

Welcometo

Empatica Care

- + Aura
- + EmbracePlus

User manual

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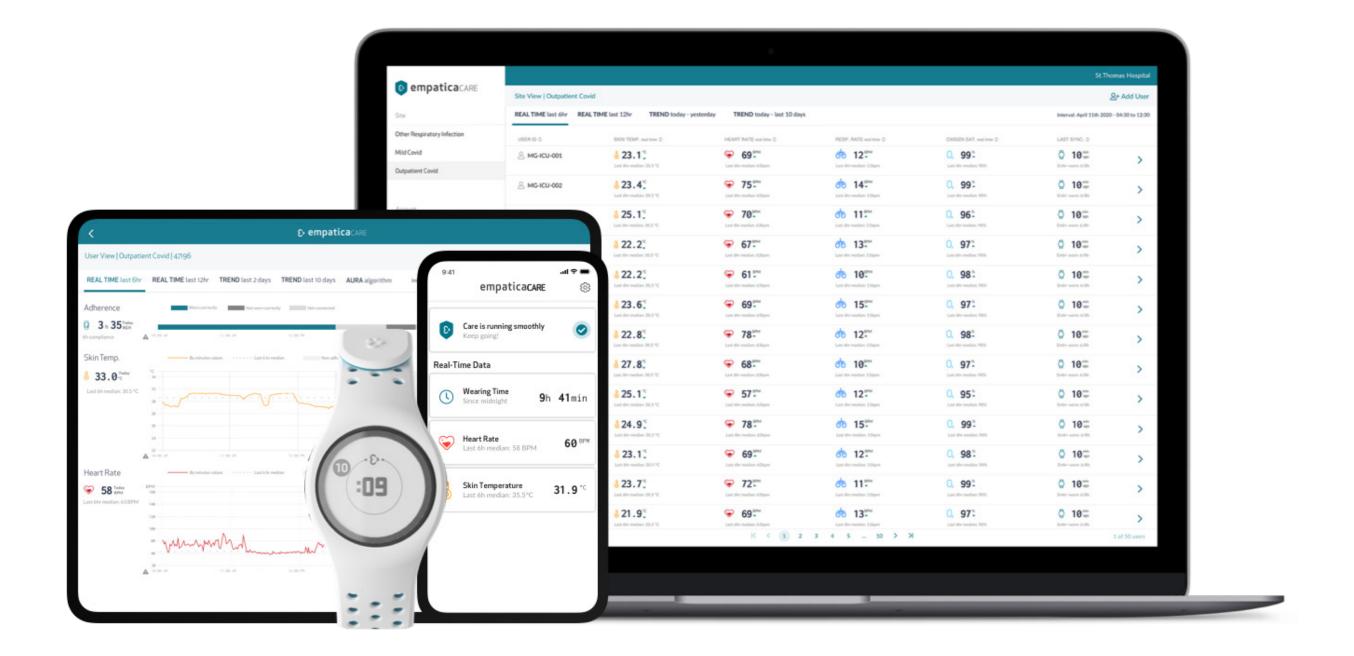
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Empatica Care at a glance



What is Empatica Care?



Empatica Care is a complete health monitoring solution that combines three different elements: a CE-certified wearable, an app, and an online portal, in order to guarantee the continuous and remote monitoring of users.

Empatica Care enables the monitoring of different health parameters and digital biomarkers, providing a view of vital signs as well as the output of any algorithms focusing on specific conditions.

How it works

This is how **Empatica Care** works:



The EmbracePlus watch (1), the wearable, collects physiological data from your wrist.

This data is then transferred to the Care App (2), an application installed on your phone, allowing you to check your vitals and verifiy that the data collection is fuctioning properly.

The Care App uploads the data to the Empatica Cloud (3), where data is stored and made available to providers via the Care Portal (4).

Systemelements

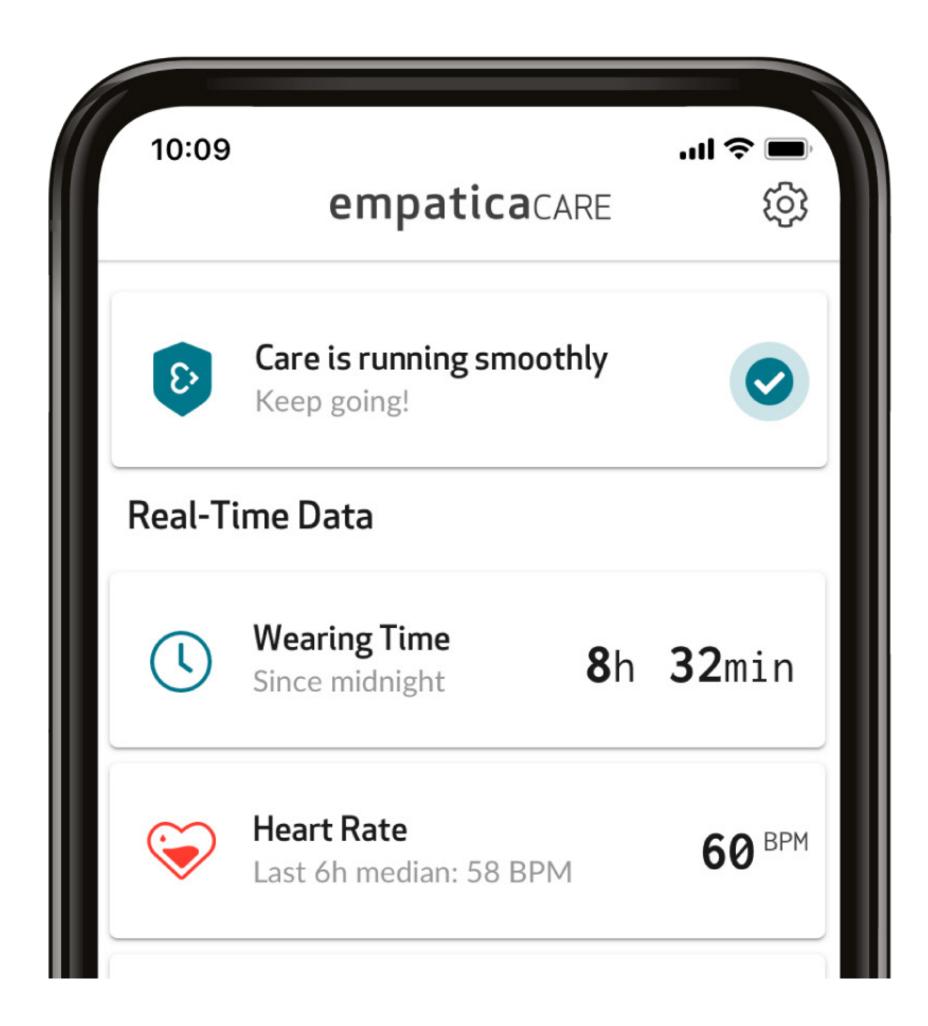
EmbracePlus Watch



EmbracePlus seamlessly collects the following physiological data from your wrist: heart rate, motion (acceleration), Electrodermal activity (EDA), and skin temperature.

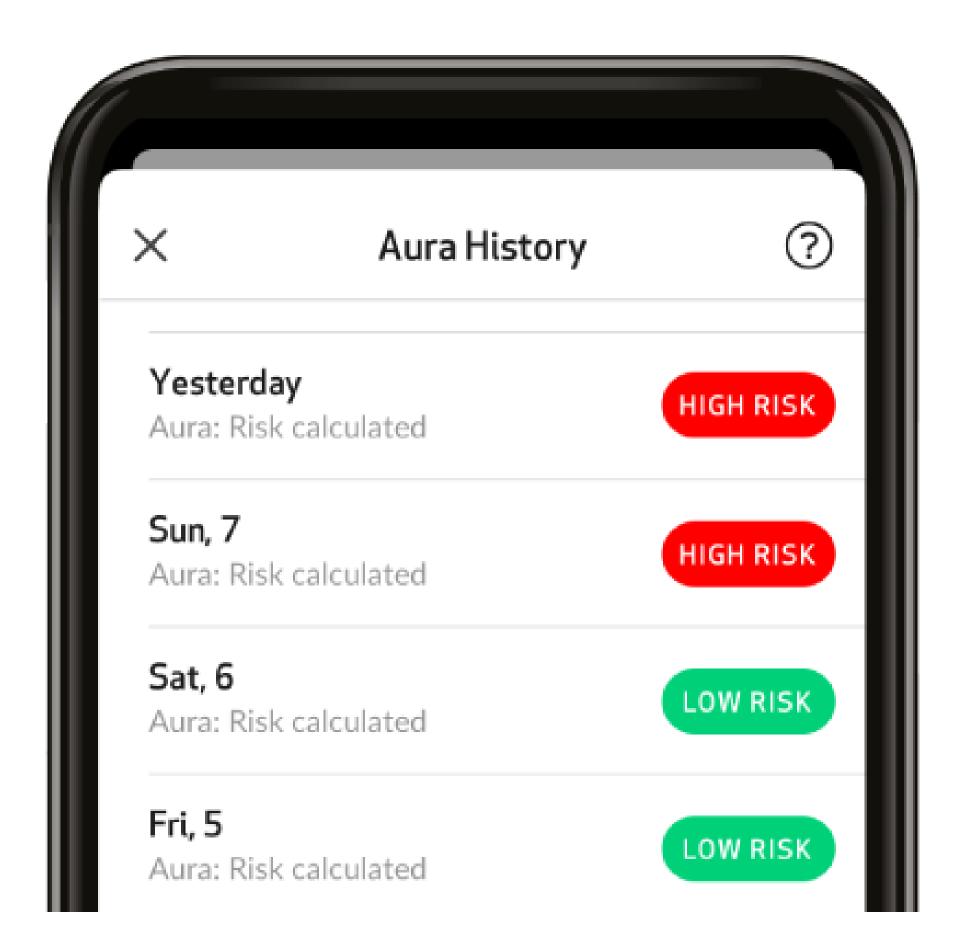
Learn more about the device in chapter 3

Care App



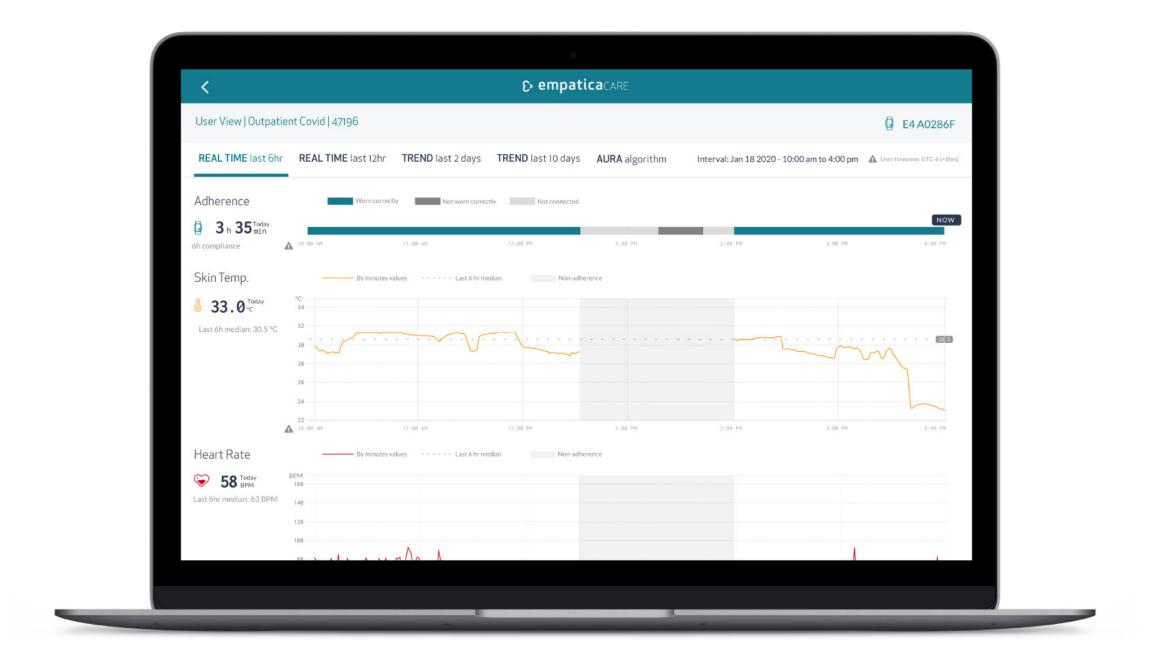
Care app is the link between your EmbracePlus and the Care Portal. The data collected by EmbracePlus is transferred to the App via Bluetooth®. The Care App then transmits the data to the Care Portal via your smartphone's internet connection (Wi-Fi or cellular data), so that it can be viewed by a professional.

Aura



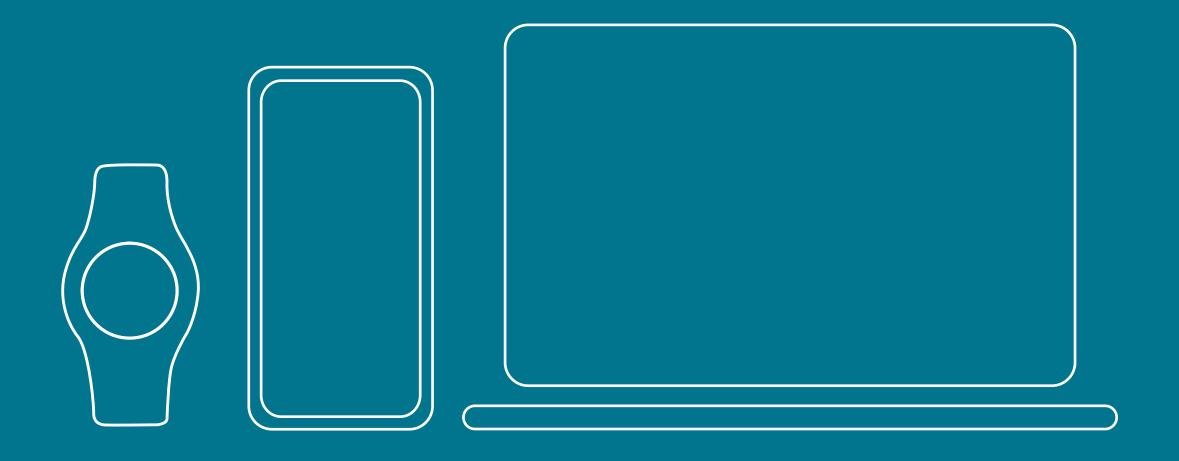
Aura is an algorithm that analyzes EmbracePlus data and calculates an individual's risk of having a possible respiratory infection. The Aura output can be accessed through Empatica Care. Aura will alert individuals through the Care App at the earliest physiological signs of a possible infection, even without symptoms being present.

Care Portal



Care portal is an online dashboard where your data is available for caregivers to monitor your vitals.

Using the system



Firstusage

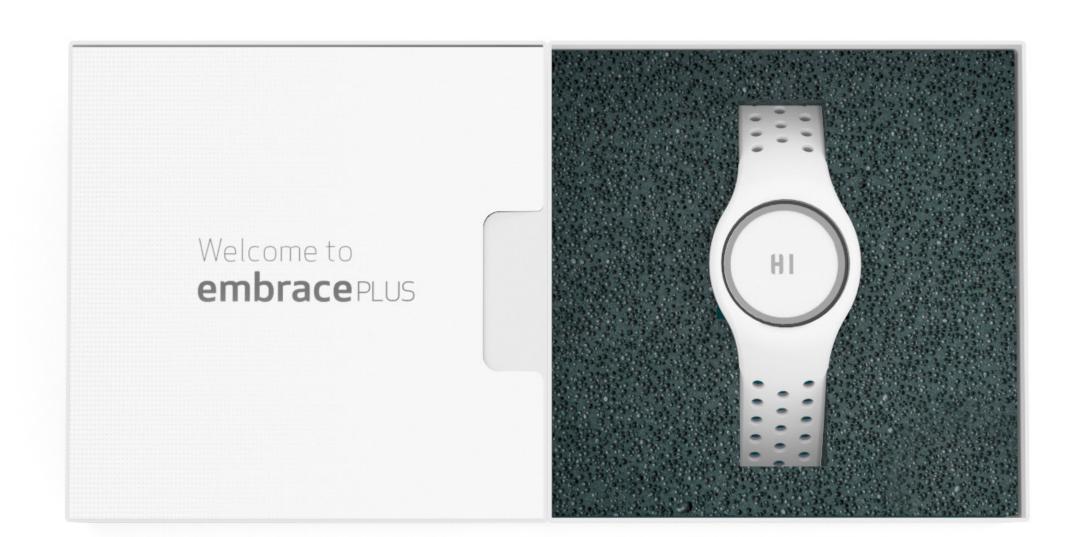
Using Empatica Care with EmbracePlus is simple.

