, to the HeartTrends Server System. Through a process internal to the Server System, this data is used to generate the HeartTrends Report.

Note that for privacy purposes, personal patient data is never sent to the server.

The Report is then shipped back to the customer, where it is imported to the HeartTrends Client System and made available for viewing.

The HeartTrends Client System also allows for managing patient information, including personal details and the information in a basic medical questionnaire. It includes functions for the management of users and for other administrative purposes.

4. INSTALLING THE HEARTTRENDS CLIENT SYSTEM

The HeartTrends Client System runs on a Windows 7 operating system.

4.1. SUMMARY OF INSTALLATION PROCEDURE

Double-click on the HeartTrends icon to start the installation process. In order to perform the installation, follow the on-screen instructions provided by the system.

4.2. INSTALLATION SCREENS

A summary of the four installation screens is provided below. Follow the on-screen instructions to enter data for each screen.

4.2.1. INITIAL SCREEN

4.2.2. CONFIRM INSTALL SCREEN

4.2.3. FINISH SCREEN

4.2.4. LAUNCH SCREEN

The HeartTrends Client System is now ready for use.

5. NOTES ON USERS, DATA COLLECTION AND PRIVACY

5.1. TYPES OF USERS

Two types of users are defined for the HeartTrends Client system:

Regular users: Physicians, nurses and other health personnel who use the system to record and to track patients are defined as *regular users*.
A regular user can access almost all of the HeartTrends System functions. He can see only his own patients – the patients that he has created in the HeartTrends System.

System Administrator users: The *System Administrator* has restricted access to patients like a regular user. He can also add new users, reset other user passwords, and delete users.

In addition to these GUI-based functions, the System Administrator may be responsible for external aspects of the system, such as system installation, backup of data, and shipment of data to and from the Service Center.

5.2. DATA COLLECTION AND PRIVACY

For each patient, HeartTrends requires basic information such as patient id, patient name, gender, date of birth, and other identifying information. Additional optional information should be provided if relevant, such as existing medical conditions and family medical history.

HeartTrends also keeps track of the individual user (typically a physician or other health care professional) who is in charge of the patient's test information. A list of users and passwords is maintained in the system and managed by a special user, the System Administrator.

In addition, HeartTrends requires information about the user's organization (a hospital, clinic or doctor's office), the organization's billing name and billing id.

The HeartTrends Client System Administrator creates and maintains this information using the User Interface screens provided in the system. These screens are described in detail in Sections 6 and 7 below.

It is important to note that no personal patient information is transmitted outside of the HeartTrends Client System. All external information is coded with only the patient's unique Test ID, which is then used in the Client System to identify the patient.

6. DEFINING CLINIC AND SYSTEM ADMINISTRATOR INFORMATION

⚠️   **Caution:** If the Client System does not run correctly, reinstall the System.

Before you begin to use HeartTrends to measure patient data, you must define the basic clinic information, and specify the name and password of the system administrator.

6.1. WELCOME SCREEN

When running the system for the first time, the Welcome screen displays:
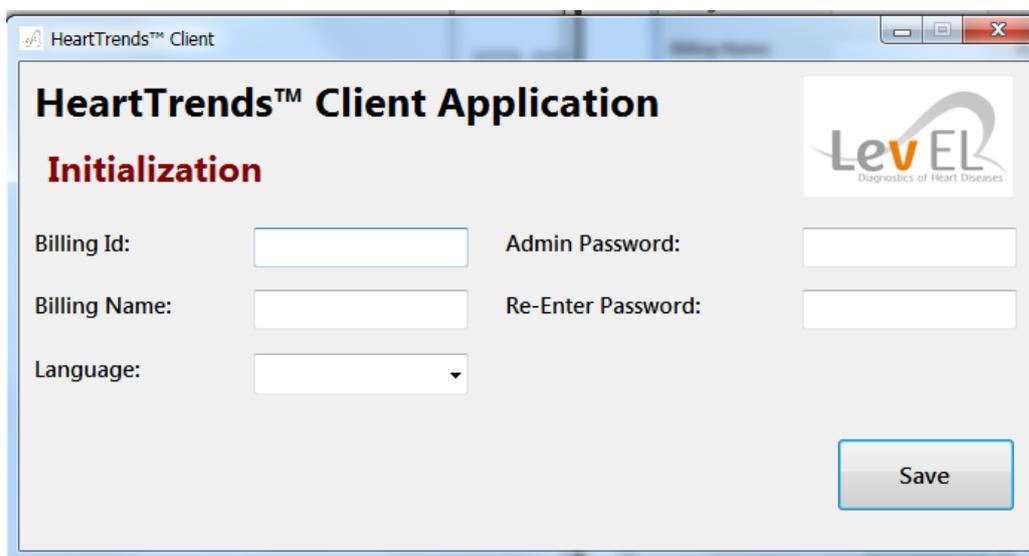
Here you will enter clinic information for the HeartTrends Client System. Note that you can choose the interface language via a dropdown list.

Click **Save** to see the Save Success message:
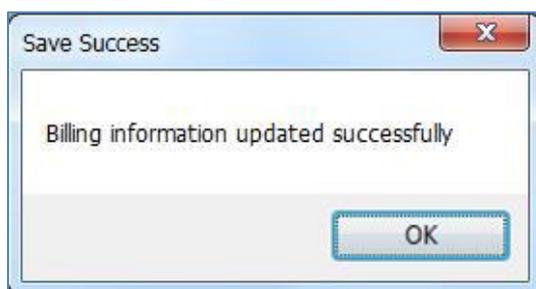
6.1.1. ABOUT THE SYSTEM ADMINISTRATOR

Every use of the system requires a user login. The initial user is called **Admin** and has System Administrator status. When you are logged in using the Admin user, you can define other regular users, as well as perform other system functions.

