



STEADYTEMP[®] SMART THERMOMETER INSTRUCTION FOR USE

Please read the instructions for use and the safety instructions carefully and follow them exactly. Improper use or disposal of the sensor patch may be harmful to health and may pose a risk for third parties.

WHAT IS MEDICARE STEADYTEMP SMART THERMOMETER

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

The system consists of a sensor patch and a smartphone application. The body temperature data measured by the sensor is transmitted via NFC (contactless) and subsequently displayed by the smartphone application.

CONTRAINDICATIONS

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

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

INTENDED USE

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

Go to pages 2 and 3 for Safety Instructions and Usage Information.

Scan the QR code opposite to download the Medicare SteadyTemp Smart Thermometer app. You can also download the app through www.flemingmedical.ie/steadytemp



INSTRUCTION FOR USE

After registering your account, follow the instructions below or within the app to apply and activate the patch. **Ensure NFC is activated on your smartphone.**

1. APPLY THE PATCH

The patch should be applied to clean dry skin, free from creams, lotions or deodorant.

To apply the patch relax your shoulder, put your hand on your hip and place 3 fingers directly under your arm.

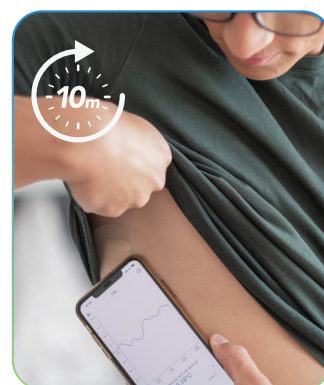


2. ACTIVATE THE PATCH

After 10 minutes you can activate the patch.

Tap on the patch icon in the app and hold the back of your smartphone against the patch in order to connect it to a user.

After connection, hold the back of your smartphone against the patch to activate it – a vibration will confirm successful activation.



3. READING THE PATCH

After a successful data transfer the app displays your current body temperature and stored temperature curves.

Please note that measured temperature values are processed by Medicare SteadyTemp Smart Thermometer for display purposes.

Reliable temperature values are available about 1 hour after the patch has been activated.



REMOVING THE PATCH

The intended wearing time of the Medicare SteadyTemp Smart Thermometer 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.

! SAFETY INSTRUCTIONS

- Medicare SteadyTemp Smart Thermometer is not intended for persons under 5 years of age.
- Medicare SteadyTemp Smart Thermometer 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.

SAFETY INSTRUCTIONS

- Measured temperature values are processed by Medicare SteadyTemp Smart Thermometer 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 patch.
- Do not apply successive patches on the same body side.
- Medicare SteadyTemp Smart Thermometer does not interfere with other electronic equipment. Medicare SteadyTemp Smart Thermometer 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.
- Medicare SteadyTemp Smart Thermometer may react unpredictably in combination with strong magnetic fields. Please remove the patch before MR or CT examinations.
- The patch is a small electronic device and should not be disposed of in normal 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 Medicare SteadyTemp Smart Thermometer 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.

