EmbracePlus

USER MANUAL

UM-22 [Rev 3.0]
March 8, 2021

CE 0051

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Glossary

AI/ML: Artificial Intelligence/Machine Learning
UI: User Interface
UX: User Experience
POD: Main EmbracePlus Body
OWC: On-Wrist charger

Product Description

Product Description & Manufacturer Information

Product Description

EmbracePlus is a medical device intended to be used for the collection, processing, storing, transferring, and remote monitoring of physiological parameters.

EmbracePlus is a wearable biosensor device that collects, processes via embedded AI/ML algorithms, stores, and wirelessly transmits physiological parameters via Bluetooth to a paired smartphone. EmbracePlus runs different on-board algorithms to continuously process sensors' acquired raw data to extract specific physiological parameters including Pulse Rate, Pulse Rate Variability, temperature, Respiration rate, SpO2, Electrodermal activity and Physical activity. The computed physiological parameters can be presented to the user via the device UI and transmitted to the paired smartphone for data transferring to a remote monitoring platform.

EmbracePlus comes in different variants, each with the same intended use and operative principles, but with different band colors and materials. The specific catalog number is provided on the device box label and follows this logic:
EMBP- {color} - {size, material} where:

- **{color}** - is a 2 character variable indicating the color (i.e. CW=Cortina White)
- **{size, material}** - is a 2 character variable where:
    1. the first character ("size") indicates the size (e.g S=Small, M=Medium)

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2. the second character (“material”) indicates the material (e.g. S=Silicone, F= Fabric etc)

EmbracePlus shall be charged using the provided On-Wrist Charger (OWC). The OWC works as a common “power bank”: when charged and attached to the EmbracePlus, the charging process starts without any power source.

As of today 2 different variants are available:

Product	Product Variant	GTIN
EmbracePlus, Cortina White, Silicon Medium	EMBP-CC-MS	00853858006232
EmbracePlus, Maddalena White, Silicon Medium	EMBP-MW-MS	00853858006287

Manufacturer Information

EmbracePlus is manufactured by
Empatica S.r.l.
Via Stendhal, 36 - 20144 Milan – Italy
Phone: +39 02 36566473
Website: www.empatica.com
Email: info@empatica.com

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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)

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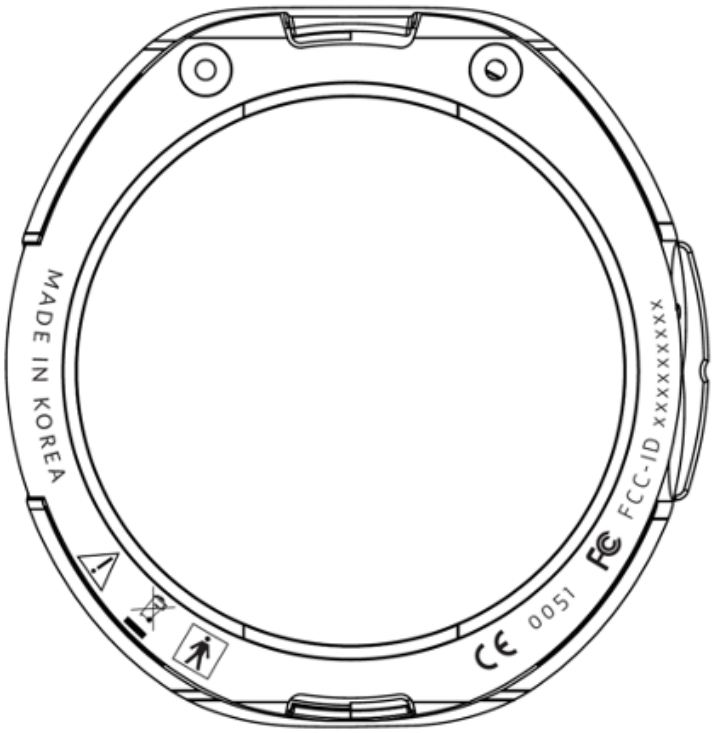

