



EpiWatch Monitoring System Instructions for Use

This instructions for use manual is applicable for the EpiWatch Monitoring System application software version 1.2.9

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

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A PDF copy of this Instruction for Use is available at <https://www.epiwatch.com/instructions-for-use> or by requesting a copy at troubleshooting@epiwatch.com

EpiWatch Support

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

Email: troubleshooting@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 MANUAL

This Instructions for Use Manual 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
API	application programming interface
ECG	electrocardiogram
EEG	electroencephalogram
EMC	electromagnetic compatibility
FAR	false alarm rate
LED	light emitting diode
PHI	protected health information
PII	personally identifiable information
PPA	positive percent agreement
PWE	people with epilepsy
RF	radiofrequency
TCS	tonic-clonic seizure
vEEG	video electroencephalogram

GLOSSARY

absence seizures – a form of generalized seizure that causes a very brief loss of awareness, may have subtle physical symptoms, and the person will quickly return to what they were doing without confusion.

application programming interface – a connection between computers or computer programs that enables different software programs to communicate with each other to share features and information. APIs are predefined, standardized and share only the necessary and relevant data and functions.

atonic seizures – seizures with sudden loss of muscle tone, in which the affected muscles can abruptly become weak.

aura – a subjective experience felt in the initial phase of a seizure. Auras can be experienced with certain motor, sensory, autonomic, or psychic phenomena without losing consciousness.

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.

electroencephalogram – A procedure that detects abnormalities in brain waves, or in the electrical activity of the brain. During an EEG, electrodes are pasted onto the scalp. These electrodes are small

metal disks with thin wires that detect tiny electrical charges that result from brain cell activity. This activity is monitored and interpreted by a clinician to look for potential problems in brain activity.

epilepsy/seizure disorder – A 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 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).

focal aware seizure – a seizure which occurs in a localized area of the brain on one side, while the person remains fully awake, alert, and aware. Symptoms depend on where the seizure originates in the brain, and the person may experience odd sensations or emotions without losing awareness.

focal impaired awareness seizure – a seizure which occurs in a localized area of the brain on one side, but awareness is impacted, and the person may perform involuntary movements called automatisms. The person may be confused for a short time afterwards.

level 4 epilepsy center – An advanced medical center that provides the highest level of specialized epilepsy care. The National Association of Epilepsy Centers (NAEC) have accredited these centers as offering the most comprehensive and specialized care for people with epilepsy, particularly complex or drug-resistant epilepsy. These centers offer neurodiagnostic monitoring, extensive medical, neuropsychological, psychosocial and surgical treatments. Care is provided by a multi-disciplinary team of neurologists, neurosurgeons, neuropsychiatrists, neuropsychologists, social workers, and advanced practitioners all focused on individual patient care.

myoclonic seizures – a brief, sudden shock-like jerks of a muscle or group of muscles, usually on both sides of the body at the same time when abnormal brain activity occurs.

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.

tonic seizures – a seizure in which the muscles may suddenly become tense or stiff. These seizures are usually short and a person is usually aware or only has a small change in awareness.

tonic-clonic seizure – A tonic-clonic seizure, formerly known as a grand mal seizure, is a type of seizure that involves a loss of consciousness and violent muscle contractions.

video electroencephalogram – A diagnostic procedure in which a patient is continuously monitored by video recording while simultaneously wearing a scalp EEG monitor to record continuous brain activity. These recordings gather data for physicians to determine what is occurring before, during and after seizures or suspected seizure activity. It is considered the gold standard for diagnosis of epilepsy and epileptic seizures.

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 consolidated physiological data to the EpiWatch app via APIs. Utilizing a proprietary algorithm, EpiWatch analyzes and assesses 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/or 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 alerts. It also provides necessary information about the state of the system.

To request a copy of the clinical study report, please contact troubleshooting@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 wrist-worn 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. The EpiWatch Monitoring System 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 have 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, 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. **All user information will be unrecoverable upon permanent deletion.**

- Network connectivity is required for timely alerting of 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 wrist-worn device (e.g. 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 a 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 messages are not related to the patient's health status. They provide information on the system's working status.

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 monitoring performance.

Prior to removal from the wrist, 'stop monitoring' should be utilized to discontinue monitoring while the watch is off wrist. Restart monitoring when the watch is returned to the wrist.

Monitoring will be automatically discontinued when the watch is charging. Restart monitoring when the watch is placed on the wrist.

Detection Logging

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

This function logs all detected events. 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 and haptic (vibration) 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 wrist-worn device (e.g., 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 personally 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:

- The Apple Ecosystem
 - Apple Watch running watchOS 10 or higher.

Apple Watch devices can be connected through a paired iPhone or through Independent Device Linking.

- 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 the “Get” button to start the download process.

Figure 1: EpiWatch on Apple Store



Note: View the EpiWatch Monitoring System App on the App Store to check device compatibility.

- 2) Next, go to the App Store on the Watch that will be used for monitoring and search for “EpiWatch”. Tap on the “Get” button to start the download process.
- 3) Confirm that the application has been downloaded successfully to both the iPhone and the Apple Watch that will be used for monitoring.

Independent Device Linking:

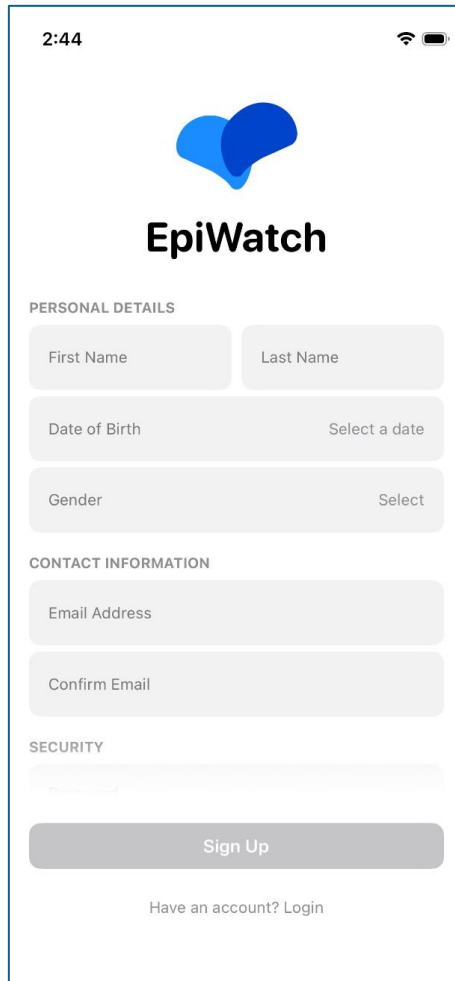
EpiWatch now supports Independent Device Linking, allowing Apple Watch devices to connect to user accounts without requiring a paired iPhone. This feature enables seizure monitoring for standalone watches (particularly those configured through Apple’s Family Setup for children) and multi-device households. An iPhone will still be needed for first time setup, and both devices will need to be connected to the internet during linking.

