
# EpiWatch Monitoring System Instructions for Use

This instructions for use manual is applicable for the EpiWatch Monitoring System application software version 1.0.0.

The software version will be displayed on the Dashboard page of the phone application and within the Settings page of the watch application.

**Caution**: Federal(USA) law restricts this device to sale by or on the order of a physician.

## Manufacturer Information

EpiWatch ,Inc.

1812 Ashland Avenue Suite 110,

Baltimore, Maryland 21205

Website: www.epiwatch.com

A PDF copy of this Instruction for Use is available at https://www.epiwatch.com/manuals/ or by requesting a copy at info@epiwatch.com

### EpiWatch Support

If you need support, you can reach out via the following:

Telephone: +1 (410) 703 3611

Email: info@epiwatch.com

### Report destination for serious incidents

Any serious incident that has occurred in relation to the device should be reported to EpiWatch, Inc. and the competent authority.

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# How to Read this Instructions for Use

This Instructions for Use provides specific information for the safe operation of the EpiWatch Monitoring System and is not intended to describe the treatment of patients. It provides instructions and important safety information for the operation of the EpiWatch Monitoring System and the required responses to alarms.

## Abbreviations

Within this document the following abbreviations and terms are used.

| Abbreviation/Term | Meaning |
|---|---|
| ADL | Activities of Daily Living |
| EEG | Electroencephalogram |
| ECG | Electrocardiogram |
| EMC | Electromagnetic Compatibility |
| TCS | Tonic-Clonic Seizure |
| LED | Light Emitting Diode |
| PWE | Patients With Epilepsy |
| RF | Radiofrequency |
| FAR | False Alarm Rate |
| PPA | Positive Percent Agreement |

## Glossary

**Epilepsy/Seizure disorder** – chronic neurologic condition diagnosed by a clinician

**False Alarm** - the EpiWatch Monitoring System may misidentify an activity as a seizure when it is not. This will trigger the Alerting feature to send out an alert to selected Caregivers, even though it is a False Alarm.

**False Alarm Rate** – The false alarm rate defines the number of false alarms per day (24 hour period).

**Tonic-Clonic Seizure** – A tonic-clonic seizure, also known as a grand mal seizure, is a type of seizure that involves a loss of consciousness and violent muscle contractions

**Caregiver** – an individual who may respond when a wearer/user experiences a seizure. Frequently set up as a contact for notification on the contacts screen.

**Positive Percent Agreement** - When a new test is evaluated by comparison to a non-reference standard, you cannot directly calculate unbiased estimates of sensitivity and specificity. Therefore, the terms sensitivity and specificity are not appropriate to describe the comparative results. Instead, the same numerical calculations are made, but the estimates are called positive percent agreement and negative percent agreement. This reflects that the estimates are not of accuracy but of agreement of the new test with the non-reference standard.

# Product Description

## General Description

The EpiWatch Monitoring System is a non-electroencephalogram (non-EEG) physiological signal-based seizure monitoring system. It is similar to other legally-marketed non-electroencephalogram (non-EEG) physiological signal-based seizure monitoring systems.

The EpiWatch Monitoring System consists of a software-only mobile medical application intended for use with a compatible wrist-worn device as an adjunct to seizure monitoring of adults and children ages 5 and up.

EpiWatch Monitoring System is a software platform composed of:

- A compatible wrist-worn device, (e.g. an Apple Watch)
- A mobile application running on smartphones called the "EpiWatch Monitoring System App".

The wrist-worn device continuously collects raw data via specific sensors, and provides the consolidated physiological data to the EpiWatch app via APIs. Utilizing a proprietary algorithm, EpiWatch analyzes and assesses the physiological data and determines if there is suspected tonic-clonic seizure (TCS) activity. The EpiWatch algorithm has been validated through testing of epilepsy patients experiencing TCSs in hospital Epilepsy Monitoring Units. Validation was performed using a gold-standard video electroencephalogram (vEEG) methodology designed by a group of epileptologists at a level 4 epilepsy center.

When a likely TCS is detected, the EpiWatch Monitoring System App communicates to the EpiWatch Server which initiates, through an external provider, a voice call, email and an SMS text message (notification parameters are set by the user at contact setup) to alert designated Caregiver(s).

In addition to initiating alerts, the EpiWatch app also continuously receives sensor data collected by the wrist worn device. The EpiWatch App is responsible for transmitting—over a cellular data plan or Wi-Fi connection—the API data, device information, and computed physiological parameters to the EpiWatch Cloud for further review and storage, which allows seizure reports and other features in addition to alerting. It also provides necessary information about the state of the system.

To request a copy of the clinical study report, please contact info@epiwatch.com.

## Indications for Use Statement

The EpiWatch Monitoring System is a prescription, software-only mobile medical application intended for use with a compatible wrist-worn device as an adjunct to seizure monitoring of adults and children ages 5 and up in home or healthcare settings during periods of rest.

The EpiWatch Monitoring System continuously records, stores, displays, and transfers data from the compatible wristworn device’s built-in physiological-based sensors to support review by healthcare professionals, and people with epilepsy (PWE) or at risk of epilepsy.

When the EpiWatch Monitoring System detects and logs physiological patterns associated with generalized tonic-clonic seizures (TCS), the EpiWatch Monitoring System application alerts the user and/or the identified caregiver(s) to notify of detected possible seizure events.

## Intended Use

The EpiWatch Monitoring System is intended as a noninvasive prescription device that acts as an adjunct for the detection and alerting of possible generalized tonic-clonic seizures in patients with epilepsy or at risk of having generalized tonic-clonic seizures, and for remote monitoring of physiological parameters which may provide supplementary support in the clinical management of epilepsy.

## Intended Patient Population and Use Environment

The EpiWatch Monitoring System is intended for use in patients ages 5 years or older with epilepsy or at risk of having epilepsy. The device is intended for use in home or healthcare settings during periods of rest.

## Use of Collected Data

EpiWatch may use collected data to provide and improve our services. Our Privacy Policy can be accessed at https://getepiwatch.com/web/legal/privacy-policy

# General Instructions

1. Users should always wear the compatible wrist-worn device while monitoring. The EpiWatch Monitoring System cannot monitor/detect seizure patterns when the compatible wrist-worn device is not worn.
2. Users should wear the compatible wrist-worn device on their most affected arm (the arm most frequently involved during seizures) for optimal monitoring and seizure detection.
3. Users should charge the compatible wrist-worn device during periods of inactivity, or when caregivers/others are nearby to respond to seizures, to maintain uninterrupted monitoring.
4. Users should not delete the EpiWatch Monitoring App from either the paired smartphone or compatible wrist-worn device.
5. EpiWatch current indication for use is the detection of tonic-clonic seizure activity.

# Contraindications/Limitations

## Contraindications

- The EpiWatch Monitoring System is not designed or intended for use except as indicated.
- The EpiWatch Monitoring System does not predict seizure onset and is not intended as a standalone seizure monitoring device.
- The safety and effectiveness of the EpiWatch Monitoring System have not been established in monitoring signals that may be associated with seizures other than tonic-clonic seizures.
- The EpiWatch Monitoring System is designed and intended to be worn on the wrist. Safety and effectiveness has not been assessed/established for any other locations other than the wrist (e.g. ankle, pendant, etc.)