Please note that the name of the System Administrator user is pre-defined as **Admin** and cannot be changed. In the **Admin Password** field, enter the password that you would like to assign to the Admin user.

6.2.HOLTER CONFIGURATION

When running the system for the first time, you are presented with the Holter Configuration screen:
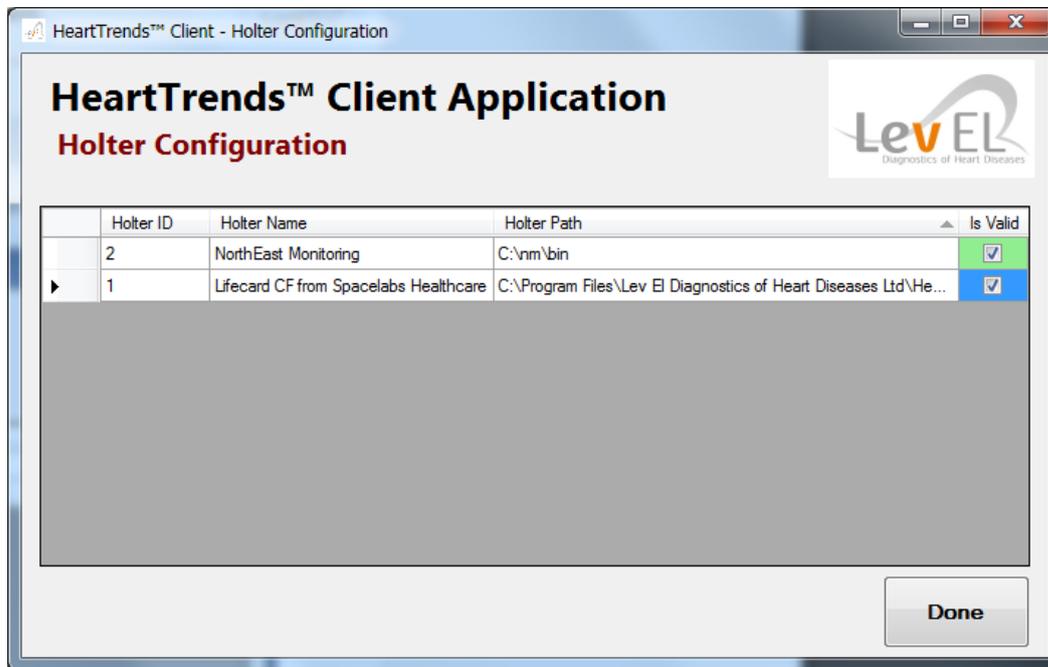
This screen provides a list of each supported Holter device, and the location of the corresponding software installation.

The **Is Valid** field is green and has a check mark for valid paths. A red color and missing check mark for the **Is Valid** field indicates a Holter device for which the appropriate software was not found in the indicated path.

Double-click on the **Holter Path** field to specify the location of the Holter software.

Note: The System Administrator can update the information on this screen at any time by pressing the **Manage Holters** button, as described on page 27.

6.3. LOGIN SCREEN

After defining clinic and Administrator information, you are presented with the Login screen:
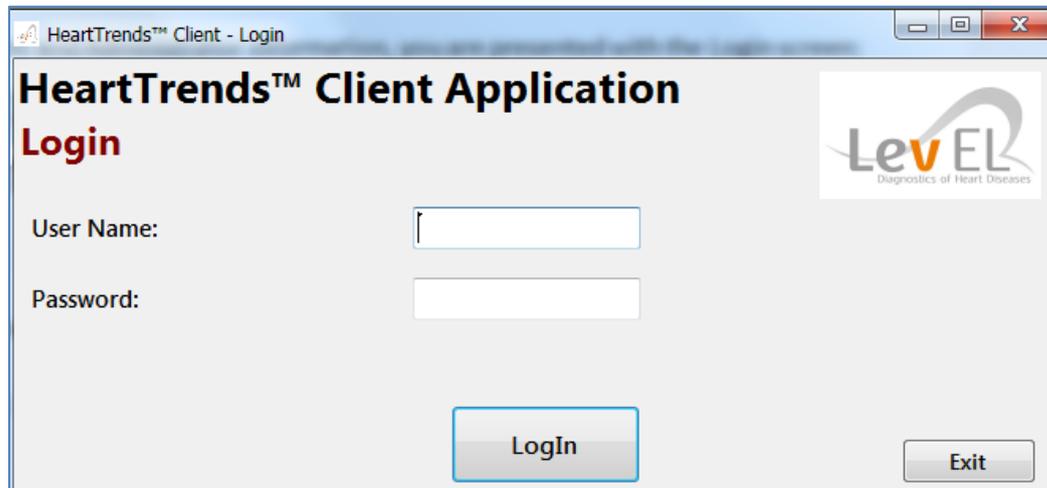
The first time you login, you will enter the User Name of **Admin** and the password that you defined above. You can then proceed to add more users to the system, as described below.

On subsequent use of the system, you may login using Admin, or using one of the ordinary users that you added to the system.

7.USING THE SYSTEM WITH PATIENT DATA

After you have installed the system and input the basic clinic information, you can use the system to collect and process patient data.

