PRESCRIPTION EMBRACE

INSTRUCTIONS FOR USE

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Product Description

Introduction

The Embrace is a medical device that is intended to be used by people living with epilepsy.

The Embrace is a prescription only (**Rx Only**), single patient use, class II medical device according to FDA 21 CFR Part 860.3 within US and a class 2a according to 93/42/CEE Directive within Europe.

It is important that the caregiver maintains the same level of care as before the use of the Embrace. The Embrace mainly consists of two components:

- The Embrace watch
- The Alert App

Indication for use statement

The Embrace is a prescription only device that is indicated for use as an adjunct to seizure monitoring of adults and children age 2 and up in home or healthcare facilities during periods of rest. The device is worn on the wrist and senses Electrodermal Activity (EDA) and motion data to detect patterns that may be associated with generalized tonic clonic seizures in patients with epilepsy or at risk of having epilepsy. When a seizure event is detected, Embrace sends a command to a paired wireless device that is programmed to initiate an alert to a designated caregiver. The System records and stores data from Accelerometer, and EDA sensors for subsequent review by a trained healthcare professional.

Limitations:

- (i) For prescription use only.
- (ii) The device is not intended to be used to guide medical therapy decisions

(iii) The safety and effectiveness of the Embrace System has not been established in monitoring signals that may be associated with seizures other than convulsive seizures

- (iv) The device is not intended to be used as a stand-alone monitoring device
- (v) The device is not intended to be used during physical activity
- (vi) The device does not predict seizure onset

Intended Environment

The Embrace is intended for use in home or healthcare environments during periods of rest.

Intended Population

The Prescription Embrace is intended for use in adults and children age 2 and up with epilepsy or at risk of having epilepsy.

Precautions for Use

The Embrace is a class II medical device according to FDA 21 CFR Part 860.3 within the US. Risk analysis has demonstrated that the Embrace can be considered a low risk profile device. It is important to not reduce seizure management practices when using Embrace.

The Embrace 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.

Warnings

A. For the timely delivery of notifications to Caregivers, the following conditions must be met:

- The user wearing the Embrace watch remains within close proximity (< 30 ft) to the paired smartphone running the Empatica Alert app.
- The paired smartphone must be connected to the internet.
- The Caregiver's phone must be connected to a wired or wireless telephone network.
- The Alert app and/or Embrace does not show any warning message (i.e. RED led).
- The Embrace, paired smartphone, and caregiver phone must be charged and operating properly.

B. Users who wear pacemakers, or have health conditions which might be sensitive to the tiny electrical signals used by the Embrace in measuring EDA should always consult their physicians before wearing an electronic device, including the Embrace watch.

C. If Embrace is used in a manner not specified by the manufacturer the protection it provides could be compromised.

D. Adult supervision is required. Due to the presence of small parts used in the Embrace it is strongly advised that the device only be used on small children under adult supervision.

E. Use the Embrace only with original accessories provided by Empatica. Other cables and accessories might impact the EMC performances.

F. The use of the accessory, transducer or cable with the Embrace other than those specified may result in increased emissions or decreased immunity of the Embrace.

G. Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment.

H. Do not store the Embrace close to other electrical equipment.

I. Portable RF communications equipment, including antennas, can affect the Embrace, thus they can be used no closer than 30 cm (12 inches) to any part of the Embrace.

J. Use USB power supply certified with IEC 60950-1

K. The Embrace charger may generate heat; be careful when handling it during the charge.

Cautions

A. Do not place the Embrace watch over broken or damaged skin.

B. Do not use unapproved accessories with the Embrace watch.

C. The buckle and the face of the Embrace are made of aluminum and nickel-free chrome plated metal, and the band is made of stretchy synthetic fabric material composed of Spandex 21% Nylon 79%. The electrodes are in surgical stainless steel (SUS316L), which should not cause any skin reactions. Nevertheless, if a person has a known metal allergy or is generally sensitive to skin contact with metals, please contact Empatica before wearing the device. Keep Embrace clean so that bacteria and dirt do not build up and cause skin itching or irritation or impair sensing.

D. Check the Embrace for sharp edges and damage before each use. Do not use it if damaged.

E. Do not leave Embrace in environments in which the device may overheat beyond the recommended environmental limits (such as a hot car). If the Embrace is left exposed to high temperatures, allow it to cool before handling it to avoid potential skin burns.

F. Users should never attempt to wear the watch while charging the battery.

Synthesis of hazards

Risk #1: In the worst case, the user and/or caregiver could change their behavior and rely too much on Embrace, leading to less than adequate supervision. It's possible that Embrace may not detect 100% of all seizures or deliver alerts accordingly; therefore, there is still a possibility of death while wearing Embrace.

Risk #2: Embrace detects the seizure and the alert is not received by the Caregiver in an appropriate time frame because:

- The Bluetooth connection between Embrace and the secondary device fails .

- The secondary device fails to communicate with the notification system (i.e., no internet connection).

- The notification system fails to efficiently deliver the call or SMS.

- The caregiver's phone/the caregiver fails to receive the notification.

Risk #3: It may occur that Embrace misidentifies an activity as a seizure, when in reality, it is not. This is called a "False Alarm". If the wearer does not cancel them in time, it could cause both the user and caregiver inconvenience and annoyance. Too many false alarms can lead caregivers to ignore alerts or patients to stop using the device.

Risk #4: Biocompatibility (skin rash; contact dermatitis)

Electrodes are made of SUS316L. The band is made of polyester and polyurethane that are commonly used in the textile industry. The band frame is made of aluminum and has a nickel-free plating, a material commonly used in wearable devices. The top cover is made of anodized aluminum, and the bottom cover is made of painted polycarbonate; both are materials commonly used in wearable devices. Empatica conducted biocompatibility analysis according to the ISO 10993 standard and will monitor with post-market data the incidence of allergic reactions. The rate to date has stayed below 1% of all users experiencing any dermatitis.

Risk #5: Failure in the software (firmware or mobile app) could cause the algorithm, connectivity, or communications to fail. We have implemented many tests, including quality and usability checks of the software. We also have data quality checks on the server side that can help identify sensor failures (although these should be rare). We have prepared a detailed analysis of this that we can share. We deem these risks to be minimal.

Risk #6: Electrical safety and hardware failure/battery damage: The Embrace is designed to reduce the risk of short circuits of battery voltage using a power supply unit. In addition, we conducted the test for IEC 60601-1 and ISO 62133 to verify that risk mitigation is successful.

Risk #7: Electromagnetic compatibility

Very Low risk level – no harm – Design validation and verification has been conducted and has demonstrated that the Embrace is safe for use with other electronic devices. It is compliant with the following standards: IEC 60601-1-2:2007 (third edition) FCC CFR 47 Part 15C e IC RSS-210_RSS-247 (Industry Canada)

ETSIEN301489-1e3V

There should be no precautions to be taken for any interference with the magnetic fields, or to the environmental conditions of use, both for the patient and/or the operator.

Risk #8: Security of IT system: The data transfer between Embrace and the mobile phone is encrypted according to Bluetooth[®]. which can be lost during use if the subject does not wear the watch snugly on the wrist.

Light condition - 100-500lx, Visual distance: 20-40 cm, Visual angle +-90°.

Environmental condition - Temperature -20°C +70°C, Relative humidity 20% - 95%, Air pressure – 500hPa to 1200hPa, Acoustic level - not relevant.

Use frequency - It is extremely variable depending on user/practitioner prescription: Standard use is continuous with the exception of charging time.

Proper storage after use - The Embrace should be properly stored. Do not expose Embrace to direct sunlight, moisture, humidity or rain.

Product disposal - Dispose Embrace, charging dock, and USB cable in accordance with local regulations. Do not dispose the battery with regular household waste. Recycle the package in accordance with local regulations.

Use with other accessories (i.e. battery charger) - It's forbidden to use the Embrace with accessories, not approved by Empatica. It is prohibited to plug the Embrace into any power supply/power adaptor that is not compliant with IEC 60950-1. Check with your retailer to ensure compliance.

Battery preservation

The Embrace can be stored in its original box for a maximum of 1 month without charging. If the Embrace will not be used for longer than 30 days, make sure to charge it at least once a month to preserve the battery.

Disinfection before use

The Embrace is designed for repeated use by a single user. You can disinfect it using methyl alcohol or soap and water.

MR Environment

The Embrace has not been evaluated for safety and compatibility in the MR environment. The Embrace has not been tested for heating or migration in the MR environment.

Remote patient monitoring

The Alert app is not intended to be used for remote real time patient monitoring. Data can only be transferred to the smartphone when Embrace is within the Bluetooth range.

EMC Environment

The Embrace needs special precautions regarding EMC and needs to be installed and used according to EMC information given below.

Mobile RF communications equipment can affect Embrace functioning.

Table 1

Guidance and Manufacturer's declaration- electromagnetic emissions			
The Embrace is intended for us in the electromagnetic environment specified below. The customer or the user of the Embrace should assure that it is used in such an environment.			
Emissions test	ns test Compliance Electromagnetic Environment/ Guidance		
RF emissions CISPR 11	Group 1	The Embraces 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 emissions CISPR 11	Class B	The Embrace is suitable for use in all establishments other than domestic and thos	
Harmonic emissions IEC 61000-3-2	Not applicable	power supply network that supplies buildings used for domestic purposes.	
Voltage fluctuations/ flicker emissions	Not applicable		
A. IEC 61000-3-3			

Table 2

Guidance and Manufacturer's declaration- electromagnetic immunity			
The Embrace is intended for us in the electromagnetic environment specified below. The customer or the user of the Embrace should ensure that it's 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 ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC 6100-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % UT (>95 % dip in UT) for 0,5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles <5 % UT (>95 % dip in UT) for 5 s	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Embrace requires continued operation during power mains interruptions, it is recommended that the Embrace be powered from an uninterruptible power supply or a battery.
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.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

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Table 3

Guidance and manufacturer's declaration – electromagnetic minumity			
C. The Embrace is intended for use in the electromagnetic environment specified below. The customer or the user of the Embrace should assure that it is used in such an environment			
IMMUNITY test	IEC 60601 TEST LEVEL	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms ISM 150 kHz to 80 MHz	3 Vrms 6 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the Embrace, including cables, than the recommended separation distance calculated from the equation, applicable to the frequency of the transmitter. Recommended separation distance $d=1,17\sqrt{P}$ $d=2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2,5 GHz 80% AM at 1kHz	10 V/m	d= 1,17 √P 80 MHz to 800 MHz d= 2,33 √P 800MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
 D. NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. E. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Embrace is used exceeds the applicable RF compliance level above, the Embrace should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Embrace. b. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. 			

Recommended distance between portable and mobile RF communications equipment and the device

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)150 kHz to 80 MHz80 MHz to 800 MHz800 MHz to 2.5 GHz $d = 1,17 \sqrt{P}$ $d = 1,17 \sqrt{P}$ $d = 2,33 \sqrt{P}$		
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.70	3.70	7.37
100	11.70	11.70	23.30

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

Note:

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

Prescription for Embrace in the US

A prescription is required for the Prescription version of Embrace. You'll need to ask your physician to upload the prescription using our platform.

If instead, you'd like to participate in the clinical trial, you'll be able start using Embrace as soon as you receive it, a prescription would not be necessary.

Get to know Embrace

Types of seizures Embrace detects

Embrace is **optimized to detect** seizures involving **convulsive movements** and a spike in autonomic stress with a duration of at least **20 seconds**. These characteristics are generally associated with **tonic-clonic** seizures.

We can't guarantee that Embrace will detect every single generalized tonic-clonic seizure. It is not meant as substitute to your current seizure monitoring practices, but rather to serve as a supplement in expediting first-response time.

At the moment we **cannot** detect the following types of seizures:

Complex Partial Seizures

Embrace is not designed to detect these types of seizures because **they usually do not generate convulsions.**

Absence seizures

These seizures are not detected by Embrace as **they do not generate significant motion and autonomic responses.**

Nonconvulsive seizures

Currently, Embrace cannot detect nonconvulsive seizures as the specific movement signature of **convulsions takes precedence in our algorithm**. EDA also takes part in our algorithm, but since it is more prone to fluctuation, relying too heavily on it would result in more false alarms.

Embrace's seizure detection system

Embrace's seizure detection is based on an algorithm we've developed that is **designed to recognize unusual movements and electrodermal activity variation.**

Most devices on the market usually consider two threads of information: how strong and how long you're moving. Instead Embrace takes into account additional variables, such as **3-axis acceleration and electrodermal activity variations**, that accompany tonic-clonic seizures. In addition, we created our algorithm using advanced machine learning methods, trained on data collected in epilepsy monitoring units in hospitals.

To learn more about Embrace's seizure detection algorithm we recommend this article: <u>Seizure</u> <u>detection accuracy</u>

We encourage you to learn more about how the Embrace works.

Compatible phones and tablets

The <u>Alert app</u> is compatible with most iOS and Android devices.

Apple iOS

Any iOS device that can run **iOS 9.3.5 or higher** as long as they support **Bluetooth® Low Energy** (BLE/4.0/Bluetooth Smart®).

