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Approval			
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Instructions manual

TELTOHEART

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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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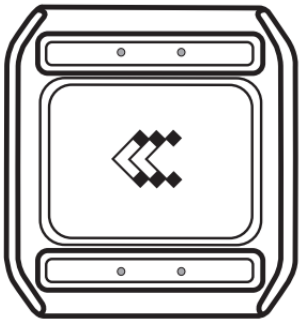
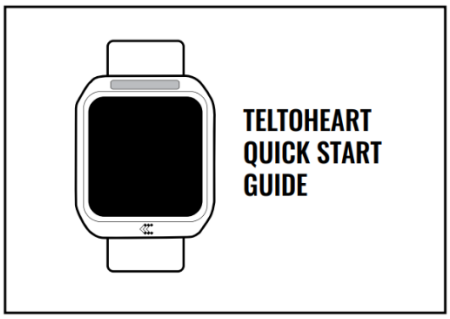
1 Scope of Delivery

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 Charging dock	1x TeltoHeart smart wearable	1x Quick start guide
		
Charging dock used to charge TeltoHeart	TeltoHeart with strap attached	Instructions with easy-to-understand illustrations.

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

Scan

Full manual

2 Product Description

TeltoHeart – a wearable device designed to monitor your heart health. TeltoHeart features ECG and heart rate measurement capabilities, providing accurate and reliable data on your heart's well-being.

With the MyHealth application, you can easily transfer the data collected by your TeltoHeart device to the TeltoCare medical platform. TeltoCare provides you with a comprehensive view of your heart health based on your ECG and heart rate data.

You can view and analyse your data, allowing you to track your heart health and assist medical practitioners in identifying any potential issues. In addition, the TeltoCare platform helps medical professionals to remotely monitor your heart health and provide expert advice and consultation based on your data.

2.1 Labeling

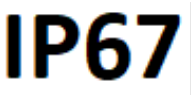
Symbol	Significance
	CE label
	FCC label **FCC ID:** 2BAIF-ECG200
	UKCA label
	**IP protection class:** 67 The first digit indicates the level of protection against solid objects and the second digit indicates the level of protection against liquids.
	Consult instructions for use
	Temperature limit
	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 2.1: Labelling

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 3: Safety instructions

3.1 Safety Terms and Symbols

This section contains general warnings, contraindications and cautions that should be followed when using the 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.

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: MyHealth 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 MyHealth mobile application

MyHealth 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.

Scan QR code to download MyHealth application

CAUTION:

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

4.2.2 TeltoCare system

TeltoCare is used to display ECG and HR data collected by TeltoHeart and transmitted by MyHealth 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.

CAUTION:

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

4.2.2.2 TeltoCare roles

4.2.2.2.1 Patient role:

In TeltoCare, patients have the ability to view their ECG, Heart rate data and personal information within the platform.

ECG Data: If a patient has undergone an ECG (Electrocardiogram) measurement, the results first stored in the TeltoHeart and get transferred to the TeltoCare system over MyHealth application. Patients are able to access their ECG data through their personal account on the platform. Personal account is acquired by receiving an e-mail with login details, which is sent by the Doctor or Clinic. The ECG data may be displayed as a visual representation of the heart’s electrical activity, and patients can review their measurement results and consult with physician.

Hear rate Data: Heart rate data is presented as a continuous record of the patient's heart rate over a specified time period, displayed in beats per minute (BPM). Patients can track their heart rate trends, identify any irregularities or fluctuations, and then discuss these findings with their healthcare provider for further evaluation and guidance.

Personal information: Patients can securely view and manage their personal information within their account settings. This may include demographic details (such as name, surname, date of birth and contact information), medication records, allergies and other relevant health information.

4.2.2.2.2 Doctor role:

Doctors within the TeltoCare platform have access to specific patient information and data for medical purposes. They are authorized to view patients' medical records, personal information, Heart rate and ECG measurement data. This access allows doctors to provide comprehensive and informed medical consultations, make accurate diagnoses, and offer appropriate treatment recommendations.

4.2.2.2.3 Distributor role:

Within the TeltoCare platform, distributors have the ability to create accounts for doctors. As part of their role, distributors facilitate the onboarding process for healthcare professionals who will be providing medical services through the platform. This involves creating accounts for doctors, granting them access to the necessary features and functionalities of the TeltoCare platform.

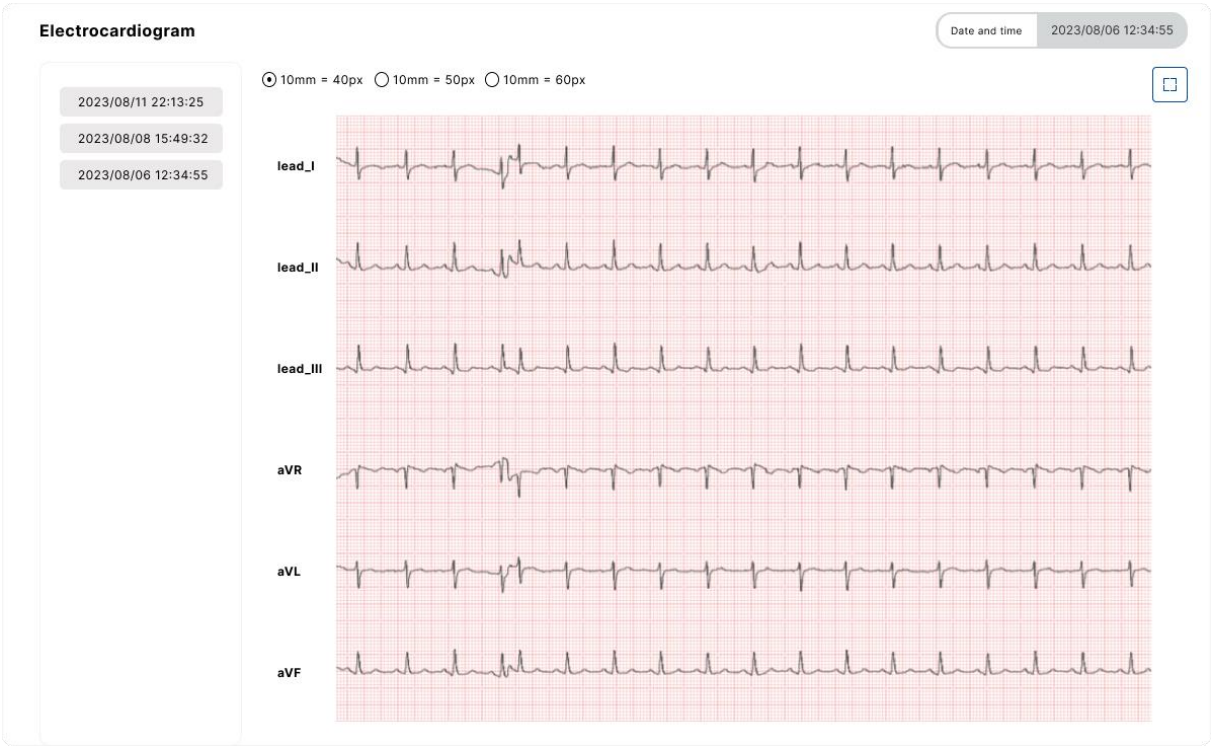
4.2.3 Time interval

Users in the TeltoCare platform can select a time interval ranging from an hour to a year to view their ECG and heart rate data.