7.1.BEFORE RUNNING THE TEST – THE NEW PATIENT/START TEST TAB

⚠️　**Caution:** Erase all data on the Memory Card before running a test.

This screen is used to enter patient identifying information. It must be completed prior to performing a test:
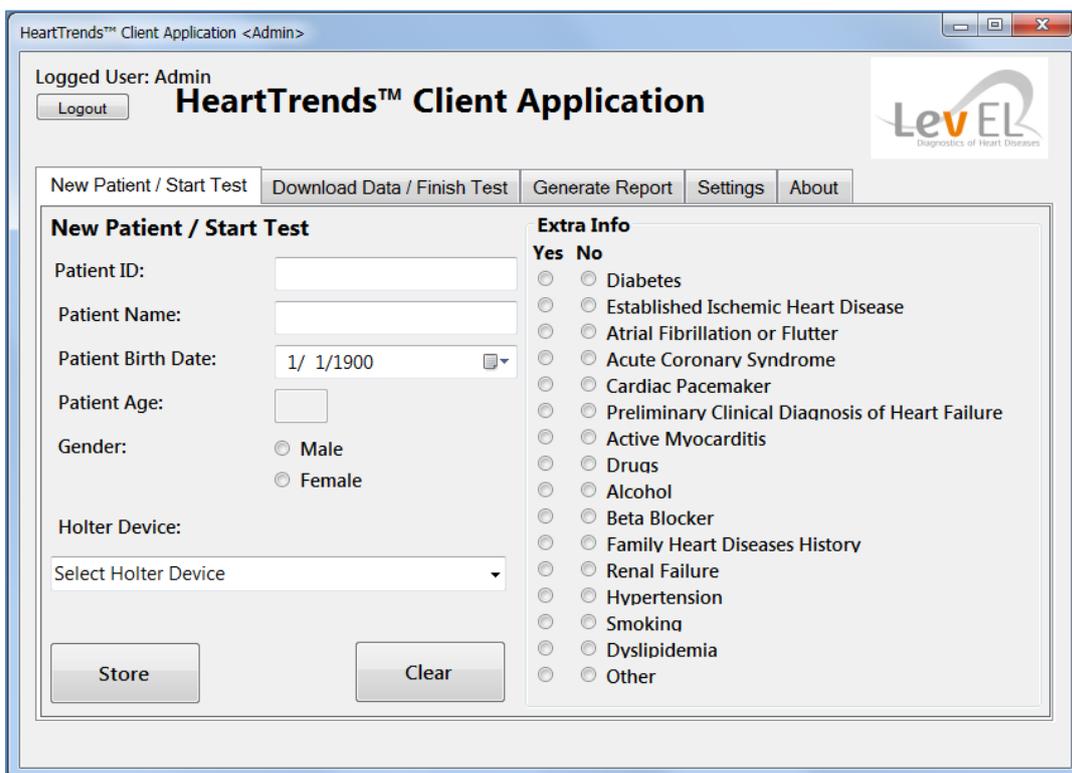
Filling the **Extra Info** information is mandatory.

If you select **Yes** for **Drugs, Dyslipidemia, Beta Blocker** or **Other,** a new window will open requesting additional information.

If you select Yes for **Drugs** or **Other,** the additional details are entered with free text:
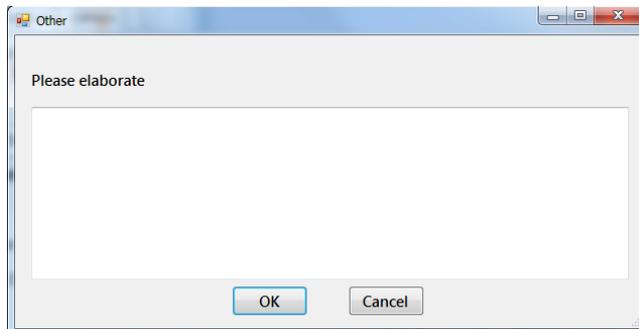
Selecting Yes for **Beta Blocker** requires entering how many **hours** have passed since the patient stopped taking the beta blocker medication:
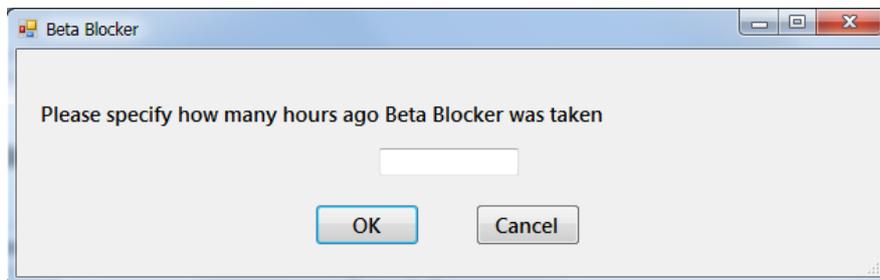
Ensure that the Memory Card from the Holter is connected to the computer before pressing **Store** in the main window.

After pressing **Store** and receiving confirmation that the information has been save to the Client Software System database and to the Memory Card, you may remove the Memory Card and place it in the Holter Recording Device. The patient should then wear the Holter for one hour.

7.2. AFTER RUNNING THE TEST – IMPORTING THE HOLTER DATA

This screen is used after running the test on the Holter Recording Device, and **before** sending the data to the HeartTrends Server System.

Insert the Memory Card into the slot on the PC and click on the **Download Data/Finish Test** tab. Select the Holter Device and press Load to upload and save the Test data on your computer.

