


TeltoCare Safety Instructions

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Safety instructions


For your safety and to maximize the effectiveness of your interactions on the TeltoCare platform, it is crucial to observe the following guidelines and precautions. Neglecting to do so may compromise the integrity of your medical data or potentially pose risks to your health or privacy. Therefore, it is essential to take the time to familiarize yourself with these instructions and ensure a clear understanding of how to utilize the platform securely and responsibly.

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

Safety terms and symbols

This section provides essential warnings, contraindications, and cautions to be observed when using TeltoCare's platform under any circumstances. Additionally, pertinent warnings and cautions are incorporated throughout the manual in sections where they are most relevant. Notes are included throughout the manual to offer more detailed insights into specific features of the TeltoCare platform.


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

-  Users with pacemakers, implantable cardioverter-defibrillator (ICDs) or other active implanted medical devices which could stimulate the heart.
-  Users with other active implantable or non-implantable medical devices which may interfere with the electromagnetic field of the wrist-worn device during its operation or while charging.
-  Not intended for users who suffer from dementia or other cognitive inability to use the device unless supervised.
-  Users with conditions that restrict their ability or willingness to use the device by its intended purpose.
-  Users who suffer from exaggerated emotional instability, elevated anxiety disorder, panic attacks or any other mental disorders in general, which may be triggered by the use of the device or app.
-  Absence, severe deformations or paralysis of upper limb (for the use of recording ECG).

- ✘ Absence, severe deformations or paralysis of both upper limbs.
- ✘ Allergy or increased sensitivity to the materials of the device.
- ✘ Compromised conditions of local tissues (skin, vascular, muscular, nerve or other tissue) at the location of contact with the device, including but not limited to wounds, fractures, ruptures, etc.

CAUTIONS

- ✘ Do not self-diagnose or self-medicate on the basis of the device readings without consulting your doctor.
- ✘ MyHealth app is not intended to detect heart attack.
- ✘ The MyHealth app must be applied only for the intended use. This also includes situations when two or more conditions appear at the same time. Atrial fibrillation may be a cause of secondary heart attack and other conditions which are not the intended use.
- ✘ In addition, atrial fibrillation may also be a consequence of heart attack and other conditions which are not the intended use. Therefore, the user should never exclude possibility of other health conditions and should contact the physician/seek emergency help without any delay if user believes he has medical emergency.
- ✘ MyHealth app is not intended to replace traditional methods of diagnosis of atrial fibrillation.
- ✘ MyHealth app does not guarantee that you are not experiencing an arrhythmia or other heart conditions when the app provides notification as normal sinus rhythm/AFib. You should notify your doctor if you experience any changes in your health.
- ✘ In some rare instances, presence of other arrhythmias may be classified as AFib. Even if the AFib may not be present, this might indicate/suggest presence of other arrhythmias and user should consult with doctor for the evaluation of the heart condition. The presence of certain non-AF arrhythmias may also result in changes of AF detection performance.
- ✘ Physician may misidentify the ECG recordings if the user shared the device with other people. This might result in wrong diagnosis and treatment.
- ✘ The device is not intended to be used during medical procedures (e.g., magnetic resonance imaging, diathermy, lithotripsy, cautery, external defibrillation procedures, surgery).
- ✘ You should talk to your doctor if your heart rate is below 50 or above 120 at rest and this is an unexpected result.
- ✘ **Notice:** trained athletes may have low heart rate due to their training and this may be considered normal heart rate for them.
- ✘ Do not take recordings during physical activity.
- ✘ Number of factors, such as motion, hand and finger movements, dark tattoos on wrist, dark skin pigmentation the amount of blood flow to your skin (which may be reduced by cold temperatures), may impact the ability of the device to take quality recordings and thus reduce the performance of AFib detection algorithm.
- ✘ Make sure that the finger, wrist and abdomen skin used for ECG/PPG recording are uncovered, clean and free of any bruises, scars or cuts.
- ✘ Quality of the recorded signals may be compromised due to too much body fat, body hair or very dry skin at the sensors contact area.
- ✘ Do not continue use until further instructed by a physician if your skin is irritated or inflamed around the smart wearable or its band.
- ✘ Do not take the recording if electrodes are dirty. Clean them first.
- ✘ MyHealth app is not intended for use and its performance was not tested on pregnant women or pediatric population (individuals under age of 22).
- ✘ In some rare cases some people may have certain physiological conditions that may prevent them from registering strong enough signal for analysis and evaluation.

- Do not take recordings in close vicinity to strong electromagnetic fields.
Implanted medical devices, like pacemakers and defibrillators, may have sensors that can react to magnets and radios in proximity. To prevent any possible interference with these devices, it is important to keep your smart wearable and its charging equipment at a safe distance away from the medical device.
- Do not take recordings while submerged in water.
- Patient health information provided by the device are potential findings and NOT a diagnosis. Diagnosis should be made using standard procedures by the qualified physician.
- People with conditions that can cause severe swelling of upper limbs, for example, decompensated heart failure, decompensated chronic kidney disease, acute kidney failure, nephrotic syndrome, nephritic syndrome, lymphedema, elephantiasis and others are advised to consult a doctor before using the product.