Figure 2 - Drawing representing the front view of EmbracePlus with band detached

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 xxxxxxxxx
- **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

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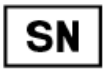
- IEC 62366-1:2015 Medical devices — Part 1: Application of usability engineering to medical devices
- ISO 10993-1:2018 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a risk management process
- EN ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests 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

EmbracePlus Symbols used in labeling

Symbols used in labeling

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

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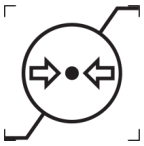
IP 67	Indicates that EmbracePlus is classified as IP67 - resistant to submersion in 1 m (about 3.3 feet) of water for up to 30 minutes		Keep in dry conditions and away from rain
	Indicates the device Lot Number		Indicates the minimum and maximum temperature at which the EmbracePlus shall be stored
	Indicates the minimum and maximum pressure at which the EmbracePlus shall be stored		Indicates the minimum and maximum humidity at which the EmbracePlus shall be stored
	Indicates the need for the user to consult the EmbracePlus instruction for use for important information, warning and cautions		Indicates the web address at which the device instruction for use can be found

Intended use

EmbracePlus is intended to collect, process with embedded AI/ML algorithms, store, transfer and remote monitoring of the following physiological parameters: Pulse Rate, Pulse Rate Variability, Respiration Rate, Temperature, SpO2, Electrodermal Activity (EDA) and Rest Detection.
EmbracePlus is intended for temperature monitoring where monitoring temperature at the wrist is clinically indicated.

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 :

- Pulse Rate;
- Pulse Rate Variability;
- Respiratory Rate;
- Temperature;
- SpO2;
- Electrodermal Activity (EDA); and

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- Rest Detection.

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

Intended population and use environment

EmbracePlus is intended to be used by 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.

Patients population and Medical Conditions

User population

- Age: from 2 years of age (there might be limitation of wrist circumference for the wearable device) to elderly
- Weight: not relevant, but there might be limitation of wrist circumference
- Health status: not relevant since EmbracePlus is not intended to be a primary diagnosis tool
- 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

- 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.

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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.

Warnings and Precautions

Warnings

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 5V (volt) USB power supply certified with IEC 60950-1 to charge EmbracePlus on-wrist charger.
11. The EmbracePlus on-wrist 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.

Precautions

1. Do not place the EmbracePlus watch over broken or damaged skin.

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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.

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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 in-person 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.

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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

EmbracePlus 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	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.

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Technical Specifications and Performance Characteristics

Performance Characteristics

Physiological Parameters measurement	**Pulse Rate**	**Range:** 30 - 220 bpm **Resolution:** 0.01 bpm **Accuracy:** 3 bpm A_{rms}
	PRV - RMSSD	**Typical range:** 0 - 300 ms **Resolution:** 0.01 ms **Accuracy:** 98% of positive agreement, with respect to the ECG. Absolute relative error < 10%. The comparison was made on recordings of healthy subjects in still conditions.
	Respiration Rate	**Range:** 4 - 60 rpm **Resolution:** 1 rpm **Accuracy:** 3 rpm A_{rms}
	Temperature	**Range:** 0ºC - +50ºC **Resolution:** 0.1ºC **Accuracy:** ± 0.1ºC within 30.0ºC - 45.0ºC range
	ElectroDermal Activity	**Range:** 0.01 µSiemens – 100 µSiemens. **Resolution:** 1 digit ~ 900 pSiemens.
	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.
	SpO_2	**Range:** 70% - 100% **Resolution:** 1 % **Accuracy:** 2% A_{rms}

A_{RMS} accuracy is a statistical calculation of the difference between device measurements and reference measurements. Approximately two-thirds of the device measurements fall within +/- A_{RMS} of the reference measurement.

