

User Manual

HeartTrends®

The *Effortless* Stress Test Alternative



Computerized Analysis of ECG Inter-beat Time Intervals



CE 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- App running on an approved Platform 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 Rate Recording Sensor worn by a subject. The App then transmits the information to the Server System. Any identifying subject information is processed in accordance to GDPR standards.

The Server analyzes the RR interval data and performs calculations that result in a Multi-Parameter Weight (MPW) indicator score value which is communicated back to the App in a PDF report.

The App then displays the result in a PDF report for the user and also stores the result on a centralized website.

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.

Physician or Technician: The person who interacts with the subject, helps the subject put on and remove the Heart Rate Recording Sensor, and uses the App to control the data monitoring/collection/analysis process.

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

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

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

HeartTrends Report: The final result of the HeartTrends system which includes the critical MPW Indicator Value (the HeartTrends Score) and is interpreted (or put into context) by a physician.

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.

Installation Guide: Intended for the Distributors, Clinics, and End-Users to select a platform and get started.

LED: Light Emitting Diode.

Platform: The smart device running the App. Typically this will incorporate either the Android or Apple operating systems.

Recorded Data: The RR Interval data recorded by the Heart Rate 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 Heart Rate Recording Sensor. The subject usually does not take the heart rate home, but remains at or near the clinic while the Heart Rate Recording Sensor is collecting data.

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

User Manual: This document – these instructions for use (IFU) – are for the doctor, technician, or any other person administering the test. No IFU is required for the subject, who is basically passive during the procedure.

Heart Rate Recording Sensor: An off-the-shelf sensor that is strapped onto the subject's body and continuously records heartrate data. The Heart Rate Recording Sensor is typically worn on a belt around the chest although it may come in the form of an authorized heart rate sensing watch, bracelet, patch, armband, or other sensor. The Heart Rate 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

HeartTrends is indicated for the screening and evaluation of at-risk populations without known CAD. This includes symptomatic subjects exhibiting one or more cardiac risk factors such as: smoking, family history, dyslipidemia, diabetes mellitus, hypertension, obesity, age (men over 40, women over 50), or other known cardiovascular risk factors. Asymptomatic subjects may also be tested as well as persons with non-cardiac Chest Pain Syndrome.

The HeartTrends software is intended for the analysis, summary and reporting of prerecorded ambulatory ECG data. It is also intended to provide measurements of MPW (Multiple Parameter Weighted) HRV. The MPW indicator value (aka HeartTrends Score) can be used as a prognostic score to assist in early 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 heart rate Recording Sensor and the HeartTrends App, can be performed by a nurse, technician, physician, authorized medical professional, or a person who has read the User Manual.

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

2.3. CONTRAINDICATIONS

HeartTrends may be applied to any individual without adverse effects. Because the accuracy of HeartTrends relies upon analysis of a *normal* heart rate unaffected by arrhythmias or other artificial stimulants, good clinical practice recommends not applying the test on the following subjects: established CAD, atrial fibrillation or flutter, diagnosis of an acute coronary syndrome or typical angina, presence of a cardiac pacemaker or arrhythmias, clinical diagnosis of heart failure, moderate or severe pulmonary disease, acute myocarditis or any presence of cardiomyopathy, clinical depression, known drug or alcohol dependence, presence of left bundle branch block, significant intra-ventricular conduction delay or significant (>1mm) ST deviations at baseline. Athletes should use a treadmill to attain true target heart rate measurements.

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 a **Heart Rate Recording Sensor**.

The purpose of the Heart Rate 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 Heart Rate 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 the Heart Rate Recording Sensor.

Using the HeartTrends App, 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 adheres to the General Data Protection Regulation (GDPR) as mandated within the European Union.

The user then assists the subject in placing the Heart Rate Recording Sensor and establishes communication between the Heart Rate Recording Sensor and the App. This is referred to as “connecting” (or pairing) the App to the Sensor.

Then, using the App, the user instructs the Heart Rate Recording Sensor to begin recording subject heart information.

After the subject has worn the Heart Rate Recording Sensor for at least 20 minutes, sufficient data has been gathered to allow analysis by the HeartTrends Server System. The user activates the App to download the heart rate data from the subject’s Heart Rate Recording Sensor which then uploads this data to the HeartTrends Server System for analysis.


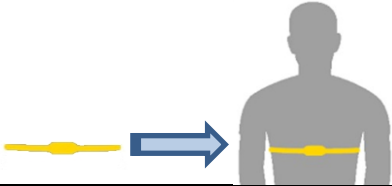


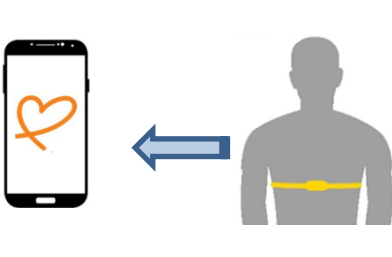




Note: If desired, the study time duration may be changed from within the Settings screen of the App. Study times less than 10 minutes will yield a zero ‘0’ result.

Through a process internal to the Server System, the subject’s heart rate data is analyzed to generate the HeartTrends Score and a subsequent Report. The user can view and email the report results from within the App (via menu item Review Test Result).

3.3.PROCESS FLOW DIAGRAM

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

<p>①</p>	<p>Set up the App on the user’s device (one-time setup by installer)</p>		<p>See Section 4. Set up the HeartTrends App.</p>
<p>②</p>	<p>Place the Heart Rate Recording Sensor on the subject</p>		<p>See Section 5.1. Subject Puts On the Sensor.</p>
<p>③</p>	<p>Connect (pair) the Sensor to the App</p>		<p>See Section 5.2. Connect the Sensor to the App.</p>
<p>④</p>	<p>Enter subject information in the App, and begin the heart rate recording process</p>		<p>See Section 5.3. Start A Test and Section 5.4. Enter Subject Information and Begin Test.</p>
<p>⑤</p>	<p>At the conclusion of the test the recorded test data is copied into the App, and sent to the HeartTrends cloud server to generate and view the Report</p>		<p>See Section 6.3. View the HeartTrends Score.</p>
<p>⑥</p>	<p>Analyze the Report</p>		<p>See Section 6.4. Analyze the HeartTrends Test Result.</p>
<p>⑦</p>	<p>Retrieve previous HeartTrends Reports and review test results, if desired</p>		<p>See Section 7. Review Previous HeartTrends Reports.</p>

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 as long as there is communications during the startup of the App.)