4.2.4 Electrocardiogram

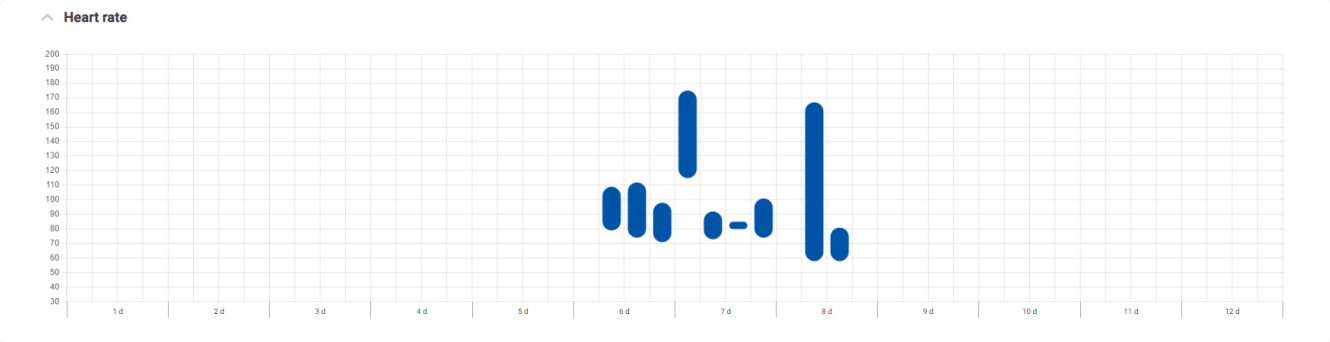
Electrocardiogram tab provides users an access to review Electrocardiogram (ECG) data. Users are able to view specific ECG leads (Lead I, Lead II, Lead III, aVR, aVL and aVF) and filter records based on date and time.

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



4.2.5 Heart rate

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).



4.3 Data transferring

TeltoHeart sends data to the MyHealth application on your smartphone via a Bluetooth connection. This data includes information such as your heart rate and ECG data. Once the data is received by the MyHealth application, it sends data to the TeltoCare platform.

MyHealth application is designed to securely transmit data from the TeltoHeart to the TeltoCare platform. This ensures that your data is transferred in a safe and reliable manner, protecting your privacy and maintaining the integrity of your data. TeltoCare platform then displays your health data, which can be used for further analysis and interpretation by a qualified clinician.

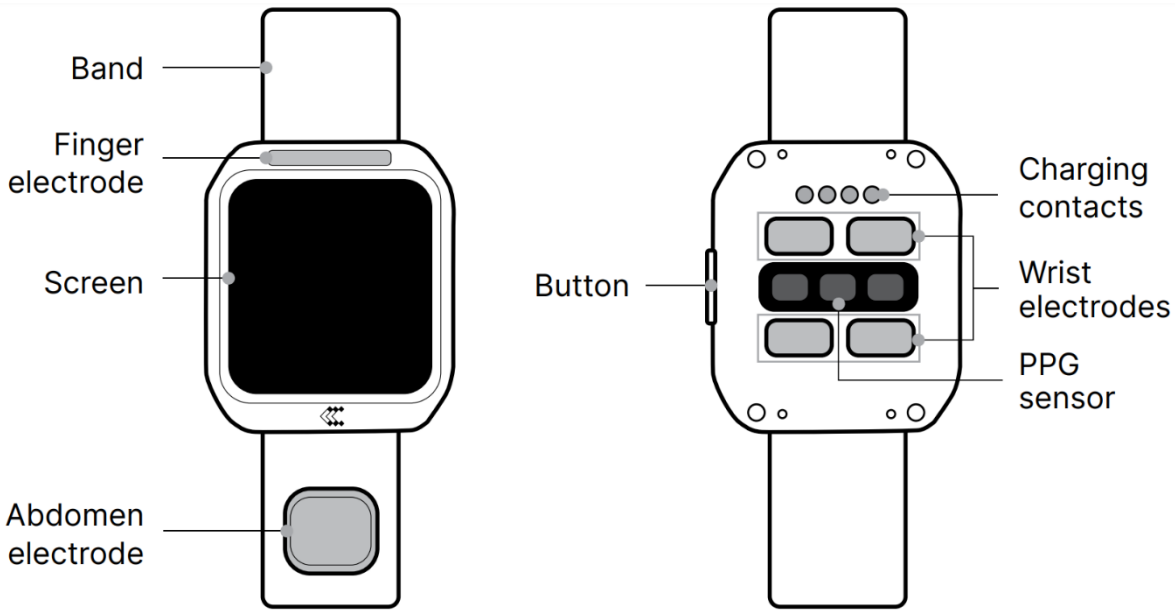
CAUTION:

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 backup the data or send information to medical experts if there is no internet connection.

4.4 Get Started



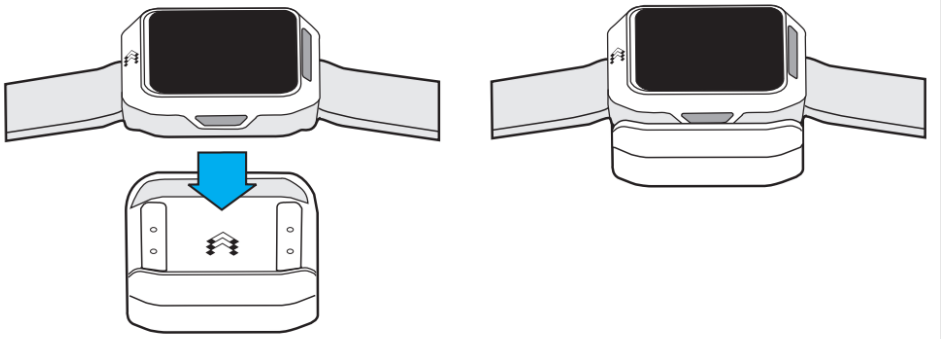
4.4.1 Charge the device

The battery life is dependent on usage and other factors.

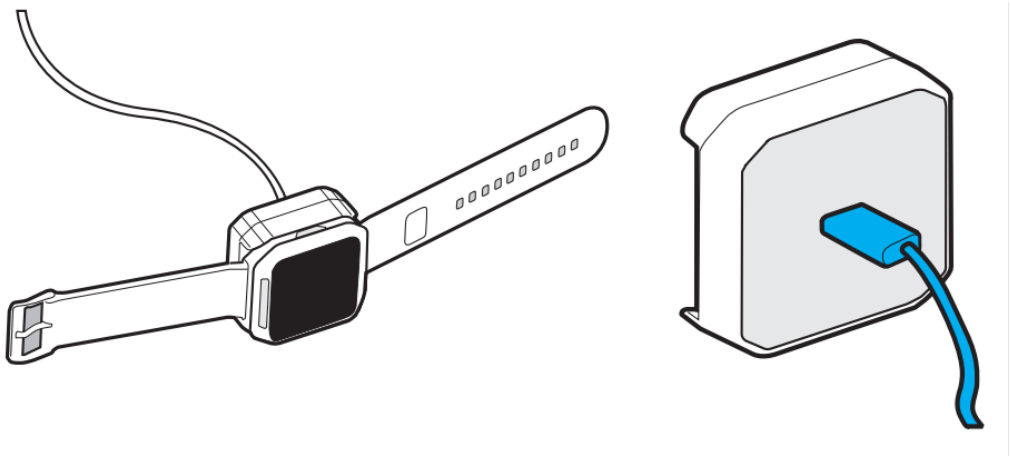
Device charging:

1. In a well-ventilated area, place charging dock on a flat surface.

   TeltoHeart comes with TeltoHeart Charging dock.



2. Plug the charging cable into the USB port in your computer or any CE certified 5 DC 1 A wall adapter.



3. Place TeltoHeart on the dock, once the device begins to charge, the charging indicator will appear on the screen.

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

4.4.1.1 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.

