

Instructions for Use

SteadyTemp

Version: 25_10

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What is SteadyTemp?

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

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.



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

The SteadyTemp App



iPhone 7 or higher | Android OS 6 or higher with NFC

App Introduction

When opening the SteadyTemp app for the first time you will be walked through the app-introduction, which shall give you an impression on how to use the SteadyTemp app.

On the last screen of the onboarding, you have to

- confirm to understand the Instructions for Use
- confirm to accept the General Terms and Conditions
- confirm to accept the Privacy Policy
- select your region (please select your region correctly)



The content you see in the app (Instructions for Use, support e-mail, shop link etc.) might be different for your region.

User management

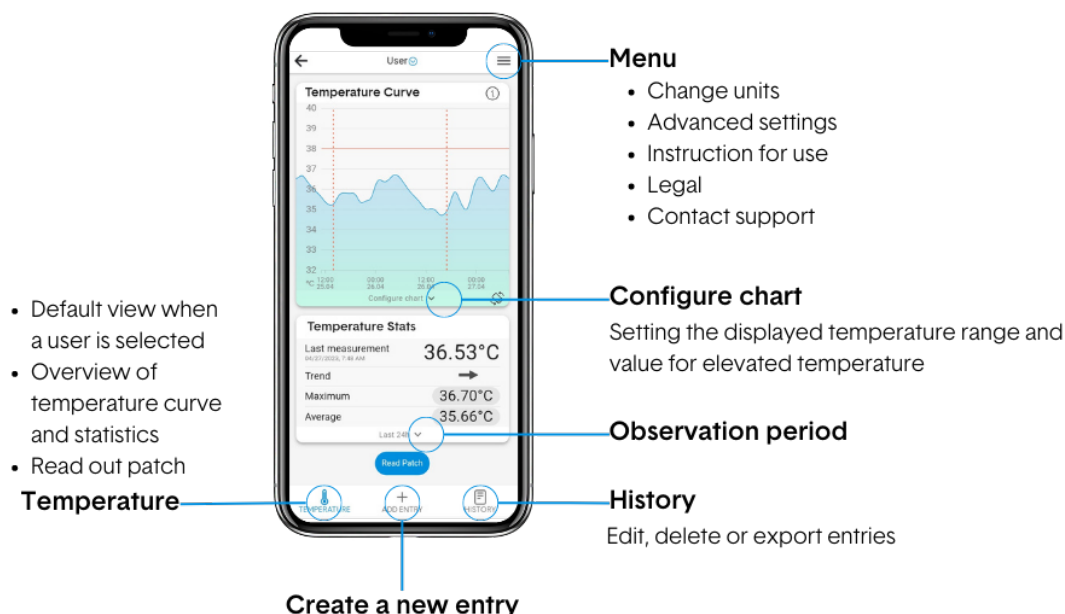
The user management is displayed when the SteadyTemp app is opened. In the user management you can create new user profiles by tapping on the "New User" icon and edit or delete existing user profiles by tapping and holding the user profile for 1 second. To view a user's temperature data, tap on an existing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



Your data in the SteadyTemp App is only stored locally. When a user profile or your app 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.

App structure



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 (90-104°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.

IT security measures

- You should use authentication methods for your smartphone, such as a strong password, digital fingerprint, or face-ID. Your password should be sufficiently long and should not contain a simple combination of numbers. Further you should not have any personal reference to the number combination, like birthday or car license plate.
- During inactivity, your smartphone should switch to the locked state as soon as possible.
- Make sure you use public WLAN networks safely.
- Download the SteadyTemp app only from an official app store (Google Play Store, Apple App Store).
- It is recommended to use antivirus software for your smartphone.
- Do not hand over your smartphone if you do not want other people to see your data in the SteadyTemp app.
- Try to keep the SteadyTemp app always up to date.
- If you want to permanently remove your information from the SteadyTemp app, all you need to do is delete your user. Please note that the information cannot be restored after deletion.
- When deleting the SteadyTemp app, all data stored on the app will be irrevocably deleted as well.
- It is not possible to migrate data of the SteadyTemp App to a new smartphone.
- Data is only stored locally on your smartphone.

Data protection

Only the data that is absolutely necessary for using the app is collected. The legal data protection requirements are met. The content is subject to the Austrian Federal Data Protection Act and the General Data Protection Regulation (DSGVO). More detailed information on the processing of personal data can be found in our privacy policy at <https://www.steadytemp.health/dataprotection/>.