## Limitations

- The EpiWatch Monitoring System operates under the following constraints:
    - The EpiWatch Monitoring System does not operate on unsupported devices.
    - The user should wear the compatible wrist-worn device on the most affected arm.
    - The results may include false positives or false negatives. The user's activity, watch band fit, and concomitant conditions (such as immersion in water) can affect the quality of the detection results.
- The EpiWatch Monitoring System is intended to opportunistically provide a detection of a possible TCS event. The absence of a notification is not intended to indicate that no disease is present. It is not intended to replace traditional methods of diagnosis or treatment.
- The EpiWatch Monitoring System cannot collect data when the compatible wrist-worn device is turned off and cannot transmit data when the paired smartphone is turned off.
- If users would like to stop using the EpiWatch Monitoring System, they may cancel their subscription. Upon subscription cancellation, and the subscription is immediately switched to an invalid state. Users maintain access to the app to review their existing information and previous reports (if applicable). A new subscription will be required for the user to restart using the EpiWatch Monitoring System.
- If users would like to stop using the EpiWatch Monitoring System permanently, they can permanently delete their account. Upon account deletion the health and personal data of the user will permanently be removed. Both the user and healthcare provider will lose access to the user's trend reports.

- Network connectivity is required for timely alerting of the caregiver contacts within the account.
- To prevent redundant notifications, the EpiWatch app has a post-detection refractory period of 10 minutes during which alerts are temporarily disabled

# Safety

**Apple Watch**

- Apple Watch is water-resistant but not waterproof. It can be worn and used during exercise (exposure to sweat is OK), in the rain and while washing hands

  Please refer to the original manufacturer document regarding the user manual and guides for Apple Watch: [https://support.apple.com/en-us/docs/watch]
- Apple Watch conforms to the following EMC and Electrical Standards:
  - Electrical safety was assessed according to IEC 62368-1 (2014), “Audio/video, information and communication technology equipment – Part 1: Safety requirements.”
  - Apple Watch conforms to EU standards EN 301 489-1 (V2.2.20), EN 301 489-3 (V2.1.1), EN 301 489-17 (V3.2.0), and EN 301 489-52 (V1.1.0).

# Warnings and Cautions

To maintain user safety, please adhere to all WARNINGS and CAUTIONS listed in these Instructions for Use and on product labels.

## Warnings

- EpiWatch, Inc. cannot guarantee that the EpiWatch Monitoring System will detect every seizure and deliver alerts accordingly. The system is not meant to substitute your current seizure monitoring practices, but rather to serve as a supplement in expediting first-response time. **It is important not to alter or reduce seizure management practices when using the EpiWatch Monitoring System.**
- For the timely delivery of notifications to caregivers, the following conditions must be met:
  - The user wearing the compatible wrist-worn device must retain cellular or Wi-Fi connectivity. unless the Apple Watch is equipped with independent cellular service. If both devices can access Wi-Fi, they remain paired and functional.
  - The caregiver’s phone must be connected to a cellular network for phone and text alerts.
  - The EpiWatch Monitoring System or the paired compatible wrist-worn device do not show any warning messages.
  - The compatible wrist-worn device and the care giver phone must be charged and operating properly.
- Wearers who wear a pacemaker, or who have health conditions which might be sensitive to small electrical signals should always consult their physicians before wearing any electronic devices, including the selected compatible wrist-worn device.
- If the compatible wrist-worn device is used in a manner not specified by the manufacturer, the protection, functionalities, and performance it provides could be compromised.
- DO NOT use the EpiWatch Monitoring System on unsupported operating systems (OS) or unsupported wrist-worn devices/smartphones.

- DO NOT wear your compatible wrist-worn device during a medical procedure (e.g., magnetic resonance imaging, diathermy, lithotripsy, cautery and external defibrillation procedures).
- The user must wear the compatible wrist-worn device correctly to ensure correct raw data acquisition, seizure detection, and physiological parameter computation. The watch should be worn on the wrist of the arm most impacted by seizure activity.
- To ensure proper data capture, the compatible wrist-worn device and the companion app/system must be charged and operating properly during the entire monitoring period.

### Cautions

- USA Federal law restricts this device to sale by or on order of a physician.
- Do not wear the compatible wrist-worn device on broken or damaged skin.
- Do not store the compatible wrist-worn device near other electrical equipment.
- Keep the compatible wrist-worn device clean. Bacteria and dirt may cause skin itching or irritation. Do not clean while wearing the device or use cleaning agents other than those recommended by the manufacturer.
- Check the compatible wrist-worn device for sharp edges and damage before each use. Do not use it if it appears damaged.
- Do not leave compatible wrist-worn device in environments in which it may overheat beyond the recommended environmental limits (e.g., a car parked in the sun). If the device is left exposed to high temperatures, allow it to cool before handling it to avoid possible skin burns.
- The battery charge level displayed on the compatible wrist-worn device display and in the EpiWatch Monitoring System user interface is only accurate if the batteries are in normal working condition.
- The compatible wrist-worn device cable charger may generate heat when connected to a power source; be careful when handling it during the charge.
- The EpiWatch Monitoring System App home screen background color is not related to the patient’s health. It provides information on the system working status only.
- The EpiWatch Monitoring System status cards are not related to the patient’s health status. They provide information on the system's working status.
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# System Features/functions

## Wearer and Caregiver Monitoring

The Wearer and Caregiver Monitoring function provides real-time monitoring capabilities for both the wearer of the EpiWatch Monitoring System device and their designated caregivers (contacts set up in the wearer's account). This function allows the wearer and caregiver(s) to control and customize the real-time monitoring settings according to their preferences and needs.

The system generates notifications and warnings to alert the wearer and caregiver(s) about the status of the real-time monitoring, such as low battery, loss of connectivity, or any other relevant issues that may affect the monitoring performance.

Monitoring will be discontinued when the watch is charging.

## Detection Logging

The Event Detection and Logging function encompasses the core functionality of the Tonic-Clonic Seizure (TCS) detector.

This function logs all detected event . The logged data includes timestamp, event type and other relevant parameters associated with the detected event. This information is securely stored and made accessible to authorized users (e.g., wearer, caregivers, healthcare professionals) through the EpiWatch Monitoring System app and web portal.

The Event Detection and Logging function includes fail-safe mechanisms to ensure that critical events are logged even in case of temporary system disruptions or connectivity issues.

## Alerting

The Alerting function is responsible for delivering timely and reliable notifications to caregivers and nearby individuals in the event of a detected seizure, or when the wearer initiates a manual alert, through multiple notification channels. This function ensures that the appropriate parties are promptly informed and can respond effectively to assist the wearer during a seizure episode.

The function is responsible for both automatic seizure detection alerts and manual alerts triggered by the wearer. The function can be configured to activate an audible alert to notify individuals near the wearer when a seizure is detected.

To ensure the reliability of alert delivery, the Alerting function incorporates robust communication protocols and redundancy mechanisms and is designed to operate independently of the wearer's smartphone proximity, ensuring that alerts can be triggered and delivered even when the wearer's phone is not nearby. The feature also includes a test function to provide wearers and caregivers with confidence that the EpiWatch Monitoring System is working appropriately.

The alerting function additionally encapsulates features for alert cancellations in the event of false positives, while minimizing the risk of accidental cancellations during actual seizure episodes.

