

EmbraceMini



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What is EmbraceMini?

EmbraceMini is a medical device designed to track and transmit key health data to a companion app/system, enabling continuous analysis and extraction of precise Digital Biomarkers.

EmbraceMini can seamlessly capture important physiological parameters from its powerful sensors, including accelerometer, gyroscope, magnetometer, and ambient light sensor. From these sensors, the following health metrics can be collected: physical activity, sleep patterns, and light exposure. For a complete list of monitored parameters, please contact your study administrator.

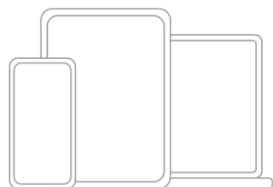
Your study may require you to use one or more EmbraceMini devices in different positions, either alone or in combination with other devices. If you have any questions, please reach out to your study administrator.





1. Device Serial Number
2. LED Indicator Light
3. Mechanical Button
4. Stainless Steel Housing

Get started with your EmbraceMini



EmbraceMini works with a companion app/system. Please be sure to have the app/system and related instructions in hand to start.

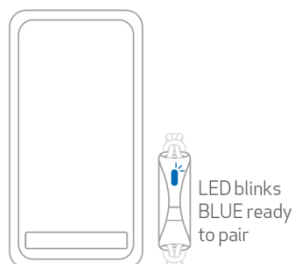
WAKE UP AND PAIR EMBRACEMINI



WAKE UP THE DEVICE

Turn on EmbraceMini by pressing the button. The white LED will turn on softly, and after 5 seconds, the blinking blue LED will signal that EmbraceMini is ready to be paired.

If EmbraceMini does not immediately wake up, we recommend placing it in the charger in case the battery is drained



PAIR VIA BLUETOOTH

To complete the pairing process, you'll need to press the button on your EmbraceMini to send a pairing request. The blue LED will start blinking faster. Then follow the instructions in the app.

Only confirm pairing with devices you recognize.

How to wear your EmbraceMini

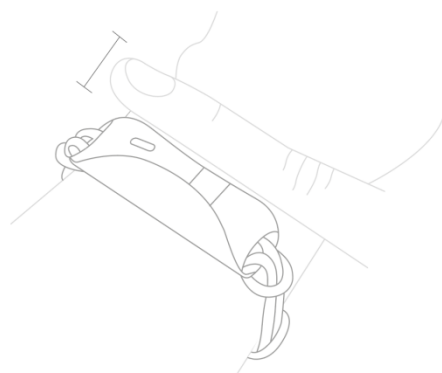
To properly wear EmbraceMini, please follow the instructions in the Help Center in the Care App or in the app used in your study. Contact your study team for detailed instructions.

Make sure to wear EmbraceMini correctly. Wearing EmbraceMini incorrectly will affect the quality of the data collected.

Please always follow the wearing instructions given by the study team.



EmbraceMini



Standard Band at the Wrist

1. Wear it on your non-dominant hand, at 1-finger distance from your wrist bone (unless otherwise instructed)
2. Fasten the band and secure EmbraceMini until you feel some pressure

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EmbraceMini Daily Use and Error Statuses

EmbraceMini is designed to collect physiological data while seamlessly integrating into the participant's daily life. It connects via Bluetooth to the companion application/system to transfer data. Data will not be lost if disconnected from the smartphone for a few hours (depending on the sensor mode).

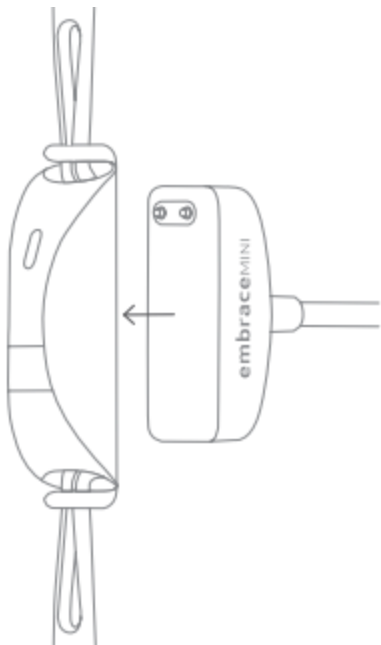
EmbraceMini may be attached to **the wrist, clothing, or other designated body areas**, depending on the form factor it comes with. The device may be worn with a **standard band or belt clip**, allowing flexibility based on user preference and study requirements. Ensuring a **secure and comfortable fit** is essential for accurate data collection, as improper positioning may impact data collection. Users should follow study guidelines and the information in the Care App to determine the appropriate attachment method and placement for their specific setup.

