










**Caution:** Investigational device. Limited by Federal law to investigational use.

March 2014

# Table of Contents – ProGuardianREST™ System User Manual

Section	Page
1. Introduction	4
2. Understanding Your ProGuardian System	4
2.1 System Components	4
3. Intended Use	5
4. Cautions	5
5. Contraindications – Use Restrictions and Limits	6
6. Before You Start Using Your ProGuardian System	6
6.1 Explanation of Symbols	7
6.2 Cleaning, Storage, and Handling	8
7. Setting Up Your ProGuardian System	9
7.1 Hub Setup	9
7.2 Setup Wizard for Hub Software	12
7.2.1 How to Enter Information on the Hub	13
7.2.2 Starting the Setup Wizard	13
7.3 Begin Seizure Monitoring	14
7.3.1 Preparation	15
7.3.2 Sensor Patch Setup	16
7.3.3 Patch and Sensor Application	18
8. Responding to Seizure Notifications	20
8.1 Confirming or Denying a Seizure Notification	21
8.2 Adjusting Seizure Notification Sensitivity	21
9. Pausing or Stopping Monitoring	22
9.1 Pausing and Resuming Seizure Monitoring	22
9.2 Turning Seizure Monitoring Off	23
10. Replacing the Patch	25
11. Using the Hub Software	26
11.1 Home Screen	26
11.1.1 How to Lock the Hub	26
11.2 Sensor 	27
11.3 Seizure Log 	27
11.3.1 Navigating the Seizure Log	28
11.3.2 Adding Seizures to the Log	28
11.3.3 Removing Seizures from the Log	28

Section	Page
11.4 Reports Menu 	29
11.4.1 Create a Report	30
11.5 System Status 	30
11.5.1 Connectivity Tab	31
11.5.2 Sensor Tab	31
11.5.3 Hub Tab	32
11.6 Settings Menu 	33
11.6.1 Seizure Detection Settings	33
11.6.2 Sound Settings	35
11.6.3 Display Settings	36
11.6.4 Date and Time Settings	37
11.6.4.1 Changing Date and Time	37
11.6.4.2 Date and Time Formats	37
11.6.5 Patient Profile	38
11.6.6 Account Information	38
11.7 Help Menu 	39
11.7.1 ProGuardian App Setup Wizard	39
11.7.2 About	40
11.7.3 Contact Us	40
11.7.4 Administrator Access	40
12. The ProGuardian App 	40
12.1 ProGuardian App Setup Wizard	41
12.2 Wi-Fi Network Changes and Registering New Devices	45
12.3 Receiving Notifications on Your Mobile Device	46
12.4 Adjusting Your Mobile Device Sound Settings	47
12.5 Configuring App Sound Settings	48
12.6 Discontinuing Use of the ProGuardian App	48
13. Troubleshooting	49
13.1 Sensor Reset	49
13.2 Common Error Messages	50
13.3 Replacing a Lost or Damaged Sensor or Hub	55
14. System Specifications	55
15. FCC Compliance Statement	56
16. Contact Us	57

# 1. Introduction

The ProGuardian System is used to sense changes in heart rate or movement during periods of sleep in people with epilepsy. When a potential seizure is detected, the ProGuardian System sends out an audio-visual notification.

When you—the Caregiver—confirm these notifications, the System compiles them into summary reports. The reports allow you to track seizure activity over time and can be used when talking to your health care provider.



While helpful in detecting potential seizure activity, the ProGuardian System is not intended to replace Caregiver supervision or prescribed healthcare. The ProGuardian System is an informational tool that may help you enhance your efforts in managing your loved one's epilepsy.




## 2. Understanding Your ProGuardian System

Your ProGuardian System comes with the components listed below. If anything is missing or damaged, contact your Customer Care Service Center (refer to Contact Us section of this manual).

### 2.1. System Components

These items are included in your ProGuardian System kit:

What it is.	What it looks like.	What it does.
Hub with power cord and country specific adaptor(s) (PG1100)		Provides a notification when a potential seizure is detected.  Seizures that are confirmed by you are stored in the seizure log.
Patches (PG1200)  (Single use, disposable) (30, individually packaged)		Adheres the Sensor to the body while sleeping.