## Application Activity Logging

This function enables comprehensive logging of application activities and events to support troubleshooting and error diagnosis. It captures detailed log data from both the EpiWatch Monitoring System mobile application running on the Wearer's/Caregiver's phone, data captured by the wearer's Apple Watch, and the cloud micro-services that handle data processing and storage.

The logging mechanism includes device identification information for each installation, allowing logs to be traced back to specific devices for targeted troubleshooting, as well as information on system

configurations, detected events, data access tracking, and other contextual data surrounding the operation of the EpiWatch Monitoring System.

### Data Record, Store, Display, and Transfer

This function handles the recording, storage, display, and transfer of physiological data captured by the compatible wrist-worn device's sensors.

The function continuously records the incoming physiological data streams during monitoring periods and securely stores this data for later access and analysis. All wearer and caregiver data, including personal identifiable information (PII) and protected health information (PHI), is stored in compliance with applicable regulations to ensure privacy and data protection.

The recorded data can be requested from the manufacturer to share with healthcare providers, allowing wearers to share their detected event summaries with physicians and aid in treatment.

## Hardware and Software Requirements

The EpiWatch Monitoring System is supported on:

- Apple
    - Apple Watch running watchOS 10 or higher
    - Apple iPhone running iOS 17 or higher

# Installation

Follow these steps to get started with the EpiWatch Monitoring System App:

**STEP 1: DOWNLOAD THE EPIWATCH MONITORING SYSTEM APP**

iPhone

1) Open the App Store on your iPhone (App Store,) and search for “EpiWatch”.


Tap on ‘Get it’ or ‘Download’ to start the download process.

**Note: You’re encouraged to download the EpiWatch Monitoring System App from the App Store to check device compatibility.**

2) Confirm that the application has been downloaded successfully to both the paired iPhone and the Apple Watch that will be used for monitoring.

**STEP 2: SIGN UP**

1) Open the EpiWatch Monitoring System App by tapping on the icon on the paired smartphone. A login screen will appear.
2) For initial access, you will need to create a new account. To do this, pres the “create account” button on the login screen and complete all required information.
3) To access the EpiWatch Monitoring System App, insert the credentials created during the onboarding process after your purchase/prescription.
   a. Remember you need to have verified your email before and, where applicable, your legal guardian needs to have provided their consent .
   b. For users under 13, COPPA consent must be completed by the legal guardian of the user. This will be sent by email after completion of the onboarding process.
4) You will need to upload your EpiWatch subscription for validation. Once your prescription has been validated, your account will be activated.
5) Once successfully logged into the EpiWatch Monitoring System application, you can set your monitoring preferences such as setting up contacts (see **Contacts** section below) and begin monitoring.

Figure SEQ Figure * ARABIC 1: EpiWatch Screen iPhone


### STEP 3: GRANTING PERMISSIONS

The user will need to grant permission through a permissions prompt on the compatible wrist-worn device for the EpiWatch Monitoring Application to function properly. These permissions allow the EpiWatch Monitoring System to send accurate alert notifications and access data for physiological data tracking for seizure detection analysis.

1) The system will query for health permissions, motion and fitness permissions, and location permissions on either the compatible wrist-worn device or the phone application.
2) The user should accept the permissions to share health information with the EpiWatch Monitoring Applicatio for the EpiWatch app to function correctly.

### STEP 4: START RECORDING DATA

Make sure to wear the compatible wrist-worn device correctly as this affects the quality of the data collection. To wear it correctly follow the below steps:

1) Wear it 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 (consult your doctor on how best to wear the compatible wrist-worn device).
2) Place the device one (1) finger's width from your wrist bone

3) Fasten the band and secure wrist-worn device until you feel a soft pressure.

*IMPORTANT: Make sure the compatible wrist-worn device fits snugly but not too tightly. Only wear on intact skin. Do not use with injured skin or other types of skin diseases located on the wrist. Do not use if the device appears to be damaged.*

*CAUTION: In case of skin irritation after prolonged use, it is suggested to switch the wearing location, by placing the wrist-worn device on to your other wrist. Also, clean the device to avoid further irritation. In case of an allergic reaction, it is suggested to immediately stop using the device and contact your doctor.*

*WARNING: Wi-Fi/cellular connections must be active for the EpiWatch Monitoring System to function as intended. For the functioning of the system, the following conditions shall be met:*

- *Although the system will notify the user in case of disconnections, it is recommended to keep that companion phone within 1 meter distance during periods when the user would have difficulty troubleshooting connection issues, such as sleep or in conditions of impairment.*
- *The paired companion app/system must be connected to the internet.*
- *The compatible wrist-worn device and the companion app/system must be charged and operating properly.*

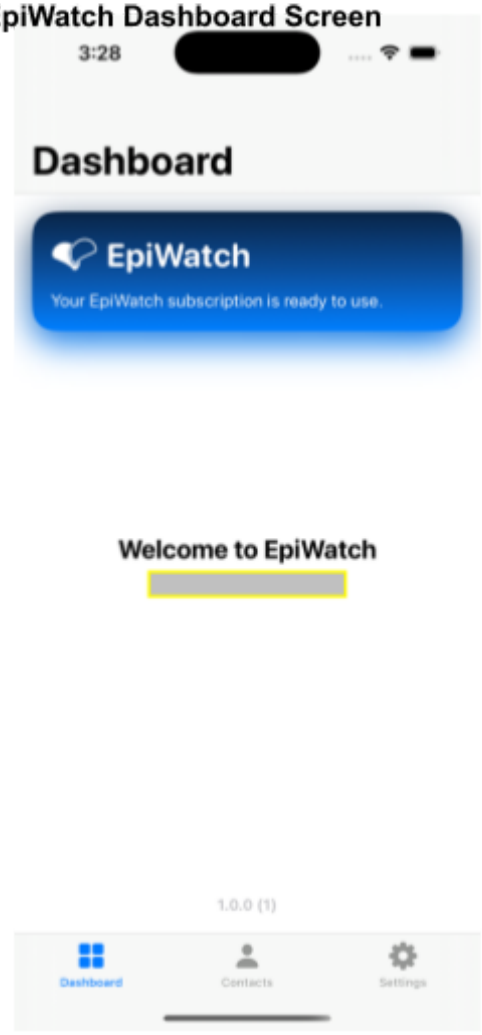
# Operation

## Using the EpiWatch Monitoring System Application

### Dashboard

Once logged in, the user will be automatically taken to the Dashboard. This is the main “Home” screen to which you can access the other functions of EpiWatch Monitoring System, such as the Settings and Contact Management.