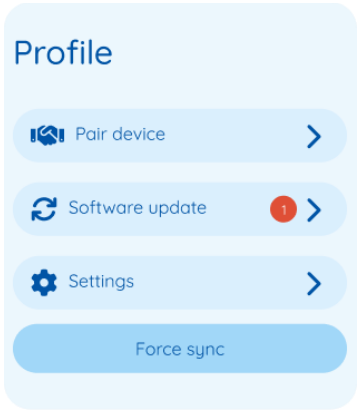
It is important to keep TeltoHeart and TeltoHeart Charging dock and the power adapter in a well-ventilated area when charging or in use.

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

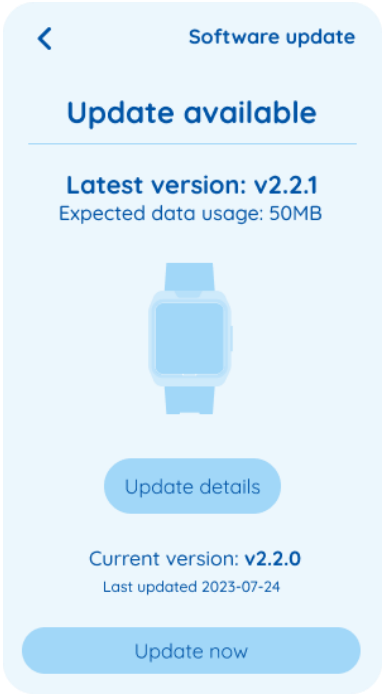
4.4.2 Update TeltoHeart firmware

Updating the firmware on your TeltoHeart smart wearable is important to ensure that your device is running optimally and is up to date with the latest features and bug fixes. First make sure that TeltoHeart is paired to your smartphone.

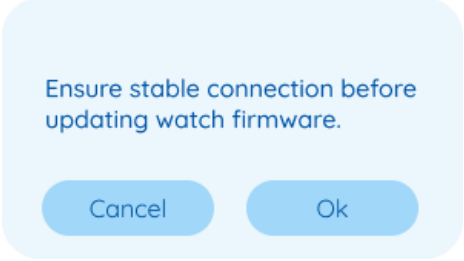
1. To update TeltoHeart firmware, open MyHealth application on your smartphone and tap **Software Update**, which is located on application's dashboard. Icon 1 indicates that there is a firmware update available to be downloaded.

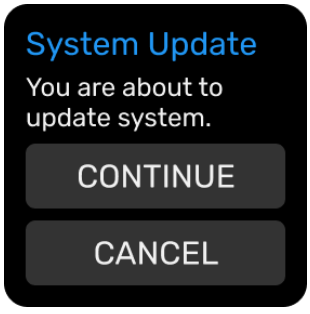


2. It is important ensure stable connection before updating TeltoHeart firmware. Keep TeltoHeart connected to your phone and keep the MyHealth application open during the firmware update process. Tap **Update now** to update TeltoHeart firmware.



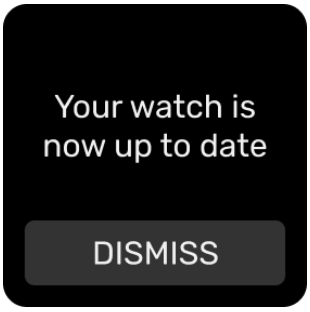
3. Make sure your TeltoHeart has stable connection before initiating firmware update. When you are sure that connection is stable, tap **Ok** in MyHealth application. In TeltoHeart tap **Continue** to proceed with the firmware update.





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

5. Once the update is complete, TeltoHeart will automatically restart and the new firmware version will be installed. TeltoHeart and MyHealth application will confirm that updated was successful.



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:

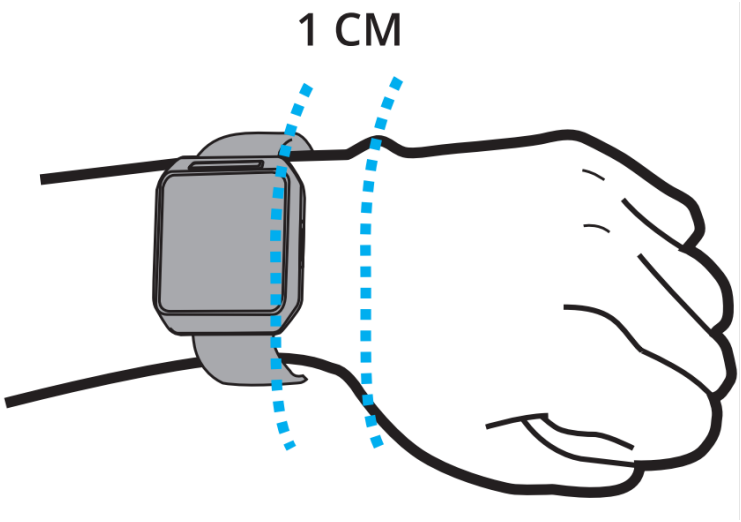
Please do not use the device during the firmware update process. Doing so could cause irreparable damage to the device and render it unusable.

4.4.3 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.

4.4.4 Power settings

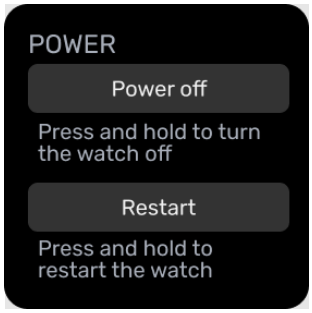
4.4.4.1 Power on

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

4.4.4.2 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.

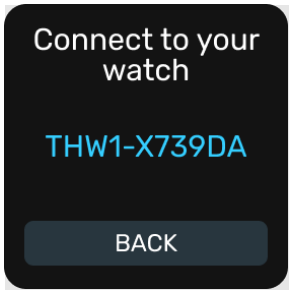


4.4.5 Start using TeltoHeart

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

1. When TeltoHeart is turned on the first time, it will ask you to download MyHealth application:

2. You will be able to locate TeltoHeart on the MyHealth application as its name will be displayed on the screen.



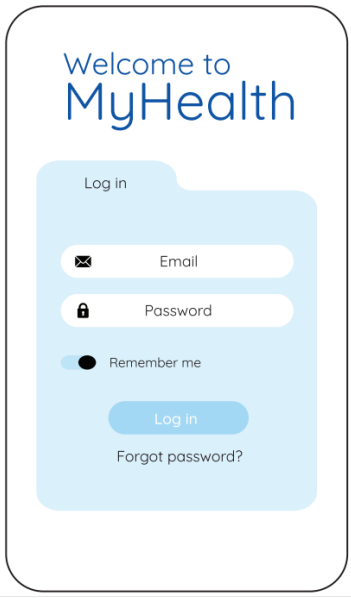
CAUTION:

⚠	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.

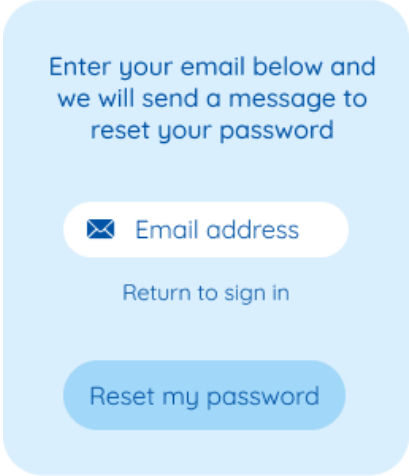
Setting up MyHealth application

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 MyHealth application.