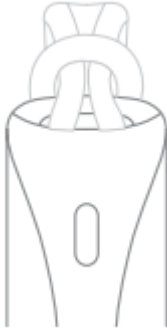
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CHARGING EMBRACEMINI

To charge EmbraceMini, plug the USB-C cable into a standard 5V power source and place the device on the charger as shown.

Be sure the pins click into place with the charging contacts on EmbraceMini.

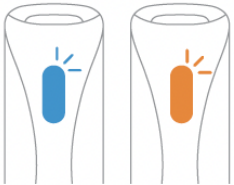
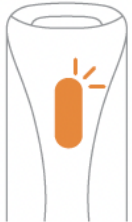
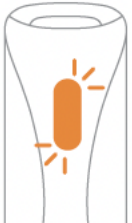


Status LED	Description	Actions
	Charging in progress	When the EmbraceMini is correctly placed on the charger, the LED turns white and starts blinking ; this means that charging is in progress.
	Charging complete	When fully charged, the LED turns off. Press the front button while on the charger; a white light means it's ready. Once removed, the LED turns on to show the current device status.

HOW TO CHECK THE STATUS?

You can check EmbraceMini's status at any time by pressing the front button once; the LED will light up to indicate the current condition.

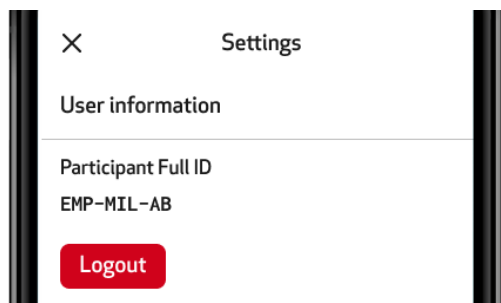
For critical issues, the LED will blink automatically, even without pressing the button.

Status LED	Description	Actions
 LED turns GREEN	EmbraceMini is working correctly	None / No action required
 LED blinks BLUE and ORANGE	Bluetooth connection issue	If the LED blinks blue and orange, it indicates a Bluetooth connection issue. EmbraceMini is still recording data. Open the companion app to reconnect the device.
 ORANGE LED blinks gently	Low battery	When the battery of EmbraceMini is low and needs to be charged, the LED blinks orange. Press the front button to dismiss the warning. We suggest charging EmbraceMini as soon as possible.
 ORANGE LED blinks quickly	Device error	If EmbraceMini detects a device error that stops data recording, the orange LED will blink automatically to alert you. Open the companion app to reconnect the device and resolve the issue.

HOW TO SHUT DOWN EMBRACEMINI?

EmbraceMini is intended to continuously collect data, so the only way to shut it down is from the mobile application to which it connects. To do so follow these instructions:

Access the Settings screen of the Care App, tap the 3 dots on the top right of the main screen.



Tap on Logout: This will sign you out of the Care App. and your EmbraceMini will stop collecting data and shut down.

HOW TO CLEAN EMBRACEMINI?

How to clean and sanitize your EmbraceMini

It's recommended you clean your EmbraceMini every week, or in the event you experience itching or skin irritation.

To clean EmbraceMini, follow these six simple steps:

1. Remove EmbraceMini
2. Take a polyester/cellulose wipe.
3. Soak the wipe in 70% isopropyl alcohol for 5 minutes.
4. Thoroughly clean EmbraceMini for at least 1 minute by wiping the whole device.
5. Visually check the whole device for traces of dirt. If you see visible contamination, repeat the cleaning procedure.
6. Let EmbraceMini dry before wearing or sanitizing it.