Figure SEQ Figure * ARABIC 2: EpiWatch Dashboard Screen

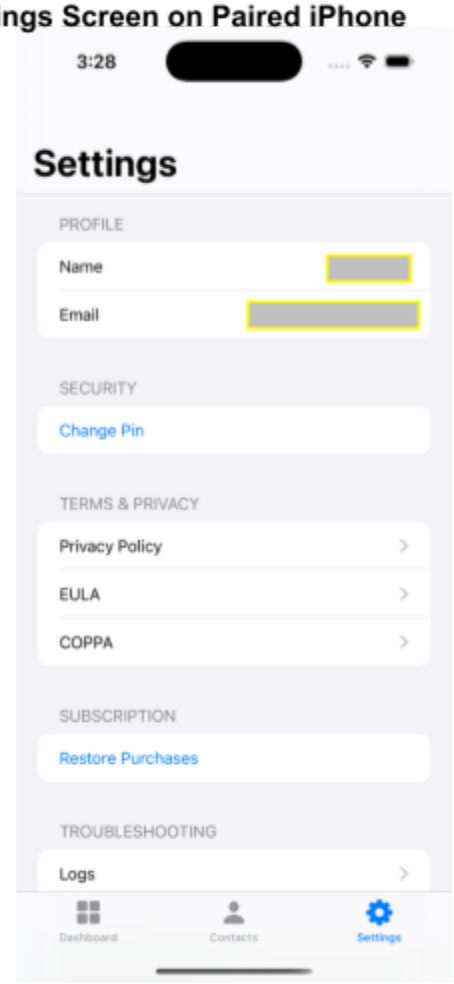



- Contacts - indicates the Contacts currently active. By tapping on the Contacts button, the user will be able to view the contacts summary. Contacts may be caregivers, family members, response personnel or other individuals able to assist in the event of a seizure.
- Settings - By pressing the settings button, the user will have access to the settings page.

## Settings

By tapping on the settings icon on the home screen, the settings page is presented to the user.

**Figure  SEQ Figure * ARABIC 3: Account Settings Screen on Paired iPhone**




This page contains the following information:

- User information
  - Username
  - User email: the email used for the account in the system
- Terms and Privacy: Contains EpiWatch's Privacy Policy, EULA, and COPPA if applicable that the user signed during onboarding and Open Source Licenses.
- Logs: Allows the user to send logs from the phone and the watch to the manufacturer for troubleshooting.
- Open Source Licenses: Contains information on the open source libraries and frameworks used in the application.
- Logout button: Allows the user to log out from the App, to confirm the log out the user will be prompted to confirm the action through a confirmation modal.

- Delete Account Button: Allows the user to delete their account. Once the account is deleted, the user will need to set up a new account if future monitoring is desired.

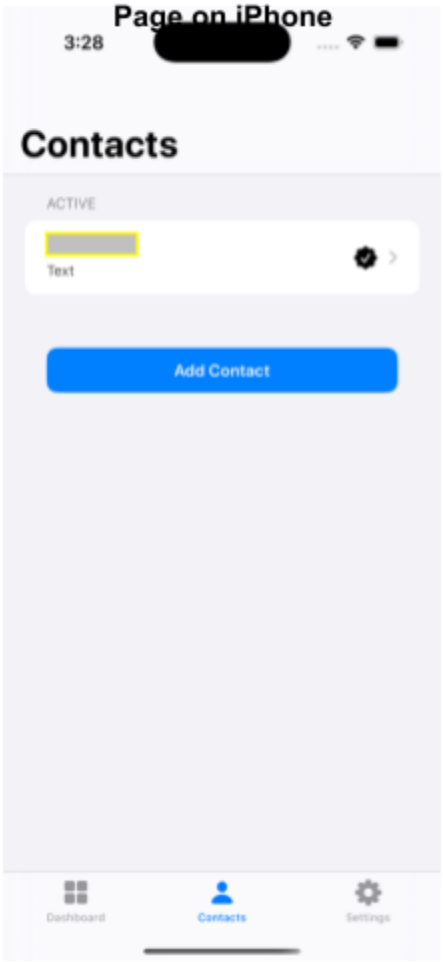
### Contacts Management

Contacts are the people who will come to your assistance when the EpiWatch Monitoring System detects a possible tonic-clonic seizure. They are very important, and we suggest that you choose them carefully and educate them about what their role consists of.

You can add a Contact in the app at any time. When you log in to the app for the first time, it will guide you through adding your first Contact. If possible, we recommend doing the set-up with the Contact next to you for a smoother experience. Make sure your Contacts are active. If deactivated, Contacts do not receive alerts.

By tapping on the “CONTACTS" image at the bottom of the phone screen, the Contacts page opens.

**Figure SEQ Figure * ARABIC 4: EpiWatch Contacts Page on iPhone**




Within this page the user will be able to manage their Contacts:

- Add Contact: By pressing on this option, the user will be able to add Caregivers.
- View Contact information: The user will view the list of Contact added in the system and manage them. By pressing on the Contact icon, they will be able to view the Contact’s full profile.

    - Contact name
    - Contact country prefix
    - Contact phone number
- Activate or deactivate Contacts: Users can control if the Contact is active or not by toggling the enable contact button.
- Set the alert modes with which to alert the Contact
- Set the number of retries the system will attempt if the alert fails. This property defaults to 3.
- Enable or disable the sending of user location to this Contact. This property defaults to True.
- Test Alert: Press the test alert button to send a test alert to the Contact and test that the application is working as intended.
- Contact Deletion: Delete the Contact by pressing the Delete Contact button. Once the contact is deleted, they will have to be manually added again to be re-enabled.

# Seizure Detection

## Understanding Seizure Detection

The proprietary seizure detection algorithm in the EpiWatch Monitoring System is designed to monitor and analyze biosignals recorded through the compatible wrist-worn device to identify potential seizure patterns in real-time. Upon detection the EpiWatch Monitoring System triggers an alert to the specified caregivers, as configured.

## What Contacts Receive When Seizure is Detected

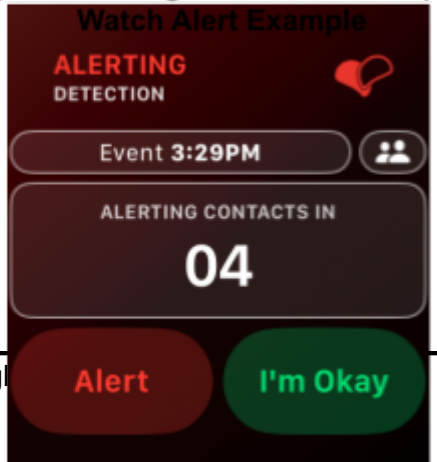
When the EpiWatch Monitoring System detects a possible seizure, it automatically alerts the activated Contacts through the chosen alert modes (call, text, and email). If the alert fails to deliver, the app will retry the alert up to the number of retries designated for that caregiver. If enabled, the user location will be included in the alert. For call alerts the location will be provided as an address, while for text and email alerts, the location will be provided on a map the Contact can interact with.

**Note:** The availability of location depends on allowing your wearable platform to track your location (you will find this in ‘settings’ on your wearable platform)

## Understanding Alerts

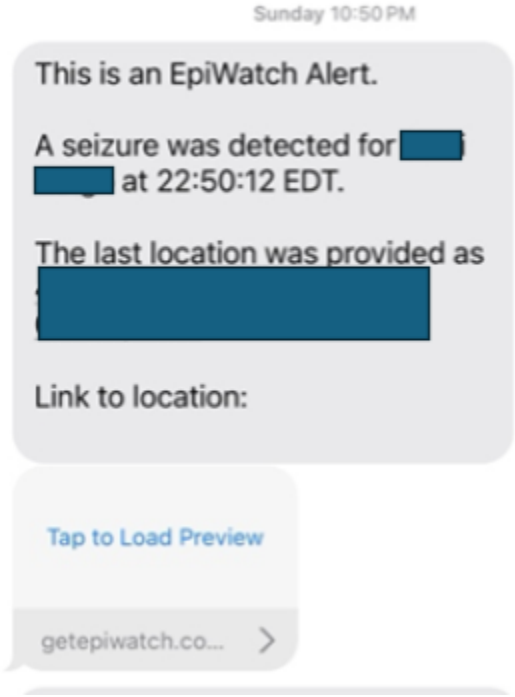
When the system detects a seizure, your compatible wrist-worn device will start vibrating and show the alert sign on the screen and a countdown timer starts. During this alert delay, the user has the option of cancelling the detection by pressing the I’m Okay button, in case it is a false detection. The alert delay may be configured in the Watch Settings, but defaults to 5 seconds.