After "load" a pop-up window will appear that indicates that the .htd file was saved in the local disk in the folder Program Data/Lev El/HeartTrends Client/Output.
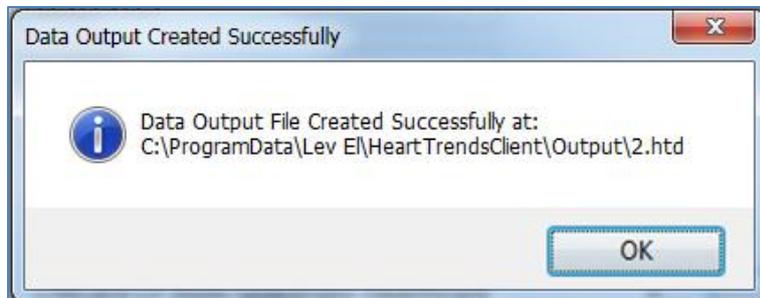
After pressing OK an additional popup window will appear saying that "File will be uploaded to the server. This operation might take a while".

When the upload process is complete, the message "Test File was successfully updated to the Web Server" will display:

Please wait while the Server analyzes the test.

If the upload did not succeed (for example, there was a communications problem), you can send the **.htd** test file to the HeartTrends Server System by an alternate method. You can send the data via regular mail (CD), email, or other media.

8. THE RESULTS REPORT

After the patient data has been processed by the HeartTrends Server System, you can then import the processed data and generate the Results Report. The Results Report is made available as a PDF file in a file location selected by the user.

8.1. LOADING RESULTS DATA AND CREATING THE REPORT – GENERATE REPORT TAB

Select the **Generate Report** tab to display the Generate Report screen:
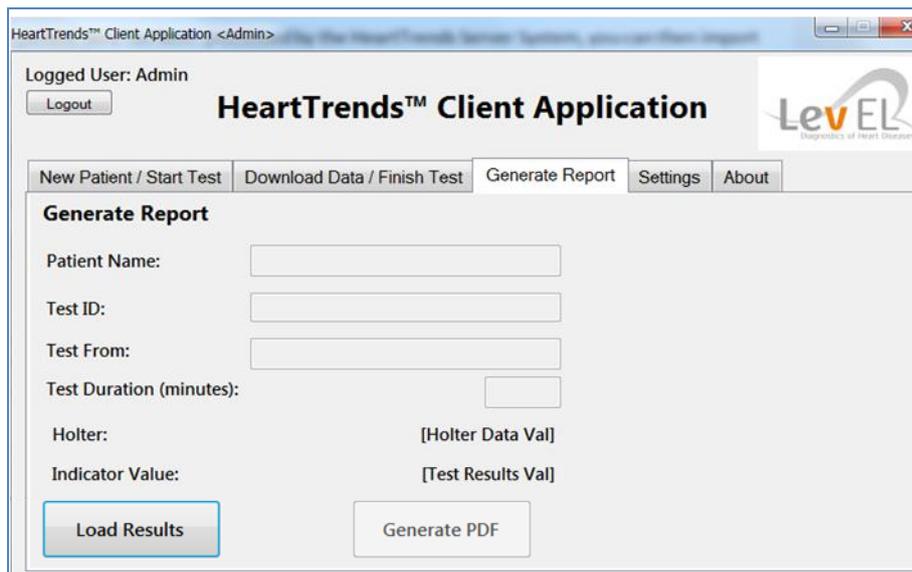
Click on **Load Results** to display the status of tests. The following screen will open:

Note: Click on the **Date, Patient ID** or **State** column header to sort by that field.

The Load Results screen has the following column headers:

Test ID – the unique test ID

Date – date of start of test, sorted in descending order (the newest on top)

Patient ID – the unique patient ID

State – may have the following values:

- "New Patient" – The test was initialized in the "New Patient" tab. The data has not yet been downloaded from the Holter.
- "In Process" – The data was downloaded from the Holter (see 7.2), and the server is calculating the test result.
- "Ready to Generate PDF" – The server has analyzed the result. Select "Open" to run the test and view the results.
  After selecting "Open", the window closes and the test details are displayed in the Generate Report screen. The user may then click on the "Generate PDF" button.
- "Finished" – After clicking "Generate PDF", the state of the test changes to "Finished". The screen will hold up to 20 finished tests.

The **Load Results** button has an option to **Browse** in order to either load an older result or to get files that were sent via email.
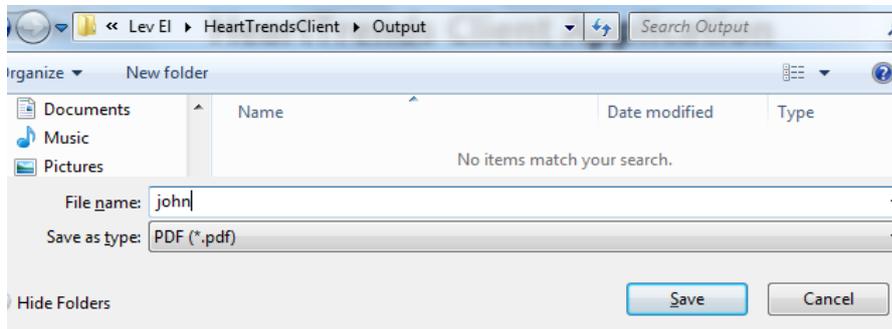
The next step is to click on **Save**. You can now choose to password-protect the PDF report file, with the following screen:
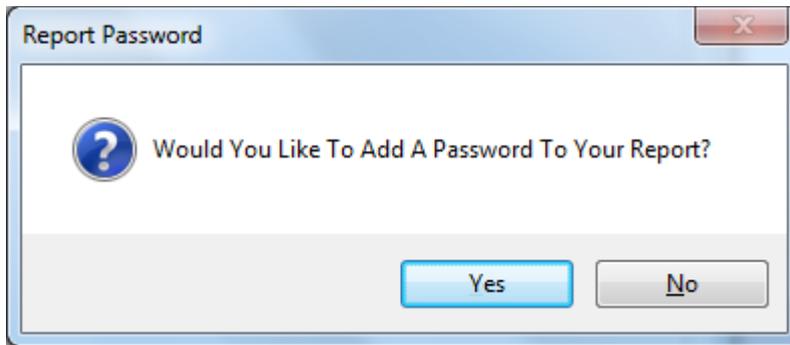
If you **do not require** a PDF password, click **No** to finish saving the report.