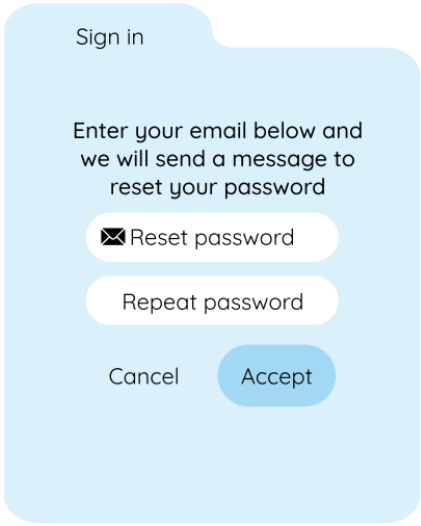
1. Download MyHealth application:
   - Google Play Store for Android OS phones.
   - Apple App Store for iPhones
2. After installing the app, tap to open the app.
   - If it is your first time using the app, sign in by entering e-mail address and password, which had been sent to your e-mail.



3. MyHealth application will prompt you to change the default password to a personal preferred password of your choice.
   - Enter your e-mail address.



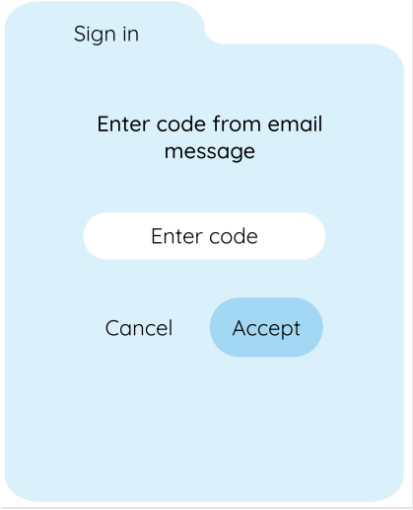
- Select **Reset password** option.



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.

- Enter the code received in e-mail.



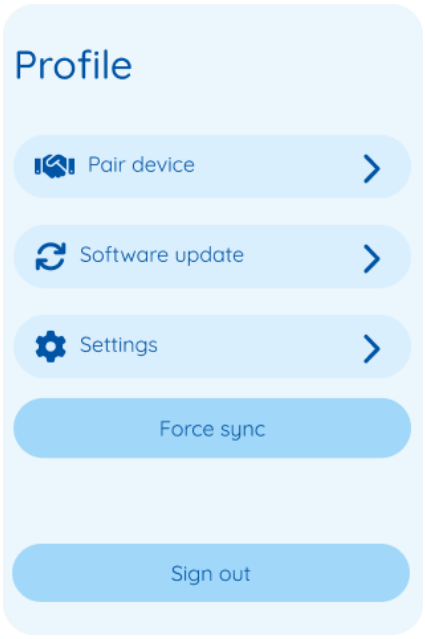
3. Once you have successfully changed your password, the next step is to review and accept the **Terms and Conditions**. You will be prompted to acknowledge and agree to the Terms and Conditions before proceeding.

MyHealth application permissions:

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

TeltoHeart pairing with MyHealth application

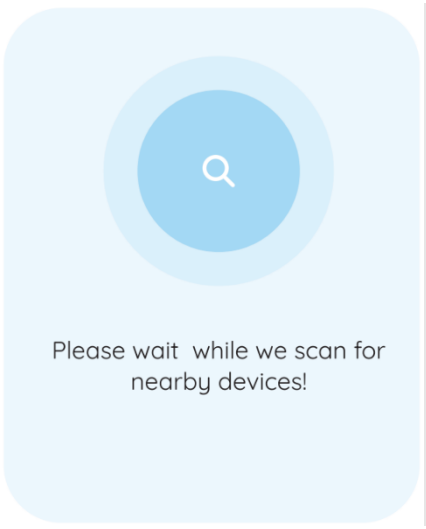
- Tap **Pair device** to proceed with the pairing process.



CAUTION:

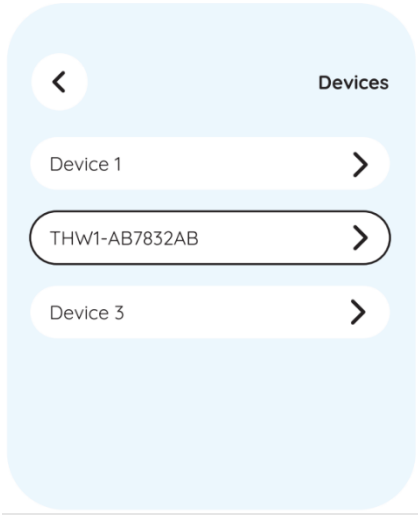
Avoid pairing the device in public places.

- MyHealth application will initiate a search of nearby devices.

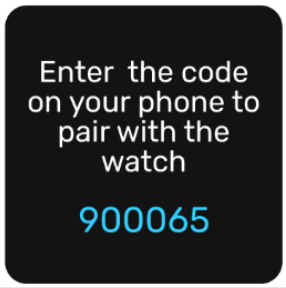


Notice: Make sure Bluetooth functionality is Enabled in your device.

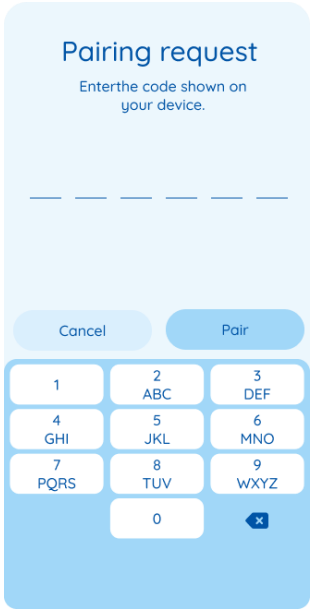
4. Select your smart wearable by tapping on it.



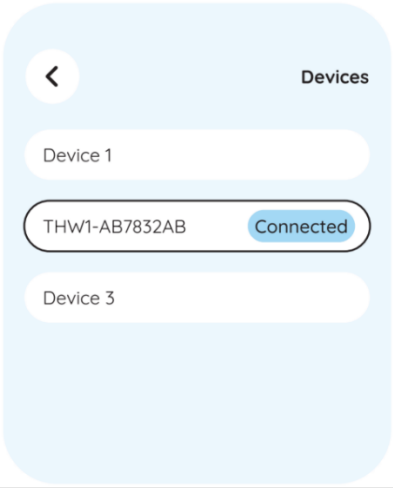
- TeltoHeart will notify you of an incoming pair request.



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



5. After successful pairing, **Connected** indication will appear.



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

7. Make sure MyHealth application is always running in the background, otherwise the data transfer will not be available.

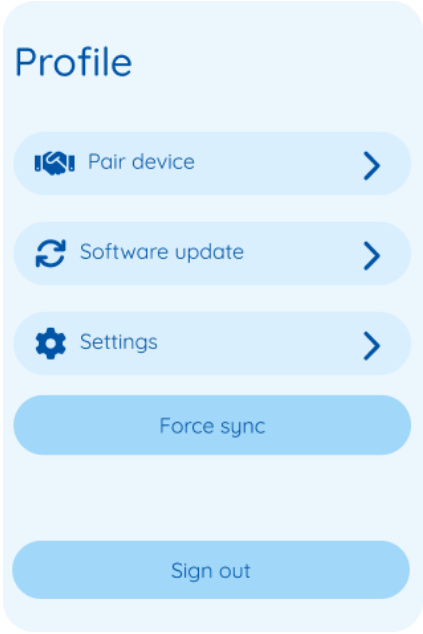
Note: To ensure uninterrupted data transfer from your smart wearable to the platform, it is important to keep the MyHealth application running in the background at all times. If you close the app, the data transfer to TeltoCare platform will not be available.