**Figure  SEQ Figure * ARABIC : Apple Watch Alert Example**



Alerts are automatically sent to your assigned contacts after the countdown has been completed, or the user selects the “Alert” button.

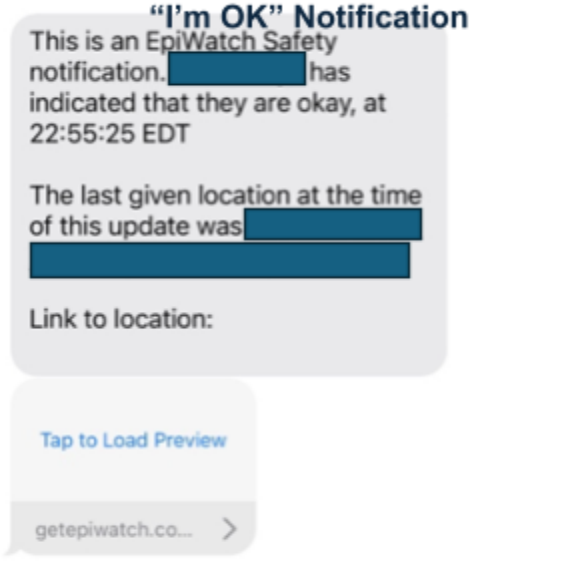
**Figure SEQ Figure * ARABIC : Example of EpiWatch Monitoring System Alert**




## Once the Alert has been Sent

After the alert has been sent, you have 4 minutes to send an automatic SMS to all of your Caregivers saying that you are OK by pressing the “I’m OK” button on the watch screen.

**Figure SEQ Figure * ARABIC : Example of “I’m OK” Notification**



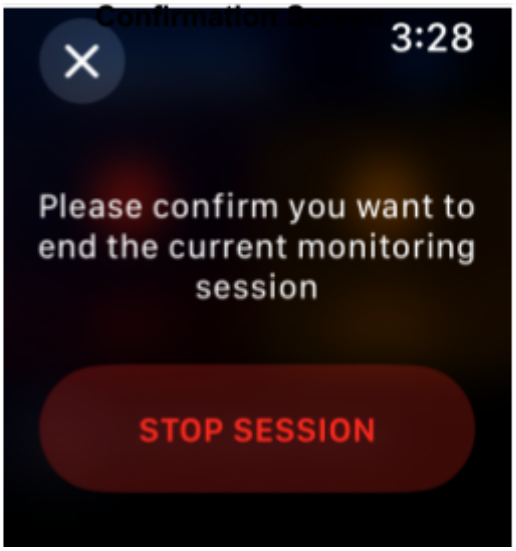
## How to Stop Monitoring

1. Users may stop monitoring at any point. To stop monitoring, open the EpiWatch Monitoring System app on the compatible wrist worn device and locate the red ‘stop monitoring’ slider.
2. Using the red arrow in the white box, slide the box to the right, until it reaches the end of the red stop monitoring button.

Figure  SEQ Figure * ARABIC :


3. Your watch screen will display a confirmation screen – tap ‘stop’ to stop monitoring. Tap the ‘x’ in the upper left corner of the watch face to cancel the stop monitoring command

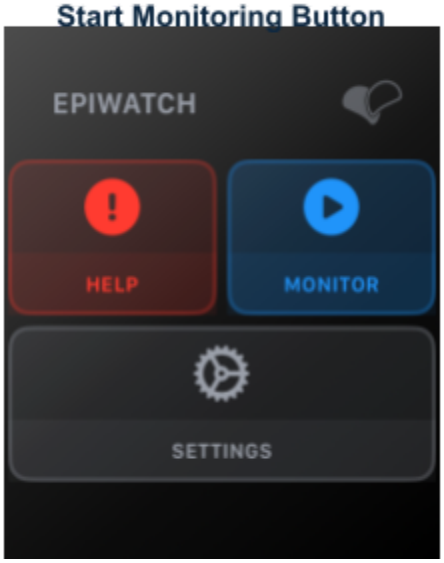
Figure  SEQ Figure * ARABIC : Stop Monitoring Confirmation Screen




4. To restart monitoring, select the “Start Monitoring” button.

   Note: The EpiWatch Monitoring System will provide haptic feedback (vibrates) when monitoring has successfully initiated.

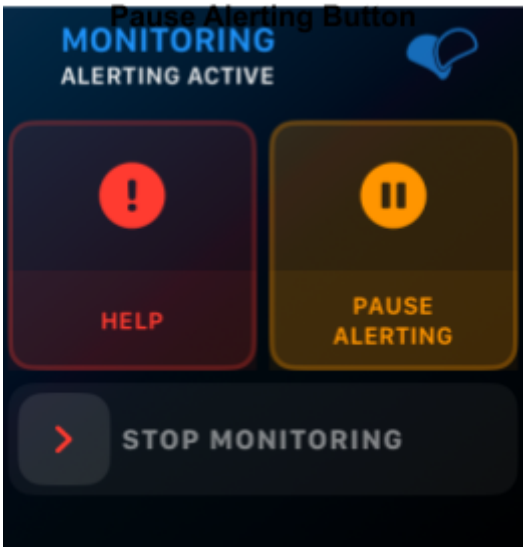
Figure SEQ Figure * ARABIC : Start Monitoring Button




## How to Pause Alerting

1. User may wish to pause the alerting function for a set period of time while they are monitoring. To pause alerting, locate the ‘pause alerting’ button on the watch face during a monitoring

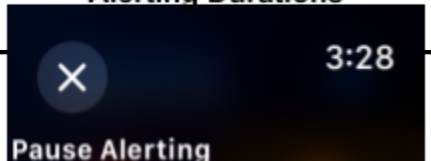
Figure SEQ Figure * ARABIC : Pause Alerting Button




session.

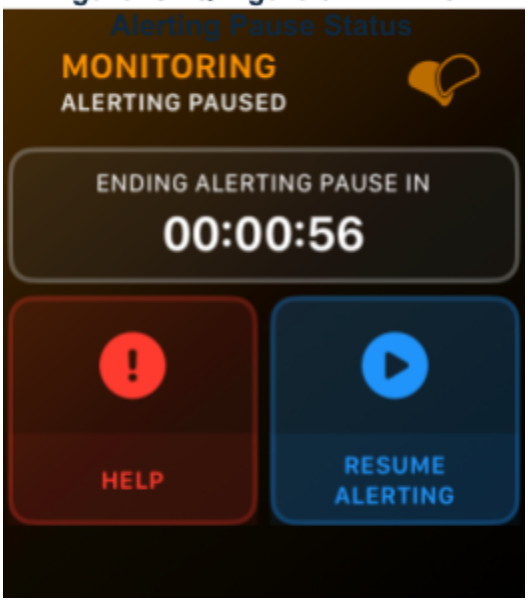
2. You will see several options for the amount of time to pause alerting – select the desired alerting pause time (1 minute to 3 hours maximum). During this time alerts will not be sent to your contacts if you have an automated detection. Manual alerting will still be active during the pause period, and contacts will receive notifications for manual alerts.

