

Instructions for Use SteadyTemp Professional

Version: v1.4

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What is SteadyTemp Professional?

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

SteadyTemp Professional is a clinical thermometer designed to continuously measure the axillary temperature and display relative changes to the user. SteadyTemp Professional is intended for use in a clinical environment.

SteadyTemp Professional consists of an Android-based app and the associated temperature measurement patch. The associated patch is a non-invasive, non-sterile, active temperature measuring device that is only applied to healthy skin under the arm, where it continuously measures the axillary body temperature at a predefined interval. The typical duration of use of the patch is 7 days.

The SteadyTemp Professional app serves as an interface for the user to interact with the patch and to display the measured temperature data. The data measured by the patch is transmitted via Near-Field-Communication (NFC). The temperature data read from the patch can then be transferred to the hospital information system (HIS) using recognized communication standards (HL7/FHIR).



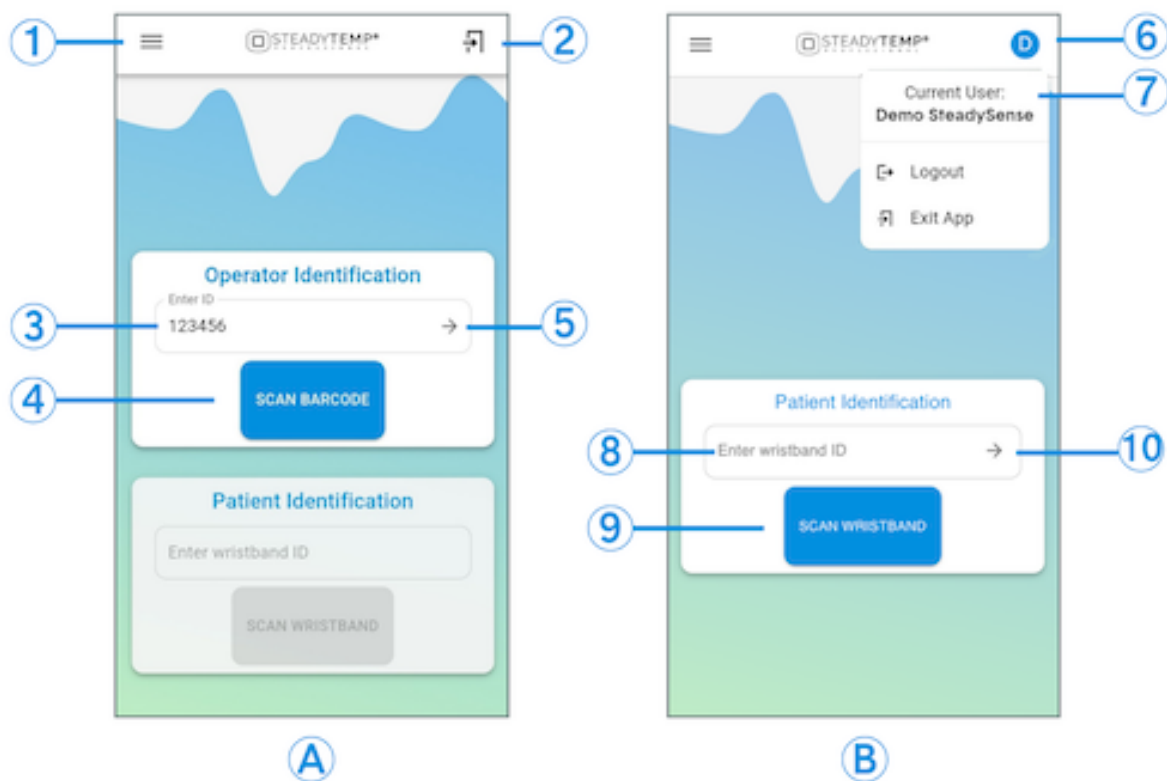
SteadyTemp Professional should not be used under following circumstances:

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

The SteadyTemp Professional app

App structure

Start screen



At the top left you will find the **menu (1)**, under which you will find tutorials, FAQs, the instructions for use, data protection information, the terms and conditions, as well as the version and UDI of the SteadyTemp Professional app.