STEP 2: SIGN UP AND CREATE ACCOUNT

Open the EpiWatch Monitoring System App by tapping on the icon on the paired smartphone. A login screen will appear. **For initial access**, you will need to create a new account. To do this, press the “Create Account” link on the login screen and complete all required information. Then click on the “Sign Up” button.

If you have previously created an account, please use the same email you used to sign up previously, and enter your password. You can choose the “Login” link at the bottom of the Sign-Up Screen.

Figure 2: Apple EpiWatch Sign-Up Screen



2:44



EpiWatch

PERSONAL DETAILS

First Name Last Name

Date of Birth Select a date

Gender Select

CONTACT INFORMATION

Email Address

Confirm Email

SECURITY

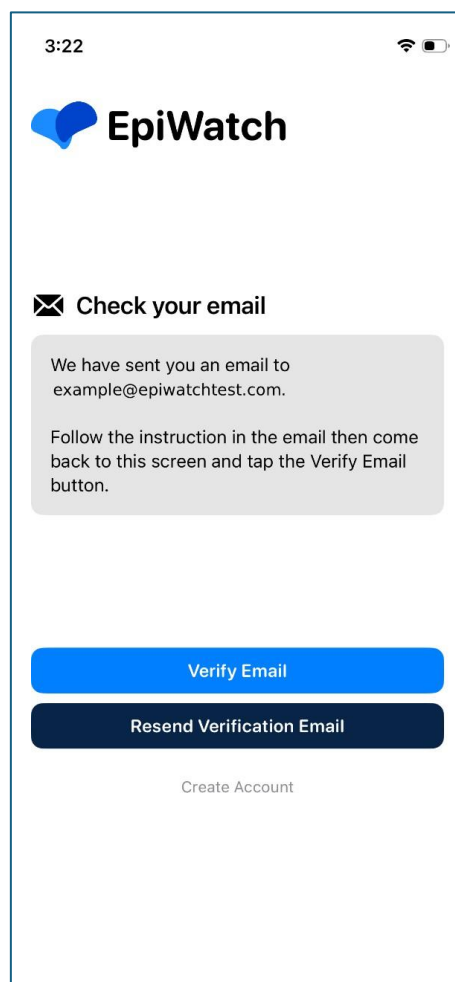
Password

Sign Up

Have an account? Login

- 1) Once you have signed up, you will be re-directed to an email verification screen. Check your email and click on the “Confirm Email” button in the verification email from EpiWatch to complete your registration and activate your account.
- 2) Then return to the EpiWatch app and click on the blue “Verify Email” button to proceed.

Figure 3: EpiWatch Email Verification Screen



- 3) Once your email is verified, you will then be guided through the onboarding process by the EpiWatch App.

Onboarding Tutorial

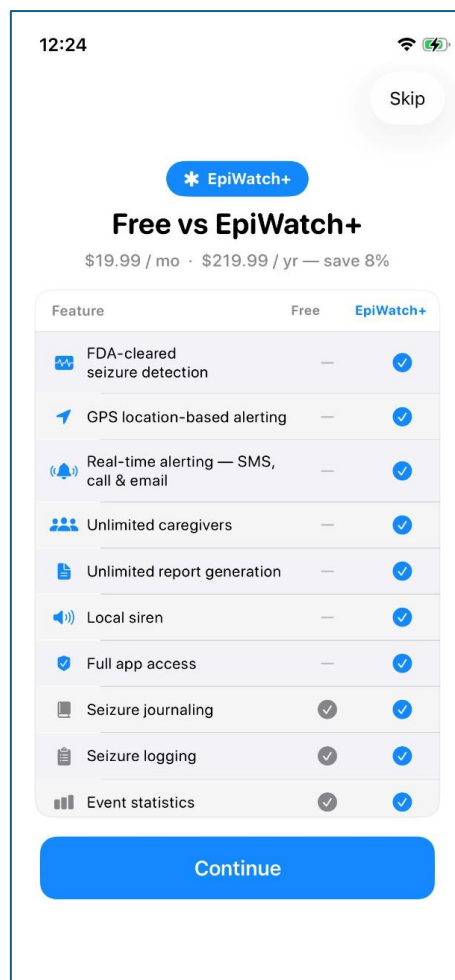
- 4) Click on the blue “Get Started” button to continue the setup process.
- 5) You must review and accept the EpiWatch Privacy Policy and the End User License Agreement.

For users under 13 years old, **COPPA consent must be completed by the legal guardian of the user.** This will be sent by email after completion of the onboarding process.

- 6) An onboarding tutorial will walk first-time users through simplified EpiWatch software screens. *This tutorial can be skipped at any point by clicking on the “Skip” button on the top right-hand corner of the screen. To continue through the tutorial, interact with the simplified EpiWatch screenshots displayed on your screen.*
- 7) To use a wrist-worn device that is already paired with the iPhone, choose the first option “Paired to this iPhone”. Choose this if your watch is connected to this iPhone and does not have its own cellular data and GPS.
- 8) Your watch will connect automatically, and a successful connection screen will display.
- 9) Click the blue “Continue” button once you verify your watch has been linked.

- 10) Once the walkthrough is complete, the application will display the features available with the EpiWatch+ Subscription vs. the free EpiWatch app. To access seizure monitoring and real time alerts, an active EpiWatch prescription is required.

Figure 4: EpiWatch and EpiWatch+ Subscription Options

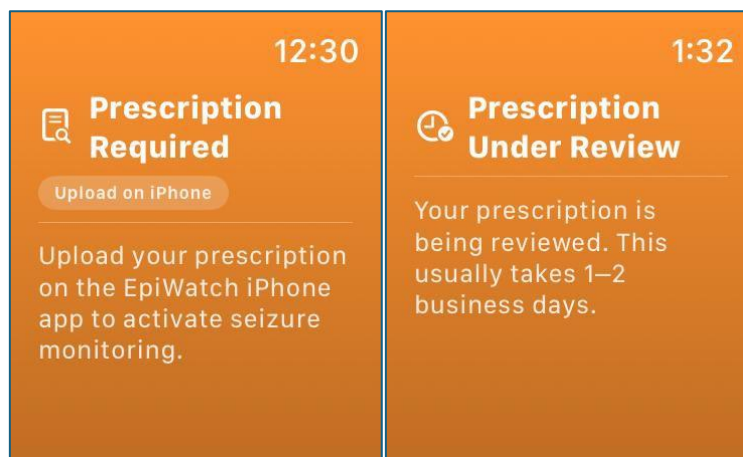


- 11) A Prescription Upload screen will display all the requirements for a valid prescription to activate seizure monitoring.
- A valid prescription **must** have: a provider name, NPI number, patient name, patient date of birth, prescribes “EpiWatch”, the healthcare provider’s signature and the date signed.
 - This can be uploaded directly from the camera or the phone gallery.
 - Once uploaded to this screen, it will display the image of the prescription to be submitted, then press continue.
 - If you do not have the prescription available, you can select “I’ll do this later” – but you will only be able to access the seizure diary features until the prescription is uploaded and validated and the subscription is activated.