Follow these steps to get started:

STEP 1: Unboxing



1. Slide the sleeve from the package and extract the envelope and the box.

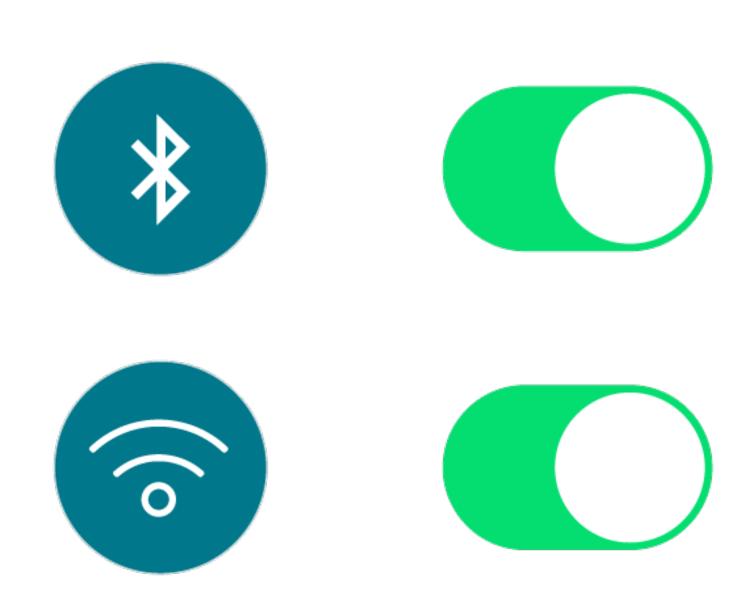


2. Open the box and gently remove your EmbracePlus.

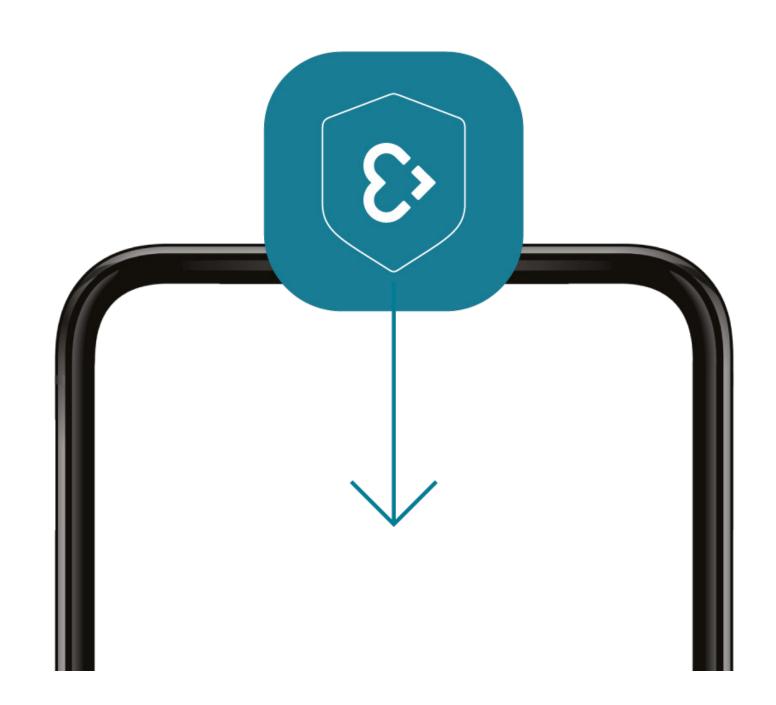


3. Get your Care Credentials either in the envelope inside the box or alternatively from your provider.

STEP 2: Log into Empatica Care App and pair EmbracePlus



1. Make sure your phone has Bluetooth® and Internet connection activated.



2. Download the Empatica Care App: empatica.com/start-care



- **3.** Wake up EmbracePlus by clicking its upper button, next to the OK; you will see a circle appear around the HI*.
- **4.** Open the app, tap on "Login with QR code", and scan the QR code on the Care Credentials card. Alternatively, you can also manually enter the provided credentials.
- **5.** Follow the instructions in the Care App to complete the pairing process. Once the phone is connected to the EmbracePlus watch, the empaheart will appear on the watch display and at the same time as on the phone will be displayed.
- 6. Review the tips on how to wear EmbracePlus and tap "Let's Go" to access the main screen of the App.
- 7. You are all set to use EmbracePlus in your daily life.



*Tips for Waking up EmbracePlus

In the unlikely event in which your EmbracePlus is out of battery, the device will not react when pressing the OK button. To wake it up you will first need to charge EmbracePlus, with the charger included in the box. Please follow the charging instructions below.

STEP 3: Wear EmbracePlus and start monitoring

Wearing EmbracePlus correctly is crucial for enabling proper monitoring. The device needs to be correctly in place in order to collect data and send it to the cloud. If it is not correctly worn, you will receive a 'Not worn correctly' status in the app.

If this happens, check if you are wearing the EmbracePlus in the correct way.

(Check how to properly wear it in chapter 3).

Daily usage

With these simple guidelines, you will be able to correctly use EmbracePlus during your daily life.



Wear EmbracePlus continuously

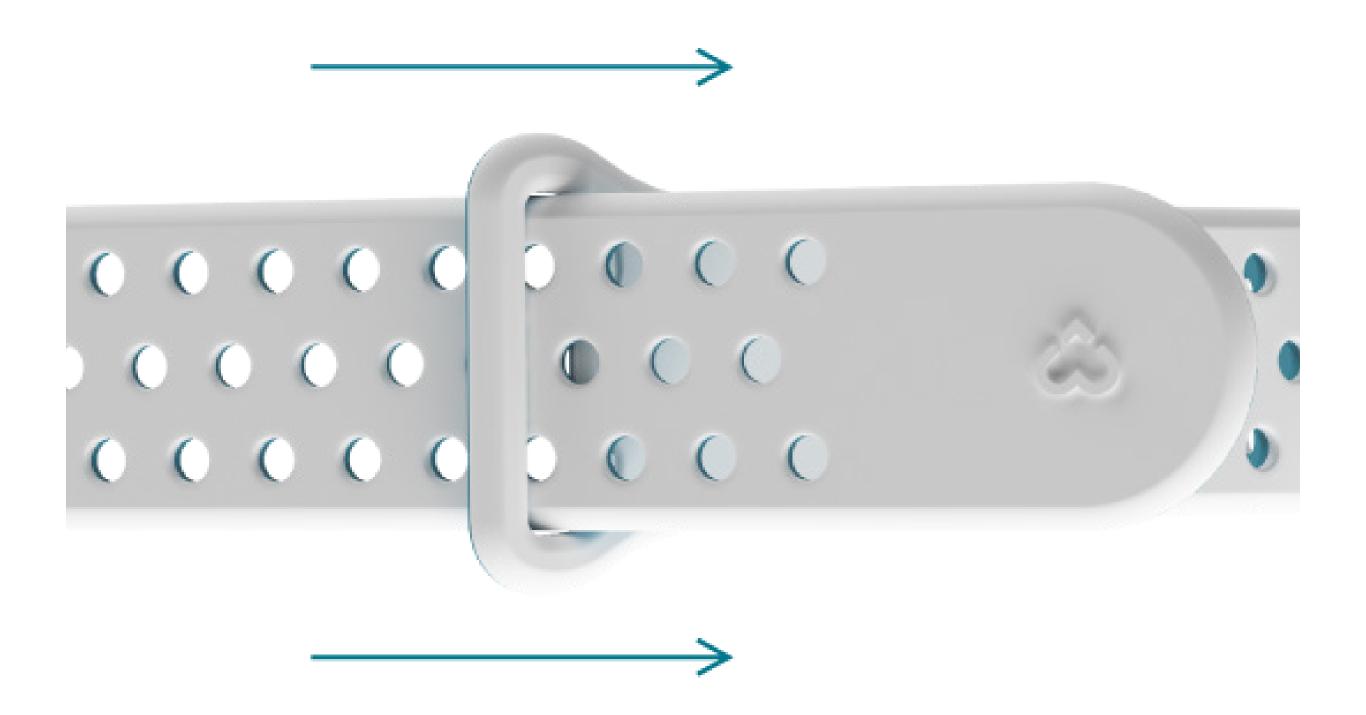
Only remove EmbracePlus from your wrist when charging it. It is important that you also wear EmbracePlus at night and during sleep. Ensure you have enough battery to last during your sleep.

The best way to wear it is by following the steps below:



1. Place the device on your wrist

Wear it on your non-dominant wrist hand for more accurate monitoring. Your device should be a finger's width from your wrist bone.



2. Adjust the band fit

Insert the band inside the loop and pull until you feel a soft pressure on your wrist.

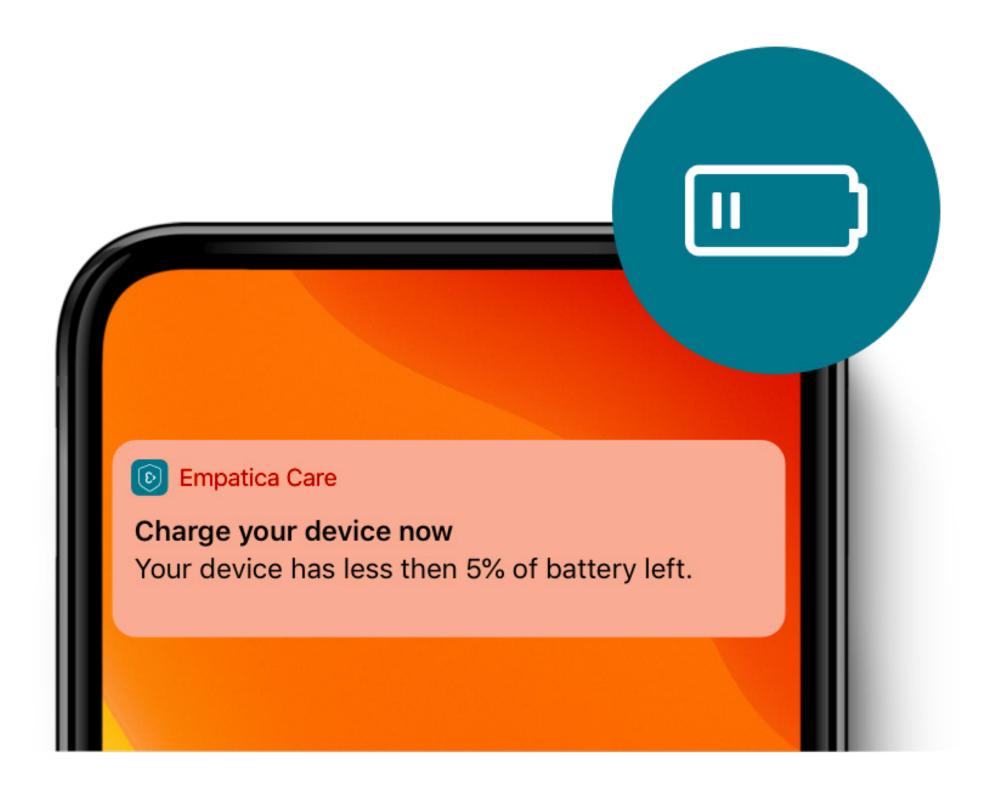
Make sure it doesn't easily change position.



3. Fasten the band

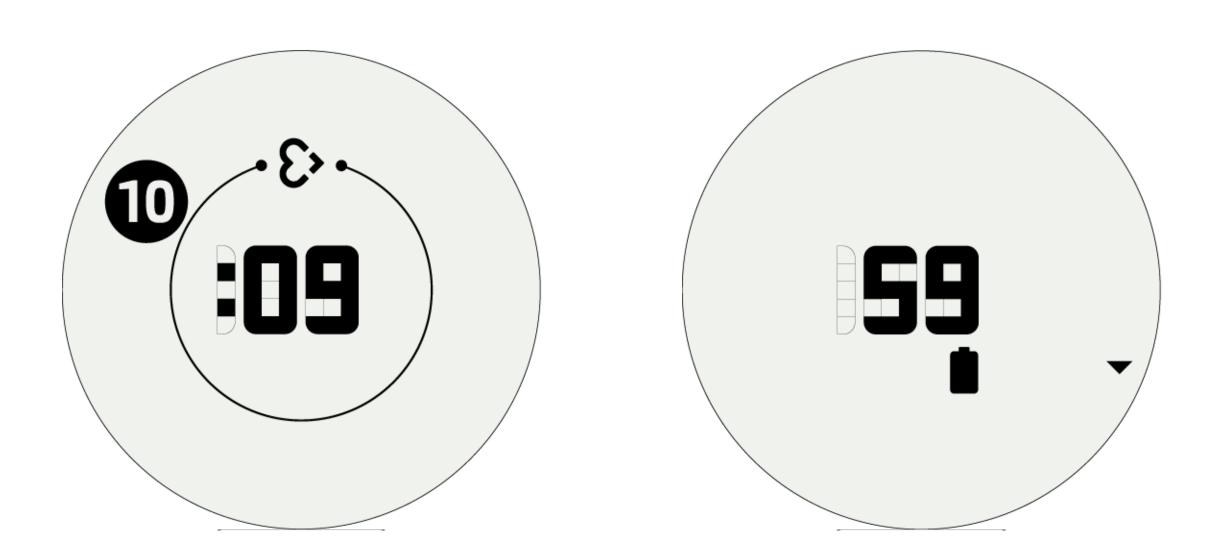
Push the pins into the holes.

Be aware that a loose band will affect monitoring.

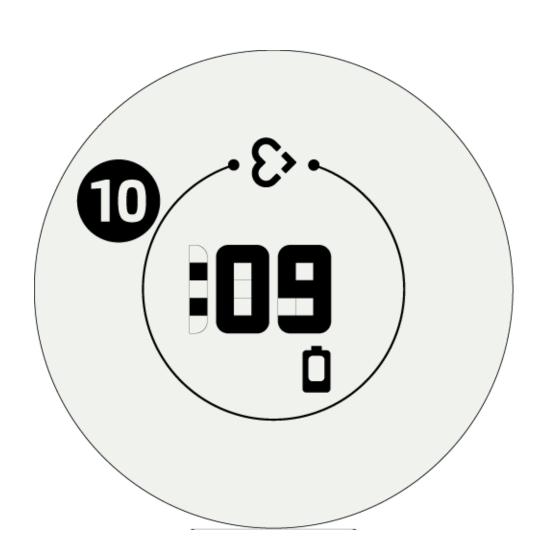


Keep EmbracePlus charged

In order for it to continuously collect your data, you need to wear EmbracePlus as much as possible, especially at night, and keep it charged. You can always check the status of your battery both on EmbracePlus and the Care App (when connected).



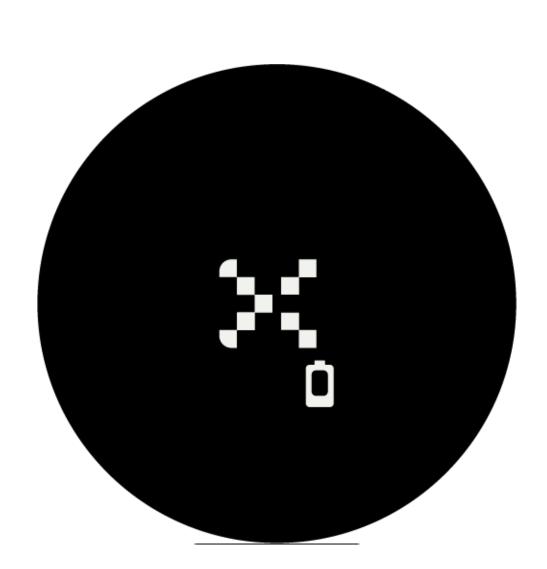
1. To check the available battery percentage, press one of the buttons on EmbracePlus or check inside the Care App by tapping on the status card.



2. When only 10% battery is left on EmbracePlus you will see a warning for a few seconds on the watch display (low) and an empty battery icon will appear under the minutes' indicator. You will receive a notification on your phone. The Care App status card will state "Oops something is wrong".



3. When EmbracePlus is almost out of battery the screen will only display "low" with no other interactions possible. You will receive a notification on your phone reminding you to charge as soon as possible. The Care status bar will state "Oops something is wrong".



4. When completely out of battery, EmbracePlus will turn off. The screen will turn dark to highlight that data recording has stopped a X with an empty battery icon will be displayed. The Care App status bar will state "Care is not working".