Contact of the data protection officer: gdpr@steadysense.at

Tel: +43 316 232 004

Application and Use



The SteadyTemp app cannot be used with temperature sensors other than the intended SteadyTemp patch.

Instruction

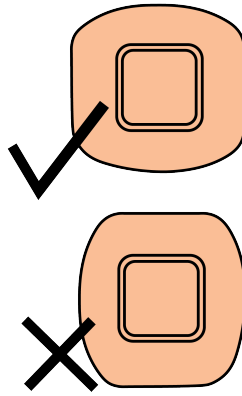
1. Preparation

The sensor patch must be applied on clean, dry skin (without cream/ deodorant). It is recommended to apply the sensor patch after showering. The adhesive area can also be cleaned with a suitable alcohol swab. However, make sure your skin is dry before applying. Apply the sensor patch only on intact skin.

2. Find position



The correct position of the sensor patch is important to achieve accurate measurements. Place your hand on your hip and relax your shoulder. The correct position of the sensor patch is three finger widths under the armpit, centered between the back and chest.



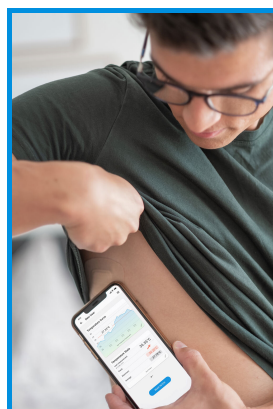
Note: Place the sensor patch so that the rounded sides face up and down.

3. Attach patch



Remove the small part of the backing, make sure you are relaxed, and apply the sensor patch to the previously determined location. Once again, make sure that your shoulder is relaxed and that your skin does not have strong wrinkles here. Then remove the rest of the backing and press the sensor patch firmly on all sides.

4. Activate patch



After you have applied the sensor patch correctly, it can be activated. To do so, tap on "Read patch" in the SteadyTemp app and hold the back of your smartphone calmly on the center of the sensor patch for a few seconds to activate it. A vibration will confirm successful activation. Once activated, the sensor patch will continuously measure your temperature.



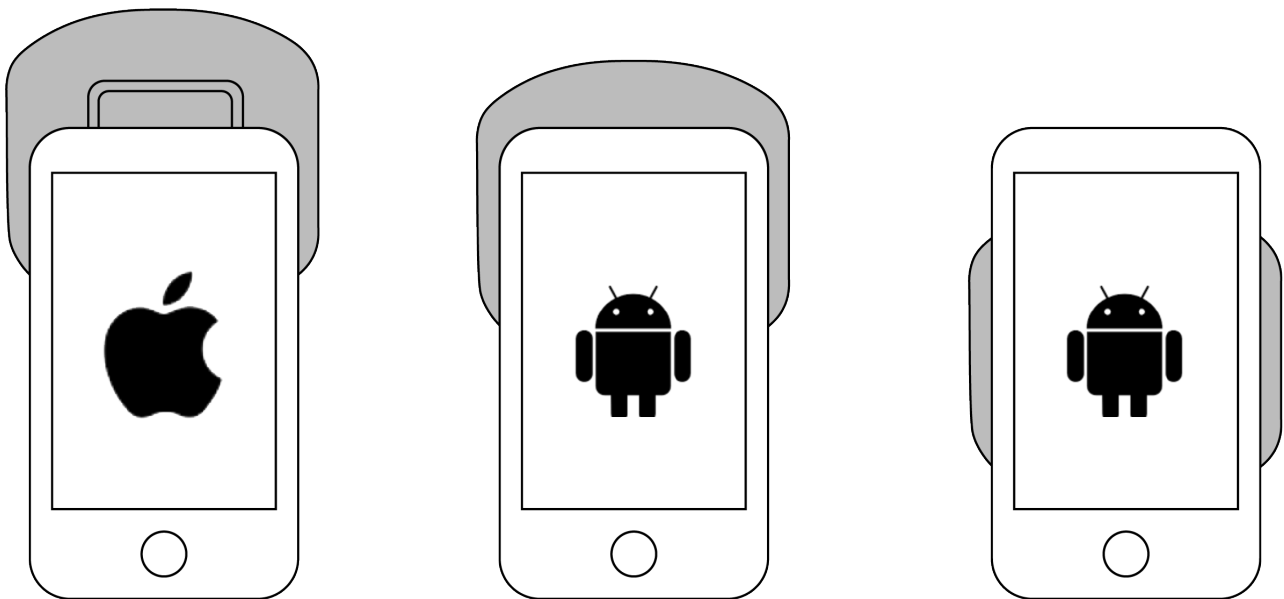
**After application, the patch must adapt to the body temperature.
Reliable temperature values are available after approximately one hour.**

Position for NFC Communication

Depending on your device manufacturer and operating system (Apple iOS or Android) the smartphone has to be held differently against the sensor patch in order to read it correctly.

iPhone: Hold the top edge of the backside of your phone, at a slight angle, to the middle of the sensor patch.

