

TeltoHeart Safety Instructions

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Safety instructions

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:

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

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

Safety terms and symbols

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

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.

Contraindications, Cautions, Warnings and Notes

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.

CAUTIONS

Handling and Care:

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.

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.
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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 an appropriate environment to avoid magnet degaussing.

Electromagnetic Fields and Ultrasound:

- ✘ Do not use the device in the 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 the device. Excessive force may break or damage accessories.
- ✘ Do not use the device in an environment where the temperature exceeds 45°C.
- ✘ The platform is not suitable for people with paralyzed, deformed arms, or absence of both arms.
- ✘ We strongly advise avoiding 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, the battery might be damaged. If the device starts heating, stop using the device immediately!

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.

NOTE

Operating Temperature:

Device operating temperature is -10 to 45 degrees Celsius.

Cleaning Instructions:

Please keep the device electrodes clean for best performance.

Environmental:

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

Account and Data:

MyHealth application and TeltoCare share the same login details.

Additional safety information

CAUTIONS:

- For correct functioning of the system, Bluetooth connection must be established.
- For correct functioning of the system, Bluetooth connection must be established.
- If the system is unable to communicate with the server, try again later.
- 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.
- 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 the appropriate environment to avoid magnet degaussing.
- Please do not use the device during the firmware update process. Doing so could cause irreparable damage to the device and render it unusable.
- If any allergic reaction occurs, stop wearing the 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.
- 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 watch 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.

- ❌ Avoid pairing the device in public places.
- ❌ User must grant data storage permissions on the mobile application.
- ❌ After unpairing TeltoHeart via MyHealth application, all data in TeltoHeart will be permanently deleted. This includes any saved settings, ECG, and HR data.
- ❌ Device is intended to be used by one person. Do not share the device with anyone.
- ❌ The system is not intended for the detection of stroke or other life-threatening conditions.
- ❌ Darker skin tones on the wrist might affect PPG performance.
- ❌ 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.
- ❌ 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, the newest records will be written on top of the oldest.
- ❌ Prolonged viewing at the device's screen is not recommended.
- ❌ 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.
- ❌ Do not use corrosive chemical materials for cleaning.
- ❌ Ensure that the magnetic connection of the docking station is clean of metallic bodies.

WARNINGS:

- ❌ 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.
- ❌ Use a password consisting of at least 8 symbols, at least one non-alphanumeric character, one uppercase, one lowercase character, and one digit.
- ❌ 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.
- ❌ The Li-Po battery in TeltoHeart should be serviced only by Teltonika Telemedic or an authorized service provider.

NOTE:

- Notice: The system will not be able to backup the data or send information to medical experts if there is no internet connection.
- Notice: Please keep the device electrodes clean for best performance.
- 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.

- Notice: Device shall be used on the left hand wrist only.
- Notice: Do NOT use the device outside of this operational temperature range.
- Notice: Usage in rain or in a very humid environment is not recommended.
- Notice: Do not share your password with anyone.
- Notice: Sign-in details will be deleted once the user is signed out of the app. To access the account, the user will have to sign in again.
- Notice: After deleting the account, all data will be lost. After 14 days, support will no longer be able to restore deleted health data.
- Notice: A physician may misidentify the ECG recordings if the user shared the device with other people. This might result in the wrong diagnosis and treatment.
- Notice: Please keep the MyHealth application running in the background to allow measurement data transfer.
- Notice: ECG recordings cannot be performed if the battery charge is less than 10%.
- Notice: Do not take recordings during physical activity.