We support:

- iPhone 5s
- iPhone 6
- iPhone 6 Plus
- iPhone 7
- iPhone 7 Plus
- iPhone 8
- iPhone 8 Plus
- iPhone X

We do support the following devices, however, the apps won't be fully optimized for them:

- iPhone 4s
- iPod 5th generation
- iPad 3rd generation
- iPad 4th generation
- iPad Air
- iPad Air 2
- iPad Mini

To check the current version of the operating system on your phone, please follow these steps:

On your phone go to:

- 1. Settings
- 2. General
- 3. About
- 4. Version

📲 vodafone IT 🗢	15:26	* 🔳
〈 General	About	
Songs		0
Videos		1
Photos		168
Applications		15
Capacity		16 GB
Available		1,33 GB
Version	11.2	.5 (15D60)
Carrier	Vodaf	one IT 31.1
Model	N	ILXN2IP/A

Android

Devices running **Android version 5.0 (Lollipop) or higher**, as long as they support Bluetooth Low Energy (BLE / 4.0 / Bluetooth Smart). We do not guarantee full compatibility with edited versions of Android or Android tablets.

To check the current version of the operating system on your phone, please follow these steps:

- 1. On your phone go to Settings
- 2. About Phone/Device
- 3. Software
- 4. Android Version

P F 🕥 ... 考 🖌 명 🖘 대 70% 🔒 3:51 PM SOFTWARE INFORMATION < Android version Samsung Experience version 8.1 Baseband version G955FXXU1AQK7 Kernel version 4.4.13-12502677 dpi@SWDD6603 #1 Mon Nov 20 16:54:39 KST 2017 Build number NRD90M.G955FXXU1AQK7 SE for Android status Enforcing SEPF_SECMOBILE_7.0_0009 Mon Nov 20 17:23:29 2017 Security software version MDF v3.0 Release 2 WLAN v1.0 Release 2 VPN v1.4 Release 8.1 ASKS v1.4 Release 161228 Knox version Knox 2.8 Standard SDK 5.8.0 Premium SDK 2.8.0 Customization SDK 2.8.0 Container 2.8.0 CEP 2.2.0 Enterprise Billing 1.3.0

Please note: not all devices that list Bluetooth 4.0 in the specifications, actually support Bluetooth Low Energy. We suggest contacting the manufacturer directly for complete information.

We do not support Windows and Blackberry phones.

How Embrace works

Embrace is designed to detect and alert for tonic-clonic (convulsive) seizures.

In order to use your Embrace you will need:

- A <u>compatible smartphone/tablet</u> with active Bluetooth® Low Energy and Internet connection.
- <u>Alert App</u>: sends alerts to your caregivers when a seizure is detected.
- <u>Embrace subscription</u>: gives you access to the alert system and allows you to choose additional features.

Embrace **collects physiological data** using its sensors (an <u>EDA</u> sensor, a gyroscope, an accelerometer and a peripheral temperature sensor). It **transmits this data** to the Alert App on the paired smartphone **through Bluetooth**[®]. The paired smartphone must be the user's phone, and it needs to remain within Bluetooth[®] range (30 feet/10 meters).

Using internet, the Alert App sends an **SMS and call to the activated caregivers** so they can help in the case of a seizure. Remember: **Both Bluetooth and Internet connection are necessary** for the Alert notifications to be sent when Embrace detects a tonic-clonic seizure.

What happens when there is a Bluetooth® disconnection?

Whenever Embrace <u>disconnects from Bluetooth®</u>, it won't be able to alert for seizures. It will continue to record your seizures on its internal memory for about 16-18 hours.

As soon as the Bluetooth® connection is restored, the information will be automatically transferred to the smartphone, freeing up Embrace's memory. Data transfer might take up to 1 hour and a half.

What happens if the smartphone isn't connected to Internet?

Alert calls and SMS are sent via Internet, so without it alerts cannot be sent to your Caregivers.

Remember that airplane mode disables internet connection and Bluetooth®.

Charging Embrace

Your Embrace comes with a **USB cable** and a **charging dock**. It takes around **2 hours** to fully charge the device. When the Embrace is **fully charged**, **a green LED circle will light up**. When charging your Embrace, be sure to have someone around that can provide help in the event of a seizure.

CHARGE YOUR EMBRACE WATCH VIDEO

(https://youtu.be/A0Hr8sOCVIY?list=PLgJGJZB1txiZM26ruTUIFP5edSZv10NqK)

Follow these steps to charge your Embrace watch:

- **Step One:** Connect the charging dock to a powered USB port on a computer, a USB <u>wall</u> <u>socket</u>, or a <u>USB Power adapter</u> connected to a power source.
- Step Two: Make sure the heart symbol matches the heart on the charging dock. If you cannot see the symbol, simply make sure the electrodes on the bottom of the device fit into the dents.
- **Step Three:** An orange light gradually fills the LED circle on the Embrace indicating that it is charging. This light will become green when it's fully charged.

If your Embrace battery was drained, a white circle will illuminate a couple of seconds after connecting the device to the charger, this indicates a reboot.

Additional tips:

When using a computer, make sure that it is connected to its external power supply, otherwise the Embrace won't charge or it may take longer to get a full charge.

For more info check:

It takes longer than two hours to charge my Embrace watch

My Embrace watch isn't charging

Embrace battery life

When fully charged, the **Embrace battery will last 30 hours.**

For optimal performance, we suggest charging the device for **2 hours daily**. We recommend charging Embrace when there's someone around, so that you're covered for the time you're not wearing it. For more information please read: <u>How Do I Charge My Embrace Watch?</u>

You can easily check the battery level of your Embrace on the status page of the Alert App. When the Embrace battery is low, you'll receive a notification on the paired smartphone, and your Embrace will start blinking an orange light.

The Embrace battery levels are listed below:

- Full (30-25 hours)
- High (25-18 hours)
- Medium (18-10 hours)
- Low (10 to 1 hour)
- Charge now (1 hour or less)

Checking Embrace's battery level

You can view the battery level in the Alert app. You'll find battery information in the Status tab.



You will receive a notification on the paired smartphone when the Embrace battery is low. Embrace will also display a blinking orange light when it's time to charge your watch.

Embrace battery level bars correspond to the number of hours of battery life left:



Advanced tip: activate the Alert app in the notifications bar so that you can easily check the battery level without opening the app. For Android devices, activation is automatic, to activate Notifications Center for iOS devices, follow <u>these steps</u>.

Tell the time with Embrace

You can check the hour by **tapping once on the Embrace cover**. The **blue light indicates the hour**, **and the flashing white light indicates the minutes.** Your Embrace will automatically sync with the time on your phone as soon as it is paired.



If you cannot see the time on your Embrace watch when you tap on its surface, please check if the <u>Light & Vibration</u> mode is deactivated.

Embrace app

Embrace works with one FDA cleared app: the Alert App.



The Alert App **notifies Caregivers** upon the detection of a **tonic-clonic seizure**. In the US, it is available only with a prescription or as part of a clinical trial.

Activating a <u>subscription plan</u> is necessary for seizure detection and sending alerts to Caregivers. With the purchase of your Embrace watch, you'll receive a 30 day free trial of the Plus plan.

For more information check out the <u>Alert App</u> section.

Embrace materials

We take great care in selecting the highest grade materials when designing our devices so that you have the most secure and comfortable experience

- Band: Polyester 80% and Polyurethane 20%
- Buckle: Aluminium, nickel-free chrome plated
- Case: Polycarbonate (PC) base and anodized aluminium
- **The electrodes:** surgical stainless steel SUS316L. The SUS316L steel alloy contains nickel but it has been carefully tested to ensure that it is compliant with safety regulations for watches and jewellery.

These materials are not likely to cause any allergic reactions, if you would like further information please see: <u>Allergic reactions to Embrace</u>

Embrace water resistance

Embrace can withstand swimming pools, sweat, rain, showers and snowball-fights. It has the **IP67** certification which means that it can be submerged in **1m (about 3.3 feet)** of water for **up to 30 minutes**.

Limitations

Embrace shouldn't be used in saltwater such as the ocean or saltwater swimming pools. In addition, **It shouldn't be submerged in a hot tub** or worn while deep sea diving.

Embrace and animals

Despite our immense love for animals, Embrace and its seizure detection system was designed to be safe and comfortable for long-term wear by adults and children only. It **has not been optimized to fit animals** at this time.
Protecting your privacy

We take personal data security very seriously. As of May 25, 2018, we are in full compliance with the General Data Protection Regulation (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 the blog, special offers, and our latest research advancements.

We have recently updated our Privacy Policy 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.

Additional protection for minors

We firmly believe that anyone underage 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 Embrace user under the age of 16.

Phone Support

We are available to answer your queries between **9:00 AM – 1:00 PM EST** (Eastern Standard Time), **Monday - Friday** at (866) 739-2049 or chat with us via our <u>website</u>

If you want to reach us outside of these hours, please contact us by <u>submitting a request</u> or sending us an email at **support@empatica.com** and we we'll respond promptly.

Empatica Account

Creating your Empatica Account

Your Empatica Account allows you to view information related to your Embrace order, shipment, and subscription. It also allows you to view and download your monthly seizure reports.

Step 1: Creating an Empatica Account is easy.

Here are the simple steps to create your Empatica account:

If you've placed an order:

1. You should have received an email with the link to create your account. If you haven't received this email, follow the steps in the next section.

2. Click on the link in that email to get started.

If you haven't placed an order:

1. Go to this page.

2. Enter the email address you used to place your order in the *email field* and fill in all the necessary fields.

3. Click on "Create My Account ".

Step 2. Review the Privacy Policy

The privacy policy describes the collection of your personal information and how it's used. Your consent is required in order to use our services.

We'll only send you emails you've given us permission to send you, unless it's an important update that affects your service.

You can always review and modify these settings directly in your Empatica Account.

Step 3. Verify your email address

Once you fill in the form, you'll receive an email with an account verification link. Please look for the email in your Inbox, and click on "Verify my Email Address" button. If it does not work, click the link below the button or copy and paste it into the address bar of your web browser.

Please note, if you are unable to find the email in the primary folder of your inbox, it is most likely that the email may have reached the Spam/Junk folders.

Step 4. Define your preferences

After verifying your email address, please proceed with the next step, which is defining your preferences for the Embrace watch.

Step 5. Sign up for Clinical Trial

For users in the US, joining the clinical trial is an essential step to receive seizure detection and alert delivery service.

Editing your shipping address

You can easily **change your address in your Empatica Account.** Once your order has entered the "Preparation" phase, it's almost ready to ship, and unfortunately the address can not be changed.

To edit your address, follow these steps:

- 1. **Sign in** to your <u>Empatica Account</u>.
- 2. Go to the **Orders section**.
- 3. Click on **"Change my shipping info"**.

		Order #			
		Status: Not Scl Read more on our	heduled		
	<mark>≥</mark> Ye	♥ You have filled in all the information will be notified a	ion needed for this order! when your order will be shipped.		
<	Shipping Inform Change my shipping inf	nation	Details Purchase Date		
	We will ship to	Shipping address	December 19 Subtotal \$249 USD Shipping cost Free shipping	,2016	
	Embrace Watch Milan Black - Stretchab	le Band	Total \$249 USD Net Paid		
	Base Price \$249 USD		\$249 USD		

4.	Make the necessary changes and click on "Update my shipping address"
----	--

다 안 왜 몸감을 알 수 없.		
U	pdate your shipping address	
We will validate	your shipping information to help the corre	ect pack
	denver y	
chii	ABC	
Shipping name		
Address Line 1	VIA PRIVATA, 00	
Address Line 2	Apartment, suite, unit building, floor, code entrée etc	
City	MILAN	
Zin		
Zip		
Country	Trany You cannot edit the Shipping Country because you already paid the shipping costs	
State / Desuises	Milan	
state / Province		

Resetting your Empatica password

Cannot access your account? Have you forgotten your password? Don't to worry! Please follow these simple few steps to reset your password:

- 1. Go to the **Empatica Account login page**.
- 2. Click on the "Forgot my password" button.

Lo: Manage vo	g into your Emp	patica Account	
Email	Enter your email address		
Password	Enter your password		
	I don't have an account!	I forgot my password!	
	Login		

3. Please enter the Email address as on your account and click on "Send me the reset link" button.

empatica E>		Log
	Get a link to reset your password	
	Receive via email the link to reset your password	
	O Click on the button below to confirm your email address.	
	Email	
	Send me the reset link	
	Login instead?	

4. The next step is to find the password reset email in your inbox. Open it and click on "Choose a New Password" The next step is to check your Inbox for the password reset email that was sent to your email address and click on "Choose a new password".



5. You will be redirected taken to another page wherein you can could input your new password.

empatica ()>		Login
	Reset your password	
Enter ti	ne new password for your Empatica Account	
New password	Enter your new password	
Confirm new password	Confirm your new password	
	Reset my pacoward	

6. Once you've set up a new password, you will receive an email confirming it confirmation for the same.

Empatica <sup to me 🗨</sup 	oport@empatica.com>	7:30 PM (13 minutes ago) 😭	•
	empatica 🏷		
	Dear		
	the password of your Empatica Account has been c	hanged.	
	Congratulations, it is a good habit to change your pa more secure.	sswords, it keeps your account	
	If you haven't requested to change your passw will take care of it	rord, reply to this email and we t.	
	Thanks for choosing Empatica,		
	The Empatica Team		

Updating your profile in the Empatica Account

You can change your personal information directly in your Empatica Account.