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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. Recorded data will be transferred to the paired smartphone as soon as the connection is re-established. EmbracePlus is dust tight, meaning dust will not enter the inner part of the device. **On-Wrist Charger**: IP 53 The On-wrist charger is safe to use under the rain. Do not use the On-Wrist charger while showering or swimming. On-wrist charger is dust protected, meaning that the ingress of dust is not entirely prevented, but the quantity of dust that might enter the device will not interfere with the satisfactory operation 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 Band Extension	**Increased circumference**: 40 mm **Features**: Can be plugged into the normal band to allow for bigger wrist sizes **Materials**: Organopolysiloxane mixture
EmbracePlus On-Wrist Charger	**Diameter**: 40 mm **Thickness**: 20 mm **Weight**: 30 gr (including battery and electronics) **Materials**: Polycarbonate **Battery type**: 3.8V Li-ion **Battery capacity**: 320mAh **Battery life**: 2 years or up to 500 cycles **Feedback**: Tap-sensitive case with 4 RGB LEDs to signal On-Wrist Charger battery level and EmbracePlus battery level **Charging port**: Type-B micro USB **Cable**: Type-B micro-USB to USB-A. Length 10 cm
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)

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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, always-on, 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, menu navigation.
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**: 0.01ºC **Accuracy**: ± 0.1ºC within 30.0ºC - 45.0ºC 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)

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Data Collection Specifications

Synchronization	**Sensor synchronization:** All sensors are always synchronized between them. The sensor raw data contains exactly the same amount of data at a nominal frequency for every sensor. **Internal synchronization**: EmbracePlus internal clock has a maximum accuracy of ± 5 ppm (parts per millions). Thus, as every other electronic system, over a long enough period of time the internal clock might drift. **Timestamp synchronization**: When EmbracePlus is connected to the phone via Bluetooth® connection, it is using the accurate UTC timestamp in milliseconds (obtained via Network Time Protocol - NTP). This synchronization allows to estimate and compensate the EmbracePlus internal drift in order to export sensor raw data with an accurate timestamping.
Data collection configuration	**Device standby**: EmbracePlus is always-on (no switch-off feature for the users) **Data recording**: EmbracePlus is always collecting data (recording only pauses while the device is charging using the cable charger, with the On-Wrist Charger the recording is not paused) **Bluetooth® reconnection**: When the paired phone is in range, EmbracePus connects to it immediately and automatically **Data synchronization**: EmbracePlus aggregates the data coming from its sensors every minute. When the Bluetooth® connection is continuously available, EmbracePlus transmits the most recent minute of data recorded to the paired phone. Otherwise, when a Bluetooth® connection is not available, EmbracePlus stores the data in its memory and then synchronizes it (oldest data first) when the connection is re-established. **Overwrite policy**: EmbracePlus is using a FIFO (first-in, first-out) policy when its memory is full, namely the most recent data is not saved in its memory (discarded) to preserve older data.

Sensors Configuration

	HR-optimized & respiration-optimized configuration	**HRV-optimized**
Description	Configuration to optimize HR and HRV performances while maintaining a good rate of battery consumption and data generated.	
Accelerometer	52 Hz, ±16g	
Gyroscope	OFF	
Temperature	1 Hz	
PPG	52 Hz (red/green wavelenghts)	104 Hz (red/green wavelenghts)
EDA	4 Hz	
Battery duration	3+ days	
Memory capacity	24+ hr	

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(duration of data recording when EmbracePlus is not connected via Bluetooth® without overwriting data)	
Transfer time (time to transfer data saved in the EmbracePlus memory)	5 minutes per hour of recording stored
Data connection requirement (amount of data uploaded from the phone to the Empatica cloud)	~ 2.4 MB per hour of recording
Data storage requirement (amount of data used in the Empatica Cloud, it's the amound of data downloaded when performing analysis on sensor raw data)	~ 10 MB per hour of recording