If you **want to create** a password, click **Yes** to display the Password screen:
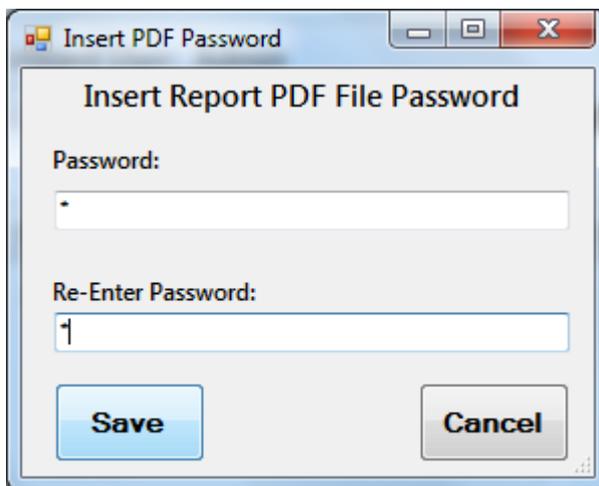
Enter the required information and click on **Save** to save the PDF report file with a password.

8.2. THE PDF REPORT

Following is an excerpt of the PDF Report, with descriptions of key fields in the report:

Page 1 -

Device ID – Type and serial number of the Holter

Test Date – The date and hour when the card was first conditioned with the patient details (taken from the local computer)

Test Duration – The duration of the test in minutes

Time Data – The remaining time in minutes after filtering out the abnormal RR intervals. Abnormal intervals may occur due to artifacts, arrhythmias or other abnormalities. Only the *Time Data* is considered for the analysis. If the *Time Data* is less than 45 minutes, the analysis cannot be performed

Total Sample Points – The total number of points (heartbeats) collected in the test, in correlation with time duration

Filtered Sample Points – The remaining number of sample points after filtering the abnormal intervals, in correlation with time data

Abnormal (%) – The percentage of "abnormal" points

Health factors – Will be displayed according to the information the doctor/nurse/technician entered in the *New Patient* tab. An "X" indicates that the health factor exists.

Please note the following exceptions:
(i) Beta Blocker – If the patient is not taking a beta blocker medication, the rectangle on the right side is empty. If the patient does take a beta blocker, the numeric value indicates the number of hours since he has taken the medication.

(ii) Drugs, Dyslipidemia and Other – An asterisk indicates that additional information, previously entered by the doctor/nurse/ technician in the *New Patient* tab, appears on the second page of the result form. See example below.

Please note: HeartTrends does not provide any results other than the risk for myocardial Ischemia. The PDF Report has further information regarding the expected results.

Additional Health Factors

Drugs:
 Drug1
 Drug2
 Drug3

Dyslipidemia:
 LDL:2.3 HDL:4.5 TG:6.7

Other:
 More information

References

1. Tsuji H, Larson MG, Venditti FJ, et al. Impact of reduced heart rate variability on risk for cardiac events: the Framingham Heart Study. Circulation. 1996;94:2850–2855.

2. Liao D, Cai J, Rosamond WD, et al. Cardiac autonomic function and incident coronary heart disease: a population-based case-cohort study: the ARIC Study. Am J Epidemiol. 1997;145:696–706.

3. Dan Oieru, Nir Shlomo, Israel Moalem, Eli Rozen, Alexey Naimushin, Robert Klempfner, Ilan Goldenberg, Ronen Goldkorn. A Novel Heart Rate Variability Algorithm for the Detection of Myocardial Ischemia: A Proespective Clinical Trial. Israel Heart Society Conference, Jerusalem, April, 2014

4. Goldenberg I. An innovative technique for the noninvasive detection of myocardial ischemia. Innovations in Cardiovascular Interventions Conference. Tel Aviv, 2013.

