TELTONIKA | Telemedic

TELTOHEART

INSTRUCTIONS MANUAL

Disclaimer

The manufacturer makes every effort to accurately depict the colors and designs of its products. The actual color and (or) design of a product may differ from the images displayed. Every display device has its own capability of displaying colors and each person may perceive those colors differently.

The manufacturer will not be held responsible for any differences that are not due to factory faults. By making a purchase, the customer acknowledges and accepts the potential for slight variations between the actual product and its representation.

The images and illustrations depicted in this user manual serve as mere examples and might vary from the actual appearance of the product. The design and technical specifications of the product are subject to potential changes without prior notification.

Should there be a serious incident or undesirable side effects during handling and use of the product which are not specified in these instructions for use, please report these to us with a detailed description of the incident or side effects. Please use the contact details below for this purpose.

When utilizing the product, it is essential not only to read the instructions but also to keep them for future reference.

Information about the product and the manufacturer

TeltoHeart

A product of

TELTONIKA TELEMEDIC UAB

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www.teltonika-telemedic.com

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Manual version: 6.0

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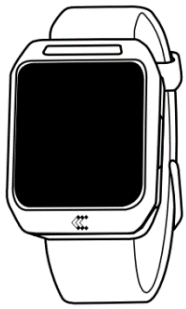
1 Scope of Delivery

1.1 Standard Scope of Delivery

TeltoHeart is supplied with charging dock which is powered via USB connector with 5 Vdc USB Type-C.

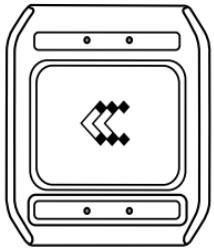
1x TeltoHeart

Heart monitoring bracelet.



1x Charging dock

USB-C charging dock that charges via USB connector via 5Vdc.

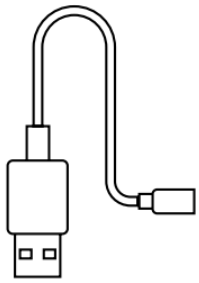


1x Short user instructions*

Short instructions providing essential knowledge.

1x USB-A to USB-C* cable

Cable for connection to charging dock.

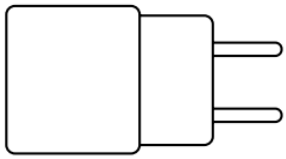


1x Quick start guide

User instructions with easy to understand illustrations.

1x USB-A charger*

EU Wall charger.



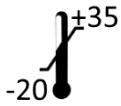
** Items marked with an asterisk (*) depend on the ordered complectation.*

The most recent version of the instructions manual is available on https://wiki.teltonika-telemedic.com/view/TeltoHeart_manuals

2 Product Description

TeltoHeart is a wearable device designed to monitor your heart health. It features ECG and heart rate measurement capabilities, providing accurate and reliable data on your heart's well-being. With the TeltoHeart application, you can transfer data collected by TeltoHeart to the TeltoCare medical platform, offering a comprehensive view of your heart health. This data helps track your heart health and assists medical practitioners in identifying potential issues.

2.1 Labeling

Symbol	Significance
	CE label
	FCC label **FCC ID:** 2BAIF-ECG200
	UKCA label
	**IP protection class:** 67 The first digit indicates the level of protection against solid objects and the second digit indicates the level of protection against liquids.
	Read the instructions for use
	Type BF applied part This device includes components classified as Type BF, meaning they are designed for direct contact with the patient and offer enhanced protection against electrical shock.
	Consult instructions for use
	Temperature limit • Extreme low (left below): -20°C • Extreme high (right top): +35°C
	Humidity limitation • Extreme low (left below): 15% • Extreme high (right top): 90%

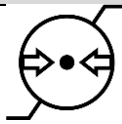
Symbol	Significance
	Atmospheric pressure limitation • Extreme low (left below): 700 hPa • Extreme high (right top): 1060 hPa
	**Manufacturer** Product manufacturer identification.
	**Do not dispose in trash.** (Required for products containing batteries of any kind, bars under the dustbin indicate products placed on the market after 08/2015)

Table 1: Labelling

2.2 Intended Use / Intended Purpose

This medical device, MyHealth app is intended to be used for patient heart monitoring in hospital and home environments. Heart monitoring functionality consists of:

- Automatic recording of heart rate extrapolated from PPG signal;
- Detection of suspected atrial fibrillation from PPG-based AF algorithm;
- Manual 6-lead ECG recording using physical electrodes.

Heart rate and rhythm data is interpreted by an algorithm which detects atrial fibrillation and alerts patient if any are detected by way of notifications on the device. Electrocardiogram (ECG) is recorded manually by the patient and can be sent to their medical practitioner (e.g. cardiologist or other qualified medical staff) for further interpretation and help in diagnosis. The device does not diagnose any medical conditions. For more precise diagnosis it is recommended to use standalone electrocardiographs or use smart wearable data only in conjunction with additional medical examination data. The diagnosis is determined only by medical practitioner.

MyHealth app is intended for use by adults aged 22 and above.

2.3 Intended User

Intended user of the device is an adult patient with confirmed or potential atrial fibrillations and/or people who are examined for preventive purposes. Intended data users are as follows:

- patient care givers,
- patient's medical practitioners (i.e., cardiologists), general practitioners,
- call center medical operators.

2.3.1 User group – Lay persons

Typical job title(s)	Patient
demographic characteristics - age - sex - language	- ≥22 - Any - English language

expected qualification (education, degree, training)	Lay person
expected job experience (related to the product or similar/competitor's products, or IT in general)	No experience is expected
typical work environment (physical, and organizational/social)	Any, except explosive and other dangerous environments or environment with very high magnetic field
core tasks	Operate the device, record an ECG when instructed
typical equipment (used during performance of the tasks)	Smartphone and smart wearable with the MyHealth app installed on them. Computer or any device with a web browser.
expected product training	Instructions for Use

2.3.2 User group – Medical practitioner

Typical job title(s)	Medical practitioner
demographic characteristics - age - sex - language	- >18 - Any - English language
expected qualification (education, degree, training)	Medical degree in relevant field
expected job experience (related to the product or similar/competitor's products, or IT in general)	Enough experience with IT to be able to safely open PDF files, use a browser, register and log into systems.
typical work environment (physical, and organizational/social)	Any
core tasks	Getting and analyzing patient ECG, AFib and/or HR historical data, Afib burden.
typical equipment (used during performance of the tasks)	Computer or any device with a web browser.
expected product training	Instructions for Use

2.4 Medical purpose

Software of this device for over-the-counter use creates, analyses, and displays electrocardiogram and HR data, and can provide information for identifying cardiac arrhythmias. This device is not intended to provide a diagnosis.

2.5 Target groups / Intended patient population

Targeted patient population is any adult person (of age 22 or older), except patients who suffer from dementia or other cognitive inability to use the device, exaggerated emotional instability, elevated anxiety disorder which could be stimulated by the use of the device and/or patients with pacemakers or implantable cardioverter-defibrillator (ICDs), who's hearts are actively stimulated or other implanted active electronic devices. These patients are informed by way of user manual that is supplied with the device and is available online.

2.6 Safety and performance

Study was performed on population with AF (n=121), sinus rhythm (n= 95) and frequent PVC/PAC (n=128) groups. Automated algorithm was capable of detecting AF with sensitivity of 94.2% and specificity of 96.9%. If only patients with sinus rhythm in the control group were included, the sensitivity and specificity were 94.2% and 100%, respectively.

2.6.1 Diagnostic measures of automated PPG-based algorithm for AF detection

Measure	**AF vs. stable SR group (n = 216)**
Sensitivity (%), (95% CI)	94.2 (88.4-97.6)
Specificity (%), (95% CI)	100 (96.2-100)
Accuracy (%), (95% CI)	99.9 (98.2-100)
LR (+), (95% CI)	-
LR (-), (95% CI)	0.06 (0.03-0.12)
AF, atrial fibrillation; SR, sinus rhythm; LR (+), positive likelihood ratio; LR (-), negative likelihood ratio.	

2.6.2 Diagnostic measures of the 6-lead ECG of the device for the detection of AF.

Measure	**AF vs. stable SR group (n = 214)**
Sensitivity (%), (95% CI)	99.2 (95.4-100)
Specificity (%), (95% CI)	100 (96.2-100)
Accuracy (%), (95% CI)	100 (-)
LR (+), (95% CI)	-
LR (-), (95% CI)	0.01 (0.00-0.06)
AF, atrial fibrillation; SR, sinus rhythm; LR (+), positive likelihood ratio; LR (-), negative likelihood ratio.	

2.6.3 Claims/Benefits

Clinical Claims

- Continuous ppg-based monitoring – contributing to early diagnosis and timely intervention,
- Enhanced AF detection accuracy – high level of accuracy and capability to detect even brief, rare and asymptomatic AF episodes,
- Reduction of false positives – high specificity
- Patient-centered monitoring – allowing continuous monitoring during daily activities,
- Promotion of health equity – have the potential to bridge healthcare gaps in remote areas

2.6.4 Product lifetime

The product version of the MyHealth app is **reviewed** and **(if needed)** updated at least once a year, reviewing the product's functionalities and making adjustments if necessary. As the MyHealth app product is a software product, it does not have a specific product lifetime and is adjusted depending on the version released.

2.6.5 Regulations and Standards

2.6.5.1 Regulations

- MDR: 2017/745/EC+COR1+2(2019)+AMD2020 - Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices
- GDPR: 2016/679/EC - Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data

2.6.5.2 Standards

The MyHealth app complies with the following safety standards:

Standard	Title
EN 62366-1: 2015 + AC:2015 + A1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
EN ISO 15223-1:2021	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements
EN ISO 14971: 2019 + A11:2021	Medical devices - Application of risk management to medical devices
EN ISO 20417: 2021	Medical devices - Information to be supplied by the manufacturer
EN 62304 2006 + Cor.:2008 + A1:2015	Medical device software - Software life-cycle processes
Additional Standards	
ISO/HL7 27931: 2009	Data Exchange Standards - Health Level Seven Version 2.5 - An application protocol for electronic data exchange in healthcare environments
ISO TR 24971: 2020	Guidance on the application of ISO 14971
IEC TR 62366-2: 2016	Medical devices - Part 2: Guidance on the application of usability engineering to medical devices
IEC TR 80002-1: 2009	Medical device software – Part 1: Guidance on the application of ISO 14971 to medical device software
IEC TR 80002-3: 2014	Medical device software – Part 3: Process reference model of medical device software life cycle processes (IEC 62304)
ISO 81001-1: 2021	Health software and health IT systems safety, effectiveness and security — Part 1: Principles and concepts
IEC 81001-5-1: 2021	Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle
ISO 13485: 2016 + AC:2018 + A11:202	Medical devices - Quality management systems - Requirements for regulatory purposes

2.6.6 Product risk classification

On the basis of Article 2 §1 of the Regulation (EU) 2017/745 for Medical Devices (MDR), the device is considered to be long-term, active, non-invasive, medical device for prevention and monitoring.

The following MDCG guidance documents were considered for classification:

- MDCG 2019-11 "Qualification and classification of software - Regulation (EU) 2017/745 and Regulation (EU) 2017/746" (October 2019)
- MDCG 2021-24 "Guidance on classification of medical devices" (October 2021)

The classification of the device under evaluation according to Annex VIII of the Regulation (EU) 2017/745 for Medical Devices (MDR) is as follows:

- Rule: **11**
- Classification: **Class IIa**

3 Safety Instructions

It is essential to thoroughly read and understand these instructions for use, as they are an integral component of the device. It is important that these instructions are always easily accessible and ready for reference. To ensure your safety and proper use of the device, it is important to follow the guidelines and precautions outlined in these instructions. Failure to do so may result in harm or damage to yourself or the device. Therefore, it is crucial to take the time to familiarize yourself with the instructions and ensure that you understand how to use the device correctly and safely.

For your own safety please observe the following:

WARNING:

Important safety or performance information or immediate response from operator required.

Failure to follow these safety instructions could result in fire, electric shock, injury, or damage to you, or TeltoHeart or other property. Read all the safety information below before using TeltoHeart.

Table 2: Safety instructions

3.1 Safety Terms and Symbols

This section contains general warnings, contraindications and cautions that should be followed when using smart wearable under any circumstances. Additionally, relevant warnings and cautions are also included throughout the manual in the sections where they are most applicable. Notes are provided throughout the manual to give more detailed information about certain features of the smart wearable.

WARNING:

Warnings alert users to potential serious outcomes (death, injury, or adverse events) to the user or environment.

CAUTION:

Cautions alert users to exercise appropriate care for safe and effective use of the product.

Contraindication:

A contraindication is a medical or clinical factor that indicates a treatment or procedure should not be administered due to potential risks or adverse effects to the individual. It serves as a cautionary guideline to avoid harm or complications.

NOTE:

Notice: Notes provide additional guidelines or information.

3.2 Contraindications, Cautions, Warnings and Notes

3.2.1 Contraindications

Do **NOT** use the device on wounds as this may cause infection and pain. Threat the wounds first".

Patients with diseases, which manifest as skin photosensitivity should not use the device.

3.2.2 *Cautions*

Handling and Care:

Do not disassemble the device.

Follow all instructions in this manual to ensure the longest lifespan of your device and battery. Damages or poor performance caused by failure to follow warnings and instructions can void your manufacturer's warranty.

Warranty and Claims:

Any modifications, performed by third parties, will void the warranty.

Warranty claims may be excluded if you do not use and maintain the device as instructed or if you repair or modify the device yourself.

Connectivity and Data Management:

If data cannot be saved locally on your smartphone, please clear cache and try again.

The device requires a stable internet connection to function properly.

Environmental and Safety Precautions:

Avoid using TeltoHeart in sandy environments.

Do not submerge the device in salty water or any other electrically conductive liquid.

Do not use the device in MRI or CT environment.

TeltoHeart is not intended to be used underwater.

Storage:

Please store the docking station in appropriate environment to avoid magnet degaussing.

Electromagnetic Fields and Ultrasound:

Do not use the device in presence of strong electromagnetic fields.

Do not use the device near ultrasound equipment.

Cleaning and Maintenance:

Ensure that the magnetic connection of the docking station is clean of metallic bodies.

Device Usage and Limitations:

TeltoHeart is not supposed to be worn in situations where it would be exposed to strong vibrations, for example while working with rammer compactors, vibrating plate compactor machines, hammer drills, etc.

Patients with diseases, which manifest as skin photosensitivity should not use the device.

Do not paint or put stickers on your device.

Do not cause excessive mechanical strain or shock to the device.

The device may be damaged, explode, or result in a fire if too much pressure is applied to it.

The device is not intended to be put in any bodily orifice.

The device is meant to be used by adults of age 22 or older.

Use on intact skin only.

Do not use excessive force while using device. Excessive force may break or damage accessories.

Do not use the device in environment where temperature exceeds over 45°C.

The platform is not suitable for people with paralyzed, deformed arms, or absence of both arms.

We strongly advice to avoid downloading or installing firmwares found in third party sites such as forums, etc. Installing unverified firmwares will result in warranty void.

Due to excess heat battery might be damaged. If device starts heating, stop using the device immediately!

3.2.3 *Warnings*

Battery Safety:

If the device starts heating, stop using it immediately to prevent damage to the battery and other components.

Do NOT short-circuit the charging contacts. Exposing the contacts with a metallic object, such a coin, a clip or a set of keys can cause accidental short-circuiting and damage battery and other components.

Environmental Safety:

Do NOT use the device outside of operational temperature conditions, for example in a sauna.