Data Flow and Access

Sensor raw data	**Description**: Raw data is the high-frequency data collected via the EmbracePlus sensors. **Flow**: Sensor Raw Data is recorded from EmbracePlus' sensors and when available, transmitted via Bluetooth® using a proprietary protocol to the paired phone. The phone aggregates circa 15 minutes of raw data and uploads them securely to the Empatica Cloud. In the Empatica Cloud data is compartmentalized and accessible according to the Study/Site/Date of acquisition (i.e. /ORGANIZATION/STUDY/SITE/YEAR/MONTH/DAY/USER/DEVICE/timestamp.avro). **Data type**: When accessing Empatica Cloud, the sensor raw data will be downloadable/accessible/synchronizable as 15-minute Avro files (https://en.wikipedia.org/wiki/Apache_Avro) identified by a chronological timestamp. The Avro schema contains the types of data EmbracePlus is collecting (see below for the complete list). **Data access**: The sensor raw data are stored in the Empatica Cloud and can be accessed either via APIs or via data bucket access. When requesting data via APIs, Empatica's Cloud will return one-time secure pre-signed URLs with a list of Avro files that correspond to the timeframe requested. When accessing directly the bucket associated with the specific organization (Empatica needs to set up this process in advance), sensor raw data can be downloaded in any amount (FTP-style download). **Data usage**: Avro files can be used through the provided tools (https://avro.apache.org/docs/current/).

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Biomarkers	**Description**: Biomarkers are pre-processed data by Empatica's algorithms that are calculated every minute. **Flow**: Biomarkers are computed in-app every minute from sensor raw data and securely uploaded to the Empatica Cloud. **Data type**: Biomarkers files can be used as normal CSV files. Each row is 1 minute for the specific day and each column is a type of biomarker calculated (see below for the complete list). **Data access**: Biomarkers are accessible in the same way as the sensor raw data when accessing the data bucket (see Data Access section above). Biomarkers can also be visible in the Care Portal (see Software section below). **Data usage**: Biomarkers files can be used in almost every editor. **API access**: The Empatica Biomarkers Service (coming in Q1 2021) makes all the biomarkers available for a given timeframe for a specific user (request up to 14 days of data in one request). The data is provided in json file format.

Sensors Raw Data Specifications

The frequencies of the sensor raw data are the ones specified in the sensor configurations above.
The Avro schema can be shared upon request together with a sample dataset.
The content of an Avro file is summarized below:

General Information	**Schema Version**: (string) Version of the Avro schema used **Firmware Version**: (string) Version of the EmbracePlus firmware **Timezone**: (int) Delta in seconds from UTC time at the location of the user **User Identifier**: (int) Internal user identifier in Empatica's systems **Serial Number**: (string) EmbracePlus Serial Number
Timestamp	(long) Timestamp in UTC (µs) of the start of the file. All the sensor's starts are synchronized with this timestamp.
Acceleration	**Description**: Data from 3-axis accelerometer sensor expressed in ADC counts. Conversion to actual gravitational units (g) can be performed using physical and digital dimensions of the selected configuration. **Sampling frequency**: refer to the sensor configurations above. **x**: (array/int) Acceleration in the x-axis (ADC counts) **y**: (array/int) Acceleration in the y-axis (ADC counts) **z**: (array/int) Acceleration in the z-axis (ADC counts)
Gyroscope	**Description**: Data from 3-axis gyroscope expressed in ADC counts. Conversion to actual degrees per seconds (dps) can be performed using physical and digital dimensions of the selected configuration. **Sampling frequency**: refer to the sensor configurations above. **x**: (array/int) Angular velocity in the x-axis (ADC counts) **y**: (array/int) Angular velocity in the y-axis (ADC counts) **z**: (array/int) Angular velocity in the z-axis (ADC counts)
Peripheral Temperature	**Description**: Data from temperature sensor expressed degrees on the Celsius (°C) scale. **Sampling frequency**: refer to the sensor configurations above. **Values**: (array/float): Temperature (°C).