Safety, Regulatory, and Compliance

Documentation Features

EMBRACEMINI SYMBOLS USED IN LABELING

Symbol	Description	Symbol	Description
	Indicates compliance with the European Medical Device Regulation 2017/745		Indicates Empatica S.r.l as the legal manufacturer of EmbraceMini
	Indicates that the electromagnetic interference from the EmbraceMini is under the limits that are approved by the Federal Communications Commission		The EmbraceMini uses Bluetooth Low Energy to transfer data.
	EmbraceMini is an electrical and electronic equipment that needs separate collection for disposal in accordance with the Waste Electrical and Electronic Equipment Directive		Indicates the device Serial Number
	EmbraceMini is a 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 the need for the user to consult the EmbraceMini instruction for use for important information, warnings, and cautions
	Indicates that EmbraceMini intentionally generates RF signals for data transmission to a connected device		Indicates the manufacturing date of the device

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LIST OF ABBREVIATIONS AND TERMS

Abbreviation/Term	Meaning
EMC	Electromagnetic Compatibility
ICU	Intensive Care Unit
LED	Light Emitting Diode
RF	Radiofrequency
BLE	Bluetooth Low Energy
Administrator(s)	Throughout this document, the term administrator(s) is used to identify healthcare professionals and researchers using the product
User(s)	Throughout this document, the term user(s) is used to identify patient(s) and clinical trial participant(s) using the product and whose physiological parameters are being monitored.
Companion app/system	Throughout this document, the term companion app/system is used to identify the mobile app (e.g., Empatica Care App) installed on the user's companion device that receives EmbraceMini data via BLE connection

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Safety Considerations

WARNING AND CAUTIONS



WARNING

A **WARNING** statement provides important information about a potentially hazardous situation that, if not avoided, could result in death or serious injury.



CAUTION

A **CAUTION** statement provides important information about a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or in damage to the equipment or other property

SAFETY CONSIDERATIONS

To support proper, safe, and accurate operation of the product, read all operating instructions carefully before you use the product.



WARNING

To maintain user safety, adhere to all **WARNING** and **CAUTIONS** listed in these Instructions for Use and on product labels



WARNING

No modification of the product is allowed. Modification of this product may cause interference with other devices, injury to the patient and user, including electric shock, burns, or death.



WARNING

Do not operate the product in areas such as magnetic resonance imaging (MRI) environments, while taking an X-ray, or in hyperbaric chambers.

WARNING: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the EmbraceMini, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.



WARNING

Risk of infection. Empatica technical staff can become infected with pathogenic germs. Disinfect and clean EmbraceMini before returning the medical device to Empatica.



WARNING

If EmbraceMini is used in a manner not specified by the manufacturer, the protection, functionalities, and performance it provides could be compromised.



WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.



WARNING

EmbraceMini and any other applied parts should be removed before patient defibrillation.



CAUTION

Read all cleaning instructions carefully before cleaning EmbraceMini. Refer to the cleaning and disinfecting chapter of the instructions for use.

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Safety and Precautions

GENERAL



WARNING

EmbraceMini and its attachment pose a choking hazard. EmbraceMini is not a toy and should not be chewed on or put in your mouth.



WARNING

Do not use EmbraceMini if it appears damaged. Check EmbraceMini for sharp edges and damage before each use.



WARNING

Use EmbraceMini only with its original accessories provided by Empatica. Other cables and accessories might affect electromagnetic compatibility performances and device safety. Using EmbraceMini with accessories, transducers, or cables other than those specified may also result in increased emissions or decreased immunity of Embrace.



CAUTION

Do not wear EmbraceMini on broken or damaged skin.



CAUTION

Do not clean EmbraceMini while wearing it.



CAUTION

Empatica does not recommend using the device with patients/clinical trial participants with a known allergy to metals, or if you are generally sensitive to skin contact with metals. If redness appears during use, remove the device.



CAUTION

Do not store EmbraceMini near other electrical equipment.



CAUTION

Users who wear a pacemaker or have health conditions that might be sensitive to small electrical signals should always consult their physicians before wearing any electronic device, including EmbraceMini.

EmbraceMini, the wearable available to be used with the health monitor component of the Empatica Health Monitoring Platform, is not a toy. Please take care of the equipment and only use EmbraceMini and the Care App as described. Please do not modify or change EmbraceMini. Please only use EmbraceMini with the accessories provided. The only accessory provided is the Cable Charger.

Please check EmbraceMini and the included cable charger before using it. If you see any damage, cracks, or splits, please stop using it and contact your administrator for a replacement. If at any point, EmbraceMini, or the cable charger is damaged, please contact your administrator to have it replaced.