Each of these steps is described in detail below.



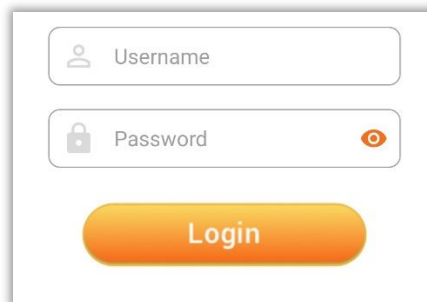
Note: The HeartTrends App requires the supplied Platform to have the Bluetooth and Location features enabled.

4.1. DOWNLOAD THE APP

Download the HeartTrends App from the Google or Apple Play Store by searching for 'HeartTrends' (with 2-'t's). Be sure to Accept all installation requests such as access to memory and location.

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. The user and password information can be obtained from your HeartTrends distributor. Pressing the "eye" icon will enable you to view the password being entered.

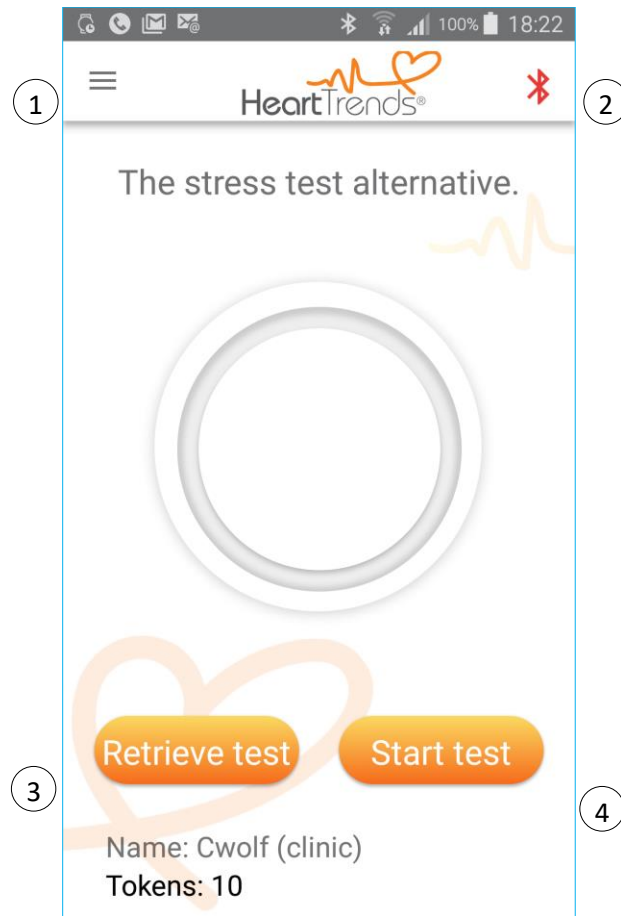


The screenshot shows a login interface with two input fields: 'Username' and 'Password'. The 'Password' field has a small eye icon to its right. Below the fields is a prominent orange 'Login' button.

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

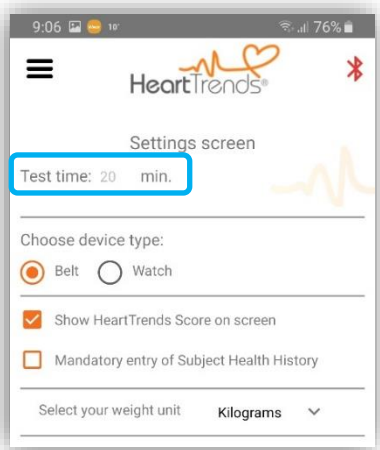
The App menu  in the upper left corner provides the following options:

 Test	Display the main screen, which allows running a new test, or viewing previous test results
 Settings	View the test time, options for data entry, and language selection. See Section 8. The Settings Screen .
 Review Test Results	View the tests already taken using the Heart Rate Recording Sensor
 Interpret Your Result	General guidance on the meaning of the test score
 About	Contains the version number, company, and certification information about the App
 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 at least 20 minutes. This is the recommended minimum testing time duration.

From the App menu, choose Settings. The Settings screen will appear:



Press the back button to continue.



Note: If Test time is less than 20 minutes (the recording sensor was removed prior to the conclusion or possibly erratic, intermittent contact between the skin and the sensor electrodes), the system will calculate a score which may be inconclusive. A score will be displayed in the Review Test Results screen of the App. A test token used for the report may 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 Heart Rate Recording 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 Heart Rate Recording Sensor, following the instructions in the sensor's Quick Start Guide. Assist the subject if necessary.





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

5.2. CONNECT THE SENSOR TO THE APP

Before you can perform a test, the Heart Rate Recording 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 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. For quick connecting, moisten the contact points on the *strap* with saliva, water, or electrode gel to improve conductivity. With the sensor applied to the subject, pull firmly on 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



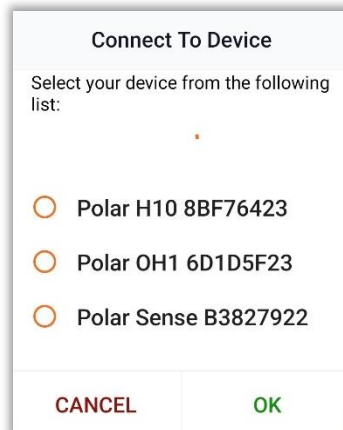
5.2.2. CONNECT BY PRESSING THE BLUETOOTH ICON

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



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

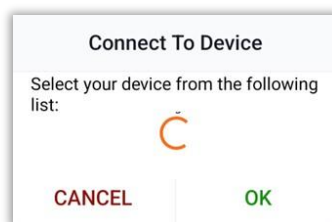
The App will show a list of sensors within Bluetooth range of the Platform (about **10** meters). As a precaution, in case there are other sensors in the vicinity, wait 60 seconds and only "wake up" the sole desired sensor by "waking" it as described above.