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ElectroDermal Activity	**Description**: Data from the electrodermal activity sensor expressed as microsiemens (µS). Uses a galvanic skin response sensor. **Sampling frequency**: refer to the HR-optimized configuration above. **Values**: (array/float) Electrodermal activity (µS).
Interbeat Interval	**Description**: List of time intervals between individual heart beats. **Values**: (array/long + array/int) Timestamps in UTC (µs) of the heartbeat + Interbeat interval (µs).
Blood Volume Pulse	**Description**: Blood Volume Pulse from photoplethysmograph. **Sampling frequency**: refer to the sensor configurations above (PPG field) **Values**: (array/float): Light absorption level (arbitrary unit).
User Tags	**Description**: Event corresponding to a user's action on the EmbracePlus (i.e. marking an event with the event tagging procedure). **Values**: (array/long): Timestamps in UTC (µs) of the event tags.
Other Info	**Sampling frequency**: 1 minute. **Charge status:** (array/int) a value that indicates whether the device is charging or not for each minute. **Battery level:** (array/int) battery levels from 0% to 100% for each minute. **Memory level:** (array/int) memory level available from 0% to 100% for each minute.

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Storage and Use Conditions

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

NOTE: After storage at the extreme temperature indicated in the table above allow the device to return to room temperature (15ºC – 30Cº) before wearing EmbracePlus by leaving it at room temperature for at least 30 minutes.

Dust and Water Resistance

EmbracePlus
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. Recorded data will be transferred to the paired smartphone as soon as the connection is re-established.

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

On-Wrist Charger
The On-wrist charger of EmbracePlus is safe to use under the rain. Do not use the On-Wrist charger while showering or swimming.

On-wrist charger is dust protected, meaning that the ingress of dust is not entirely prevented, but the quantity of dust that might enter the device will not interfere with the satisfactory operation of the device.

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Compatibility with MR and X-ray Scanning

You must not wear EmbracePlus 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

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 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 FCC id of the EmbracePlus is:

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, 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)

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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.

Electrostatic discharge might cause EmbracePlus to reset. Reset will last approximately 20 seconds, after which EmbracePlus will restart recording data. Based on the performed risk analysis missing 20 seconds of data has been identified as an acceptable risk, since it does not have impact on the user safety.

Immunity Test	IEC 60601-1-2 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 EmbracePlus, 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 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.

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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

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Getting started with EmbracePlus

How EmbracePlus works

EmbracePlus physical device is worn on the user's wrist and continuously collects raw data via its sensors installed on the device body, named POD, or on the device strap. EmbracePlus is equipped with the following sensors:

- EDA (Electrodermal Activity)
- PPG (Photoplesmography)
- Accelerometer
- Temperature

The collected data is elaborated quasi-realtime by a set of specific algorithms and models onboarded on the device firmware, the results of the algorithms are specific physiological data. The algorithms and models available for EmbracePlus will be:

- Pulse Rate;
- Pulse Rate Variability;
- Respiratory Rate;
- Temperature;
- SpO2;
- Electrodermal Activity (EDA); and
- Rest Detection.

All these algorithms are included in a system component called EmpaDSP.

The elaborated data will be further elaborated to make them sendable to a mobile device using BLE protocol. The mobile device paired with the EmbracePlus device will have a specific compatible mobile application installed that will receive the data and show them to the user. This compatible mobile application will also send the data via mobile device data connection to a specifically developed Backend (Cloud) where the data will be unpacked and further elaborated if requested by specific algorithms.

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What EmbracePlus comes with

The EmbracePlus package contains:

1 EmbracePlus POD

Already connected to

EmbracePlus Strap (or Band)

1 EmbracePlus OWC

Charging cable

Please be careful when unboxing EmbracePlus to avoid possible damages to the device

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How to wear EmbracePlus

It is important that EmbracePlus is worn correctly to ensure all the device sensors are in contact with the user's body. Correct contact between sensors and the user's body ensures correct physiological parameters collection and computation.