To modify your profile, follow these steps:

- 1. Log in to your Empatica Account.
- 2. Click on the "Account" tab in the top right corner.
- 3. Go to the "Update Profile" section.
- 4. Change the information that you'd like to modify.
- 5. Once, you've made the desired changes, click on "Update my profile".

	The second s			
	Update your profile			
Please enter the	information of the person that will we watch	ar the Emb	race	
First name	ABC			
Lett name	UST			
Ernall Of Charge my small	wyst@acchnail.com A not verified <u>verify nov</u> @We will send all communications to this amail address			
Password O'Durge my password				
Mobile phone	United States * +1 1234567040			
Country of Residence	United States Transited for Replicompliance purposes	•		
Day and month of birth	7 * January	•		
Year of birth	1933 Pre-entationneed is required for anyone under 13.	•		
Embrace preferences	C Complete the questionnaire			
Clinical Trial Agreement	Of Complete the Consent Form			

Parental Consent for minors under 16

All users of the Embrace watch who are **under the age of 16** need to provide Empatica with their parent's verifiable **consent**, as the U.S. Children's Online Privacy Protection Act (<u>COPPA</u>) requires us to obtain it before we collect, use or disclose their personal information. Obtaining your parental consent allows us to protect the privacy of your child.

Parental Consent during account creation

When you insert a birthdate of a user under the age of 16, you will see a special form where to enter the parents' personal information.

Make sure the email address entered in the Parental Consent email field is **different** from the one associated with your **Empatica Account**. Once you have entered all the necessary information, click the Create Account button. An email will be sent to the parent's email address with the link to **consent** to the collection of personal information from their child.

Changing my communication preferences

You can review and update your communication preferences directly from your Empatica Account by clicking on <u>Communication Settings.</u>

You can choose to start or stop receiving updates from Empatica about:

- Blog
- Special offers and discounts
- Product and research advancements

Please note that we will still inform you via email about updates to our service and how it's running. It isn't possible to opt-out from System notifications as we cannot securely deliver our services without them.

Exporting my data

You can request a full account of your personal data to verify its accuracy. You can submit a request to export your data through your Empatica Account, by clicking <u>here.</u>

What will be included in the file?

- Your seizure history
- Your personal information

It may take up to 30 days to receive the exported data in your inbox.

Deleting my Empatica Account

Before you decide to delete your account, please **note that it is permanent and cannot be undone**. It will also result in a full cancellation of our services to you.

What will be deleted?

- Personal Data (Full Name, Email address(es), Phone number, Date of birth)
- Caregiver(s) Data (Caregiver phone number, Caregiver email address)
- Parent email address (if any)

What will remain?

• Purchase information (orders, shipping address, invoices)

The following information will remain but will be de-identified:

- Usage logs and data
- Physical details (height, weight, year of birth)
- Embrace processed data

How to delete your account

- 1. Log in to your Empatica Account
- 2. Go to Account tab and open **Privacy Tools** section, then click "Edit Privacy Settings"
- 3. Click on "Delete My Account"
- 4. Scroll down and click "Delete My Account"
- 5. Send us the **"Delete Account" email.** A brief explanation for the request would be appreciated.

Please note, it may take up to 30 days to fully delete all of your information. We'll notify you as soon as the process has been completed.

GDPR FAQs for Embrace

What is GDPR?

It stands for the General Data Protection Regulation, legislation passed by the EU and effective from the 25th of May 2018. It's **intended to give EU citizens more transparency and control in the use of their personal data**, and **holds organizations accountable for how they collect**, **store**, **and process that data**.

How does GDPR apply to me?

We've implemented new security measures across the board, so **regardless of whether you reside in the EU**, **you'll benefit from the new practices** put into place. For any blog or newsletter subscribers, we've **made it super easy to select which topics you'd like to be notified about**. As an Embrace user, **you'll be able to request that we permanently delete your personal data or export it to you**. You can access your privacy tools and manage your communication preferences directly in your <u>Empatica</u> <u>Account</u>.

What personal information does Empatica collect?

We collect the **minimum amount of data needed in order to provide our services.** For example, in order to deliver the Embrace and provide its service we ask for name, date of birth, and contact details. The delivery of alerts requires that we collect the name and phone number of each Caregiver. Detecting seizures requires that we process physiological data, such as acceleration, rotation, temperature, and EDA. We also collect some technical information such as IP address, dates and times of access to the app.

How does Empatica use my information?

Your personal information is used **solely for completing a transaction** (e.g., purchasing Embrace or a subscription plan), **delivering and improving our services** (e.g., seizure detection, alert delivery), and communicating with you (e.g., emails or notifications about important product updates pertinent to its functionality).

How can I review and modify my privacy settings?

You can quickly and easily do this directly through your <u>Empatica Account.</u>

How can I ask to have my information deleted?

It's a simple request made through your <u>Empatica Account</u>. Please note this **step is permanent**, **and we would no longer be able to provide you with our services**.

What personal data are available for your download upon request?

The following data are available for download: **seizure history** (including detected seizures as well as those added manually), **name**, **date of birth**, your **contact details**, and the **name and contact details of your Caregivers**. You can submit a request to export your data through your Empatica Account.

Seizure Report

Keeping track of when seizures occur and what happened around that time helps you recognize possible triggers. In your <u>Empatica account</u>, you can view a monthly report of the detected seizures.



How to add a new seizure

In the report, you can not only see the seizures registered by Embrace but also add the ones that were not detected. You can insert the missed seizures manually by tapping the lightning bolt icon at the right bottom corner of your monthly graph (see also the article <u>Can Embrace work with any type of seizure</u>?)

5	8:23 PM	-	-	View
				Add Seizure 4
	3	3 8:23 PM	3 8:23 PM -	3 8:23 PM

You can add the date, exact time, duration of the seizure as well as any additional info. This will provide a complete overview of your events in a clear and organized manner.

Wher	n did th	ie seizu	ire happ	pened	?			
Day		Month			Year	Hour	Minute	
22	\$	Oct	ober	\$	2016	\$ 14	\$ 15	\$
What	shoul	d be no	ted abo	out this	seizure?			
	g the s	eizure	l experi	enced				
Durin								
Durin								

Insert notes and duration of seizures

To obtain a bigger picture of the history of your events, you can insert the exact duration of the seizures as well any additional info that might be helpful for yourself or your physician. As time passes you might forget what happened or how you felt before the seizure occurred. The Seizure Report might serve as a helpful diary so you'll never miss any significant info.

	his is a seizu	re detected by yo	u Embrace	. You can ad	ld notes or mark	as a false alarm.	
When did	the seizu	ure happened	d?				
Decembe You cannot e	r 15, 201 dit this date	6 @ 10:50 AM because it was de	A etected by	your Embra	ce		
How long	did the s	eizure last?					
Minutes		Seconds					
3	\$	30	\$				
What sho	uld be no	ted about th	is seizu	re?			
During th	e seizure	I experience	d				
							4
				_	Weisser		

Mark a detected seizure as false alarm

If you notice any incorrectly displayed seizures you can mark them as false. They will not appear in your Seizure Report; however, they will still be available on your Alert App.



Print the report

You can share this report with others, i.e. your physician or family members. The reports provide a neat summary of your events which you can print out, save as PDF or send via email. To do so, just click the print button, this will open a print friendly page which can be printed or saved as PDF.

		Print or save as PDF your seizure report to share it with your doctor		
December 201		🕀 Print		
Date	Time	Duration	Note 🕲	
12/07/2016 🥳) 12:03 PM	30s	Nocturnal, eye t	View

This is an example of your report:



Seizure Report

Review the seizures detected by the Embrace and reported by Timmy. If you want to know more about the seizure detection capabilities of the Embrace, we have prepared a short note at the end of this report.



Research and Medical

Studies behind the Embrace

In 2007, the <u>research team at MIT Media Lab</u> lead by Prof. Rosalind Picard – Empatica's Chief Scientist – developed a wearable that measured autonomic activity. While trying to help people with autism be better understood, Picard's team found an unusually high response from one participant. It turned out to be a seizure.

This led to new investigations with **Boston Children's Hospital**. With data from over **90 patients**, the team learned they had built a more accurate method for seizure detection.

Their research was **published** in top peer-reviewed medical and engineering journals, such as **Epilepsia**, patents were issued, and a version of their sensor was then used in hundreds of top labs, universities, and hospitals.

In one of the published studies (<u>Poh et al. 2012b</u>), the vast majority of complex partial seizures in a group of children caused a significantly large autonomic response. This work has been replicated in adults (<u>Thome-Souza et al. 2014</u>) as well, however, their autonomic responses tended to be milder.

The published results cited above were from predicate devices. To view recent findings using Embrace please see: <u>How Accurate is Embrace's seizure detection algorithm</u>

Consulting your physician about Embrace

We highly encourage that you **consult your physician to determine if Embrace is right for your needs.** The below articles will make it easier to cover everything you may want to discuss with your physician, including Embrace's detection capabilities, algorithm, and the research behind it.

- <u>Types of seizures Embrace detects</u> Use this article with to determine with your physician if Embrace is right for your seizure type.
- <u>Get to know Embrace's seizure detection system</u> Use this article to learn more about our advanced machine learning algorithm used to detect tonic clonic seizures.
- <u>Seizure Detection Accuracy</u> Use this article to learn about the accuracy we've achieved so far with Embrace.
- <u>Scientific literature behind the Embrace</u> Use this article to learn about the scholarly journals that have published our findings.
- <u>Studies behind Embrace</u> Use this article to learn about the research behind Embrace.
- <u>Understanding Electrodermal activity (EDA)?</u> Use this article to learn more about EDA and how we use it.

Embrace and seizure prediction

Embrace **cannot predict or prevent seizures**. Our technology is designed to detect convulsive seizures lasting longer than 20 seconds, to learn more, check out the <u>types of seizures Embrace can</u> <u>detect</u>.

Using Embrace with a Vagus Nerve Stimulator

From our knowledge there **shouldn't be any problems using an Embrace alongside a VNS**, as Embrace does not contain any magnetic parts. Actually, the VNS would be great to use alongside Embrace, because it activates the parasympathetic branch of the autonomic nervous system. What we measure with the Embrace arises from the sympathetic branch of the autonomic nervous system.

Scientific literature behind Embrace

The research behind **Embrace is based on scientific work published in two top medical journals**, as well as on additional studies that have replicated that work. The ways in which our sensors can help revolutionize health are profound, and our goal is that people get the personalized advances in treatments that can help them most. For this reason, we are involved in a variety of clinical trials that use our sensors and analytics.

The first two peer-reviewed journal articles that published our findings were based on trials run at Boston Children's Hospital (#1 pediatric hospital in the USA) and Brigham and Women's hospital in Boston:

- Poh, M.Z., Loddenkemper, T., Reinsberger, C., Swenson, N.C., Goyal, S., Sabtala, M.C., Madsen, J.R., and Picard, R.W., "Convulsive Seizure Detection Using a Wrist-worn Electrodermal Activity and Accelerometry Biosensor", Epilepsia, Mar 20, 2012. <u>Abstract</u>
- Poh, M.Z., Loddenkemper, T., Reinsberger, C., Swenson, N.C., Goyal, S., Madsen, J.R., Picard, R.W., "Autonomic Changes with Seizures Correlate with Postictal EEG Suppression", Neurology, Apr 25, 2012. <u>Abstract</u>

Wearing Embrace during an MRI or X-Ray scan

We strongly advise you not to wear Embrace during either an MRI or x-ray scan.

During an x-ray, the physician will usually ask you to remove all metal objects as it blocks visibility of underlying structures. In the case of an MRI, it's especially important to remove all metal objects as they may be attracted by the the MRI's magnets.

Seizure detection accuracy

We are constantly validating and improving our algorithm; to test its accuracy we collaborate with top hospitals.

162 patients provided overall 434.7 days (10,434.0 hours), with a median of 64 hours of data per patient (min-max range = 3 - 386.8 hours) of ACM and EDA measurements.