Press on the name of the sensor in the list (Polar H10 8BF7 in this example), and then press on **CONNECT** to connect the App and the sensor. Note: if the sensor is similar in type to a Polar Verity Sense where patient data recording occurs first, you will connect via this screen only after the data has been recorded. Take extra care to verify the sensor ID as belonging to the patient wearing the sensor. Best advice: have the subject leave the sensor on their person when connecting to the sensor device.



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

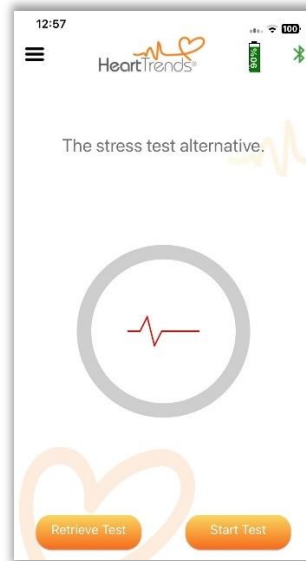


If list remains empty, the sensor may need a firmware update (Appendix IV)

5.2.3. CONNECT BY STARTING A TEST

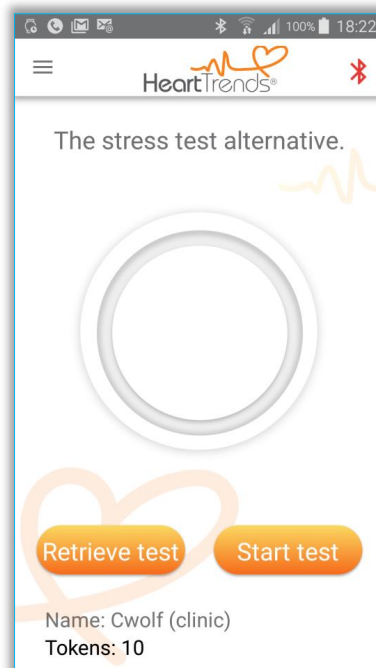
If you did not previously connect by pressing the Bluetooth icon, as described above, the App will automatically prompt you to connect when you start the test.

Heartbeat and Battery Indicators: To visually assist connection of the sensor, once the Bluetooth connection is established, a moving heartbeat caricature is displayed indicating the presence of heartbeat. The battery charge status of the sensor is displayed vertically at the top of the screen. Both are illustrated here:



5.3. START A TEST

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



Main screen

The App will display a screen showing a list of sensors, as explained in Section **5.2.2. Connect by Pressing the Bluetooth Icon**.



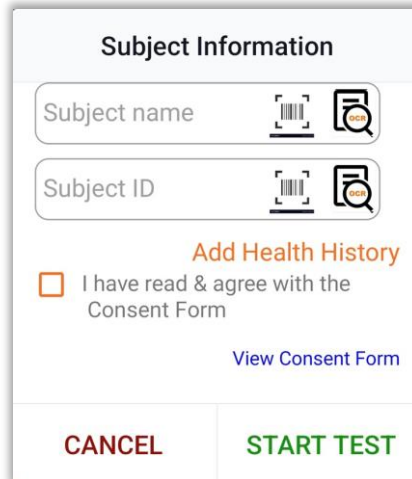
Note: Sensors typically move into “sleep” mode to conserve battery if no heart rate is detected. If the sensor was previously connected but is now “asleep”, pull firmly on the straps at either end of the sensor, flick the sensor with your finger, and/or unsnap/re-snap the belt to “wake” the sensor. It is possible that the sensor has inconsistent contact with the skin possibly due to inactivity or excessive hirsuteness.

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 health history (strongly encouraged).

5.4.1. ENTER SUBJECT'S IDENTIFYING INFORMATION

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



Please enter the subject's name and ID.

To reduce data entry errors and minimize incorrect subject identification, you may optionally enter the Subject Information via (1) Barcode (2) QR code or (3) Optical Character Recognition (OCR) by pressing the appropriate icon. Be sure to carefully, visually verify the contents of the Subject Name & ID fields displayed against the actual subject's name & ID. Be sure to grant access to the camera if prompted.

You should review HeartTrends Consent Form by pressing on the text link "View Consent Form".

Please review the Consent Form and check the box "I have read & agree with the Consent Form".

Press **START TEST** on this screen to begin the test, or you may optionally press **Add Health History** to enter optional health & clinical information, as explained below. This optional health information may be edited or corrected following the test given that it has no direct effect upon the HeartTrends calculations. Actual measurements, Subject Name & ID, and subject HeartTrends score may not be altered. See the Settings menu to prompt the user for this information entry.