Charge EmbracePlus

When you need to charge EmbracePlus follow these simple steps:

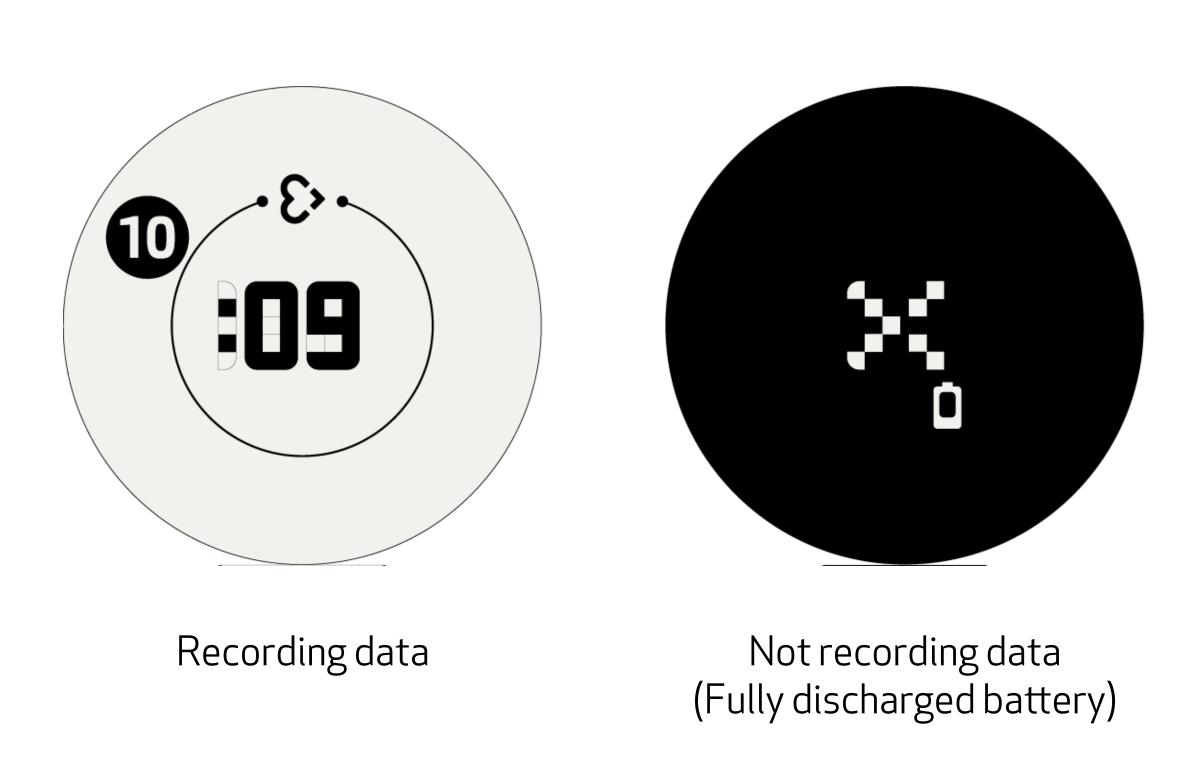


- 1. Use the charger (included in the Empatica EmbracePlus kit) and plug it into a standard 5V USB 2.0 power source.
- 2. Slide EmbracePlus into the charger making sure the display is facing upwards and the buttons towards the open side of the charger.
- 3. The charger and EmbracePlus will automatically attach through magnets. You should feel a slight pull and EmbracePlus should snap into place.
- **4.** Once the charge starts the display will turn dark and show the available battery percentage. The status card on the Care App will display "Care is in standby". A full charge takes about one hour and a half.
- 5. When EmbracePlus is fully charged gently remove it from the charger by holding the charger and slide

out the device. For about 10 seconds EmbracePlus will still have a dark background. Once the display background turns white and the time is shown, EmbracePlus is up and running and ready to be used.

Ensure EmbracePlus is recording data

When EmbracePlus is recording data, the display background is white and all the symbols and numbers are in black.



When EmbracePlus is not recording data, the display background will turn dark. This behaviour is to be expected only in these cases:

- . When EmbracePlus is charging in the Cable charger.
- . For 10-15 seconds after it is removed from the Cable charger.
- . For a few seconds when starting up or rebooting.

In all other cases, when the display background is dark, it is an issue that should be addressed using the Care App.

Tips and tricks

- While wearing the EmbracePlus watch make sure that:
 - 1. Bluetooth® is ON on your phone.
 - 2. Care App is running in the background.
 - 3. You regularly have your smartphone within Bluetooth® range within 10 meters/30 feet range.

Real-time vitals will be visible in the Care App when EmbracePlus is connected to your phone and there is no data left to sync.

- Wear the EmbracePlus watch preferably on your non-dominant wrist continuously, especially at night during your sleep, and only remove the device when charging it.
- Keep your phone connected to the Internet
 (WiFi/Cellular data). If there is no Internet
 connection, data will be uploaded as soon as your
 phone connects to the Internet.

 Regularly charge the EmbracePlus charged to be monitored. We recommend that you charge every 2-3 days to ensure you always have enough battery during your sleep.

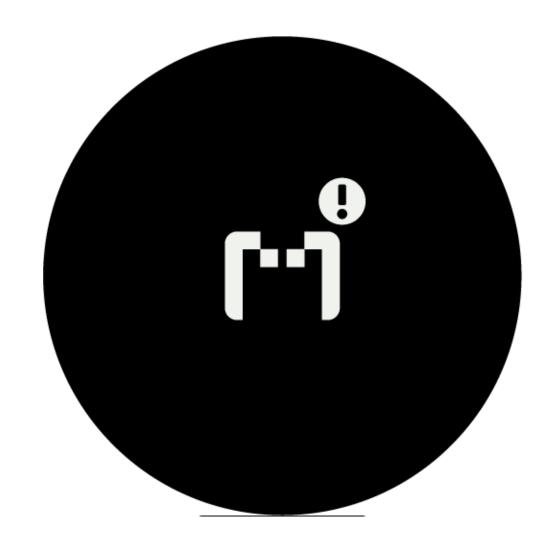
When the EmbracePlus battery is low, the low battery icon will turn on.

EmbracePlus should regularly be within the Bluetooth® range of your phone (10 meters/30 feet). If your EmbracePlus has not been connected for a long time, once it connects again please ensure it stays connected for some time (at least one hour) to allow data to be downloaded.

The sicon on the display will tell you if EmbracePlus is connected to your phone and therefore syncing with the Care App.

Errors and Warnings

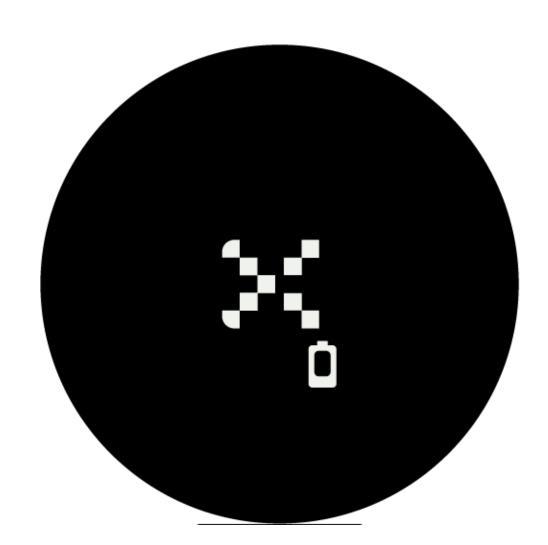
Memory Full



EmbracePlus memory is full of already recorded data and therefore cannot record any new data. Please make sure your phone is paired with the Bluetooth® on and within range. Once the phone connects the Empaheart will appear, EmbracePlus will start to offload its memory to your phone. The display background will turn white and the time will be displayed again.

Please keep the phone within range for at least 1 hour to ensure the whole memory is offloaded.

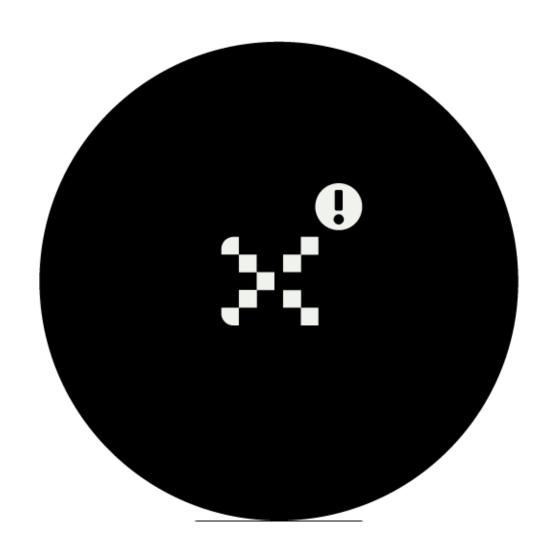
Out of battery



When EmbracePlus is out of battery it cannot record data and therefore the display background will turn dark. Charge it to start recording data again.

Please note that while charging, the display background will stay dark.

Missing timestamp



The display will show this error for both Missing timestamp and Sudden reboot

Please make sure your phone is paired with the Bluetooth® on and within range. Once the phone connects the Empaheart will appear and the display background will turn white.

If this procedure does not work, try to kill and restart the Care App on your phone. Alternatively forget your device and pair it again (see instructions below)

Sudden reboot

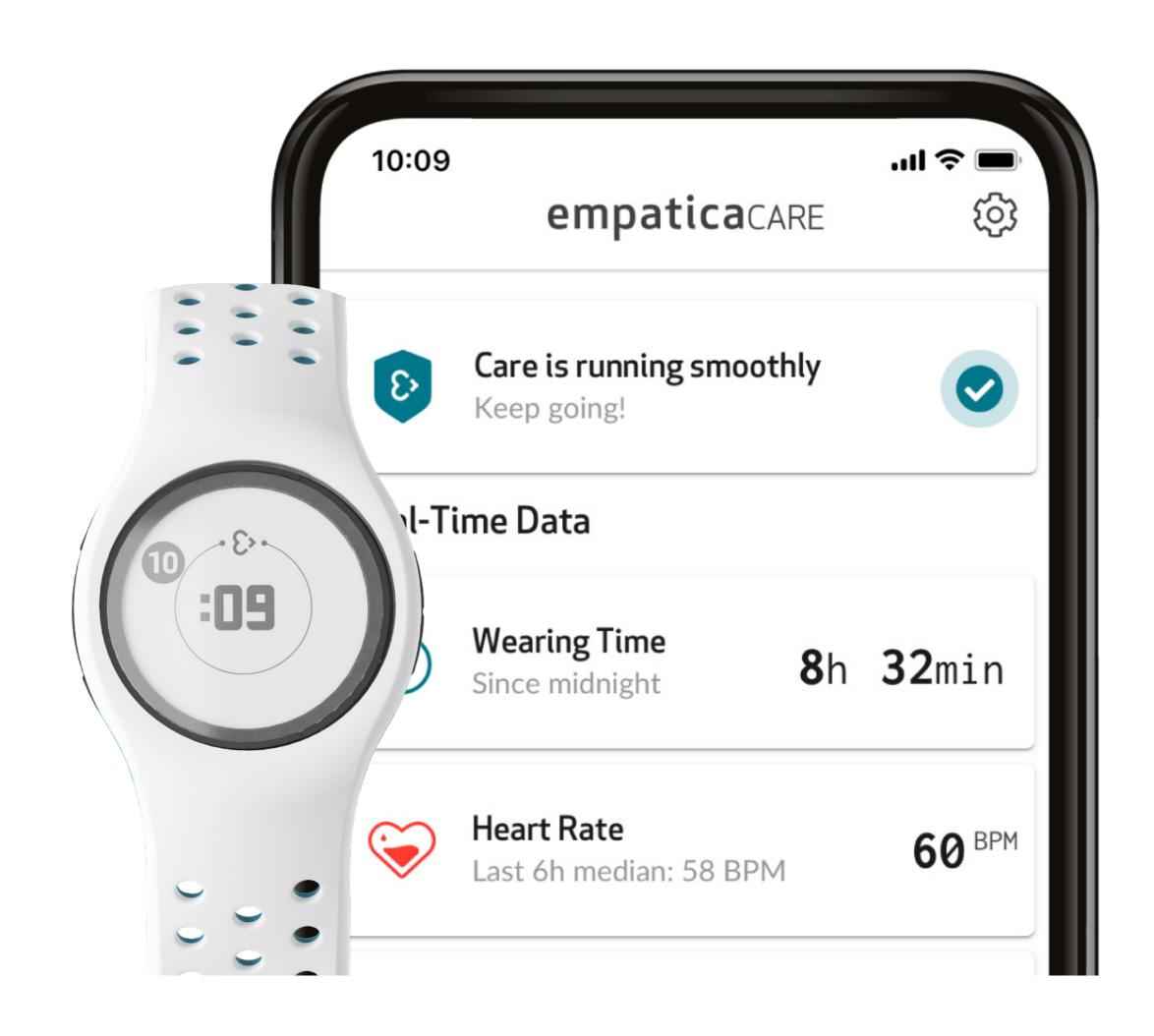
In case EmbracePlus self reboots, you will see a black display with an X for a few seconds. During this very brief interval data recording will stop. To resume recording EmbracePlus needs to be connected to the phone via Bluetooth® in order to retrieve a new timestamp. Once recording resumes the display background will turn white again..



Tips for checking if everything is working

You can always check the app to see if the EmbracePlus is connected and transmitting data.

Ideally, the Care App should display a teal checkmark on the main screen of the app, as shown in the picture.



During normal use, the EmbracePlus background will be white, unless it is charging the \$\mathbb{E}\rightarrow\$ icon will be visible and no battery icon will be displayed.

EmbracePlus



EmbracePlus Overview

EmbracePlus has the following set of elements:

EmbracePlus Case



EmbracePlus Band

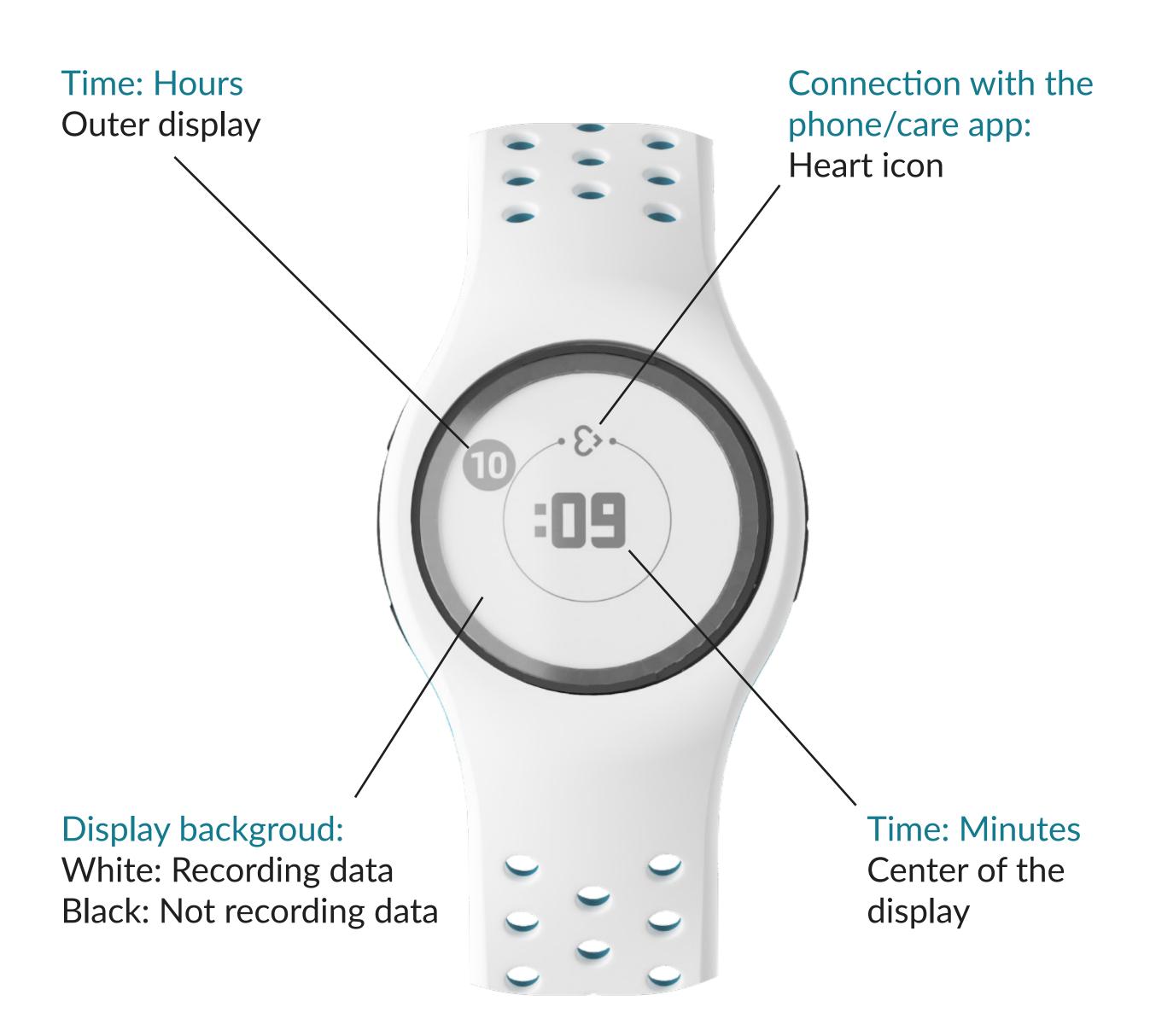


EmbracePlus Cable Charger



Display and interaction Guide

EmbracePlus has a display which uses E ink technology which can always display something even if the device is out of battery.



How to read the time

The standard EmbracePlus watchface is the time. The outer circle of digits (from 1 to 12) displays the hour, while the digits at the centre of the screen display the minutes. There is no distinction between AM and PM. The time indicated by EmbracePlus is based on the paired phone system time.

EmbracePlus 37

Reading time examples



How to check the connectivity

The \(\bigcep \) icon will be ON/OFF if EmbracePlus is connected or disconnected from the phone. Although EmbracePlus can work stand alone for sometime, the more it is connected to the phone the better.