CAUTION:

User must grant data storage permissions on mobile application.

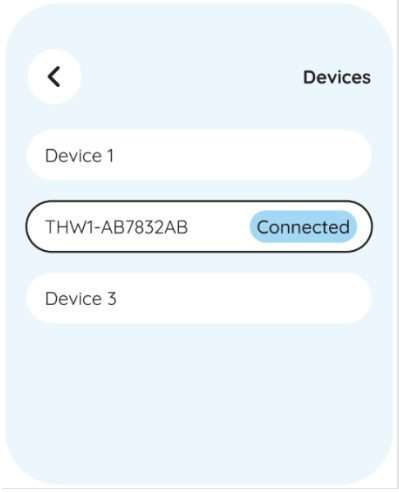
4.4.6 Unpair TeltoHeart

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

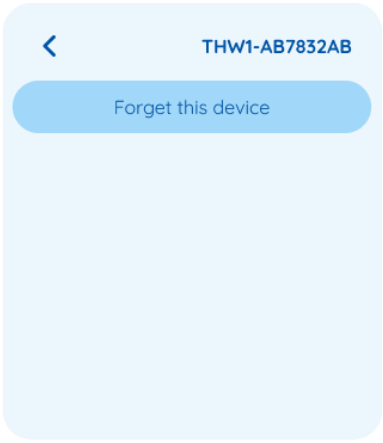


After unpairing TeltoHeart via MyHealth application, all data in TeltoHeartwill be permanently deleted. This includes any saved settings, ECG and HR data.

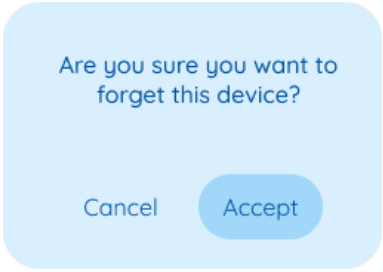
- Find your paired TeltoHeart smart wearable and tap on it.



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



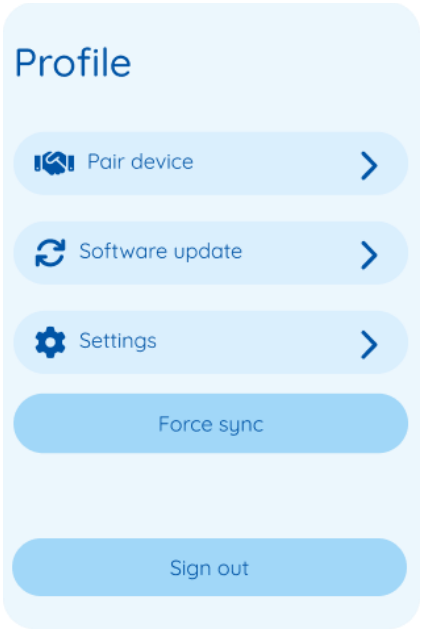
- Confirm the selection by tapping **Accept** to forget this device



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

4.4.7 Sign out from MyHealth app

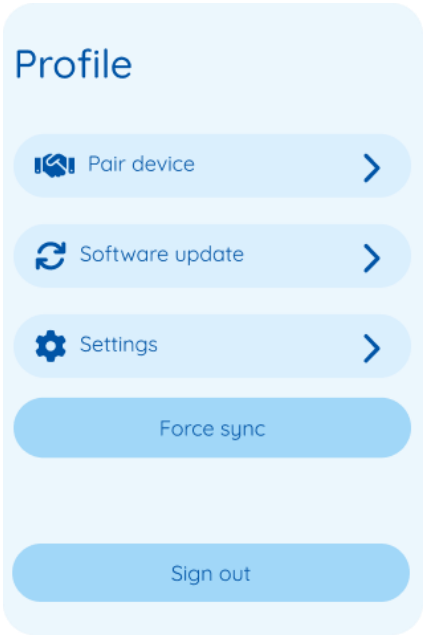
- To **sign-out** from user profile, tap **Sign out** at the bottom of the main screen.



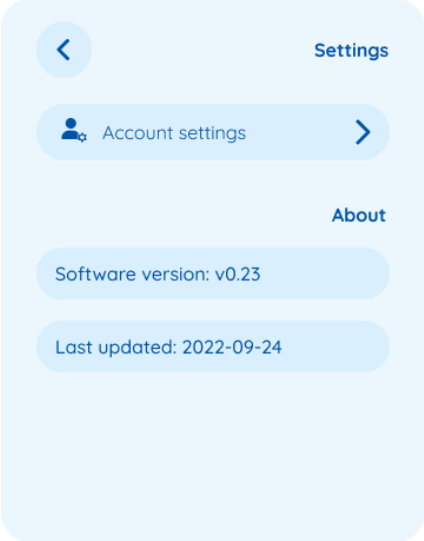
Notice: Sign in details will be deleted once user is signed out of the app.
To access the account, user will have to sign in again.

4.4.8 User account data deletion

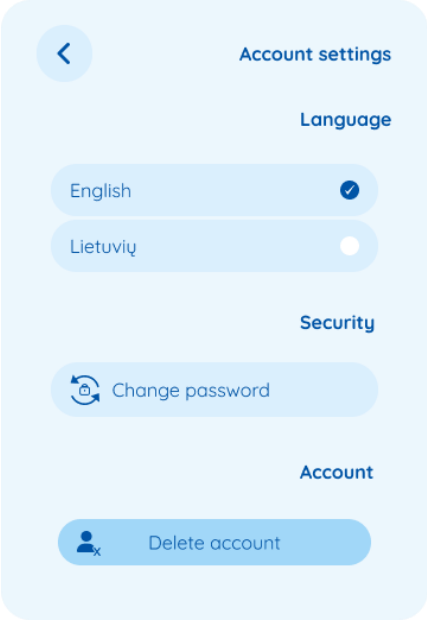
- To **Delete MyHealth application and TeltoCare account,** tap **Settings** on the main screen.



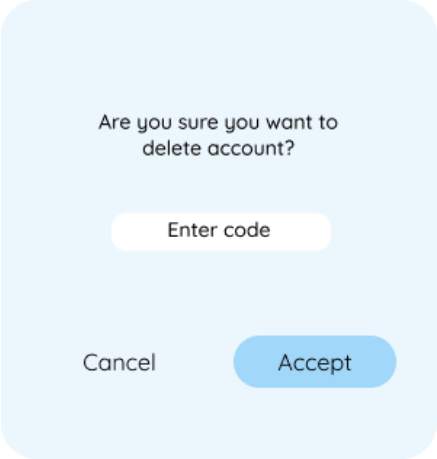
- Tap **Account settings**.



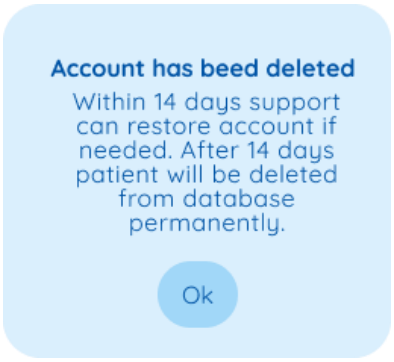
- Tap **Delete account** to delete your account and all collected data.



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



- 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.

4.5 Recording an ECG

4.5.1 Before you start

- To measure and record physiological parameters, TeltoHeart utilizes photoplethysmography (PPG) and electrocardiogram (ECG).
- To transmit ECG data, ensure that TeltoHeart and MyHealth are paired with iOS 14 or later / Android 10 or later.
- 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.