5. Dan Oieru, Nir Shlomo, Anat Berkowitz, Diego Meme, Robert Klempfner, Ilan Goldenberg, Ronen Goldkorn. A Novel Heart Rate Variability Algorithm for the Detection of Myocardial Ischemia: Pilot Data from a Proespective Clinical Trial. Annals of Noninvasive Electrocadiography, 2014 (in press)

www.levhm.com

8.3. DEFINE CLINIC DETAILS – THE SETTINGS TAB

This screen lets you view clinic information. If you are logged in with the Admin user, you can also edit the information and add or change other users (as described in *Section 10.Managing Users*).
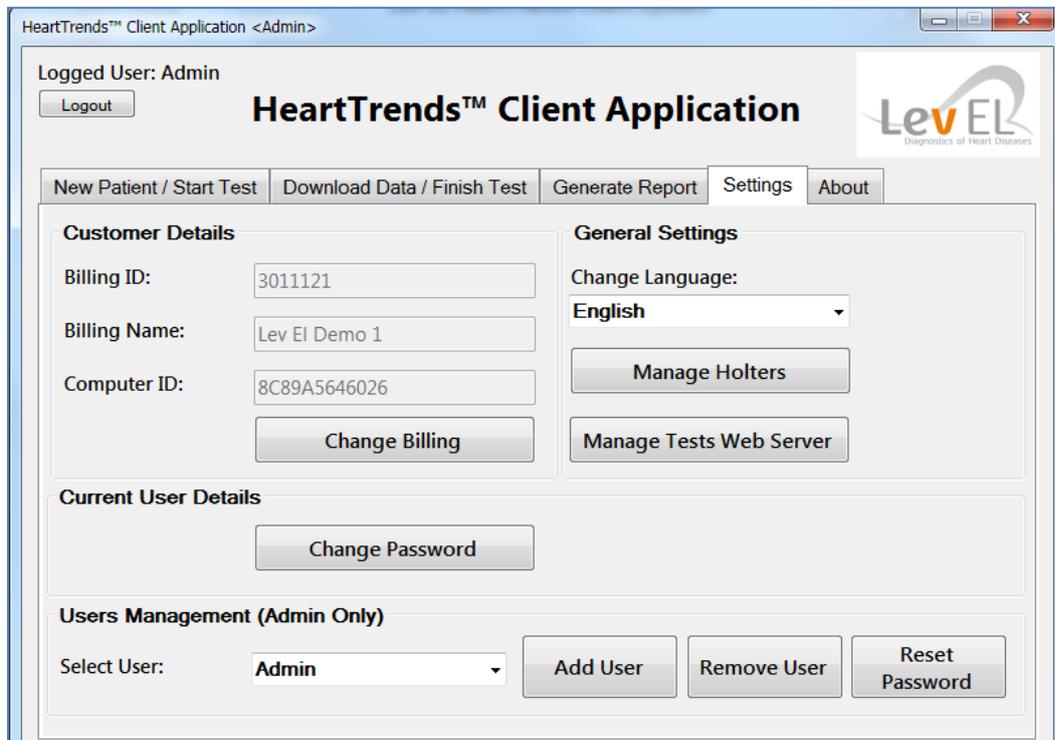

The **Change Billing** button is available for the System Administrator only. It is used to change the Billing Id or Billing Name of the client system.
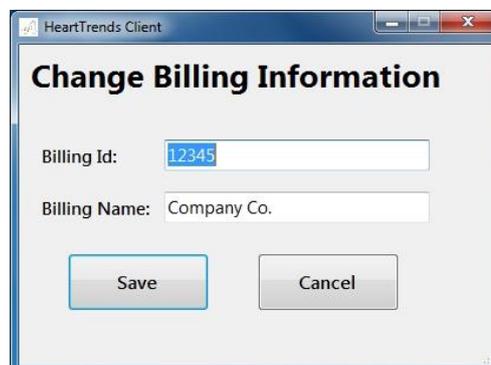

The **Manage Holters** button is also available for the System Administrator only. It is used to display the Holter Configuration Screen. This screen is used to change the location of the software installations for the supported Holter devices. See page 15 for a description of the Holter Configuration Screen.

The **Manage Tests Web** button is used to display the Server's setting. It is available for system administrator only and should be changed per manufacturer request, to change the location of the Server.
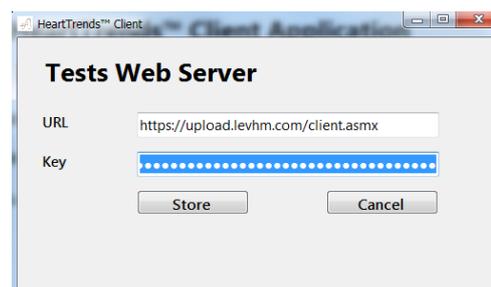
8.4. GENERAL INFORMATION – THE ABOUT TAB

Click **About** to view basic system information.
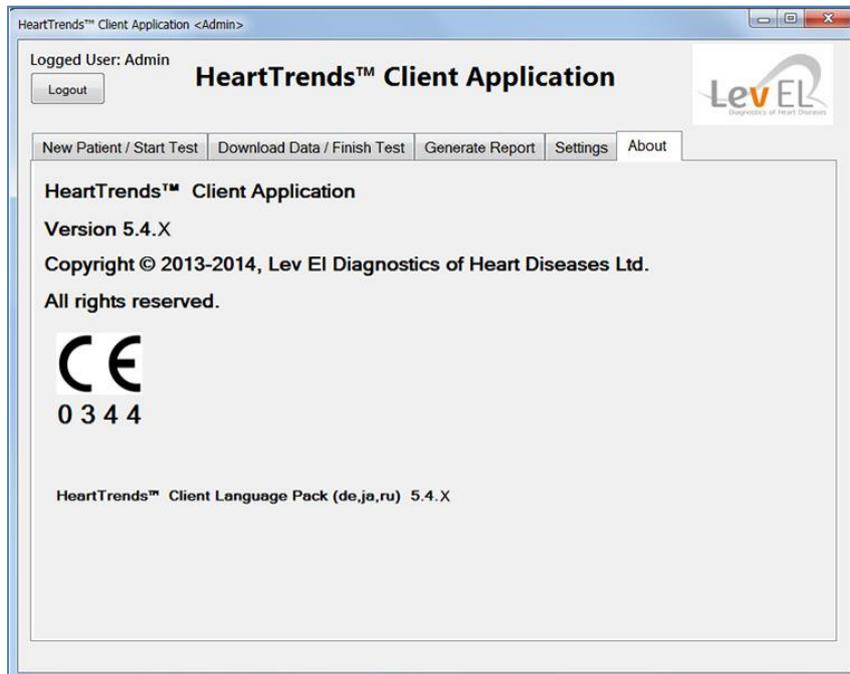
9. HOW TO USE THE HOLTER RECORDING DEVICE – INSTRUCTIONS FOR THE PATIENT

