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 software application designed to provide users of all ages with information about their body temperature. In addition to the SteadyTemp app, a battery operated sensor patch is required to measure temperature.

The sensor patch is a non-invasive, non-sterile, active temperature measurement device capable of detecting sub-degree (< 0.18°F/ 0.1°C) changes in body temperature by continuously measuring armpit temperature. The sensor patch is a disposable product that is applied only to healthy skin under the arm. The maximum application duration is 10 days. The sensor patch continuously records body temperature.

The SteadyTemp app serves as an interface for the user and for interacting with the sensor patch and displaying the measured temperature data. The data measured by the patch is transmitted via near-field communication (NFC).

The SteadyTemp system shall 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

The SteadyTemp App

Download on the App Store

ANDROID APP ON Google Play

iPhone 7 and higher | Android Smartphones 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.

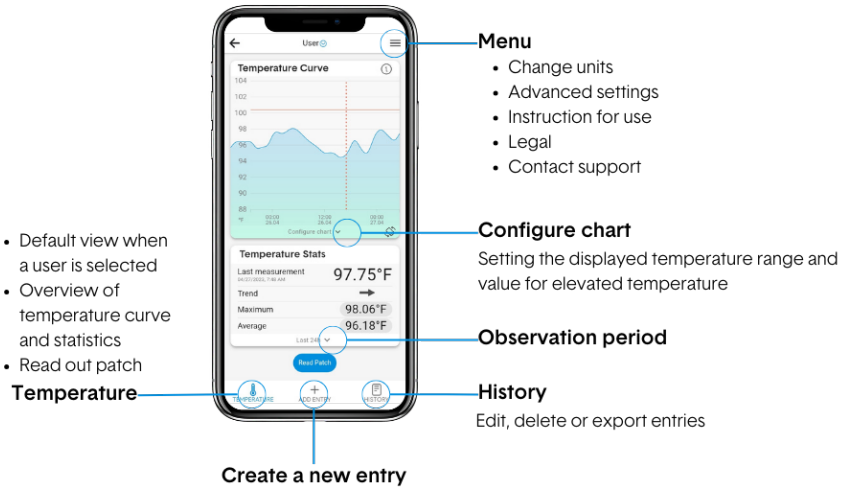
User management

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.

When creating a new user, a number of additional information (name, 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.

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.

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, 100.4°F (38°C) is set as the temperature threshold, a temperature range of 90-104°F (32-40°C) 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 is stored exclusively on your phone.

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. Data saved in the history can be downloaded and shared with medical professionals. 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 temperature data and additional information 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 instruction for use, tutorials, FAQs and contact options of the support. You can also find legal information 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 used 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 WiFi 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 (GDPR). 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

The SteadyTemp System (App + Patch)

The SteadyTemp app cannot be used with any temperature sensors other than the designated sensor patch.

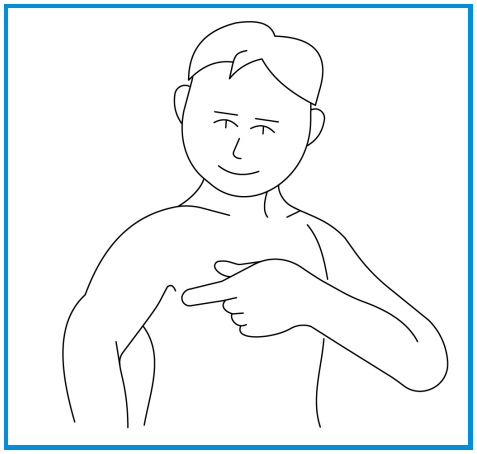
Instruction

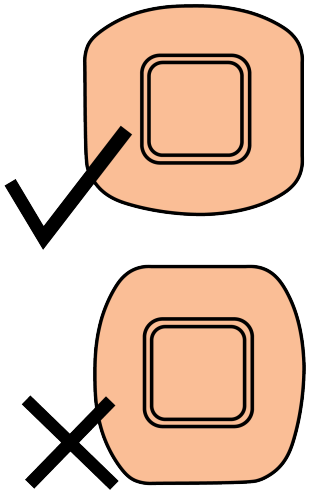
1. Preparation

The sensor patch must be applied on clean, dry skin (without cream/ deodorant). It is recommended to shave the armpit 24h prior to application, and to apply the sensor patch after showering. The patch application area should 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 directly under the arm, centered between the chest and back. Place the patch so that the upper edge of the patch is directly under the arm and the rounded sides of the patch are facing up and down