Until your prescription is submitted, an orange banner will be visible at the top of the EpiWatch Dashboard, indicating the need for prescription submission.

- a) To submit a prescription, click on the orange banner on the top of the Dashboard screen to Upload your Prescription.
- b) The paired watch will display an orange “Prescription Required” screen until a prescription is uploaded on the phone. This is required to activate seizure monitoring and alerting.
- c) Once uploaded, the text on the banner will change to “Prescription under review”. Users can click on the banner to check the status or upload a new prescription.
- d) The paired watch will also display an orange screen that the “Prescription is Under Review”.

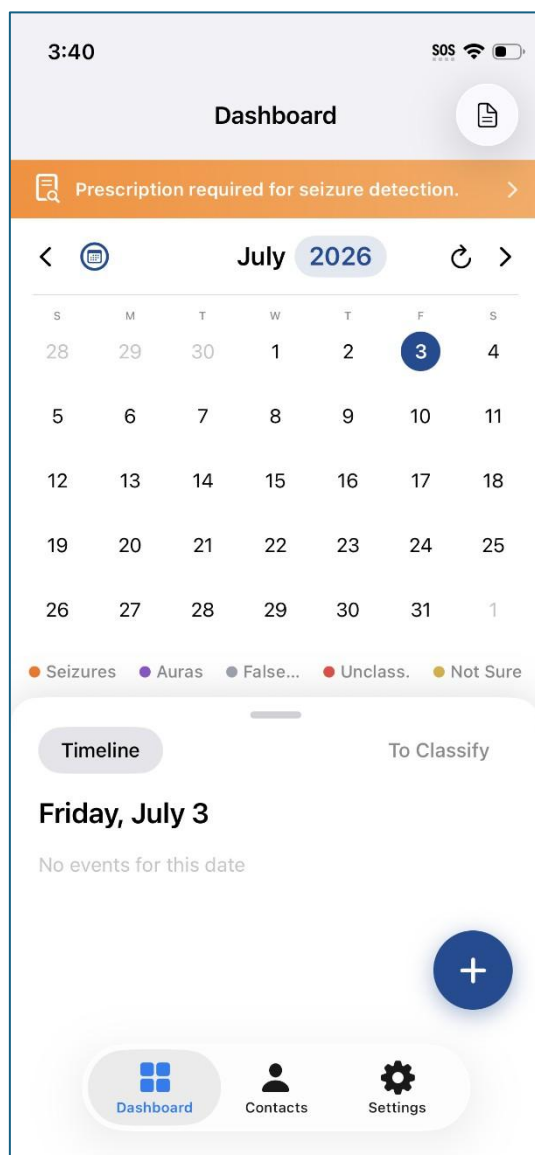
Figure 5a: Watch Displaying Prescription Required and Prescription in Review Screens



- e) Users can set up Contacts, modify Settings, and use the Seizure Journal functionality while waiting for prescription verification or without an active subscription.

Shortly after your prescription has been uploaded, it will be manually validated by EpiWatch personnel. If there are any issues with your prescription, the EpiWatch team will contact you via the email provided at sign-up. Please check your email or spam folder for an email from **no-reply@epiwatch.com**.

Figure 5b: EpiWatch Dashboard with Prescription Required Banner



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.

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 all permissions to share health information with the EpiWatch Monitoring Application 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 use the following 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 or cellular connections must be active for the EpiWatch Monitoring System to function as intended. For the functioning of the system, the following conditions should 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.*

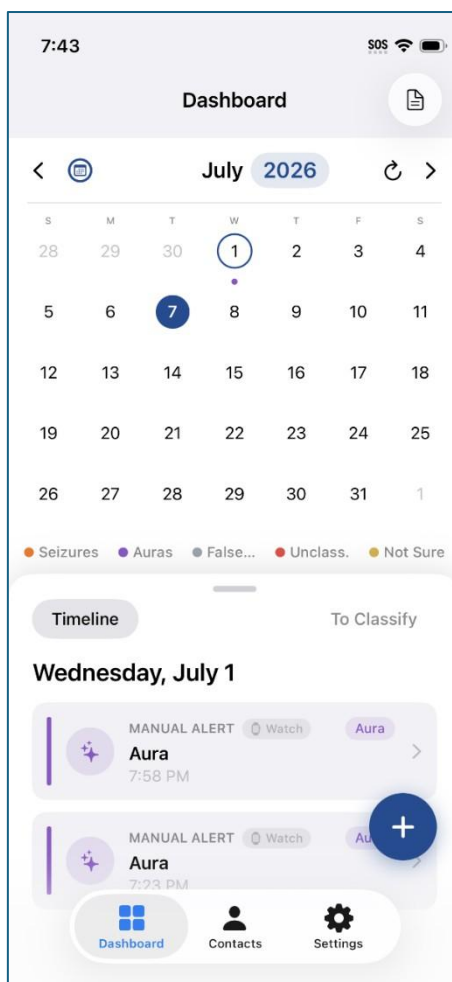
OPERATION

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 6: EpiWatch Dashboard



- **Dashboard** - By tapping on the Dashboard icon, the user will return to the main dashboard page.
- **Contacts** - By tapping on the Contacts icon, the user will be able to view the contacts that have been added; this includes active and inactive contacts. 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 icon, the user will have access to the EpiWatch settings page.

Contacts Management

Contacts are the people who will come to your assistance when the EpiWatch Monitoring System detects a possible TCS or when a manual help alert is triggered. **They are very important, and we suggest that you choose them carefully and educate them about what their role consists of, and how they may be contacted (phone, SMS message, and/or email) in case of a detection event.**

If possible, we recommend doing the set-up with the contact next to you for a smoother experience. **When you set up any contact for the first time, their first name, last name, phone and email will be required, and you must verify the phone number and email address at the time of contact setup.**

You can add a contact to 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.