The patient should use the Holter according to the instructions provided by the manufacturer of the device.

Please ensure that the Holter recording device used is listed in Section *Specifications* on page 34.
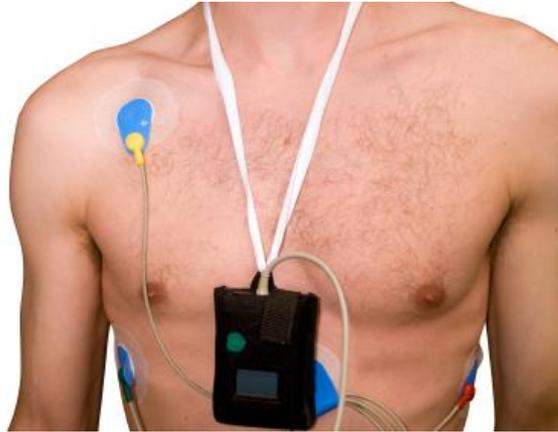
⚠️ **Caution:** The patient must wear the Holter Recording Device for one hour.

9. HOW TO USE THE HOLTER RECORDING DEVICE – INSTRUCTIONS FOR THE PATIENT

10. MANAGING USERS

The Administrator user can use HeartTrends to add, change and delete user information.

10.1. ADDING A NEW USER

From the **Settings** tab, click on **Add User** to display the Add New User screen:
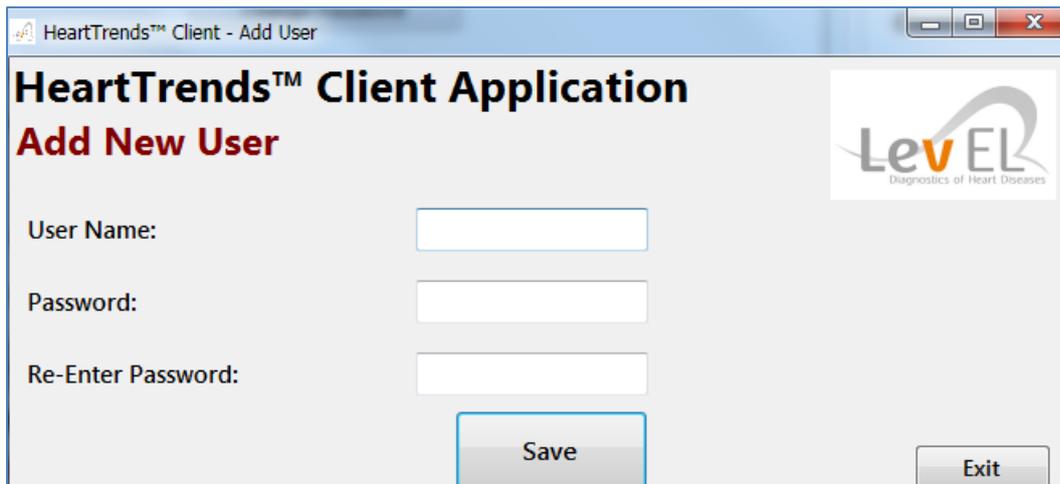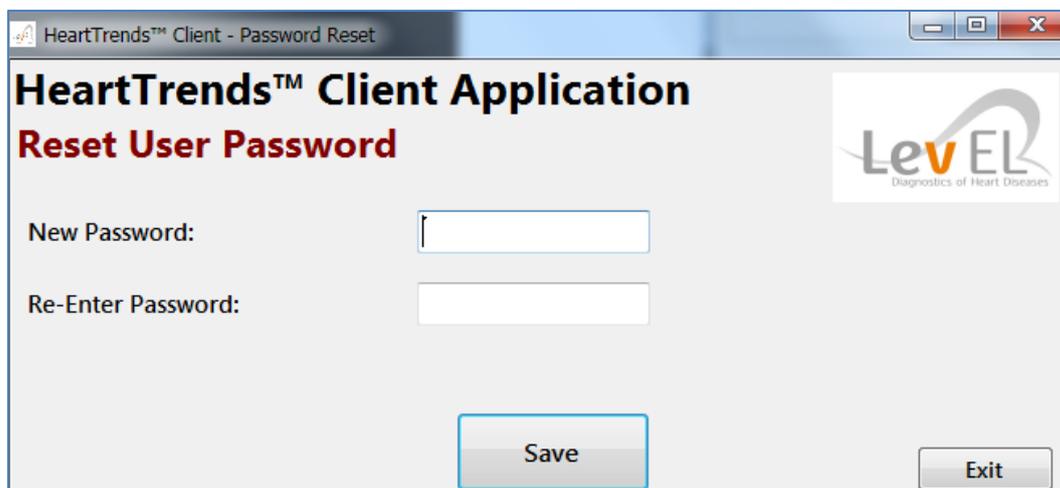