5.4.2. ENTER SUBJECT’S HEALTH INFORMATION (OPTIONAL)

If you pressed **Add Health History**, a screen allows you to enter health information for the subject:

The form is titled "Subject Health History". It contains the following fields and options:

- Gender: Undefined (dropdown menu)
- Birth Year: _____
- Weight (kg): _____
- Health Factors (checkboxes):
 - Diabetes
 - Alcohol
 - Ischemic Heart Disease
 - Atrial Fibrillation Or Flutter
 - Cardiac Surgery
 - Cardiac Pacemaker
 - Heart Failure Prelim. Diagnosis
 - Active Myocarditis
 - Family Heart Disease History
 - Renal Failure
 - Hypertension
 - Smoking
 - Drugs
 - Beta Blocker
 - Dyslipidemia
 - Other

Buttons: RESET (red), SAVE (green)

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 unless desiring a prompt to remind user to enter this information from within the Settings menu. HeartTrends does not utilize this information in its calculations. This information is solely for the purpose of helping the physician to evaluate the result in the HeartTrends Report in context with the other well-known cardiac risk factors such as smoking, cholesterol, high blood pressure, etc. We recommend filling in this information to maximize subsequent medical evaluation of the subject. Handling the privacy of subject name or subject ID is in strict accordance with GDPR privacy regulations.

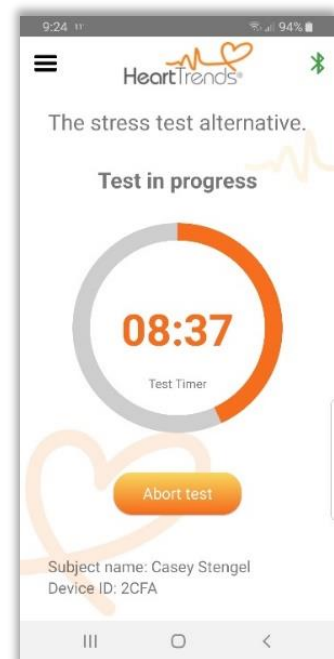
The previous screen will redisplay:

The screen is titled "Subject Information". It displays:

- Test Name: Wednesday Test
- Subject ID: 613248365
- Option: Add Health History
- Consent: I have read & agree with the Consent Form
- Link: View Consent Form
- Buttons: CANCEL (red), START TEST (blue)

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

The test may be aborted by pressing **“Abort test”** after which all test data will be erased from the recording device with no charge for 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.

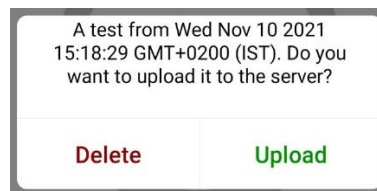
6.1. RECONNECT THE SENSOR TO THE APP AND REQUEST THE REPORT



Note: If the sensor stayed within Bluetooth range during the entire test (the subject did not move more than **10** meters from the Platform), 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**.

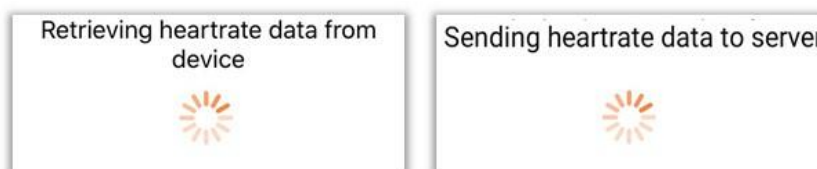
A screen similar to the following will display:



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

6.2. INTERMEDIATE SCREENS

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



6.3. VIEW THE HEARTTRENDS SCORE

The HeartTrends report will appear as shown here. If desired, the score display may be suppressed via the Settings menu.



HeartTrends Report, Showing MPW 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 put into context by a physician's diagnosis and interpretation.

Following are some general examples of test scores:

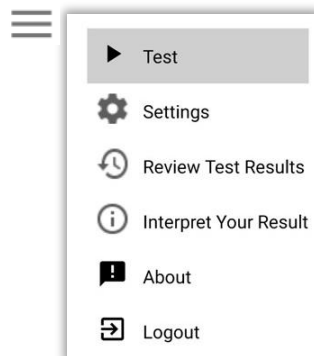
- Scores greater than 2.6 are considered a high score indicative of passing an early detection stress test and showing reduced overall cardiac risk.
- Scores greater than or equal to 2.0 but less than 2.6 are considered an intermediate score, indicative of passing an early detection stress test with little effect on the cardiac risk one way or another.
- Scores less than 2.0 are considered low and may also 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 for the second test (a test token is not deducted) if the first score is less than 2.0 provided the *identical* Name and ID are entered within 72 hours.

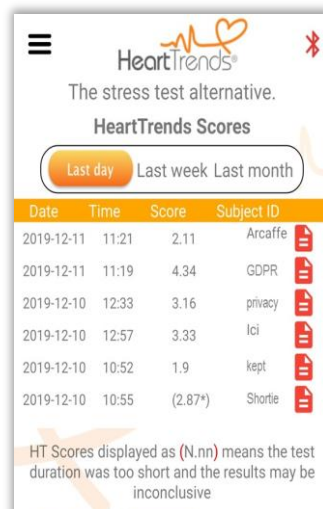
7. REVIEW PREVIOUS HEARTTRENDS REPORTS

HeartTrends reports can be retrieved via the **App menu**



App menu

Press the **Review Test Results** option. A list of previously generated HeartTrends reports will display.
Note: Only Physicians (not Technicians) will be able to view this menu item.



Date	Time	Score	Subject ID
2019-12-11	11:21	2.11	Arcaffe
2019-12-11	11:19	4.34	GDPR
2019-12-10	12:33	3.16	privacy
2019-12-10	12:57	3.33	Ici
2019-12-10	10:52	1.9	kept
2019-12-10	10:55	(2.87*)	Shortie

HT Scores displayed as (N.nn) means the test duration was too short and the results may be inconclusive

List of previous reports

Press on the icon to download a print-ready PDF report. It is also available from the Web Dashboard.