To Add a Contact:

- 1) Click on the “Add Contact” button.
- 2) Fill in the First Name, Last Name, Phone Number, and Email address of your contact.
 - a) Before you can proceed, you must verify the phone number and email addresses. This will prompt you to enter a six-digit code received by text (SMS) or phone call for the verification of the phone number and a six-digit code received by email for verification of the email address of the contact. These codes expire after 10 minutes, so it is best to set up the contact while the person is nearby with access to their devices.
- 3) Choose which alert modes are preferred to reach your contact in case of a detection event.
 - a) Contacts may be contacted by phone, text, and/or email. Ensure that at least one mode is selected for timely delivery of alerts.
- 4) Alert properties allow for modification of the automated alert settings.
 - a) Phone call retries. Text retries, and Email retries allow the automated alert system to retry contacts in the case of failure or bounce back of the alerts. This will automatically retry the designated number of times before it fails and can be set to retry between 1-5 times.
 - b) Share location can be toggled off and on for each contact. When on, the address of the detection event will be shared with the contact. This relies on the precise location permissions being authorized for the EpiWatch application.
 - c) “Alert on Help Button Press” is when the user holds down the Help button on the left side of the monitoring screen. This can be turned off and on for each contact.

To Edit a Contact:

- 1) Click on the Contacts Icon on the paired phone application.
- 2) Click on the name of the contact you wish to edit.
- 3) From the Edit Contact screen, users can enable/ disable contacts, update contact information, alert modes, and alert properties.
 - a) You may change any of the contact information, but changes to phone number or email address will require re-verification.

To Inactivate / Activate a Saved Contact:

- 1) Contacts can be temporarily inactivated by toggling the “Enable Contact” switch off then choosing “Save”. This will keep the contact data but temporarily stop notifications. The contact will be moved to “Inactive”.
- 2) To reactivate a contact, click on the contact’s name and in the Edit Contact screen select “Enable Contact”, which will turn the toggle button to green. The user can then select “Save” and the contact will move back to being “Active”.

To Delete a Contact:

- 1) Click on the contact's name to go to the Edit Contact screen.
- 2) Scroll down to the bottom of the screen and click on the red "Delete Contact" button.
- 3) A prompt will appear to confirm that you want to delete the contact. Click on Delete to confirm.

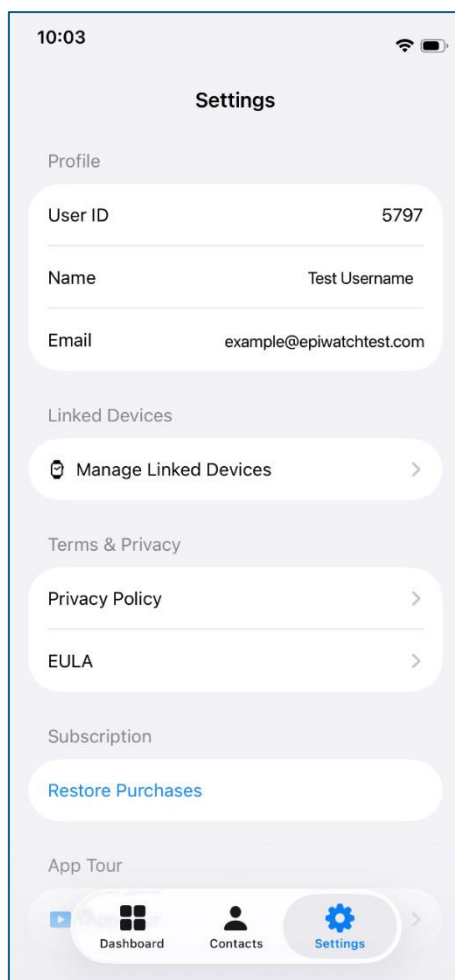
Make sure your contacts are active. If deactivated, contacts do not receive alerts.

If no contacts have been added or all contacts have been deleted, a large blue banner will alert the user that there is currently No Data for contacts, and the user can click on the "Add Contact" button on the banner.

Settings

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

Figure 7a: EpiWatch Settings Page

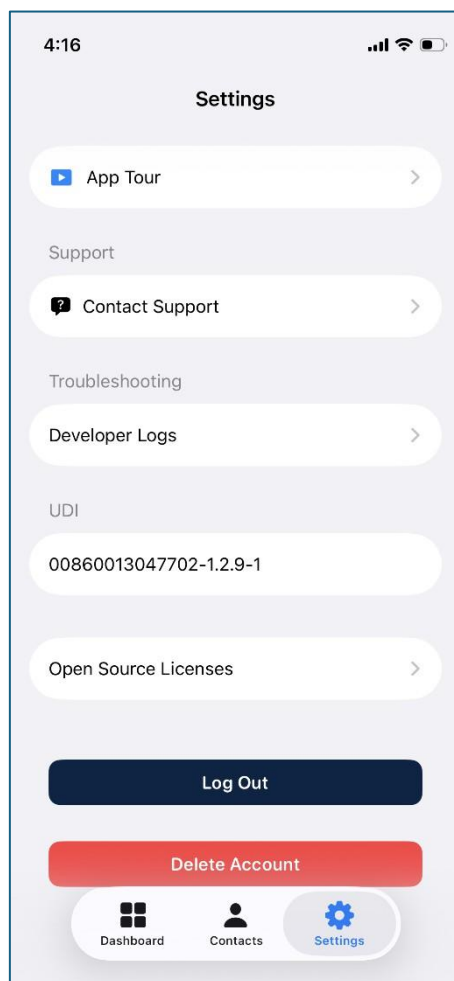


This page contains the following information:

- **Profile:**
 - User ID Number: This will be automatically assigned.
 - Name: this should reflect **the person with epilepsy and match the prescription.**
 - User email: the email used for the account in the system.