Figure SEQ Figure * ARABIC : Pause Alerting Durations



3. You will see a confirmation screen confirming alerting has been paused, with a countdown timer indicating the duration of the alerting pause.

Figure SEQ Figure * ARABIC :

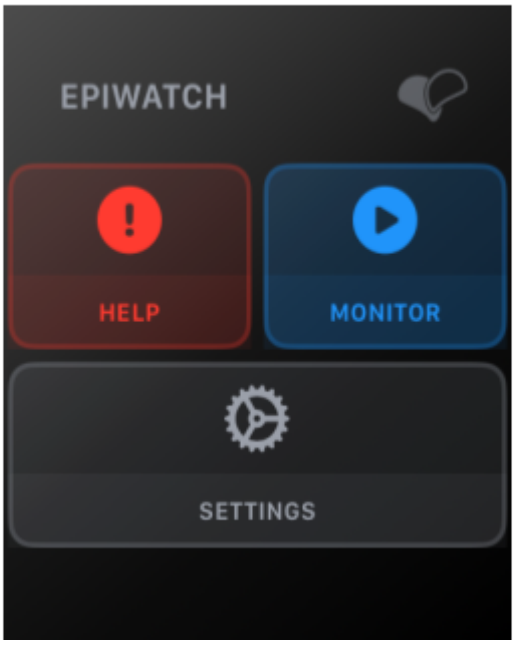


## How to Manually Send an Alert

If you need to immediately alert your Caregivers that you need help, the EpiWatch Monitoring System allows you to manually initiate an alert. To do so:

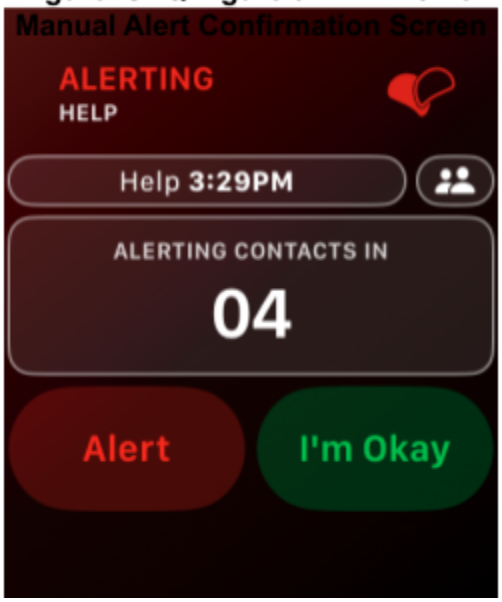
1. When the Monitoring function is on, there is an emergency (panic) button, in red.
2. Press the red “Help” button on the middle on the watch screen.

**Figure SEQ Figure * ARABIC : Monitoring Settings - Emergency Button**




3. A confirmation screen will appear to confirm the manual alert.
    a. If this was a mistake, you can still cancel the alert by selecting the “I’m Okay” button (see “**How to Cancel an Alert**” section).

**Figure SEQ Figure * ARABIC 16: Manual Alert Confirmation Screen**



4. The assigned contact(s) will be alerted via the provided alert preferences (SMS, email, and/or phone call)

**Figure SEQ Figure * ARABIC 17: Manual Alert Message (SMS)**

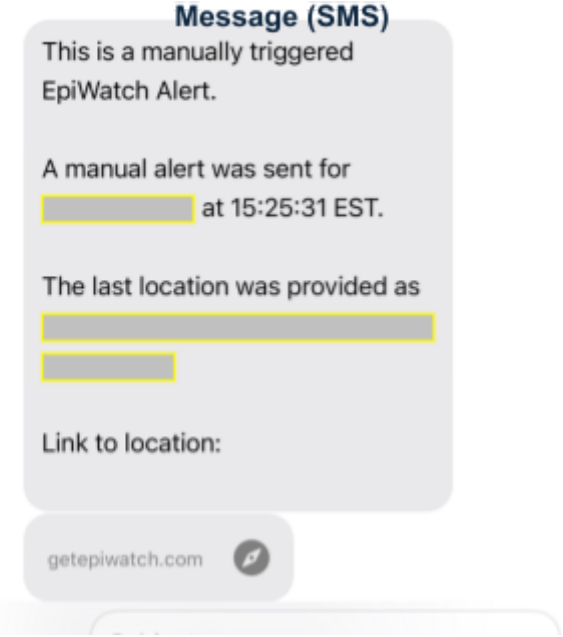
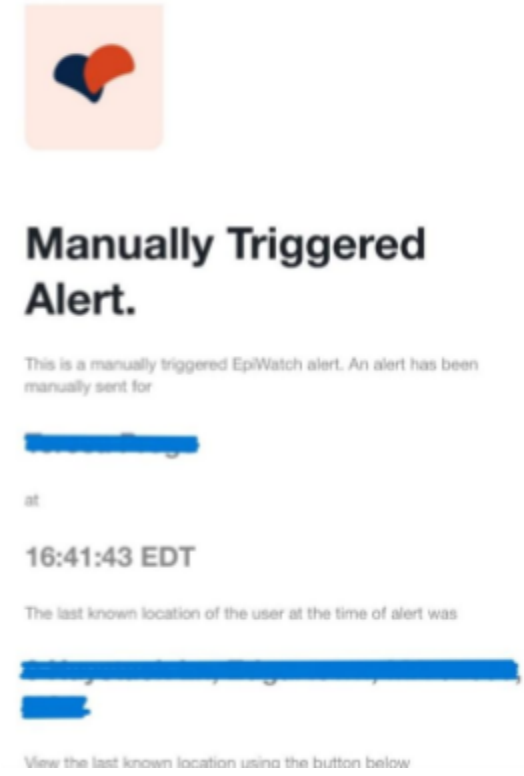



**Figure SEQ Figure * ARABIC 18: Manual Alert Message (Email)**



# False Alarms

The EpiWatch Monitoring System is optimized to detect patterns that may be associated with tonic clonic seizures (TCS). Some types of activity that you engage in during the day may occasionally seem like a TCS to the EpiWatch Monitoring System, when they are not actual seizure activity.

## How to Cancel an Alert

During the alert delay countdown, if you are not having a seizure, you can cancel the alert before it is sent so that you do not unnecessarily alert your Caregivers.

To cancel the alert:

1. Press the “I’m Okay” button to cancel the alert
2. Once the cancellation is confirmed a checkmark will be displayed on the compatible wrist-worn device. No alert will be sent to your Caregivers.

If you do not cancel, an alert call and an SMS will be sent to all your active Caregivers. Alerts can be canceled both from the app and the compatible wrist-worn device.

# Troubleshooting

EpiWatch, Inc. encourages all users to check our support center [or contact help@epiwatch.com] for the latest troubleshooting tips and procedures.

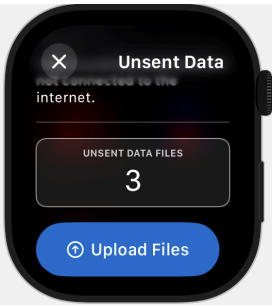
**Note:** It is expected that the user (or caregiver) can set up the compatible wrist-worn device and the companion app/system. They should also be able to charge the compatible wrist-worn device.

