User Manual

HeartTrends®

The *Effortless* Stress Test Alternative
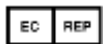

Computerized Analysis of ECG Inter-beat Time Intervals

HeartTrends®

CE Notice

$$C\,E_{0344}$$

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

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1. INTRODUCTION

1.1. THE HEARTTRENDS SYSTEM

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

The system consists of a Lev El-approved Android device and App and a cloud-based Server System. This User Manual documents the App.

The App is used by health professionals to retrieve information recorded by an off-the-shelf certified heart monitoring device (TICKRx) worn by a subject. The App then transmits the information to the Server System. Any identifying subject information is processed locally by the App, and is not sent to the Server.

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

The App then generates the result in a PDF report for the user.

1.2. ABOUT THIS USER MANUAL

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

1.2.1. WARNINGS, CAUTIONS AND NOTES

Three types of special messages appear in this User Manual:

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

Clinic: The HeartTrends customer -- this is the entity that purchases tokens (or credits) from a distributor to perform data analysis.

Doctor or **Technician:** The person who interacts with the subject, helps him put on and remove the TICKRx Heart Rate Monitor, and uses the App to control the data monitoring/collection/analysis process.

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

HeartTrends App: The software running on the clinic's Android device, as documented in this User Manual.

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

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

HeartTrends Server: The cloud-based software that analyzes the recorded data from the HeartTrends App, 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 Manual.

LED: Light Emitting Diode.

Recorded Data: The RR Interval data recorded by the TICKRx Recording Sensor.

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

Subject: The person who will wear the TICKRx Heart Rate Monitor. The subject does not take the TICKRx home, but remains at or near the clinic while the TICKRx is collecting data.

Token: Electronic authorization to perform one RR analysis on the Server. Tokens are purchased by the clinic and can also be considered as "credits".

User Manual: This document – the instructions for use (IFU) for the doctor or technician. Note that no IFU is required for the subject, who is basically passive during the procedure.

Wahoo TICKRx Heart Rate Monitor Recording Sensor: An off-the-shelf sensor that is strapped onto the subject's body and continuously records heartrate data. TICKRx is worn on a belt around the chest, for about an hour. The Recording Sensor should be used according to the manufacturer's instructions.

2. SAFETY

2.1.GENERAL SAFETY INSTRUCTIONS

Warning: Changes or modifications not expressly approved by Lev El 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 Manual.

2.2. INDICATIONS

The HeartTrends software is intended for the analysis, summary and reporting 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 their own opinion. HeartTrends does not offer a diagnostic opinion to the user.

Data collection and reporting, using the TICKRx Recording Sensor and the HeartTrends App, 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 subject in conjunction with the subject's clinical history, symptoms, and other diagnostic tests, as well as the physician's clinical judgment.

2.3. CONTRAINDICATIONS

HeartTrends is contraindicated in subjects with a pacemaker, and arrhythmias.

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 App** and the **HeartTrends Server,** and is used with the **Wahoo TICKRx Recording Sensor**.

The purpose of the TICKRx Recording Sensor is to gather information about the subject's heartbeat. 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 **App** is the main focus of this User Manual. It is used by health professionals to record and download information from the TICKRx Recording Sensor, and to prepare data files for processing by the Server System. The **App** also receives report data which are prepared by the Server System, and assembles the report for the user. The report is referred to as the **HeartTrends Report**.

- The **Server System** receives data files which are prepared by the App, performs the HeartTrends proprietary analysis, and returns the HeartTrends Report to the App. A detailed description of the Server System is beyond the scope of this User Manual.

3.2.PROCESS DESCRIPTION

The HeartTrends System is designed to allow the gathering and analysis of RR Interval data from a TICKRx Recording Sensor.

Using the HeartTrends App on an Android device, the user logs into the App and enters subject information such as name and ID number. Other optional information such as year of birth, weight, gender, and various cardiac risk factors may be also be entered. Subject information may be useful later to the user, as an aid in analyzing the HeartTrends Report. Subject information is confidential and is never duplicated outside of the Android device.