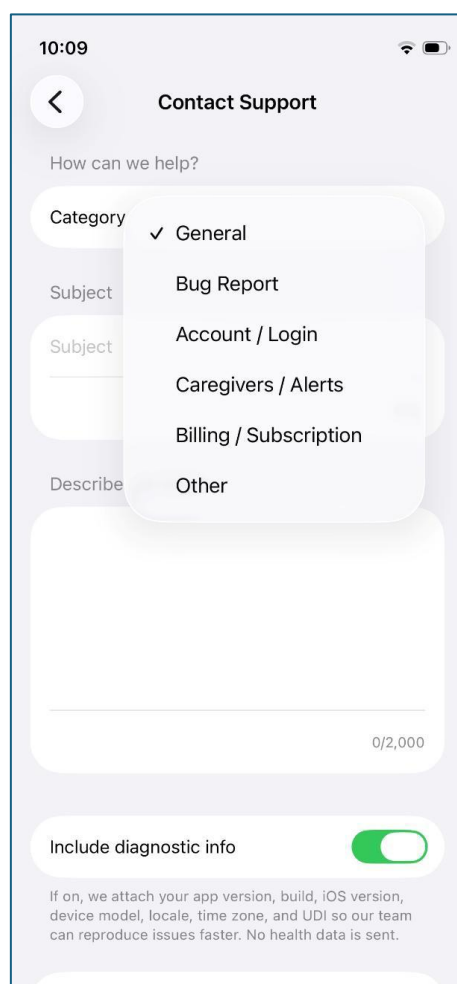
- **Linked Devices:** Allows users to manage **independently linked devices only**; watches paired with Bluetooth directly to the iPhone will not appear here.
- **Terms & Privacy:** Contains EpiWatch’s Privacy Policy, EULA, and COPPA, if applicable, that the user signed during onboarding.
- **Subscription:** Allows users to restore purchases.

Figure 7b: EpiWatch Settings Page (Continued)



- **App Tour:** This opens a page where users can have a full tour of the app functionality or choose specific individual demonstrations of how to use EpiWatch features. The demonstrations are interactive and allow the user to simulate EpiWatch features on a wrist-worn device or app screen.
- **Support:** This allows users to send emails to customer support directly from the application. Users can choose a category for their support request, a subject line and space for describing the issue. It also allows users to automatically include diagnostic information, which will include app version, build, iOS version, device model, locale, time zone, and UDI, but does not include health data.

Figure 8: Contact Support Page



- **Troubleshooting:** Allows the user to send developer logs from the phone and the watch to the manufacturer for troubleshooting. This requires the user to have set up the default Apple Mail application with their email address prior to sending developer logs.
- **UDI:** Unique Device Identifier is a series of numbers that identifies only your device and the version of EpiWatch software.
- **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 that this will stop monitoring and alerting for all devices linked to the account. Logging out does not delete any user data.
- **Delete Account Button:** Allows the user to delete their account. This removes all EpiWatch data, including seizure activity, manual alerts, seizure journal history and contacts from the user's account and is **not recoverable**. EpiWatch cannot restore the data once deleted.

Linked Devices

Independent Device Linking allows Apple Watch devices to connect to user accounts **without requiring a paired iPhone**.

The Linked Devices screen in settings shows all independently linked devices, including the Device Name and Last Used time.

To revoke access for a device, select the trash can icon on the right side of the row, tap "Revoke," and confirm the action.

The watch is immediately logged out within a 5-minute window, returns to the linking screen, and all credentials on the watch are cleared.

Devices paired directly to your iPhone are connected automatically and do not appear in this list. This screen only shows devices linked via the 6-digit code.

SEIZURE DETECTION

Seizure Detection and Monitoring

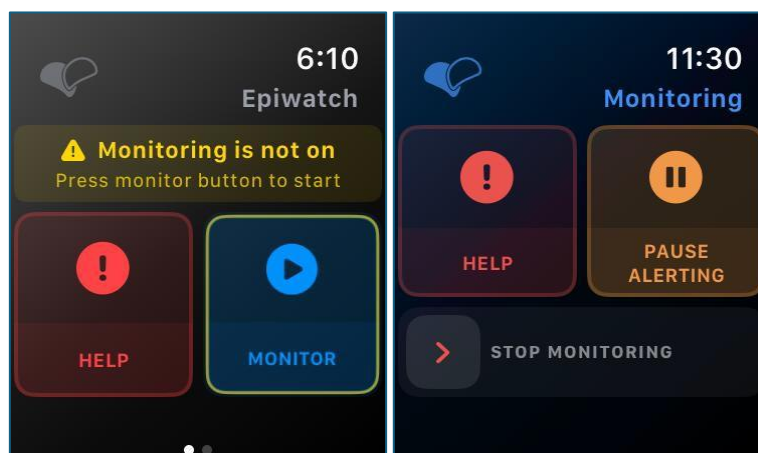
The wrist worn device must be worn by the person with epilepsy, and should be fully charged, fit snugly, without being too tight, and placed on the arm that is most affected by seizure onset.

Monitoring must be started by the user when first donning the watch after charging or removal.

To begin monitoring:

- 1) You must open the EpiWatch application and press the “Monitor” button each time the wrist worn device is worn. If monitoring is not on, a yellow caution banner will display on the screen, indicating that “Monitoring is not on. Press “Monitor” button to start”.
- 2) When monitoring is active, blue text will appear across the top of the EpiWatch application screen with the word “Monitoring”, and the “Monitor” button will be replaced with “Pause Monitoring” button as an option.

Figure 9: Start Monitoring on the Wrist Worn Device and Active Seizure Monitoring



Understanding Seizure Detection

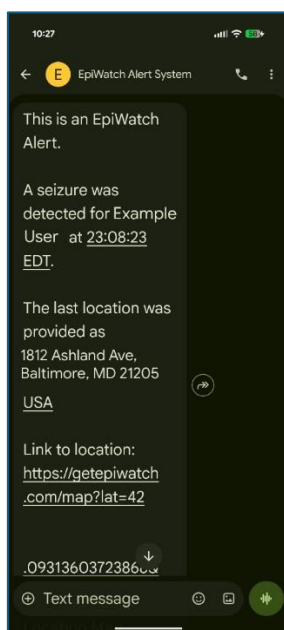
The proprietary seizure detection algorithm in the EpiWatch Monitoring System is designed to monitor and analyze biosignals recorded through the compatible wrist-worn device to identify potential seizure patterns in real-time. Upon detection, the EpiWatch Monitoring System triggers an alert to the specified caregivers, as configured. **Note:** This will not automatically alert Emergency Medical Services, it only contacts Active Contacts as defined by the user.

What Contacts Receive When Seizure is Detected

When the EpiWatch Monitoring System detects a possible seizure, it automatically alerts the activate Contacts through the designated alert modes (call, text, and/ or 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 wrist worn device to track your precise location. Users can choose whether to share location or not to share location with individual contacts on the Contacts screen. Caregivers should note that locations are approximate and may be limited to the street address or building but will not be specific enough to determine unit number, room, level etc.