Operating characteristics	Test Cohort	Adults	Pediatrics
Total hours of recording	10434 hrs	6252 hrs	4182 hrs
Hours of recording per patients (min-max)	64 (3 - 386.8) hrs	92 (17.2-386.8) hrs	44.5 (3 - 155.2) hrs
Total GTCS per epileptologists' labels	57	26	31
GTCS detected by Empatica Classifier	55	26	29
PPA (PPA_corr ^a , [95% CI] ^b) ^c	0.9649 (0.9202, [0.8671; 0.9549])	1 (0.9029, [0.8846; 0.9162])	0.94 (0.8617 [0.7666; 0.9244]
Total False Alarms - all patients ^d	350	141	209
Overall FAR per 24 hrs FAR e, [95% CI] ⁷ - all patients ^d	0.8025 [0.614; 1.031]	0.5336 [0.3462; 0.7865]	1.1935 [0.8428; 1.6193]
Mean FAR per 24 hrs FAR °, [95% CI] ⁷ - all patients ^d	1.1331 [0.788; 1.5802]	0.6167 [0.3432; 1.0077]	1.495 [0.9566; 2.2197]
Overall FAR per 24 hrs FAR °, [95% CI] ⁷ - patients with GTCS ^g	0.6941 [0.3638; 1.2268]	0.4777 [0.1099; 1.3352]	1.0011 [0.5772; 1.5227]
Mean FAR per 24 hrs FAR ^e , [95% CI] ^{1.} - patients with GTCS ^g	0.9633 [0.4415; 1.7247]	0.6513 [0.1261; 1.6298]	1.2342 [0.559; 2.399]
Overall FAR per 24 hrs FAR ^e , [95% CI] ^r - patients without GTCS ^h	0.8351 [0.6217; 1.0961]	0.5477 [0.3694; 0.768]	1.2643 [0.8194; 1.8193]
Mean FAR per 24 hrs FAR ^e , [95% CI] ^r - patients without GTCS ^h	1.1687 [0.766;1.7066]	0.5961 [0.3235; 1.0251]	1.5407 [0.9201; 2.3832]

The full details of this work are included in the table below:

^a PPA is reported as the observed sample proportion and as PPA_corr, which accounts for extreme probabilities and clustering in the data. ^b Confidence intervals were computed using bootstrapping with replacement for 100,000 iterations and the percentile method. CTest Cohort: 57 GTCs, N= 33 patients; Adults: 26 GTCs, N= 16 patients; Pediatrics: 31 GTCs, N= 17 patients. ^d All patients refers to: N= 162 patients for the Test Cohort, N= 68 patients for the Adults, and N= 94 for the Pediatrics. • Overall FAR per 24 hrs is computed using all false positives across all the monitoring days. Mean FAR per 24 hrs is computed as the average of the FARs per 24 hrs of each subject. Confidence intervals were computed using bootstrapping with replacement for 100,000 iterations and the bias-corrected and accelerated method. Patients with GTCS refers to: N= 33 patients for the Test Cohort, N= 16 patients for the Adults, and N= 17 for the Pediatrics. Patients without GTCS refers to: N= 129 patients for the Test Cohort, N= 68 patients for the Adults, and N= 94 for the Pediatrics.

Clinical Testing

Clinical testing was performed to demonstrate the ability of the Embrace to function as an assessment aid for monitoring for seizure related activity in the intended population and for the intended use setting.

Patients:

162 patients diagnosed with epilepsy were admitted to the Epilepsy Monitoring Unit (EMU) for standard care were enrolled in the studies: 94 children (49 males), ages 3 months -17 years, median: 11 years; 68 adults (29 males), ages: 18-63 years, median: 37 years.

Observed GTCS:

33 EMU patients experienced a total of 57 generalized tonic clonic seizures (GTCSs) while 129 EMU patients didn't experience any seizure. The 57 recorded GTCSs included 13 primarily generalized tonic-clonic seizures and 44 secondarily generalized tonic-clonic seizures. Every recorded seizure was classified as epileptic. Seizures other than GTCSs were discarded from the analysis.

Recorded data:

162 patients provided overall 434.7 days (10,434.0 hours), with a median of 64 hours of data per patient (min-max range = 3 - 386.8 hours) of ACM and EDA measurements.

Performance:

Positive percent agreement (PPA) was found to be 0.9649 (corrected PPA=0.9202), with a 95% confidence interval of [0.8671; 0.9549], relative to a panel of three readers, and false alarm rate (FAR) was found to be 0.8025 false alarms per 24 hours with a 95% confidence interval of [0.614, 1.031], corresponding to a mean FAR (average of FARs across patients) of 1.1331.

Understanding the importance of electrodermal activity

Electrodermal activity is generated by the sweat glands on a microscopic level, and tends to increase with emotional and physical stimuli.

Increases in EDA have been shown to occur with most generalized tonic-clonic seizures, therefore making EDA plus motion a more reliable system for detecting seizures.

What affects EDA?

Several components can result in an elevated EDA, such as **sports, excitement, and stress**. In addition, your own individual **biochemical levels** also play a role. EDA can also fluctuate based on daily **water intake** and with certain **medications**. The measurements of electrodermal activity can be affected by **skin hydration** and where the sensors are placed. For a more in-depth explanation of EDA, you can check out our <u>website</u>.

How does Embrace measure EDA?

Nerves transmit signals from the brain to the body. Some of the signals activate patches of sweat glands, changing the conductance across the surface of the skin. Embrace measures subtle electrical changes **across the surface of the skin**.

What role does EDA play in Empatica's seizure detection algorithm?

EDA is part of our algorithm but **does not take precedence over other factors**, given its susceptibility to variation. **We're analyzing characteristic EDA signatures during seizures** so we can decrease the number of <u>false alarms</u> and refine Embrace's algorithm.

Allergic reactions to Embrace

Embrace is made of the highest quality of **hypoallergenic materials** (ISO 10993 compliant), therefore it's very **unlikely that you'll develop an allergic reaction** from it. Contact our support team (support@empatica.com) with a photo of the irritation if it doesn't go away in a few days.

Important Notes

Embrace should only be worn on the surface of healthy skin. We advise that you 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 please make sure to clean Embrace regularly.

Materials Used

If you are allergic to the following materials, we don't recommend wearing Embrace:

- Top Cover:
 - Anodized aluminum
 - Polycarbonate (PC) light pipe
- Bottom cover:
 - Polycarbonate (PC) base
 - SUS316L electrodes (contains some nickel, but has been tested to ensure it is below the safe limit for watches and jewelry)
 - XM7 screws
- Band Frame
 - Aluminum, nickel-free chrome plated
- Stretchable Band
 - Polyester: 80%
 - Polyurethane: 20%
 - Aluminium, nickel-free chrome plated buckle

Placing an Order
Package lost in transit

If you feel your package may have been lost in transit, please follow the instructions below:

- Verify the tracking number and delivery address.
- Double-check that your package has not been left at the front desk of your apartment building, office, or with a neighbor.
- **Contact the courier** and provide them with the tracking number so that they can look into it further to try and locate the package.

If you're still unable to locate it, reach out to support@empatica.com and provide us with the tracking number, so that we can look further into it.

My Embrace is listed as "delivered", but I can't find it

If your tracking number states that the package has been delivered, but you can't find it, please follow the instructions below:

- Verify the shipping address in your Empatica Account.
- Look for a **notice of an attempted delivery** (which may be stuck to a door or mailbox).
- Carefully **inspect the location around** which your package was supposed to be delivered. Sometimes packages are delivered in a discrete location such as under a doormat.
- Contact the courier listed in the shipment confirmation email to track the package.

How to order Embrace

You can order your Embrace directly on our Online Store.

You can select one of the following colors: Flamingo Pink, Sky Blue, Seoul Grey, Milan Black and Boston Blue.



We ship every Thursday and the delivery may take three to five business days.

Follow these steps to order your Embrace:

- 1. Go to our Online Store.
- 2. Choose the color you'd like, and any additional bands to personalize your look.
- 3. Insert your shipping details.
- 4. **Proceed** with payment.
- 5. Wait for Embrace to arrive within 10 business days.

Embrace hardware is cleared by FDA. When Embrace arrives you'll be able to choose the FDA Cleared version of the Alert App or the investigational version of the Alert App.

FDA Cleared version of the Alert App

After receiving your Embrace, you'll need to provide us with a medical prescription so that you can start using the FDA Cleared Alert App.

Investigational version of the Alert App

Empatica is continuously developing improvements to Embrace's algorithm that are available under clinical trials. You can optionally provide your consent to participate in the clinical trial in order to use the investigational version.

Shipping Embrace to your country

We ship Embrace under the incoterms DDU (delivery duties unpaid). Orders shipped outside of the US and EU may be subject to import taxes, custom duties or fees. The person who will be receiving the Embrace is responsible for covering these charges, we cannot predict or estimate the cost of these fees.

Customers in the US can choose between the Prescription version of Embrace, or opting into our clinical trial with the investigational device which uses the latest non-FDA Cleared software we've developed.

Embrace cannot be shipped to the following countries because the **Alert system is not available there**: North Korea (DPRK), Colombia, Indonesia, Malta, Macao, Ukraine, Ecuador, Peru, Cyprus, Kuwait, Honduras, Guatemala, Mozambique and Iran.

Some countries may prohibit access to the Play Store/App Store, so we recommend verifying that you are able to download the apps.

Cancelling your Embrace order

You may cancel your purchase only if the status is "Not Scheduled." To check the status of your order, go to the "Orders" section of your Empatica Account. If the status is "Not Scheduled" please fill in our <u>contact form</u> or email <u>support@empatica.com</u> and we will proceed with the cancellation and refund.

empatica (;>				Home	Orders	Profile
		Order #SP2 Status In Your order was shipped or Track Ship	016-XXXX Transit I: December 12, 2016			
	Shipping Informatio	N Shipping address	Details Purchase Date November 23, 201 Subtotal \$249 USD			
	Items Embrace Watch Sky Blue - Stretchable Band Base Price \$249 USD Serial Number		Discount -\$50 US Shipping o \$20 US Total \$219 U Net Paid \$219	sD cost D ISD P USD		
	Check device warranty and s	Back				

Insurance reimbursement for Embrace

Getting Embrace reimbursed by insurance **depends on the patient's specific plan and coverage level.**

Patients may ask you to fill out this form to improve their chances of reimbursement:

Embrace Pre-Determination-template-withFDAapproval.docx

We recommend the below articles if you'd like more information about Embrace:

- FDA Approval Summary
- Epilepsia 2017 journal results
- PAME 2018 Poster

These materials can improve your chances of reimbursement; however please keep in mind that this material may not guarantee reimbursement.

We suggest to contact your insurance agent directly for any questions regarding insurance coverage of the subscription plan.

If you submit a request to get your Embrace or the subscription plan costs reimbursed, please let us know about the outcome so that with this knowledge we can help the Embrace community.

Embrace Return Policy

Embrace warranty

If your Embrace stops working or does not function effectively within a year of regular use (within 2 years for EU residents), please email us at support@empatica.com to resolve your issue. Make sure to include a detailed description of the problem as well as the pictures whenever possible.

Empatica is not responsible for general wear and tear of product usage such as cosmetic damage (for example scratches, discoloration or damage of the band during use).

- Lifespan of Embrace battery 500 cycles
- If your Embrace watch needs servicing and it's out of the warranty period, you will be charged for the shipping and repair costs.
- Loss of the device isn't covered by warranty

Returning Embrace for a refund

If you wish to return your Embrace, please contact us and we'll help you with the process.

1. Request a Return Merchandise Authorization (RMA)

Your Embrace(s) return requires an authorization from the Empatica Team.

Timing: Your RMA request will be processed within 5 business days.

You can send us an email to support@empatica.com including your current shipping address to request for an RMA. For faster processing time, use the same email address associated with your order.

Once your request is processed, you'll receive an RMA document (PDF) summarizing the details of your case. Please read it carefully and verify if your information is correct.

2. Ship your Embrace back to Empatica

In some cases Empatica will provide a pre-paid shipping label to facilitate the return delivery. If you are returning your device for a refund, the charge for both shipping and return shipping will be deducted from the total amount of your refund. If you are returning your device for services covered under warranty, you will not have to bear any shipping costs.

Timing: Ship the device back within 5 business days of receiving the RMA document.

- Place the device in its original box and include all the accessories.
- Print, sign and include a copy of the RMA document in the package.

• Pack the Embrace box securely in a padded shipping envelope. (Note: Please do not use the same envelope that the Embrace arrived in. Multiple shipping labels may cause transit or delivery issues. You can use another padded envelope instead.)

- Attach the shipping label (if provided) included in the RMA document to the package
- Drop the package off at the nearest post office or the nearest collection box, or arrange a pickup with the courier.

N.B. Empatica does not assume any risk of loss or damage to the device(s) while in transit for return.

N.B. Empatica will not be responsible for any customs/VAT/duty charges upon return of devices.

3. Inspection of Returned Embrace

In case of a return for refund, before issuing the refund we need to be sure your Embrace is functioning well and is not damaged (this includes also the band and the charger). In case of return for service, this step will identify the cause of the issues that you are experiencing and will help decide if we can repair your Embrace or if a replacement is required.

Timing: Once your Embrace(s) arrives at Empatica, our team will inspect the device within 10 business days of receipt.

Some examples of failed inspections

- The Embrace has clear signs of physical damage
- Part(s) of the Embrace is missing
- The device was opened/ attempted to be opened
- Damaged Band/Charger/USB cable

4.a Receiving your refund

If your Embrace passes our inspection, we'll proceed with a refund and send you an email you as and when the refund is issued. The refund will not include original shipping fees. If you were provided with a pre-paid shipping label, this amount will also be deducted from the total value of your refund.

Timing: The time frame for the issual of the refund is 10-14 business days.

Please note: Empatica reserves the right to change these policies or procedures at any time without notice.