The user then assists the subject in placing the TICKRx Recording Sensor on the subject's chest, and establishes communication between the TICKRx and the App. This is referred to as "connecting" the App to the TICKRx.

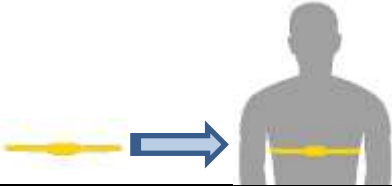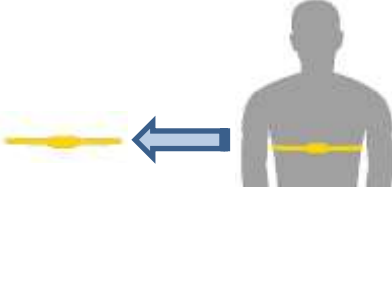Then, using the App, the user instructs the TICKRx to begin recording subject heart information.

After the subject has worn the TICKRx for at least 45 minutes (a time period of 60 minutes is listed in the Settings screen of the App), sufficient data has been gathered to allow analysis by the HeartTrends Server System. The user uses the App to download the heartrate data from the subject's TICKRx, and to upload this data to the HeartTrends Server System for analysis.

Through a process internal to the Server System, the subject's heart rate data is analyzed to generate the HeartTrends Score and subsequent Report.

Finally, the HeartTrends Server System sends the HeartTrends data to the App, where the user can view and email the report results.

3.3. PROCESS FLOW DIAGRAM

The overall process flow of the HeartTrends System is shown below.

1	**Set up the App** on the user's Android device (one-time setup by installer)		See Section *4. Set up the HeartTrends App.*
2	**Place the TICKRx sensor** on the subject		See Section *5.1. Subject Puts On the Sensor*.
3	**Connect the TICKRx sensor** to the App		See Section *5.2. Connect the TICKRx Sensor to the App.*
4	**Enter subject information** in the App, and **begin the TICKRx measuring process**		See Section *5.3. Start A Test* and Section *5.4. Enter Subject Information and Begin Test.*
5	At the conclusion of the test, copy the recorded test data into the App, and send to the HeartTrends cloud server to **generate and view the Report**		See Section *6.3. View the HeartTrends Score*.
6	Analyze the Report		See Section *6.4. Analyze the HeartTrends Test Result*.
7	Retrieve **previous HeartTrends Reports** and review test results, if desired		See Section *7. Review Previous HeartTrends Reports.*

4. SET UP THE HEARTTRENDS APP

When you set up the HeartTrends App, the following one-time steps are necessary:
- Run the App
- Log in (your login credentials will be remembered for subsequent times that you run the App)

Each of these steps is described in detail below.

Note: The HeartTrends App requires the supplied device to have the Bluetooth and Location features enabled.

4.1. DOWNLOAD THE APP

Not performed by the user but, if the App is not accessible, contact Support where instructions for re-downloading the App may be given.