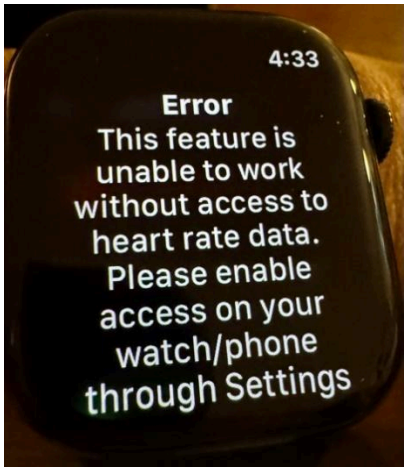
## Messages/Information

The error messages that you see in the EpiWatch Monitoring System App display the status. The following outlines the meaning behind each status, and what action is needed, if any.

| Error Message | Steps To Resolve |
|---|---|
| **No Internet Connection**<br><br>"Your device does not appear to be connected to the internet. Please make sure you are connected to a Wi-Fi/cellular network on your watch or are near your phone. | 1. When the application detects a loss of network connectivity, it will show a no internet icon in the top right.<br>  <br>2. Upon pressing the icon, you will be presented with all of the current errors with the device that need to be resolved. In this case, click on the no internet error icon.<br>  <br>3. The detailed error description will state what is causing the error, and how to resolve it. |

| | |
|---|---|
| |  <br>4. Move into a location where the watch has network connectivity.<br>5. If using WiFi, ensure the watch is connected to the Wifi through settings.<br>6. Wait for approximately 30 seconds. If the device senses the connectivity has returned, the message will resolve.<br><br>7. Contact EpiWatch Support if message persists. |
| **Checking for Files in Memory:**<br><br>“There are files that are on your device that need to be processed. This may be because you are not connected to the internet.” | 1. When the application detects biosignal or detection data files on the device that have not been uploaded for an extended period of time, it will show an unsent data file icon in the top right.<br><br>  <br>2. Upon pressing the icon, you will be presented with all of the current errors with the device that need to be resolved. In this case, click on the no internet error icon.<br><br>  <br>3. The detailed error description will state what is causing the error, and how to resolve it. |

| | |
|---|---|
| |  <br>4. Ensure that the watch has network connectivity so the device is able to upload the unsent data to the EpiWatch cloud.<br>5. Press the upload files button, and wait for the files to upload to the EpiWatch cloud.<br>  <br>6. Once the files have been uploaded, the issue will resolve.<br>7. Contact EpiWatch Support if the message persists. |
| **Low Battery**<br><br>“The compatible wrist-worn device battery is low” | 1. When the device battery falls below 15%, the watch application will show a low battery icon in the top right.<br>  <br>2. Upon pressing the icon, you will be presented with all of the current errors with the device that need to be resolved. In this case, click on the no internet error icon. |

| | |
|---|---|
| |  <br>3. The detailed error description will state what is causing the error, and how to resolve it.<br>  <br>4. Charge the compatible wrist-worn device to get the battery percentage over 15%. The issue will resolve by itself when this occurs.<br>5. Contact EpiWatch Support if the issue persists.<br><br>**Warning: While the device is charging, monitoring will be discontinued, and the EpiWatch Monitoring System will be unable to detect any seizure events.** |
| **No Access to Physiologic Data**<br><br>“The feature is unable to work without access to (name of health related) data | If permission is not granted for the health/physiological measures needed to detect seizures, the watch face will display an error message:<br>  |

| | |
|---|---|
| | 1. To resolve, go to EpiWatch on the Health Setting (found under Privacy and Security)<br>2. Ensure that all permissions are on, to allow EpiWatch access to the physiological data.<br>3. Contact EpiWatch Support if message persists. |
| **Memory Full**<br><br>"The compatible wrist-worn device memory is full" | The available memory space on the compatible wrist-worn device/mobile device is insufficient. To resolve:<br><br>1. Make sure that the compatible wrist-worn device and paired mobile device are connected<br>2. Keep the compatible wrist-worn device and the companion mobile device nearby until the issue is solved<br>3. Contact EpiWatch Support if message persists. |
| **Device is Syncing**<br><br>"The compatible wrist-worn device is syncing" | Syncing data stored in its memory with the mobile device. This is likely to happen when the compatible wrist-worn device has been disconnected from the mobile device (Bluetooth® was off, the mobile device was switched off, or the compatible wrist-worn device and mobile device were not within 30 feet of each other). To resolve:<br><br>1. Wait until the synchronization is complete to begin monitoring.<br><br>**Warning: While the compatible wrist-worn device is syncing, monitoring may be disrupted, and the EpiWatch Monitoring System may be unable to detect any seizure events.** |
| **Needs Attention**<br><br>"The EpiWatch Monitoring System needs your attention" | The system is working, but something needs to be addressed as soon as possible. This can include:<br>● A software update is available<br>● Notifications have been disabled<br><br>To resolve:<br>1. Tap on the message card to identify the issue. |
| **Application is Not Working**<br><br>"The EpiWatch Monitoring System is not working" | The system has stopped working. This can include:<br>● The compatible wrist-worn device is not connected to the paired mobile device.<br>● The compatible wrist-worn device is out of battery<br>● Seizure detection: Off sensing precision<br>● The App has stopped working<br>● Internet/Wi-Fi is not connected<br>● The version of the EpiWatch Monitoring System application is out of date<br>● Server is down<br>● No Caregivers/Contacts have been assigned in the system<br>● Internal error<br><br>To resolve:<br>1. Make sure the compatible wrist-worn device is turned on, has enough battery, and connected to the Internet.<br>2. Make sure that the paired wrist-worn device and mobile device are within 30-40 feet of each other. |

| | |
|---|---|
| | 3. Make sure that there is a least one Caregiver/Contact assigned.<br>4. Contact EpiWatch Support if message persists. |

## Mobile Phone Connections

To properly operate the EpiWatch Monitoring System, it is important to make sure the following conditions are always met:

- The mobile phone on which the EpiWatch Monitoring System app is installed is always connected to the internet via a cellular connection or Wi-Fi connection.

**Note**: Connections are required to be active to ensure the system can generate and send alerts to your designated caregivers, which can help to make sure that you get timely assistance if needed in the event of a seizure.

If your mobile phone is not able to connect to the internet through a cellular or Wi-Fi connection, the EpiWatch Monitoring System will not be able to send alerts to your caregivers. The system is designed to notify you when the connection is not active through visual notifications on your mobile phone.

# Device Specifications

## Technical Specifications

| Device Specifications | EpiWatch Monitoring System |
|---|---|
| Anatomical Sites | Designed to be worn on the wrist |
| Measurement Device/Method | The EpiWatch Monitoring System utilizes a compatible wrist-worn device (see Compatibility with Intended Platform) that can capture and wirelessly transmit sensor data via Bluetooth to a paired remote device |
| Compatibility with Intended Platforms | Compatible wrist-worn devices:<br>● Apple Watch: watchOS version 10 or higher<br><br>Smartphones:<br>● iOS version 17 or higher |
| Algorithm | Uses algorithms to analyze physiological data to detect patterns in the data that may be associated with TCSs. |
| Sensor Technology | Utilizes compatible wrist-worn device's built-in physiological-based sensors to acquire seizure-related data. |
| Data Communication | Communicates wirelessly to a smartphone application, which alerts the healthcare provider or caregiver in one or more ways (phone call, text message, etc.). |
| Electrical Safety | Not applicable. The device does not contain any electrical components. |
| Biocompatibility | Not applicable. The device does not contain any patient contacting materials. |
| Electromagnetic Compatibility (EMC) | Not applicable. The device does not contain any electrical components. |
| Thermal Safety | Not applicable. The device does not generate any localized heat. |
| Chemical Safety | Not applicable. Patients are not exposed to any chemicals during use of the device. |
| Radiation Safety | Not applicable. Device does not use any ionizing radiation |
| Electromagnetic Compatibility (EMC) | Not applicable. The device does not contain any electrical components. |
| Thermal Safety | Not applicable. The device does not generate any localized heat. |

# Clinical Performance Testing

EpiWatch, Inc. is dedicated to continually improving our algorithms. To test the EpiWatch Monitoring System, we collaborated with top epilepsy centers.