4.b Receiving your refurbished/replacement Embrace

Depending on the nature and complexity of the given issue, we will either ship back a refurbished Embrace or send you a replacement.

Timing: Your returned Embrace will be inspected within 10 business days of receipt. We will then ship back your device (or a replacement) within 10 days after inspection.

Returning your Embrace for service

If your Embrace doesn't work properly, you have 1 year from the delivery date to request servicing.

Embrace very rarely requires servicing. Most often, the Embrace problem is software related and can be solved remotely without the need for a the return.

To learn more about what's covered, please read the Embrace warranty.

Embrace Subscriptions

Updating your billing details

You can update your billing details by going to the '<u>Subscriptions</u>' section on your Empatica Account.

To update, please follow the steps below:

- On the Subscriptions page, tap on 'Update Billing Details'
- Enter your new billing details and click 'Payment Info'
- On the next page, enter your card information and click 'Update my Billing Details'.

	Manage your subscription			
Active Subscription	Billing	Receipts		
Pa Pia	William Coldman	Date	Total	
Plus € 449.00 (yes	A STREET, STRE	Jul 27, 2017		3
Addue Print Unimited FREE	Secure at Interface	Jul 23, 2017		3
Caregivers	MasterCard Eve.	Jun 23, 2017		;
Akhai Pise	and and an E.	410.05.0547		
Selzure Reports FREE				
Adversed Red Record	Byden VyRing Dinas			
Active Jul 27, 2018				
O Losm more socialisato renevas				
	Get 2 months free			
(Updat Historia (Um	Switch to annual billing to get 2 months			
	free for your subscription.			
	1000.00.00000			

Your new billing information would be saved and your next payment would be deducted from the new card information you have entered.

If you encounter any trouble updating your payment information, please write to us at support@empatica.com

What to do if you've subscribed to plan with a different Empatica Account.

The Embrace Subscription plan should be purchased using the account that you have used to pair the watch. In the event that you have purchased the plan using another account, please follow these steps:

- Launch the Alert App on the phone currently paired with the Embrace
- In the app, go to More >> Settings >> "Remove Embrace"
- In the smartphone open Settings>>Bluetooth®>>Embrace>>Forget device/Unpair
- Launch the Alert App again
- Log in using the email address and password of the account used to purchase the plan
- Follow the in-app instructions for pairing

Once you have paired the Embrace with the account you used to subscribe, the subscription plan would reflect in the app and would be automatically activated.

What to do if you see a warning when subscribing to a plan

When making subscriptions purchases from the Alert app for iOS devices, you might see a "warning" message (see the image below). Don't worry though. Please just refresh the page - this should resolve the issue. If the problem persists, please email us at support@empatica.com.



Once you purchase your subscription, open up the Alert app to explore your new plan.

Available subscription plans

Empatica offers Lite, Standard and Plus subscription plans for the Embrace watch. Each plan is comprised of different feature combinations that enables you to use Embrace at different capacities, depending on your needs and financial resources.

See below table to explore what each subscription plan entails:

	LITE	STANDARD	PLUS
	\$ 0.33/day \$9.90/month	\$0.65/day \$19.90/month	\$1.49/day \$44.90/month
Seizure detection and Alerts Automatically alert your loved ones upon the detection of a convulsive seizure.	\checkmark	\checkmark	\checkmark
Seizure History View, print, and share your seizures.	\checkmark	\checkmark	\checkmark
Activated Caregivers Number of people that will receive alerts when a seizure is detected	1	3	Unlimited

Free trial

With the purchase of your Embrace, you get free access to 30 days of the Plus subscription plan, which is the most comprehensive plan that we offer. Once the 30-day free trial period has expired, you will be prompted to purchase the subscription plan that best suits your needs. If you select a subscription plan and enter your billing details before the end of the 30-day free trial, you'll get an additional 30 days free of cost.

Please note that failure to subscribe for a plan will disable the sending of alerts to Caregivers once the 30-day free trial period of the Plus plan expires.

Purchasing a subscription plan

You can purchase a subscription plan directly from your Empatica Account. Please follow the steps below:

- 1. Go to <u>myembrace.empatica.com/plans</u> and sign in with your Empatica Account credentials
- 2. Select the subscription plan of your choice then click "Proceed with XXXX"
- 3. Confirm the details of the plan you are purchasing and click "Pay Now XXX"
- 4. Enter your name and address and proceed to "Payment Info"
- 5. Fill in the required fields with your billing details and click "Update Subscription"

That's all it takes. You'll be able to review your plan in your Empatica Account.

You can cancel the subscription at any time, however we cannot refund subscription fees. For more details please check:

- How can I cancel my Embrace subscription plan?
- Can I get a refund for my subscription?

Using the Embrace without a subscription

The Alert System will be disabled; therefore, your caregivers will no longer receive notifications upon detection of a seizure.

Changing your subscription plan

You can change (upgrade or downgrade) your subscription plan at any time.

• Open your <u>Empatica Account</u> and click "View My Subscription Details". You'll be redirected to your subscription page

- Click on "Update My Subscription" in the "Active Subscriptions" section
- Select a new plan and proceed with payment by clicking "Checkout"
- Review your subscription and click "Update Subscription"

The new plan will become active immediately after the upgrade/downgrade.

Upgrading your subscription plan

If you decide to upgrade your subscription plan, the difference between the prices will be used towards the purchase of your new plan. This means that you'll pay a prorated amount based on the time left until your next billing cycle.

For example, if you're using the Lite subscription plan (USD 9.90 a month) and you'd like to upgrade to Plus (USD 44.90 a month) one week into the billing cycle, you'd pay USD 29.07. You'll start paying the full amount for the Plus plan from the second month.

Downgrading your subscription plan

If you're downgrading an existing plan halfway through the billing cycle, the credit from the unused portion of the previous plan will be deducted from the first-month fee of the new plan. This means that you'll pay a prorated amount based on the time left until your next billing cycle.

For example, if you're using the Plus subscription plan (USD 44.90) and you downgrade to the Standard plan (USD 19.90) a week into the billing cycle, you will have USD 20.76 left from your Plus plan, so you won't be charged when you make the switch from the Plus plan to the Standard plan.

At the beginning of the next billing cycle, you'll be charged USD 17.35 to account for the USD 2.55 left from your Plus subscription. You'll start paying the full amount for the Standard plan from the following month.

What happens once I've downgraded my subscription plan?

After downgrading your plan, the features covered by the previous subscription plan will no longer be available. For example, if you downgrade from the Standard to the Lite Plan, the number of activated Caregivers will decrease from 3 to 1 and you will not have access to the Standard features.

Changing from monthly to annual subscription plan

If you'd like to switch from a monthly to annual plan, please email us at support@empatica.com. If you subscribe to the annual plan you will receive 12 months of service for the cost of 10 months.

If you are halfway through your monthly plan and decide to switch to an annual plan, the unused portion of your monthly plan will be deducted from the price of the annual plan. You will be billed at the time of the switch and the annual billing cycle will begin that day.

Adding or removing an add-on feature

Adding an add-on:

You can add an add-on to your subscription plan directly from your Empatica Account:

- Open your <u>Empatica Account</u> and click "View My Subscription Details". You'll be redirected to your subscription page.
- Click on "Update My Subscription" in the "Active Subscriptions" section.
- Click on "Add-ons" tab at the top of the screen.
- Select the add-on of your choice and click "Add", then click "Checkout" and proceed by clicking "Update Subscription".

Removing an add-on:

You can remove an add-on at any time. To remove an add-on from your subscription plan:

- Open your <u>Empatica Account</u> and click 'View My Subscription Details'. You'll be redirected to your subscription page.
- Click on "Update My Subscription" in the "Active Subscriptions" section.
- Click on "Add-ons" tab at the top of the screen.
- Click on the "Purchased" tab in the box of the add-on you'd like to remove and click "Checkout" and proceed by clicking "Update Subscription".

Cancelling your subscription plan

When you subscribe to a plan, it is automatically renewed every month/year. If you decide to discontinue using Embrace subscriptions, you can cancel it - this means your subscription plan will not be automatically renewed the following month.

If you want to disable auto-renewal in order to cancel your subscription, you can do so by contacting us directly from your Empatica Account.

- 1. Open <u>Your Subscriptions page</u> in your Empatica Account
- 2. Click "Learn more about auto-renewal"
- 3. Click "Contact our customer support"
- 4. An email window will pop up. Fill out the form and we'll get back to you within 2 business

days.

Empatica Subscriptions Receipts

This article has all the related information that will help you understand the receipts generated for your chosen subscription plan and add-ons.

Once the free trial period ends, with every renewal of the subscription plan, a receipt for the equivalent amount will be generated automatically for the amount of the purchased plan. Your subscription plan will be renewed monthly or yearly, based on the option you choose. Each renewal and change in plan (upgrade/downgrade) is associated with a receipt.

To locate your receipts:

1. Go to your <u>Empatica Account</u> and click on "View My Subscription Details".

- 2. You will be redirected to your <u>Subscriptions Page</u>, which lists out all the information related to your billing details, existing plans and receipts.
- 3. Under the 'Receipts' tab, click on a date to view or print the receipt of that particular purchase of subscription plan.

Understanding your Receipts:

Payment Status:

- 1. **PAID:** If the transaction is successful, then your receipt will show the payment status as 'Paid'.
- 2. **NOT-PAID:** If the transaction does not go through due to some issues, then the payment status is termed as 'Not Paid'. Some possible reasons for a payment decline could be:
- Incorrect card details
- Insufficient funds/credit
- Expired/blocked Card

In such cases, to ensure uninterrupted service, you could change the credit card with another one. If you add another credit card, a charge will be attempted in the next 24 hours of the change. For more information on the failed transaction, we recommend contacting your bank.

Some other examples of Subscription Receipts:

• Upgrade/Downgrade Subscription Plan: The following image shows you the format of receipt when you upgrade/downgrade from one plan to another. In this particular example, the subscription plan has been upgraded from Standard plan to Plus plan. The receipt generated is for the amount that is to be paid after the change in plan.

- **Excess credit:** When you change from one plan to another, if there is an excess amount after implementing the new plan, this is converted into credit which will automatically be applied to the next receipt generated.
- **Receipt with a Debt:** If you choose to switch your subscription plan from one to another and the new plan exceeds the available credit by a few cents/pennies, this amount will reflect as a debt on the current receipt. When a new receipt is generated, this deficit will be debited along with the charge for the chosen plan.

We refrained from enabling the possibility to cancel the subscription plan without contacting us to avoid the situation when the user cancels the subscription accidentally, causing the interruption of the service.

Subscription Plans are not refundable, therefore please email us at least 2 business days before the start of the next billing cycle so that you won't be billed for the following month/year.

When a plan is canceled, the Alert System will be disabled when your subscription expires; therefore, your caregivers will no longer receive notifications upon detection of a seizure.

You can easily renew a plan or subscribe to another plan from your Empatica Account.

What Happens If I Don't Subscribe to any Plan?

Subscription payment rejected

If there is a problem with the payment of your subscription plan, we will notify you via email.

In case of a failed payment your subscription service will not be interrupted immediately. We will make 3 attempts to bill your card. At each attempt we'll send you an email notification:

- The first attempt will occur one day after the failed attempt.
- The second attempt will be made 3 days later, and our last attempt will be made 3 days after that.
- This amounts to a total of a 7 day grace period to update your billing details this means your subscription will not be cancelled for these 7 days while we're attempting to bill your card.

There a few reasons why your regular subscription payment might have failed. Most common reasons are:

- Expired or cancelled Credit Card if this is the case, please contact your Credit Card issuer to request a new card and update your billing details in your Empatica Account to ensure uninterrupted service.
- Insufficient funds on your Credit Card please restore the funds on your Card before our last attempt to take the payment

If the payment doesn't go through after 3 attempts, the service plan will be interrupted (alerts will not be sent to Caregivers) until we have received payment.

You can update your billing information directly from your Empatica Account:

- 1. Go to "Your Subscription" page and click "Update my billing details"
- 2. Enter your address and payment info and confirm by clicking "Update my billing details"

Refunds and subscriptions

It is not possible to get a refund for subscriptions. If an existing plan is canceled halfway through the billing period, you will be able to use up the subscription for the remaining month/year and the subscription won't be renewed after that. For more info about cancellation please refer to this article: <u>How can I cancel my Embrace subscription plan?</u>

Getting started with Embrace

What Embrace comes with

In the Embrace box you'll find:

- Charging Dock
- Micro-USB cable
- Embrace watch
- <u>LED and Quick start guide</u>

The Embrace is packaged with utmost care. To see how to unbox your Embrace, check out this video:

https://www.youtube.com/watch?v=y_Vb5LFjr3Q&feature=youtu.be&list=PLgJGJZB1txiZM26ruT UIFP5edSZv10NqK

How to wear Embrace

Which wrist?

We recommend consulting your physician on this question. Motion detection is among the dominant characteristics of our algorithm, so we recommend wearing Embrace on the wrist that generates the most movement during seizures.