User Safety:

Comply with all safety warnings and regulations regarding mobile device usage while operating the vehicle. While driving, safely operating the vehicle is your first responsibility. Never use your mobile device while driving, if it is prohibited by law. For your safety and the safety of others, use your common sense.

Do not perform any servicing or maintenance on the ME equipment while it is in use. Attempting to do so may result in serious injury, equipment damage, or operational failure. Always ensure the equipment is fully powered down and disconnected from all power sources before beginning any maintenance or service procedures.

3.2.4 *Note*

Operating Temperature:

Notice: Device operating temperature is -10 to 45 degrees Celsius.

Cleaning Instructions:

Notice: Please keep the device electrodes clean for best performance.

Environmental:

Notice: Usage in rain or in very humid environment is not recommended.

Account and Data

Notice: TeltoHeart application and TeltoCare share the same login details.

4 Operation

4.1 Unpacking of the Device

Handle all components with care when removing them from their packaging. Carefully inspect the components to ensure that everything listed in *chapter 1 (Scope of Delivery)* is included, and to check for any signs of damage. If any components are missing or damaged, do not proceed to use the device. Instead, contact your specialized distributor immediately for assistance.

4.2 Compatible Software

4.2.1 TeltoHeart mobile application

TeltoHeart mobile application is used to receive electrocardiogram (ECG) and Heart rate (HR) information from the TeltoHeart smart wearable and transfer the data to TeltoCare data viewing platform.

Visit teltonika-telemedic.com/products/teltoheart to download the app or scan the QR code.

Download from Apple Store

Download from Play Store

CAUTION:

For correct functioning of the system, Bluetooth connection must be established.

4.2.2 TeltoCare system

TeltoCare is used to display electrocardiogram and heart rate data collected by TeltoHeart and transmitted by TeltoHeart mobile application for further analysis and interpretation by qualified clinicians.

TeltoCare system is reachable via: https://teltocare.com

4.2.2.1 How to identify that you are entering a legitimate TeltoCare website

Check the URL: Look at the website URL to ensure that it is spelled correctly and matches the website you intended to visit. Phishing scam websites often use similar-looking URLs to trick users into thinking they are on a legitimate website.

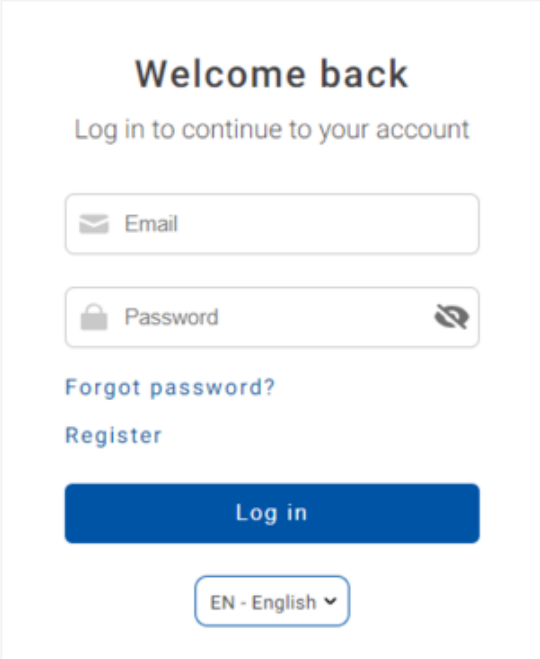
Check for SSL encryption: Look for the padlock icon or "https" in the website address to indicate that the website is using SSL encryption to secure your connection. Phishing scam websites often do not have SSL encryption or may have invalid SSL certificates.

Look for branding inconsistencies: Check for any inconsistencies in the branding, logos, or design of the website, as phishing scam websites often use inaccurate or outdated branding to appear legitimate.

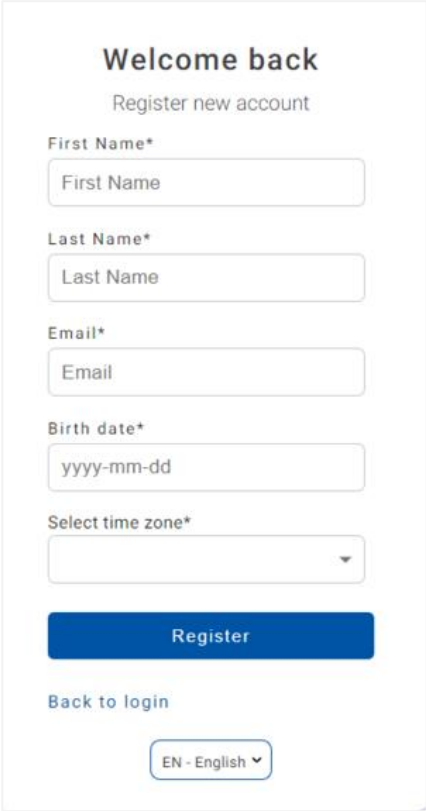
4.2.2.2 Login to TeltoCare

4.2.2.2.1 Registration

1. Visit https://teltocare.com
2. Click Register.



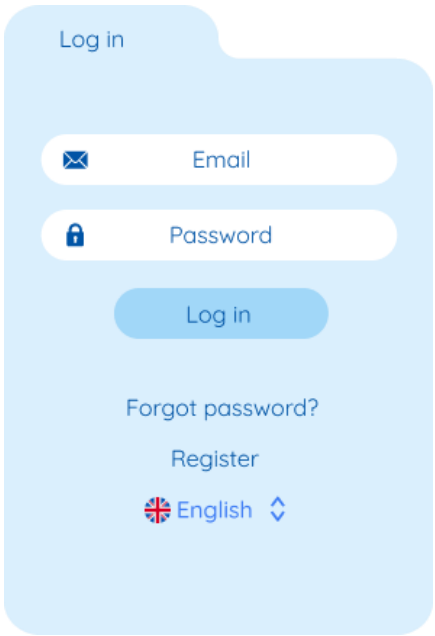
3. Fill in the required information.



4. After registration, fill in login details in TeltoHeart mobile application to Log in.

4.2.2.2.2 Login provided by clinic

1. Sign in by entering your email address and the password provided by the clinic you're associated with. Tap Log in to proceed.



2. TeltoHeart application will prompt you to change the default password to a personal preferred password of your choice.

3. Once you have successfully changed your password, the next step is to review and accept the Terms and Conditions. You will be prompted to acknowledge and agree to the Terms and Conditions and Privacy policy before proceeding.
4. Once signed-in, TeltoHeart application will ask for Bluetooth permissions. Tap Allow to let the application use Bluetooth connection.

CAUTION:

If the system is unable to communicate with the server, try again later.

4.2.2.3 Compatibility

Computer or any device with a web browser is compatible with:

- Mozilla firefox browser v114 or newer
- Google chrome browser v100 or newer
- Safari browser v16.5 or newer

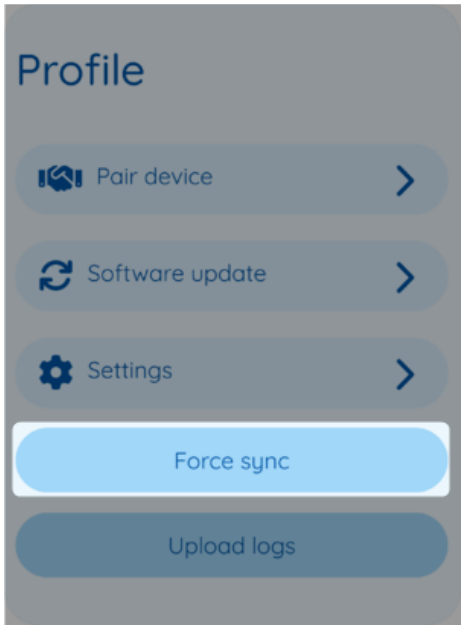
Notice:

- Using a browser version earlier than specified might result in reduced functionality or compatibility issues.
- If you are using a different browser not listed here, you might experience compatibility issues. We recommend switching to one of the supported browsers for a better experience.
- Always ensure that your browser is up-to-date for the best security and performance.

4.2.2.4 Data transfer to TeltoCare platform

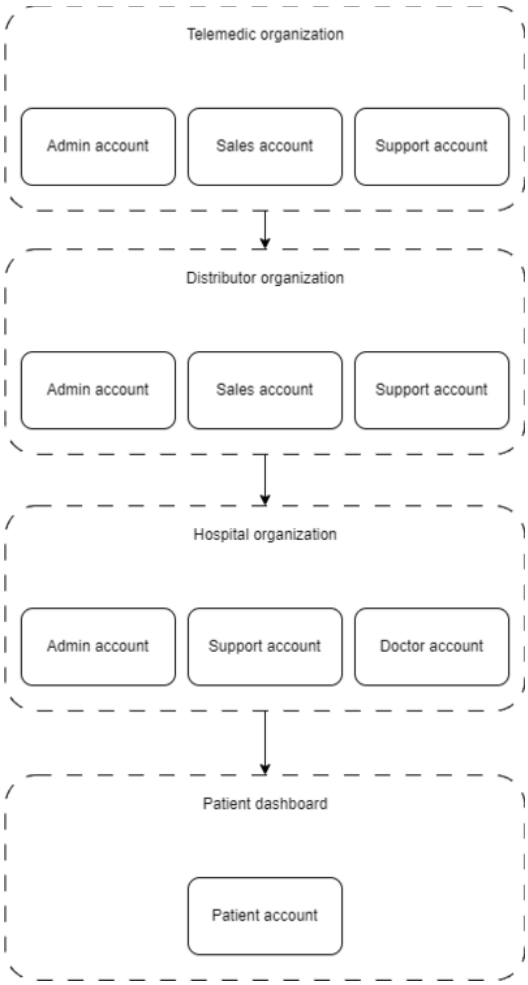
When the TeltoHeart mobile application is running in the background, data collected by the TeltoHeart smart wearable is scheduled to transfer to the TeltoCare web platform automatically on an hourly basis. This automatic transfer ensures that your health data remains up-to-date and readily available for analysis and management on the TeltoCare platform.

Additionally, users have the option to manually initiate a data sync through the TeltoHeart mobile application. By tapping the **Force Sync** button within the app, users can trigger an immediate transfer of collected data to the TeltoCare web platform. This feature provides users with control over the timing of data transmission, allowing them to ensure that their latest health information is promptly uploaded, regardless of the scheduled hourly transfer.



4.2.2.5 TeltoCare roles and environments

TeltoCare offers various environments and roles tailored to meet specific client needs. This setup allows clients to effectively manage user access and operations within the platform.



4.2.2.5.1 Distributor Environment

4.2.2.5.1.1 Distributor Admin

As a Distributor Admin, you manage user accounts within the distributor environment, including creating, deleting, and modifying permissions. You handle distributor and hospital information, oversee administrative tasks, and ensure that the distributor's operations run smoothly.

Permissions:

- Create/delete/suspend/unsuspend/restore/edit permissions for admin users within the distributor account.
- Edit distributor admin information (including mandatory and non-mandatory).
- Suspend, delete, unsuspend, and restore distributors.
- Suspend, delete, unsuspend, and restore hospitals.
- See internal users.
- See the list of distributors (all).
- See the list of hospitals (all).
- See the statistics dashboard for distributors.
- Get usage history between Telemedic and the distributor.

4.2.2.5.1.2 Distributor Sales

As a Distributor Sales user, you manage sales information and activities within the distributor environment. You oversee sales-related user accounts and ensure that sales processes are efficiently handled.

Permissions:

- Create/delete/suspend/unsuspend/restore/edit permissions for sales users within the distributor account.
- Edit distributor sales information (including mandatory and non-mandatory).
- See internal users.
- See the list of distributors (all).
- See the statistics dashboard for distributors.

4.2.2.5.1.3 Distributor Support

In the Support role within the distributor environment, you are responsible for technical support and user assistance. You manage support-related information and help maintain the distributor's systems and operations.

Permissions:

- Create/delete/suspend/unsuspend/restore/edit permissions for support users within the distributor account.
- Edit distributor support information (including mandatory and non-mandatory).
- See internal users.
- See the list of distributors (all).
- See the statistics dashboard for distributors.

4.2.2.5.2 Hospital Environment

4.2.2.5.2.1 Hospital Admin

As a Hospital Admin, you manage user accounts and administrative information within the hospital environment. You ensure that hospital operations are properly managed, including handling administrative data and overseeing hospital-wide statistics and data usage.

Permissions:

- Create/delete/suspend/unsuspend/restore/edit permissions for admin users within the hospital account.
- Edit hospital admin information (including mandatory and non-mandatory).
- See internal users.
- See the list of hospitals (all).
- See the statistics dashboard for hospitals.
- Get each hospital's data usage history.

4.2.2.5.2.2 Hospital Support

In the Hospital Support role, you provide technical and user support within the hospital environment. You manage support-related user accounts and information, ensuring that hospital systems function smoothly.

Permissions:

- Create/delete/suspend/unsuspend/restore/edit permissions for support users within the hospital account.
- Edit hospital support information (including mandatory and non-mandatory).
- See internal users.
- See the list of hospitals (all).
- See the statistics dashboard for hospitals.

4.2.2.5.2.3 Doctor

As a Doctor in the hospital environment, you have permissions to edit patient and medical information. You manage patient data and your own professional information, ensuring that patient care is properly documented and managed.

Permissions:

- Edit patient information (including mandatory and non-mandatory).
- Edit hospital doctor information (including mandatory and non-mandatory).
- See internal users.
- See the list of hospitals (his).
- See the statistics dashboard for hospitals.
- Get each hospital's data usage history.

4.2.2.5.3 Patient Environment

4.2.2.5.3.1 Patient

As a Patient, you have access to your own personal and medical information. You can view and download your data, and you can also delete your data.

Permissions:

- Access their own patient information (view and edit).
- See and download their own data.

CAUTION:

If data cannot be saved locally on your smartphone, please clear cache and try again.

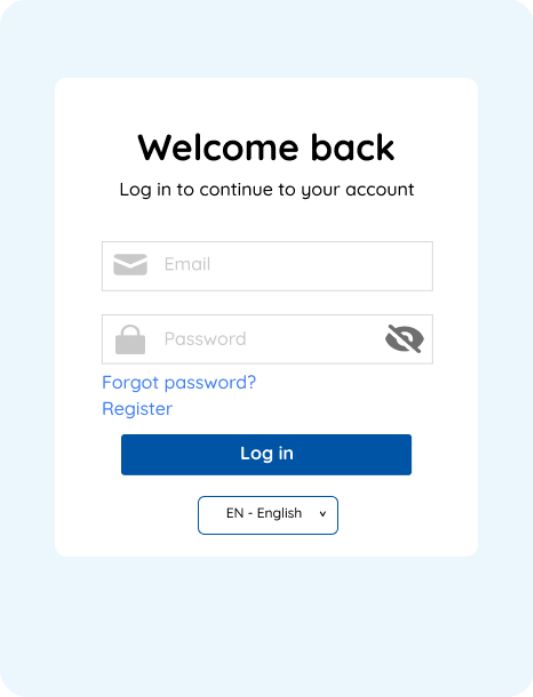
The device requires a stable internet connection to function properly.

Notice: The system will not be able to back up the data or send information to medical experts if there is no internet connection.