EpiWatch conducted a single arm, blinded study of 242 subjects (total 16,189 hours) to evaluate the performance of the EpiWatch algorithm for detecting TC seizures. Potentially eligible subjects were identified among the in-patient population in Epilepsy Monitoring Units (EMU) at six geographically diverse trial sites. Typical duration of enrollee participation ranged from 0.42-11.25 days, based on the length of each subject's stay in the EMU. The length of stay was not influenced by enrollment in the study. Subjects included a broad demographic range of children and adults (See **Table 1**)

There were no serious adverse events (SAEs) or adverse device effects.

**Table 1: Demographic Distribution**

| Subject Total : N-242 | |
|---|---|
| Age | **Mean**: 22.68<br>**Standard Deviation**: 14.2<br>**Median**: 18 **Min**: 5 **Max**: 76 |
| | N= (%) |
| **Age Group (years)** | |
| <13 | 55 (22.7) |
| 12-21 | 92 (38.0 |
| >21 | 95 (39.3) |
| **Gender** | |
| Female | 131 (54.1) |
| Male | 111 (45.4) |
| **Race** | |
| White | 162 (66.9) |
| African American | 60 (24.8) |
| Asian | 5 (2.1) |
| Native American | 0 (0.0) |
| Pacific Islander | 1 (0.4) |
| Other | 14 (5.8) |
| Not Reported | 1(0.41) |
| **Ethnicity** | |
| Hispanic | 21 (8.7) |
| Non-Hispanic | 202 (83.5) |
| Not Reported | 19 (7.8) |

### Sensitivity (Positive Percent Agreement(PPA))

The 242 study subjects had 16,189 hours of study monitoring. They had 47 TCSs confirmed by the central panel; 46 (98%) of these were detected by EpiWatch. The EpiWatch PPA (sensitivity) was

- 0.94, adjusted for all age groups;
- 1.0 for ages 5-12 years,
- 0.95 for ages 13-21 years and
- 1.0 for adults (>21 years).

## False Alarm Rate (FAR)

There were 56 false alarms of which 20 were seizures with motor signs. This resulted in a FAR for detecting TCSs at 0.083 per 24-hour period. This point estimate equals an estimated rate of one false alarm in 12.4 days. The age groups all had similarly low FARs. (See **Table 2**). More than 1/3 of the false alarms, however, were seizures with motor signs.

The PPA and FAR details are included in the following table:

**Table 2: PPA and FAR Results**

| Age Group (years) | Total TCS | Detected TCS | PPA | FA | Hours | FAR |
|---|---|---|---|---|---|---|
| 5-12 | 6 | 6 | 1.00 | 8 | 2701.5 | 0.071 |
| 13-21 | 19 | 18* | 0.95 | 22 | 5411.5 | 0.098 |
| 22+ | 22 | 22 | 1.00 | 26 | 8076.2 | 0.077 |

*The single undetected TCS was in an adolescent whose watch arm was restrained by a caregiver.

# Cybersecurity

EpiWatch, Inc. has taken significant steps to protect its product from cyberattacks, but the user has a crucial role in maintaining cybersecurity. The guidelines in this section must be followed.

The EpiWatch Monitoring System runs on compatible wrist-worn devices and is connected to the user's mobile device, where the companion app/system is installed.

Communications between the compatible wrist-worn device and the EpiWatch Monitoring System App are encrypted using the 128-bit AES-CCM encryption standard.

**Apple Watch**

EpiWatch's EpiWatch Monitoring System App can be installed on an iOS device running iOS 17 or above. The requirements for applications to be made available on the Apple App Store are robust and therefore considered resilient to cyberattacks. No health information is stored in the mobile device's local storage.

*Please refer to Apple Watch Information for up-to-date information on smartphone compatibility.

## General Guidelines for Security

- It is recommended that any mobile device with the EpiWatch Monitoring System installed also has a device passcode set.
- You should never disclose your EpiWatch Monitoring System username or password.
- You should never write down your EpiWatch Monitoring System username or password.
- You should never provide access to the EpiWatch Monitoring System App to an unauthorized user
- You should never leave the mobile phone with the EpiWatch Monitoring System installed, logged in, or unattended.

## Cloud and Network Dependencies

The EpiWatch Monitoring System can only generate seizure alerts and transmit physiological parameters to the EpiWatch Cloud if there is an active cellular data connection or Wi-Fi. The EpiWatch Monitoring System requires cellular data (or Wi-Fi) for the continued functionality of the notification system. The connection between the EpiWatch Monitoring System App and the EpiWatch Cloud might be delayed in case of poor cellular coverage, Wi-Fi issues, or a limited cellular data plan.

In case of missing cellular data or Wi-Fi connection, or in the rare event of the unavailability of EpiWatch's servers, the EpiWatch Monitoring System App will notify you of this status. In the event of service interruption, it is recommended that you inform your Caregiver. If there are cellular data or Wi-Fi connection errors, consult with your service provider. EpiWatch's servers reside on an AWS infrastructure that guarantees an uptime of our cloud infrastructure > 99.95%.

## Password Policy, Password Expiration, and Auto-Logout

A combination of username and password are used to control access to the EpiWatch Monitoring System.

You will create your username and password during the first use of the product. As a user of the EpiWatch Monitoring System App, you can change or reset your password.

### Software Updates and Patches

The user should update the EpiWatch Monitoring System software as soon as a new version becomes available.

When a new version becomes available, the EpiWatch Monitoring System App will notify the user through a specific on-screen notification. Clicking the notification will take the user to the appropriate app store (e.g. Apple App Store), where the up-to-date version can be downloaded.

## Regulatory and Compliance

### Labeling

EpiWatch Monitoring System labeling information is included in the product itself. The Regulatory and Compliance page can be accessed from the Settings screen of the EpiWatch Monitoring System App.

The Regulatory and Compliance page contains the following information:

- Product name
- App version
- Release year
- UDI-DI
- Intended use
- Legal manufacturer information

### Wireless Information

EpiWatch Monitoring System connects to EpiWatch Cloud through a cellular/Wi-Fi connection. The quality of Service of this connection is dictated by your cellular plan. Data transfer to EpiWatch Cloud might be delayed in case of poor cellular coverage, Wi-Fi issues, or a limited cellular data plan.

## Document History

| Revision | Date | Description |
|---|---|---|
| 1.0 | August 2024 | Initial release of the document |
| 1.1 | November 2024 | Update for Regulatory Release |
| 1.2. | May 2025 | Update for Commercial Release |