Please do not place any parts of EmbraceMini or the cable charger in your mouth, as it can be a choking hazard.

Please keep EmbraceMini out of direct sunlight, and when not in use, please store it in a clean, dry place. Please keep it away from sources of heat.

Once your administrator lets you know that you do not need to use EmbraceMini any longer, please do not dispose of EmbraceMini. It will be collected by your administrator.

Please remove EmbraceMini and other equipment before you receive an MRI. EmbraceMini and other equipment should also be removed before defibrillation.

EMBRACEMINI

EmbraceMini should be worn according to your study's guidelines, which may include placement on the **wrist, clothing, or other designated areas**, depending on the attachment method provided. Ensure the device is **securely positioned** for accurate data collection.

Do not wear EmbraceMini over **open wounds, sores, or irritated skin**. If you experience **redness, discomfort, or irritation**, remove the device and consult your study administrator for further guidance. Switching to an alternative attachment (e.g., a different band type or placement) may help improve comfort.



CAUTION

The user must wear the EmbraceMini correctly to ensure correct raw data acquisition and physiological parameter computation.



CAUTION

For the functioning of the system, the following conditions shall be met:

- The user must wear the EmbraceMini properly and have it remain within close proximity (<30 feet or 10 meters) to the paired companion app/system;
- The paired companion app/system must be connected to the internet;
- The EmbraceMini does not show warning messages;
- The EmbraceMini and the companion app/system must be charged and operating properly.

EMBRACEMINI CABLE CHARGER

Take care when handling the cable charger.

When charging EmbraceMini, connect the cable charger only to an IEC 62388-1 (or IEC 60950-1) certified USB power adapter with the following specifications: Output: 5V, maximum current 3A.

- As Empatica does not provide a USB power adapter with the product, you can use this certified power adapter:
 - Phihong, Code: AQ18A-59CFA-H

Before charging, please check the charging contacts on EmbraceMini and the cable charger and, if dirty, clean with a dry cloth.



WARNING

To avoid electrical shock, inspect all cables before use. Never use cables that appear cracked, worn, or damaged in any way



WARNING

The EmbraceMini cable charger must be connected only with an IEC 62388-1 (or IEC 60950-1) certified 5V (volt) USB power supply



WARNING

Prevent liquid spillages onto the cable charger. If the cable charger is immersed in liquid, stop using it and return it for service.



WARNING

EmbraceMini may only be charged using the cable charger provided by Empatica.



WARNING

Users shall not perform servicing and maintenance activities on EmbraceMini.



CAUTION

EmbraceMini cable charger may generate heat when connected to a power source; be careful when handling it during the charge.



CAUTION

The battery charge level reported by EmbraceMini and displayed in the companion app/system user interface is only accurate if the battery is in normal working condition.

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TRANSPORT, STORAGE AND USE CONDITIONS

Transport and Storage Conditions	Temperature	-25°C to +70°C
	Humidity	20 – 95% Relative Humidity, non-condensing
	Pressure	1060 hPa to 500 hPa
	Battery preservation	EmbraceMini can be stored in its original box for a maximum of 3 months without charging. If EmbraceMini is not used for more than 90 days, make sure to charge it at least once every 3 months.
	Storage after use	EmbraceMini should be properly stored. Do not expose EmbraceMini to direct sunlight, moisture, or rain.
Use Conditions	Temperature	(Use) -10°C to +40°C (Charging) 0°C to +40°C
	Humidity	15 – 95% Relative Humidity, non-condensing
	Pressure	1060 hPa to 700 hPa

IMPORTANT

After storage at the extreme temperature indicated in the table above, allow the device to return to room temperature (15°C – 30°C) before wearing EmbraceMini by leaving it at room temperature for at least 30 minutes.

DUST AND WATER RESISTANCE

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

Please note that the Bluetooth connectivity will not work correctly while EmbraceMini is submerged in water, and thus, data cannot be transferred to the paired companion app/system. Recorded data will be transferred to the paired companion app/system as soon as the connection is re-established.

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

EMBRACEMINI DISPOSAL



WARNING

Risk of infection. EmbraceMini must be disinfected and cleaned before disposal



WARNING

EmbraceMini contains a lithium-ion battery. Do not incinerate the device or place it in a trash compactor.
Do not puncture the battery

When disposing of EmbraceMini, please return it to Empatica and observe all applicable laws and regulations. Its return to Empatica will be arranged via Empatica Support.