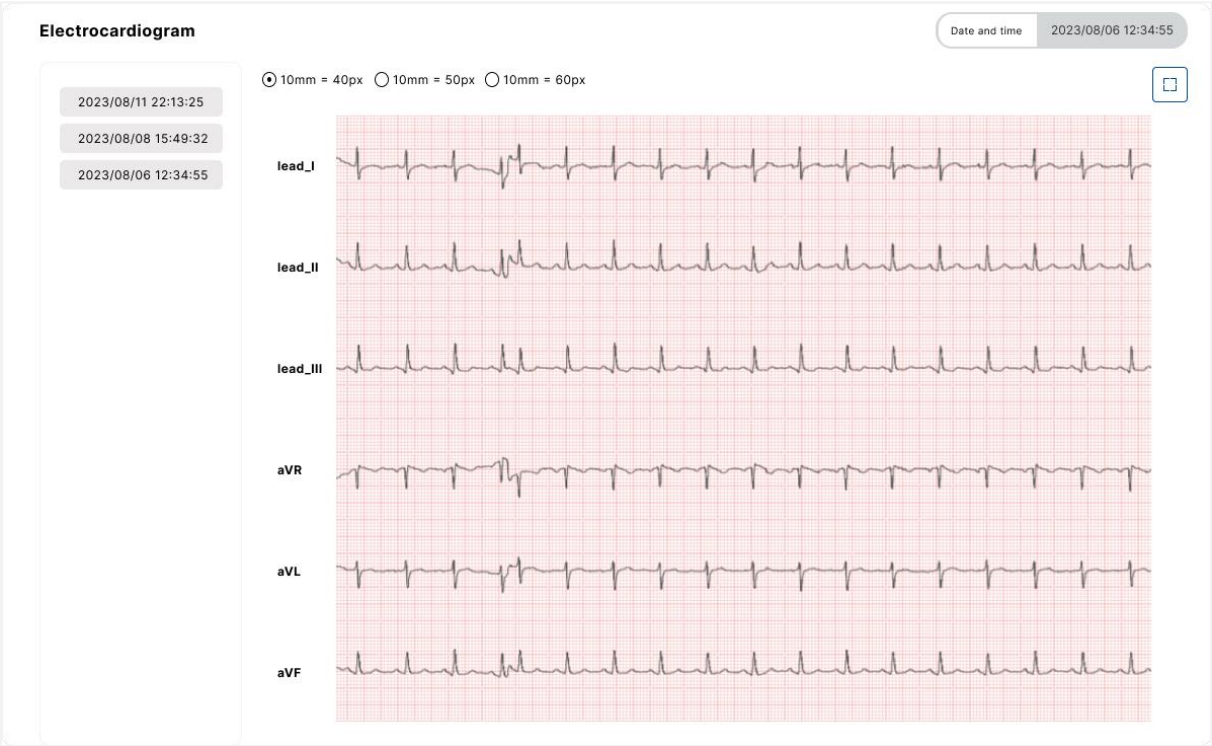
4.2.2.6 How to view ECG data in TeltoCare

1. Open a web browser and go to the URL: https://teltocare.com.
2. Enter your password in the login field.

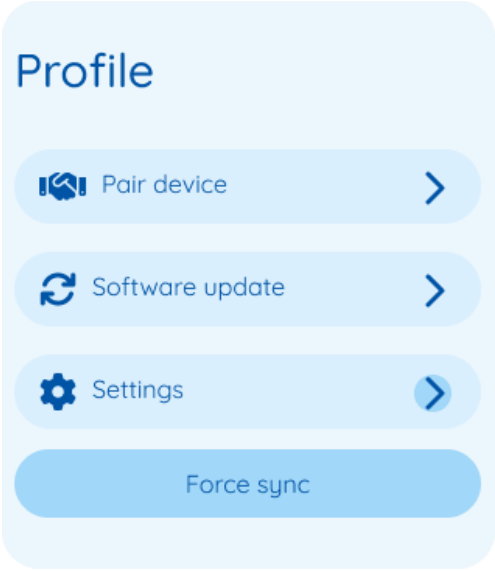
Notice: TeltoHeart application and TeltoCare share the same password.



3. Click the Login button to access your TeltoCare account.
4. Once logged in, you will be directed to the Patient Dashboard where you can view various patient-related information.
5. Look for the Electrocardiogram section.
6. Review the ECG recordings displayed in the Patient Dashboard to access the relevant data related to the patient's electrocardiogram.



7. If you do not see your ECG measurement data reflected in the TeltoCare platform yet, you have the option to perform a **Force sync** connection within the TeltoHeart mobile application. This feature allows you to manually initiate a data transfer and ensure that your ECG data is sent to the TeltoCare platform. Although data is sent periodically, if there are any delays or missing data, using the **Force sync** option in the TeltoHeart application enables you to trigger the data transfer process and ensure the availability of your ECG measurements in the TeltoCare platform.



4.2.2.7 Reviewing ECG records

After taking an ECG measurement, the recorded data is stored in the TeltoHeart mobile application. If you wish to review the results of the ECG record, you can access the TeltoCare web platform. From

there, you can navigate to the Electrocardiograph dashboard, where you will find the relevant information and details regarding your ECG recording.

Electrocardiogram tab provides users an access to review Electrocardiogram (ECG) data. Users are able to view specific ECG leads (Lead I, Lead II, Lead III, aVR, aVL and aVF) and filter records based on date and time.

Choose the ECG record you want to view by clicking on the date and time located on the left side of the interface.

4.2.2.8 ECG Analysis

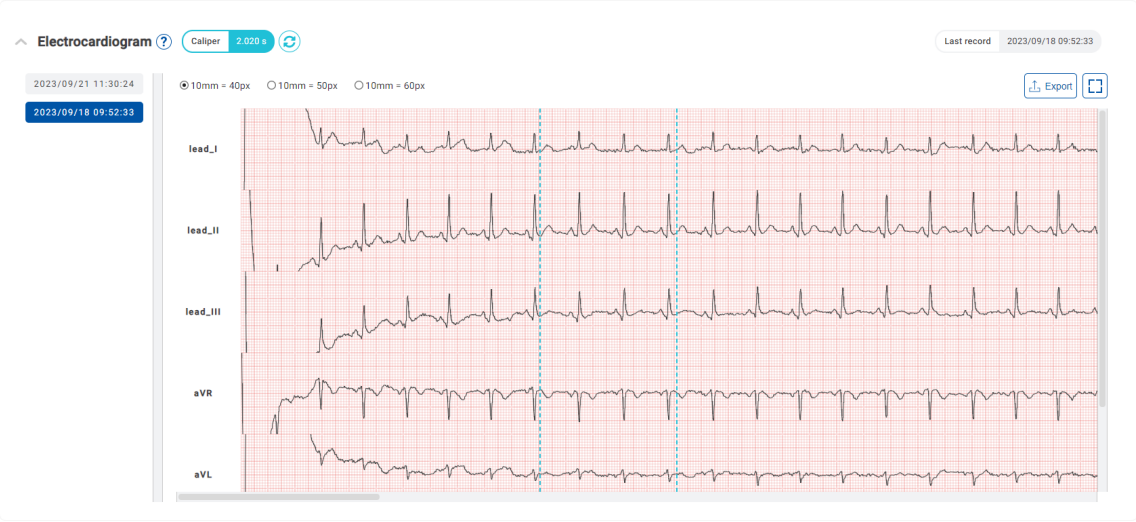
In ECG graph, you may observe various waveforms, such as P waves, QRS complexes and T waves. These patterns can provide insights into the heart's rhythm, rate and potential abnormalities.

- The presence of AFib in your ECG results should be considered as a possible indication. If you have any symptoms or concerns, it is important to reach out to your doctor. In the event of a medical emergency, please contact emergency services.
- Low heart rate can occur due to specific medications or when the electrical signals in the heart are not adequately conducted.
- An elevated heart rate can be attributed to factors such as exercise, stress, alcohol consumption, dehydration, infection, AFib or other forms of arrhythmia.
- All ECG and heart rate data are sent to TeltoCare platform. You may share your ECG or heart rate data with your medical practitioner.

4.2.2.9 Caliper

Caliper Tool is a feature designed to streamline the analysis of ECG waveforms. With this tool, users can effortlessly measure the time interval between two chosen points on the ECG waveform. This tool simplifies beat-to-beat interval measurement and enhances the precision of ECG feature analysis.

To begin, open your ECG analysis software and select the desired ECG waveform. Locate the ECG Caliper Tool and position the calipers on the two points you want to measure, typically R-waves for RR intervals. The tool will automatically calculate and display the time interval in a readable format. To start a new measurement, simply use the reset function.



4.2.2.10 ECG graph navigation

You can zoom and scroll to navigate through the ECG graph. Scrolling allows you to move horizontally or vertically within the graph, while zooming allows you to adjust the level of magnification. There are three zoom modes:

- 10mm = 40 px;

- 10 mm = 50 px;
- 10 mm = 60 px;

If you wish to enlarge an ECG graph, tap on icon, which is located in the **Electrocardiogram** dashboard.

Notice: When navigating, each ECG derivation graph is automatically displayed in the same time frame.

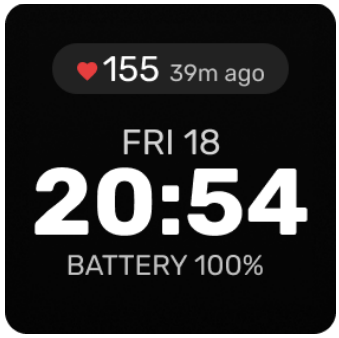
4.3 Heart rate check

4.3.1 Check heart-rate

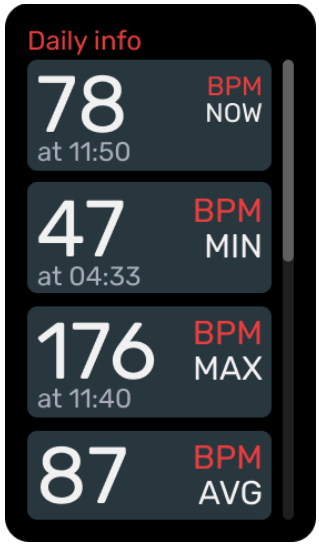
1. You can check your heart rate by looking at the home screen of TeltoHeart.

- If no measurement has been made yet, smart wearable will display "–", which means that no heart rate has been detected. Make sure the band over your wrist is not too loose.

2. If measurement has been made and smart wearable detects a heartbeat, device will display a numeric value (BPM) and time since last heart rate measurement.

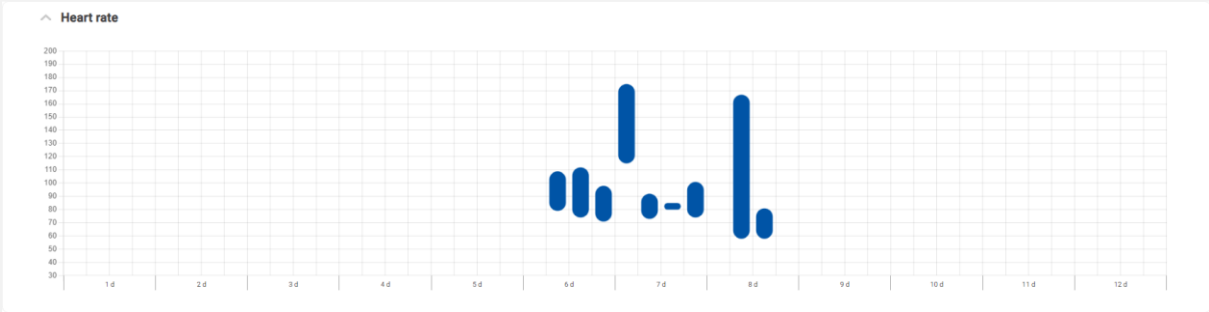


- To access this function, push the side button to bring up a menu, and then select **Heart Rate** from the list of options. The heart rate function on TeltoHeart also shows the minimum, maximum, and average heart rate values that were recorded during the measurement period. After a day the measurement values are reset.



4.3.2 Check heart-rate in TeltoCare

Heart rate tab lets user to view both minimum and maximum heart rates, as well as the date on which these measurements were taken. Heart rate is measured in beats per minute (BPM).



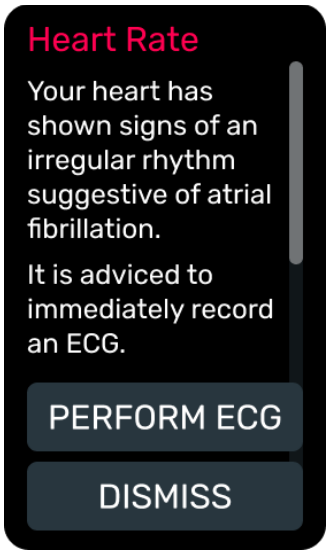
4.4 Atrial Fibrillation detection

If an atrial fibrillation is detected, a message appears notifying the user of an irregular rhythm suggestive of atrial fibrillation.

User is given two options to select from:

- Perform ECG

- Dismiss



- If **Perform ECG** is selected, refer to instructions on screen.

4.5 Atrial Fibrillation detection in TeltoCare

TeltoCare offers a dedicated Atrial Fibrillation Monitoring feature, designed to assist you in managing your atrial fibrillation condition effectively. This feature provides a detailed overview of your atrial fibrillation episodes and allows you to access critical information related to each episode.

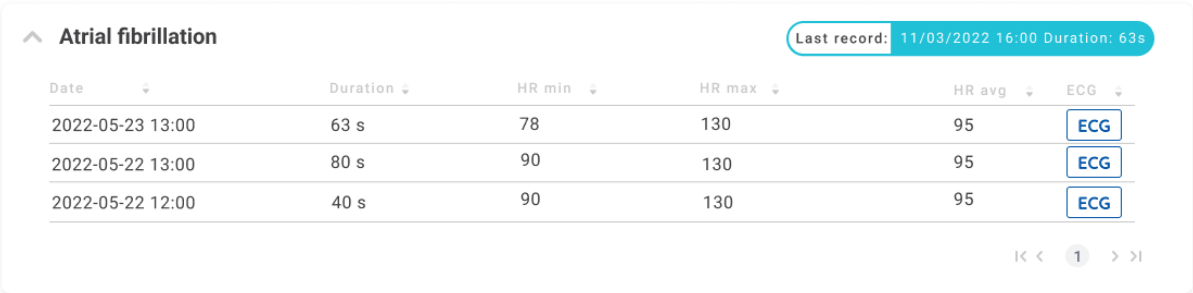
4.5.1 Atrial fibrillation features

When you access the Atrial Fibrillation tab, you will find essential information about your atrial fibrillation episodes:

- **Date**: The date on which each episode occurred is listed, helping you track the timing and frequency of your episodes.
- **Duration**: This field displays how long each atrial fibrillation episode lasted, giving you insights into the severity of each event.
- **Min Heart Rate**: You can view the minimum heart rate recorded during each episode, which is vital in understanding heart rate fluctuations.
- **Max Heart Rate**: The maximum heart rate during each episode is presented, aiding in gauging the intensity of these episodes.
- **Heart Rate Average**: This field provides the average heart rate during each episode, offering a comprehensive view of your heart's performance during atrial fibrillation.

4.5.2 Accessing detailed records

Each episode listed comes with a dedicated button. By clicking on this button, you can directly access the corresponding ECG record. This feature enables you to visually examine and analyze the electrical activity of your heart during atrial fibrillation episodes, enhancing your understanding of these events.



CAUTION:

⚠ Various factors, including motion, hand and finger movements, dark tattoos on the wrist, different amount of melanin in the skin, and the potential reduction in blood flow due to colder temperatures, can collectively influence the device's ability to capture high-quality recordings, potentially diminishing the effectiveness of the AFib detection algorithm.

⚠ In some rare instances, presence of other arrythmias may be classified as AFib. Even if the AFib may not be present, this might suggest presence of other arrythmias and user should consult with doctor for the evaluation of the heart condition. The presence of certain non-AFib arrhythmias may also result in changes of AFib detection performance.