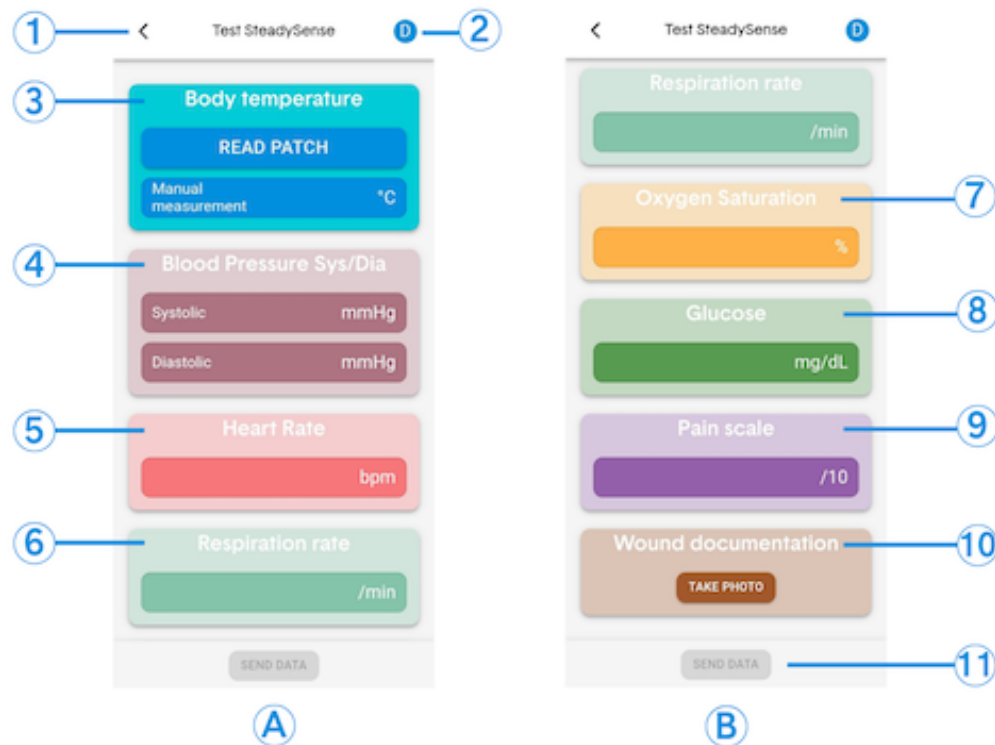
In **view (A)** you can **leave the SteadyTemp Professional app (3)** by clicking on the icon in the top right. You can enter the operator identification manually in the **text field (3)**. You can also scan the operator ID using the **button (4)**. To go to the patient identification, click on the **arrow (5)** after you have scanned or entered your operator number.

Once you are logged in, the start screen changes to **view (B)**. At the top right you can see your **operator icon (6)**. It shows that you are logged in. By clicking on this **icon (6)**, the **view (7)** opens. Here you can see the logged-in user, log-out and leave the SteadyTemp Professional app.

You can enter the patient identification number manually in the **text field (8)**. You can also scan the patient number using the **button (9)**. To go to the temperature screen, click on the **arrow (10)** after you have scanned or entered the patient number.

Vitalparameter

Depending on the configuration of your app, the additional input of vitalparameter can be available in the SteadyTemp Professional app. Vitalparameter can fully or partially be configured for your app. The vitalparameter overview is scrollable. Here you can find an overview of all possible vitalparameter.



(1) Leave vitalparameter overview

(2) Operator icon

(3) Body temperature

This is always active when vitalparameters are configured. Click on "READ PATCH" to activate or read the patch of a patient. For more information see section **"Temperature screen"**. If configured, you can also add manually measured temperature data.