This medical device is subject to the EU Directive 2012/19/EU (WEEE). It may not be disposed of at municipal collection points for waste electrical and electronic equipment.

EMBRACEMINI PERFORMANCE CHARACTERISTICS

Physiological Parameters measurement	Rest Detection	Range: 0 - 400 (0-99: wake epoch; 100-299: rest epoch; 300-399: rest interruption epoch; 400: for future use) Accuracy: The Rest detection algorithm did not miss any of the 46 PSG-derived sleep periods (Sensitivity = 100%). On average, the Rest detection algorithm detected an earlier sleep onset and a later sleep offset, with an overall longer sleep period duration compared to PSG.
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TECHNICAL SPECIFICATIONS

EmbraceMini Pod	Dimensions: 43 x 14 x 22 mm / 1.69 x 0.55 x 0.47 in Weight: 15 g / 0.53 oz (including battery, band, and electronics) Color: Black with a metal outer case Materials: Stainless Steel and Polycarbonate case, Thermoplastic Polyurethane button
Ingress Protection Classification	IP 67 <i>EmbraceMini can be worn while showering or in the rain. You can also wear it in pools (not in saltwater). You should not submerge EmbraceMini in water that is deeper than 3.3 feet or 1 meter, or for more than 30 minutes. Avoid using EmbraceMini in a hot tub, sauna, or steam room.</i>
 EmbraceMini Standard Band	Min wrist circumference: Size S = 120 mm / 4.70 in Size L = 150 mm / 5.90 in Max wrist circumference: Size S = 170 mm / 6.70 in Size L = 220 mm / 8.70 in Dimensions: 43 x 14 x 12 mm / 1.69 x 0.55 x 0.47 in Color: Black Materials: FKM (Fluoroelastomer) and Stainless Steel <u>Compatibility: works only with S/N starting with 3C</u>
 EmbraceMini Cable Charger	Dimensions: 33 x 12 x 13.50 mm / 1.30 x 0.47 x 0.53 in Weight: 8.9 g / 0.31 oz (including the cable) Materials: Polycarbonate outer shell Cable: USB Type-C connector

EmbraceMini Battery	Type: 3.8V Li-ion Capacity: 75 mAh Battery life: 2 years or up to 500 cycles Charging time (0% to 100%): 90 minutes Battery duration (100% to 0%): At least 5 days (depends on the sensor configuration)
EmbraceMini Memory	Type: NOR Flash Memory Capacity: 128 MB Hours of data stored: 36 to 480 hours (depends on the sensor configuration)
Status LED	Type: RGBW (Red, Green, Blue, White) Features: Status report through different color and intensity patterns
Button	Type: Mechanical button Actions: status check, dismiss notifications, confirmation, event tagging
Inertial Measurement Unit	Type: High precision 3D microelectromechanical accelerometer and gyroscope Range: ± 16 g, ± 4000 dps Resolution: 16 bit (0.488 mg/LSB, 140 mdps/LSB) Accuracy Accelerometer: $\pm 0.01\%/^{\circ}\text{C}$ Accuracy Gyroscope: $\pm 1\%$ on sensitivity, $\pm 0.007\%/^{\circ}\text{C}$ Sampling Rate: Up to 100 Hz
Magnetometer Sensor	Type: 3-axis magnetic sensor Range: ± 2000 μT Resolution: 16 bit (0.1 μT) Accuracy: $\pm 0.010\%/^{\circ}\text{C}$ Sampling Rate: Up to 400 Hz
Ambient Light Sensor	Type: Digital ambient light sensor with high-precision human-eye response Range: From 0.01 lux to 83 klux Resolution: 23 bit (0.01 lux/LSB) Accuracy: $\pm 0.01\%/^{\circ}\text{C}$ Sampling Rate: Up to 2.6 MHz
<u>Compatibility</u>	For the latest information, please check: https://www.empatica.com/embraceplus-compatibility/ iOS operating system: iOS 16 or higher Bluetooth® 5.0, which is supported from iPhone 8 or higher, iPhone SE (2nd gen)
	Android smartphones running Android 12, 12.1, 13, or 14 as released by Google. Bluetooth® 5.0 with 2M PHY is supported from Android 11.0 or higher (might depend on the specific manufacturer)
Connectivity	Standard: Bluetooth® 5 Range: Maximum 10 meters / 30 feet (in line of sight) Radio Frequency: 2.4 - 2.5 GHz Maximum speed: Up to 2 Mbps on supported smartphones Security: AES 128-Bit (Advanced Encryption Standard)