7.1. DATA COLLECTION AND PRIVACY

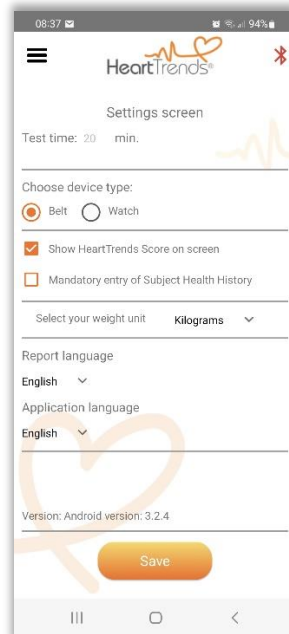
For each HeartTrends Report, HeartTrends requires the basic information of subject ID and subject name. Additional optional information may be provided by the user if desired, such as gender, weight, and other medical information relating to cardiac risk factors.

It is important to note that no personal subject information is transmitted outside of the HeartTrends System adhering to GDPR policy for data privacy. You may read more about the Privacy Policy at this link: www.hearttrends.com/privacy-policy.

8. THE SETTINGS SCREEN

The Settings screen shows basic system parameters.

To show the Settings screen, first press  to view the App menu, then press **Settings**.



Settings screen

The Settings screen has the following information:

Test time – the minimum time that the Heart Rate Recording 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.

Show HeartTrends Score on screen –displays the actual numeric score rather than “test completed...”
This is the default. If discreteness is desired, uncheck the box.

Mandatory entry of Subject Health History –to force entry of optional data for clinic records

Select your weight unit – to select between metric, imperial, and U.S. units of weight

Report language – the language used in the HeartTrends Report

Application language – the language used in the HeartTrends App

Version – the software version of the HeartTrends App

Note: When changes are Saved, any existing Bluetooth link to the sensor is disconnected but will **not** affect any ongoing recording in progress.

9. TROUBLESHOOTING

9.1. TROUBLESHOOTING TABLE

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

Condition	Possible Cause	Recommended Action
Heart Rate Recording Sensor fails to connect (pair) to the Platform	Poor contact between the sensor and the skin	<p>Moisten the 2 contact points on the strap with saliva, water, or electrode gel to improve conductivity. (Especially useful for hirsute individuals.)</p> <p>Make sure the Sensor is sitting snugly and directly on the skin and not over a garment or shirt.</p> <p>For smartwatch, bracelet, or armband users, ensure the strap fits snugly around the wrist or arm.</p>
Wahoo TICKRx Heart Rate Recorder fails the Bluetooth connection after selecting from Connect to Device window	Firmware needs to be updated	See Appendix IV
<p>Polar OH1 armband not recording</p> <p>or</p> <p>Repeated message stating that Polar sensor connected to another device.</p>	Requires manually Starting and Stopping the heart rate recording by pressing the silver button twice or sensor's Bluetooth is not connected.	See Appendix V
Zero score reported. Insufficient/invalid data on the Heart Rate Recording Sensor.	Less than 10 minutes of net recorded heartbeat data were found on the sensor. There is possibly intermittent and/or poor contact between the sensor and the skin.	Be sure the device sensor is secured snugly around the chest or arm. Record data (repeat test) 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 your distributor; or the Lev EL Diagnostics of Heart Diseases Ltd. Website: www.hearttrends.com/contact; or directly via email at info@LevHM.com

For the ability to download additional copies of the User Manual, please visit the Clinics tab on our website at www.hearttrends.com/clinics where the most current version is available for download. Older, archived copies may also be downloaded at the same location.

Should you desire a printed copy of the User Manual, please contact your distributor or contact us directly at info@LevHM.com.

Subjects being tested who encounter a serious incident that has occurred in relation to the device should report it to the local distributor, to Lev-EL ([see](#) above), and to the Competent Authority of the Member State in which the subject is located.

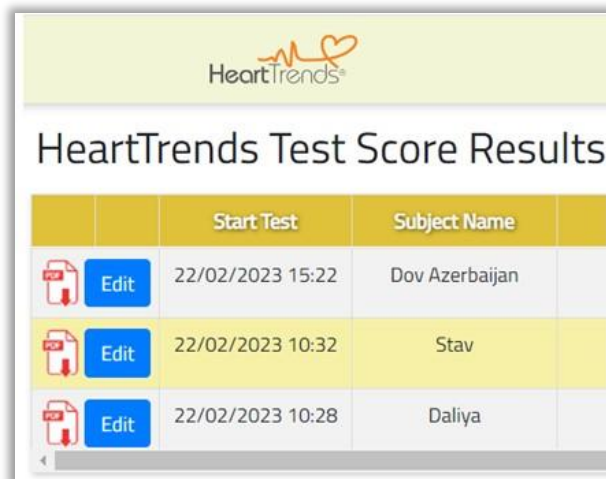
11. WEB DASHBOARD


11.1. GENERAL

Intended for large clinics and distributors to manage all the tests performed within the organization from a single location. With this Web Dashboard, users may request old HeartTrends reports, sort subjects by various criteria, and obtain a spreadsheet suitable for further, in-depth, data analysis or integration into electronic patient records.

11.1.1. ACCESSING THE WEB DASHBOARD

1. Web Dashboard login is accessed via the Clinic tab on the HeartTrends website: www.hearttrends.com/clinic-login. Use the same Username and Password as used for the smart device app.
2. Users wishing to print reports a) select the report language desired and b) click the PDF icon whereupon the desired PDF report will be downloaded to the default download folder.
3. To analyze and back up all the test results in a single Excel spreadsheet file, press <Save> at the bottom of the table. **Note:** Personal Data (Subject Name and ID) will be *automatically deleted after 6 months (if not set for sooner)*. Managers are responsible for backups.