Wear the EmbracePlus with the pod on top of the wrist, so the display faces upwards and the PPG sensors is on the bottom, touching the skin. The EDA electrodes found on the band should line up on the bottom of the wrist. Line them up under the middle and ring fingers.

Wrap the band over snaps and tighten. Make sure the EmbracePlus band is tight enough to ensure the EDA electrodes do not change position on the skin during normal movement but not so much as to constrict blood flow or cause discomfort. Adjust the band by sliding up the wrist towards the elbow until it is snug. Reposition the band if it becomes loose during use.

Charging EmbracePlus

EmbracePlus shall be exclusively charged using the provided On-Wrist Charger. While worn, the EmbracePlus should be charged with the OWC not connected to a power source. While the EmbracePlus is not worn, the OWC can be connected to a power source and either charge the EmbracePlus' battery or its own battery.

EmbracePlus battery cannot be replaced neither from the user nor from Empatica personnel

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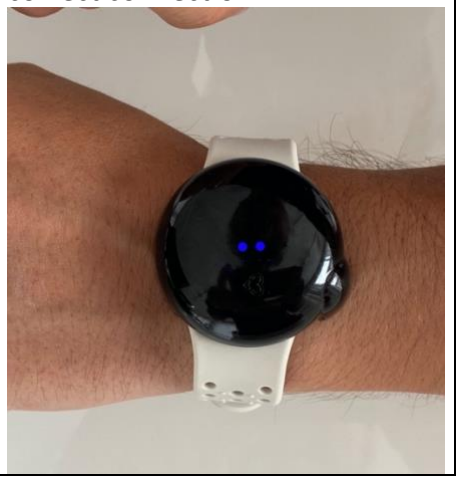
How to correctly position the OWC on the EmbracePlus

EmbracePlus Top View 	EmbracePlus Side view – charging pins are visible 	OWC Top View 
OWC Bottom View – charging pins are visible 	Position the OWC on top of the EmbracePlus display. 	Make sure to position the OWC charging pins in line with the EmbracePlus charging pins 
Connect the OWC charging pins to the EmbracePlus charging pins 	Completelly lower the OWC on the EmbracePlus. 	By tapping on the OWC top surface LEDs appear to indicate correct connection 

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Setting up EmbracePlus

EmbracePlus should be switched on by placing the On-wrist charger on top of the eInk.

Using EmbracePlus with compatible Care App

EmbracePlus is compatible with Empatica Care App. For using EmbracePlus with the Care App please refer to the specific Care App instruction for use.

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Maintenance & Cleaning of EmbracePlus

EmbracePlus does not need particular inspections, maintenance or calibration to reach its intended performances. Good general care shall be taken when using the device to avoid involuntary damages such as falling or crash damages.

Cleaning of the EmbracePlus

EmbracePlus is designed to be suitable for repeated use by multiple users. The customer must ensure that the device is properly disinfected before being transferred between individual users to prevent the transmission of skin diseases.

EmbracePlus and all its accessories were cleaned before shipment but must be considered as non-sterile. Before switching between users and at least weekly, it is recommended to clean the device. The disinfection process should include one or more of the following methods:

- Exposure to UVC lamp with a wavelength between 200 – 280 nm,
- Cleaning the EmbracePlus by wiping it with isopropyl alcohol (concentration ≥70%),

Remember to power off the device before cleaning. Make sure any residual cleaning solution has dried prior to powering on the EmbracePlus after cleansing.

