

Instructions for Use SteadyTemp



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NFC required



Explanation of Symbols:



Lot number



Manufacturer



Expiration date



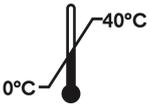
Medical Device



Single Use Product



Do not dispose in household waste



Storage temperature



Read electronic Instructions for Use (www.steadytemp.health/ifu)



Safety advice



Information

Instructions for Use

Please read the instructions for Use and the safety instructions carefully before using SteadyTemp and adhere to them.

Intended Use

SteadyTemp is a clinical thermometer intended to continuously measure axillary temperature and to display relative changes in axillary temperature to the user.

The SteadyTemp system can be used by medical professionals in clinical environments and consumers in a home care environment. It is intended to be used on people older than 5 years of age.

The system consists of a sensor patch and a smartphone application, the body temperature data measured by the sensor is transmitted via Near-Field-Communication (NFC) and subsequently displayed in the App.

Contraindications



The SteadyTemp system should not be used under following circumstances:

- **Emergency situations**
- **Known allergy to ingredients of skin patches**
- **Wounds, skin diseases or abrasions in the application area of the SteadyTemp patch**



Safety Instructions

- SteadyTemp is not intended for persons under 5 years of age
- SteadyTemp does not substitute the consultation of a medical professional.
- The patch shall not be used by individuals who are not capable of using the device correctly.
- Do not use the patch for any purpose other than measuring axillary temperature.
- Measured temperature values are processed by SteadyTemp for display purposes.
- Do not use the patch more than once, it is a single use product.
- Do not apply the patch on injured skin.
- Do not use the patch if it has been damaged or contaminated.
- Do not attempt to disassemble or open the patch. Do not fold or twist the SteadyTemp patch.
- Do not apply successive patches on the same body side.
- Do not use the patch when undergoing an MR or CT examination.
- The SteadyTemp Patch is a mini electronics device. Do not dispose of the patch in the regular household waste.
- Do not throw the patch in the fire, the battery could explode.
- Do not wear the patch for longer than 7 days.
- Store the patch out of the reach of children, pets and people with impairments.
- The SteadyTemp patch is not intended to be used by individuals (including children) with reduced physical, sensory or mental capabilities, or lack of experience and/or knowledge, unless they have been given supervision or instruction concerning use of the device by a person responsible for their safety.
- Children must be supervised to ensure that they do not play with the device.
- The patch must be worn in the correct position under the arm to ensure reliable temperature readings.
- Use the patch only within the specified operating conditions as operation outside the defined conditions can damage the patch and cause discrepancies in the accuracy of the measurements.

- Do not take an extended bath or go swimming while wearing the patch.
- The patch should be stored in a dry place and protected from direct sunlight.
- If the patch becomes uncomfortable, please remove it immediately.
- When applied, the patch can cause local and temporary skin irritations.
- Increased immune system activity (for example due to a vaccination) can promote temporary skin reactions in the patch application area. Remove the patch immediately if the patch feels uncomfortable



Usage Informations

- Before applying the patch, wash with nongreasing soap and thoroughly dry the skin under the arm. The patch application area can also be cleaned using a suitable alcohol pad.
- Do not use deodorant or cream beforehand.
- When applying the patch, remove the small part of the carrier foil first.
- Do not touch the adhesive side of the patch, this could reduce overall adhesiveness.
- After applying the patch, smooth it out gently on all sides to fix it in place.
- The patch should be read via NFC at least once a day.
- Hold your smartphone as still as possible while activating and reading the patch.
- Remove the patch immediately if it becomes uncomfortable or causes skin irritation.
- Do not do physically intense sport or any other activities that cause excessive perspiring (sauna or steam room) while wearing the patch.
- Throughout the day, small variations in body temperature occur, which are shown by the continuous measurement.



Support: For questions or problems with the product please contact us via E-Mail:

support@steadysense.at

Quick Use Guide



1. Apply Patch

Please clean the patch application area before attaching the SteadyTemp Patch. The patch should be applied to clean dry skin, free from cream or deodorant. The application area can also be cleaned using an alcohol wipe.