(4) Blood pressure sys/dia*

(5) Heart rate*

(6) Respiration rate*

(7) Oxygen saturation*

(8) Glucose*

(9) Pain scale*

(10) Wound documentation*

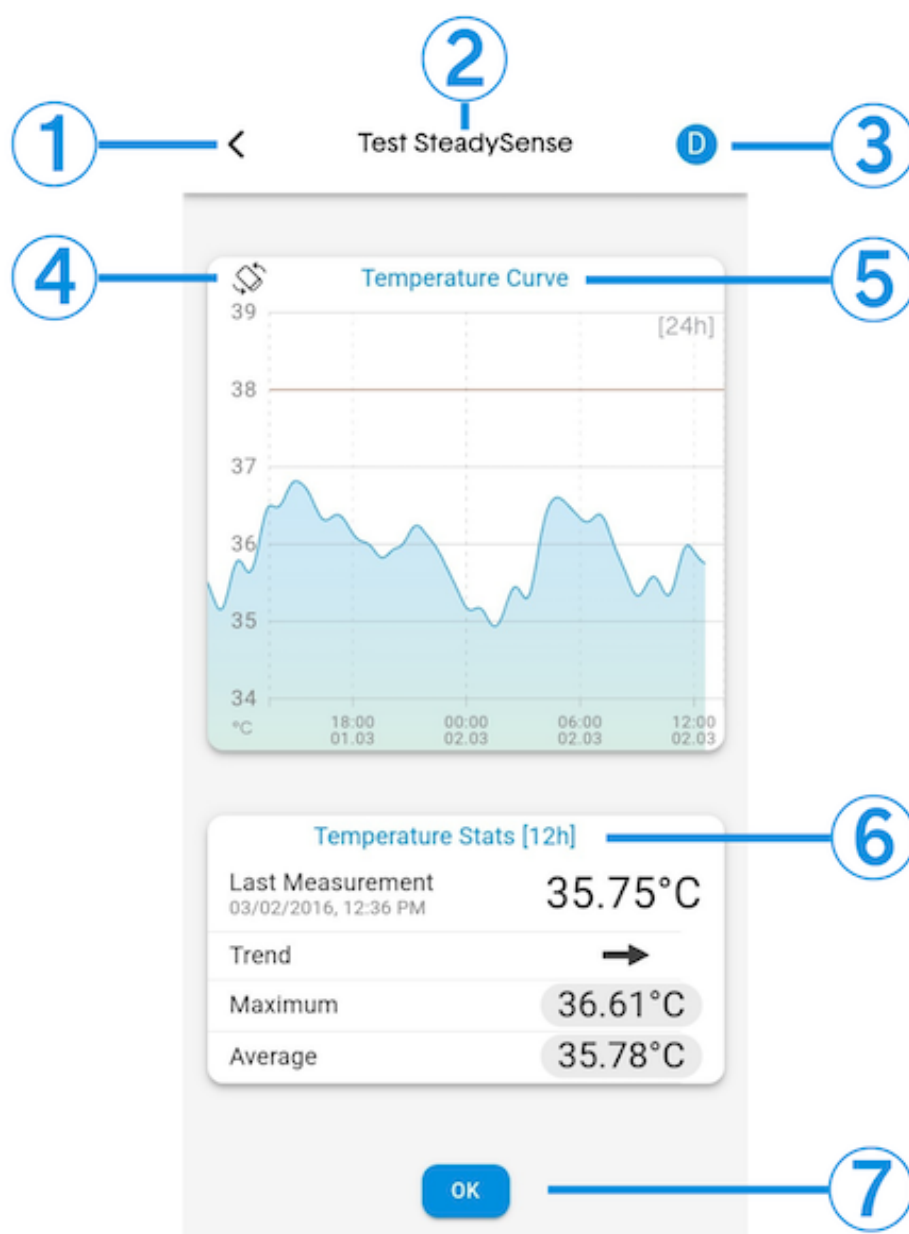
(11) Sent data

The "SEND DATA" button is disabled as long as no vital parameters are entered or a patch has been read. Once vitals have been entered or patch data is available, the button turns blue and the data can be transferred to your HIS.