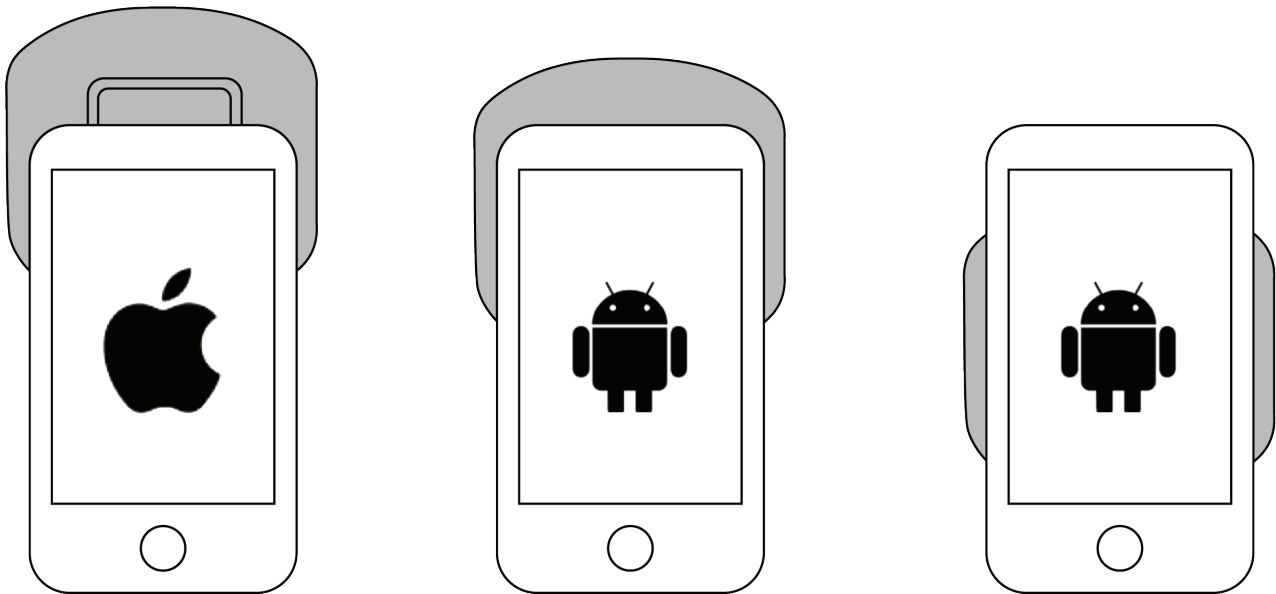
USAGE INFORMATION

- 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 cleansing pad.
- Do not use deodorant, lotions or creams beforehand.
- When applying the patch, remove the small part of the barrier foil first.
- Do not touch the adhesive side of the patch, this could reduce overall adhesiveness.
- After applying the patch, smooth it out gently on all sides to fix it in place.
- The patch should be read via NFC at least once a day.
- Hold your smartphone as still as possible while activating and reading the patch.
- Remove the patch immediately if it becomes uncomfortable or causes skin irritation.

USAGE INFORMATION

- Do not do physically intense sport or any other activities that cause excessive perspiring (sauna or steam room) while wearing the patch.
- Throughout the day, small variations in body temperature occur, which are shown by the continuous measurement.
- Do not overstretch the patch during application as this may cause skin irritation.
- 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.
- When you remove the patch, carefully peel it off. We recommend doing this after showering or wetting the patch with a wet washcloth first.

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 patch in order to read it correctly.

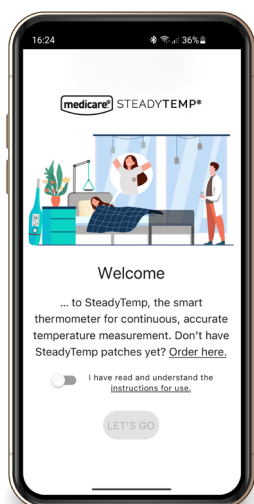
- **iPhone:** Hold the top edge of the back of your phone, at a slight angle, on the middle of the patch.
- **Android:** On an Android phone the NFC antenna can be located in different positions. Hold either the area around the camera or the back of the smartphone against the middle of the patch.

Please make sure that NFC is switched on.

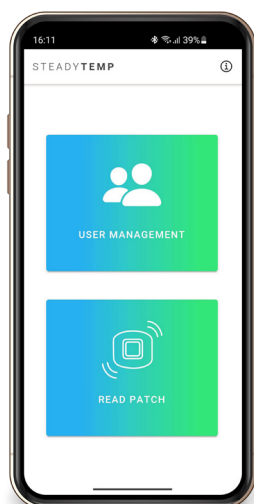
NFC can be switched on in the quick menu or in the settings.

MEDICARE STEADYTEMP SMART THERMOMETER APP DETAILS

WELCOME



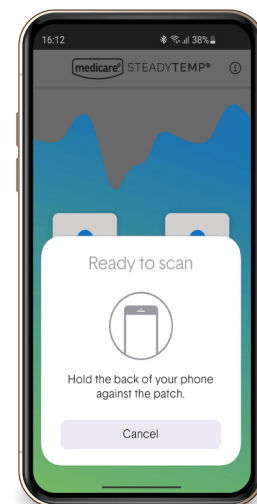
OPTIONS



LOGIN



READ PATCH



USER MANAGEMENT

In the user management section you can view the data of all users created in the app. If you want to change a user name or delete the user, then swipe the user name to the left to make the changes.