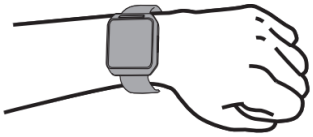
4.5.2 Setup

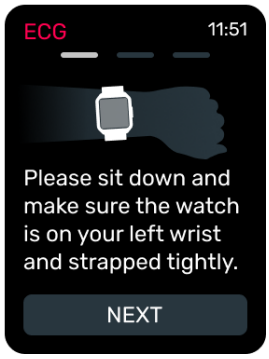
- Push the side button once to open up a menu.
- Open ECG function icon using TeltoHeart.
- Follow instructions on screen.

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

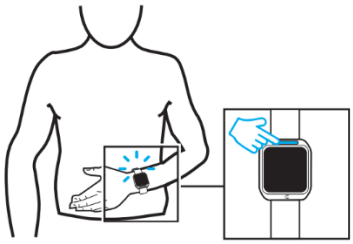
4.5.3 How to take ECG recording

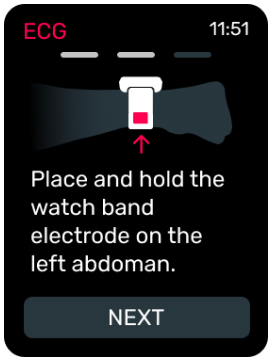
1. Follow the instructions on screen and tap **NEXT**.
2. Please sit down and make sure TeltoHeart is on your left wrist and strapped tightly, but comfortably.



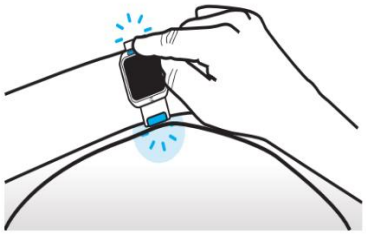


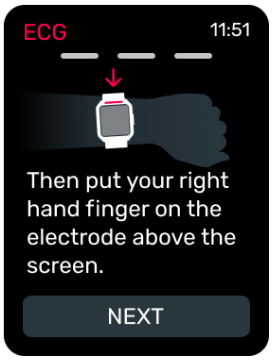
3. Place and hold the abdomen electrode on the left side of the abdomen side.



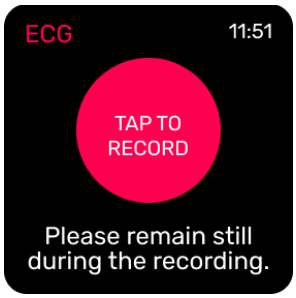


4. While holding the electrode on the left side of the abdomen, put your right hand finger on the finger electrode above the screen.





8. 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.



5. The recording lasts for 60 seconds.
6. 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 MyHealth application running in the background to allow measurement data transfer.

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

4.5.4 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. 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.

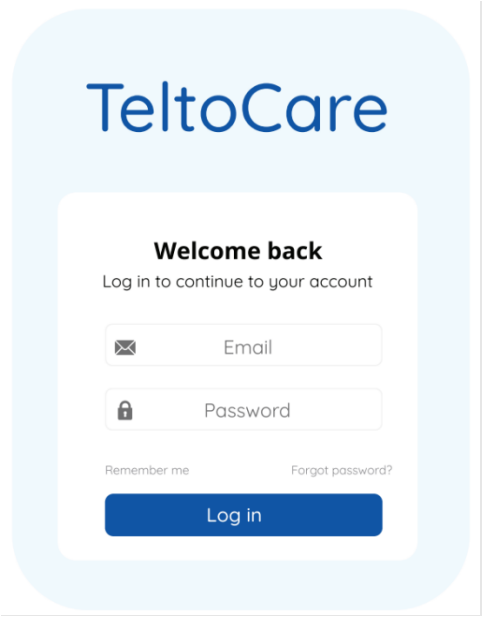
If TeltoHeart storage is full newest records will be written on top of the oldest.

Notice: Do not take recordings during physical activity.

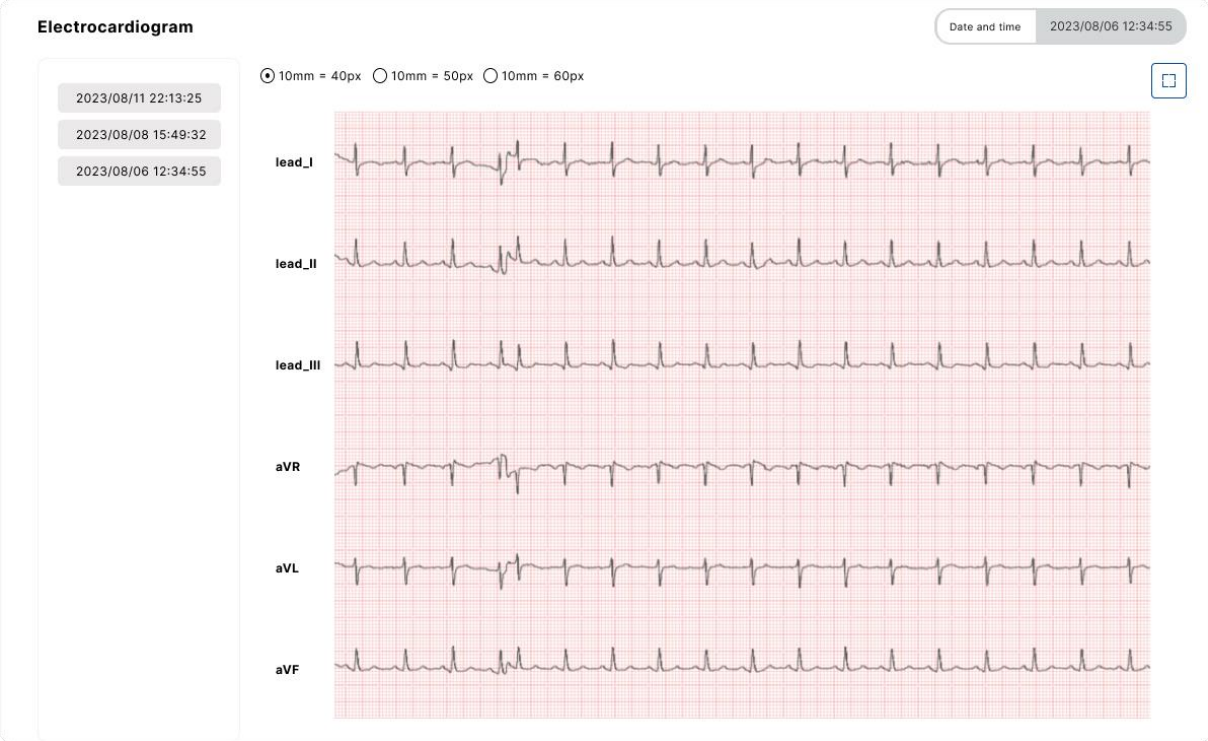
4.5.5 How to view ECG data in TeltoCare

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

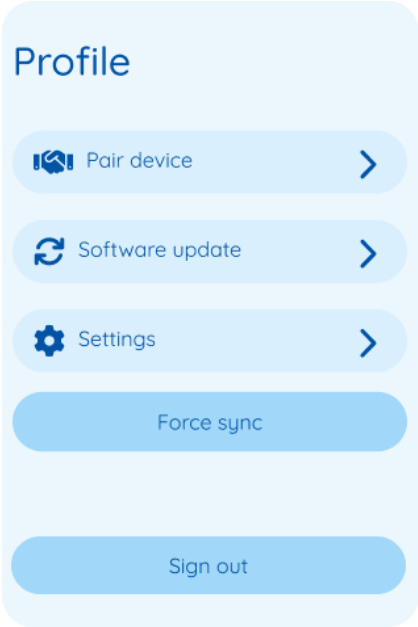
Notice: MyHealth application and TeltoCare share the same login details.