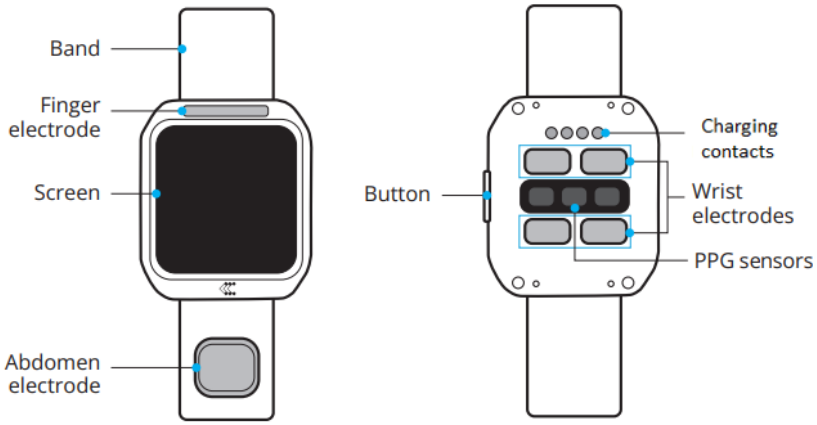
⚠ Diagnosis should be made using standard procedures by the qualified physician.

⚠ Different melanin levels in the skin on the wrist may impact PPG performance.

NOTICE:

- Do not take recordings during physical activity
- Do not take measurements under water

4.6 Get Started

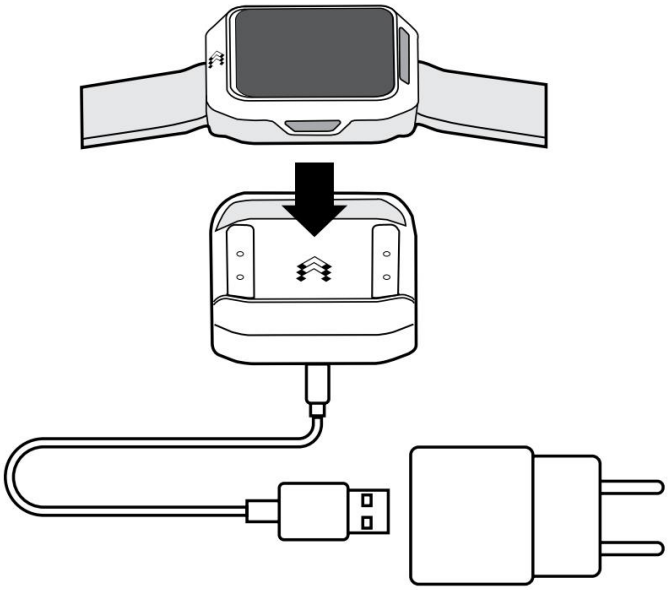


4.6.1 How to charge TeltoHeart

The battery life is dependent on usage and other factors.

Device charging:

1. Insert cable into the charging dock.
2. Place your TeltoHeart on the charging dock
3. Insert the charging unit into the power source.



Notice: Please keep the device electrodes clean for best performance.
Battery life lasts approximately 24 hours depending on the usage and other factors.
TeltoHeart supports only USB-C to USB-A cable for charging.

4.6.1.1 Begin charging TeltoHeart

To charge your TeltoHeart, align the concave end of the USB-C cable with the back of the smart wearable and let the magnetic connector attach. The charging symbol and progress will be displayed on the wearable screen once charging starts.

WARNING:

Chargers and accessories shall comply according to compatibility requirements provided in instructions for use.

Charge TeltoHeart smart wearable with USB type-C cables that are compliant with USB 2.0 or later and with applicable country regulations and international and regional safety standards.

Using damaged cables or chargers, or charging when liquid or moisture is present, can cause electric shock, fire, injury or damage to TeltoHeart, other property or the user.

When using the TeltoHeart Charging dock to USB-C Cable, make sure the cable or dock is fully inserted into the power adapter before you plug the adapter into a power outlet.

CAUTION:

Do not clean or use water on the device while charging.

Make sure the charging contacts are dry prior to charging the device.

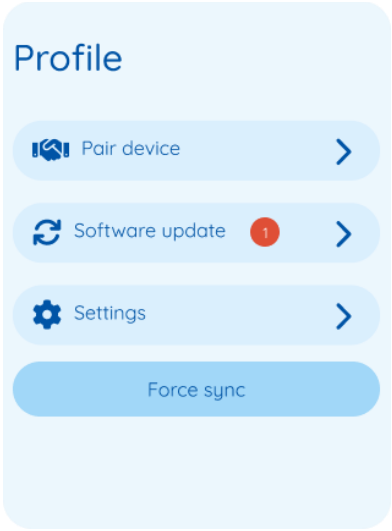
It is important to keep TeltoHeart and TeltoHeart Charging dock and the power adapter in a well-ventilated area when charging or in use.

Please store the charger and docking station in appropriate environment to avoid magnet degaussing.

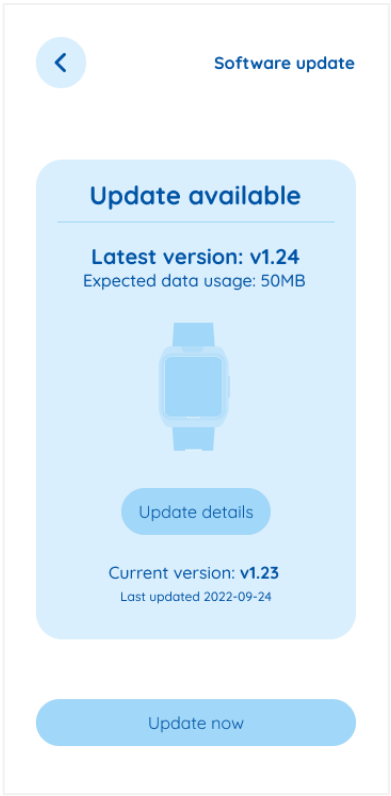
4.6.2 Update TeltoHeart firmware

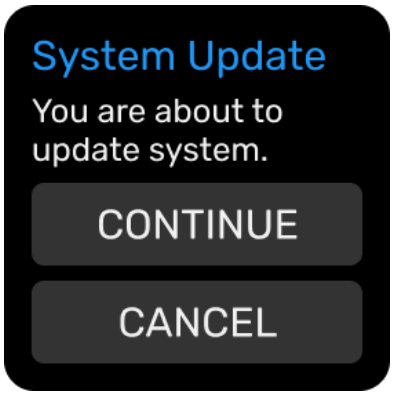
Make sure your TeltoHeart smart wearable is paired with your smartphone before proceeding with the firmware update. Keeping your device up to date is important for optimal performance and access to the latest features and bug fixes.

1. To update the firmware of your TeltoHeart device, launch the TeltoHeart app on your smartphone and navigate to the **Software Update** section located on the app's dashboard. Look for the 1 icon, which indicates that a firmware update is ready for download.



2. It is important ensure stable connection before updating TeltoHeart firmware. Keep TeltoHeart connected to your phone and keep the TeltoHeart application open during the firmware update process. Tap **Update now** to update TeltoHeart firmware.





3. TeltoHeart firmware update may take up to 10 minutes. Please hold your smartphone and TeltoHeart next to each other during the update process.

4. Once the update is complete, TeltoHeart will automatically restart and the new firmware version will be installed.

Notice: Do NOT reset the device during firmware update.
Notice: Please charge the device before initiating any firmware updates.
Notice: Please leave the device in synchronization for the duration of firmware update.

CAUTION:

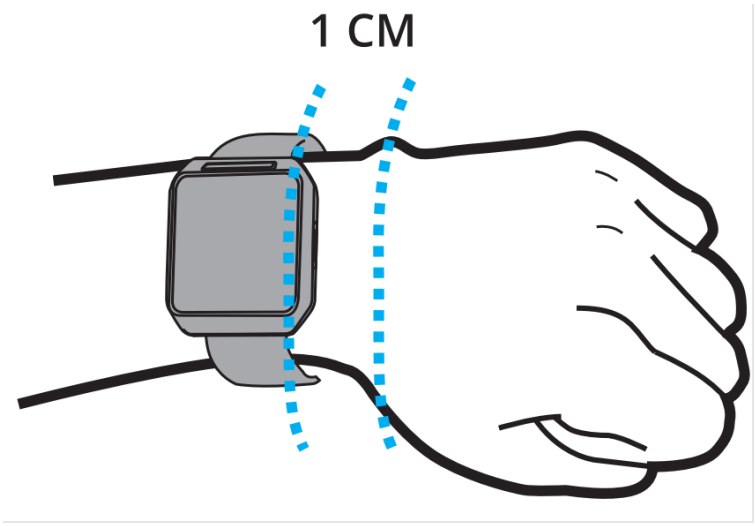
Please do not use the device during the firmware update process. Doing so could cause irreparable damage to the device and render it unusable.

4.6.3 TeltoHeart placement for wear

Secure TeltoHeart around your lower arm, above your wrist bone, as illustrated. Avoid fastening it too tightly or too loosely.

Fasten the band

1. Place the smart wearable around your left-hand wrist.
2. Slide the bottom band through the first loop in the top band.
3. Tighten the band until it fits comfortably.
4. Slide the loose end of the band through the second loop until it lies flat on your wrist.
5. Make sure the band is not too tight and is loose enough for it to move back and forth on your wrist.
6. Wear device a 1 cm above your wrist bone.



CAUTION:

If any allergic reaction occurs, stop wearing device immediately and consult with your doctor.

Do not wear the device on moles, birthmarks, psoriasis, or other skin surface defects.

Do not bend the wristband excessively.

The bracelet must be replaced if a defect in the strap or metal buckle is observed.

Notice: Device shall be used on left hand wrist only.

4.6.4 Power settings

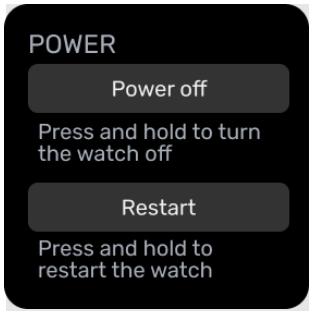
4.6.4.1 Power on

To activate the TeltoHeart, just press and hold the button until the device screen powers on.

4.6.4.2 Power off and restart

In the home screen, swipe up and tap on  icon to select the option to power off or restart the TeltoHeart press and hold on to the display button to perform the action. TeltoHeart completely powers off after 1 minute.

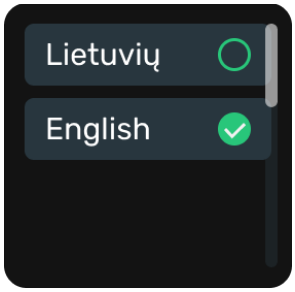
Restart can also be performed by holding the button for not less than 10 seconds and then releasing the button.



4.6.5 Start using TeltoHeart

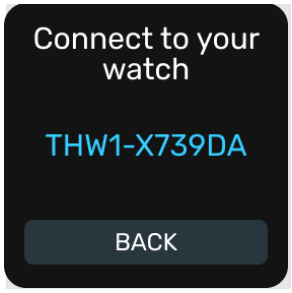
TeltoCare platform and TeltoHeart application work in conjunction with TeltoHeart, allowing you to access and review your medical information.

1. TeltoHeart will prompt you to select your preferred language.



2. You will be prompted to download the TeltoHeart application.

3. You will be able to locate TeltoHeart on the TeltoHeart application as its name will be displayed on the smart wearable screen.



CAUTION:

Use of the device may harm patients with exaggerated emotional instability or other elevated anxiety disorder in general and therefore is contraindicated in these subjects.

If TeltoHeart smart wearable is damaged or has malfunctions, contact your provider.

If you start feeling nauseous or symptoms of a headache, consider not using the device until you feel better.

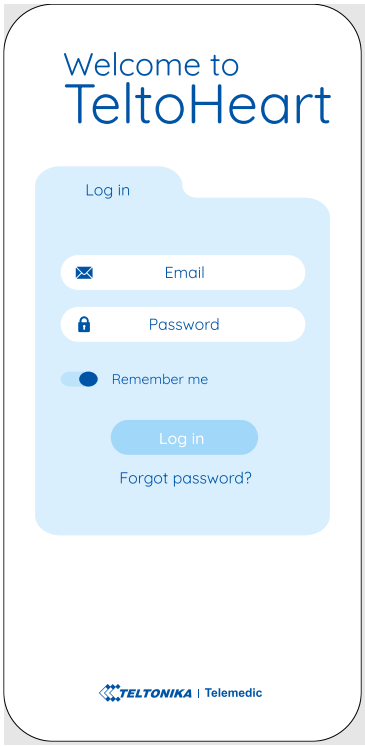
Notice: Do NOT use the device outside of this operational temperature range.

Notice: Usage in rain or in very humid environment is not recommended.

4.6.5.1 Setting up TeltoHeart application

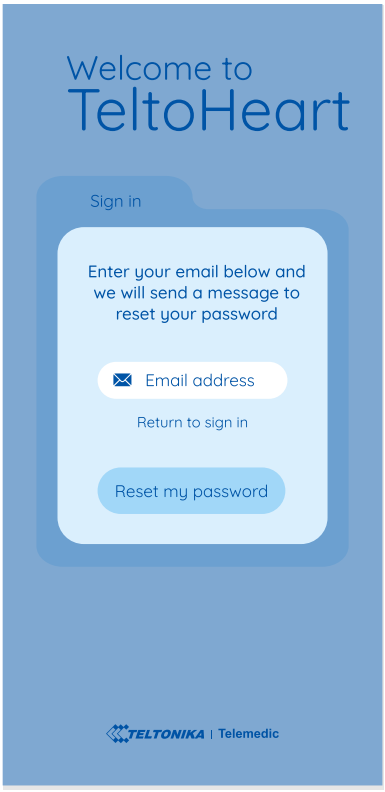
In order to pair the TeltoHeart, you must have a smartphone running IOS 14 or Android OS 10 or a later version, as well as the TeltoHeart application.

1. Download TeltoHeart application:
   - Google Play Store for Android OS phones.
   - App Store for iOS phones.
2. After installing the app, tap to open the app.
   - If it is your first time using the app, sign in by entering e-mail address and password, which had been sent to your e-mail.

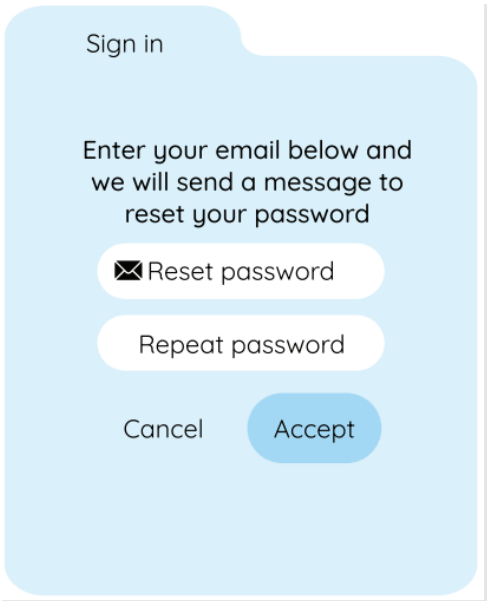


3. TeltoHeart application will prompt you to change the default password to a personal preferred password of your choice.

    - Enter your e-mail address.



    - Select **Reset password** option.



Use a password consisting with at least 8 symbols, at least one is a non-alphanumeric character, one uppercase, one lowercase character and one digit.

Notice: Do not share your password with anyone.