***The vital parameters can be fully or partially configured by your IT department.**

Temperature screen



You can exit the **temperature screen at the top left (1)**. Top center you can see the **patient name and/or ID (2)**. At the top right, you can see the **logged-in operator (3)**. By clicking on the **full screen mode (4)** you can view the temperature curve in full screen. The top area shows the **temperature curve of the patient (5)**. The lower area shows the **temperature statistics (6)**. By clicking on "OK" **(7)** you go back to the vitalparameter overview, where you can enter additional vitalparameter and transfer the data to your HIS.

IT security measures

- No data is stored within the SteadyTemp Professional app.
- Do not give the device on which the SteadyTemp Professional app is installed to third parties or unauthorised personnel.
- Log out of the app before you hand over the device to another person.
- The admin area can only be used by authorised users (IT administrators).
- Make sure that you scan the patch of the previously identified patient to avoid confusion of temperature data.

Data protection

As the manufacturer of the SteadyTemp Professional app, SteadySense GmbH does not process any of the personal data collected/entered in the app. All data collected in the context of use of the SteadyTemp Professional App is forwarded to the business partner responsible for transferring the data to a hospital information system (HIS). The storage and further processing of the data collected by the SteadyTemp Professional app is the responsibility of the hospital in which the SteadyTemp Professional App is used.

The legal data protection requirements are fulfilled. 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

Application

Attach the patch to the patient according to the following instructions. After you have attached the patch, the patient ID is assigned and the patch is activated/read out.



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

(GTIN: 09120095900045).

Instruction

1. Preparation

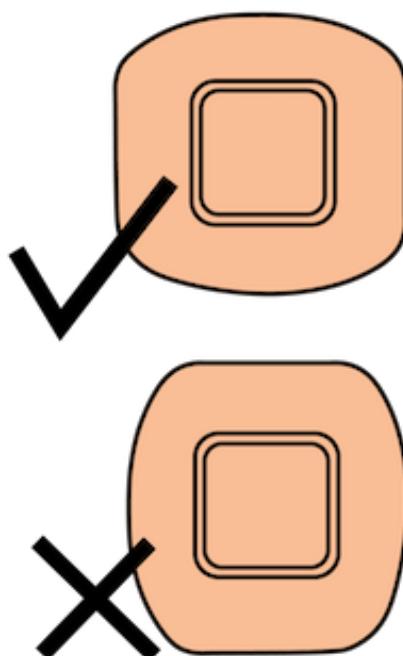


The sensor patch must be applied on clean, dry skin (without cream/ deodorant). The adhesive area can also be cleaned with a suitable alcohol swab. However, make sure that the skin is dry before applying. Apply the sensor patch only on intact skin.

2. Find position



The correct position of the sensor patch is important to achieve accurate measurements. The patient's shoulder must be relaxed. If the patient is able to sit/stand up, ask the patient to place their hand on their hip and relax their shoulder. The correct position of the sensor patch is directly under the arm, centred between the back and chest. Place the patch so that the rounded sides of the patch are pointing up and down.