If both arms manifest equal movement during your convulsive seizures, then we recommend wearing it on your non-dominant wrist to reduce false alarms

Positioning

The Embrace heart should be in the 3 o'clock position. The sensors on the bottom should always remain in contact with the skin, so remember to wear your Embrace snugly, but not too tight, it should feel comfortable.

https://www.youtube.com/watch?v=vKuRIaVPUKg#action=share

Setting up Embrace

Setting up your Embrace watch is easy and straightforward. Follow the steps below to get started:

Step 1: Charge your Embrace watch

It takes about 2 hours to fully charge Embrace.

Step 2: Enable bluetooth and Internet connection on your smartphone

Step 3: Download the Alert app and pair the Embrace watch with your Android or iOS smartphone/tablet

iOs devices:

• Install iOS 9.3.2 or higher on your smartphone (<u>Check your iOS version</u> and <u>how to upgrade</u>

<u>it</u>)

- <u>Download the Alert app</u>
- Open the Alert app and sign in with your Empatica Account email address and password.
- Follow the in-app instructions to pair your Embrace watch
- The pairing is automatic. If it doesn't happen at first try, give it a few more tries.

Note: While pairing, make sure your Embrace watch is right next to your smartphone and that Bluetooth and Internet connection are on.

Android devices:

- Install Android 5.0 or higher on your smartphone and make sure the device supports Bluetooth Low Energy (BLE/4.0/Bluetooth Smart)(<u>Check your Android version and how to</u> upgrade it)
- Download the Alert app
- Open the Alert app and sign in with your Empatica Account email address and password.
- Follow the in-app instructions to pair your Embrace watch
- If you're prompted to enter a pin, insert 123456
- We suggest activating <u>location services</u> on your Android smartphone when pairing the Embrace.

Note: Make sure your Embrace watch is right next to your smartphone and that Bluetooth and Internet connection are on.

Once you pair your Embrace watch for the first time, you'll start 30 days of free trial of the Plus <u>subscription plan</u>. Before the expiration of the free trial, you'll be prompted to <u>select the plan</u> that best suits your needs.

Step 4: Wear your Embrace watch

It should fit snugly above the wrist joint.

- Loosen the band by sliding the buckle towards the Embrace.
- Wear the Embrace on the dominant wrist (More info: <u>Which wrist should I wear Embrace</u> <u>on?</u>)
- Tap the surface of the Embrace watch once to see the <u>current time</u>.

The Embrace should fit comfortably snug so that the three sensors on the bottom remain in constant contact with the skin surface. Adjust the tightness of the band to ensure that the Embrace is comfortable and does not shift in position on the arm during movement.

Check out our videos for a swift and simple setup.

Having problems pairing your Embrace?

Check out this article for some troubleshooting tips: Why can't I pair the Embrace with my Smartphone?

Embrace LED lights Guide

Embrace communicates with you through LED lights. Each signal has a unique meaning. We've included a handy LED guide in the Embrace watch package. You can also <u>download the LED guide</u>.

Here's a quick snapshot of what each LED light means:



White and blue lights - time (hour and minutes)



LIGHTS+VIBRATION Red spinning circle - Unusual event detected (convulsive seizure or false alert)



LIGHTS+VIBRATION Red X (four red dots) - Embrace is disconnected from the paired smartphone)



White smile - Embrace reconnected



Red triangle (3 red dots) - General connection problem



Yellow cross (4 yellow dots) - Embrace memory full



Orange circle (gradually filling Embrace surface) - Embrace charging





Orange dot blinking - Embrace battery low



White circle - Embrace rebooted

For more information about the Embrace LED lights, check out this video:

https://youtu.be/MBG4c7SS2D0?list=PLgJGJZB1txiZM26ruTUIFP5edSZv10NqK

The importance of being a Caregiver

Being a Caregiver is really important as you will be the person responsible for providing assistance when a seizure occurs. We highly encourage you to set up an <u>emergency action plan</u> with the user so you can efficiently assist them. If you choose not to accept this responsibility, please reach out to them asking to be removed from the Alert App.

Embrace is a smartwatch that **detects tonic-clonic seizures**. When the Embrace detects a seizure it **sends an Alert** in the form of a **call and SMS to** the user's **Caregivers**.

For more information on this process, please read this article: How Embrace works







Seizure detection

Embrace sends Alert

Caregivers receives Alert

Receiving Alerts

You will receive an automated call and SMS when Embrace detects a tonic-clonic seizure, if you only receive the text or only receive the call please let the user know so they can reach out to us to resolve the problem.

False Alarms

Some activities such as riding a bike on a bumpy road, chopping vegetables or brushing teeth, **resemble the movement signature of a seizure, and can trigger false alarms**. If the user doesn't cancel false alarms on time, you will receive an automated call and SMS. The user can also notify you through the Alert App to let you know it wasn't a seizure.

To reduce the number of false alarms, we suggest wearing Embrace on the non-dominant wrist, as long as convulsive movement is generated there.

Added as a Caregiver by mistake

If you don't know the user that has added you, or feel you've been added by mistake, just email us at support@empatica.com. Please include your phone number in the email.

Get Started With Alert
Main functions of the Alert App

The main function of the Alert App is to notify caregivers when their loved one has experienced a <u>generalized tonic-clonic seizure</u>. The Embrace detects changes in physiological signals and autonomic activation and sends out an alert to caregivers through phone call/SMS, so that the wearer of the Embrace can get the needed help at the right time.



The person wearing the Embrace must always keep their paired mobile device (with Bluetooth and Internet connection) nearby so that the app can properly transmit notifications (see <u>How does the Embrace Work</u> for more information.)

In the Alert App you'll be able to:

- Pair your Embrace to your smartphone.
- Check your Embrace status.
- Activate or deactivate <u>Caregivers</u>.
- Check your recent Alerts.

How the Alert app works

Embrace records physiological signals on its internal memory and sends it to the paired smartphone via Bluetooth® connection



From the paired smartphone, these physiological signals are sent to Empatica's servers through WiFi or mobile data internet connection.

When the Embrace detects a seizure, caregivers enabled on the paired smartphone are alerted through phone calls and SMS, as long as there is stable Bluetooth and Internet connection on the paired smartphone.



For more details see How Does The Embrace Work

To know more about what happens if a seizure is detected but the Embrace is not correctly connected, read <u>What does Alert not sent mean?</u>

Setting up the Alert App

Setting up the Alert App is easy. As a first step, <u>download</u> the Alert app on a <u>compatible smartphone</u>. Once the App has been installed on your smartphone, launch it and login with your Empatica Account credentials.

If you do not remember your password, tap <u>"forgot password?"</u>. You'll receive an email with the password reset link. Follow the instructions in the email to change the password. You can then <u>pair</u> <u>your Embrace</u> with your smartphone.

Alert App Statuses

The Alert App will communicate if there's anything wrong with the connection between the paired smartphone and the Embrace.

Everything is OK

If the Alert App status page says "**Everything is OK. Your Embrace is working fine**" this means the device is connected correctly to its paired smartphone and is recording data properly.



No Internet Connection

If you see the following warning, **"No Internet Connection"** on the Alert App status page, it means your phone isn't connected to the Internet. Embrace will still record your physiological data, but **alert calls and SMS will not be sent to caregivers if Embrace detects a seizure.**

<u>What to do:</u> For the Embrace to function properly please make sure that your paired smartphone is always connected to the Internet via WiFi or mobile data.



Bluetooth is off

If you see the **"Bluetooth is Off"** warning message, it means that Embrace is no longer connected to your phone via Bluetooth. This could happen when your phone is in Airplane mode, or power saving mode which turns off the Bluetooth. If a seizure is detected but the Embrace doesn't reconnect within one minute, the Alert calls and SMS won't be sent.

<u>What to do:</u> Turn on the Bluetooth connection on your paired smartphone and wait a few seconds.

For iOS devices: How to turn on Bluetooth

- 1. Go to Settings
- 2. Tap Bluetooth
- 3. Enable Bluetooth by swiping the button to the right.

For Android devices: How to turn on Bluetooth

- 1. Go to Settings
- 2. Find Bluetooth in the list
- 3. Swipe the button to the right to enable Bluetooth



Embrace not found/Embrace disconnected

If the status page of the Alert app shows "Embrace not found"/"Embrace disconnected", it means that the phone is not within range of Embrace and it has lost connection or that Embrace is not charged. Alert calls and SMS will not be sent to caregivers if Embrace detects a seizure.

<u>What to do:</u> Check if Embrace is in the Bluetooth range of the paired smartphone and if it's not, move it closer to the phone. Embrace should reconnect automatically. If it doesn't reconnect, try turning off the Bluetooth for 10 to 15 seconds, and then turn back on.



Warning

If you see the following warning message, "There is a problem that the Alert app is trying to resolve. It might take a couple of minutes", this means Embrace has encountered an issue and is trying to resolve it on its own.

<u>What to do:</u> Wait for 3 minutes, and it should be resolved. If the issue persists, see <u>Alert app:</u> <u>Warning. What should I do?</u>

Understanding Embrace Alerts

Your Embrace watch runs software that is trained to detect convulsive seizures. When seizure-like movement patterns are detected by Embrace – the watch vibrates and a red spinning warning light is illuminated on the watch-face, and an SMS and automated phone call are dispatched to your Caregiver. Some types of activity that you engage in during the day may seem like a seizure to Embrace when they are really not. This is called a "false alarm". For more information on false alarms please see <u>What is a False Alarm?</u> and <u>How Can I Cancel An Alert?</u>

What Embrace Sync to Alert means

Embrace Sync to Alert indicates the last time your Embrace sent data via bluetooth to your smartphone. If there is no Bluetooth connection between your Embrace watch and your smartphone for longer than 14 hours, Embrace memory will get filled up and it will stop recording data. Keep Embrace connected to your phone with Bluetooth to ensure automatic data transfer and avoid filling up Embrace memory.

You can check Embrace memory status and the last time your Embrace synced with the Alert app in Alert app>>More>>Settings>>Advanced Settings.

What Last Sync to Cloud means

In the Alert app you can find information related to the state of your Embrace data. Open Alert app>>More>>Settings>>Advanced Settings to view the info.

Last Sync to Cloud indicates the last time data was sent from the Alert app to Empatica cloud servers. Make sure your phone is connected to internet to keep data synced.



False alarms

Your Embrace watch is optimized to detect unusual events such as <u>convulsive seizures</u>. Some types of activity that you engage in during the day may seem like a seizure to the Embrace when they are really not. This is called a "false alarm". Some examples of activities that could cause a false alarm include, but are not limited to:

- On the road: riding a car or bike, on a bumpy road surface.
- In the bathroom: brushing your teeth
- In the kitchen: grating cheese, beating eggs, or chopping vegetables.

False alarms due to stimming

Stimming (used to describe repetitive movements, typically in autism) and seizures can sometimes similar motion and EDA patterns, and therefore **may result in false alarms**. The signatures can vary a lot from person to person. In some of the examples published in our work in Epilepsia (<u>Poh et al.</u> <u>2012</u>), stimming did cause <u>false alarms</u> for some people.

How to cancel alerts

When Embrace detects an unusual event, it vibrates and a red spinning light shows on the watch surface. If it is a false alarm or you wouldn't like to notify your caregiver about the unusual event, you have **15 seconds** to cancel the alarm.

How to cancel an alert?

There are two methods to cancel: via the Alert app or by tapping the Embrace cover with a special pattern.

Via the Alert App

You'll receive a notification on your phone that a seizure was detected. Tap on the message to open up the Alert App.

Once you are in the app, you just have to tap on "I'm ok, Cancel Alert".



You should then receive this message letting you know the alert has been cancelled, and the alert will be categorized as a false alarm in the Alerts section of the app.



On the Embrace Cover

Quickly tap the Embrace surface twice. A blue circle will appear showing that the cancellation attempt has been submitted.

To confirm the cancellation touch the watch surface again and don't release the finger until you see a green circle. The cancelled alert will be automatically marked as a false alarm in the Alerts section of your app.

https://youtu.be/UUINu5jixBw

Notify Caregivers that you're ok

If you weren't able to cancel the false alarm, you can still let your caregivers know it was only a false alarm, so they needn't worry.

After the alert has been sent, the following screen will appear in the Alert app for 5 minutes.

Tap "Send SMS I'm ok".

🖬 vodafone IT ᅙ 17:40	1 * 🔲	
ALERT SENT		
A call and SMS have been sen your caregivers. If this was a fa alarm, let your caregivers kno	t to alse wv.	
دع		
Activated Caregivers		
M		
Martina		
Send SMS I'm ok	\supset	
Skip		

That's all it takes. Now your caregivers will receive an SMS that the alert sent was a false alarm.



We are presently working hard to reduce the number of false alarms triggered by the Embrace and <u>marking them as false</u> will help improve our algorithm. To learn more read these articles:

- Does Embrace confuse stimming with epileptic events?
- How does Embrace's seizure detection work?

Marking false alarms

In the **Alerts tab of the Empatica Alert app** you can easily check the alert history (alerts sent in the last 7 days) and mark them as false alarms if the alerts weren't seizure-related. For more info check out: <u>What is a False Alarm?</u>

Once you mark an event as a false alarm, it will automatically go to the **False Alarms** tab on the Alerts page.