CAUTION

Removing the EmbraceMini from the mobile device Bluetooth range will prevent transmission of signal data, and therefore, physiological parameters will not be generated for the user until the EmbraceMini is reconnected.



CAUTION

Bluetooth connectivity will not work if EmbraceMini is submerged in water, and therefore, data cannot be transferred to the companion app/system

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Regulatory and Compliance

Note: UDI-DI, Intended Use, Indication for use, and CE Mark only apply to Empatica Care App. If you are using Empatica Care Lab App, these fields do not apply.

EMBRACEMINI LABELING

The information directly printed on the EmbraceMini itself is presented in Figure below..



Figure 1 - Back view of EmbraceMini

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

- > Product Name and Manufacturer name: EmbraceMini by EMPATICA
- > Device Serial Number: S/N 123456789
- > CE Mark
- > Applied Parts type BF symbol
- > Precaution Symbol

EMBRACEMINI LABORATORY TESTING

EmbraceMini 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

INTENDED USE

EmbraceMini is intended to collect and monitor activity-based and sleep-based physiological parameters in ambulatory individuals in home healthcare and professional healthcare environments.

INDICATIONS FOR USE

EmbraceMini is a wearable device intended to be used by trained healthcare professionals or researchers to remotely monitor limb or body movements in ambulatory individuals in home-healthcare environments and professional healthcare environments.

The device supports continuous data collection for monitoring the following physiological parameters:

- Physical movement associated with applications in physiological monitoring
- Activity associated with movement during sleep

EmbraceMini can be used to analyze circadian rhythms and assess activity in any instance where quantifiable analysis of physical motion is desirable

LIMITATIONS

EmbraceMini is not intended for use in high-acuity environments, such as an ICU or operating room.

CONTRAINDICATIONS

This device is contraindicated in patients with pacemakers and implantable cardioverter-defibrillators (ICDs). The product shall not be used with other magnetically susceptible medical devices. Do not operate the product while taking an X-ray or in hyperbaric chambers.

INTENDED POPULATION AND USE ENVIRONMENT

EmbraceMini is intended to be used by the general population (age 6 and up). The collected physiological parameters are intended to be retrospectively reviewed by Healthcare providers or researchers.

EmbraceMini is intended to be used in home-healthcare and professional healthcare environments.

PATIENT POPULATION AND MEDICAL CONDITION

User population:

- > Age: from 6 years of age (there might be a limitation on wrist circumference for the wearable device) to elderly¹
- > Ambulatory Patients
- > Weight: not relevant, but there might be a limitation on wrist circumference
- > Nationality: not relevant
- > Health status: not relevant

Professional Population:

- > Healthcare professionals
- > Occupational doctors
- > Clinical Researchers
- > Academic Researchers
- > Nurses

ESSENTIAL PERFORMANCE STATEMENT AND SAFETY INFORMATION

Based on the performed Risk Analysis, Empatica has determined that the product use does not depend on Essential Performance.

The EmbraceMini, when used is considered "Applied Part".

EmbraceMini charging pins, when the device is not used are considered "Accessible Parts"

EmbraceMini users (patients) shall be considered as "Intended Operators" in the meaning of IEC 60601-1.

EmbraceMini users can safely use all the EmbraceMini functions.

SERVICE LIFE

EmbraceMini's expected service life is 2 years.

DETERMINE MANUFACTURING DATE FROM SERIAL NUMBER

To identify every single device, a unique Serial Number is assigned during the production.

The serial number looks like PMFDDLLSSS (e.g. 4YK1N132JY) where:

- P identifies the product: 4 (EmbraceMini)
- M identifies the model: Y (black POD)
- F identifies the factory where the device has been assembled:
 - M=Milan/Italy,
 - K=Korea
- DD identifies the Date Code. (week of the year when the device has been assembled), specifically: the first digit represents the semester during which the device was manufactured, while the second digit represents the week. See the tables below for reference:

¹ Users' minimum age varies based on the country. The minimum is 6 years and up in the EU, and 18 years and up in the US.