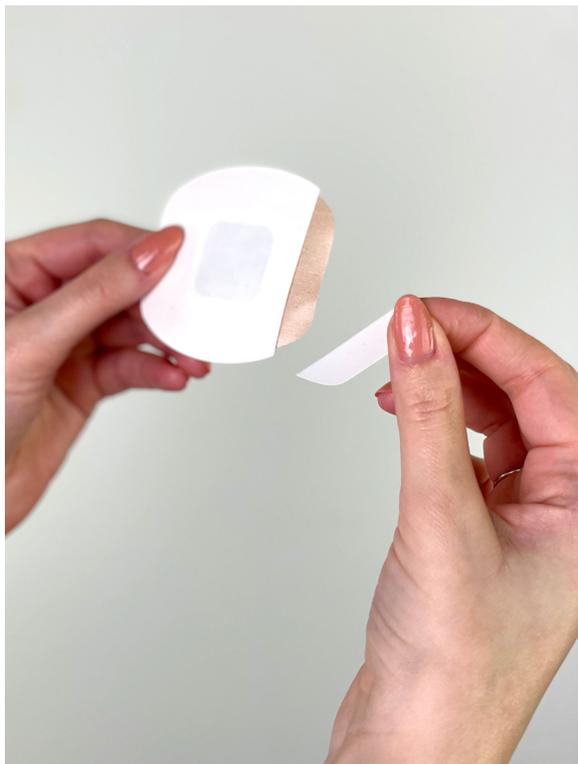


In the SteadyTemp product packaging you will find a quick guide on how to apply the patch

Step 1: Find position: Relax your shoulder, place your hand on your hip and place 3 fingers under your armpit. This will determine the position of the patch, please remember it.



Step 2: Remove small carrier foil: Remove the small part of the carrier foil, so that you can apply the patch in the next steps.



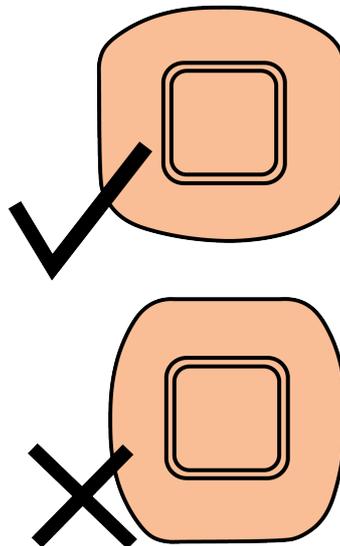
Step 3: Patch-application posture: Now put one hand on your hip again and relax your shoulder. Step 4 describes how the patch should be applied.



Step 4: Attach Patch: Now attach the patch to the previously determined position. The patch should be applied in such a way that the upper edge of the patch is 3 fingers width beneath your armpit, on your side, between back and breast. Make sure that during application, your shoulder is in a relaxed position and your hand is braced on your hip. Then pull off the remaining part of the carrier foil and smooth the patch down gently on all sides.



Hint: Please stick the patch so that the rounded sides point up and down.

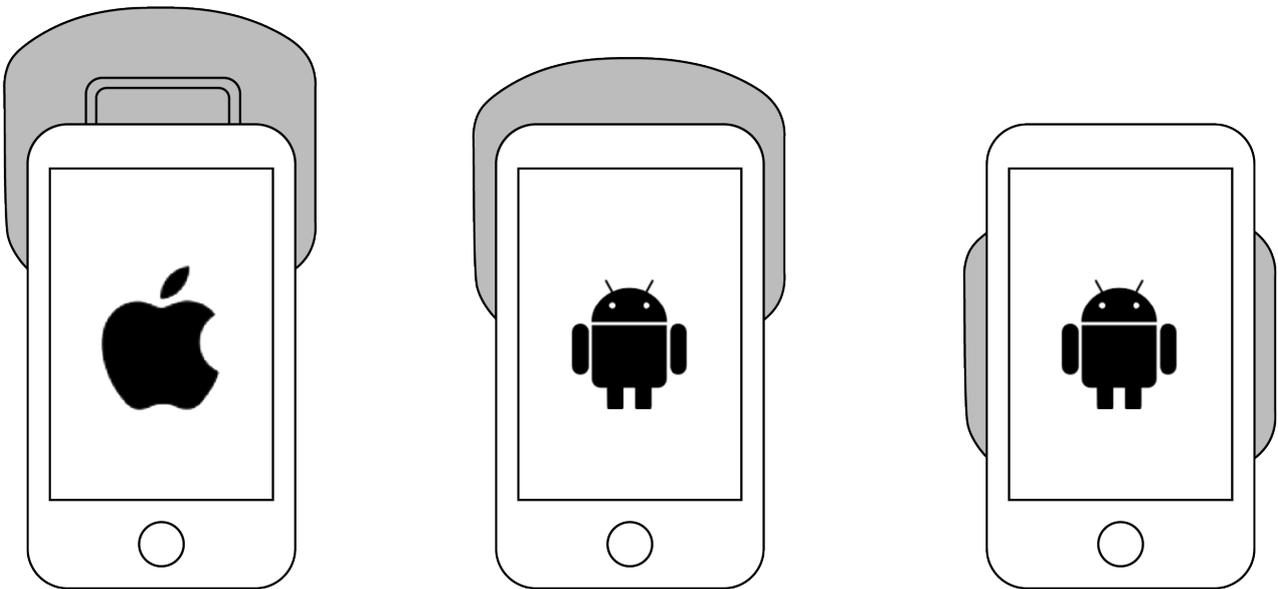




2. Activate Patch

After 10 minutes you can activate the patch. Patch activation is a two step process. Tap on the "Read Patch" button in the app and hold the backside of your smartphone against the patch in order connect the patch to a user. After connection, hold the backside of your smartphone against the patch to activate it. A vibration will confirm successful activation.