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

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EmbracePlus User Interface Guide – Frequently used functions

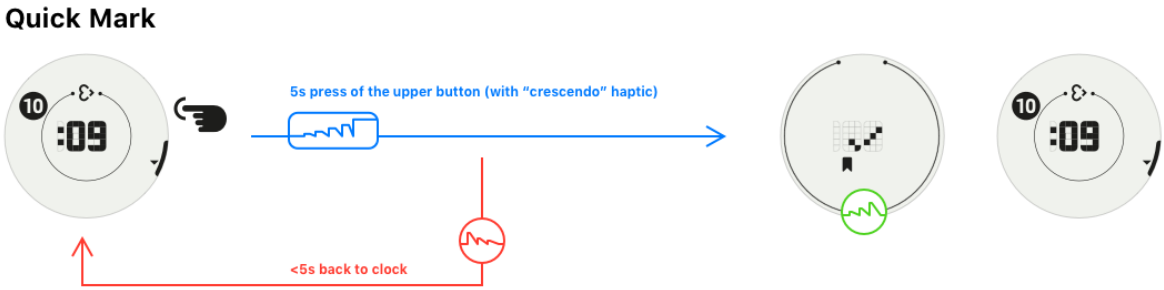
EmbracePlus main interactions, frequently used functions, with users are:

- **Present local hour**

EmbracePlus hour is continuously presented and updated every minute, the local time is acquired by the paired smartphone

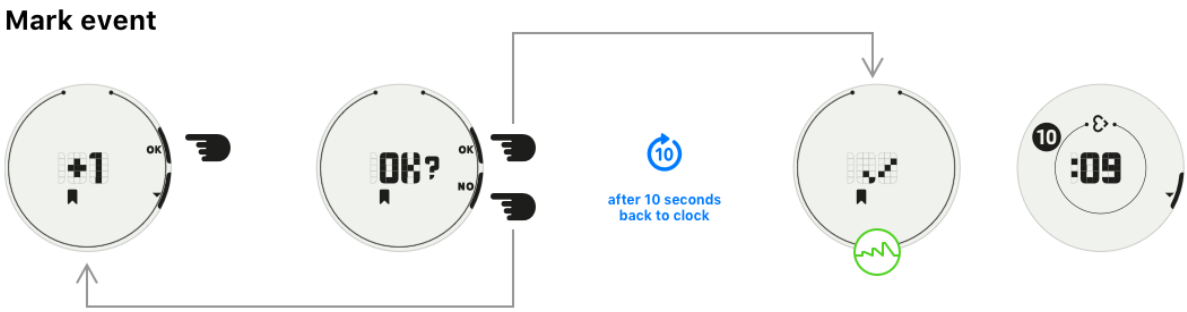
Blinking colon symbol (:) indicates the device is working as expected.

- **Quick Mark Event**



Users are able to mark events using the EmbracePlus. Marking events is performed by holding the top button for 5 seconds. Confirmation of positive execution is visually presented on the device eInk and by a device vibration happening at the same time

- **Mark Event**



The more complex mark event feature works as follows:

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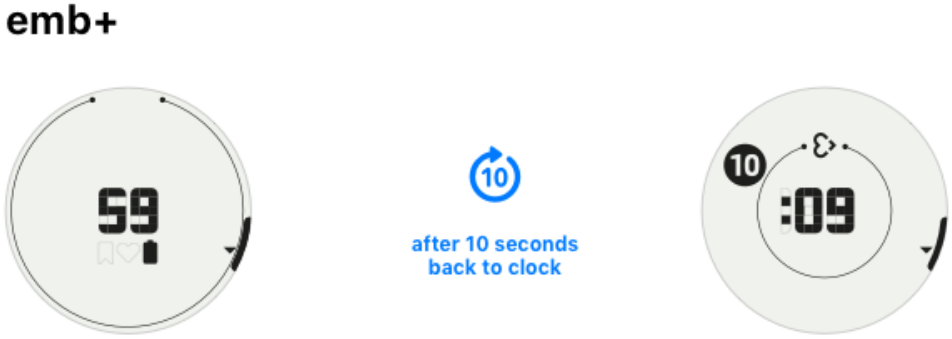
Starting from the main EmbracePlus screen → Click top button → Visualize +1 page → Click top button → Visualize OK? page → Click top button to confirm OR Click bottom button to say NO :

- IF clicked OK → When timestamp has been saved: Visualize tick mark and success vibration – two seconds timeout – Main clock face
- IF clicked NO → Go back to main watch face

If, at any point in the flow, there's no interaction with either button, the usual 10s timeout applies and the screen goes back to the main EmbracePlus screen.