Android: On an Android phone the NFC antenna can be located in different positions. Hold either the area around the camera or the back of the smartphone against the middle of the sensor patch. Please make sure that NFC is switched on. NFC can be switched on in the quick menu or in the settings.



5. Read out patch

After startup, you should read the sensor patch at least once a day. You can read out the sensor patch as often as you would like. Tap on "Read patch" and hold the smartphone on the sensor patch as described in point 4 (Activate patch). Your temperature data will be read out and displayed graphically in the app.

6. Remove patch

The typical application duration is 10 days. After that, the sensor patch should be removed to avoid over-stressing the skin by wearing it for too long.

To remove it, it is helpful to moisten the sensor patch with warm water to soften the adhesive (e.g. when showering or using a washcloth). Then you can carefully remove the sensor patch.

If the sensor patch feels uncomfortable to wear, or if you feel itching or a burning sensation, please remove it.

Disposal

The sensor 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 packaging of the sensor patch is recyclable and can be disposed off in the paper bin.

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 sensor 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 sensor 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 sensor patch could not be read. Try again and make sure to hold the smartphone steady on the sensor 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 sensor 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 sensor 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 sensor 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 sensor patches have a shelf life of 2.5 years. The expiration date is located on the cardboard packaging of the sensor patch. If you experience this error within this time frame, please contact the particular store where you purchased the sensor patch. When in doubt, you can contact our support.
- **"Unsupported patch. This patch is not compatible with this app."** The sensor patch used is misconfigured, please contact support.



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 disassemble 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 10 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 non-greasing 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.



Reporting obligation

Report all serious incidents (damage, injuries, infections, etc.) that occurred in connection with the product to the manufacturer (via e-mail to: support@steadytemp.health) and the competent authority of the EU member state in which you reside. In Austria, the competent authority is the BASG. Their current contact information can be found on the website: www.basg.gv.at/en/

Legal

Manufacturer



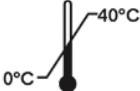
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Austria

Symbols

			
Manufacturer	Green Dot	Type BF	Information
			
CE certified	Single Use Product	NFC required	Safety advice
			
Medical Device	Do not dispose in household waste	Expiration Date	Observe electric operating instruction
			
LOT Number	Protect from sun and heat	Storage temperature	MR unsafe

Indication

SteadyTemp can be used as a diagnostic tool when the continuous measurement of axillary temperature of an individual is required. SteadyTemp is designed to continuously measure and display relative changes in axillary temperature over a period of up to 10 days at predefined intervals.

Contraindications

The SteadyTemp system should not be used under the following circumstances:

- Emergency situations
- Known allergies to ingredients of skin patches
- Wounds, skin diseases or abrasions in the application area of the sensor patch

Product life

SteadyTemp patch:

- GTIN (Global Trade Item Number) SteadyTemp 3 Patches: 09120095900342
- GTIN (Global Trade Item Number) SteadyTemp 1 Patch: 09120095900564
- The patch is supplied in product packs of 1 or 3 patches
- The patch is a single use product and has a shelf life of 2,5 years
- Batch number and expiration date can be found on the back of the product package
- The patch is typically worn on the body for a period of up to 10 days after application
- The sensor patch is a microelectronic device and should be disposed of according to local disposal regulations or returned to the manufacturer for recycling. See the **Disposal** section for more information.

SteadyTemp App:

- The SteadyTemp App is available in the Apple App Store & Google Play Store and is updated regularly.

Further information

- Legal Notice: <https://www.steadytemp.health/legal-notice/>
- Data protection: <https://www.steadytemp.health/dataprotection/>
- GT&Cs: <https://www.steadytemp.health/conditions/>



Technical Data

- Type of device: Clinical thermometer
- Measuring Site: Axilla
- Type of use: Single use product
- Typical application duration: 10 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
- UDI-DI App Store (iOS): 09120095900151
- UDI-DI Play Store (Android): 09120095900168

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: ± 8 kV	PASS	-
	Air discharge: ± 2 kV ± 4 kV ± 8 kV ± 15 kV	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 sensitive components.