How to check the battery level

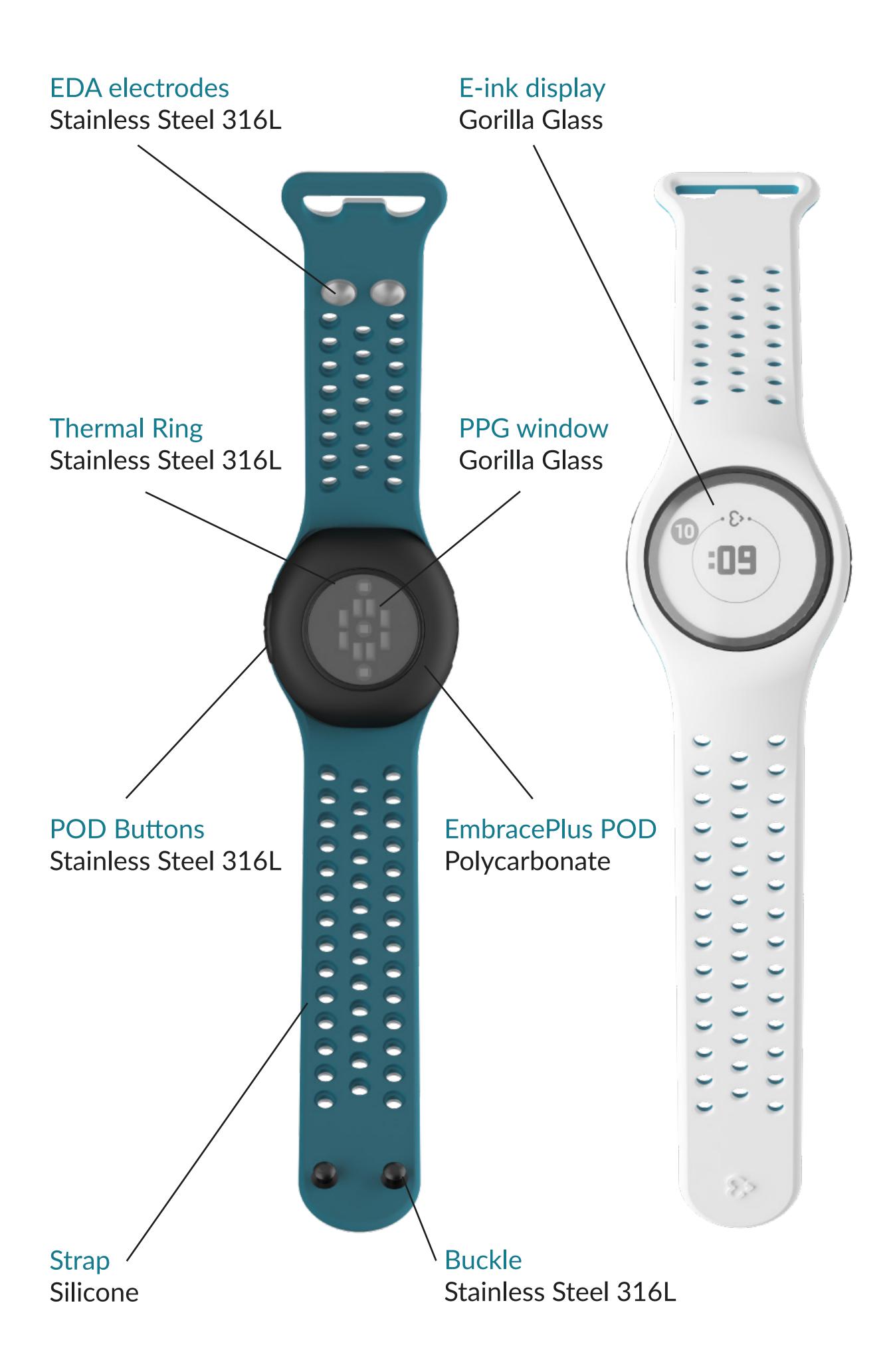
By pressing the buttons on the right side of the screen, the time information will disappear, and the battery charge percentage will be shown. You can go back to the watchface by pressing one of the buttons or waiting for 10 seconds.

Maintaining your device

 It is recommended to regularly clean the device.
 The EmbracePlus can be cleaned with cotton soaked with a small quantity of ethyl or isopropyl alcohol.

 Do not use cleaning agents other than those described above without explicit written instructions from Empatica.

Materials



IMPORTANT!

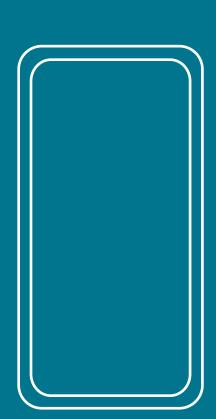
Make sure the EmbracePlus fits snugly but not too tightly. Only wear the EmbracePlus device on intact skin. Do not use the EmbracePlus if it appears to be damaged.

The materials used in the manufacturing of the EmbracePlus device are widely used in wearable devices. Empatica performed biocompatibility tests according to the ISO 10993 standard series and the device successfully passed those tests. However, after a prolonged use above 24h, the user should inspect the skin and determine if a skin irritation was produced by the device, probably due to the mechanical interference between the skin and the device. In this situation, it is suggested to switch the recording location, by placing the EmbracePlus on the other wrist. In case of an allergic reaction persisting beyond 2-3 days, it is suggested to immediately stop using the device and contact the healthcare provider.

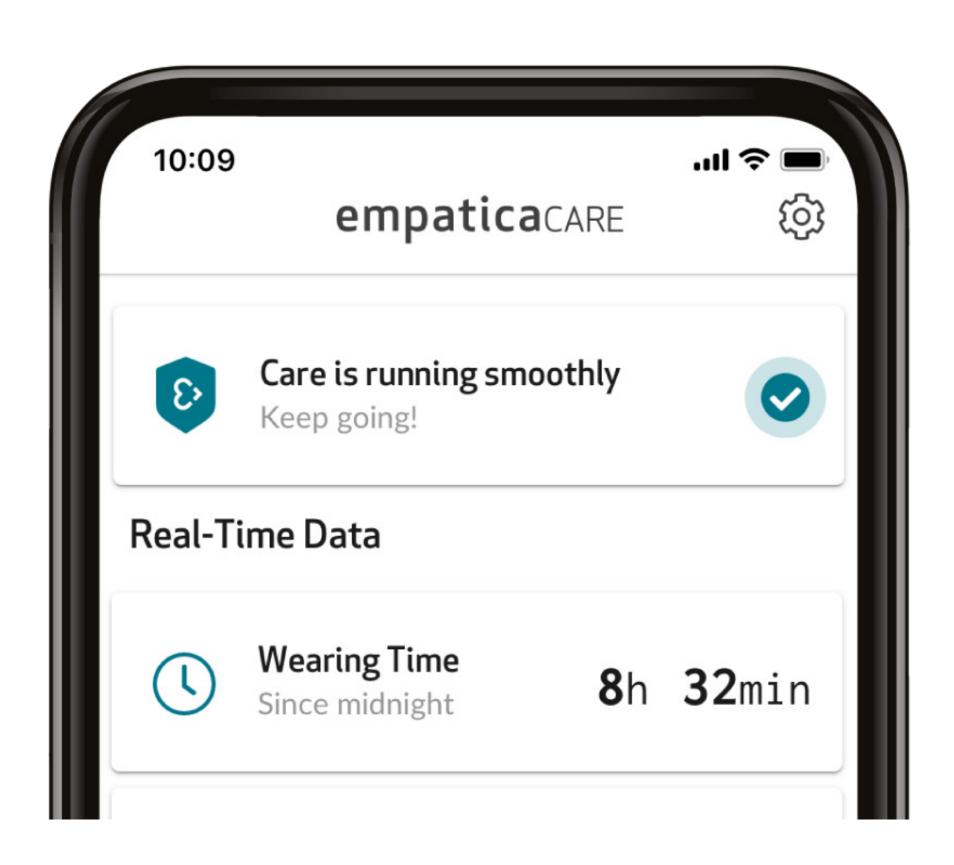
IMPORTANT!

Do NOT use the EmbracePlus with injured skin or other types of skin diseases located in the area where you plan to wear the EmbracePlus. During summer, the mechanical interference between the EmbracePlus band and the skin may cause the skin to become itchy. This is not related to any allergy, but if this happens, we suggest pausing the use of the device for a few hours.

Care App



The **Care App** is what allows you to collect data from your EmbracePlus watch. It also provides you with the necessary information about the state of your EmbracePlus and your vital signs.



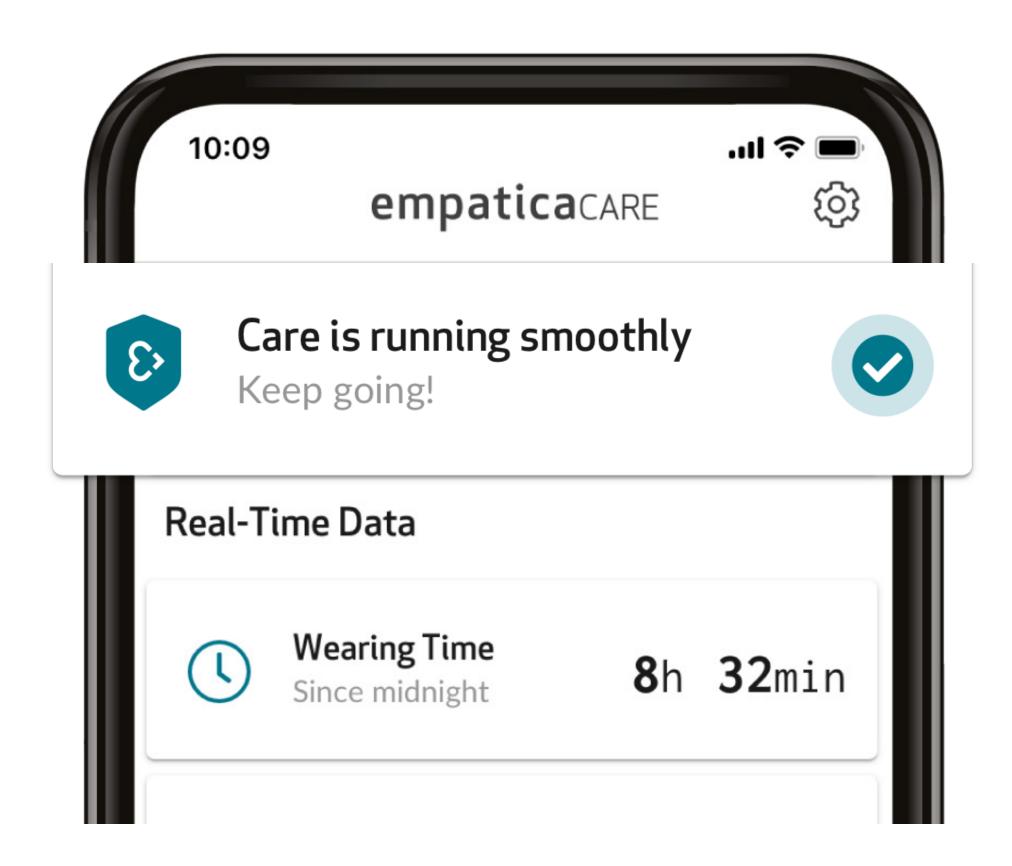
App overview

There are two main sections inside the Care App:

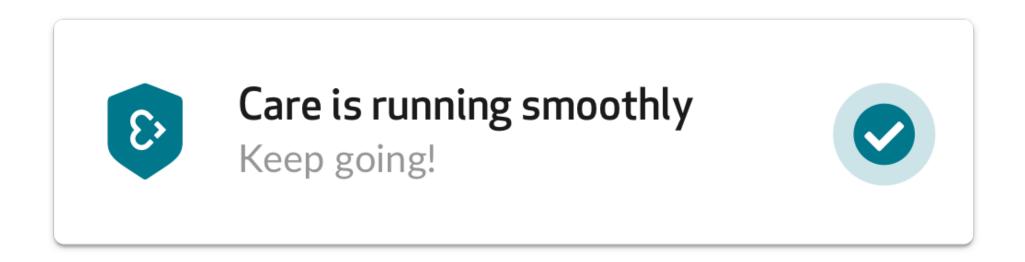
- The Care App status: a card to understand the status of the system composed of the Care App and your EmbracePlus. It will tell you what you should do to always keep the system up and running smoothly.
- Real-time data: three cards where you can find the values of the vital signs calculated using the data gathered from your EmbracePlus. The calculation frequency is 1 minute, meaning that the values

you see are calculated looking at all the samples available in the last 60 seconds.

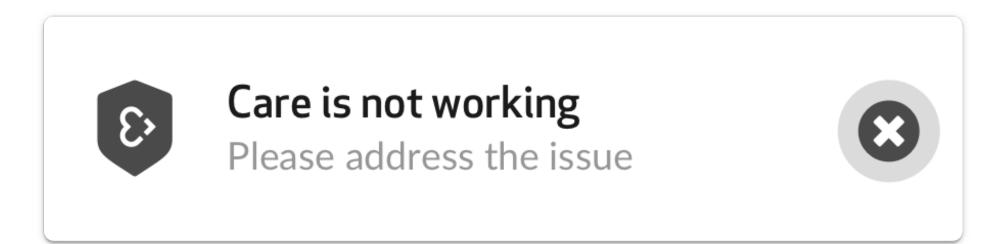
Care App statuses



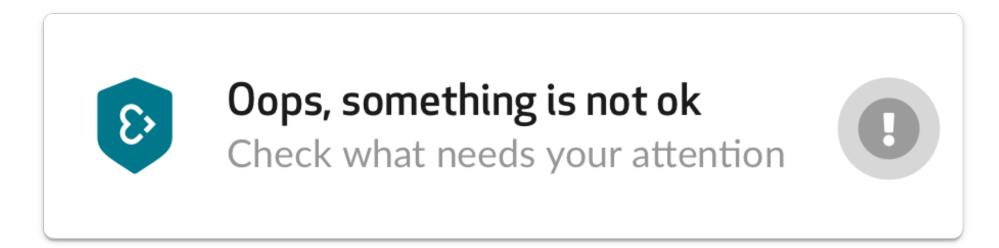
The first card that you see in the Care App displays the App status:



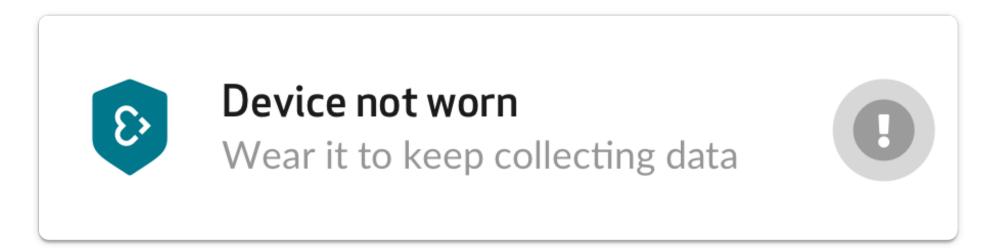
 Care is running smoothly: Care App and EmbracePlus are working fine and you are collecting data.



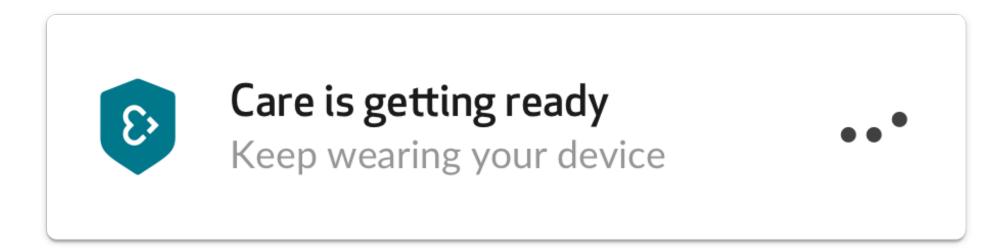
 Care is not working: EmbracePlus is not connected to the phone and therefore data cannot be processed.



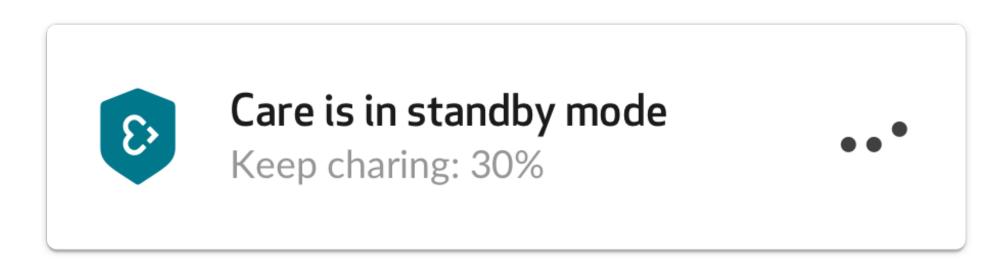
• Oops something is not ok: Something needs your attention as soon as possible. Click to find more details and address the issue.



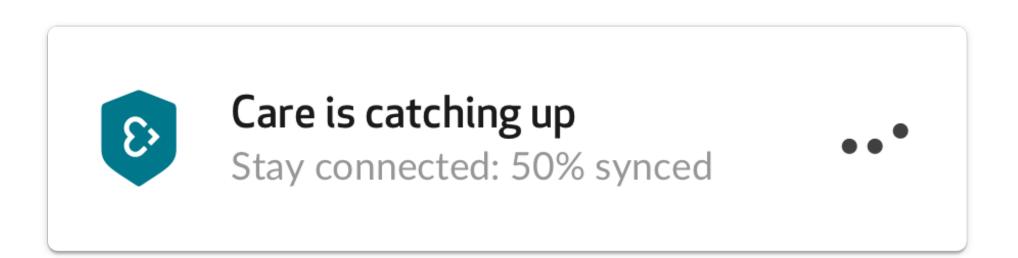
Device not worn: You are not wearing
 EmbracePlus, or it is not positioned properly.
 Please check the "How to wear it section".