		Start Test	Subject Name
	Edit	22/02/2023 15:22	Dov Azerbaijan
	Edit	22/02/2023 10:32	Stav
	Edit	22/02/2023 10:28	Daliya

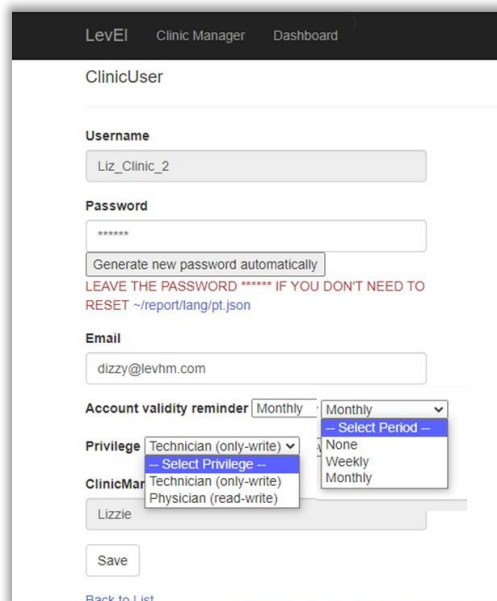
11.1.2. ADMINISTRATOR ACCESS PRIVILEGES TO WEB DASHBOARD

The following are options available to the account administration from the Web Dashboard:

1. Administrators (typically a Clinic Manager) create & close User accounts from this site: www.hearttrends.com/distributor-secure-login using their Administrator/Clinic Manager username and password.
2. GDPR actions: In compliance with GDPR policy, there are two user privileges in the system: (a) **Physicians** (Read/Write) who may both generate tests and retrieve test results from either the Dashboard or the Review Test Results menu item on the App. (b) **Technicians** (Write-Only), who may only generate tests but do not have the ability to review test reports nor access the Dashboard.
3. In further compliance with GDPR privacy policy, Subject Name and Subject ID are the only 2 items (“Personalized Data”) stored in a separate and secure database. This database is

maintained for a default period of 180 days after the test to enable users to obtain back copies of test reports. After that the personal information will be erased and only the anonymized data will be retained. It will not be possible recreate a personalized patient report after that period.

- a. Customize Personalized Data Retention Time/Clinic: Optionally, the Clinic Manager may select a shorter time period ranging from 1 to 180 days in which to have the Personalized Data deleted. This is accessed from the Clinic Manager's Settings menu
4. Enabling Optimal Levels of Cyber Security:
- a. Administrator / Clinic Manager should be the sole person using Clinic Manager Username & Password. It should not be shared with or used by any other personnel in the Clinic.
 - b. To provide the highest level of cyber security, Clinic Manager should then create individual Clinic User accounts assigning (1) a unique Clinic Username, (2) password (which may be changed by the Clinic User, (3) a unique email address for the Clinic User, (4) the Privilege of the User (described in 2. above), and (5) designate an Account Validity Reminder interval.
 - c. In the event of employee departure or device theft, the Clinic Manager may immediately change or delete the individual account in question, thereby disabling any further access by an individual or device.
 - d. The Clinic Manager may request an automatic message called **Account Validity Reminder** for a periodic reminder and review of all accounts.



LevEL Clinic Manager Dashboard

ClinicUser

Username
Liz_Clinic_2

Password

Generate new password automatically
LEAVE THE PASSWORD ***** IF YOU DON'T NEED TO
RESET ~/report/lang/pt.json

Email
dizzy@levhm.com

Account validity reminder Monthly Monthly
-- Select Period --

Privilege Technician (only-write) -- Select Privilege --
None
Weekly
Monthly

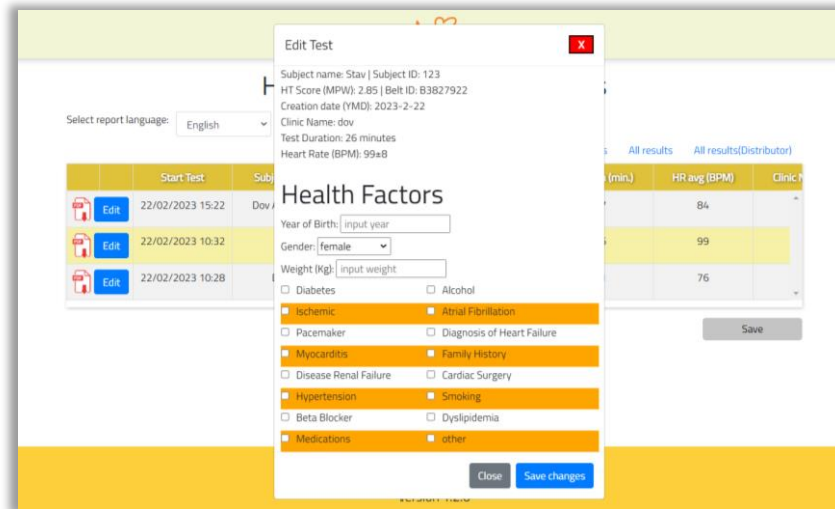
ClinicMar Technician (only-write)
Physician (read-write)
Lizzie

Save

[Back to List](#)

5. **Add Personalized Logo to HeartTrends Report:** Clinic Manager's may optionally append a logo of their choice to each page of the HeartTrends Report. Simply press the More Settings menu and add any JPEG file up to 1 Mbyte in a square (500x500 pixel) format.
6. **Secure Upload of HeartTrends Result into Electronic Medical Records:** To send HeartTrends data securely into 3rd party patient records, select the HL7 option in the More Settings menu where you will enter the secure IP Address of the secure server. All patient test data, (not the PDF file) will then be transmitted to this address in addition to the normal PDF files generated by the App.

- Post-Test Editing of Subject Health History:** Any user with read-write privileges may alter and update the Subject Health History after the test was completed. This is useful if a test was performed and the Health Factors were not entered at the time of the test. Data such as Subject Name & ID, HT Score, and other such data may *not* be altered post-test. Just press Edit next to the desired report to make the alterations you require. After visually verifying the changes, press Save Changes when done.



APPENDIX I: INSTALLATION GUIDE

Here are the steps required to provide a user (Clinic, Distributor, or Customer) with an operational HeartTrends Client system.