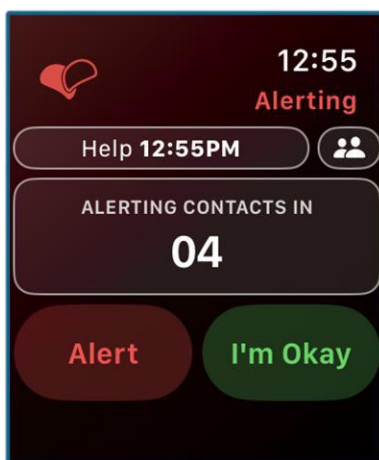
Figure 10: Example EpiWatch Caregiver SMS Message with Location Enabled



Understanding Seizure Alerts

When the system detects a seizure, your compatible wrist-worn device will start vibrating, playing a siren, and will show “Alerting” on the screen, and a countdown timer will start. During this alert countdown, the user has the option of cancelling the detection by pressing the “I’m Okay” button, in the event of a false detection. The alert delay may be configured in the Watch Settings, but defaults to 5 seconds. Users can choose to immediately bypass the countdown by choosing the red “Alert” button or cancel caregiver notifications by selecting the green “I’m Okay” button on the right. The wrist worn device will play a siren sound and vibrate to notify the wearer and anyone nearby that there has been a seizure detected. Alerts are automatically sent to your assigned contacts after the countdown has been completed, or the user selects the “Alert” button.

Figure 11: EpiWatch Alerting Screen



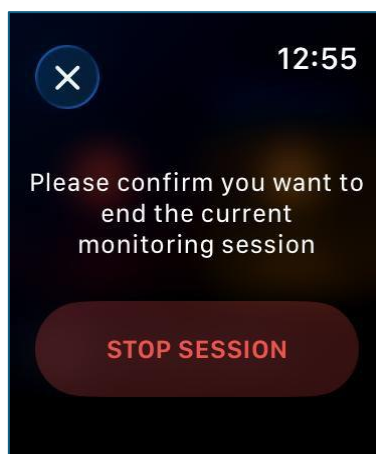
Once the Alert has been Sent

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 Okay” button on the watch screen.

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 arrow to the right, until it reaches the end of the red stop monitoring button.
- 3) A message will appear on the wrist worn device screen, confirming that the user wants to end the current monitoring session.
- 4) The user must press the red “Stop Session” button on the bottom of the screen. This stops the current monitoring session. Tap the “x” in the upper left corner of the watch face to cancel the stop monitoring command.

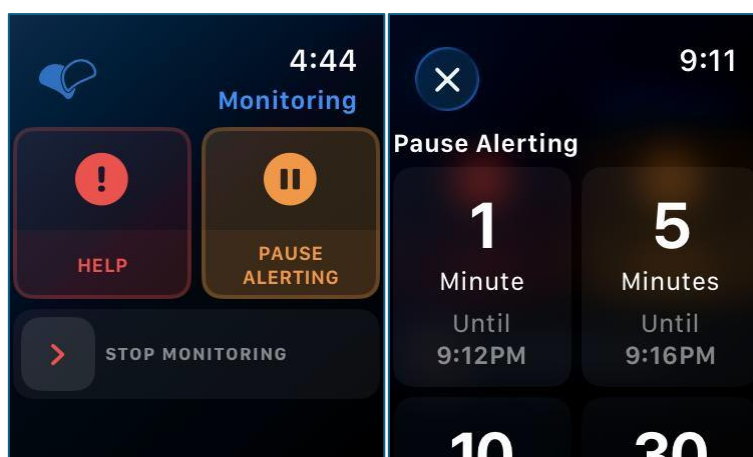
Figure 12: Stop Monitoring Confirmation



How to Pause Alerting

- 1) Users may wish to pause the alerting function for a set period of time while they are monitoring. To pause alerting, locate the orange “Pause Alerting” button on the watch face during a monitoring session.

Figure 13: Pause Alerting and Monitoring for Designated Periods of Time



- 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 a seizure detection. Manual alerting will still be active during the pause period, and contacts will receive notifications for manual alerts.

- 3) You will see a confirmation screen confirming alerting has been paused, with a countdown timer indicating the duration of the alerting pause. *To cancel the pause*, you can press “Resume Alerting” and monitoring with resume immediately.

Figure 14: Paused Alerting Screen with Countdown Timer for When Monitoring Resumes

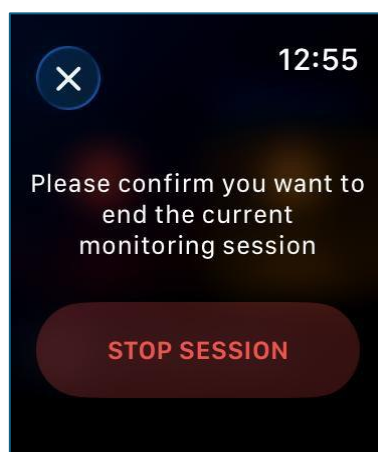


How to Manually Send an Alert

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:

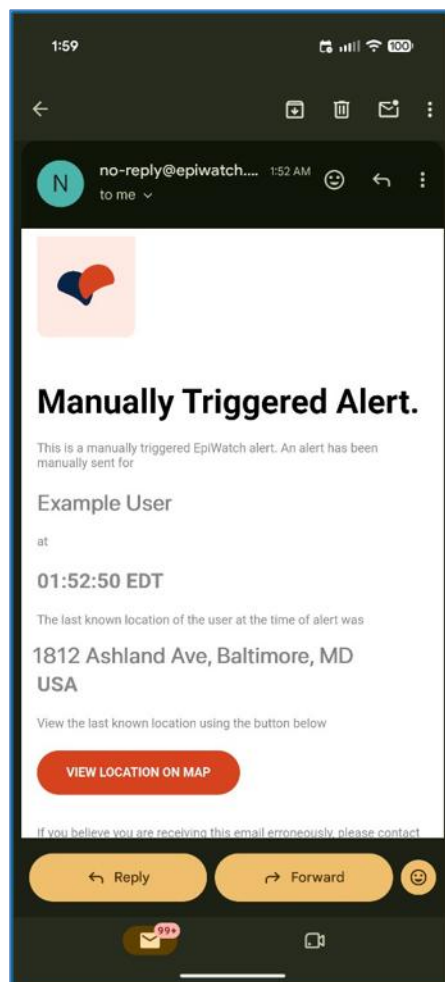
- 1) When the monitoring function is on, there is an emergency (Alert) button, in red.
- 2) Press the red “Help” button on the middle on the watch screen.

Figure 15: Press and Hold the Help Button to Trigger Manual Alert



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

Figure 15: Manual Alert Caregiver 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, SMS and / or email will be sent to all your active caregivers. Alerts can be canceled both from the app and the compatible wrist-worn device.

SEIZURE REPORTS

The EpiWatch monitoring system can automatically generate a report of all detection events and manual alerts from a chosen time period.