4.2. RUN THE APP AND LOG IN

The first time that you use the HeartTrends App, you will be asked to enter your user and password information, and your identifying PIN ID. The user and password information can be obtained from your HeartTrends distributor. Choose any PIN uniquely ensuring your data privacy.
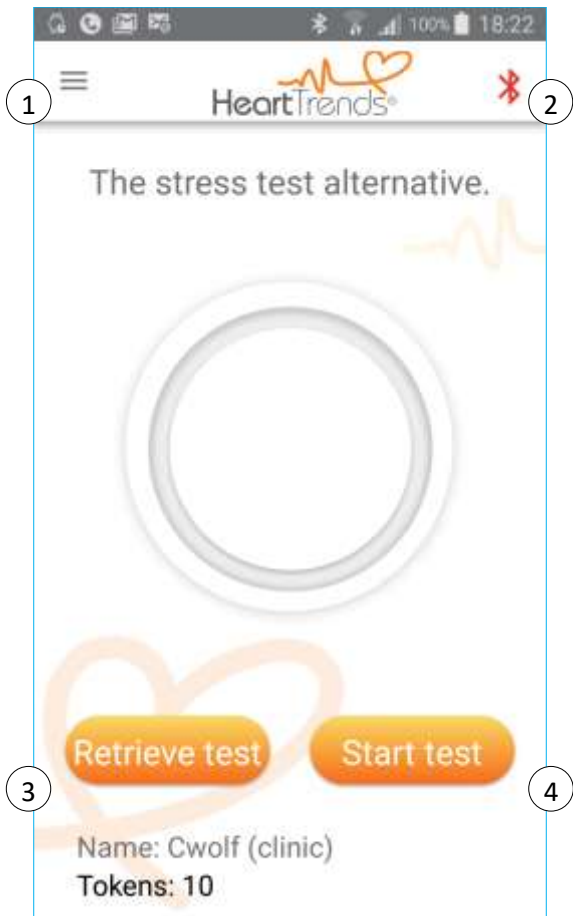
Caution: Losing the PIN used for any given test will make it impossible to recreate that Subject Name and ID.
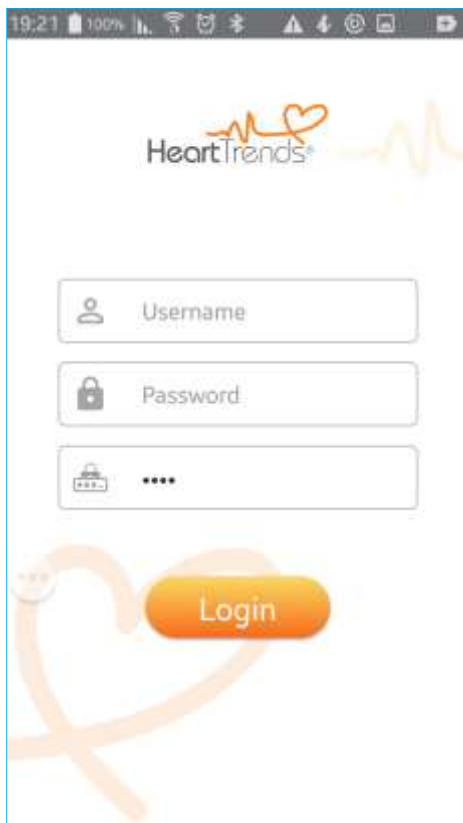
Login screen

4.3. HEARTTRENDS MAIN SCREEN

The main screen appears as follows:

Main screen

| Key to Main Screen	
1	App menu – see Section App Menu
2	Bluetooth status – see Section Connect by Pressing the BlueTooth Icon
3	Retrieve test residing on sensor – see Section *6. Retrieve the HeartTrends Test*
4	Begin a new test – see Section Perform a Test

4.4. APP MENU

The App menu ☰ in the upper left corner provides the following options:

▶	Test	Display the main screen, which allows running a new test, or viewing previous test results
⚙	Settings	View the test time, and change the belt type and language. See Section *8. The Settings Screen*.
↺	Review Test Results	View the tests already taken using the TICKRx sensor
ⓘ	Interpret Your Score	General guidance on the meaning of the test score
⇥	Logout	Exit from HeartTrends

4.5. VERIFY THE TEST TIME PARAMETER

An essential first step before performing a test is to ensure the user is aware that the **Test Time** is set to 60 minutes. This is the recommended testing time.