YEAR/SEMESTER

Year/Semester	ID	Year/Semester	ID	Year/Semester	ID
2025/1	1	2027/1	5	2029/1	9
2025/2	2	2027/2	6	2029/2	C
2026/1	3	2028/1	7	2030/1	D
2026/2	4	2028/2	8	2030/2	F

WEEK

ID	1	2	3	4	5	6	7	8	9	C	D	F	G	H
Week	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Week	28	29	30	31	32	33	34	35	36	37	38	39	40	41

ID	J	K	L	M	N	P	Q	R	T	V	W	X	Y
Week	15	16	17	18	19	20	21	22	23	24	25	26	27
Week	42	43	44	45	46	47	48	49	50	51	52	53	

DEALING WITH A LOST OR STOLEN EMBRACEMINI WEARABLE DEVICE

In case an EmbraceMini medical device is lost or stolen, please notify your administrator.

RISKS AND BENEFITS

RISKS

The list below represents all aspects that should be considered as cautions resulting from the Risk Management Process of the EmbraceMini. 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, user 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 user experience have been implemented to mitigate the risk. Moreover, the EmbraceMini is not intended to diagnose a disease; only trained personnel may interpret the data.

Physiological Parameters computation - including any hazard that might result from sensor failure or low algorithm performance. Low risk level – no significant harm – State of the art validation protocols have been performed to validate EmbraceMini physiological parameters. Moreover, the EmbraceMini is not intended to diagnose a disease; only trained personnel may interpret the data.

EmbraceMini 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 EmbraceMini cleaning procedure and listed cleaning agents.

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

EmbraceMini Safety - including any hazard that might result from electrical and mechanical failure. Low risk level – no significant harm – EmbraceMini has been designed, developed, and manufactured using state of the art techniques. In addition, safety tests according to relevant regulatory requirements have been performed.

EmbraceMini Electromagnetic Compatibility - including any hazard that might result from internal or external interferences. Low risk level – no significant harm – EmbraceMini 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.

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

EmbraceMini Usability - including any hazard that might result from the user errors or design failure. Low risk level – no significant harm – EmbraceMini user interface and user experience have been designed and tested following relevant regulatory requirements. Moreover, EmbraceMini labeling documents contain all the relevant information for a flawless use of the device.

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

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

BENEFITS

The known and potential indirect benefits of EmbraceMini for clinical use are:

- ◁ Facilitating remote clinical oversight of changes in health status without hospital admission;
- ◁ Improving access to care for patients in remote geographic locations or with mobility challenges limiting travel to traditional clinical settings and
- ◁ Reducing in-person touchpoints between healthcare providers and patients or between patients and outpatient caregivers can reduce the transmission of infectious diseases.

BENEFITS-RISK DETERMINATION

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

EMBRACEMINI MATERIALS AND BIOCOMPATIBILITY

EmbraceMini components relevant to the biocompatibility of the device are presented in the table below. This table presents the part name, the quantity per device, the manufacturing material, and the manufacturing process.

Part Name	Qty	Material	Production Method
Pod Case	1	Stainless Steel and Polycarbonate	Injection molding
Front Button	2	Thermoplastic Polyurethane	Injection Molding
Status LED cover	1	Polycarbonate	Injection Molding
Charging contacts	1	Gold-plated Copper	Electroplating
Flexible Band	1	Biocompatible FKM (Fluoroelastomer)	Injection molding
Flexible Band Buckle	2	Stainless Steel 316L	CNC
Cable charger housing	1	Polycarbonate	Injection molding

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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 EmbraceMini. However, some people may notice a slight reaction on their skin. If this happens, please contact the entity that provided EmbraceMini to you with a picture of the affected area(s).

COMPATIBILITY WITH MRI AND X-RAY SCANNING



WARNING

You must not wear EmbraceMini during either an MRI or an X-ray scan.

During an X-ray, the doctor will usually ask you to remove all metal objects since they can affect the quality of the scan. For an MRI, it is especially important to remove all metal objects because the MRI's magnets will attract them.