- User should select a smart device platform.
 - a. If an Android device is chosen, ensure it supports Bluetooth Low Energy (BLE), has WiFi, and GPS, a minimum of 16 GB memory, and 2GB RAM with the Android operating system version 14 or higher.
 - b. If iOS is selected be sure it is iOS 17 or higher.
- Purchase a qualified Heart Rate Recording Sensor (for example: Polar H10, Verity Sense, or OH1)
- Download the HeartTrends App from the Google or Apple Play Store by searching for 'HeartTrends' (with 2 't's')
 - a. Be sure to Accept/Confirm all installation requests such as access to memory and location.
- Log in to the App using your account login credentials provided by your Distributor or Clinic Manager. See Section **4.2. Run the App and Log In.**
- Connect the Bluetooth to the Heart Rate Recording sensor writing down the serial number that appears on the App. See **Section 5.2.2. Connect by Pressing the Bluetooth Icon**
- Suggestion: Print one (1) serial number label using a Brother P-Touch label maker or similar
 - Attach the label to the front face of the sensor to keep from confusing several heart rate recorders at once.
- See the Quick User Guide, viewed and downloadable from the HeartTrends website: www.hearttrends.com/quick-user-guide

APPENDIX II: WEB DISTRIBUTOR & CLINIC MANAGER GUIDE

For distributing and managing Examination Test Tokens, adding new clinics, individual users, revoking privileges and maintaining privacy.

ACCESS

Distributors and Clinic Managers may login to the Web Client account from the Distributor tab of the HeartTrends website: www.hearttrends.com/distributor-secure-login using the same username and password that was assigned for the App. Inactivity of more than 10 minutes will log out the user.

TASKS

From this platform, Distributors create Clinic Administrators/Managers. Clinic Administrators can create Clinic Users. The Distributor assigns Examination Test Tokens from their pool of tokens. The only difference being that all Clinic users share the same pool even when creating new Clinic Users.

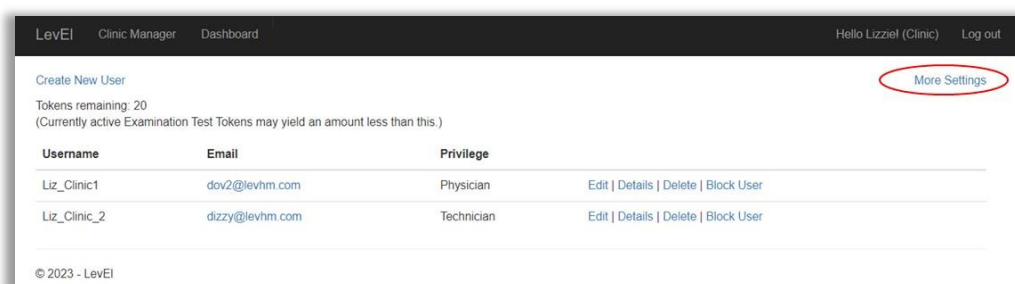
1.1. Distributor Functions

- 1.1.1. Check Examination Test Token Surplus Pool
- 1.1.2. Create a New Clinic (i.e., Clinic Manager)
- 1.1.3. Assign Test Tokens from the Surplus Pool
- 1.1.4. Edit Clinic access details including Username, Password, Contact email for low token notification
- 1.1.5. Block Clinics in case of dispute, non-payment, or violation of CE/GDPR regulations

1.2. Clinic Manager Functions

- 1.2.1. Check Examination Test Token Surplus Pool
- 1.2.2. Create Clinic Users (Username should be one word only. No spaces)
- 1.2.3. Set Account Validity Reminder in cases Users leave the Clinic in order to delete them from the account
- 1.2.4. Assign Privilege: Either Physician (Read/Write) or Technician (Write-only)
- 1.2.5. Add a Personalized Logo to the HeartTrends Test Report
- 1.2.6. Customize Personalized Data Retention Time per Clinic
- 1.2.7. Secure Upload of HeartTrends into Electronic Medical Records using HL7
- 1.2.8. Edit Subject Health History Post-Test

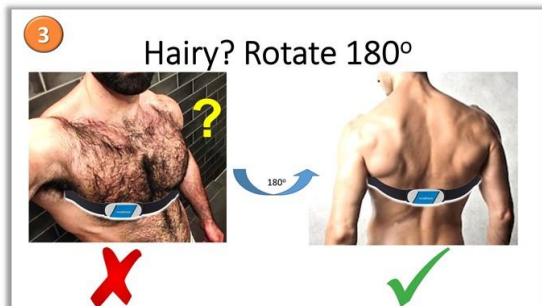
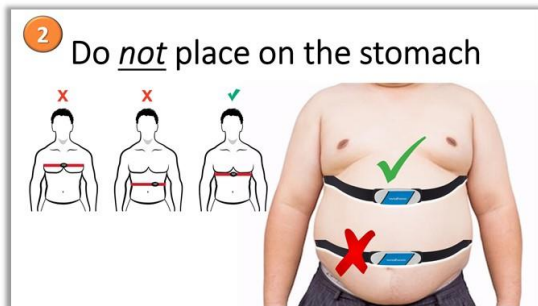
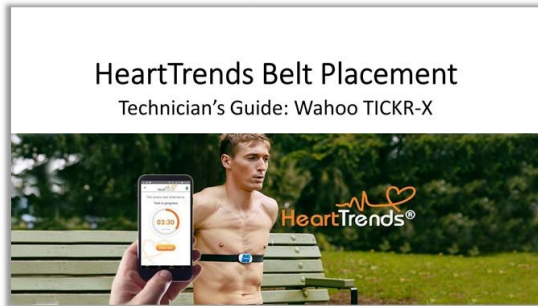
See Chapter 11 for a more detailed explanation of the Clinic Manager functions.



APPENDIX III: TECHNICIAN GUIDE FOR PROPER CHEST BELT PLACEMENT

A heart rate recorder should be placed snugly across the xiphoid sternum of the chest to minimize piezo-electric noise which could generate false heartbeat artifacts. Proper placement of the Heart Rate Recorder is graphically depicted here ensuring the highest quality recording.