From the App menu, choose Settings. The Settings screen will appear:
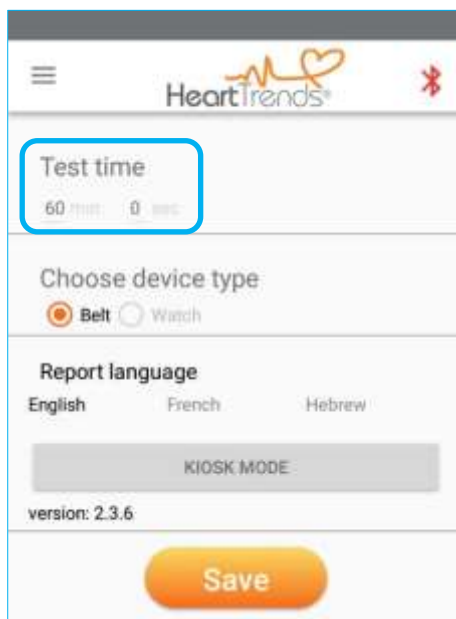
Settings screen – Verify Test Time

Press the back button to continue.

> **Note:** If Test time is less than 45 minutes (belt was removed prior to the conclusion), the system will calculate a score which may be inconclusive. It will be noted on the Test Results screen of the App. The token used for the report will be charged.

> **Note:** See Section *8. The Settings Screen* for a full discussion of the Settings screen.

5. PERFORM A TEST

Performing a test requires helping the subject put on the TICKRx sensor, connecting the App to the sensor, and using the App to enter subject information and begin the test.

5.1. SUBJECT PUTS ON THE SENSOR

The subject should put on the TICKRx sensor, following the instructions in the sensor's Quick Start Guide. Assist the subject if necessary.

Note: The TICKRx sensor must be worn directly on the chest. Do not place it on top of a shirt or other garment.

5.2. CONNECT THE TICKRX SENSOR TO THE APP

Before you can perform a test, the TICKRx sensor must be connected to the App.

The sensor can be connected two ways: by pressing on the Bluetooth icon on the top right of the App screen or by pressing the Start Test button. These two methods are described below.

Note: If the App is not connected to the TICKRx sensor, the Bluetooth icon displays as red When the sensor is connected, the icon changes to green

5.2.1. "WAKE" THE SENSOR

The sensor must be worn by the subject, as explained above. With the sensor applied to the subject, pull firmly at the straps at either end, flick the sensor with your finger, and/or unsnap and resnap the strap. One of the sensor's LEDs should blink blue, indicating that the sensor is "awake".


Pull firmly on the straps

5.2.2. CONNECT BY PRESSING THE BLUETOOTH ICON

Press on the red Bluetooth icon on the top right of the screen:

The Android Device's Bluetooth and Location Services (GPS)
must be enabled. If not, you will be prompted.

The App will show the TICKRx device that is within Bluetooth range of the Android device (about **10** meters).

> To connect, select your device
> from the following list:
>
> TICKR X 23AD
>
> CANCEL   CONNECT
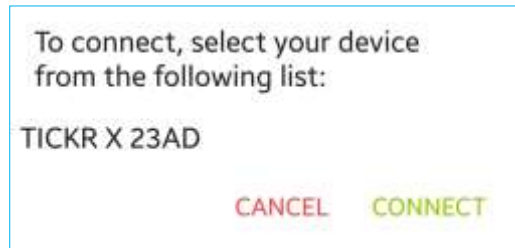
Press on the name of the TICKRx sensor in the list (TICKR X 23AD in this example), and then press on **CONNECT** to connect the App and the sensor.

Note: If there is no TICKRx sensor nearby, or the sensor is "asleep", then the App will show an animated circular arrow and an empty list:

> To connect, select your device
> from the following list:
>
> C
>
> CANCEL   CONNECT
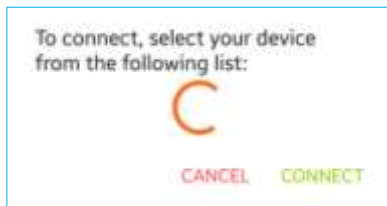
5.2.3. CONNECT BY STARTING A TEST

If you did not previously connect by pressing the Bluetooth icon, as described above, the App will automatically prompt you to connect when you start the test.

5.3. START A TEST

Press the **Start test** button to start the test.