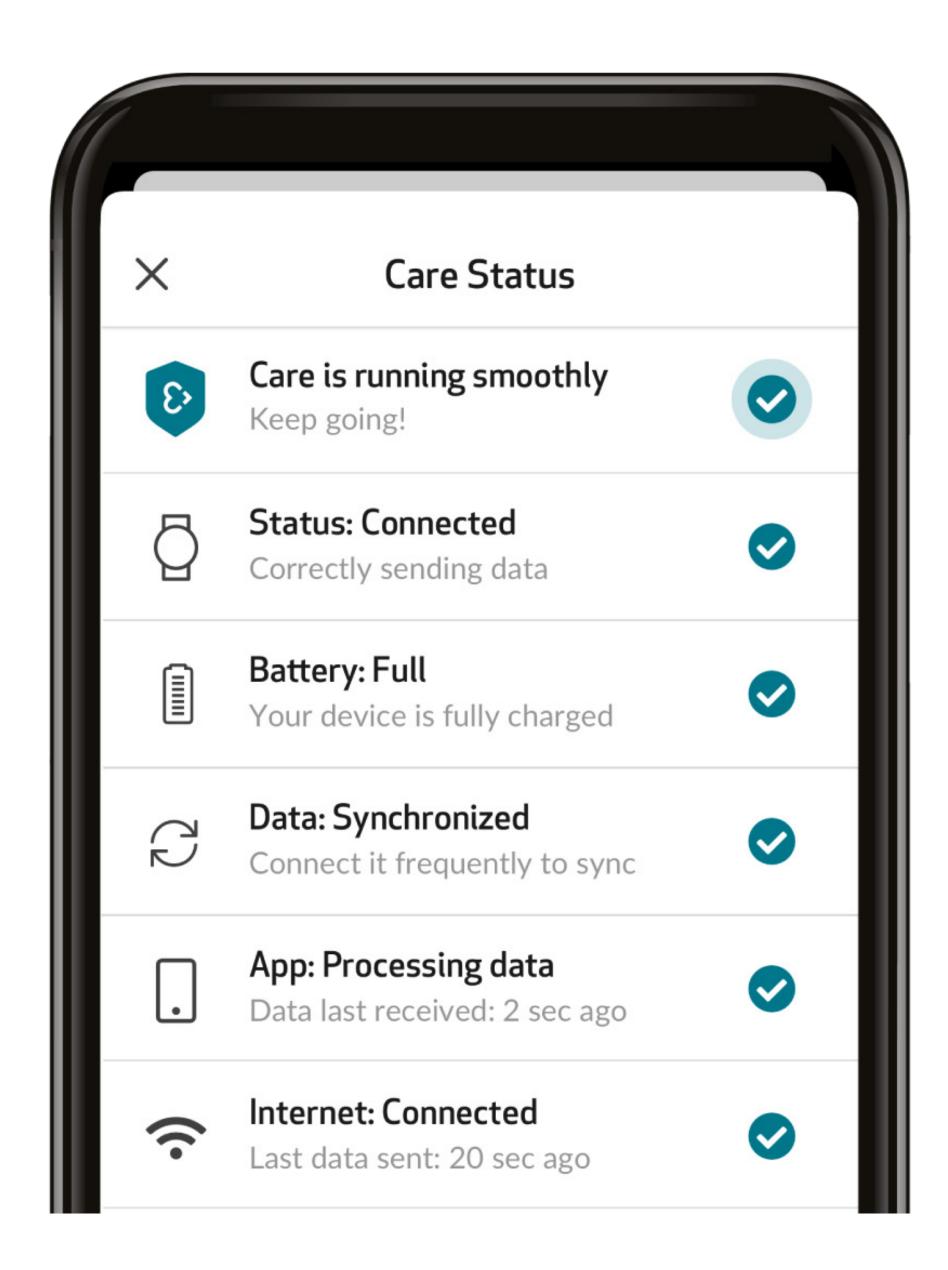
• Care is getting ready: Care and EmbracePlus are calibrating. It will take a few seconds.



Care is in standby mode: EmbracePlus is charging.



• Care is catching up: EmbracePlus is syncing its memory with the phone. Keep your phone connected and close by until it has finished. The realtime biomarkers will not appear while this is happening.



By tapping the Care Status card you get more details of what is happening.

Care Status

- Connected: When Bluetooth® is ON, the Care
 App is running in the background/foreground,
 and the EmbracePlus is within 10 meters/30 feet
 range, the EmbracePlus will remain connected.
- Disconnected: This status will appear if your EmbracePlus watch is turned OFF, or it has disconnected from the app (not within Bluetooth® range, Bluetooth® off). In addition, all the other indicators below that refer to EmbracePlus will turn to "Not Available".

Not worn: This warning will appear if the EmbracePlus watch is worn too loosely, or if you have removed the device from your wrist and the device is still on and within range.

• Not available: EmbracePlus is not connected and/or out of battery therefore no information is available.

Battery

- X%: Your EmbracePlus has about X% of battery left. The battery status will be displayed in the Care App. Please note that battery life cannot be visualized if the EmbracePlus watch is disconnected/OFF.
- X% Charged: Your EmbracePlus is charging and so far it has charged X% of its battery.
- Fully Charged: Your EmbracePus is charging and it is now fully charged. Time to put it on.
- Not available: EmbracePlus is not connected and/or out of battery therefore no information is available.

App

• Processing data: The Care App transmits data to Care Portal via Internet connection. If Internet connection is not available, data will be temporarily stored on the app. The stored data will be uploaded automatically once the Internet connection is available again.

• Bluetooth® off: Please turn on the Bluetooth® on your phone and connect to EmbracePlus.

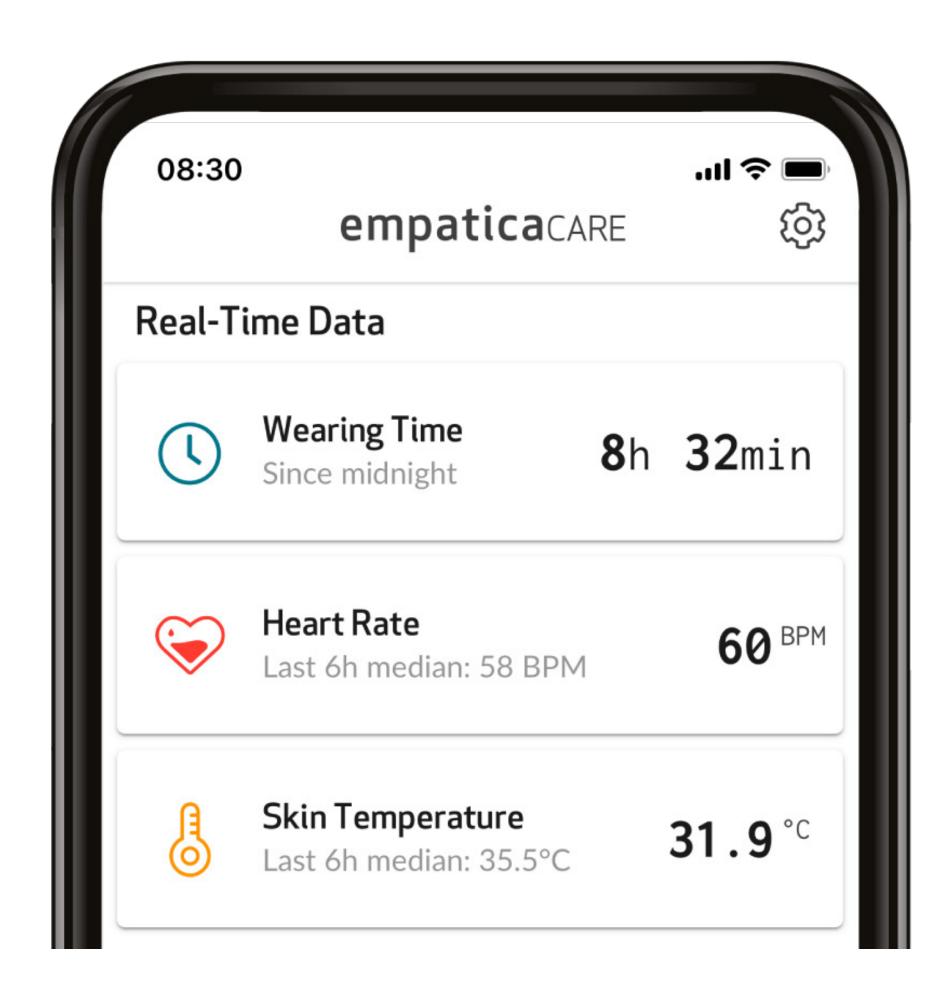
Internet

- Connected: Your phone is connected to the internet and uploading data.
- No connection: Your phone is not connected to the Internet. Connect to a WiFi or Cellular data to re-establish a connection and continue the data upload.

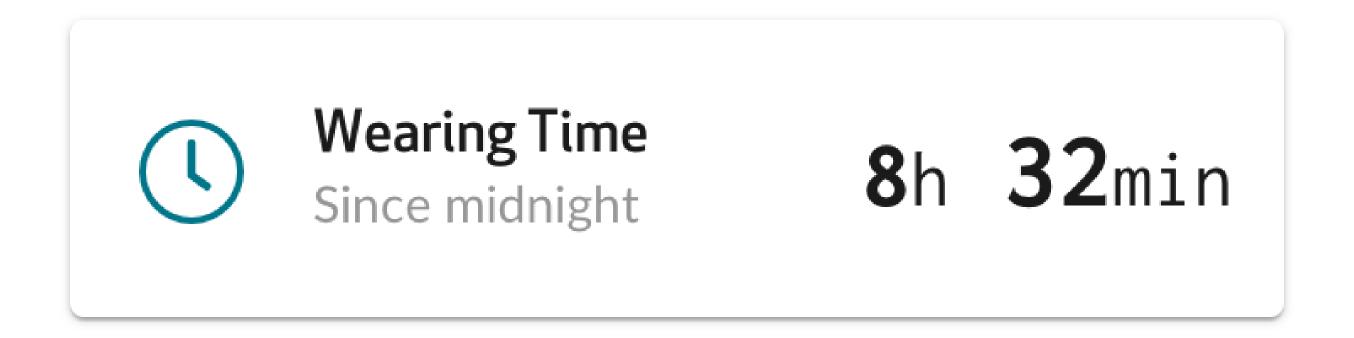
Data

- X% synchronized: Your EmbracePlus is syncing the data stored in its memory and it has already synced X%.
- Synchronized: Your EmbracePlus data is in synch with your phone.

Real-time data



The Real-time data are the Biomarkers gathered from your EmbracePlus device and they are visualized in the Care App as:



Wearing time since midnight

It displays the amount of time you have correctly worn your device since midnight. Your provider can advise on the optimal wearing time. If you think the values are not correct, please make sure you are weaning your device correctly.



Heart Rate

Last 6h median: 58 BPM

60 BPM

Heart Rate data (including median Heart Rate for the last 6 hours).

It displays an estimation of your heart rate over the last minute. To get a good reading, the back of the device should always be in contact with your skin. Please note that many factors can affect the heart rate measurements from the wrist, like level and type of activity, emotional and cognitive stimuli and environmental factors.

Please note that the value provided in the app is the minute average of your Heart Rate.



Skin Temperature

Last 6h median: 35.5°C

31.9°C

Skin temperature (including median skin temperature for the last 6 hours).

The value provided in the app is the minute average of your skin temperature and represents the peripheral temperature measured on the wrist, not core body temperature, hence slightly different than usual temperature values. Temperature data is displayed in Celsius or Fahrenheit depending on the phone language settings.



Heart Rate

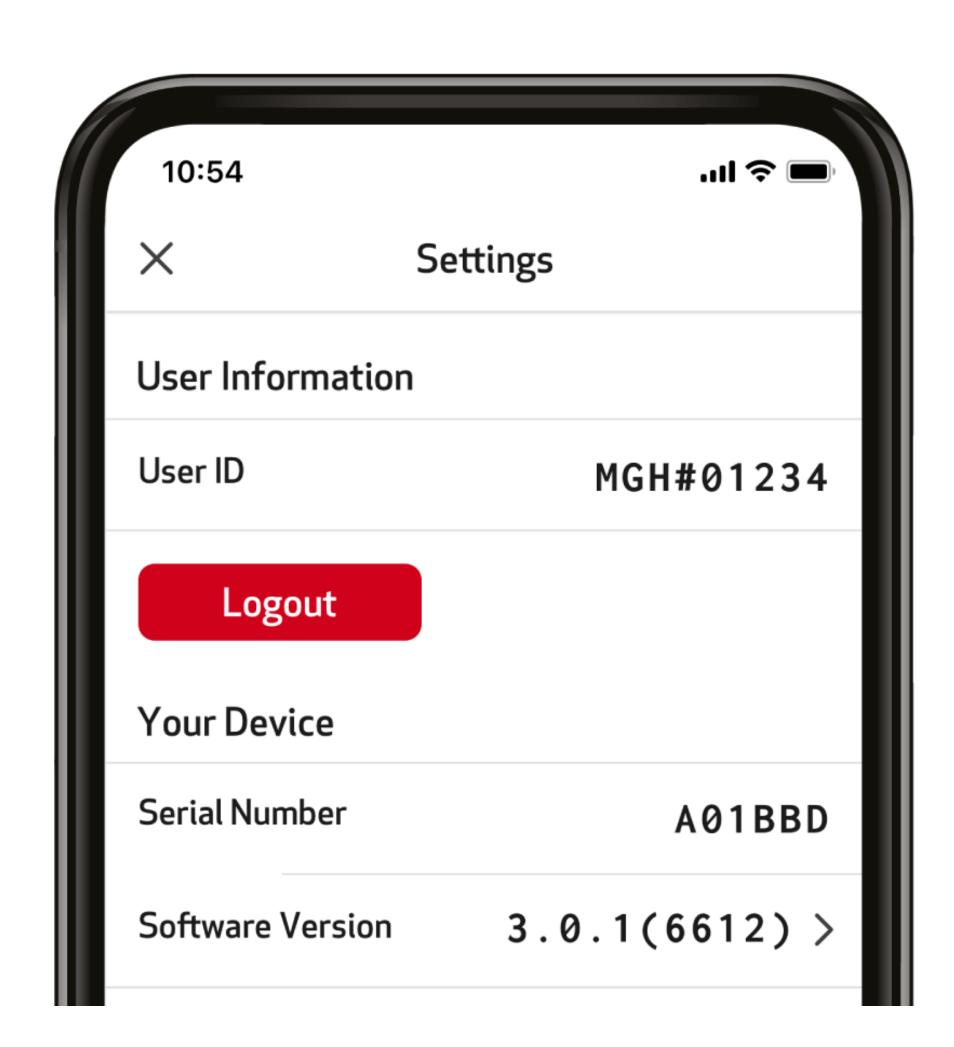
Last 6h median: 58 BPM

In case EmbracePlus is not worn correctly the vital signs icons will become gray. You can check the EmbracePlus status on what you should do to make them active again.

When the Care status is **Care is catching up**, biomarkers will be grayed out and not available until the EmbracePlus memory will be fully synced.

Setting screen

In order to access the **Settings screen** of the Care App, you should **tap on the gear icon at the top right of the main screen.** Here you'll be able to visualize additional information about your device..



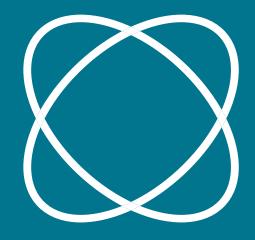
- 1. The Settings screen displays the following information:
- User ID: The Unique Identifier that was assigned to you. This number, as well as the EmbracePlus serial number, can come in handy in case you need to report any issues to your Provider.
- Serial number (also available on the bottom of the device).

- Software version The version of the software running on the device.
- Copyright and App version: The version of the Empatica Care App you are currently using.