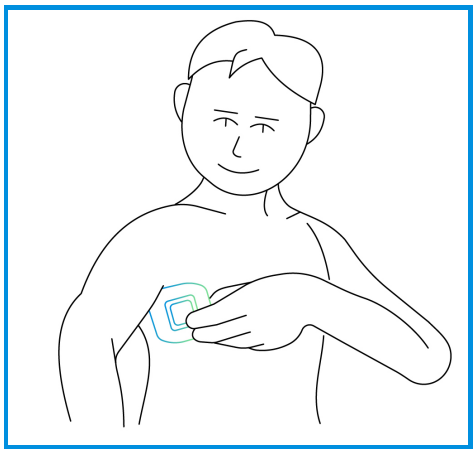




Note: Place the sensor patch so that the rounded sides face up and down.

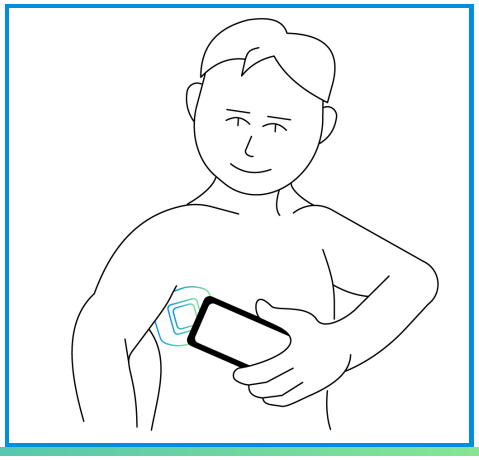
3. Attach patch

Remove the small part of the backing, make sure your shoulder is relaxed and your arm is placed on your hip. Ensure that the application area is wrinkle free before applying the sensor patch. Apply the sensor patch to the top of the armpit. Then remove the rest of the backing and press the sensor patch down firmly on all sides to ensure that is is well attached.



4. Activate patch

To activate the patch, 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. You will then be asked to either select an existing user or create a new user for this patch. After user assignment, you are automatically asked to read out the patch again to activate it. A phone vibration will confirm successful activation. Once activated, the sensor patch will continuously measure your temperature.



As the sensor patch needs to warm-up to your individual body temperature, the first temperature value will be available 10 to 12 minutes after activation.

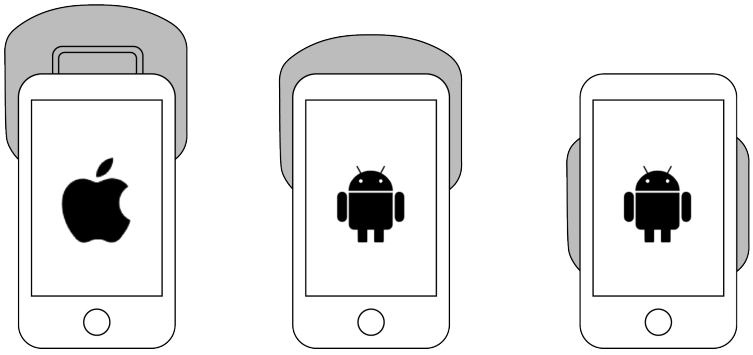
Make sure to assign the correct user to the patch as this cannot be changed once this step has been performed.

Position for NFC Communication

Depending on your phone 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

Once activated, you can read out the sensor patch as often as you like. We recommend to read out the patch at least once a day, to be always up to date. To read out the patch, tap on "Read patch" (either in the user overview or when a user is selected) 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.