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

3. Attach patch



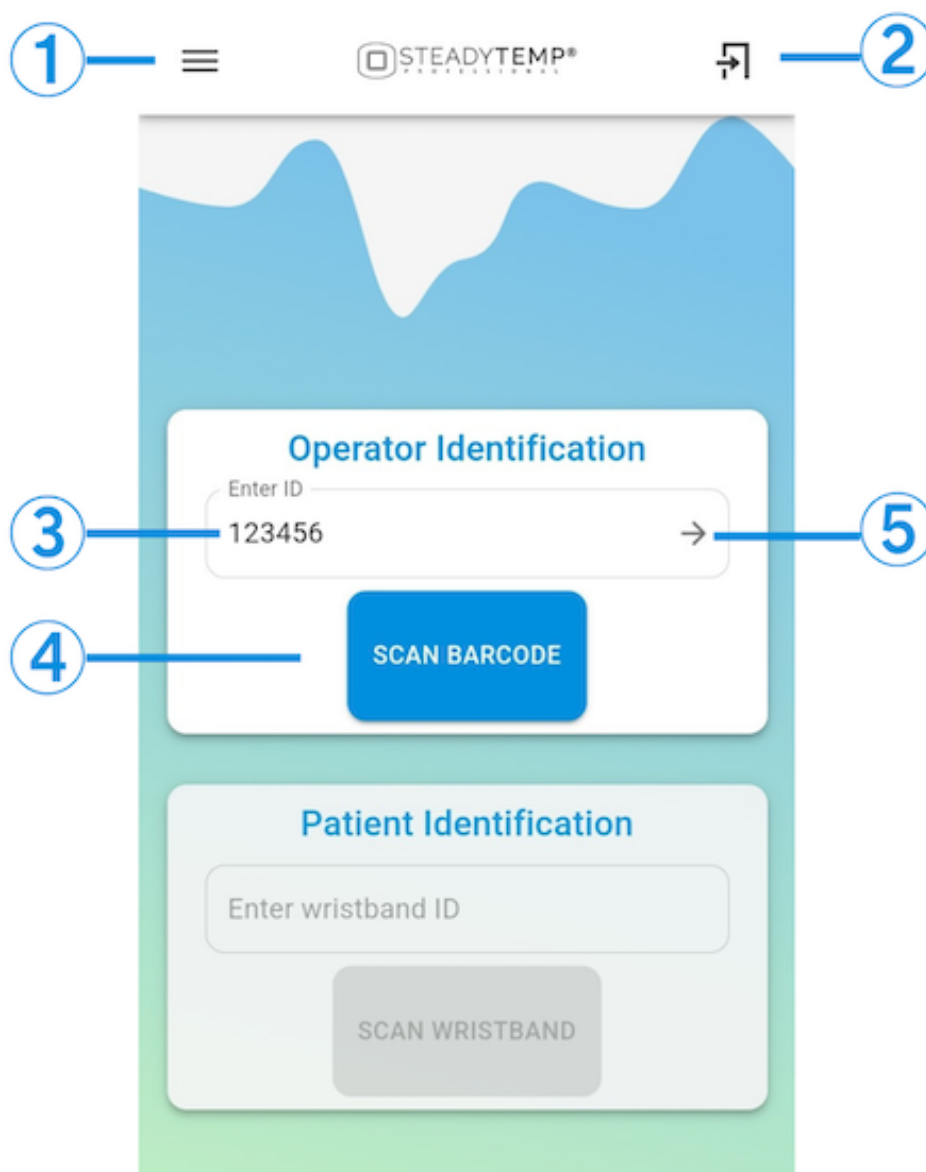
Remove the small part of the backing film, ensuring that the patient is in a relaxed position, and apply the sensor patch to the previously determined location. Make sure once again that the shoulder is relaxed and that the skin does not have any pronounced wrinkles. Now remove the rest of the backing film and apply the sensor patch firmly on all sides.

4. Log in

To use the SteadyTemp Professional app (activate/read out patch, enter vital parameters, send data, etc.), you must first log in.

The following image shows the start screen of the SteadyTemp Professional app. At the top left you will find the **menu (1)**, under which the instructions for use can be found. At the top right you can exit the **SteadyTemp Professional app (2)**.