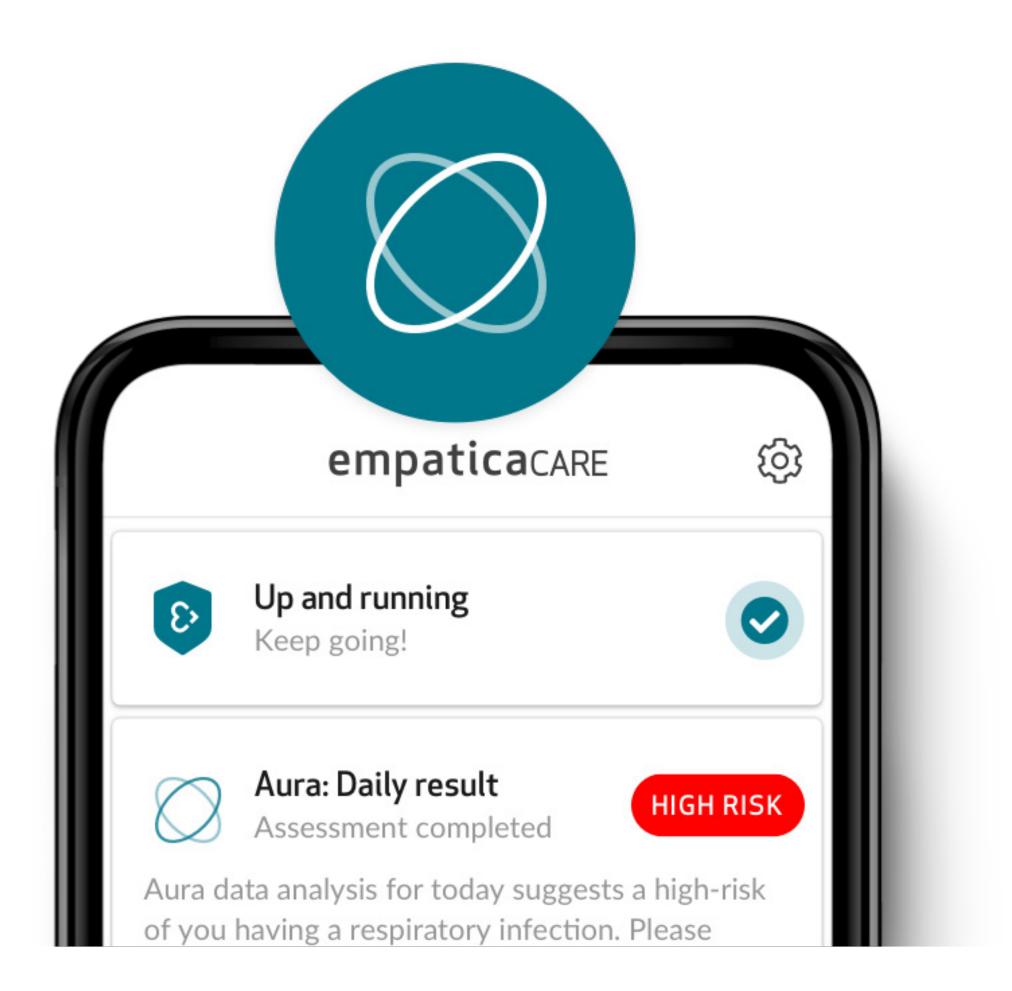
2. Other tools (for troubleshooting purposes only):

- Forget Device: Allows you to disassociate your paired device from your smartphone. If you forget the device from your smartphone, it will disconnect resulting in data loss. In order to reconnect the device, you will need to pair/connect the wristband from scratch (see instructions in section 2).
- Logout: Allows you to sign out of the Care App.
 Please note that if you sign out, your device will stop collecting data, resulting in data loss.
 To reconnect, log back in using the credentials provided by your Provider.

Aura



What is Aura?

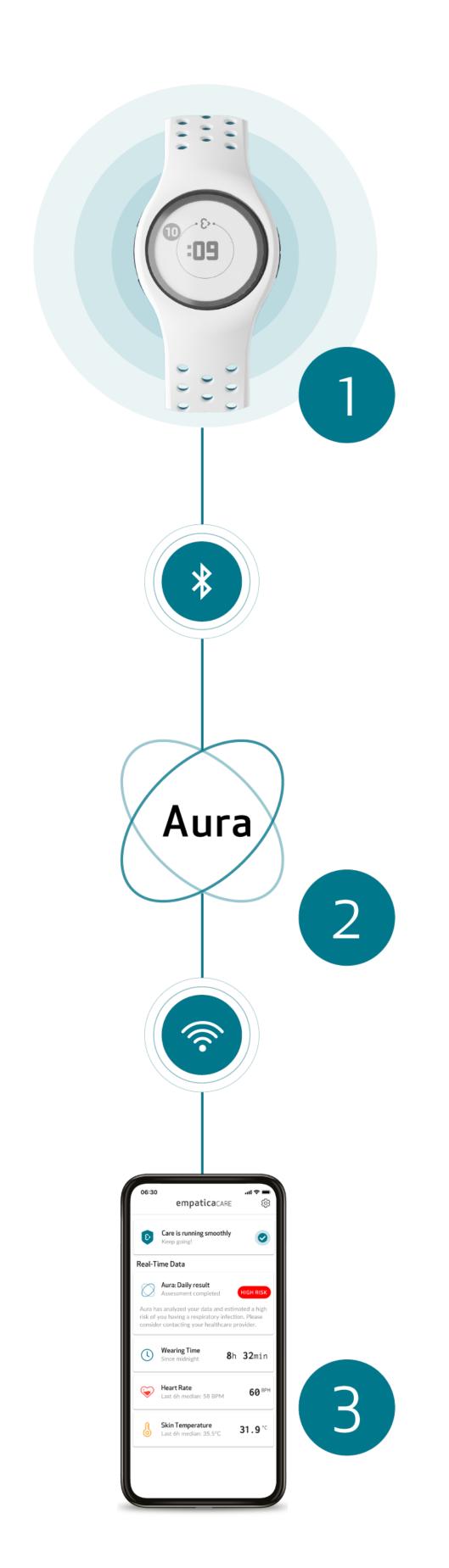


An Al-enabled respiratory infection detection system for your peace of mind.

Aura runs a smart algorithm that continuously analyzes your data to spot changes that may be associated with a respiratory infection. It does this by looking at a range of physiological signals like Heart Rate, Peripheral Temperature, Movement, and Electrodermal activity.

How it works

The **Aura algorithm** can be integrated within the Empatica Care platform where it can alert and display a calculated output both to the user and their caregiver when a high risk of infection is detected.



Wearables (1), User wears the EmbracePlus.

Aura algorithm (2), Aura runs a continuous risk assessment on the data collected.

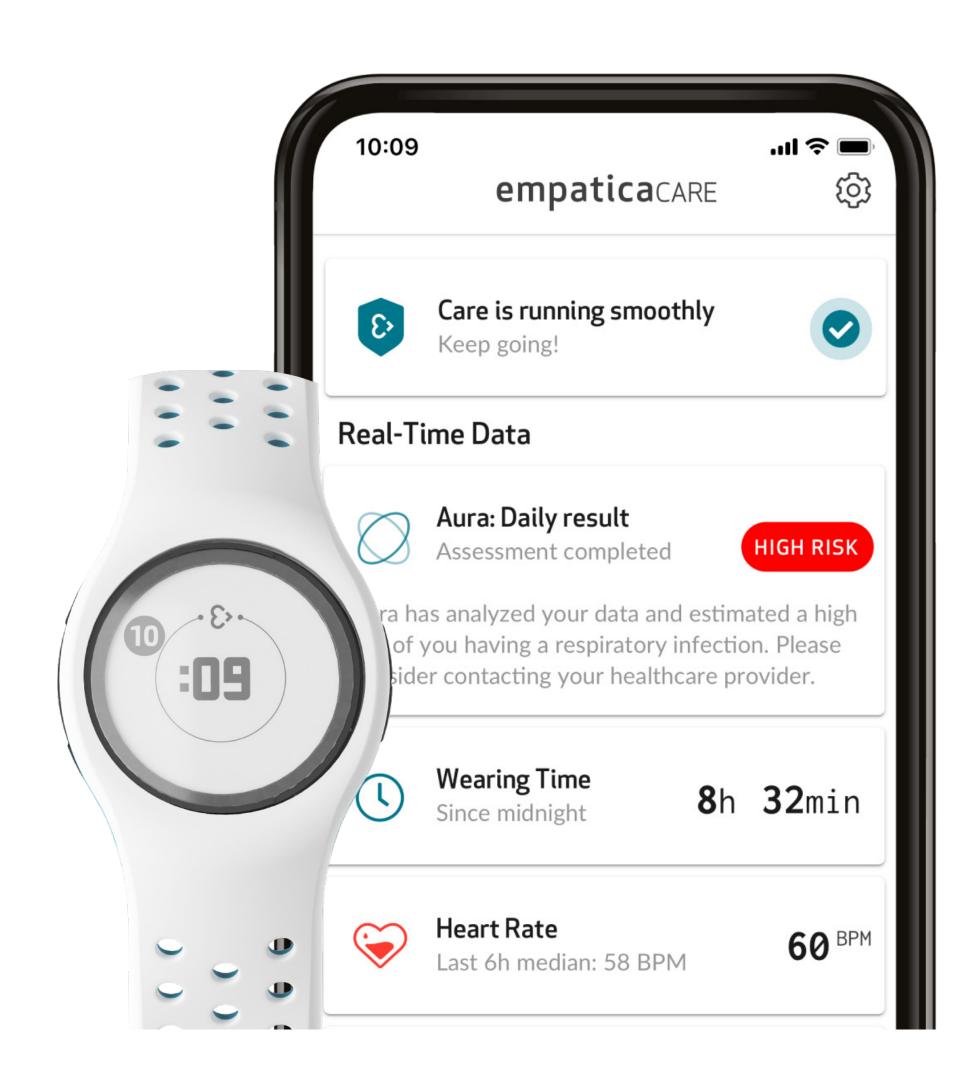
App (3), "High risk"

Users are alerted via a

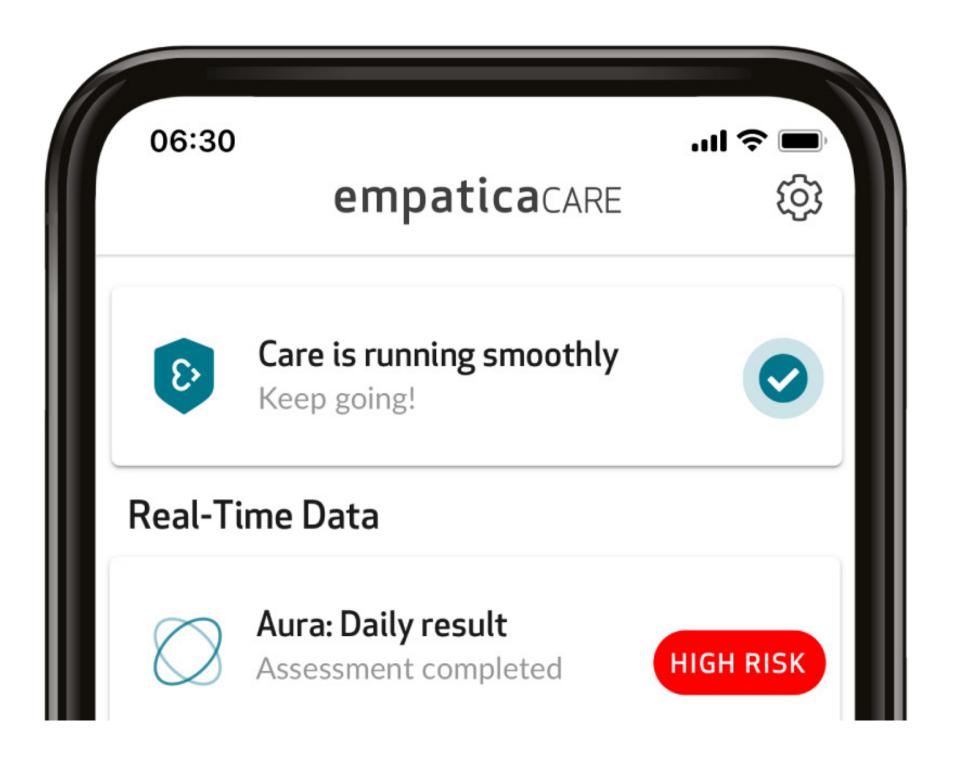
notification on their phone
so they can self-isolate and
contact their healthcare
provider.

Daily usage

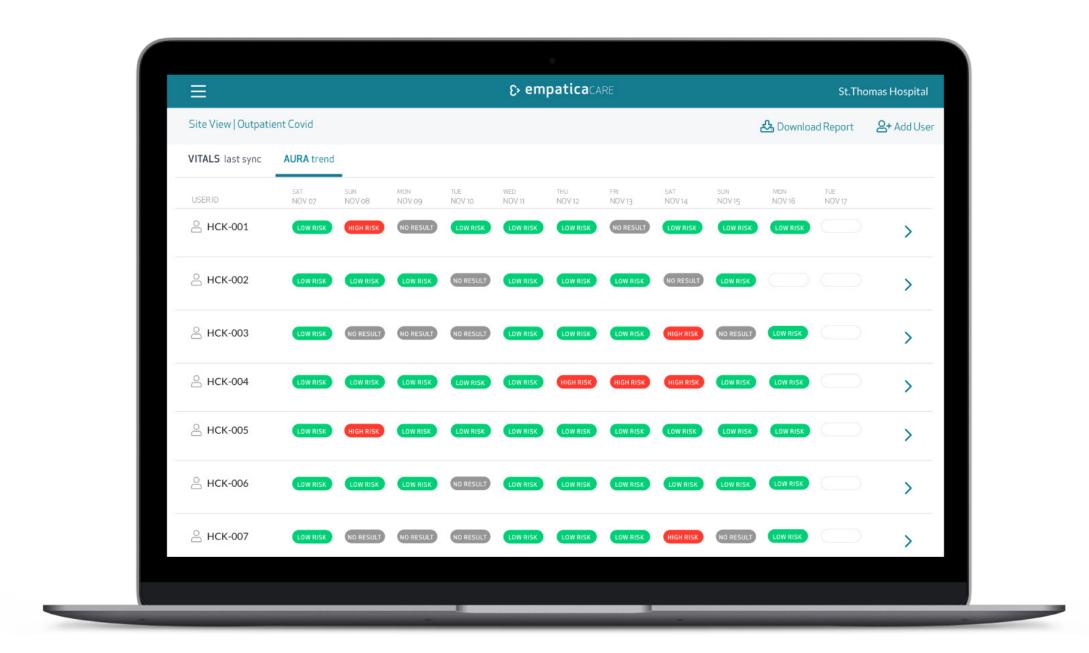
Once you have paired the Device with Care App,
Aura will start working automatically. In order for it to
work, the Aura algorithm needs to collect a few days
of data to understand your physiological baselines.



1. Wear your device while keeping your everyday routine. EmbracePlus collects the users' physiological data and vitals, and transmits the information to the Care Portal via the Care App.

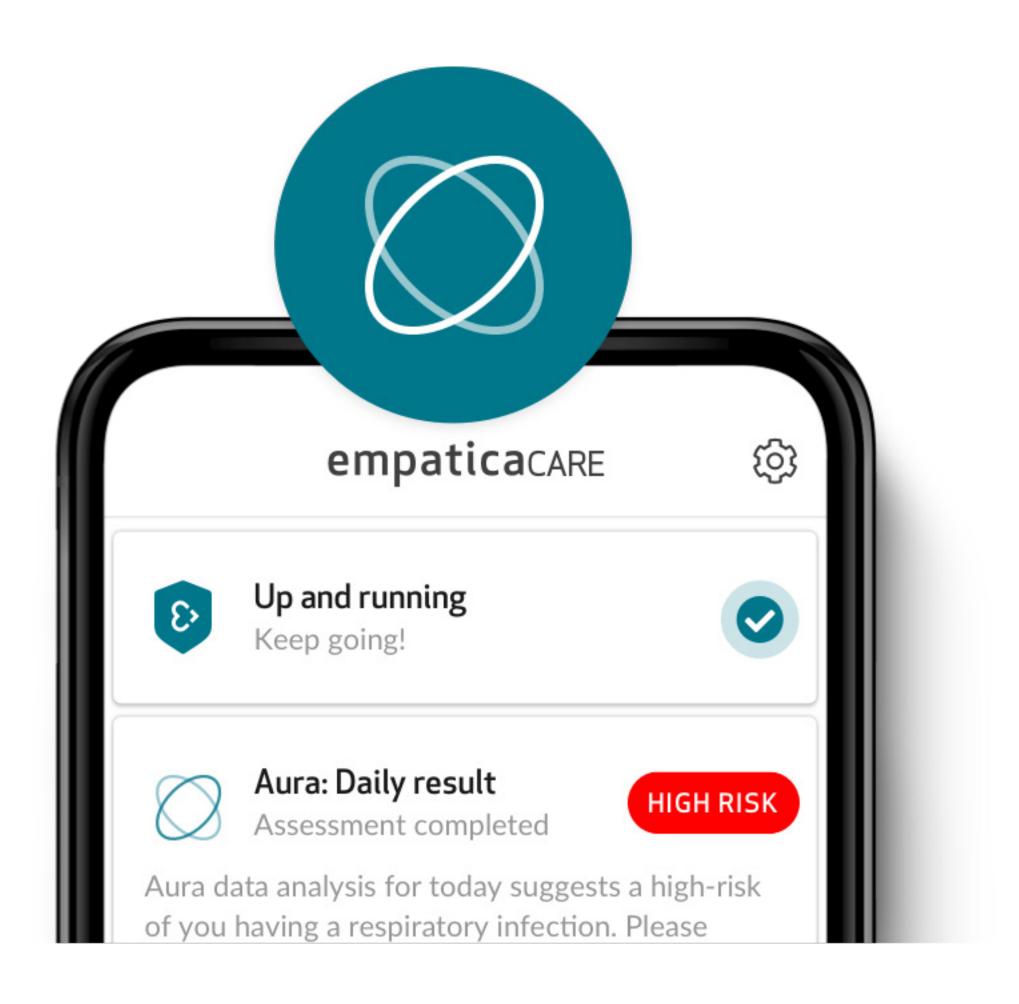


2. The Aura algorithm computes and reports a daily risk assessment inside the Care App. With the correct amount of data within the system, Aura can interpret and assess the user's health and risk of infection, allowing for early intervention or self-isolation.