The App will display a screen showing a list of TICKRx sensors, as explained in Section *5.2.2. Connect by Pressing the BlueTooth Icon*.
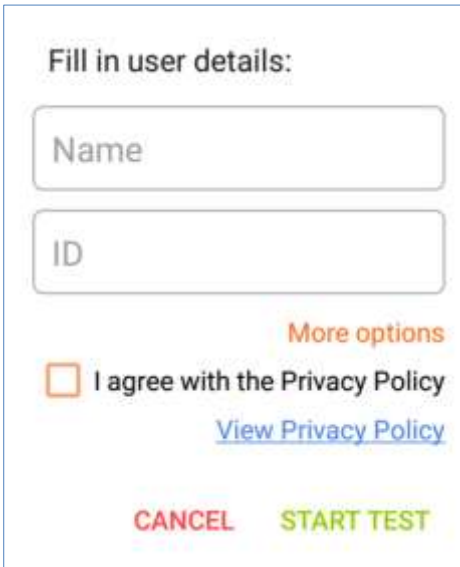
Note: If the sensor was previously connected but is now "asleep", pull firmly on the straps at either end of the sensor, flick the sensor with your finger, and or snap/unsnap the belt to "wake" the sensor.

5.4. ENTER SUBJECT INFORMATION AND BEGIN TEST

The next step is to enter the subject's name and ID into the App. Optionally, you may also enter information on the subject's medical condition.

5.4.1. ENTER SUBJECT'S IDENTIFYING INFORMATION

After you press **Start Test**, the following screen will display:

Fill in user details:

Name

ID

More options

☐ I agree with the Privacy Policy

View Privacy Policy

CANCEL   START TEST

Please enter the subject's name and ID.

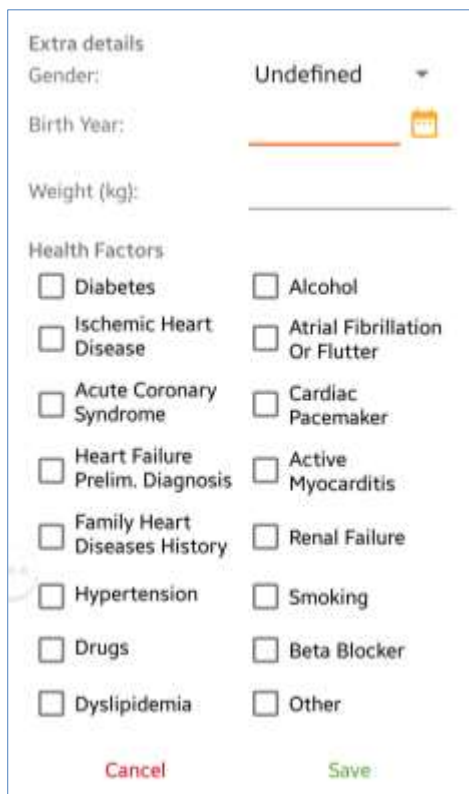You may review HeartTrend's privacy policy by pressing on the text link "View Privacy Policy".

Please check the box "I agree with the Privacy Policy".

Press **START TEST** on this screen to begin the test, or you may press **More options** to enter optional medical information, as explained below. We encourage you to enter the optional medical information since it cannot be entered once the test has begun.

5.4.2. ENTER SUBJECT'S MEDICAL INFORMATION (OPTIONAL)

If you pressed **More options**, a screen allows you to enter medical information for the subject:
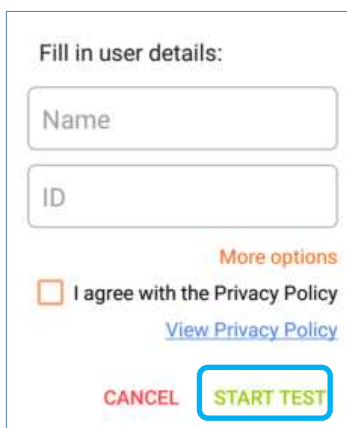

Press **Save** to update the App with this information. Press **Cancel** to discard any changes you made on this screen.