The down button is utilized in the +1 screen to continue the navigation to the battery percentage visualization.

- **Device Battery Percentage Visualization**



EmbracePlus battery percentage can be visualized by clicking once the bottom button of the EmbracePlus

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- **Connection-Disconnection**

On the main EmbracePlus screen the empatica logo functions as a sign of active or inactive connection with the paired device.

Shaded icon means absence of connection while a well defined icon means EmbracePlus is connected to the paired smartphone.

- **Memory Full**

When EmbracePlus memory is 90% full, a warning is visualized.

The screen transitions to night mode, at the same time:

- the ! icon on top row appears
- vibration with warning pattern occurs x1
- screen shows the animation FU LL x2
  - total duration of the animation 5 seconds

After the animations, the screen transitions back to the main EmbracePlus screen, fixed to night mode. The ! icon on the top row remains fixed until the memory usage goes below 90%. When memory usage goes below 90% the screen transitions back to day mode

- **Battery Low Warning**

When the EmbracePlus battery reaches 20%, a warning is visualized.

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The screen transitions to night mode, at the same time:

- the half battery icon on bottom row appears
- vibration warning pattern occurs x1
- screen shows “low” message for 5 seconds
  - total duration of the screen is 5 seconds

After the “low” screen, the screen transitions back to the clock face, fixed to night mode. The half battery icon on the bottom row remains fixed until the EmbracePlus is put in charge. When EmbracePlus is put in charge the screen transitions back to day mode.

On-Wrist Charger LEDs guide

The On-Wrist Charger has 4 LEDs on its top to communicate its charging status. It can also interact with the user by receiving a single tap.The interactions are the following:

- Startup animation: white LEDs toggle to signal device has re-booted.
- Single-tap event: the two central LEDs turn blue to signal tap-event has been detected, intended to verify that device is alive.
- State-of-charge during charging: when USB is plugged in, state-of-charge is reflected by the number of green LEDs.
  - 1LED= 0-25%
  - 2LED = 25%-50%
  - 3LED = 50%-75%
  - 4LED = 75% - 100%
- Short circuit on output: 4 red LEDs to signal fatal error.

How to safely dispose of EmbracePlus

Dispose of the EmbracePlus, the EmbracePlus On-wrist charger, the EmbracePlus straps and USB cable in accordance with local regulations. Do not dispose of the battery with regular household waste. Recycle your EmbracePlus package in accordance with local regulations.

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Troubleshooting

Empatica Support

For information concerning EmbracePlus and its use, please review our Support Center articles at https://support.empatica.com.
We are available to answer your questions at +1 (866) 739-2049.
You can also contact us by submitting a request at https://support.empatica.com/hc/en-us/requests/new, or sending us an email at support@empatica.com and we'll respond as soon as we can.

Privacy

Protecting your privacy

We take personal data security very seriously. We are in full compliance with **GDPR** and have extended its security benefits to all of our customers **worldwide**.

How we use your data

We'll use your personal data for the **sole purpose of providing our services**, and to contact you about updates that could compromise the service if no action is taken.
You have the **right to choose** if you'd like to receive other updates, such as blog posts, special offers, and our latest research advancements.
We have recently updated our Privacy Policy (https://www.empatica.com/privacy/) so you can easily understand exactly what personal information we collect and how it will be used.

How you can manage your data

You can always review and update your information and how we use it at any time. If you'd like to be removed from our database, **you can request a permanent removal of your account** and personal information. You can also ask us to export and send you your personal information. You can send these requests to support@empatica.com.

Additional protection for minors

We firmly believe that minors should be specially protected from the collection of personal data. We've implemented an **additional security** measure for them which maintains that parental consent is provided for any EmbracePlus user under the age of 13.

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