⚠ **The patch can internally store data for up to 77 hours. When not reading the patch within 77 hours, older temperature data will be overwritten.**

6. Remove patch

The maximum application duration is 10 days. After that, the sensor patch should be removed to avoid overstressing 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 of 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

- The SteadyTemp system is suitable for people of all ages.
- SteadyTemp does not substitute the consultation of a medical professional.
- SteadyTemp shall not be used by individuals who are not capable of using the device correctly.
- Do not use the sensor patch for any purpose other than measuring armpit temperature.
- Measured temperature values are processed by SteadyTemp for display purposes.
- Do not use the sensor patch more than once, as it is a single use product. In the event of reuse, the adhesive strength of the sensor patch is no longer ensured and the sensor patch may become detached. Furthermore, reuse may cause skin irritation due to contamination.
- Do not apply the sensor patch on injured skin.
- Do not use the sensor patch if it has been damaged or contaminated.
- Do not attempt to dissemble or open the sensor patch. Do not fold or twist the sensor patch.
- Do not apply successive sensor 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 sensor 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.
- Do not put the sensor patch in the microwave.
- Remove the sensor patch before an MRI or CT scan. The sensor patch has not been evaluated for safety and compatibility during an MRI or CT scan. It has not been tested for heating, migration, or image artefact during an MRI or CT scan. The safety of the sensor patch during an MRI or CT scan is unknown. Undergoing an MRI or CT scan with the sensor patch applied may result in injury.
- Remove the sensor patch before an X-ray scan as the patch might block visualization in the application area.
- The sensor patch is an electronics device. Do not dispose of the sensor patch in the regular household waste.
- Do not throw the sensor patch in the fire, the battery could explode.
- The maximum application duration is 10 days. After that the sensor patch should be removed.
- Store the sensor patch out of the reach of children, pets and people with impairments.
- Do not apply the sensor patch on animals.
- The SteadyTemp system 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 sensor patch must be worn in the correct position under the arm to ensure reliable temperature readings.
- Use the sensor patch only within the specified operating conditions as operation outside the defined conditions can damage the sensor patch and can cause discrepancies in the accuracy of the measurements.
- Do not take extended baths or go swimming while wearing the sensor patch.
- The sensor patch should be stored in a dry place and protected from direct sunlight.
- If the sensor patch becomes uncomfortable, please remove it immediately.
- When applied, the sensor 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 application area or the sensor patch. Remove the sensor patch immediately if it feels uncomfortable.
- A high BMI (>30) can increase discomfort and the risk of skin irritation. It can also result in a decrease of accuracy and even damaging of the sensor.

Usage information

- Before applying the sensor patch, wash with non-greasing soap and thoroughly dry the skin under the arm. The application area of the sensor patch can also be cleaned using a suitable swab for skin cleansing.
- Do not use deodorant or cream beforehand.
- When applying the sensor patch, remove the small part of the carrier foil first.
- Do not touch the adhesive side of the sensor patch, this could reduce overall adhesiveness.
- Do not overstretch the sensor patch during application as this may cause skin irritation.
- After applying the sensor patch, smooth it out gently on all sides to fix it in place.
- It is recommended to read the sensor patch once everyday, but to omit loss of temperature data, perform a read-out at least once every 77 hours. The patch can be read as often as desired.
- Hold your smartphone as still as possible while activating and reading the sensor patch.
- Remove the sensor patch immediately if it becomes uncomfortable or causes skin irritation. Carefully remove the sensor patch to avoid further irritation, then use a soothing ointment afterwards.
- Avoid physically intense sport or any other activities that cause excessive perspiring (sauna or steam

room) while wearing the sensor patch.

- After contact with water (e.g., shower), let the applied sensor patch air dry.
- 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 sensor patch, carefully peel it off. We recommend doing this after showering or wetting the sensor patch with a wet washcloth first. If you have sensitive skin, you might want to use some sort of remover (e.g., body oil or an adhesive remover spray).