Creating the Report(s):

- 1) From the paired iPhone, go to the EpiWatch application and click on the “Dashboard” icon on the bottom of the screen to view the Dashboard.
- 2) From the Dashboard screen, click on the document icon on the top right of the screen.
- 3) This will open a “Seizure Report” screen, in which the user can choose a specific date range for the report.
 - a. Reports can be generated for any period between 1 and 365 days.
 - b. Users have the option to include False Positive in the Event Log.
- 4) Once the date range has been selected, the user will press the blue “Generate Report” button at the bottom of the screen.
- 5) A report preview with user data will appear on the paired iPhone. This report can then be shared, saved or printed by selecting the “Share” icon in the top right-hand corner of the screen.

Report Sections:

- **Summary Statistics** – this section serves as a quick snapshot of
 - **Total Confirmed Seizures** – contains information about how many seizures were detected automatically and confirmed by the user or caregiver(s) as TCS following the alert.
 - **Total Auras** – how many manual alerts were triggered when an aura was detected.
 - **Seizure-Free Days** – Displayed as a ratio of days without a detected or recorded seizure compared to the total number of days in the selected time period (e.g. 14/15 Seizure Free Days).
 - **Average Seizures per Week** – This is an automatic calculation of the number of confirmed seizures divided by the number of weeks in the date range specified by the user.
- **Seizure Type Breakdown** – Count of seizures broken down by type classified by the user.
- **Monthly Trend** – Compares the month-to-month number of seizures, auras, false-positives and unknown detections experienced by the user. The user can specify the number of months to compare by modifying the date range for the report.
- **Event Log** – This log serves as a comprehensive list of past events for the selected date range. Each line will have the date and time stamp of either a detection event or manual alert. Each alert will be classified either automatically when detected or if confirmed or modified by the user. For each event, the user can add additional information, such as seizure type, duration, and severity of the event, as well as additional information, such as suspected triggers, events proceeding the detection, etc.

TROUBLESHOOTING

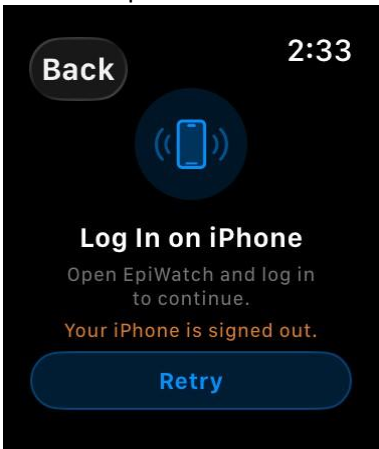
EpiWatch, Inc. encourages all users to check the instructions for use. Users should contact troubleshooting@epiwatch.com for the latest troubleshooting tips and procedures.

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

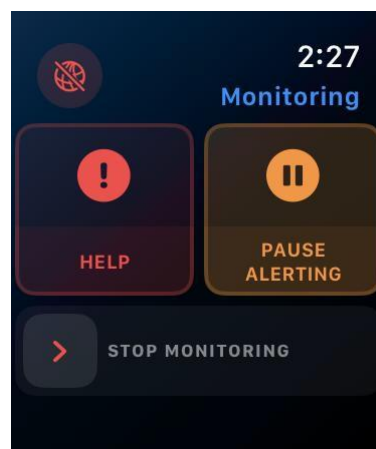
The error messages in the EpiWatch Monitoring System App display the status of the app. The following outlines the meaning behind each status, and what action is needed, if any.

Users may encounter the following Independent Device Linking error messages: "Code Expired" (The 10-minute window has passed. Generate a new code on the iPhone), "Code Used" (The code was already redeemed. Generate a new code on the iPhone), "Invalid Code" (Fewer than 6 digits entered. Enter all 6 digits), "Too Many Attempts" (Rate limit exceeded (5 codes/minute). Wait 1 minute before generating a new code), and "Connection Error" (Network issues. Check internet connection and retry).

Error Message	Steps To Resolve
"Log in on iPhone" Error on Watch Display Open EpiWatch and log in to continue. Your iPhone is signed out.	1. On your paired iPhone, open the EpiWatch app. 2. Sign in with your email and password.  3. Once signed in, choose how your watch is normally connected: paired device or linked independent device. 4. Once your watch is successfully connected, a green checkmark and "Watch Linked" confirmation text will show on your watch screen before proceeding to the EpiWatch Monitoring Screen.
No Internet Connection Error	1. When the application detects a loss of network connectivity, it will show a "no internet" icon in the top left.

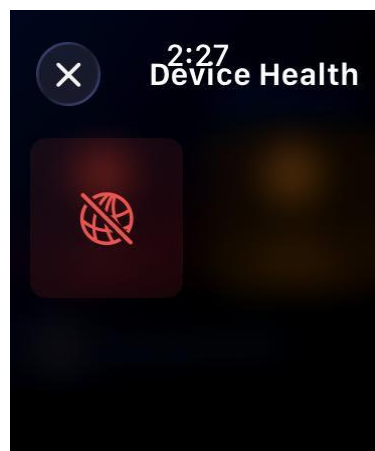
“Your device does not appear to be connected to the internet. Please make sure you are connected to a Wi-Fi/cellular network on your watch or are near your phone.”

Error code -1,009

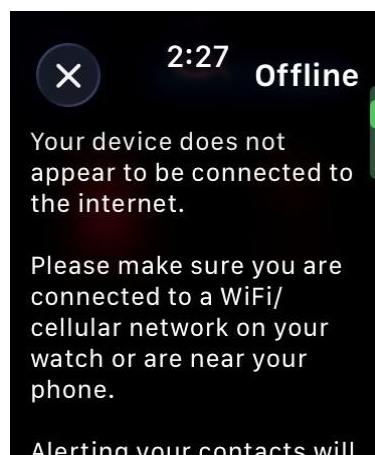
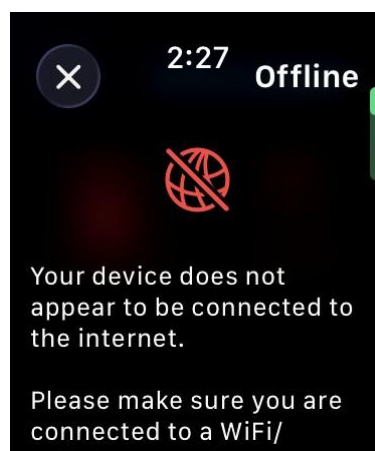