> **Note:** Entering medical information about the subject is optional. This information is solely for the purpose of helping the user to evaluate the result in the HeartTrends Report. We strongly recommend filing in this information to maximize subsequent medical evaluation of the subject. At no time is any subject name or subject ID shared or sent to any location outside of the Android device.

The previous screen will redisplay:

Press **START TEST** to begin the test.

6. RETRIEVE THE HEARTTRENDS TEST

This Retrieve Test function will check for the existence of an unanalyzed test residing on the heart rate recorder sensor. This is typically useful if the user obtained a dormant heart rate sensor and is unsure if an unanalyzed test exists on the sensor.
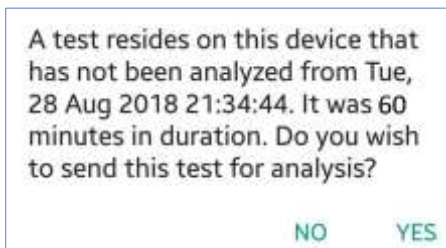
6.1. RECONNECT THE TICKRX SENSOR TO THE APP AND REQUEST THE REPORT

Note: If the sensor stayed within Bluetooth range during the entire test (the subject did not move more than **10** meters from the Android device), it is not necessary to reconnect the sensor. The HeartTrends Report, as shown in Section *6.3. View the HeartTrends Score*, will display as soon as the Test Time interval has expired.

If it is necessary to reconnect the sensor to the App, follow the directions given in Section *5.2.1. "Wake" the Sensor* and Section *5.2.2. Connect by Pressing the BlueTooth Icon*.

A screen similar to the following will display:

A test resides on this device that has not been analyzed from Tue, 28 Aug 2018 21:34:44. It was 60 minutes in duration. Do you wish to send this test for analysis?

NO   YES

Press **YES** to request the submit HeartTrends test for analysis. Note that this uses one test token.

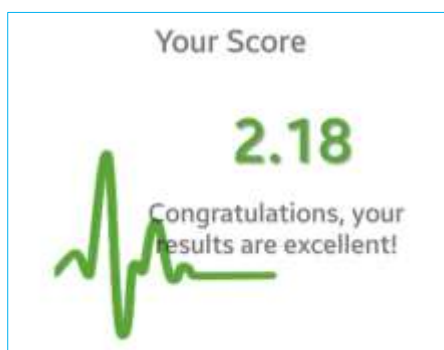### 6.2. INTERMEDIATE SCREENS

While the test is being processed, some intermediate screens may display momentarily:

Retrieving your data

Please wait...

Sending data to the server

Please wait...
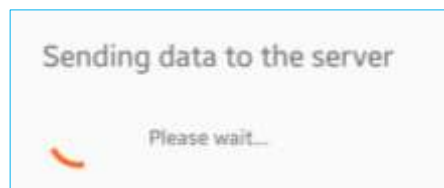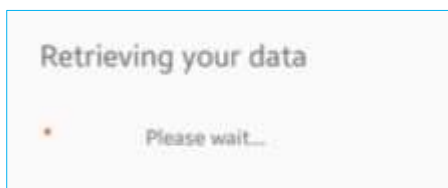
6.3. VIEW THE HEARTTRENDS SCORE

The HeartTrends report will appear as follows:

Your Score

2.18

Congratulations, your results are excellent!

HeartTrends Report, Showing Dy/Dx Indicator Value

6.4. ANALYZE THE HEARTTRENDS TEST RESULT

Caution: The test score is only one of many factors relating to subject health and must be interpreted by a physician.