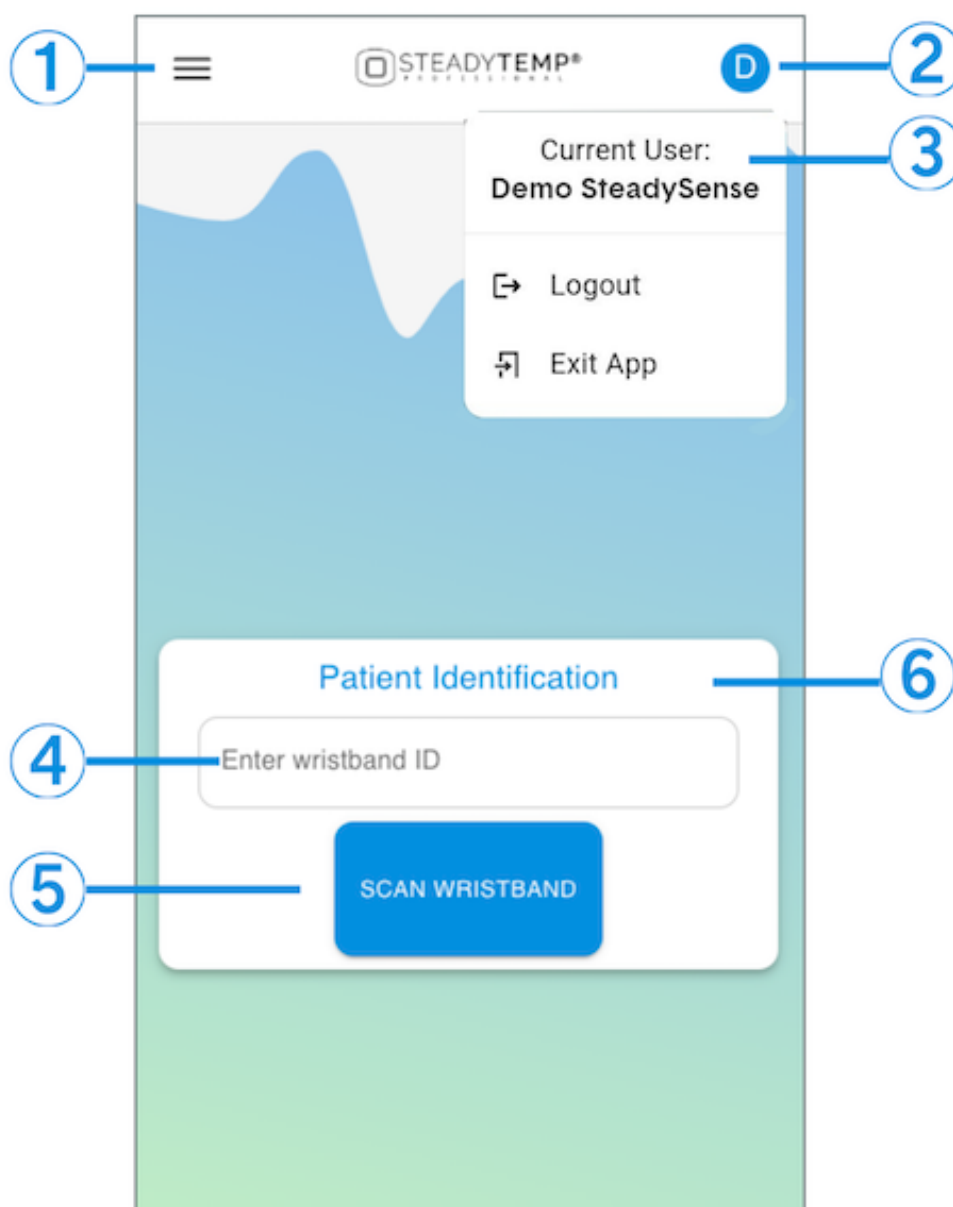
Scan (4) your personal identification number or enter it manually in the **text field (3)**. Confirm your personal ID by clicking on the **arrow (5)**.



5. Connect patient

The following image shows the start screen of the SteadyTemp Professional app after you have logged in. At the top left you will find the **menu (1)**. To connect a patient, a user must be logged in (see **4. Log in**). The **operator icon (2)** shows that a user is logged in. Click on it to open the **view (3)**. Here you can see the logged-in user, log out and exit the SteadyTemp Professional app.

Scan (5) the patient identification number or enter it manually in the **text field (4)**. Confirm the patient ID by clicking on the **arrow (6)**.