EMC ENVIRONMENT

Guidance and Manufacturer's declaration - electromagnetic emissions

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

Emission Test	Compliance	Electromagnetic environment
RF emission CISPR 11	Group 1	EmbraceMini 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 EmbraceMini device is suitable for use in domestic establishments and in establishments directly connected to the low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emission EN 61000-3-2	Not Applicable	
Voltage Fluctuation/ flicker emission EN 61000-3-3	Not Applicable	

FCC COMPLIANCE

The EmbraceMini 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, and
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 EmbraceMini is intended for use in the electromagnetic environment specified below. The user of the EmbraceMini should ensure that it is used in such an environment.

Immunity Test	IEC 60601 test level	Compliance Level	Electromagnetic environment- guidance
Electrostatic Discharge (ESD) EN 61000-4-2	8 kV contact 2/4/8/15 kV Air	IEC 60601-1-2 Test level	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %
Radiated electromagnetic field IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	IEC 60601-1-2 Test level	Portable and mobile RF communications equipment should be used no closer to any part of EmbraceMini, including cables than the recommended minimum separation distance of 30 cm
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.
 Interference may occur in the vicinity of equipment marked with this symbol.			

RECOMMENDED SEPARATION DISTANCE BETWEEN PORTABLE AND MOBILE RF COMMUNICATIONS EQUIPMENT AND EMBRACEMINI

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

Frequency Range and Level: RF wireless communication equipment			
Test Frequency (MHz)	Modulation	Minimum IMMUNITY Level (V/m)	IMMUNITY Level Applied (V/m)
385	Pulse Modulation: 18 Hz	27	27
450	Pulse Modulation: 18 Hz	28	28
710 745 780	Pulse Modulation: 217 Hz	9	9
810 870 930	Pulse Modulation: 18 Hz	28	28
1720 1845 1970	Pulse Modulation: 217 Hz	28	28
2450	Pulse Modulation: 217 Hz	28	28
5240 5500 5785	Pulse Modulation: 217 Hz	9	9

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields

Test Frequency (MHz)	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz ^{a)}	CW	8
134,2 kHz	Pulse modulation ^{b)} 2,1 kHz	65 ^{c)}
13,56 MHz	Pulse modulation ^{b)} 50 kHz	7,5 ^{c)}
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50 % duty cycle square wave signal. c) r.m.s., before modulation is applied.		

WIRELESS INFORMATION

EmbraceMini connects to the mobile device through a BLE connection with the following specification:

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 2 Mbits on supported Phones

Security: AES-128 (Advanced Encryption Standard 128-bit)

Empatica suggests having only EmbraceMini connected to the mobile device via BLE connection for optimal system usage. Data transfer to the Care App might be delayed in case of BLE connection problems, such as being out of range from the device or having too many devices connected via BLE to the mobile device at the same time.

Care App connects to the Care Portal through a cellular/WiFi connection. Quality of Service of this connection is dictated by your cellular plan. Data transfer to the Care Portal might be delayed in case of poor cellular coverage, WiFi issues, or a limited cellular data plan.

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MANUFACTURER INFORMATION

Empatica Health Monitoring Platform, EmbraceMini, Care App and Care Portal 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

EmbraceMini is manufactured in the Republic of Korea

EU PRODUCT CLASSIFICATION

	Classification	CE Marking
EmbraceMini	Medical Device, Class I, 2017/745 Annex VIII, Rule 13	

EUROPEAN REGULATORY REPORTING

Any serious incident that should occur in relation to the Empatica Health Monitoring Platform shall be immediately reported to Empatica and to the competent authority of the EU member state in which the patient is established.

ELECTRONIC LABELING INFORMATION

A PDF copy of this Instruction for Use is available at <http://empatica.com/manuals/>.

In case you want a paper copy of this Instruction for Use, you can request it from the administrator. The paper copy will be provided to you within 7 calendar days and free of charge.

EMPATICA SUPPORT

If you need support, contact the administrator. Unless specifically instructed to, please do not contact Empatica directly.

DOCUMENT HISTORY

Revision	Date	Description
1.0	July 2025	Initial release of the document



This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signatures.

Signatory Table

Action Name	User Name	Title	Signature Date
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* Dates are displayed according to the system time zone: (GMT+02:00) Central European Summer Time (Europe/Rome)

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