What it is.	What it looks like.	What it does.
Sensor (PG1000)  (Body worn)		Collects heart rate and movement information while sleeping.
ProGuardian Application (Accessory)  Can be downloaded from <a href="http://www.ProGuardianSystem.com">www.ProGuardianSystem.com</a>		Receives notifications on an Android mobile device while away from the Hub (active when connected to home Wi-Fi Network).
USB Flash Drive	  (Picture may not represent actual item)	Transfers summary reports from the Hub.

No component of the ProGuardian System is provided sterile, or made with natural rubber latex. For additional information about the System, please see Section 14, System Specifications.

### 3. Intended Use

The ProGuardian System is a monitoring device for people with epilepsy five years of age and over. The system aids in detecting, notifying, and recording potential seizures during periods of sleep. It is capable of detecting seizures that are accompanied by changes in heart rate or movement.

### 4. Cautions

Follow these Cautions to avoid the possibility of harm to the user or damage to the device.

- The ProGuardian System will not detect all seizures and is not intended as a life-saving device. Talk to your healthcare provider (HCP) immediately if you have any concerns or if the condition of the person with epilepsy worsens.

- Do not rely on the seizure notification feature for delivery of life sustaining medical treatment, such as administration of rescue medication.
- If the Hub loses power, the System may miss seizure detections.
- If you experience symptoms of skin irritation or allergic reaction such as redness or swelling with the use of the Patch, remove immediately. If symptoms do not improve or get worse after removal of the Patch, please consult your healthcare provider.
- The ProGuardian System should not be used while undergoing any diagnostic medical procedures, such as MRI or X-Ray.
- The ProGuardian System should not be used in an oxygen rich environment (e.g., oxygen tent, hyperbaric chamber).
- The ProGuardian System should not be used on an airplane.
- The ProGuardian System includes radio frequency technology. For complete FCC compliance information please see Section 15.
- Do not drop the Sensor or Hub. Doing so may damage the ProGuardian System.
- Only use the power cord supplied with the Hub. Failing to do so can damage the System and present a fire hazard.
- Only use ProGuardian Patches. Other types of Patches will not work with your System.
- Do not expose the Patch to fire or heat sources, as it contains a battery that could explode.
- Do not expose the Hub, Sensor, and Patch, to water or any other liquid. Doing so may damage the ProGuardian System.
- Dispose of the lithium coin cell battery in the Patch in accordance with local regulations.

## 5. Contraindications – Use Restrictions and Limits

The ProGuardian System should not be used on anyone who is:

- Under 5 years of age
- Implanted with a cardiac management device (e.g., cardiac defibrillator, pacemaker)

## 6. Before You Start Using Your ProGuardian System

- **Read this manual.**

To use the System correctly and be most comfortable using it, you need to understand how it works and be familiar with its screen displays and system features.

- **Inspect each component of the System.**

If you see any damage to any system components or if you are missing any component, call your Customer Care Service Center immediately.

- **Complete the Setup Wizard.**

You must complete the Setup Wizard before using the ProGuardian System for the first time. The settings you put into the system are critical for providing accurate and useful information.










**Note:** The date and time must be entered correctly in order for seizures to be accurately recorded in the seizure log.


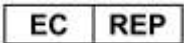









- **Understand what the System does.**

The ProGuardian System is used to sense changes in heartrate or movement and to notify you of potential seizure activity. The system is not intended to replace supervision and should not be expected to detect all types of seizures.

## 6.1. Explanation of Symbols

The symbols below are used in the manual, in other package labeling, or on the product components for the ProGuardian System.