6. Activate patch

Once you have confirmed the patient ID, the vitalparameters overview opens. By clicking on "READ PATCH", an NFC dialogue opens and you can activate the patch. Hold the handheld device with the NFC sensor on the patch. This may be installed differently in the device depending on the model. If you are unsure where the NFC sensor of your device is located, please refer to its operating instructions.

Successful activation is confirmed in the NFC dialogue. You will then be redirected to the vitalparameters overview. There is no temperature data available yet to send to your HIS. If you have entered vital signs, you can transfer them to your HIS by clicking on "SEND DATA". If you have not entered any data, you can return to the start screen at the top left.



Make sure that you connect the patch to the correct patient. This step cannot be changed later.



The availability of the first temperature values depends on the measuring interval set for the patch. Normally, the first temperature values are available after 5 to 10 minutes. Please contact your IT department for more information on the patch measurement interval.

7. Read out patch, enter vitalparameter and send data

To read an already activated patch, first connect your device to the respective patient as described under **5. Connect patient**. To do this, you must be logged into the app (see point **4. Log in**). Then hold your device with the NFC sensor on the patch (see also point **6. Activate patch**). After a successful readout, you will see the last measured value at the top of the vitalparameter overview under "Body temperature".

Click on this measured value to view the patient's temperature curve. You can enter additional vital signs in the vitalparameters overview (depending on the configuration of your app). Click on "SEND DATA" in the vitalparameters overview to transfer the data to your HIS.



Depending on the individual settings of your SteadyTemp app, the patch can save data for a certain period of time. By default, the SteadyTemp Professional can store data for up to 77 hours (3 days). However, this period may be longer depending on the settings. Contact your IT department for the exact duration.

8. Remove patch

The typical application period for the sensor patch is 7 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. in the shower or with a cloth). The sensor patch can then be carefully peeled off. If the sensor patch feels uncomfortable when worn, or if itching or a burning sensation occurs, please remove the patch.



When you should remove the patch earlier:

- For itching, burning sensation or discomfort
- Before MRI or CT examinations
- Before X-ray examinations, as the patch can interfere with imaging

Apply a new patch on the other side of the body to avoid skin irritation.

Disposal

The sensor patch is powered by a button cell battery. Therefore, the patch should be disposed of properly. 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

There are three types of error messages:

1. Read error

- **"Read failed** - The patch could not be read. Please try again."
- **"Activation failed** - The patch could not be activated. Please try again."
- Patch does not respond to the readout device

Try to read the patch again. If the problem persists, remove the patch and apply a new patch to the other side of the body (exception: patients with pacemakers).

2 Patch error

- **"Patch damaged** - Please remove the patch and apply a new one."

Remove the patch and apply a new patch on the other side of the body (exception: patients with pacemakers).

3 Server error

- **"404** - Not found"
- **"429** - Too Many Requests"
- **"500** - Internal Server Error"

If a server error or another error unknown to you occurs, please contact your IT department.



If the SteadyTemp Professional app exhibits unexpected behaviour, please contact your IT department.



Safety instructions

- SteadyTemp Professional suitable for people of five years and older.
- The sensor patch 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 axillary temperature.
- Measured temperature values are processed by SteadyTemp Professional for display purposes.
- Do not use the sensor patch more than once, 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 disassemble 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 Professional does not interfere with other electronic equipment. SteadyTemp Professional is not affected in the normal range of application.
- For patients with pacemakers: Only apply the patch to the side of the body away from the heart, as the read-out device could interact with the pacemaker.
- Do not put the sensor patch in the microwave.
- Remove the patch before an MRI or CT scan. SteadyTemp Professional has not been tested for safety and compatibility during an MRI or CT scan. It has not been tested for heating, migration or image artefacts during an MRI or CT scan. The safety of the patch during an MRI or CT scan is not known. Examination of patients wearing a patch may result in patient injury.
- Remove the sensor patch before an X-ray scan as the patch might block visualization in the application area.
- This is a miniature electronic device. Please dispose of the patch properly.
- Do not throw the sensor patch in the fire, the battery could explode.
- The typical application duration is 7 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 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 cause discrepancies in the accuracy of the measurements.
- 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 of the sensor patch. Remove the sensor patch immediately if it 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 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. Remove the sensor patch gentle to avoid further irritation and use a soothing ointment afterwards.

