Instructions for Use STEADYTEMP

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NFC required

 0494

Explanation of Symbols:

LOT Lot number

Manufacturer

Expiration date

MD Medical Device

Single Use Product

Green Dot

Do not dispose in household waste

Storage temperature

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

Observe electronic operating instructions (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.

The STEADYTEMP app is designed to serve as a health diary. Medications, symptoms, pain, blood pressure and the like can be recorded in the app. In this way, the app can provide information about the course of the disease.

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. In the event of reuse, the adhesive strength of the patch is no longer ensured and the patch may become detached. Furthermore, reuse may cause skin irritation due to contamination.

- Do not apply the patch on injured skin.

- Do not use the patch if it has been damaged or contaminated.

- Do not attempt to dissemble or open the patch. Do not fold or twist the STEADYTEMP patch.

- Do not apply successive patches on the same body side.

- STEADYTEMP does not interfere with other electronic equipment. STEADYTEMP is not affected in the normal range of application.

- For users with pacemakers: Wear the patch only on the side of the body away from the heart, as the smartphone could interact with the pacemaker. If you are unsure, ask your doctor.

- STEADYTEMP may react unpredictably in combination with strong magnetic fields. Please remove the patch before MR or CT examinations.

- The STEADYTEMP Patch is a 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.
- A high BMI (>30) can increase discomfort and the risk of irritation. It can also result in a decrease of accuracy and even breaking of the sensor.

ⓘ Usage Information

- 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.
- Do not overstretch the patch during application as this may cause skin irritation.
- 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.
- After contact with water (e.g. shower), make sure that the patch dries well.

- When wearing tight garments (bras, chest binders, etc.), make sure they do not chafe.

- Throughout the day, small variations in body temperature occur, which are shown by the continuous measurement.

- When you remove the patch, carefully peel it off. We recommend doing this after showering or wetting the patch with a wet washcloth first.

> (i) **Support:** For questions or problems with the product please contact us via E-Mail:
>
> support@steadytemp.health

Quick Use Guide

(i) 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.

> (i) **The STEADYTEMP product packaging includes 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.
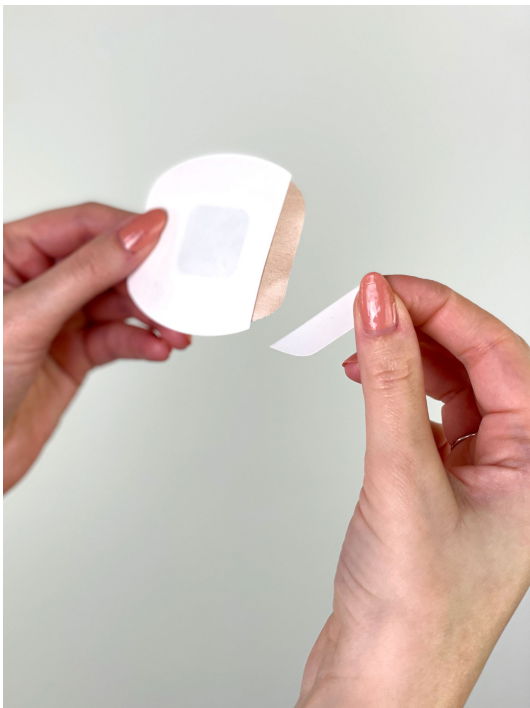
Step 3: Patch-application posture: Now put one hand on your hip again and relax your shoulder. Step 4 describes how the patch should be applied.

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.
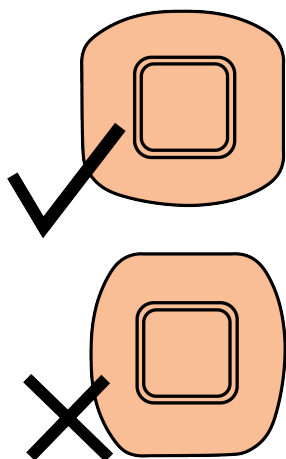
ⓘ 2. Activate Patch

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.**

(i) 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.
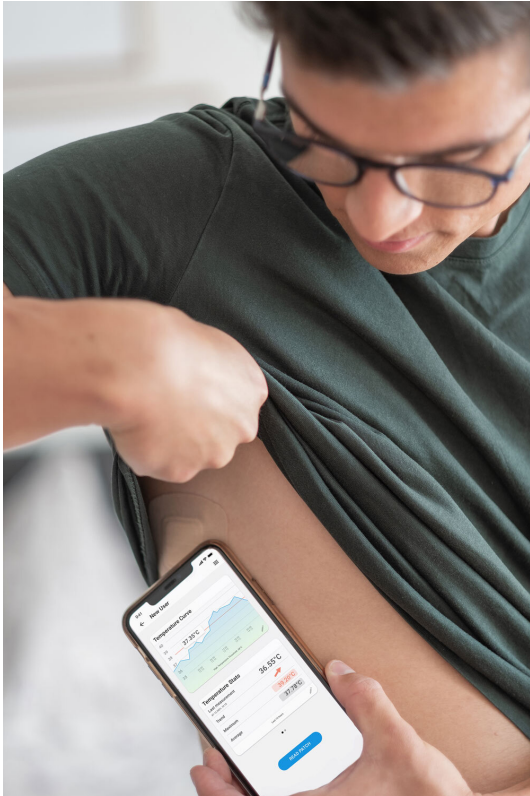
(i) 4. Remove Patch

The intended wearing time of the STEADYTEMP patch is 7 days. It is recommended to remove the patch after 7 days to avoid skin irritation. To remove the patch, it is helpful to moisten the patch with warm water (e.g. after showering or with a washcloth). Then carefully pull off the patch.