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 MyHealth 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 MyHealth application enables you to trigger the data transfer process and ensure the availability of your ECG measurements in the TeltoCare platform.

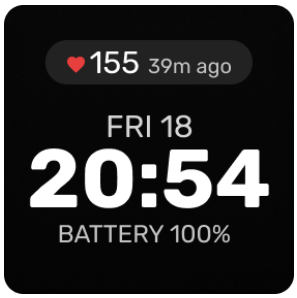


4.6 Heart rate check

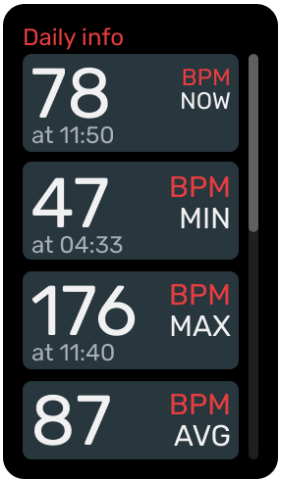
4.6.1 Check heart-rate

1. You can check your heart rate by looking at the home screen of TeltoHeart.
2. If no measurement has yet been made, TeltoHeart 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 TeltoHeart 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.



4.6.2 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.

4.7 Displays and Signals

4.7.1 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.

4.7.2 Control center

Swipe up on TeltoHeart to access the control center, which offers convenient access to a range of settings and functions, including quick ECG measurement, power settings, and display preferences.

4.7.3 Battery

Battery percentage can be checked on the bottom of the main screen:

WARNING:

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

4.7.4 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.

4.7.4.1 Enter display settings

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

4.7.4.2 Adjust display brightness

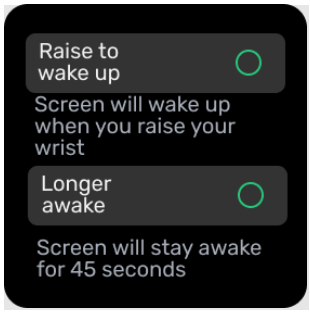
Slide your finger to the right on the brightness bar to increase the brightness, or slide it to the left to decrease the brightness. You can adjust the brightness to your preferred level.

4.7.4.3 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.

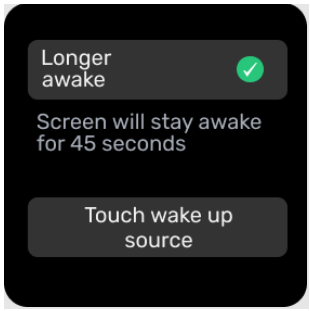
4.7.4.4 Longer awake

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.

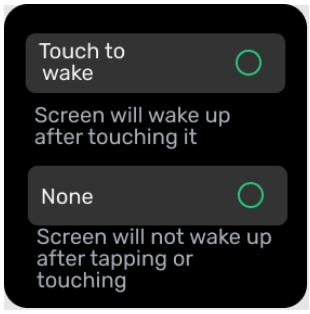


4.7.4.5 Touch wake up source

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

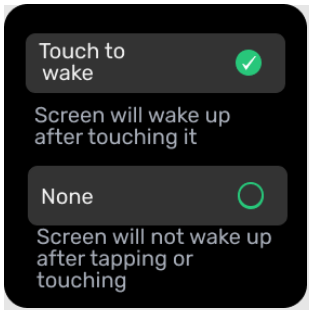


Tap on this section to enter the **Touch wake up source** settings. Here, you can choose which touch actions will wake up your device when the screen is off. To enable or disable selected function, simply tap on the corresponding ○ icon. When the function is active, a checkmark ✓ icon will appear.



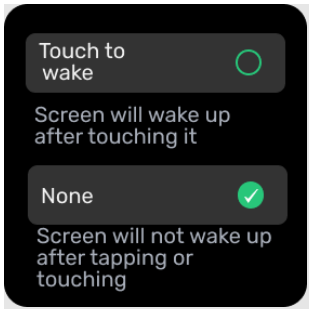
4.7.4.6 Touch to wake

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



4.7.4.7 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.

4.7.5 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.

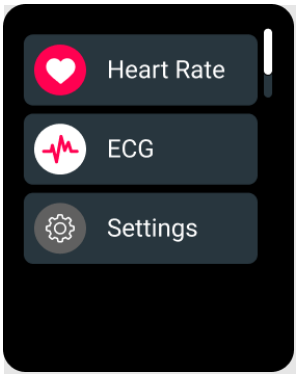
Event	Indication
Connected/Disconnected events	
Connected	Short low burst

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

4.8 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.

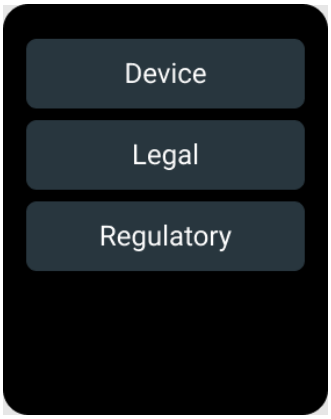
Press the side button to bring up a menu.



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

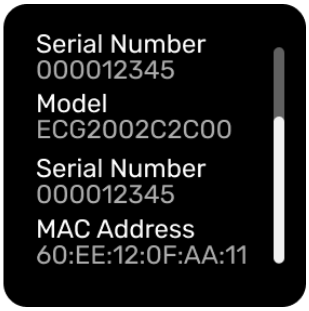
4.8.1 About

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



4.8.1.1 Device

Under the Device Information section, you can view details such as the device name, software version, model, serial number, MAC address. 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.



4.8.1.2 Legal

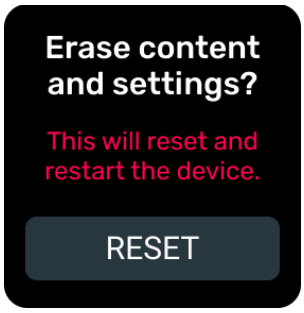
The Legal Information section asks you to visit the MyHealth application legal section, where you can find important legal information related to the use of the MyHealth application, TeltoCare and the TeltoHeart.

4.8.1.3 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.

4.8.2 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 data and reverse the TeltoHeart 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.

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:

1. Turn off your smart wearable and remove it from the charger.
2. Wipe your TeltoHeart clean with nonabrasive, microfiber cloth. If necessary, lightly dampen the cloth with fresh water and clean the smart wearable. Other cleaning products and soaps shall not be used to clean TeltoHeart.
3. Dry your TeltoHeart lightly swiping with microfiber cloth.

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 MyHealth application:** Make sure that your TeltoHeart is properly paired with the MyHealth application on your phone. If it's not, follow the pairing instructions provided in 4.4.5.3 TeltoHeart pairing with MyHealth 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 MyHealth application and select to pair your TeltoHeart.
2. **Restart Teltoheart:** Sometimes, restarting TeltoHeart 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 wearablehas outdated firmware, it may cause issues with the time and date display. Check for any available updates for TeltoHeart on MyHealth mobile application and install them as necessary.