Enter the new user name and password and click on **Save** to create the new user.
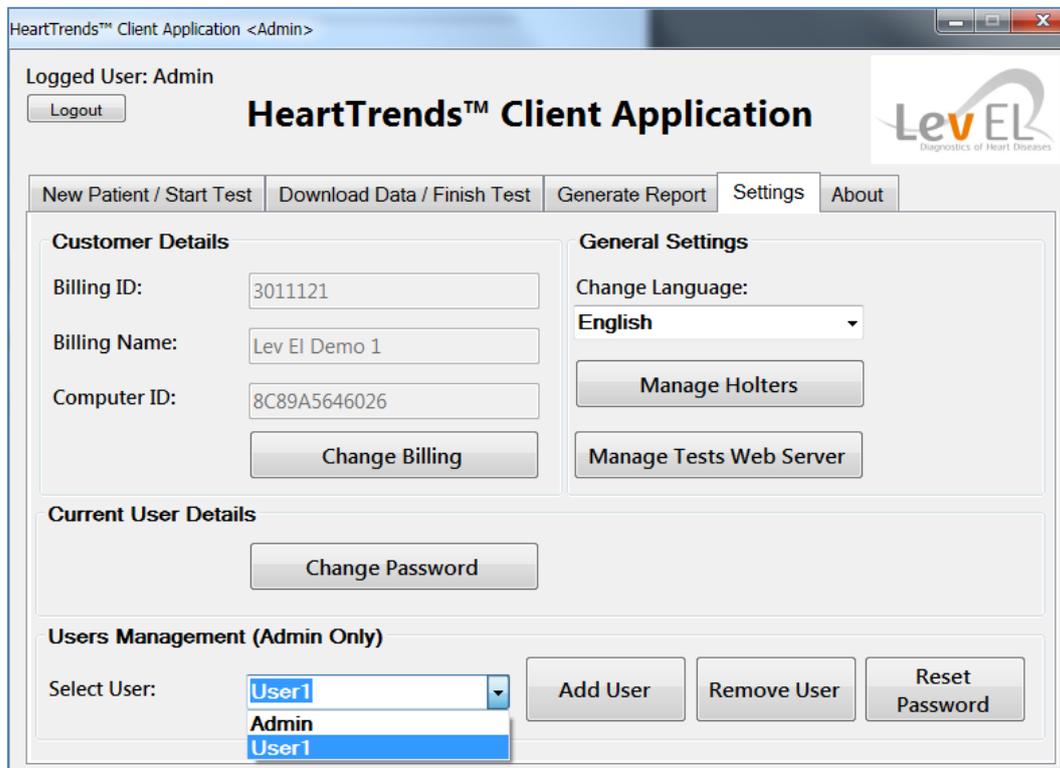
10.2. CHANGING A USER'S PASSWORD

From the **Settings** tab, select the user whose password you wish to change from the list (here we are choosing **user1**). Then click on **Reset Password**, to display the Reset User Password screen:

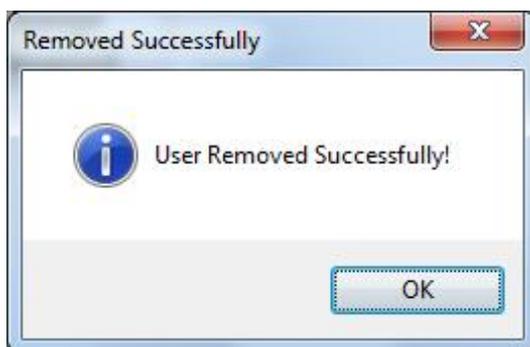

After you have entered the required information, click on **Save** to change the password.

10.3. DELETING A USER

From the **Settings** tab, select the user that you wish to remove (here we are choosing **user1**). Then click on **Remove User** to remove the user from the system.

The following confirmation message will appear:

11. TROUBLESHOOTING

11.1. TROUBLESHOOTING TABLE

The following chart lists typical conditions that may occur with the HeartTrends Client System.

Condition	Possible Cause	Recommended Action
Insufficient/invalid data on the Holter Recording Device	Less than one hour of recording time	Record data again
Test failed to upload to server	Lack of Internet connection	Repeat the upload procedure
Failed to install software due to missing .NET framework	Missing .NET framework	Download and install .NET 4.5 framework
Failed to initialize/find a CF card	Windows failed to locate the appropriate drive	Re-insert the CF card into the reader. Initialize using CFIP.exe GUI

12. MAINTENANCE AND SERVICE

12.1. GENERAL

HeartTrends does not require maintenance or calibration on a routine basis.

Technical specifications and service for the HeartTrends Client System are given below.

12.2. TECHNICAL SPECIFICATIONS

Computer	
CPU	Pentium IV Processor or better
RAM Memory	At least 1 G
Free Hard Disk Space	At least 80 GB
Operating System	Windows 7 and 8
Additional Software	Acrobat Reader
Holter Recording Device	
Approved Device	Lifecard CF compact flash Holter Recorder
Approved Device	North East Monitoring, model DR200

12.2.1. OBTAINING SERVICE FOR THE HEARTTRENDS CLIENT SYSTEM

For questions regarding use of the HeartTrends Client System, please contact Lev El Diagnostics of Heart Diseases Ltd. at support@Levhm.com.

For additional information, please visit our website at www.Levhm.com.