MARK AS FALSE ALARM

To mark an alert as a false alarm simply tap on alert and choose "Mark as False Alert".

Marking false alarms is important as it helps us improve our algorithm.

UNMARK A FALSE ALARM

To unmark a false alarm go to the False Alarms tab on the Alerts page of your Alert app, tap on the alert and choose the "Not a False Alert".

••••• Lycamobile 🗢	11:41 🕒 @ 🕇 🖇 55% 💷	••••• Lycamobile 奈 11:41 € @ 7 \$ 55% ➡⊃
Status Embrace	Alerts More	Alert Details
Seizure Reports View Online	(ht	Date Time Wednesday 16 Aug 21:36 Contacted Caregivers Alert not sent
A monthly summary and analys and those added manually by ye	is of seizures detected by Embrace bu. Learn More	Rest Mode Deactivated
Recent Alerts	False Alerts	a degli Apuli
UP TO 7 DAYS AGO		Yiato
16 Aug 2017 - 21:30 Alert not sent	5 >	Legal ande
16 Aug 2017 - 21:33	3	Duration > Add the length of the seizure
12 Aug 2017 - 21:52 Alert not sent	2 >	Notes > Add a Describe of the Seizure
		Not a False Alert

Updating the Alert App

Each release of the app includes important bug fixes that you have reported to us. Also, through your feedback we constantly improve and add new features to the app. Each new version of the Alert app is optimized to work best with the latest firmware version. This means that you also need to have the latest firmware version at all times. Also, if you experience any issues with the Alert app, you may need to check the that the version of the Alert app that you have installed is the latest one.

To check which version of the Alert app you're currently using:

- Go to the More tab in your Alert App.
- Look at the bottom of the screen where the number is displayed.

To check which one is the latest release of the Alert App:

- Go to the App Store (for iOS devices) or Play Store (for Android devices).
- Type 'Alert Empatica' and select the app; or use this link https://myembrace.empatica.com/download-alert
- For **iOS devices** tap the Alert App logo at the right top corner to access details of the app; scroll down and check 'Version' in the Information section.
- For Android devices tap READ MORE and scroll down to the specifications of the app.
- You will see the number indicating the latest version of the Alert app.
- You will receive a notification each time there is a new version of the Alert app available. Tap 'install' and the app will be updated automatically.

Adding Caregivers

A caregiver is someone who will receive a call and SMS upon the detection of a tonic-clonic seizure. Although the alerts can be delivered to caregivers at any distance, we suggest that caregivers are nearby so that they are able to assist in a timely manner. Caregivers do not need to have internet connection, and they don't need to install the Alert app. The only thing they need is a working phone signal, as alerts can also be sent to landline phones.

To add caregivers:

- Open the Alert app and tap on the 'Caregivers' tab at the bottom of the screen.
- Tap on the + sign on the next screen to add a Caregiver.
- Enter the information required name, country, phone number and email address
- Tap on 'Save Caregiver'

To enter the phone number of the caregiver, tap on 'phone' and select the country from the drop down. The country dial code automatically populates, you only need to enter the remaining digits of the phone number.

The caregiver's contact could also be added directly to a search in the phone's address book. Please bear in mind that phone numbers should be added without the zero as written in the national phone number format, especially for users in the UK.

Correct 🤡	Wrong 🔀
+44 306 999 0812	+44 0306 999 0812
+1 202 555 0167	+1 0202 555 0167
+1 613 555 0128	+1 0613 555 0128

	📶 Lycamobile 🗢	7:32 PM 🕒 🕑 🜱 🖉	\$ 50% 🔳
\bigcirc	Cancel	Add Caregiver	Save
+ Add a Caregiver			
S Sis Activated	· >	Tap to Edit	
D Dad Deactivated	Name		
Mum Deactivated	> Phone		
	Email		_
	\subset	Search Contact List	
Status Caregovers Embrace Alexte Ma	•••		

You can add up to 5 caregivers. You can activate and deactivate caregivers based on who's available and nearby. For example in the case of children, the parents could be activated as caregivers in the morning, the teacher at school during school hours, the nanny after school and the parents in the night. This ensures that the Embrace user is covered at all times.

You need to have at least 1 Caregiver activated so that they can be notified when Embrace detects a tonic-clonic seizure. You can activate a Caregiver by tapping on the toggle along their name.

The number of Caregivers that can be activated varies based on the <u>subscription plan</u> you choose.

- Lite plan: You can activate 1 Caregiver at a time. The activated Caregiver will receive a phone call and an SMS when Embrace detects an unusual event. Please note that you can add more than one Caregiver but can only activate one Caregiver at a time.
- Standard plan: You can activate up to 3 Caregivers at a time. They will be notified simultaneously via phone call and SMS in case of a seizure. Please note that you can add more than one Caregiver but activate three Caregivers at a time.

• Plus plan: You can activate an unlimited number of Caregivers with this plan.

Unlimited Caregivers feature is also available as an add-on.

You can activate and deactivate Caregivers based on who's available and nearby. For example, in the case of children, the parents could be activated as Caregivers in the morning, the teacher at school during school hours, the nanny after school and the parents again at night. This ensures that the Embrace user is covered at all times.

https://youtu.be/DZsBhN6GxPM?list=PLgJGJZB1txiZM26ruTUIFP5edSZv10NqK

Checking Embrace memory level

Embrace records physiological data on its internal memory and the memory capacity is around 14 hours. If Embrace is connected to your smartphone the signals are automatically uploaded, and therefore, does not use up Embrace memory. Therefore, free memory on the Embrace remains at 100%. However, if Embrace isn't connected to your smartphone (for example, when Bluetooth is off, or Embrace is out of the Bluetooth range) the data will be stored in Embrace.

Advanced Settings		
EMBRACE DATA Embrace collects data and ser bluetooth. Your data is then se Empatica Cloud via the interne	nds it to your Alert app via ent from Alert app to et.	
Embrace Memory	100% free	
Embrace memory can store up memory is full, reconnecting E bluetooth will automatically tra the memory. More info	o to 14 hours of data. If imbrace to your phone by ansfer the data and free up	
Embrace Sync to Alert	8 seconds ago	
Indicates the last time Embrac Keep Embrace connected via automatic data transfer [and a memory]. More info	e sent data to your phone. bluetooth to allow woid filling up Embrace	
Alert Storage	Nothing to upload	
If your phone has no connecti sent from your Embrace will re an internet connection is avail reconnect, data will automatic	on to the internet, data main in the Alert app until able again. Once you ally upload to the cloud.	

You can check the memory level of your Embrace watch in the Advanced Settings of the Alert app (Alert app>>More>>Settings>>Advanced Settings>>Embrace Memory). Below the memory info, you'll find "Embrace sync to Alert" - which provides you with the information on when was the last time data was sent from your Embrace to your smartphone via Bluetooth.

If the memory of your Embrace is full, your Embrace will flash a yellow cross (four yellow dots). For a detailed guide on how to free up Embrace memory space, please see: <u>What does the Yellow Cross</u> <u>mean?</u>

"Alert Storage" in the Alert app

"Alert Storage" in the Alert app shows if the data recorded by Embrace was transferred to your smartphone and was sent to Empatica servers, or whether the transferred data remains in your smartphone (See <u>How does Embrace work</u> for more information). Data upload is automatic when you have stable internet connection. Experiencing troubles uploading data? Check <u>data upload</u> troubleshooting.

Upgrading Embrace firmware

The firmware is the brain of the Embrace. It enables the hardware and software to work together. It also houses seizure algorithm.

Whenever a new firmware version is available for your Embrace watch, you will receive a notification through the Alert app. You can upgrade firmware by tapping on the notification and following the instructions.



You can also upgrade Embrace firmware by going to Alert App>>More>>Settings>>Firmware

- If new firmware is available, tap Upgrade Now
- Tap on the firmware version displayed on the next screen
- In the next pop-up, tap yes, upgrade!

If no update is available, you would see "Up to date" along the Firmware section of the Alert app.



Upgrading Embrace firmware gives you access to the latest improvements and the newest features of the device. <u>Find out what's new with Embrace with each firmware update</u>.

When upgrading Embrace firmware make sure that:

- 1. Embrace battery level and free memory are at least 30%
- 2. Embrace is placed next to its paired smartphone
- 3. The paired smartphone is connected to Internet (via mobile data plan or WiFi)
- 4. Keep the Alert app open in the foreground. The upgrade may take up to 5 to 10 minutes.

Having problems upgrading firmware? Check out the firmware upgrade troubleshooting tips.

Caregivers and the Alert app

Alerts are sent in the form of an automatic call and sms. Caregivers only need a mobile with cellular signal. In fact, the automatic calls will even go to a landline, but of course the sms wouldn't be received in this case.

Light & Vibration setting

This setting can be used to deactivate lights and vibration on the Embrace, and can be useful during the night not to disturb sleep. When Embrace "Light & Vibration" is off, caregivers will still be alerted when a seizure is detected. However, if Embrace disconnects from the Alert App, the red LED "X" and vibration will not be triggered to let the user know about the disconnection, and if a seizure happens to occur in that moment, the Alert calls and SMS cannot be sent.

In addition, if the Embrace memory fills up or it has a low battery, the respective LED lights will not show up to notify the user.

Once Embrace is connected to the charger, the "Light & Vibration" setting will automatically turn on.

Turning off your Embrace

The Embrace was designed to be a round-the-clock companion to people living with Epilepsy so that they are fully covered at any time of the day when they might have a seizure and caregivers can be notified. It therefore does not have a power ON/OFF button for switching off the device. Having it on <u>Night mode</u> might however, help to conserve the battery as it deactivates vibrations and lights that may otherwise drain the battery faster.

If the Embrace detects a seizure when Lights and Vibration is turned off, the watch will not vibrate as usual but will only display the spinning red circle. Alert calls and SMS will still be sent out and delivered to caregivers.

Please note that time indicator LEDs will not be displayed when you tap on your watch if the Light and Vibration is off.

Yellow Cross on Embrace

The Yellow Cross flashing on your Embrace watch indicates that the onboard memory of the device is full. This means your Embrace watch has been <u>disconnected from the paired smartphone for</u> <u>longer than 14 hours</u>. The data stored in the Embrace watch needs to be **downloaded** to its paired phone.

To transfer data and free Embrace memory, activate Bluetooth on your smartphone, make sure your Embrace watch is connected (Alert app says " Everything is OK"). Keep Embrace close to its paired smartphone and the onboard memory will clear as data is wirelessly transferred to the phone. It can take up to 2 hours to transfer all data from your Embrace watch to your smartphone.

You can <u>check the memory level</u> of your Embrace in the Advanced Settings of the Alert app (Alert app>>Settings>>Advanced Settings>>Embrace Memory).



Red X on Embrace

The **Red X** (four red dots) flashing on your Embrace indicates that the device has disconnected - it cannot connect to its paired phone. This usually happens when your phone is not in bluetooth range. When you go closer to your paired phone, Embrace will reconnect automatically.

Should it fail to reconnect, turn the bluetooth off for about 10 seconds and then turn it back on.

For more information check:

How does Embrace work?

Why does Embrace keep disconnecting?



Red Triangle on Embrace

Red triangle (three red dots) flashing on your Embrace watch indicates a connection problem. To resolve it, **turn off bluetooth on your smartphone and turn it back on**.

Should this not help, then force the Alert app to close and open it again.

For iOS devices: How to force an app to close

- 1. Double-click the Home button to see your most recently used apps.
- 2. Swipe right or left to find the app that you want to close.
- 3. Swipe up on the app's preview to close the app.

For Android devices: How to force stop an app

- 1. Open your device's Settings app
- 2. Tap apps
- 3. Pick the app from the list
- 4. Tap Force stop



Troubleshooting Embrace

How to check if Embrace is working properly

You can check whether Embrace watch is working by tapping once on the watch surface: if you can see the **white and blue lights** indicating <u>time</u>, it means your Embrace is still active (please note that time LEDs don't show on Embrace when Embrace <u>Light & Vibration</u> is turned off.)

To check if everything is working correctly, open the **Alert app** and take a look at the status bar at the bottom of the <u>Alert Status</u> page.


Trouble with seeing time on Embrace

If you cannot see <u>white and blue dots</u> when tapping Embrace, make sure that the Embrace is charged and the <u>Lights and Vibration</u> have not been disabled and check again.

Make sure that you are wearing Embrace when checking the time. If you tap on the Embrace watch when it's off the wrist, the LEDs normally won't light up.

If the Lights & Vibration are on and you still can't see the time indicator LEDs on your Embrace watch, try rebooting the device.

To reboot:

- Let Embrace battery drain fully

- Then connect the device to the charger: you'll notice a white circle in a few seconds - it indicates a reboot.

In a few minutes after the reboot, remove the watch from the charger, wear it on your wrist and tap once to check if the blue and white dots appear.



Embrace disconnections

Embrace needs to be connected to a dedicated smartphone via Bluetooth. When the Bluetooth connection is obstructed, Embrace will disconnect.

There might be a few different causes for this issue:

- Your Embrace is out of range from your paired phone
- Some interferences are obstructing Bluetooth connection.