6.4 Paired device prior to registering/logging in

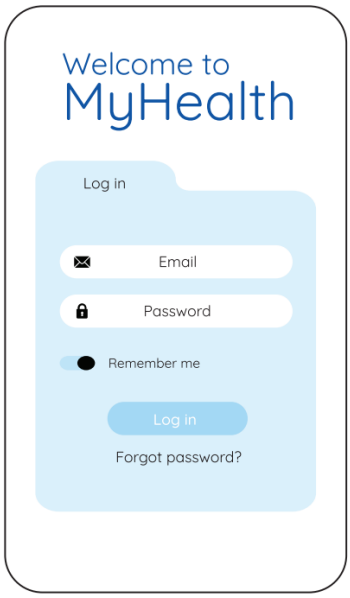
If you have paired your TeltoHeart to your phone through Bluetooth settings instead of the MyHealth application, you may run into a few issues, including poor functionality or even disconnection issues. Here are some troubleshooting steps to help you resolve this problem:

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**.
3. **Download the MyHealth application:** If you haven't already, download the MyHealth application for your TeltoHeart from the app store. Once downloaded, login to your account and select **Pair Device** (follow the steps provided in 5.4.3.3 TeltoHeart pairing with MyHealth application).
2. **Check for firmware updates:** After pairing your smart wearable through the MyHealth application, check for any available firmware updates and install them as necessary.

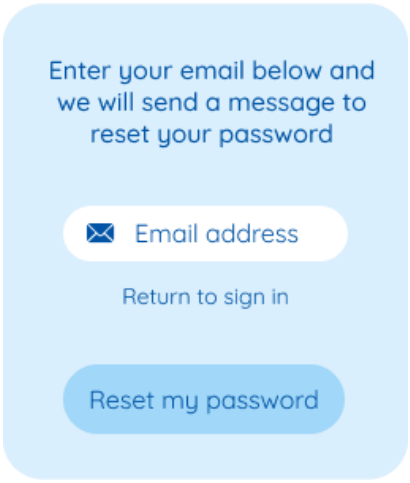
6.5 Forgot password for MyHealth or TeltoCare account

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

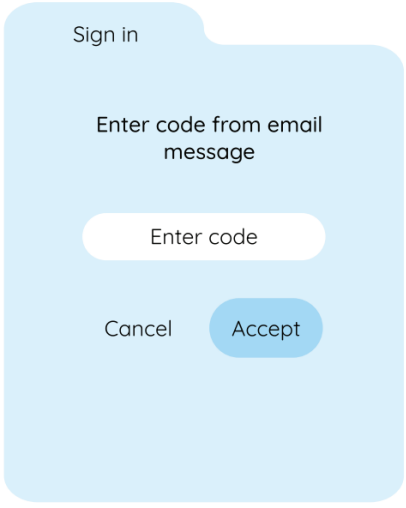
1. **Click on the Forgot Password option:** On the login page of the application, look for **the Forgot Password** option and click on it.



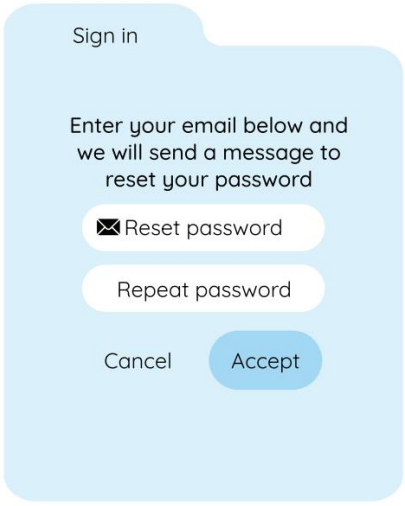
2. **Enter your email address:** You will be asked to enter the email address associated with your account. Enter the correct information and click on **Reset my password**.



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

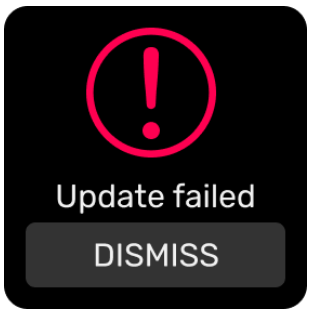
If the heart rate sensor on your TeltoHeart has difficulty detecting your Heart Rate "–" appears.

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.

6.8 TeltoHeart has displayed Update failed message

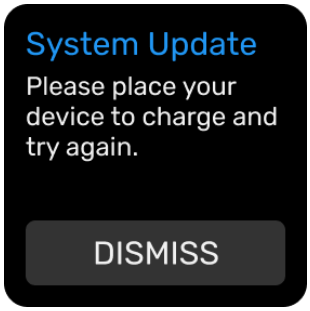
During firmware update, TeltoHeart has displayed Update failed message.



1. Make sure Bluetooth connection on your phone is enabled.
2. Make sure your mobile phone and TeltoHeart are in Bluetooth range during the firmware update.

6.9 TeltoHeart is not updating firmware

1. Make sure TeltoHeart is charged at least 50%. If you are trying to update the firmware with less than 50% of the battery, TeltoHeart will display a following message.



2. Should the battery of your TeltoHeart be charged at over 50% and the firmware update encounters issues, please get in touch with our Support team.

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 Disposal

7.1 Disposal and recycling

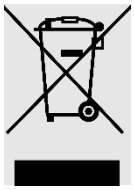
Do not dispose of the device as domestic waste. As a rule, you can get information on proper disposal at your local government or specialized waste disposal plants.

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.

7.1.1 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.

7.2 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.

8 Technical Data

8.1 Technical Parameters

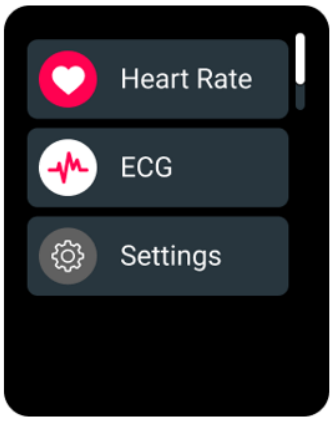
BODY	
Dimensions (Width x Length x Height):	40.5 (1.6") x 47 (1.9") x 14.7 (0.6") mm
Weight :	52 g
Main CPU:	nRF5340 2x ARM Cortex M33 cores for application and network
Platform (OS):	Zephyr RTOS
DISPLAY	
Brightness:	250 NITS
Resolution:	240 x 240 px
Type:	LCD TFT
Size:	1.3“
Cover lens:	Corning gorilla 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 or TPE with an integrated stainless-steel electrode	
Strap material:	Silicone or TPE
STRAP SIZE	
Band with electrode (W x L x H):	22 x 115 x 3 mm
Band with buckle (W x L x H):	22 x 75 x 3 mm
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
Temperature range Operation: Charging temperature range: Storage temperature range:	• -10 to +45 ℃ • 0 to +35 ℃ • -20 to +35 ℃

9 Label information

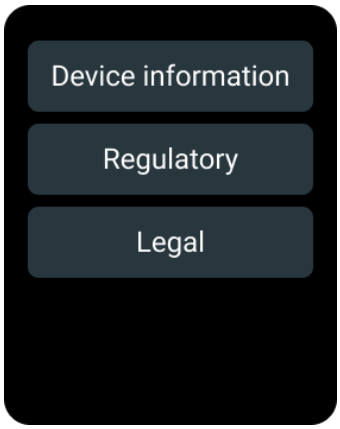
Follow these steps to access the device labeling information:

1. Press TeltoHeart side button to bring up a menu.
2. Tap **Settings** selection.



3. Tap **About** button.

4. Tap **Regulatory** button.



In **Regulatory information** section you can view the certifications associated with the device.

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/teltoheart-privacy-policy

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, 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

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

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

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.
These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates,
uses and can radiate radio frequency energy and, if not in-stalled and used in accordance with the instructions, may cause harmful interference
to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does
cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged
to try to correct the interference by one or more of the following measures:
—Reorient or relocate the receiving antenna.
—Increase the separation between the equipment and receiver.
—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
—Consult the dealer or an experienced radio/ TV technician for help.