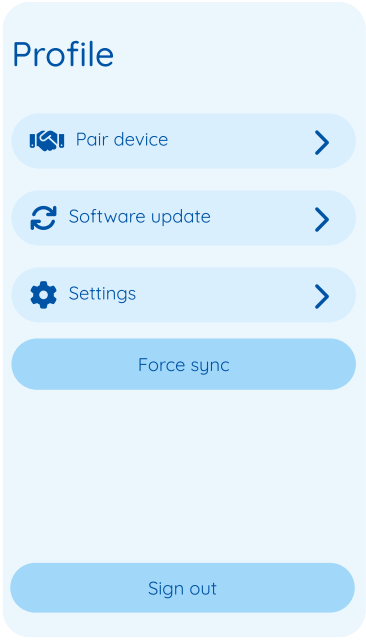
4. Once you have successfully changed your password, the next step is to review and accept the Terms and Conditions. You will be prompted to acknowledge and agree to the Terms and Conditions before proceeding.

TeltoHeart application permissions:

- Once signed-in, TeltoHeart application will ask Bluetooth permissions. Tap Allow to let the application use Bluetooth connection.

TeltoHeart pairing with TeltoHeart application

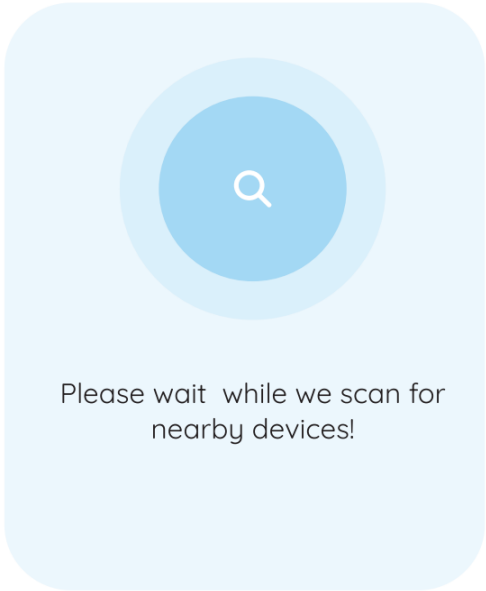
5. Tap **Pair device** to proceed with the pairing process.



CAUTION:

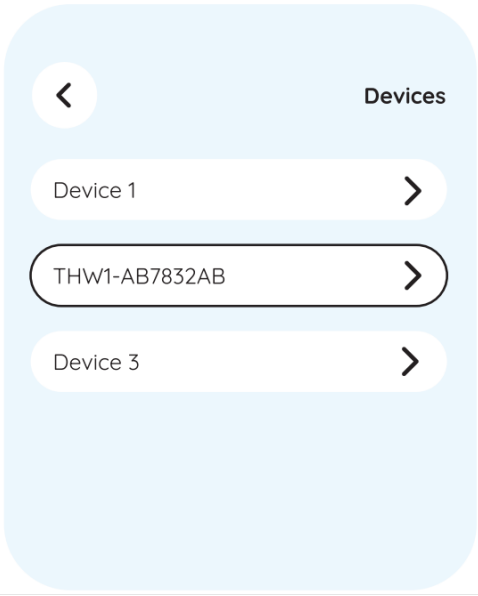
Avoid pairing the device in public places.

6. TeltoHeart application will initiate asearch of nearby devices.

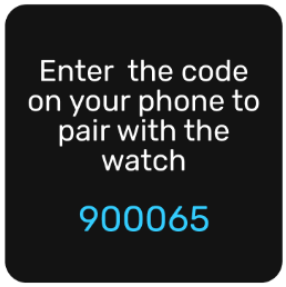


Notice: Make sure Bluetooth functionality is Enabled in your device.

7. Select your smart wearable by tapping on it.

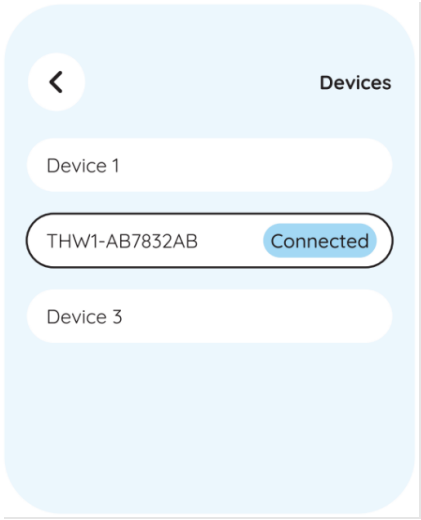


8. TeltoHeart will notify you of an incoming pair request.



9. When prompted to do so, enter the pass key shown on your TeltoHeart into the Bluetooth pairing request window in the TeltoHeart application.

10. After successful pairing, Connected indication will appear.



11. TeltoHeart will display an indication, that it is successfully paired with the phone.

Note: Make sure TeltoHeart application is always running in the background, otherwise the data transfer will not be available.

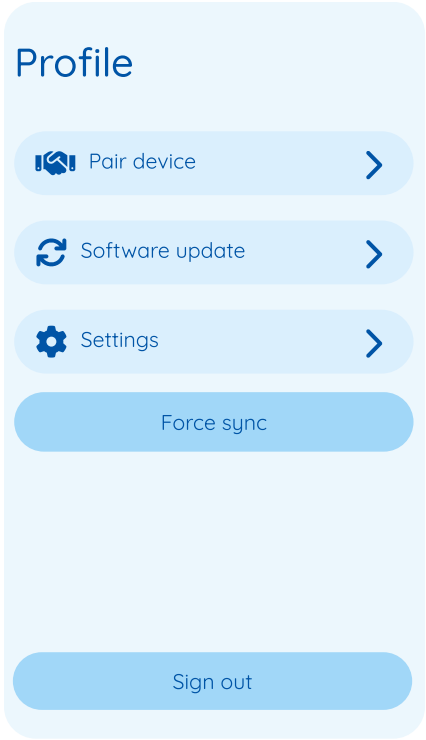
To ensure uninterrupted data transfer from your smart wearable to the platform, it is important to keep the TeltoHeart application running in the background at all times. If you close the app, the data transfer to TeltoCare platform will not be available.

CAUTION:

User must grant data storage permissions on mobile application.

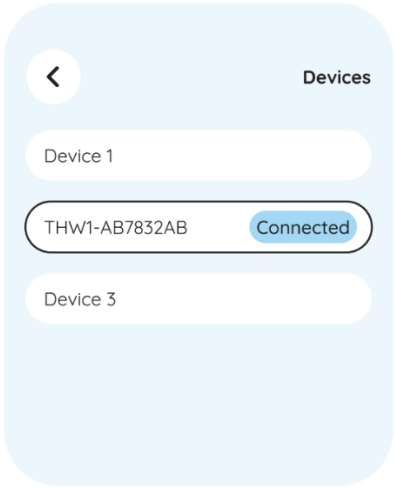
4.6.6 Unpair TeltoHeart

1. To unpair TeltoHeart in the dashboard, tap **Pair device**.

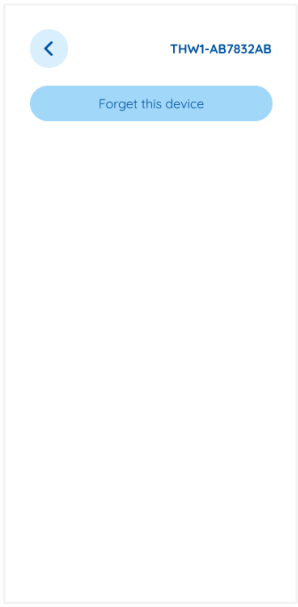


After unpairing TeltoHeart via TeltoHeart application, all data in TeltoHeartwill be permanently deleted. This includes any saved settings, ECG and HR data.

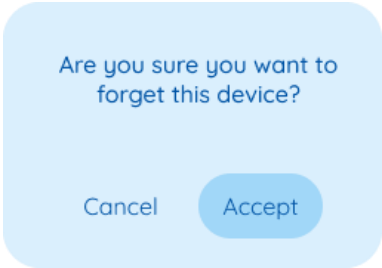
2. Find your paired TeltoHeart smart wearable and tap on it.



3. Tap **Forget this device** to unpair TeltoHeart.



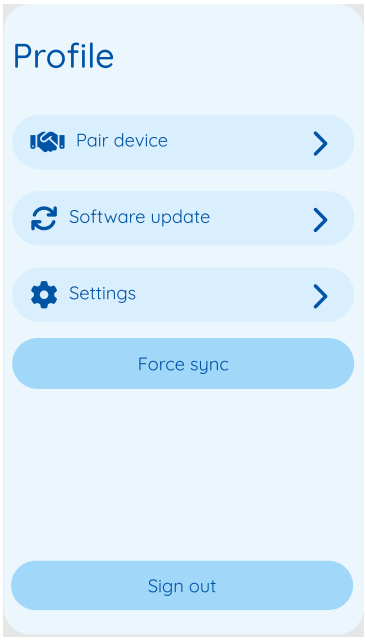
4. Confirm the selection by tapping **Accept** to forget this device



5. Head over to **Unpair and reset** section to completely unpair and reset TeltoHeart.

4.6.7 Sign out from TeltoHeart app

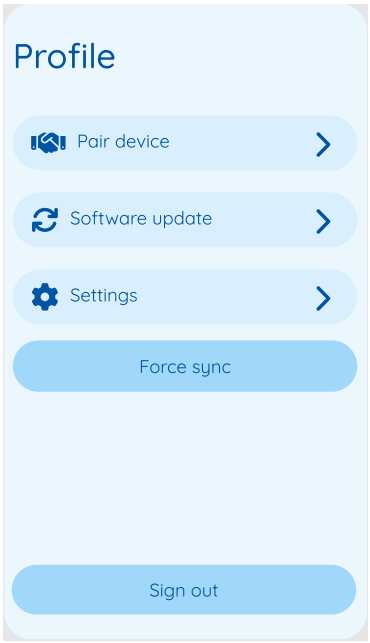
- To **sign-out** from user profile, tap **Sign out** at the bottom of the main screen.



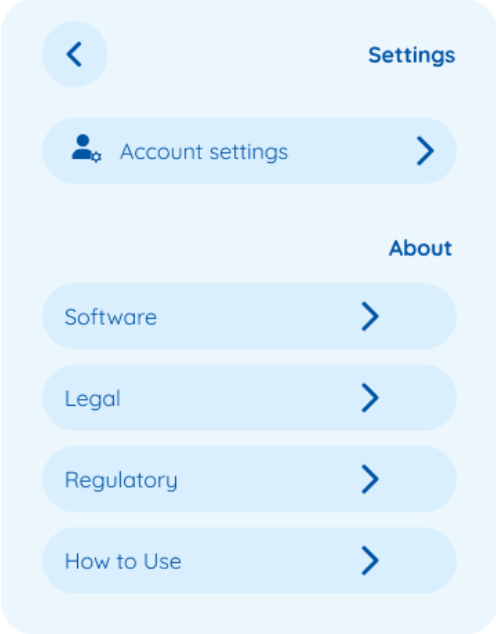
Notice: Sign in details will be deleted once user is signed out of the app.
To access the account, user will have to sign in again.

4.6.8 User account data deletion

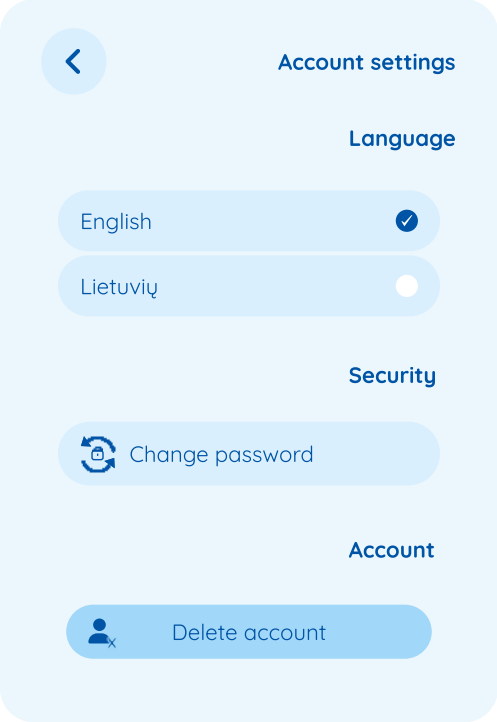
1. To **Delete TeltoHeart application and TeltoCare account,** tap Settings on the main screen.



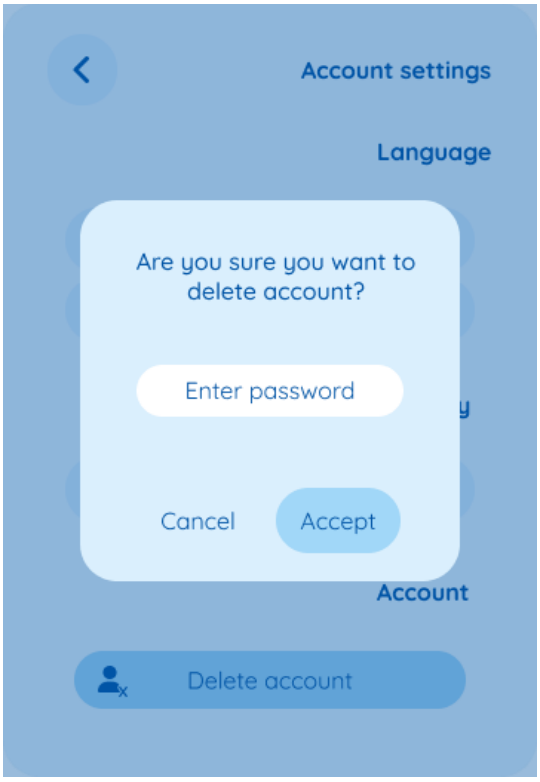
2. Tap **Account settings**.



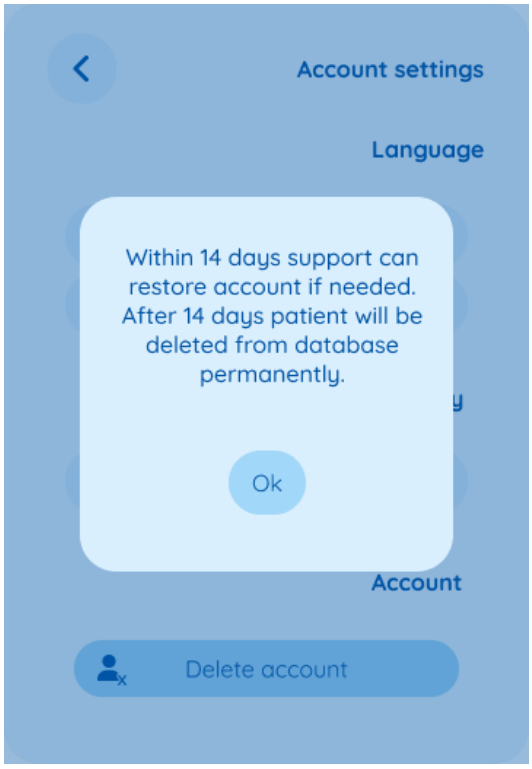
3. Tap **Delete account** to delete your account and all collected data.



4. Enter the confirmation code provided, which is sent to user e-mail to confirm the account deletion.



5. If there has been a mistake or you wish to restore your account, please contact your provider or Teltonika Telemedic and within 14 days support can restore account if required. After 14 days patient will be deleted from database permanently.



Notice: After deleting the account, all data will be lost. After 14 days support will no longer be able to restore deleted health data.