HeartTrends Belt Placement



APPENDIX IV: UPDATE FIRMWARE OF TICKRx HEART RATE RECORDER

If, when selecting the TICKRx (Gen2) heart rate recorder from the Connect to Device list, the device fails to connect, a message will appear stating that the firmware needs to be updated using the Wahoo Fitness app and follow these instructions.

TO PERFORM A FIRMWARE UPDATE ON A NEW (NEVER-PAIRED) TICKRx Gen 2 SENSOR:

1. Download the "Wahoo Fitness" app for [iOS](#) or [Android](#) from the Play Store to your smart device.
2. Install the app -- Enabling *all* permission requests
3. Select "Skip" (no need to register or login)
4. **Power on** and/or wake your sensor (by touching the contact points for TICKR), ensuring the LED lights flash, then **follow the prompts to pair or link sensors**, then **add a new sensor**.
5. Select **Setup Wizard** to set up your new sensor.
6. Simply select **Install Update** to begin!



TICKRx (Gen 2) Heart Rate Recorder

APPENDIX V: POLAR OH-1 INSTRUCTIONS OF USE

The Polar OH1 optical armband requires the manual initiation of Start and Stop heart rate recording. This initiation is accomplished by pressing the silver button twice...rapidly. Tests begin in Standby Mode and record heart rates in Record mode. See the summary table below.



Note: there is no tactile feedback from the silver button, thus requiring visual verification of the green flashing light after each action. Flashing twice per second means it is in recording mode. Flashing once per second indicates Standby mode. Also, take care not to lose the miniscule USB charger. They are light and easy to misplace.

Polar OH-1 armband Manual Start/Stop required





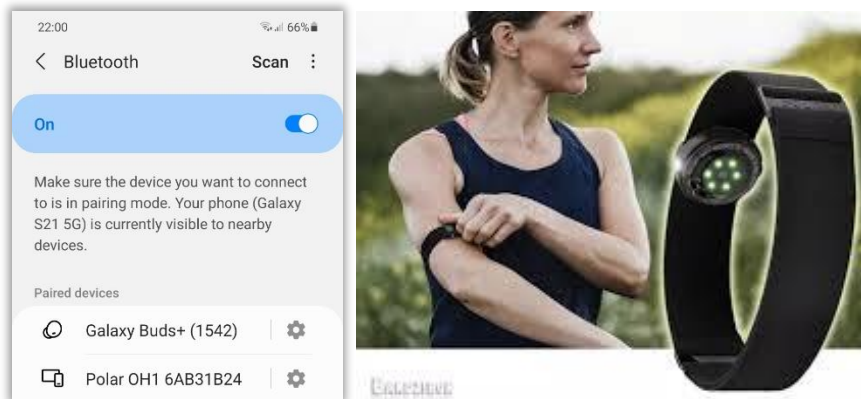
SILVER BUTTON
On/Off -- Record Start/Stop

LED STATUS INDICATOR

FUNCTION	SILVER BUTTON ACTION	LED FLASHING
ON (standby) / OFF	Long press	Once/second
RECORD start	Press twice (x2) quickly	Twice/second
RECORD stop	Press twice (x2) quickly	Once/second
Low battery	----	Green + Red



Note: Occasionally repeated attempts to connect the Polar OH1 sensor may yield the following message: **“Connection Problem: The Polar sensor may be connected to another device”** Keep retrying a few more times and verify that the sensor is truly is *not* connected to another device. If the problem persists, try unpairing the sensor from within the smartphone’s generic Bluetooth Settings menu (below) and pressing the small Settings icon on the right next to the sensor in question.



APPENDIX VI: POLAR VERITY SENSE INSTRUCTIONS OF USE

The Polar Verity Sense is the next-generation of Polar’s optical heartrate sensing armband. Polar has altered its operation such that recording of a subject’s heart rate takes place **first** (**GREEN** Mode) after which, at the end of the recording period, the test data gets downloaded (**BLUE** Mode) and assigned with a Subject Name and ID. The Verity Sense sensor requires manually starting and stopping of the recording accomplished by long-pressing the silver button. See the summary table below. You can only switch modes by first powering-off the sensor and then powering it back on. Working with the Verity Sense out of the box, power-on the sensor and connect to the App by pressing the Bluetooth icon.



Take care not to lose the miniscule USB charger. They are light and easy to misplace. Do not re-enter Record (green LED) Mode more than once. Each time you put the sensor into Record Mode, any previous recordings will be erased. Suggestion: when terminating Record Mode, give the button a **long** press to ensure power-off in which recording ceases.



Person receiving the test data from this device should carefully verify from whom the device was removed by recording the Subject Name & ID into the App as soon as possible.

8. Polar Verity Sense armband

A. Record B. Retrieve/Assign Test

A. Record Heart Rate:

1. Power-on Verity Sense - long-press the silver button
2. Enter Record Mode* - *quickly* press silver button until the LED lights up **GREEN**

B. Retrieve Heart Rate Recording & Assign Test:

1. Test complete? Power-off Verity Sense (long-press the silver button)
2. Power-on via the silver button. LED will turn **BLUE** for Playback Mode
3. Connect to Bluetooth & App

SILVER BUTTON LED STATUS INDICATOR
PRESS BUTTON TO SEE LED

FUNCTION MODE*	SILVER BUTTON ACTION	LED COLOR
Heart rate/PLAYBACK	Long press for power-on/off	BLUE (default)
RECORD Start	Press once <i>after</i> power-on	GREEN
RECORD Stop	Long press (power-off)	None
Swim (not relevant - restart)	Power-off	WHITE
Low battery	----	RED blinking

* - 1st time use: Use App Bluetooth to connect Verity-Sense & follow instructions
Mode can only be changed by powering the sensor OFF and then ON again