Here are the most common reasons for a Bluetooth disconnection:

Embrace out of range

Too much distance between the Embrace and your smartphone can cause dropped connections. The maximum range for Embrace is 30 feet/10 meters. To recover from this situation, try moving closer to your Embrace and reconnection should be automatic. In the screenshot you can see the notifications sent by the Alert app: at 7:46 AM, the user had left their room, where the phone was resting, that same minute they walked back in and automatically reconnected.

O ALERT	ven 07:46
Embrace Connected	
O ALERT	ven 07:46
Embrace Disconnected	

Some users might find it tricky to keep the Embrace watch within the bluetooth range of the paired smartphone, especially if Embrace user is a young kid. In this case we suggest using a running belt to keep the smartphone, to make sure that the two devices are always in range.

Bluetooth Interference

Bluetooth is essentially a series of radio waves. These radio waves send information back and forth buzzing invisibly through the air. They do this very well in a clear range of sight, but can be zapped by obstructions. So what are these obstructions? Well, walls for one being the most obvious. However there are other more discrete obstructions as well. For example, crossing your arms so that the

Embrace is covered by your other arm might cause Bluetooth to disconnect. In addition, it's also possible that sleeping with your arm underneath your head or pillow could interfere with the signal.

Bluetooth connection can be a bit tricky, like any wireless technology. Once you know how it works it becomes easier to understand what you need to do in the case of a disconnection. Also, if Embrace detects a seizure while disconnected and reconnects within 1 minute, the alert will still be sent.

Alert installed on more than one Smartphone

The Alert app should only be downloaded to one smartphone at a time. Having the app on two different phones, especially when the phones are within the same area could lead to frequent disconnections. We therefore recommend that you keep Embrace paired with one dedicated phone and only pair with a different one if you decide to change the original phone.

Embrace taking too long to charge

- If your Embrace watch has been connected to the power source for longer than 2 hours and it still isn't fully charged:
- Check if Embrace electrodes are fitting correctly into the dents of the charging dock (two hearts are matching)
- Try adjusting the Embrace watch slightly in the charging dock, in case there's poor contact between Embrace electrodes and charging dock dents. The watch should click in place when properly seated in the charging dock.
- Try a different USB cable (any standard USB cable would work)
- Try a different power adapter



Embrace isn't charging

If your Embrace isn't charging (you don't see orange LED lights gradually filling the Embrace surface while connected to the charger):

- Make sure that the electrodes fit properly into the dents on the charging dock
- Make sure that both hearts match (heart on Embrace and heart on charger)
- If you're charging Embrace through a laptop, make sure it's connected to the external power source.
- Try a different USB cable (any standard USB cable is fine)
- Try a different power source, as Embrace can be a bit picky at times.
- Let Embrace battery drain fully and connect it to the charger check if you can see a white circle on Embrace surface in a few seconds (indicating a reboot and beginning of charging)

If none of the above works, contact our support team at support@empatica.com to get further assistance.



Lost or damaged charger

If you've lost or damaged your charger, don't worry. You can easily **order a new one** on our <u>online</u> <u>store</u>.

Once you get there, make sure to scroll down until you see the Embrace accessories.

Pairing Embrace with a different smartphone

You can easily unpair (disconnect) Embrace from the smartphone you initially paired it with and pair Embrace with a different one.

- 1. As first step **forget (unpair) Embrace** from the bluetooth settings of your phone (<u>iOS devices</u>, <u>Android devices</u>). Before pairing it with the new device make sure to disable the Bluetooth connection and log out from the Alert app on the previously paired phone.
- 2. <u>Download the Alert app</u> on the other smartphone, sign in with the same email address and password and **pair your Embrace** with the new smartphone by going to Alert app>>More>>Settings>>Restore pairing.

Please bear in mind that the Alert app should only be downloaded to one smartphone at a time. Having the app on two different phones, especially when the phones are within the same area could lead to frequent disconnections. We would therefore recommend that you keep one dedicated phone and only pair with a different one if you decide to change the original phone.

Embrace not transferring data

When Embrace is connected to the paired smartphone via bluetooth, the device automatically sends data to your smartphone. However, if you have problems uploading data when Embrace memory is <u>full</u>, reboot the Embrace watch and try again.

To reboot the device:

- Let the Embrace watch battery drain fully
- Connect the device to the charger in a couple of seconds you'll notice a white circle it indicates reboot
- Keep the Embrace watch close to your smartphone data should be transferred automatically after the reboot

Difficulty upgrading Embrace firmware

You can access the latest features of the Embrace watch by <u>updating Embrace firmware</u>. If you encountered issues updating firmware please make sure that:

- Your Embrace watch has at least 30% memory
- Your Embrace battery level is at least 30%
- Your smartphone has access to Internet
- Your Embrace watch is right next to your smartphone
- Alert app is running on the foreground

If you still cannot upgrade Embrace firmware, try with a different smartphone:

- Unpair Embrace watch from your smartphone
- Download and sign in to the Alert app on a different smartphone/tablet
- Open More>>Settings>>Firmware to upgrade Embrace firmware.
- Then unpair Embrace from the second smartphone and pair with the previous phone

Cleaning your Embrace

We suggest cleaning the Embrace **once a week** with a moistened cloth and a **mild soap or detergent**. Make sure to rinse the soap off thoroughly before wearing your Embrace. If you want to clean the band separately, you can <u>remove it from the watch</u> using a spring bar removal tool. Once dry, attach the band to the watch case with the spring bar removal tool. We recommend that Embrace is **completely dry before charging it**.

Note on detergents:

Do not expose the Embrace to Hydrogen Peroxide, Sodium Hypochlorite, or Peracetic Acid based disinfectants or abrasive cleaners, as they may permanently damage the device.

Troubleshooting the Alert App

Pairing Embrace with a different account

You can pair Embrace with one phone and one Alert app account at a time. If you'd like to pair Embrace with a different Alert app account, you need to unpair (disconnect) Embrace from the previous Alert app account first.

Follow the steps below to disconnect Embrace from the previous Alert app account (Alert app A) and pair with a new one (Alert app B):

- 1. Sign in to the Alert app with Alert app account A
- 2. Open Alert app>>>More>>Settings>>Remove Embrace
- 3. In the smartphone open Settings>>Bluetooth>>Embrace>>Forget device/Unpair
- 4. Sign out of the Alert app and sign in with the Alert app account B
- 5. Follow the in-app instructions to pair the Embrace watch

If you cannot access the Alert app Embrace was originally paired with, please contact us at support@empatica.com.

< Sett	tings
EMBRACE	
Serial Number	1FNXF11193
Firmware	Upgrade now
The Firmware is the brain of notify you to install the lates available for the best perform More info	Embrace. Alert app will t version whenever it's mance.
Advanced Settings	>
EMBRACE PAIRING	
Restore Pairing	
If you've removed Embrace t on your phone, you can pair this option.	from the Bluetooth settings Embrace again by selecting
Remove Embrace	
Disconnect Embrace from ye tapping this button. More info	our Alert app account by

Trouble pairing Embrace

If your Embrace is charged, it is placed close to your smartphone, Bluetooth and Internet connection is on and you still cannot pair your Embrace watch, try the following steps:

ANDROID DEVICES

- Make sure you have the latest Alert app
- Enable location services on your Android phone: go to Settings>>Scroll down to "Location">>Tap location>> tap "On". If it's already on, swipe the toggle a couple of times to disable and enable the location services.
- In your smartphone go to Settings>>Bluetooth and check if Embrace is in the list of the available or paired devices. If yes, tap on it and tap "forget" so that you can start pairing from scratch.
- Open Alert app. Sign into the Alert app and follow the in-app instructions for pairing.
- If you're asked to enter a pin during pairing, enter 123456.

If you still cannot pair Embrace, disable and enable bluetooth a few times and try again.

If you've initially paired/ tried **pairing your Embrace watch with a different smartphone** and you're now trying to pair it with a new device, please make sure to remove Embrace from the bluetooth settings of the previous phone/tablet.

Note: some Android devices that meet Embrace <u>compatibility requirements</u> might still have compatibility issues. For example, not all devices that list Bluetooth 4.0 in the specifications, actually support Bluetooth Low Energy.

iOS DEVICES

- Tap on the Bluetooth icon in the menu bar and select Bluetooth Settings.
- Select the Embrace, then click the icon underneath the list.
- Click Remove in the confirmation window.
- Turn off your phone.
- Turn back on.
- Log in to Alert app.
- Make sure that Embrace is charged and directly next to your phone.
- Make sure that Bluetooth is enabled
- Begin the pairing process.

If you are trying to pair the Embrace with a new iOS device, be sure to unpair it from the old phone and follow steps 1-3 above to 'forget' it from the old device's bluetooth settings before starting to pair it with the new device.

Transferring data from the Alert App

The data stored in the app on your smartphone won't be uploaded if your phone isn't connected to the Internet . You can check the data pending to be sent from your Alert app to the cloud by going to **Alert app>>More>>Settings>>Advanced Settings>>Alert Storage**. If Alert Storage says "Nothing to upload " it means there is no data to be sent from your smartphone.

If there's a number along Alert Storage- it means there's data to be synced, so make sure to upload them - the process is automatic - just activate Internet connection on your smartphone (cellular data or WiFi connection - the latter is necessary if you've activated the option to upload data only via WiFi).

	ed occumps
Indicates the last time Em Keep Embrace connected automatic data transfer [a memory].	brace sent data to your phone. I via bluetooth to allow and avoid filling up Embrace
Alert Storage	Nothing to upload
If your phone has no conn sent from your Embrace w an internet connection is i reconnect, data will auton More info	nection to the internet, data vill remain in the Alert app until available again. Once you natically upload to the cloud.
Last Sync to Cloud	Just now
This indicates the last tim app to the Empatica Clou connected to internet to k More info	e data was sent from the Alert d. Make sure your phone is keep data synced.
Upload using WiFi only	
Turning on this option will	save cellular data usage - You

If Internet connection is active, but you're still not able to upload data, force the app to close and reopen it again.

For iOS devices: How to force an app to close

For Android devices: How to force stop an app

Trouble with Embrace Light & Vibration

It's bedtime (or any other time), so you try to turn off Embrace Light & Vibration but hit a snag? Not to worry, it's a little glitch that can be fixed by doing any of the following:

• Reboot your smartphone. Once it has successfully restarted, go the Alert app screen and try again (if night mode isn't on already).

- Force stop the app (<u>iOS, Android</u>) and relaunch it.
- The glitch can sometimes be resolved by being persistent and tapping on the Light & Vibration off/on a couple of times.

If the issue is not resolved, please write to support@empatica.com with a screenshot and we would help to resolve it.

"No internet connection" status

If you are connected to the internet, but you still see the 'no internet connection' notification, you should switch off your phone and switch it back on.

If using cellular data, check to see that you have an active connection. If you're using WiFi, try to disconnect and reconnect your phone from the WiFi network.

If you have an active subscription, and a seizure is detected when there is no internet connection, alerts to Caregivers cannot be sent.



"Bluetooth off" status

To resolve this issue, turn off Bluetooth for 20 seconds, and then turn it back on. If this fails to resolve the issue, please restart the paired phone.

Without Bluetooth connection, data won't be sent from the Embrace to the Alert App, should a seizure occur, the Alert calls and SMS cannot be sent.



"Embrace not found" status

If your Embrace is charged, it is close to the paired smartphone but the error message "**Embrace not** found" is still displayed in the Alert app:

- 1. Turn off **Bluetooth** on your paired smartphone and turn it back on
- 2. Force the app to close (<u>iOS, Android</u>) and open it again

If you still see the "Embrace not found" message, try the following steps:

- 1. **Forget** the Embrace from your smartphone (<u>iOS devices, Android devices</u>)
- 2. Then log out of the Alert app and login again
- 3. Restore pairing from Alert app>>More>>Settings>>Restore Pairing (pairing is automatic for Android devices)

Make sure that the Embrace is charged and it is close to the smartphone when pairing.

Should the warning sign persist, report the issue from the Support section of the Alert App attaching a screenshot of the Status Page or contact support through support@empatica.com.

Warning Notification

If you see the warning status for more than 3 minutes follow these steps to resolve the issue:

- 1. Turn off Bluetooth on the paired smartphone.
- 2. Force the app to close on your <u>iOS</u> or <u>Android</u> device.
- 3. Launch the Alert app again.
- 4. Turn Bluetooth back on.

Should this not resolve the problem, we suggest turning off and on your smartphone and re-launching the Alert app.

Should it still not work, report the issue from the Support section of the Alert App attaching a <u>screenshot</u> of the Status Page.

Alert Not Sent

"Alert not sent" occurs if there was a seizure detected, but Embrace was not able to send the alert due to the following reasons:

- 1. **Bluetooth disconnection**: Embrace wasn't connected to the paired smartphone so it couldn't send the Alert. See: <u>Why Does my Embrace keep Disconnecting?</u>
- 2. No internet connection: The paired smartphone wasn't connected to the Internet and therefore the Alert App wasn't able to send the Alert calls and SMS. Please see: <u>How does</u> <u>Embrace work?</u>
- 3. No activated caregivers. Please see: How do I add my caregivers?