4.7 Recording an ECG

4.7.1 Before you start

1. To measure and record physiological parameters, TeltoHeart utilizes photoplethysmography (PPG) and electrocardiogram (ECG).
2. To transmit ECG data, ensure that TeltoHeart and TeltoHeart are paired with iOS 14 or later / Android 10 or later.
3. To activate the ECG function, simply open the ECG function in TeltoHeart

CAUTION:

Device is intended to be used by one person. Do not share the device with anyone.

The system is not intended for detection of stroke or other life-threatening conditions.

Darker skin tones on wrist might affect PPG performance.

While TeltoCare is designed to provide accurate readings, it is not intended to replace professional medical advice or diagnosis. Always consult with a healthcare professional for any concerns regarding your health or the interpretation of device readings.

4.7.2 Setup

1. Push the side button once to open up a menu.
2. Open ECG function  icon using TeltoHeart.
3. Follow instructions on screen.

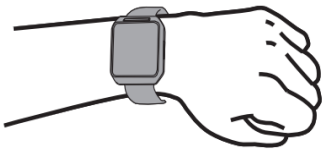
Notice: Physician may misidentify the ECG recordings if the user shared the device with other people. This might result in wrong diagnosis and treatment.

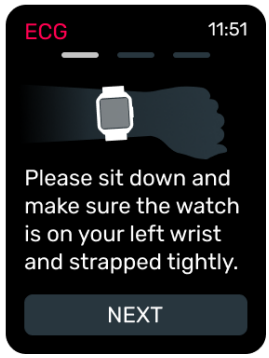
ECG signal overload or saturation will be shown as a flat line on the ECG graph's baseline (zero line)

Should you notice a horizontal line intersecting the zero line of the ECG recording, it indicates an overload or saturation of the ECG part of the smart wearable. If this occurs, please cease use and refer to troubleshooting guidelines in this manual.

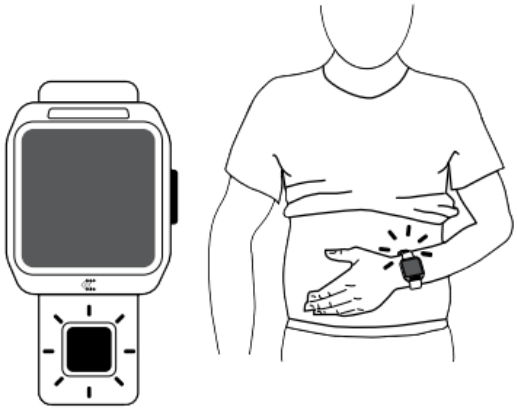
4.7.3 How to take ECG recording

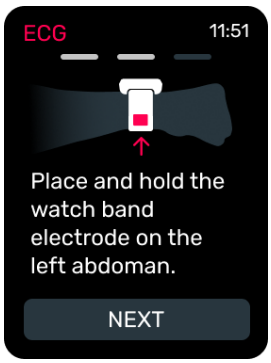
1. Follow the instructions on screen and tap **NEXT**.
2. Please sit down and make sure TeltoHeart is on your left wrist and strapped tightly, but comfortably.



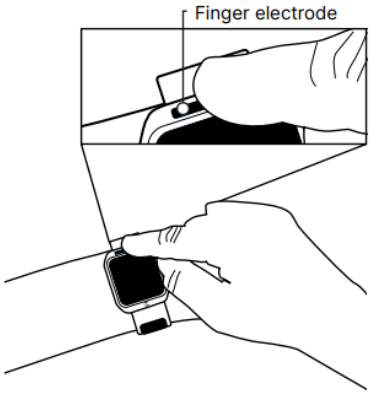


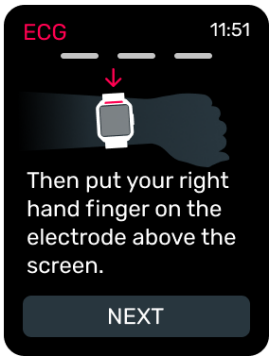
3. Place and hold the abdomen electrode on the left side of the abdomen side.



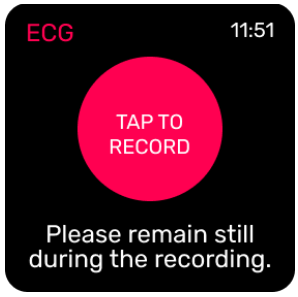


4. While holding the electrode on the left side of the abdomen, put your right hand finger on the finger electrode above the screen.





5. Select Tap to Record and during the countdown, perform the actions described above. Do not forget to keep your right hand finger on the finger electrode and remain still during recording.



6. The recording lasts for 60 seconds.
7. Once the recording is finished, you will see the message **Recording completed** displayed on the TeltoHeart screen.

CAUTION:

Oily, muddy, or otherwise contaminated skin surface will worsen the ECG and PPG quality! Make sure your skin is clean before recording ECG or PPG.

PPG glass scratches or cracks may affect device PPG performance.

Notice: Please keep the TeltoHeart application running in the background to allow measurement data transfer.

Notice: ECG recordings cannot be performed if battery charge is less than 10%.

4.7.4 Tips for accurate ECG recordings

When recording an ECG with the TeltoHeart, it is important to avoid the following:

1. Moving your arm or body during the recording, as this can interfere with the accuracy of the ECG reading.
2. Wearing TeltoHeart too loosely, as this can cause the electrodes to lose contact with your skin and produce inaccurate readings.
3. Recording an ECG while TeltoHeart battery is below 10%, as this can affect the quality of the recording.
4. Using the ECG recording function as a substitute for medical advice or treatment. The TeltoHeart smart wearable is intended for general wellness purposes only and is not a medical device. If you have any concerns about your heart health, consult your healthcare provider.

WARNING:

Exaggerated movement impairs the system's ability to take measurements.

Users with bruised skin, cuts, scars, too much body fat, very dry skin, or too much body hair may experience reduced performance of the sensors of the device due to the physiological conditions that compromise signal quality.

CAUTION:

The device is not suitable for people with paralyzed, deformed arms, or absence of both arms since the recordings in such cases may not be possible. The user is recommended to try other methods of monitoring in such cases.

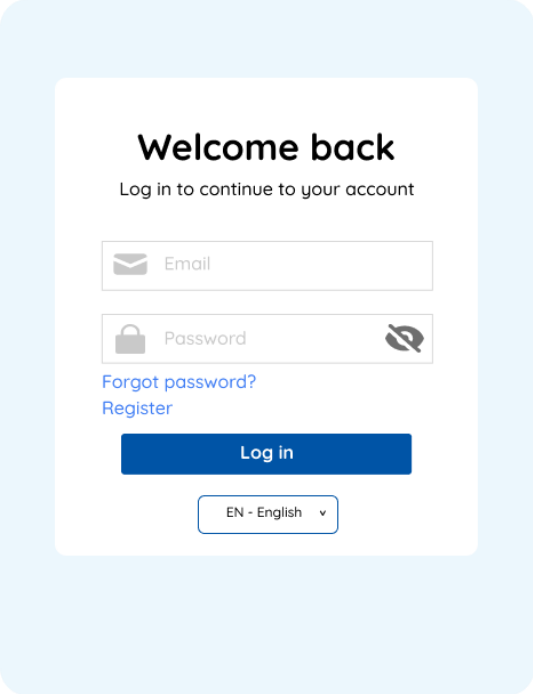
If TeltoHeart storage is full newest records will be written on top of the oldest.

Notice: Do not take recordings during physical activity.

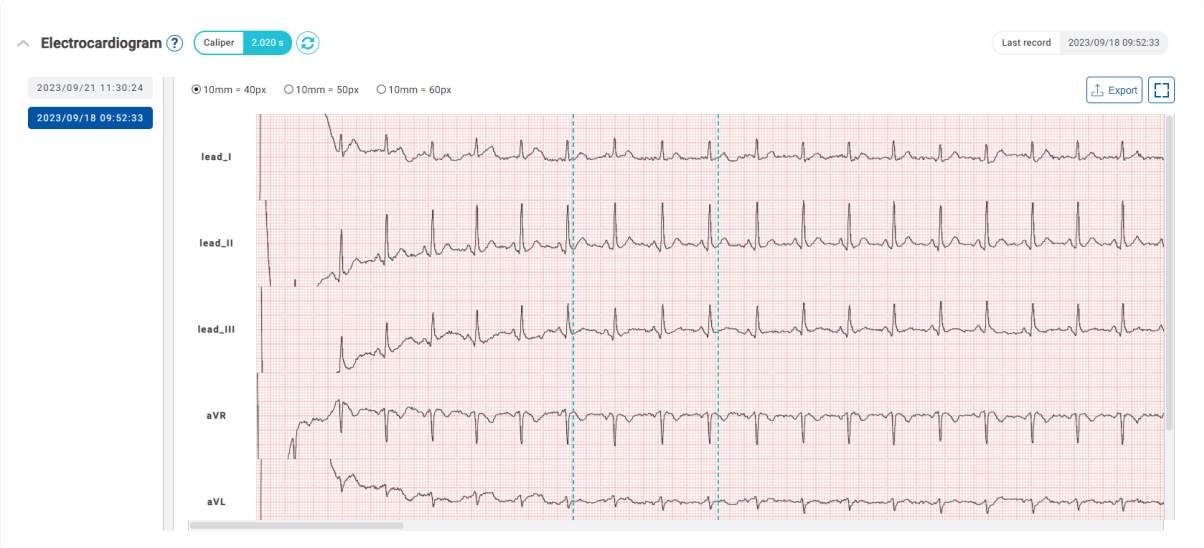
4.7.5 How to view ECG data in TeltoCare

12. Open a web browser and go to the URL: https://teltocare.com.
13. Enter your password in the login field.

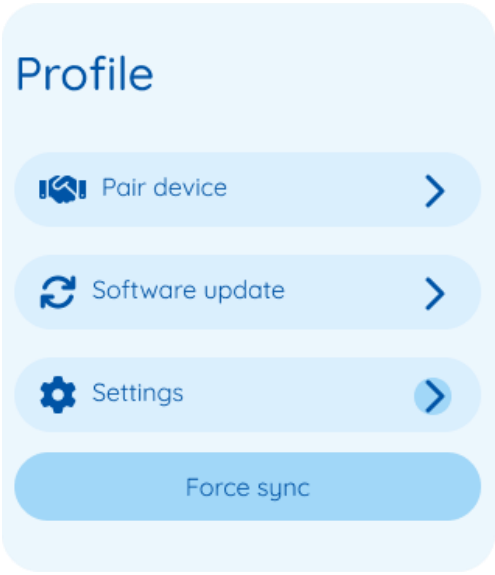
Notice: TeltoHeart application and TeltoCare share the same login details.



14. Click the Login button to access your TeltoCare account.
15. Once logged in, you will be directed to the Patient Dashboard where you can view various patient-related information.
16. Look for the Electrocardiogram section.
17. Review the ECG recordings displayed in the Patient Dashboard to access the relevant data related to the patient's electrocardiogram.



18. If you do not see your ECG measurement data reflected in the TeltoCare platform yet, you have the option to perform a Force sync connection within the TeltoHeart application. This feature allows you to manually initiate a data transfer and ensure that your ECG data is sent to the TeltoCare platform. Although data is sent periodically, if there are any delays or missing data, utilizing the Force sync option in the TeltoHeart application enables you to trigger the data transfer process and ensure the availability of your ECG measurements in the TeltoCare platform.

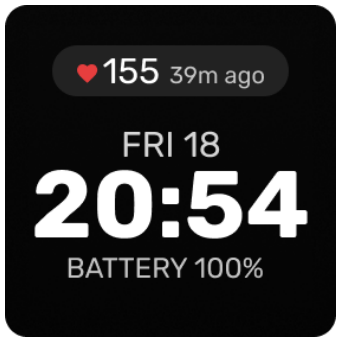


4.8 Heart rate check

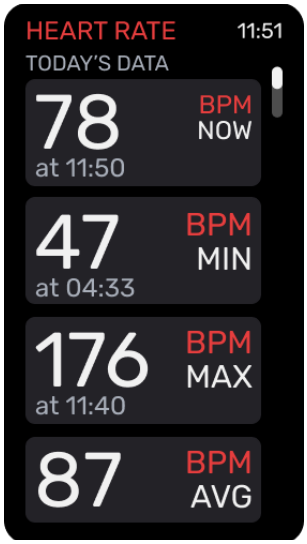
4.8.1 Check heart-rate

1. You can check your heart rate by looking at the home screen of TeltoHeart.
2. If no measurement has yet been made, the smart wearable will display "–", which means that no heart rate has been detected. Make sure the band over your wrist is not too loose.

3. If measurement has been made and smart wearable detects a heartbeat, device will display a numeric value (BPM) and time since last heart rate measurement.



4. To access this function, push the side button to bring up a menu, and then select **Heart Rate** from the list of options. The heart rate function on TeltoHeart also shows the minimum, maximum, and average heart rate values that were recorded during the measurement period. After a day the measurement values are reset.



Notice: TeltoHeart heart rate range is 50 – 150 bpm

TeltoHeart measures heart rate (HR) with an average difference of 3 beats per minute (BPM) compared to a standard ECG Holter heart rate measurement within the 35-200 BPM range.

4.8.2 Cases of what affects heart rate measurement

Intense physical movements or activities can cause motion artifacts, which lead to inaccurate heart rate readings. When the smart wearable is not properly fastened to the wrist or when there is excessive movement during exercise, it can interfere with the sensor's ability to accurately measure heart rate.

A smart wearable must be worn snugly on the wrist for accurate heart rate measurement. If the smart wearable is too lose or positioned incorrectly, it may not be able to maintain proper contact with the skin, resulting in unreliable readings.

4.9 Displays and Signals

4.9.1 Navigating TeltoHeart

To navigate through TeltoHeart, swipe up and down on the screen or tap on it to access different features and functions. To go back to the previous screen, use the side button.

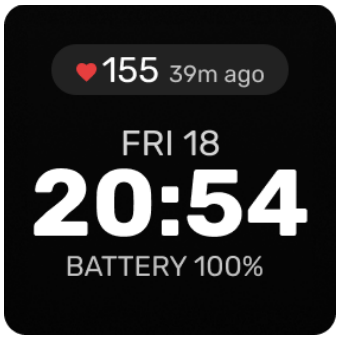
In order to preserve battery power, thescreen turns off, when not used for 15 seconds or 45 seconds if **Longer awake** function is enabled.

4.9.2 Control center

Control center that can be accessed by swiping up on the TeltoHeart. The control center provides you with quick access to various settings and functions.

4.9.3 Battery

Battery can be checked on the main screen:



WARNING:

The Li-Po battery in TeltoHeart should be serviced only by Teltonika Telemedic or an authorized service provider.

4.9.4 Display settings

In TeltoHeart display settings, you can customize various aspects of your screen and behaviour. Two key settings that you can adjust are the screen brightness and device raise to wake up function. Depending on your preferences and lighting conditions, you may want to increase or decrease the brightness to make the screen easier to see.

Raise to wake up function allows your TeltoHeart to automatically wake up when you raise your wrist, which can be a convenient way to quickly check the time or view your heart rate measurement.

Prolonged viewing at the device's screen is not recommended.

4.9.4.1 Enter display settings

Open the control center by swiping up the screen. Tap the sun  icon to open device display settings.

4.9.4.2 Adjust display brightness

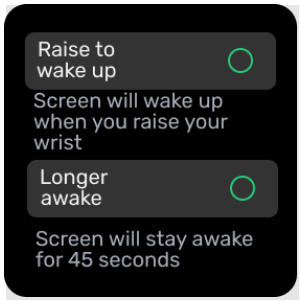
Slide your finger to the right on the brightness bar to increase the brightness, or slide it to the left to decrease the brightness. You can adjust the brightness to your preferred level.