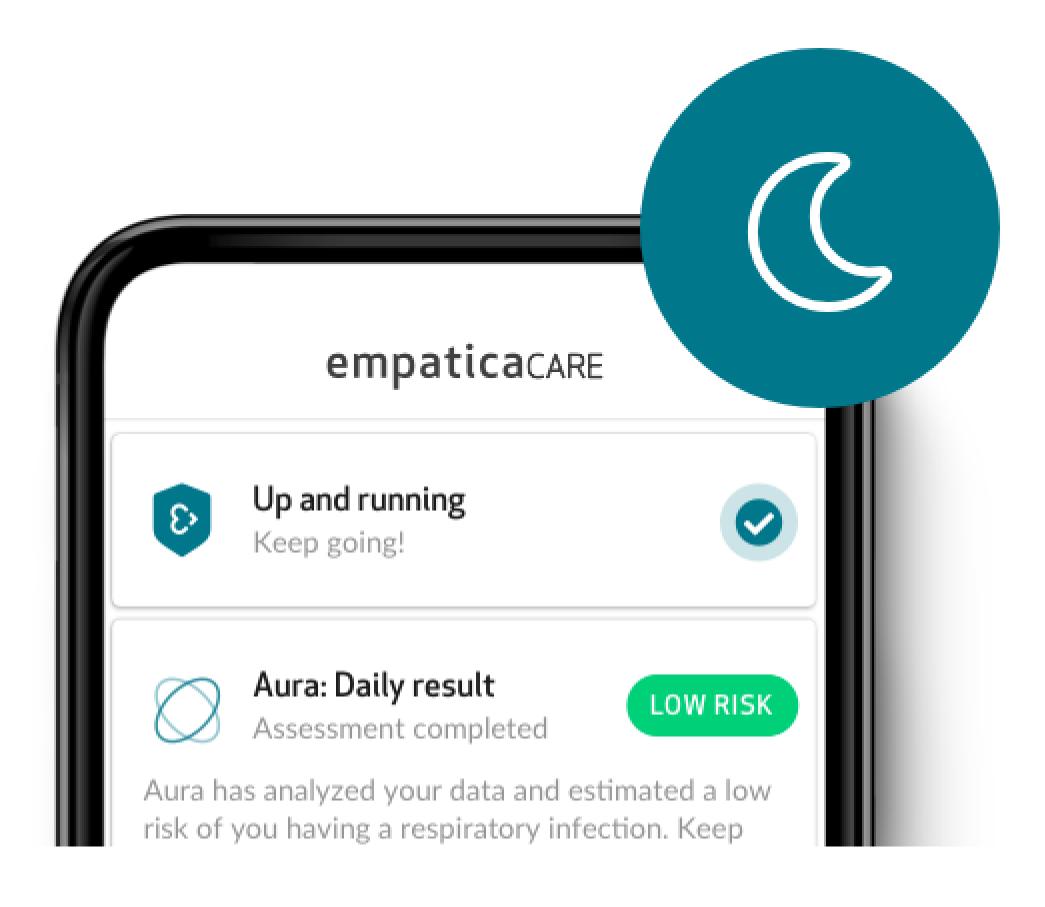
3. The Portal will then display the risk score and your relevant health stats. Aura can also be used in a clinical setting, tracking multiple recovering patients remotely, or to safeguard schools and workplaces always preserving the privacy of wearers.

Tip to make it work properly



Use it everyday

Aura continuously collects data and compares the changes in your physiology across time. After it analyzes at least three consecutive days of data, it displays a daily risk assessment indicating the presence of a respiratory infection.



The importance of data at rest

Sleep quality is an important indicator of how our body is doing and, if it's the case, how it is responding to an ongoing infection. Aura mostly relies on your data while resting or sleeping to identify a respiratory infection, so remember to keep wearing your device when going to bed. To have the best experience, wear it all day long.

FAQS



How can I quickly check if the EmbracePlus is ON and transmitting data?

To verify that EmbracePlus is on, the screen should be displaying the time and change every minute. If the empaheart is displayed, the watch is connected to the phone. Additionally you can check the back of the device (the part that is in contact with your wrist). When the device is on, the light sources under the device are always activated. If the lights are off, then the EmbracePlus is likely to be off as well.

You can also check inside the Care App to see if EmbracePlus is connected and data is being transmitted properly.

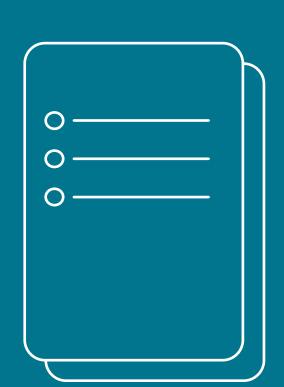
How can I turn the EmbracePlus on/off?

Once you unbox EmbracePlus and wake it up, it will always be ON if charged. In case it runs out of battery (you will see a X with the battery icon), please place it back in the charger and it will automatically switch ON.

How can I receive more assistance?

Please contact your Provider. Do not contact Empatica directly.

Regulatory and compliance



EmbracePlus product labeling

The information directly printed on the device itself is presented in Figures 1 and 2.

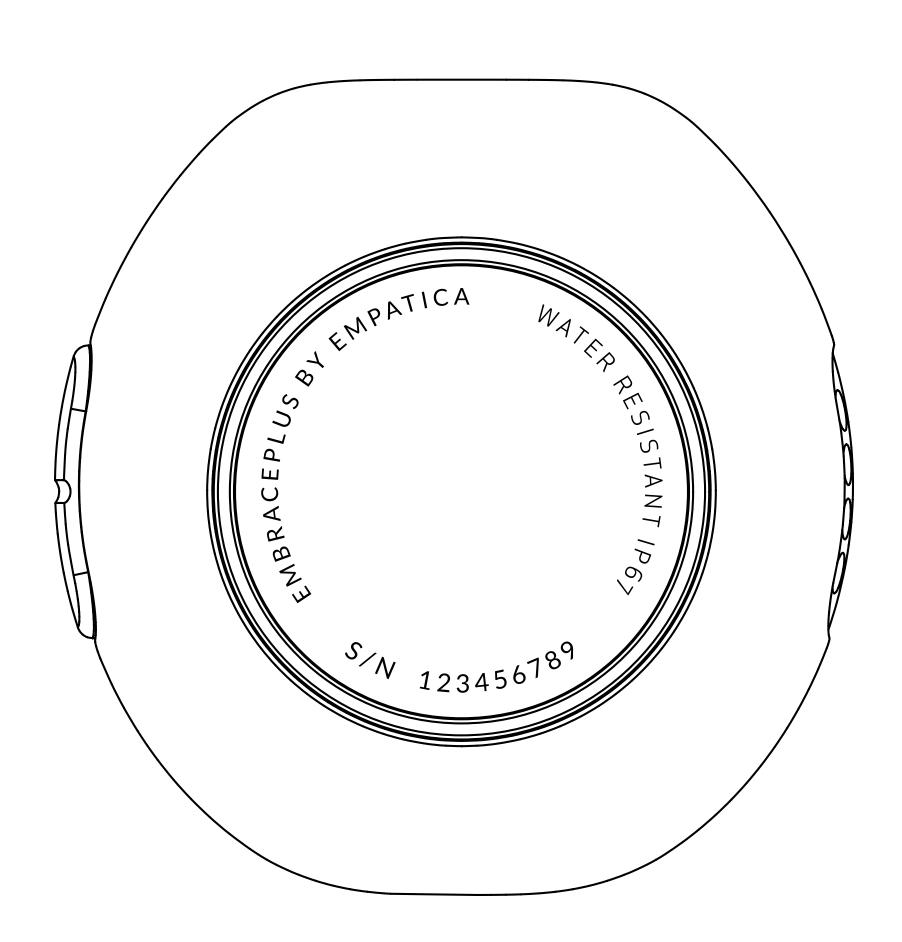


Figure 1 - Back view of EmbracePlus

On the back of the device the following information is displayed:

- Product Name and Manufacturer name:
 EmbracePlus by EMPATICA
- Device Serial Number: S/N 123456789
- IP Classification: Water Resistant (IP67)

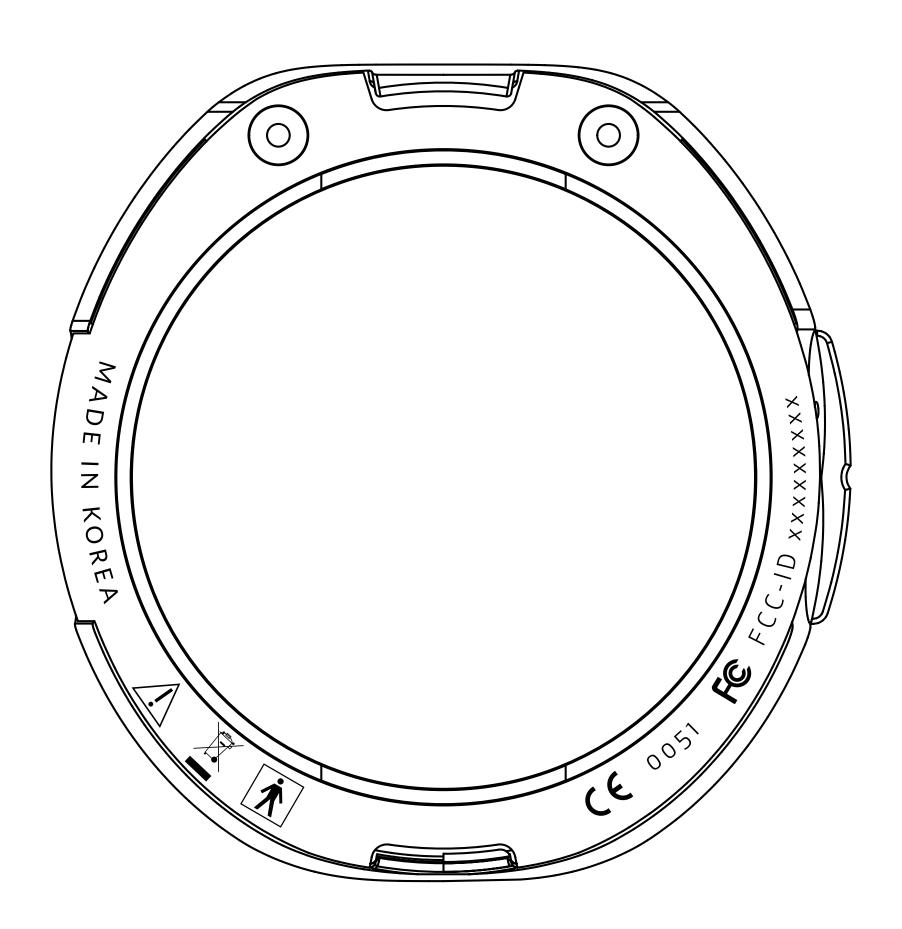


Figure 2 - Drawing representing the front view of EmbracePlus with band detached

On the front of the device the following information is displayed, note that the information is visible after detaching the band:

- Place of manufacturing: Made in Korea
- FCC symbol and FCC ID: FCC-ID xxxxxxxxxx
- CE Mark and identification of Notified Body: CE 0051
- Applied Parts type BF symbol
- Precaution Symbol
- WEEE Symbol

EmbracePlus laboratory testing

EmbracePlus has been subject to specific laboratory testing to assess its safety, electromagnetic compatibility, usability and biocompatibility. Tests have been performed according to the following standards:

- EN 60601-1:2006/A1:2013 (IEC 60601-1:2005/A1:2012): Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- EN 60601-1-2:2015 (IEC 60601-1-2:2014): Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- IEC 60601-1-6:2010 + Amd1:2013: Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance Collateral standard: Usability
- IEC 60601-1-11:2015 Medical electrical equipment Part 1-11: General requirements for basic safety and essential performance Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 62366-1:2015 Medical devices Part 1: Application of usability engineering to medical devices

- ISO 10993-1:2018 Biological Evaluation of Medical Devices Part 1: Evaluation and Testing within a risk management process
- EN ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10: 2010 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- FCC 47 CFR Part 15 Radio Frequency Devices
- IEC 62133-2: 2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes Safety requirements for portable sealed secondary lithium cells, and for batteries made from them, for use in portable applications Part 2: Lithium systems

Symbols used in labeling

Symbol	Description
C E 0051	Indicates compliance with the European Medical Device Directive 93/42/EEC. 0051 is the identification number of the Notified Body responsible for the CE Certification Process.
FC	Indicates that the electromagnetic interference from the EmbracePlus in under the limits that are approved by the Federal Communications Commission.
	EmbracePlus is an electrical and electronic equipment and needs separate collection for disposal in accordance with Waste Electrical and Electronic Equipment Directive
	EmbracePlus has two metal contact points that are used by the EDA sensor. This is type BF part which means that it may generate a leakage current when in contact with the skin. ISO 60601-1 safety test demonstrated that this part is safe.
	Indicates that EmbracePlus intentionally generates RF signals for data transmission to a connected device.
(W) (P) 67	Indicates that EmbracePlus is classified as IP67 - resistant to submersion in 1 m (about 3.3 feet) of water for up to 30 minutes.

Symbols used in labeling

Symbol	Description
	Indicates Empatica S.r.I as the legal manufacturer of EmbracePlus and Empatica Care.
	The EmbracePlus watch uses
*	Bluetooth® Low Energy to transfer data.
SN	Indicates the device Serial Number.
LOT	Indicates the need for the user to consult the Empatica Care instruction for use for important information, warning and cautions.
	Indicates the manufacturing date of the device.
	Keep in dry conditions and away from rain.
i	Indicates the web address at which the device instruction for use can be found.
	Indicates the need for the user to consult the EmbracePlus instruction for use for important information, warning and cautions.
	Indicates the minimum and maximum humidity at which the EmbracePlus shall be stored.
	Indicates the minimum and maximum temperature at which the EmbracePlus shall be stored.

Symbol	Description
	Indicates the minimum and maximum pressure at which the EmbracePlus shall be stored.
LOT	Indicates the device Lot Number

Intended use and limitations

EmbracePlus watch Intended Use

EmbracePlus is intended to collect, process with embedded AI/ML algorithms, store, transfer and remote monitoring of the following physiological parameters: Heart Rate, Heart Rate Variability, Respiration Rate, Temperature, Electrodermal Activity (EDA) and Rest Detection.

EmbracePlus is intended for temperature monitoring where monitoring temperature at the wrist is clinically indicated.

Empatica Care Intended Use

Empatica Care is intended for remote physiological parameters monitoring and early detection of physiological parameters patterns that could indicate the user being at risk of developing respiratory-related infectious diseases.

Empatica Care App Intended Use

Care App is intended to collect physiological parameters from a compatible wearable medical device, present these parameters to the user, and transmit the collected data to the Care Portal.

Empatica Care Portal Intended Use

The Care Portal is intended to:

- enables remote monitoring of physiological parameters for ambulatory patients;
- provide healthcare providers or caregivers with patient-specific information that could be used to support diagnostic or therapeutic desicion-making in non-emergency situations, and
- detect, via the Aura algorithm the insurgence of possible respiratory infection.

Indication for use statement

EmbracePlus Indication for Use statement

EmbracePlus is intended for continuous patient monitoring of patients (age 2 and up) in professional healthcare facilities, such as hospitals or skilled nursing facilities, or in their own home. EmbracePlus collected data are intended to be used for patient monitoring by trained healthcare professionals only. EmbracePlus is intended for continuous monitoring of the following physiological parameters in ambulatory patients who are 2 years of age or older:

- . Heart Rate;
- . Heart Rate Variability;
- . Respiratory Rate;
- . Temperature;
- . Electrodermal Activity (EDA); and
- . Rest Detection.

EmbracePlus is intended for temperature monitoring where monitoring temperature at the wrist is clinically indicated.

Empatica Care Indication for use statement

Care App is a mobile software application intended for lay-person use. It is designed to continuously collect and transmit to the Care Portal the physiological parameters captured by compatible wearable medical devices. The Care App is used to visualize a subset of the collected physiological parameters (Heart Rate and Skin Temperature). The Care App also presents system-related messages to the user, such as the battery charge and connection status of the connected wearable device, status of the internet connection and total wear time.

The Care Portal is a web-based software application intended to be used by healthcare providers and caregivers. It is designed to continuously receive, collect, display and securely store the physiological parameters transmitted from the Care App. The Care Portal allows the healthcare providers and caregiver to visualize raw data and trend data of the physiological parameters in real time.

Intended Population and Use Environment

EmbracePlus is intended to be used by the general population (age 2 and up) that want/need to monitor their physiological parameters at home or in healthcare environments. Physiological Parameters might be reviewed by Caregivers or Healthcare providers.

Care App is intended to be used by subjects (users) at risk of developing respiratory-related infectious diseases or by subjects (users) for which remote monitoring is deemed necessary by their Caregivers.

Care Portal is intended to be used by caregivers for the remote monitoring of users' physiological parameters. Caregivers can be healthcare professionals, occupational doctors or nurses.

Patient Population and Medical Condition

User population

Age: age 14 and up.

Weight: not relevant, but there might be limitation of wrist circumference.

Health status: healthy individuals, absence of baseline abnormalities in the physiological characteristics used as inputs to the Aura algorithm.

Nationality: not relevant

Patient status: the patient is often the same as the operator and is should be willing and capable of managing its use

Caregiver population - EmbracePlus

Healthcare professionals

Occupational doctors

Nurses

Essential Performance Statement and Safety Information

EmbracePlus Essential Performance

EmbracePlus shall be able to continuously collect, via specific sensors, user's physiological parameters and transfer them to the paired smartphone without being corrupted or lost. The maximum allowed quantity of data not being collected or loss during the normal use of the device is 5% of the duration of an acquisition session. An acquisition session is defined as a time period during which the user is correctly wearing a device with the purpose of acquiring data for reaching its intended use.