The image below illustrates, how Apple or Android smartphones should be held to the patch for proper NFC communication.

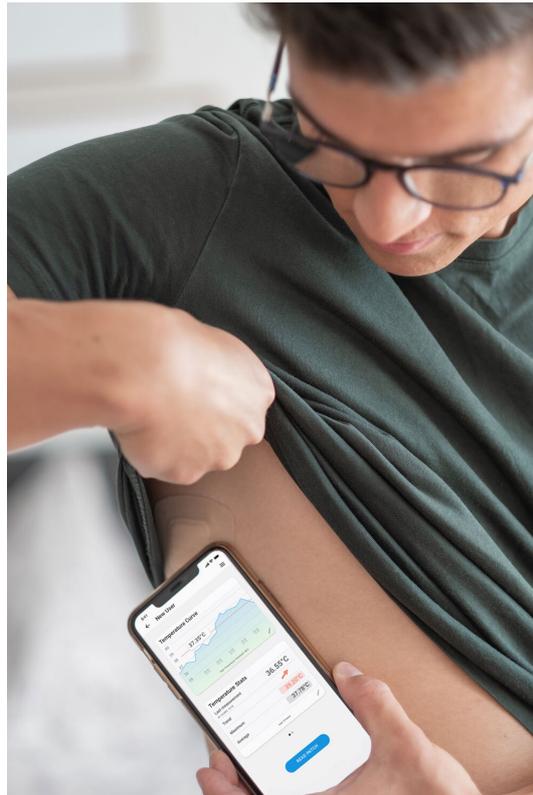


After patch application, the patch must adjust to the body temperature. First reliable values are available 1 hour after patch activation.



3. Read Patch

After a successful data transfer the app displays your current body temperature and stored temperature curves as well as additional temperature information. Please note that measured temperature values are processed by SteadyTemp for display purposes.



Notifications

App-notifications about unusual body temperature values can temporarily appear due to extreme environmental influences

If that is the case, please check if the patch is still properly attached and read it again after some time. Should the problem persist for more than 6 hours, please contact our technical support via E-Mail: **support@steadysense.at**

Notification:* *"Temperature outside range"*

If your currently measured temperature is outside the defined measurement range, then it will not be displayed in the temperature chart. In the field: "Last measurement", either "Lo" for low temperature or "Hi" for high temperature will be displayed.

Notification: *"Threshold notification"*

If the recorded temperature data exceeds the set temperature threshold for a longer duration, the App will display a notification.

User Management

The user management is displayed when the SteadyTemp App is opened. In the user management you can create new user profiles by tapping on the "New User" icon and edit or delete existing user profiles by tapping and holding the user profile for 1 second. To view a user's temperature data, tap on an existing user profile.



Disposal

The patch is powered by a button cell battery. Therefore, it should not be thrown out in the regular household waste but disposed of according to the local waste regulations for batteries and electrical goods. The SteadyTemp packaging is recyclable and can be disposed of in the paper bin.



Technical Data

- Type of device: Clinical thermometer
- Measuring Site: Axilla
- Type of use: Single use product
- Typical application duration: 7 days
- Measurement range: +30 to +42°C (+86 to +107.6°F)
- Measurement accuracy: SteadyTemp displays relative changes of the axillary temperature with a maximum deviation of +/-0.3°C (+/-0.54°F)
- Operating mode: Direct mode, continuous
- Measurement interval/time response: 300 seconds
- Operating conditions:
 - Environmental temperature +15 to +42°C (+59 to +107.6°F),
 - Humidity: 15 to 95%,
 - Air pressure: 86 to 106 kPa
- Transport and storage conditions:
 - Environmental temperature: 0 to +40°C (32 to 107.6°F),
 - Humidity: 15 to 95%,
 - Air pressure: 86 to 106 kPa
- System requirements:
 - Apple: iOS 13 or higher on iPhone 7 or newer models,
 - Android: Android OS 6
- Dimensions: 65 x 60 x 3 mm (2.56 x 2.36 x 0.12 in)
- Weight: 3 g (0.11 oz)
- Power source: 3V lithium button cell battery (not replaceable)
- IP-Classification: IPX5: Protection against waterjets from any direction