4.9.4.3 Raise to wake up

Tap on ○ to activate or deactivate **raise to wake up** function. When the function is active, a checkmark ✓ icon will appear.

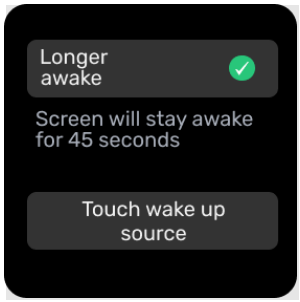
4.9.4.4 Longer awake

To enable or disable the **Longer awake** function, simply scroll down on your device and tap the corresponding ○ icon. When active, a checkmark ✓ icon will appear to indicate that the function is enabled.

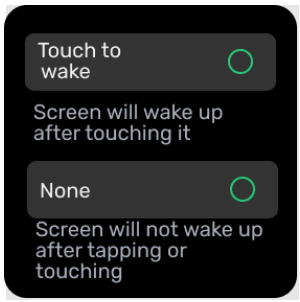


4.9.4.5 Touch wake up source

To access the **Touch wake up source** settings, continue scrolling down on TeltoHeart. You should see a section labelled **Touch wake up source**.

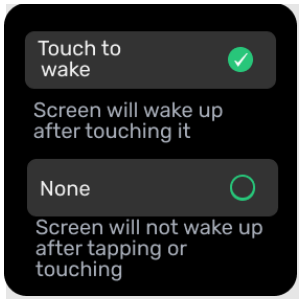


Tap on this section to enter the **Touch wake up source** settings. Here, you can choose which touch actions will wake up your device when the screen is off. To enable or disable selected function, simply tap on the corresponding icon. When the function is active, a checkmark icon will appear.



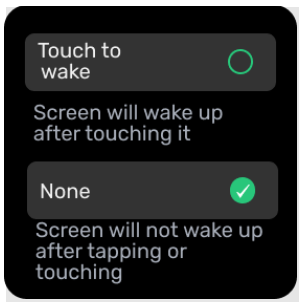
4.9.4.6 Touch to wake

When this feature is turned on, your TeltoHeart screen will only become active once it has been touched.



4.9.4.7 None

To prevent TeltoHeart from waking up when tapped or touched, you can activate the **None** function.



Once you have selected your desired touch actions, simply click button on the side of the TeltoHeart to exit the settings and save your changes.

4.9.5 Vibrations

TeltoHeart provides several different vibration patterns that are used to provide feedback to the user in response to specific events and status updates. These vibration patterns have been designed to be easily distinguishable from one another, making it easier to understand what is happening without having to refer to a manual or guide.

Vibration patterns

- **Short low burst**: This is a quick and low-intensity vibration pattern that lasts for 100 milliseconds. It is used to indicate a brief notification or feedback.

- **Short mid burst**: This is a slightly stronger vibration pattern that lasts for 400 milliseconds. It is used to indicate a more significant notification or feedback.
- **Long mid burst**: This is a longer vibration pattern with medium intensity. It consists of three parts, where the first and third parts last for 400 milliseconds, and the second part lasts for 100 milliseconds. This pattern indicates a significant event or notification that requires the user's attention.

Vibration events and indications

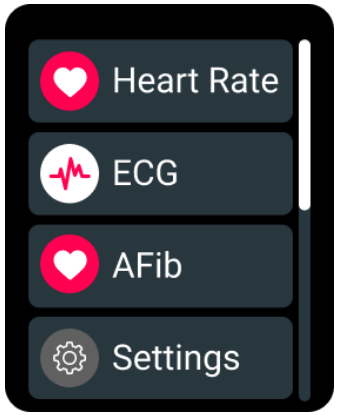
List of different events or status updates that are associated with each vibration pattern.

Event	Indication
Connected/Disconnected events	
Connected	Short low burst
Disconnected	Short low burst
Charging status	
Started	Short mid burst
Battery level status	
Low	Long mid burst
Critical	Long mid burst
Firmware upgrade status	
Started	Short low burst
Uploaded	Short low burst
Finished	Short low burst
Atrial fibrillation (AFib) event	
Started	Long mid burst

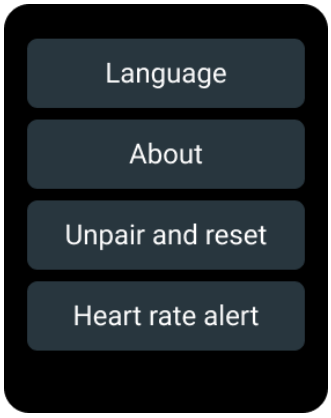
4.10 Settings

Within the Settings tab of a device, there are several options available, including the ability to view HR Calibration, device information, access regulatory information and perform a device factory reset.

Press the smart wearable button to bring up a menu.



From there, find and tap on the Settings option to access the TeltoHeart settings.

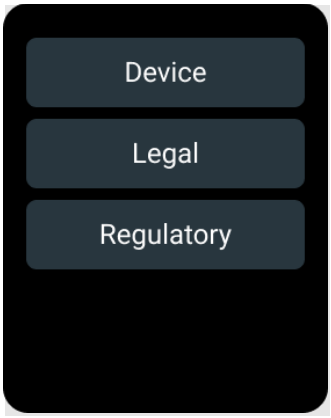


4.10.1Language

The Language option allows you to select the preferred language for the device's interface. Changing the language will affect all text displayed on the device.

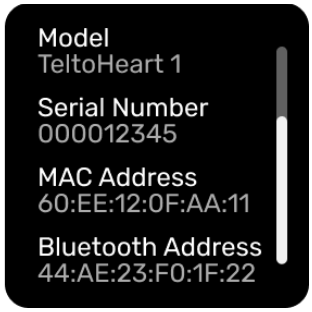
4.10.2About

The About section in the TeltoHeart smart wearable provides you with device information, legal information, and regulatory information.



4.10.2.1 Device

Under the Device Information section, you can view details such as the device name, software version, model, serial number, Bluetooth and MAC addresses. This information can be useful if you need to troubleshoot issues or if you want to confirm that you have the latest software version installed.



4.10.2.2 Legal

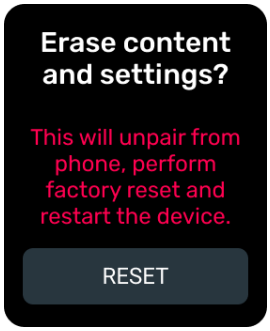
The Legal Information section asks you to visit the TeltoHeart application legal section, where you can find important legal information related to the use of the TeltoHeart application, TeltoCare and the TeltoHeart.

4.10.2.3 Regulatory

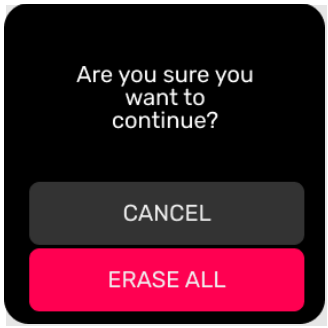
Regulatory section includes information related to device certifications. This information can be useful if you need to ensure that the TeltoHeart is compliant with regulatory requirements in your region.

4.10.3 Unpair and reset

1. To reset device to factory settings, tap **Unpair and reset.** Confirm the selection by tapping **Reset** button again.



2. The user will be prompted with a message asking to confirm to erase all data. Tap ERASE ALL to erase all TeltoHeart data and reverse the smart wearable back to factory settings.

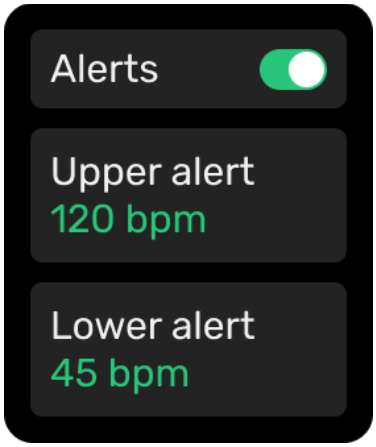


CAUTION:

If you choose to **Unpair and reset** your TeltoHeart, all data in TeltoHeart will be permanently deleted. This includes any saved settings, ECG and HR data.

4.10.4 Heart rate alert

Heart Rate Alert feature allows you to set up notifications for when your heart rate goes above or below specified thresholds. This helps you monitor your heart rate and take action if necessary.



To adjust the threshold, tap the "+" button to increase or the "–" button to decrease the value. Once you have set the desired threshold, tap the "CHANGE" button to save it. The device will then use this new threshold for heart rate alerts.

5 Cleaning

5.1 Cleaning of the Device Surface

It is important to clean the device surface of TeltoHeart before using it because a dirty or oily surface can interfere with the accuracy of the ECG readings. Any oil, dirt, or sweat on the surface of the device can create a layer of resistance that can affect the electrical conductivity between the device and your skin.

Inaccurate ECG readings can lead to false alarms or missed diagnoses, which can have serious consequences for your health. By keeping the device surface clean, you can ensure that it maintains optimal conductivity and accuracy, which can help to improve the overall quality of the ECG readings.

Follow these steps to clean TeltoHeart smart wearable:

1. Ensure your TeltoHeart smart wearable is powered off before you begin cleaning.
2. Use a soft cloth and apply a small amount of Isopropanol Alcohol (70%), commonly used in medicine for sterilization, onto it.
3. Gently wipe the surfaces of the TeltoHeart main body and the band with the alcohol-covered cloth. Be careful around sensitive areas like the screen and any ports.
3. Pay special attention to the crevices and edges, ensuring any dirt or grime is effectively removed.

4. Use a dry, soft cloth to remove any excess cleaner from the TeltoHeart main body and the band.
5. Check the device to ensure there are no remaining traces of alcohol or residue.
6. Once everything is dry, power on your TeltoHeart and ensure it functions properly.
7. Clean your TeltoHeart regularly to maintain its appearance and functionality.

Notice: Keep the smart wearable clean and dry. Cleaning products, soaps, ultrasonic cleaning, abrasive materials and external heat sources can cause damage to the device.

CAUTION:

Do not use corrosive chemical materials for cleaning.

Ensure that the magnetic connection of the docking station is clean of metallic bodies.

6 Troubleshooting

6.1 TeltoHeart is not turning on

1. If your TeltoHearthas recently been turned off and you are having trouble turning it back on: Wait for at least one minute: If it has been turned off recently, it may need some time to fully power down. Wait for at least one minute before attempting to turn it back on.
2. **Charge the smart wearable:** Ensure that TeltoHeart is charged. Connect TeltoHeart to the charging dock and make sure that it is charging. If it is not charging, try a different charging cable or adapter.
3. **Check the charging connections:** Ensure that the charging contacts on TeltoHeart and the charging dock are clean and free of any debris or corrosion. If they are dirty, gently clean them with a soft, dry cloth.
4. **Check the button:** Make sure the button on the side of TeltoHeart is not stuck. Press the button gently a few times to see if it is functioning properly.
5. **Contact customer support:** If none of the above troubleshooting steps work, contact the customer support for further assistance.

6.2 TeltoHeart is not sending data

If your TeltoHeart is not sending any data to the TeltoCare platform, here are some troubleshooting steps to help you resolve the issue:

1. **TeltoHeart is not paired with TeltoHeart application:** Make sure that your TeltoHeart is properly paired with the TeltoHeart application on your phone. If it's not, follow the pairing instructions provided in **4.6.5.1 Setting up TeltoHeart application**.
2. **Check the phone storage:** If the phone storage is full, it may not be able to receive or process data from TeltoHeart. Try deleting any unnecessary files or apps from your phone to free up some space.

3. **Contact customer support:** If none of the above troubleshooting steps work, you may need to contact the TeltoCare customer support team for further assistance.

6.3 Incorrect time or date

If TeltoHeart is showing incorrect time or date, it could be due to a few different reasons. One common cause of this issue is that TeltoHeart is not properly paired with your phone or has lost its connection to the phone. Here are a few steps to help you fix this problem:

1. **Check the Bluetooth connection:** Ensure that your phone's Bluetooth is turned on and TeltoHeart is connected to it. If it isn't, go to the settings on your phone and turn on Bluetooth. Then, try to reconnect your smart wearable by going to the TeltoHeart application and select to pair your TeltoHeart.
2. **Restart Teltoheart:** Sometimes, restarting the smart wearable can fix the issue. To do this, on the home screen, open the control center by swiping up the screen. Tap on  icon to select the option to restart the TeltoHeart or simply hold the button for not less than 10 seconds and then release the button to restart the device.
3. **Update the firmware:** If your smart wearable has outdated firmware, it may cause issues with the time and date display. Check for any available updates for TeltoHeart on TeltoHeart mobile application and install them as necessary.

6.4 Paired device prior to registering/logging in

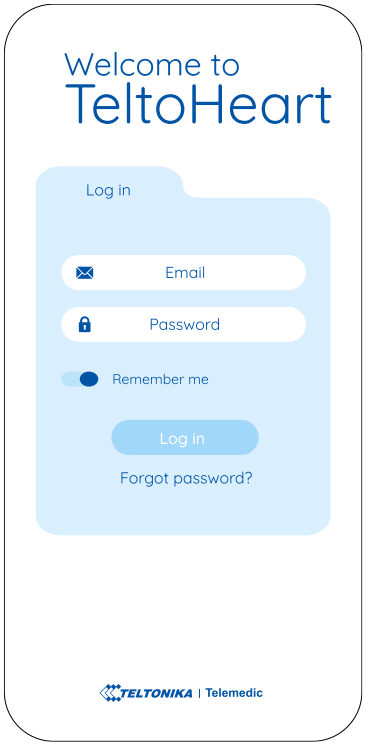
If you have paired your TeltoHeart to your phone through Bluetooth settings instead of the TeltoHeart application, you may run into a few issues, including poor functionality or even disconnection issues. Here are some troubleshooting steps to help you resolve this problem:

1. **Unpair TeltoHeart:** First, unpair your smart wearable from your phone by going to the Bluetooth settings on both devices and selecting **Forget** or **Unpair**.
2. Download the TeltoHeart application: If you haven't already, download the TeltoHeart application for your TeltoHeart from the app store. Once downloaded, login to your account and select Pair Device (follow the steps provided in 4.6.5.1 Setting up TeltoHeart application.
3. **Check for firmware updates:** After pairing your smart wearable through the TeltoHeart application, check for any available firmware updates and install them as necessary.

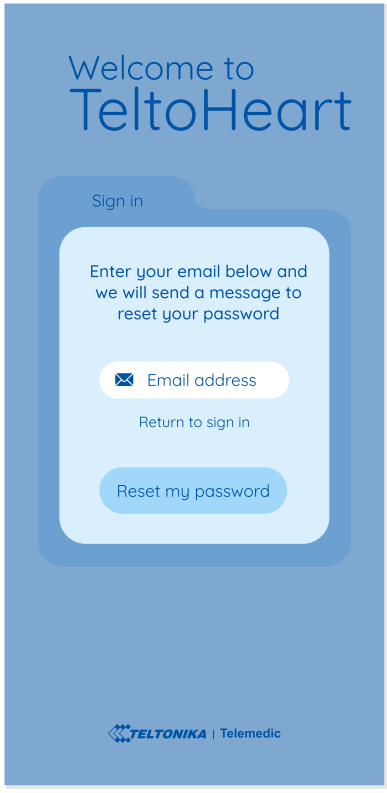
6.5 Forgot password for TeltoHeart or TeltoCare account

If you have forgotten the password for your TeltoHeart application or TeltoCare:

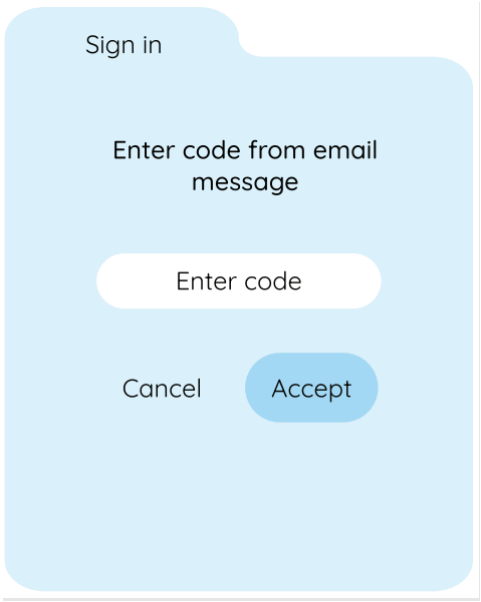
1. **Click on the Forgot Password option:** On the login page of the application, look for **the Forgot Password** option and click on it.