Evaluation of missing data is performed via specific data portal by an healthcare professional.

The connection between EmbracePlus and the paired smartphone can be lost for a maximum of 5% of the time but the device should be able to automatically reconnect to the paired smartphone.

The entire device is considered as an "Applied Part". EmbracePlus users shall be considered "Operators" in the meaning of IEC 60601-1

EmbracePlus users can safely use all the EmbracePlus functions.

On-Wrist Charger Essential Performance

The on-wrist charger shall be safe for the user and allow the EmbracePlus to be charged while being worn.

Service Life

EmbracePlus expected service life is 2 years

Limitations

- **1.** EmbracePlus is not intended as a primary diagnostic tool.
- 2. EmbracePlus is compatible only with iOS devices and Android devices.
- 3. Bluetooth® connectivity will not work if EmbracePlus is submerged in water, and thus data cannot be transferred to the paired smartphone.
- 3. Empatica Care is not intended as a primary diagnosis or detection of respiratory infection.
- **4.** Empatica Care is not intended as a primary diagnosis or detection of respiratory infection.
- **5.** Empatica Care is not able to determine the source and severity of the respiratory infection.
- 6. Empatica Care is not able to determine the type of pathogen causing the respiratory infection.
- 7. Empatica Care performance has not been evaluated in the neonatal and pediatric population.

- 8. Empatica Care performance has not been evaluated in patients with physiological parameters baseline abnormalities caused by existing comorbidities.
- 9. Empatica Care "High Risk" output indicates that a physiological pattern was detected which might indicate the presence of a respiratory infection.

 Additional testing and confirmation procedures should be performed in consultation with public health and/or other authorities to whom reporting is required. Positive results should be reported in accordance with local, state, and federal regulations.
- **10.** Empatica Care "Low Risk" output, does not preclude the presence of a respiratory infection and should not be used as the sole basis for user management decisions.
- **11.** To provide an output Aura needs at least 4 hours of physiological parameters recorded during rest periods.

Warnings & Precautions

- 1. The user must wear the device correctly to ensure correct raw data acquisition and physiological parameter computation.
- 2. Do not clean EmbracePlus while wearing it.
- 3. Do not use EmbracePlus if it appears damaged. Check EmbracePlus for sharp edges and damage before each use.
- **4.** Users who wear a pacemaker, or who have health conditions which might be sensitive to small electrical signals should always consult their physicians before wearing any electronic device, including EmbracePlus.
- **5.** If EmbracePlus is used in a manner not specified by the manufacturer, its performance characteristics can be altered
- **6.** Adult supervision is required. Due to the presence of small parts used in EmbracePlus, it is strongly advised that the device only be used on small children under adult supervision.
- 7. Use the EmbracePlus only with its original accessories provided by Empatica. Other cables and accessories might affect electromagnetic compatibility performances and device safety. Using EmbracePlus

with accessories, transducers or cables other than those specified may also result in increased emissions or decreased immunity of Embrace.

- 8. Do not store EmbracePlus close to other electrical equipment.
- **9.** Portable RF communications equipment, including antennas, can affect EmbracePlus, thus they can be used no closer than 30 cm (12 inches) to any part of Embrace.
- 10. Use only USB power supply certified with IEC 60950-1 to charge EmbracePlus on-wrist charger.
- **11.** The EmbracePlus charger may generate heat when connected to a power source; be careful when handling it during the charge.
- **12.** Users should never attempt to charge the EmbracePlus on-wrist charger while it is connected to a worn EmbracePlus.
- **13.** You must not wear EmbracePlus during either an MRI or an X-ray scan.
- **14.** Empatica cannot guarantee that Aura will detect a respiratory infection and deliver notification to caregivers accordingly. The system is not meant to

substitute for respiratory infection diagnosis kits.

- **15.** For the functioning of the system the following condition shall be met:
 - a. The user must wear the EmbracePlus properly and remains within close proximity (<30 feet or 10 meters) to the paired smartphone running the Care App.
 - b. The paired smartphone must be connected to the internet.
 - c. The Care App and the EmbracePlus do not show warning messages.
 - d. The EmbracePlus and the paired smartphone must be charged and operating properly.
- **16.** To provide an output Aura needs at least 4 hours of daily physiological parameters recorded during rest periods over 5 consecutive days.
- 17. Users who wear a pacemaker, or who have health conditions which might be sensitive to small electrical signals should always consult their physicians before wearing any electronic device, including the wearable device for physiological parameter collection.
- **18.** Only wear the wearable device on one of your wrists.
- 19. If the Care App, the Care Portal and the Aura

algorithm are used in a manner not specified by the manufacturer, the protection, functionalities and performance they provide could be compromised.

Precautions

- 1. Do not place the EmbracePlus watch over broken or damaged skin.
- 2. Empatica does not recommend wearing the device if you have a known allergy to metals, or you are generally sensitive to skin contact with metals.
- 3. Keep EmbracePlus clean: bacteria and dirt may cause skin itching or irritation.
- 4. Do not leave EmbracePlus in environments in which it may overheat beyond the recommended environmental limits (e.g., a car parked under the sun). If EmbracePlus is left exposed to high temperatures, allow it to cool before handling it to avoid possible skin burns.
- **5.** Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

- **6.** Avoid using EmbracePlus in a hot tub, sauna or steam rooms.
- 7. Do not use the On-Wrist charger while showering or swimming.

Risks and Benefits

Risks

The list below represents all aspects that should be considered as cautions resulting from the Risk Management Process of the EmbracePlus. The user is required to carefully read this manual before using the device.

Physiological Parameters presence and quality

Including any hazard that might result from sensors failure, electrical components damage, use errors or low algorithm performance. Low risk level – no significant harm – On-board memory, state of the art electrical design, fault detection algorithms and clear use experience have been implemented to mitigate the risk. Moreover, the EmbracePlus is not intended to diagnose a disease; only trained personnel may interpret the data.

Physiological Parameters computation

Including any hazard that might result from sensors

failure or low algorithm performance. Low risk level

– no significant harm – State of the art validation
protocols have been performed to validate

EmbracePlus physiological parameters. Moreover, the
EmbracePlus is not intended to diagnose a disease;
only trained personnel may interpret the data.

EmbracePlus Cleaning

Including any hazard that might result from wrong cleaning procedure or use of non-compatible cleaning agents. Low risk level – no significant harm – State of the art validation protocols have been performed to validate EmbracePlus cleaning procedure and listed cleaning agents.

EmbracePlus Biocompatibility

Including any hazard that might result from use of non-biocompatible construction material. Low risk level – no significant harm – EmbracePlus is made of a well-known biocompatible material, biocompatibility tests have been performed according to relevant regulatory standards.

EmbracePlus Safety

Including any hazard that might result from electrical and mechanical failure. Low risk level – no significant harm – EmbracePlus has been designed, developed and manufactured using state of the art techniques, in addition safety tests according to relevant

regulatory requirements have been performed.

EmbracePlus Electromagnetic Compatibility

Including any hazard that might result from internal or external interferences. Low risk level – no significant harm – EmbracePlus has been designed, developed and manufactured using state of the art techniques, in addition electromagnetic compatibility tests have been performed according to relevant regulatory requirements.

EmbracePlus Environmental conditions

Including any hazard that might result from the storage or use of EmbracePlus in extreme environmental conditions.. Low risk level – no significant harm – EmbracePlus has been designed, developed and manufactured using state of the art techniques and materials that can withstand a wide range of environmental conditions. Indication of the environmental conditions in which the device shall be stored and used are presented in this manual.

EmbracePlus Usability

Including any hazard that might result from the use errors or design failure. Low risk level – no significant harm – EmbracePlus user interface and user experience has been designed and tested following relevant regulatory requirements. Moreover

EmbracePlus labeling documents contain all the relevant information for a flawless use of the device.

EmbracePlus Cybersecurity

Including any hazard that might result from data corruption and loss of data confidentiality. Low risk level – no significant harm – EmbracePlus software architecture includes state of the art controls to ensure data integrity.

EmbracePlus Functionality

Including any hazard that might result from failures in device functionalities. Low risk level – no significant harm - EmbracePlus functionalities have been designed, developed and tested using state of the art techniques.

Benefits

The known and potential benefit of EmbracePlus for clinical use are:

- . The Remote monitoring capabilities enabled by EmbracePlus could reduce the caregivers' risk of exposure to potential health risks.
- . Facilitate users remote health status control without the need of hospitalization
- . The Remote monitoring capabilities of EmbracePlus could alleviate the burden to the healthcare system by providing an additional option for remote

monitoring of hospitalized users to minimize inperson interactions. Healthcare workers are at
particular risk of infections transmission, especially
when conducting procedures that require direct
user contact, such as taking vital signs. Remote
monitoring practices can reduce the risk of
transmission.

Benefits-Risk determination

Based on the presented known benefits and the residual severity and probability of the identified risks we determine EmbracePlus residual risks are outweighed by the potential benefits.

EmbracePlus Materials & Biocompatibility

EmbracePlus components

Part Name	Qty	Material	Production Method
POD Case	1	Polycarbonate	Injection molding
Thermal Ring	1	Stainless Steel 316L	Lathe
PPG Window	1	Gorilla Glass	Molding and Ion-exchange
POD Buttons	2	Stainless Steel 316L	Lathe
EINK Display	1	Gorilla Glass	Molding and Ion-exchange
Strap	1	Silicon	Injection molding
EDA Electrodes	2	Stainless Steel 316L	Lathe
Buckle	1	Stainless Steel 316L	Lathe
OWC Housing	1	Polycarbonate	Injection molding
OWC Cap	1	Polycarbonate	Injection molding

Biocompatibility information

Empatica takes great care in selecting the highest grade materials when designing its devices, so that users have the most secure and comfortable experience when using them. It is therefore unlikely that users will develop an allergic reaction from EmbracePlus. However, some people may notice a slight reaction on their skin. If this happens, please

contact our support team with a picture of the affected area(s).

Important Note:

EmbracePlus should only be worn on the surface
of healthy skin. We advise the user to suspend
or discontinue use if the skin becomes red, itchy
or if any pain is felt. Without regular cleaning
skin irritation is more likely to occur, so Empatica
suggests the user to clean EmbracePlus regularly. If
the user is allergic or hypersensitive to the materials
listed in the above table we don't recommend using
EmbracePlus.

EmbracePlus wristband Technical Specifications

Technical Specifications

EmbracePlus Case (POD)

Diameter: 32 mm Thickness: 15 mm

Weight: 38 gr (including battery, band and

electronics)

Color: Black with a matte finish

Materials: Case in Polycarbonate, PPG Glass

(Gorilla Glass 3)

Ingress Protection Classification

EmbracePlus: IP 67

You can wear EmbracePlus while taking a shower, or in the rain. You can also wear it in pools (not in saltwater). You should not submerge EmbracePlus in water that is deeper than 3.3. feet or 1 meter or for more than 30 minutes. Avoid using EmbracePlus in a hot tub, sauna or steam rooms.

Please note that the Bluetooth® connectivity will not work if EmbracePlus is submerged in water, and thus data cannot be transferred to the paired smartphone.

EmbracePlus is dust tight, meaning dust will not enter the inner part of the device.

EmbracePlus Band

Min wrist circumference : 140 mm Max wrist circumference: 184 mm

Width: 22.4 mm

Color: White upper face and teal back face

Materials: Biocompatible silicone

(Organopolysiloxane mixture) and EDA electrodes in stainless steel (SUS 316L)

Features: Includes electrodes that compose Empatica's custom-made EDA sensor. Easily

interchangeable

EmbracePlus
Battery

Type: 3.8V Li-ion Capacity: 155 mAh

Battery life: 2 years or up to 500 cycles Charging time (0% to 100%): 90 minutes

(worst case)

Battery duration (100% to 0%): Depends on

the sensor configuration (see below)

EmbracePlus Memory

Type: NOR Flash Memory

Capacity: 128 MB

Hours of data stored: Depends on the sensor

configuration (see below)

E Ink Display

Type: Glass-protected E Ink display

Display size: 25.9 mm

Glass: Corning® Gorilla® Glass 3

Glass features: High resistance to scratch and sharp contact damage; high retained strength

after use; superior surface quality

E Ink specifications: Black & White, alwayson, no backlight, 62 segments, 2Hz max

refresh rate

Display features: always-on clock face (time-synchronized with phone), battery level (in percentage), Bluetooth® connection/disconnection indication, error states, menunavigation.

Buttons

Type: two mechanical buttons

Actions: menu navigation, confirmation,

event tagging

Haptic Feedback

Type: Multi-pattern Linear Resonant Actuator

(LRA) vibration motor

PPG Sensor

Channels: 4 acquisition channels (via 8

photodiodes)

Wavelengths: Red, Infra-Red, Green

Sampling Rate: 26 Hz - 208 Hz

Temperature Sensor	Range: 0 - 85° Resolution: 0.01°C Accuracy: ± 0.1°C within 30.0°C - 45.0°C range (medical application calibration) Sampling Rate: 1 Hz - 4 Hz
Accelerometer Sensor	Type: High precision 3D microelectromechanical accelerometer and gyroscope Range: from ±2 to ±16g, ±2000 dps Resolution: 16bit (0.488mg/LSB, 70mdps/LSB) Accuracy Accelerometer: ±0.01%/°C, 110µg/√Hz Accuracy Gyroscope: ±1% on sensitivity, ±0.007%/°C, 3.8mdps/√Hz Sampling Rate: 26 Hz − 208 Hz
EDA Sensor	Range: 0.01 μSiemens – 100 μSiemens Resolution: 1 digit ~ 55 pSiemens Sampling Rate: 1 - 4 Hz
Compatibility	iOS operative system: iOS 11 or higher Empatica support iPhone 8 and higher. Android 5.0 or higher Bluetooth® 5.0 is supported from Android 8.0 (Oreo) or higher (might depend on the specific manufacturer).
Connectivity	Main standard: Bluetooth® 5 Fallback standard: Bluetooth® Low Energy 4.2 Range: Maximum 10 meters / 30 feet (in line of sight) Radio Frequency: 2.4 - 2.5 GHz Maximum speed: Up to 2Mbits on supported Phones Security: AES 128 Bit (Advanced Encryption Standard)

EMCenvironment

Guidance and Manufacturer's declaration - electromagnetic emissions

EmbracePlus is intended for use in the electromagnetic environment specified below. The user of the EmbracePlus should assure that it is used in such an environment.

Emission Test	Compliance	Electromagnetic environment
RF emission CISPR 11	Group 1	EmbracePlus uses RF energy only for its internal function. Therefore its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emission CISPR 11	Class B	The EmbracePlus
Harmonic Emission EN 61000- 3-2	Not Applicable	device is suitable for use in domestic establishments and in establishments
Voltage Fluctuation/ flicker emission EN 61000- 3-3	Not Applicable	directly connected to the low voltage power supply network that supplies buildings used for domestic purposes.

FCC Compliance

The EmbracePlus device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

- 1. This device may not cause harmful interference.
- 2. This device must accept any interference received, including interference that may cause undesired operation (FCC Title 47, Subpart A, Part 15.19(3)).

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment (FCC Title 47, Subpart A, Part 15.21).

Guidance and Manufacturer's declaration - electromagnetic immunity

The EmbracePlus is intended for use in the electromagnetic environment specified below.

The user of the EmbracePlus should assure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic environment
Electro- static Dis- charge (ESD) EN 61000-4-2	± 8 kV contact ± 15 kV Air	± 8 kV contact ± 15 kV Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Power Frequency (50/60 Hz) Magnetic Field EN 61000- 4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Portable and mobile RF communications equipment should be used no closer to any part of the EmbracePlus device than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:

	10 V/m 80 - 2700 MHz	10V/m	$d = 1.2\sqrt{P} 80 \text{ MHz to}$ 800 MHz $d = 2.3\sqrt{P} 800 \text{MHz to}$ 2700 MHz
--	----------------------------	-------	---

where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:



Recommended separation distance between portable and mobile RF communications equipment and EmbracePlus

EmbracePlus is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the EmbracePlus can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitter) and the EmbracePlus as recommended below, according to the maximum output power of the communication equipment.

Rated maximum output power of	Separation distance according to frequency of transmitter (m)		
transmitter (W)	80 MHz to 800 MHz d = 1.2 √P	800 MHz to 2.7 GHz d = 2.3 √P	
0.01	0.12	0.23	
0.1	0.38	0.73	
1	1.2	2.3	
10	3.8	7.3	
100	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Notes:

- 1. At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- 2. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Manufacturer information

EmbracePlus wristband and Empatica Care are manufactured by

Name: Empatica S.r.L.

Address: Via Enrico Stendhal, 36

City: Milan

Zip: 20144

Phone: +39 02 36566473

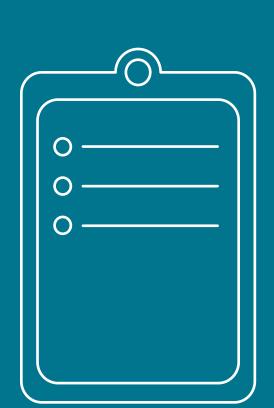
Website: www.empatica.com

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A PDF copy of this Instruction for Use is available at http://empatica.com/manuals/embraceplus-aura

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Document history



Revision	Date	Description
Rev 1.0	December 18, 2020	Initial release of the document