If the patch feels uncomfortable when you wear it, or if you feel itching or a burning sensation, please remove the patch. Apply a new patch on the other side of the body to avoid skin irritation.

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@steadytemp.health**.

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.

Troubleshooting

If the STEADYTEMP app displays an error message, please take a screenshot. If you are not able to solve the problem on your own, please contact our support team with the screenshot directly in the app via "Contact support" or via mail to support@steadytemp.health.

In order to fix errors as soon as possible, here are the most common error messages:

- **"Please try again."** The readout attempt failed, try reading the patch again. If this problem persists, please contact support.
- **Patch could not be started. Please try again"** The activation process could not be completed. Please try again. If the problem persists, please contact support.
- **"The patch could not be read. Please try again."** The patch could not be read. Try again and make sure to hold the smartphone steady on the patch for a few seconds. If the problem persists, please contact support.
- **"The NFC function on this device is disabled. Click OK to enable NFC in the settings."** You have not enabled the NFC function. Enable it to be able to read the patch.

- **"This device does not support NFC. You cannot use STEADYTEMP patches with this device."** You are using a smartphone without NFC. NFC is a requirement to be able to use STEADYTEMP patches.

- **"There was a software error with your patch, please take off your patch and contact support. (406) "** This error message is sent when a special software error occurs that stops the measurements. The patch can therefore no longer be used. In case of this error, please contact support to clarify the cause of the error.

- **"Battery empty. Please use another patch. "** The STEADYTEMP patches have a shelf life of 2 years. The expiration date is located on the cardboard packaging of the patch. If you experience this error within this time frame, please contact the particular store where you purchased the patch. If in doubt, you can contact our support.

- **"Unsupported patch. This patch is not compatible with this app. "** The patch used is misconfigured, please contact support.

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.

> **ⓘ** **When a user profile is deleted, all associated temperature data and entries are irrevocably deleted.**

When creating a new user, a number of additional information (name, social security number, birthday, etc.) can be filled in. These are optional and only serve to allow the user to collect all relevant information in one place. Only the username (which can be the first name or even a nickname) is necessary to create a user profile. All data entered by you will be treated confidentially and will not be disclosed to third parties.

Temperature

In the temperature screen the temperature curve and the temperature statistics are displayed. The temperature threshold and the temperature range can be set by clicking on the down arrow in the temperature curve. By clicking on the down arrow in the statistics, the time period of observation can be set.

By default, 38°C (100.4°F) is set as the temperature threshold, a temperature range of 32-40°C (89.6-104°F) and an observation period of 24 hours.

By clicking on the full screen button you can view your temperature curve in full screen.

Entries and History

New (diary) entries can be created with "Add entry". Medication intake, symptoms, pain, activities, general well-being and blood pressure can thus be recorded. All data entered by you will be treated confidentially and will not be passed on to third parties.

Individual entries are collected and displayed in the history. Entries are also displayed graphically on the temperature curve. Entries can be changed as well as deleted in the history.

You can also export your data in the history. You can read more about this in the "Export data" section.

Export data

You can export your data as a PDF using the "Export data" function in the history. To do this, enter the date range you want to export and click on "Export data". You can send your data saved as a PDF (temperature curve, user information and entries) directly from the app.

This function is especially helpful if you want to discuss your disease progression with your doctor, for example. This way they have all important information stored in one (printable) document.

Menu

In the menu you can find the tutorials, FAQs and contact options of the support. You can also find legal information, the online store and the possibility to rate STEADYTEMP in the App Store or Play Store.

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

(i) **EMC**

Guidance and manufacturer's declaration – electromagnetic emissions			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Emission test	**Frequency Range**	**Compliance**	**Compliance Level**
EN 55011B/ EN 55032B RF Interference field	30-1000 MHz	Class B	PASS

Guidance and manufacturer's declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should assure that it is used in such an environment.			
Immunity Test	**IEC 60601-1 test level**	**Compliance level**	**NOTE**
EN 61000-4-2: Electrostatic discharge	Contact discharge: ±8 kV	not applicable	Contact discharge is to be applied according to EN 61000-4-2 due to conducting surfaces of the DUT
	Coupler plate: ± 8kV	PASS	-
	Air discharge: ± 2kV ±4kV ±8kV ±15kV	PASS	-
EN 61000-4-3: Electromagnetic fields	10 V/m 80MHz to 2,7 GHz	PASS	-
EN 61000-4-8: Magnetic fields	-	not applicable	Device is not sensitive against power frequency magnetic fields. It has no magnetic field senstive components.