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 FDA through MedWatch.
For more information see: www.accessdata.fda.gov

Legal

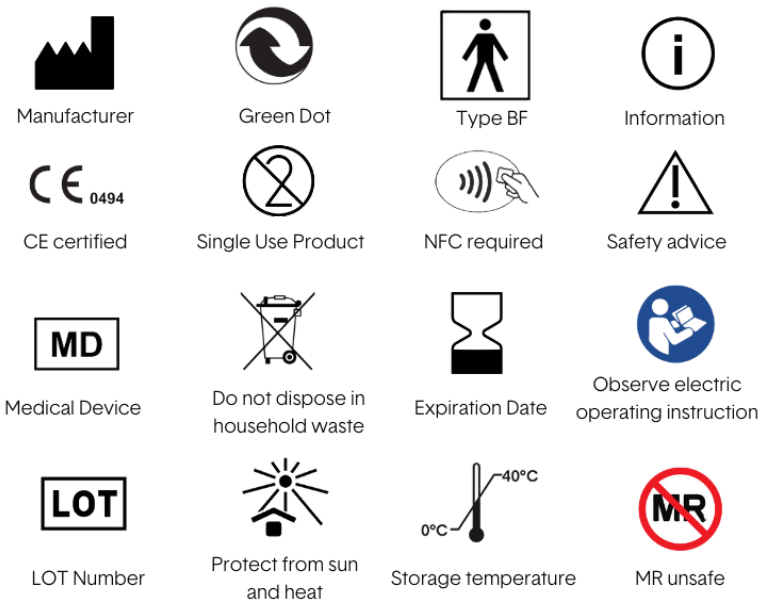
Manufacturer

©SteadySense GmbH

Johann-Schreiner-Straße 3

8074 Raaba-Grambach, Austria

Symbols



Indication for Use

The SteadyTemp system is a wireless thermometer intended to provide precise body temperature for users of all ages. The SteadyTemp system comprises a single-use temperature measuring sensor, the SteadySense Patch, and the SteadyTemp application. SteadySense Patch measures and stores axillary skin temperature data up to 10 days. The typical application duration when using the system is 7 days.

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

Clinical benefit

The clinical benefit of SteadyTemp is the continuous measurement of axillary temperature.

Intended user group

The target user group for SteadyTemp is people of all ages. There is a special recommendation for children under the age of twelve (see **Recommendation for children**).

The user of the SteadyTemp app must be able to read and understand the instructions for use. The user must also be able to follow the instructions of the SteadyTemp app and act appropriately. In addition, the user must be familiar with smartphone applications and be able to operate an NFC-enabled smartphone. Existing experience with smartphone applications is recommended but not required to properly operate SteadyTemp.

There are no restrictions regarding the nationality of the users.

In general, there are no restrictions on user weight. However, extreme weight ratios may have a negative impact on SteadyTemp accuracy and may also cause discomfort, skin irritation and damage to the sensor. As a guideline, a normal BMI (Body Mass Index) between 18.5 and 30 is recommended to ensure proper function.

Recommendations for children

Children under twelve years of age require a caregiver, who will apply the sensor patch and operate the SteadyTemp app. Children must be supervised by their caregiver to ensure that they do not play with the device.

Additionally, there are special recommendations for the use of SteadyTemp in combination with the sensor patch on children under the age of twelve. Children's skin is more sensitive than that of adults. Therefore it is not necessary to clean the area before applying the sensor patch (this could reduce the adhesive power of the patch).

When removing the sensor patch, gentle removal is important to avoid irritating the sensitive skin. Removal of the sensor patch can be made easier by, for example, warming the adhesive with warm water to liquefy it slightly or carefully removing the sensor patch with oil (e.g., baby oil). Patch remover sprays can also make removal easier.

If the sensor patch seems to bother the child or skin irritation occurs, please remove it immediately. Again, gentle removal is important to avoid further irritation.

Intended use environment

The product is intended for home use: Users can use the medical device in a home environment and/ or at a location of their choice.

Remove the sensor patch before an MRI or CT scan. The sensor patch has not been evaluated for safety and compatibility during an MRI or CT scan. It has not been tested for heating, migration, or image artefact during an MRI or CT scan. The safety of the sensor patch during an MRI or CT scan is unknown. Undergoing an MRI or CT scan with the sensor patch applied may result in injury.