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

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

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 the following email address: support@flemingmedical.ie

“Temperature outside range” is a notification you may receive 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 “Low temperature” or “High temperature” will be displayed.

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.

MEDICARE STEADYTEMP SMART THERMOMETER APP DETAILS

ENTRIES & HISTORY

New (diary) entries can be created with "Add entry". Medication intake, symptoms, pain, activities, general wellbeing 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 Medicare SteadyTemp Smart Thermometer in the App Store or Play Store.









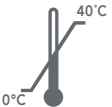






If you experience a problem with Medicare SteadyTemp Smart Thermometer, a technical defect or side effects, please contact us at: support@flemingmedical.ie or tap "Contact Support" in the Medicare SteadyTemp Smart Thermometer app menu.

Go to www.flemingmedical.com/steadytemp for more support information.

DISPOSAL

The patch is powered by a battery and is therefore considered an electronic device, it should not be thrown in the normal household waste, but disposed of in accordance with local waste regulations for batteries and electrical appliances. The Medicare SteadyTemp Smart Thermometer box and transport packaging is made of recyclable paper or cardboard and should be disposed of in paper waste. The individual packaging can be separated and disposed of in plastic or paper waste.

SYMBOL DESCRIPTION

	Lot number/batch code - To identify the manufacturer's batch or lot code.
	Manufacturer - To identify the manufacturer of the product.
	Use by date - To indicate that the device should not be used after the date accompanying this symbol.
	Medical Device.
	Do not re-use - To indicate that the item is for single use only and must not be used more than once.
	WEEE - To indicate that separate collection for waste electric and electronic equipment (WEEE) is required.
	Storage temperature limit - To indicate the maximum and minimum temperature limits at which the item shall be stored.
	Follow electronic instructions for use (www.flemingmedical.ie/SteadyTemp).
	Observe electronic instructions for use (www.flemingmedical.ie/SteadyTemp).
	Green dot - Indicates that the producer of the packaging has contributed financially to the recycling of that packaging.
	Caution - To indicate that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.
	Product information - To identify a place where information may be found.
	NFC - Near Field Communication (contactless) required.

TROUBLESHOOTING

If the Medicare SteadyTemp Smart Thermometer 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 email to support@flemingmedical.ie.

In order to be able to correct errors as quickly as possible, you can find the most common error messages below with their suggested solutions.

ERROR MESSAGE	POSSIBLE CAUSE	SUGGESTED SOLUTION
Please try again.	The readout attempt failed	Try to read out 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 you 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 remove 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 Medicare SteadyTemp Smart Thermometer 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 store where you purchased the patch or support.
Unsupported patch. This patch is not compatible with this app.	The patch used is misconfigured.	Please contact support.



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 sensitive components.



TECHNICAL SPECIFICATIONS

- **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
- **Measurement accuracy:** Medicare SteadyTemp Smart Thermometer displays relative changes of the axillary temperature with a maximum deviation of +/-0.3°C.
- **Operating mode:** Direct mode, continuous
- **Measurement interval/time response:** 300 seconds
- **Operating conditions:**
 - **Environmental temperature:** +15 to +42°C,
 - **Relative Humidity:** 15 to 95%,
 - **Air pressure:** 86 to 106 kPa
- **Transport and storage conditions:**
 - **Environmental temperature:** 0 to +40°C,
 - **Relative Humidity:** 15 to 95%,
 - **Air pressure:** 86 to 106 kPa
- **System compatibility:**
 - **Apple:** iOS 13 or higher on iPhone 7 or newer models
 - **Android:** Android OS 6.0 Marshmallow or newer on an NFC enabled smartphone
- **Dimensions:** 65mm x 60 mm
- **Weight:** 3 grams
- **Power source:** 3V lithium button cell battery (not replaceable)
- **IP-Classification:** IPX5 - Protection against water jets from any direction

CONTACT DETAILS



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