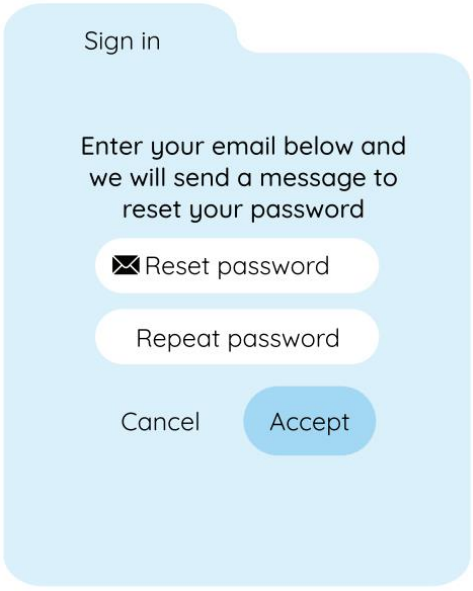
2. **Enter your email address:** You will be asked to enter the email address associated with your account. Enter the correct information and click on **Reset my password**.



3. **Follow the instructions:** You will receive an email with a code to reset your password. Enter the password to the TeltoHeart application.



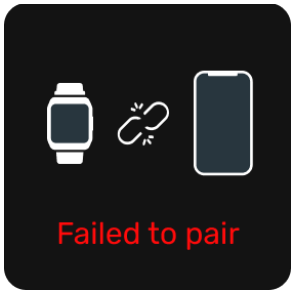
4. **Create a new password:** After following the instructions, you will be prompted to create a new password. Make sure to create a strong and secure password that you will remember easily.



5. **Log in with your new password**: Once you have created a new password, use it to log in to the TeltoHeart application or TeltoCare.

6.6 Connection Lost

If TeltoHeart is displaying a **Failed to pair** message on the screen, it means that the smart wearable is currently out of range from the Bluetooth signal of your phone.



To resolve this issue, you will need to move your phone closer to the smart wearable or bring it closer to your phone until the devices are within Bluetooth range.

6.7 Heart Rate signal missing

If the heart rate sensor on your TeltoHeart has difficulty detecting your Heart Rate "–" appears.

In case your smart wearable fails to detect a heart-rate signal, follow these steps to troubleshoot the issue:

1. Check if your smart wearable is being worn correctly on your wrist.
2. Try tightening or loosening the band to ensure a proper fit. After adjusting the band, check the smart wearable to see if the heart-rate signal has been detected.
3. Ensure that the LED contacts of TeltoHeart are free from dirt or debris. If the issue persists, try resetting TeltoHeartor consult the user manual for further troubleshooting steps.

In case of failures which cannot be eliminated directly, have the device repaired by the manufacturer or your specialist distributor. Do not continue to operate the device in order to avoid major damage.

7 Frequently asked questions

7.1 TeltoHeart

1. How to turn on TeltoHeart?

   Turn on TeltoHeart by holding the button for at least 10 seconds or by placing it on the charging adapter.

2. Where can I see the data?

   Smart wearable displays: minimum, maximum, and current heart rate values, and the time of the last suspected atrial fibrillation episode. In TeltoCare, you can see these and additional data such as ECG, atrial fibrillation burden (AFib Burden), and more.

3. How to change the language?

   In TeltoHeart, go to the menu, select "Settings" -> "Language." In the window that opens, all supported languages will be displayed. Select the language and press the corresponding button.

4. How to set the heart rate frequency?

   The heart rate is displayed on the main screen and in the "Heart rate" app.

5. Why is my ECG bad, unreadable?

   During recording, try to stay still and ensure good contact between the skin and electrodes. The contact area between the skin and electrodes should be as large as possible. The pressure should be such that the muscles are relaxed during measurement.

6. Why are there no data on the TeltoCare platform?

   To transfer data from the smart wearable to TeltoCare, ensure the smart wearable and mobile device are connected via Bluetooth and press the "Force Sync" button in the TeltoHeart app. This way, all data in the smart wearable will be transferred immediately. This process also occurs in the background at least once an hour when a Bluetooth connection is present.

7. What to do if it shows an AFIB message?

   If you receive a notification about suspected atrial fibrillation, you should register an ECG and consult a medical professional.

8. Why does the battery drain quickly?

   This depends on how often the user performs ECGs, how often data is transferred to the mobile app, the screen brightness, and how often it is turned on.

9. Why did the ECG recording stop by itself?

   The screen may activate due to accidental touch. For unwanted recordings, we suggest disabling screen wake-up on lifting and screen wake-up on touch. This can be done by swiping up on the main screen and opening the screen settings menu.

10. How to set notifications?

    To enable or disable atrial fibrillation monitoring and notifications, press the button on the main screen, open the "AF" section, and change the "Active" status. To enable or disable high and low HR monitoring and notifications, press the button on the main screen, select "Settings" in the menu that appears, then "Heart rate notifications" and change the "Alert" status to the desired one.

11. Does the bracelet automatically record ECG?

    No. ECG recording can only start when the user selects "Record ECG" or "Start ECG" on the screen.

12. How does the bracelet notify about AFIB?

    If atrial fibrillation is suspected, the smart wearable vibrates and displays a notification suggesting to take an electrocardiogram.

13. How to create a patient account?

    To create a patient account, log in to the TeltoCare system with your doctor or administrator account. Go to the "Patient List" section and select "Create Patient." Fill in the required patient information and click "Create."

14. Where to see patient data?

    After logging in to TeltoCare, patient data can be seen in the patient profile, which can be found in the patient list. Here you can see all information related to the patient, including medical records, ECG data, etc.

15. How can a patient create an account?

    A patient can create an account using the TeltoHeart mobile app or the TeltoCare (https://teltocare.com) website. Select the registration option, enter the required personal information, and you will receive a temporary password via email, which you will use to change to your desired password. After completing these steps, you can log in to your new account.

16. How to verify a patient?

    A hospital administrator can verify a patient in the TeltoCare system by clicking on "Patients." Select the patient with the "In Queue" status, click the button, and select "Invite."

17. How to print/download ECG?

    In the patient's profile, in the "Electrocardiogram" section, select the desired ECG record and click "Export" or "Print." This will allow you to download the PDF and print it.

18. Is there a caliper function?

    Yes, TeltoCare has a caliper function designed to measure ECG intervals accurately. This function is available in the "Electrocardiogram" section.

19. Where to see AFib notifications?

    Atrial fibrillation notifications can be seen in the "Atrial Fibrillation" section.

20. Does the bracelet automatically record ECG?

    No, the TeltoHeart bracelet does not automatically record ECG. You can record an ECG by pressing the right button on the bracelet, selecting ECG, and pressing "START ECG" or swipe up on the main screen to open the quick menu and then press "RECORD ECG."

21. How does the bracelet notify about AFIB?

    In the event of atrial fibrillation, the bracelet will notify you by displaying a message "Suspected AF" on the screen.

22. Will I see all patients or just my own?

    Hospital and doctor accounts can see the entire hospital's patient list. The doctor account can also see the list of patients assigned to them.

23. How to delete a patient?

    You can delete a patient by selecting the patient in the patient list, clicking the button, and then selecting "Delete."

24. Are patient data saved after deletion?

    Deleted data will no longer be visible in the system, but it is stored for 14 days. Your account can be restored within 14 days by the hospital, technical support, or administrator.

25. How to transfer a patient to another doctor or clinic?

    Go to the patient's profile, click edit patient, and then assign a doctor from the doctor list.

26. How to restrict patient visibility to other doctors within the clinic?

    Go to the doctor's account, click edit doctor, then go to "User Permissions" and set the permissions.

27. How to delete an "unreadable ECG"?

    Currently, there is no option to delete ECG recordings.

28. Can a patient be assigned to multiple clinics?

    No, a patient cannot be assigned to multiple clinics at the same time.

29. How to filter patient ECGs by indication (selected after ECG recording)?

    In the "Electrocardiogram" section, next to the ECG record, you will find a symbol indicating the patient's reason for the ECG recording.

30. How to filter pulse display chart (time interval setting)?

    You can set the time interval by selecting 

, where you can set the start and end dates or choose filtering by hours, days, weeks, months, or years.

31. How to see weekly, monthly, yearly data (ECG and pulse)?

    You can set the time for ECG and pulse data by selecting 

, where you can set the start and end dates or choose filtering by hours, days, weeks, months, or years.

32. Can I log in to TeltoHeart application with a doctor, hospital and distributor accounts?

    No, only a patient account can link the TeltoHeart smart wearable and send data from the TeltoHeart to the TeltoCare platform. Other accounts are not meant for data collection.

8 Disposal

8.1 Disposal and recycling

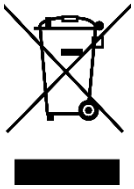
Do not dispose of the device as domestic waste. As a rule, you can get information on proper disposal at your local government or specialized waste disposal plants.

TeltoHeart and/or battery should not be disposed of with household waste. Dispose of your device and/or battery in accordance with local environmental laws and guidelines.

8.1.1 Battery replacement

The lithium-polymer battery in TeltoHeart should be replaced by Teltonika Telemedic or an authorized service provider, and must be recycled or disposed of separately from household waste.

8.2 European Union—Disposal Information



The WEEE symbol above means that according to local laws and regulations TeltoHeart and/or its battery must be disposed of separately from household waste. When this product reaches its end of life, take it to a collection point designated by local authorities for safe disposal or recycling. The separate collection and recycling of TeltoHeart and/or its battery will help conserve natural resources, protects human health, and help the environment.

9 Technical Data

9.1 Technical Parameters

BODY	
Dimensions (Width x Length x Height):	40.5 (1.6") x 47 (1.9") x 14.7 (0.6") mm
Weight:	52 g
Main CPU:	nRF5340 2x ARM Cortex M33 cores for application and network
Platform (OS):	Zephyr RTOS
DISPLAY	
Brightness:	250 NITS
Resolution:	240 x 240 px
Type:	LCD TFT
Size:	1.3“
Cover lens:	Corning gorilla glass 3
Surface hardness:	>8 H
Display area:	547.56 sq mm
TELTOHEART MEMORY	

Capacity:	128 Mb
CONNECTIVITY	
Bluetooth version:	5.3
Remote access:	Cloud
PERFORMANCE	
Operating frequency:	2402 MHz – 2480 MHz
Max. output power:	3 dBm
FEATURES	
• **ECG sensors for electrocardiogram** • **PPG sensors for AFib detection** • **Heart rate monitoring** • **Low/High heart rate** • **Cloud-based firmware updates, configuration app (Bluetooth)** • **Water resistant 1 m (for 30 minutes)** • **Protection level against ingress of solid objects and water: IP 67**	
POWER SUPPLY	
Build-in rechargeable Li-Po battery (not replaceable by the user):	410 mAh 1.56 Wh
Charging voltage:	USB-C, 5 V ⎓
Operating voltage:	Internal Battery 3.8 V ⎓ • External power supply 5 V ⎓
Max. Input current:	0.5 A
SENSORS AND COMPONENTS	
• **Accelerometer** • **Gyroscope**	
BUTTONS	Side button (Turn on, Restart, Back)
STRAPS	
The wristband with an electrode is made of silicone with an integrated stainless-steel electrode	
Strap material:	Silicone
AVAILABLE STRAP SIZES	
S	Fits on wrist 14 up to 20 cm
M	Fits on wrist 16.5 up to 22 cm
L	Fits on wrist 19 up to 24.5 cm
SUPPORTED PERIPHERALS	
ACCESSORIES:	• TeltoHeart charging dock
Compatibility with other manufacturer accessories:	• Any CE marked wall charger with 5 V⎓/1A output and USB type-A connector. • Any CE certified USB-A to USB-C cable.

	• Any smartphone operating on Android OS version 10 or above with Google Play store service. • Any smartphone using iOS version 14 or above.
COMPATIBILITY WITH MRI OR CT WAS NOT CHECKED AND USE OF DEVICE IN MRI OR CT ENVIRONMENT IS PROHIBITED	
Bluetooth compatibility:	Devices that use Bluetooth v5.0 or later in 2.4 GHz (2.402 – 2.480 GHz) band and SMP protocol are compatible with the device
CONDITIONS FOR USE	
Operation temperature range: **Charging temperature range:** **Storage temperature range:** 1 Month: 6 Months:	• -10 to +45 ℃ • 0 to +45 ℃ -20 to +35 ℃ -20 to +30 ℃
Humidity limitations:	• Extreme low (left below): 15% • Extreme high (right top): 90%
Atmospheric pressure limitations:	• Extreme low (left below): 700 hPa • Extreme high (right top): 1060 hPa

10 Limitation of Liability

To the extent not prohibited by applicable law, under no circumstances shall the company or its employees be liable for any lost profits, revenue, sales, data or costs of procurement of substitute products or services, property damage, personal injury, interruption of business, loss of business information or for any special, direct, indirect, incidental, economic, punitive, special or consequential damages, however caused and whether arising under contract, tort, negligence, or other theory of liability arising out of the use of or inability to use the software, even if advised of the possibility of such damages.

Some jurisdictions do not allow the limitation of liability for personal injury or incidental or consequential damages, so this limitation may not apply in these cases.

In no event shall the company's total liability for all damages (other than as may be required by applicable law in cases involving death or personal injury resulting from the company's negligence) exceed the amount of price for the product and/or service.

11 Privacy policy

To review our privacy policy, please visit our website at: https://teltonika-telemedic.com/about-us/policies-certificates/privacy-policy-telemedic

12 Warranty

The warranty conditions and term of warranty shall apply in accordance with agreed conditions between you and your supplier.

It is important to carefully read and follow information for user (included but not limited quick start guide, technical specifications and user manual) and terms and conditions provided by the manufacturer. Failure to adhere to these guidelines may result in malfunctions or damage to the product, for which the manufacturer cannot be held responsible. It is the responsibility of the user to ensure that they fully understand and comply with the information provided by the manufacturer and terms and conditions before using the product. By doing so, users can help ensure the safe and effective use of the product and avoid any potential damage or liability.

13 Declaration of Conformity

TELTONIKA TELEMEDIC UAB hereby declares that device TeltoHeart is in conformity with essential requirements and other relevant requirements of Directive 2014/53/EU.

Thus, CE placed on the product.

FCC statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

FCC ID: 2BAIF-ECG200

IC warning

This device contains license-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's license-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes:

1) L'appareil ne doit pas produire de brouillage.

2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

IC ID: 27304-ECG200

HVIN: ECG200-2C_A

All latest certificates may be found in our Wiki[1].

[1] https://wiki.teltonika-telemedic.com/view/TeltoHeart_Certification_%26_Approvals