- 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 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



©SteadySense GmbH

Johann-Schreiner-Straße 3

8074 Raaba-Grambach, 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



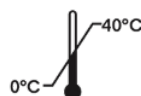
Observe electric
operating instruction



LOT Number



Protect from sun
and heat



Storage temperature



MR unsafe

Indication for use

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

SteadyTemp 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.

Steadytemp consists of a sensor patch and accessories - the measurement module and the smartphone application. The body temperature data measured by the sensor is transmitted via Near-Field-Communication (NFC), parsed and processed in the measurement module and subsequently displayed by the smartphone application.

Contraindications

The SteadyTemp Professional 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 Professional is the continuous measurement of axial temperature. No data will be stored within the SteadyTemp Professional app. The data measured by the patch can be transferred to the hospital information system (HIS) with the help of the SteadyTemp Professional app using recognised communication standards (HL7/FHIR). Data is transferred between the patch and the SteadyTemp Professional app via near-field communication (NFC).

Intended user group

The target user group for SteadyTemp Professional is healthcare professionals.

The user must be able to read and understand the instructions for use. The user must also be able to follow the instructions of the SteadyTemp Professional app and act appropriately. In addition, the user must be familiar with software applications and be able to operate the respective readout device. Existing experience with software applications is recommended but not required to operate SteadyTemp Professional properly.

There are no restrictions regarding the nationality of the user.

Intended patient group

The target patient group of SteadyTemp Professional are people older than five years.

In general, there are no restrictions on patient weight. However, extreme weight ratios may have a negative impact on SteadyTemp Professional 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.

There are no restrictions regarding the nationality of the patient.

Intended use environment

The product is intended to be used by trained professionals in a clinical environment. The SteadyTemp Professional app is connected to the internal hospital network.

The temperature data is stored in the sensor patch for up to 77 hours. The app does not store any data. Data is transferred using near-field communication (NFC). The temperature data must be read out regularly using the SteadyTemp Professional app, from where it is then transferred to the hospital information system (HIS).

Target market

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

- Austria
 - Germany
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Product life & scope of delivery

- GTIN (Global Trade Item Number) SteadyTemp Professional: 09120095900045
- The patch is individually packaged and supplied in boxes of 50.
- The sensor 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 product labelling.
- The sensor patch is typically worn on the body for a period of up to 7 days after application.
- The sensor patch is a microelectronic device and should be disposed of properly. See the **Disposal** section for more information.

Scope of delivery

- **Sensor patch:** The patches are supplied in boxes of 50; the patches are individually packaged
- **App:** The SteadyTemp Professional app is pre-installed and pre-configured on the readout devices
- **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
- Measurement range: +30 to +42°C (+86 to +107°F)
- Measurement accuracy: SteadyTemp Professional displays relative changes of the axillary temperature with a maximum deviation of +/-0.3°C (+/-0.54°F)
- 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 Professional conversion routine
- Network Type: wireless
 - WLAN: application -based data transmission, connection to hospital IT-system required
 - Near-Field-Communication (NFC): For data transmission between App and sensor patch
 - Operating distance (NFC): up to 2,5 cm (1 inch)
- Operating conditions:
 - Environmental temperature +15 to +40°C (+59 to +104°F),
 - Humidity: 15 to 95%,
 - Air pressure: 86 to 106 kPa
- Transport and storage conditions:
 - Environmental temperature: 0 to +40°C (32 to 104°F),
 - Humidity: 15 to 95%,
 - Air pressure: 86 to 106 kPa
- 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
- GTIN app: 09120095900373
- GTIN sensor patch: 09120095900045



Electromagnetic radiation does not negatively impact the functionality of the sensor patch. 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. 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.

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 80 MHz 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.