**No Internet Connection Error
(continued)**

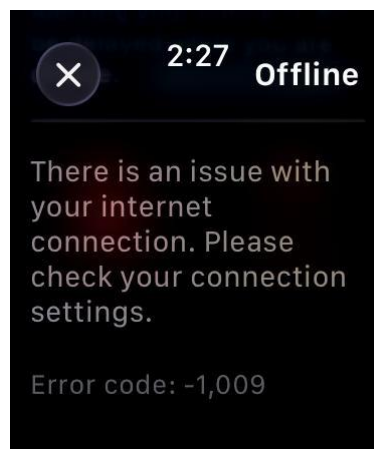
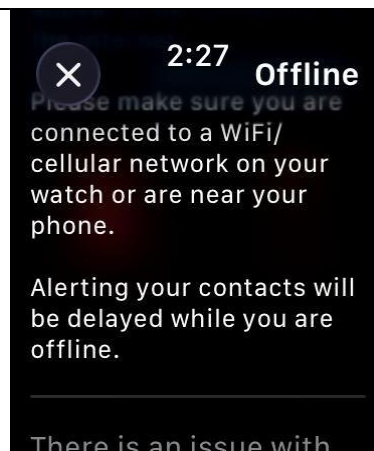
2. Upon pressing the icon, all of the current errors with the device that need to be resolved will be visible. In this case, click on the “no internet” error icon.



3. The detailed error description will state what is causing the error, and how to resolve it.



**No Internet Connection Error
(continued)**



4. Move into a location where the watch has network connectivity.
 5. If using Wi-Fi, ensure the watch is connected to the Wi-Fi through settings.
 6. If this does not resolve the issue, confirm that the watch and the iPhone are not in airplane mode with Wi-Fi disabled.
- Wait for approximately 30 seconds. If the device senses connectivity has returned, the message will resolve.
7. Contact EpiWatch Support if message persists.

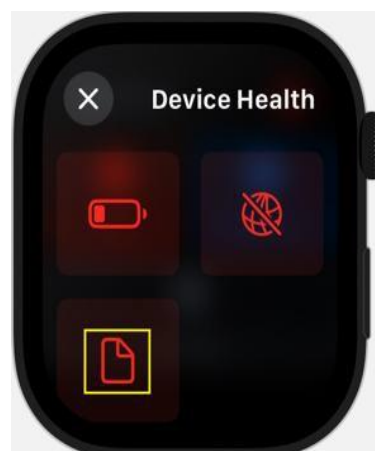
Unsent Data:

“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 left.



2. Upon pressing the icon, all of the current errors with the device that need to be resolved will be visible. In this case, click on the “unsent file” error icon.



3. The detailed error description will state what is causing the error, and how to resolve it.

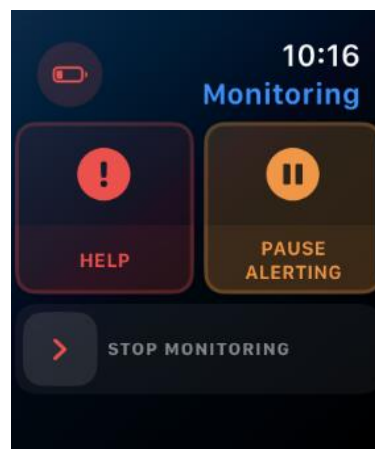


4. Ensure that the watch has network connectivity, so the device is able to upload the unsent data to the EpiWatch cloud.
5. Press the upload files button and wait for the files to be uploaded to the EpiWatch cloud.
6. Once the files have been uploaded, the issue will be resolved.
7. Contact EpiWatch Support if the message persists.

Low Battery

“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 left.

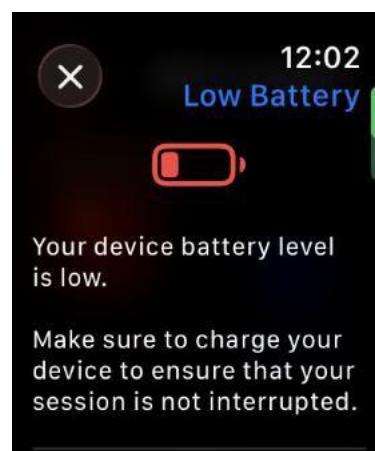


2. Upon pressing the icon, all of the current errors with the device that need to be resolved will be visible. In this case, click on the “low battery” error icon.

Low Battery (continued)

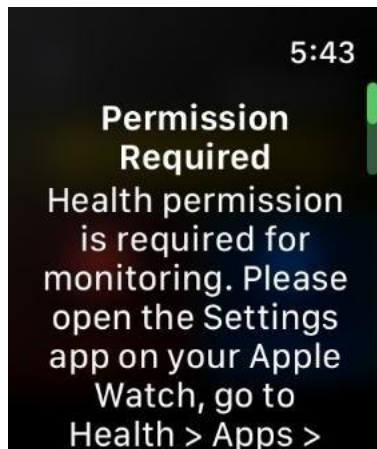


3. The detailed error description will state what is causing the error, and how to resolve it.



4. Charge the compatible wrist-worn device to get the battery percentage over 15%. The issue will resolve by itself when this occurs.
5. Contact EpiWatch Support if the issue persists.

Warning: While the device is charging, monitoring will be discontinued, and the EpiWatch Monitoring System will be unable to detect any seizure events.

Error: Health permission is required for monitoring.	If permission is not granted for the health/physiological measures needed to detect seizures, the watch face will display an error message:  1. To resolve, on your paired iPhone, go to Settings. 2. Click on Privacy & Security 3. Scroll down and click on Health. 4. Under Apps click on EpiWatch. 5. Choose "Turn on All" at the top or scroll down and toggle on the switch next to "Heart Rate". To Resolve on Watch: 1. Go to Settings 2. Click on Health 3. Go to Sources click on "Apps" then click "EpiWatch" 4. Go to Turn on All -to allow EpiWatch to write and read data. 5. Contact EpiWatch Support if message persists.
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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 connected to the internet via a cellular connection or Wi-Fi connection, or the Apple Watch is enabled with cellular connectivity.

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 watch 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.

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: • Apple Watch: watchOS version 10 or higher Smartphones: • 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.
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 some of the 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 Standard Deviation: 14.2 Median: 18 Min: 5 Max: 76
	N= # participants (%)
<u>Age Group (years)</u>	
<13	55 (22.7)
12-21	92 (38.0)
>21	95 (39.3)
<u>Gender</u>	
Female	131 (54.1)
Male	111 (45.4)
<u>Race</u>	
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)
<u>Ethnicity</u>	
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.
- 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	2024-08-XX	Initial release of the document
1.1	2024-11-XX	Update for Regulatory Release
1.2	2025-05-XX	Update for Commercial Release
1.2.0	2026-03-XX	Update for Independent Device Feature
1.2.9	2026-09-04	Updated for enhanced clarity, expanded troubleshooting and updated interface for 1.2.9