Following are some general examples of test scores:

- Scores greater than 2.0 are indicative of being healthy
- Scores less than 2.0 may occur if the subject was too active or stressed
- Suggest having the subject repeat the test in a quieter and more sedentary surrounding
- If the second test is also below 2.0, suggest that the subject consult their physician

Note: There is no charge (the test token is not used) if the score is less than 2.0.
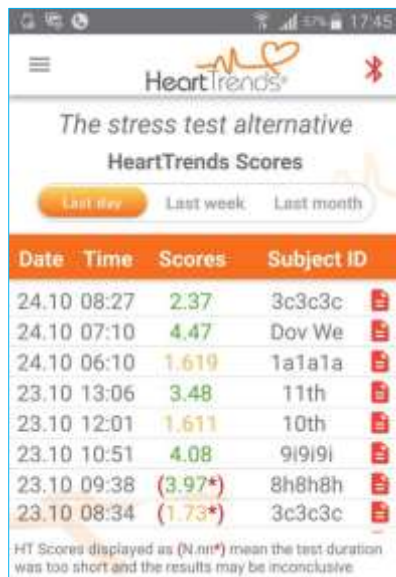
7. REVIEW PREVIOUS HEARTTRENDS REPORTS

HeartTrends reports that were created previously on the Android device can be retrieved via the
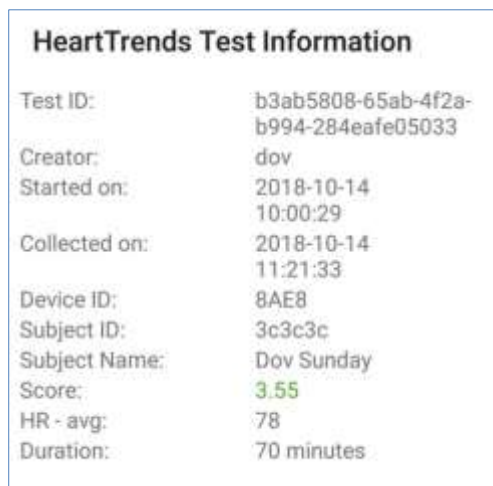**App menu** ☰
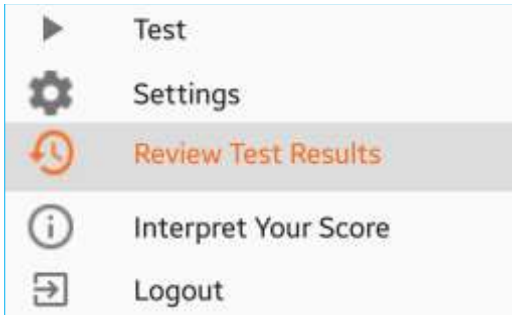
App menu

Press the **Review Test Results** option. A list of previously generated HeartTrends reports will display:

List of previous reports

Press on any line to see the test information or on the icon for a print-ready report.

Test Information for a Report

## 7.1. DATA COLLECTION AND PRIVACY

For each HeartTrends Report, HeartTrends requires the basic information of subject ID and subject name. Additional optional information may be provided by the user if desired, such as gender, weight, and other medical information relating to cardiac risk factors.

It is important to note that no personal subject information is transmitted outside of the HeartTrends App.
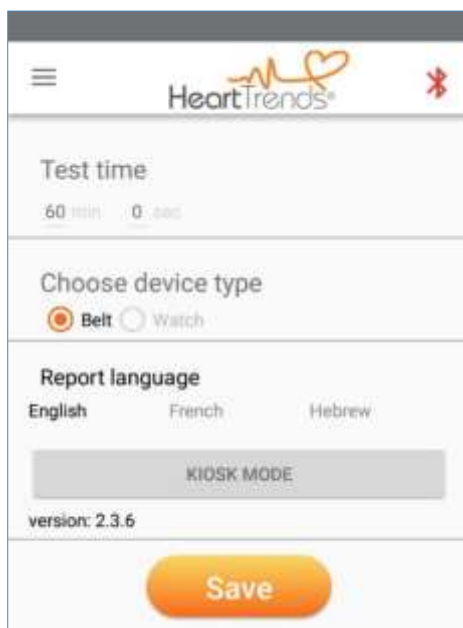
8. THE SETTINGS SCREEN

The Settings screen shows basic system parameters.