Remove the sensor patch before an X-ray scan as the patch might block visualization in the application area.

Target market

The target market is the countries where the SteadyTemp app is available and the sensor patch is available for purchase. These countries are:

- United States of America

Product life & scope of delivery

Sensor patch:

- GTIN (Global Trade Item Number) SteadyTemp 3 Patches: 09120095900342
- GTIN (Global Trade Item Number) SteadyTemp 1 Patch: 09120095900458
- The sensor patch is supplied in product packs of 1 or 3 sensor patches.
- The sensor patch is a single use product and has a shelf life of 2.5 year.
- Batch number and expiration date can be found on the back of the product package.
- The sensor 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.
- The SteadyTemp App is compatible with all sensor patches distributed in the US.

Scope of delivery

- **Sensor patch**: each product package contains one sensor patch; sensor patches are individually packaged.
- **Quick Guide:** each package contains a Quick Guide. This is to remind you how to use the sensor patch. You are using SteadyTemp for the first time? Then check out our **Instruction** above.
- **SteadyTemp App:** the SteadyTemp app can be downloaded for free from the App Store. You will need this to be able to use the sensor patch.
- **SteadyTemp instructions for use:** the electronic user manual is available in paper form upon request. Please contact support at **support@steadytemp.health**. The manual will be mailed to you within seven calendar days, free of charge.

Technical Data

- Type of device: Clinical thermometer
- Measuring Site: Axilla
- Type of use: Single use product
- Typical application duration: 7 days
- Maximum application duration: 10 days
- Measurement range: +86 to +107.6 °F (+30 to +42 °C)
- Measurement accuracy: SteadyTemp displays relative changes of the axillary temperature with a maximum deviation of +/-0.54 °F (+/-0.3 °C)
- Transient time: < 5 minutes (=standard measuring interval)
- Operating mode: Direct mode, continuous
- Measurement interval/time response: 300 seconds
- Data transmission: NFC
    - NFC frequency: 13.56MHz
    - NFC power: 1.5 -7.5 A/m according to ISO 14443 standard
    - NFC security: Temperature data stored on the sensor patch can only be retrieved using the proprietary SteadyTemp conversion routine
- Network Type: wireless
    - Near-Field-Communication (NFC): For data transmission between App and sensor patch
    - Operating distance (NFC): up to 1 inch (2,5 cm)
- Transport and storage conditions:
    - Environmental temperature: 32 to 104 °F (0 to +40 °C),
    - Humidity: 15 to 95 %,
    - Air pressure: 10.2 to 15.4 PSI (70 to 106 kPa)
- Dimensions: 2.56 x 2.36 x 0.12 in (65 x 60 x 3 mm)
- Weight: 0.11 oz (3 g)
- Power source: 3V lithium button cell battery (not replaceable)
- IP-Classification: IPX5: Protection against waterjets from any direction
- UDI-DI App Store (iOS): 9120095900410
- UDI-DI Play Store (Android): 9120095900427

System Requirements & Operating Conditions

- System Requirements:
  - Apple: iOS 13 or higher on iPhone 7 or newer models
  - Android: Android OS 6
- Operating conditions:
  - Environmental temperature +15 to +40°C (+59 to +104°F),
  - Humidity: 15 to 95%,
  - Air pressure: 86 to 106 kPa

EMC

Electromagnetic radiation does not negatively impact the functionality of the sensor patch[1]. Recorded temperature values influenced by electromagnetic radiation are marked as invalid by the sensor patch and are removed from analysis during processing of the temperature data.

Electrostatic discharges causing a temporary over/under voltage of the supply line are automatically detected by the sensor patch[1]. Temperature values recorded during the event of electrostatic discharges are not saved to the internal storage of the sensor patch. Recorded temperature data is preserved.

[1]*Sensor patch: GTIN (Global Trade Item Number) 09120095900281*

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

EMC

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.