To show the Settings screen, first press ☰ view the App menu:
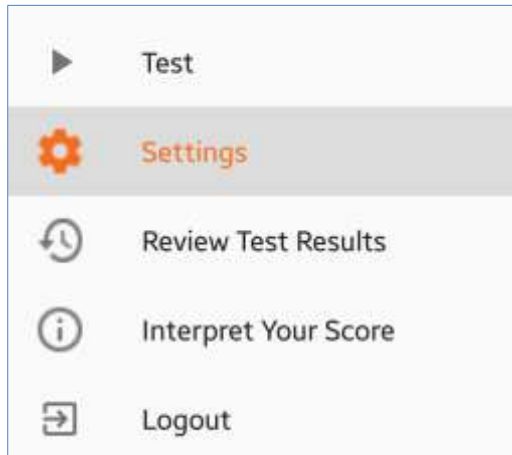
App menu

Then press **Settings** to view the Settings screen:

Settings screen

The Settings screen has the following information:

Test time – the minimum time that the TICKRx sensor must be worn in order to generate valid data for a HeartTrends report

Choose device type – the type of measuring device used to collect subject heartrate data. Currently, only the Belt (TICKRx sensor) is supported.

Report language – the language used in the HeartTrends Report

Kiosk Mode – to be used by the Installer only (see *Appendix: Installer's Guide*)

Version – the software version of the HeartTrends App

9. TROUBLESHOOTING

9.1.TROUBLESHOOTING TABLE

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

Condition	Possible Cause	Recommended Action
Insufficient/invalid data on the TICKRx Recording Sensor	Less than the minimum recording time	Record data again
Test failed to upload to server	Lack of Internet connection	Establish an internet connection and try to upload again. Data in sensor will not be deleted until successful upload to the Server.

10. MAINTENANCE AND SERVICE

10.1. GENERAL

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

10.1.1. OBTAINING SERVICE FOR THE HEARTTRENDS APP

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

For additional information, please visit our website at www.HeartTrends.com.
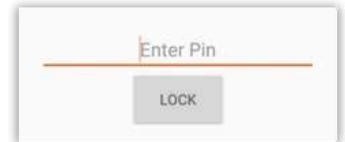
APPENDIX: INSTALLER'S GUIDE

As Installer, here are the steps required to provide a Clinic, Distributor, or Customer with an operational HeartTrends Client system.

- Provide an Android device: Samsung Galaxy T580 Tab A10.1 WiFi with 16 GB memory and 2GB RAM with the Android operating system version 6.0 or higher
- Purchase a TICKRx heart rate sensor recorder by Wahoo Fitness
- Download the HeartTrends App from the Google Play Store by searching for 'HeartTrends'
- Convert the App to Kiosk Mode*[1]

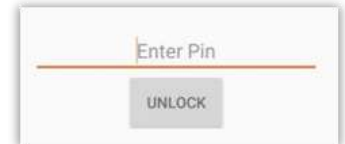|			
1. Enter the Settings screen and click on "Kiosk Mode"		**2.** Enter the PIN code "kiosk" and click on Lock.	
3. You will receive a message "Device is locked".		**4.** To exit Kiosk Mode, repeat the above and click on Unlock. (Not mandatory. Leave device in Locked mode for user.)	

- Log in to the App using your login credentials. See Section **4.2. Run the App and Log In**.
- Connect the Bluetooth to the TICKRx sensor writing down the serial number that appears on the App. See **Section 5.2.2. Connect by Pressing the BlueTooth Icon**
- Print one (1) serial number label using a Brother P-Touch label maker
  - o Attach the label to the front face of the sensor
- Logout from the App
- Bring tablet and sensor to Clinic or Distributor site
- Give the User Manual hyperlink for download
- Make sure user has received their username and password. If not, consult Administrator
- Observe the Clinic or Distributor as they login and perform the first test

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[1] **Kiosk Mode** allows a single Android application to have full control of the system. The user is prevented from leaving the current application or running other applications.