Symbol	Description
	Notice for reader to pay special attention to details that follow
	Serial number (located on both the Hub and Sensor)
	Storage temperature ranges
	Batch code (located on patch packaging)
	Date of manufacture
	Consult Directions for Use
	Provides helpful usage tips and guidelines

Symbol	Description
	Manufactured by
	Authorized Representative
	RF-enabled
	Do not put in regular trash. Requires special disposal.
	Single Use
	Storage humidity limitation
	Bluetooth-enabled
	Type BF medical device
	Storage and use atmospheric pressure limitation
	Class 2 medical device
	Ingress protection rating for allowable exposure to moisture and dust

## 6.2. Cleaning, Storage, and Handling

As with any device, proper storing and handling guidelines should be followed to ensure the ProGuardian System operates most effectively. Follow the guidelines listed below.

- When handling the ProGuardian System, make sure you have dry, clean hands.
- Do not expose the Hub, Sensor, and Patch to water or any other liquid.
- Operate the System in temperatures ranging 5- 40°C (41- 104°F) and 15-93% relative humidity. When not in use, the System can be stored in temperatures ranging -25 - 70°C (-13 -158°F) and 15- 93% relative humidity.
- Each Patch contains a small battery. Dispose used patches in compliance with local regulations for lithium coin cell batteries.
- Do not cover the Hub, as this could result in over-heating.
- Do not place the Hub near equipment that generates heat.
- Use a soft damp cloth to clean the Hub display and Sensor. Do not use harsh chemicals or abrasives.



- Do not open individual Patches until needed. Doing so may cause the adhesive to be less effective.
- If you need to dispose of the Sensor or the Hub, please return the device back to Cyberonics.

## 7. Setting Up Your ProGuardian System

This section instructs you on how to set up the Hub and Sensor so you can begin using your system. The ProGuardian System also works with an optional ProGuardian App that can be activated during initial setup or configured at a later time (see Section 12, “The ProGuardian App” for more details).

To begin using your ProGuardian System, set up the following parts of the system:

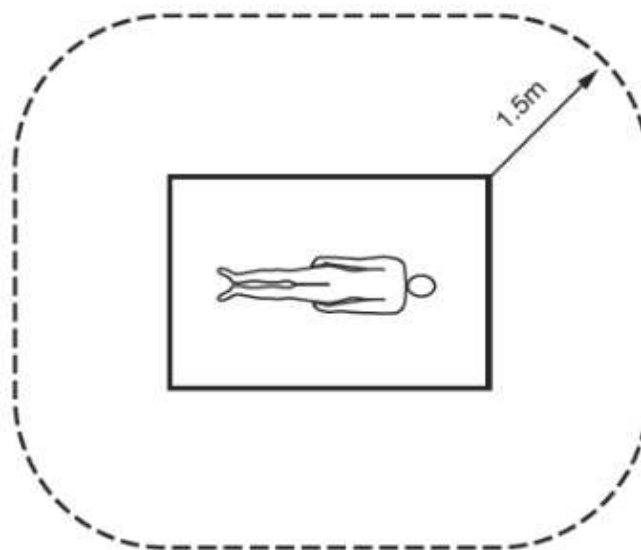
- Hub
- Hub Software
- Sensor and Patch

### 7.1. Hub Setup

The Hub is where you enter and receive information. When set up with an active Sensor, it provides a notification when a potential seizure is detected. Confirmed seizures are stored in the seizure log.

Follow the steps below to set up the Hub. The Hub must be placed at least 5 feet (1.5 meters) away from the sensor wearer’s support system (such as a bed or couch) when he or she is sleeping (Figure 1).

**Figure 1: Hub Placement**



1. Become familiar with the buttons and LED locations on the Hub (see Figure 2, Figure 3, and Figure 4).

**Figure 2: Hub Front**



**Figure 2:**

**A -Connectivity LED** – Provides a visual indicator for the System connectivity:

- **Blue:** No connectivity issues exist while connected to the Sensor.
- **Solid amber:** Either the Hub-to-Sensor or Hub-to-ProGuardian App communication is disrupted (when enabled).
- **Flashing amber:** During Sensor setup or anytime the System is paused.
- **Not lit:** When the neither the sensor nor the Caregiver App are registered or connected.

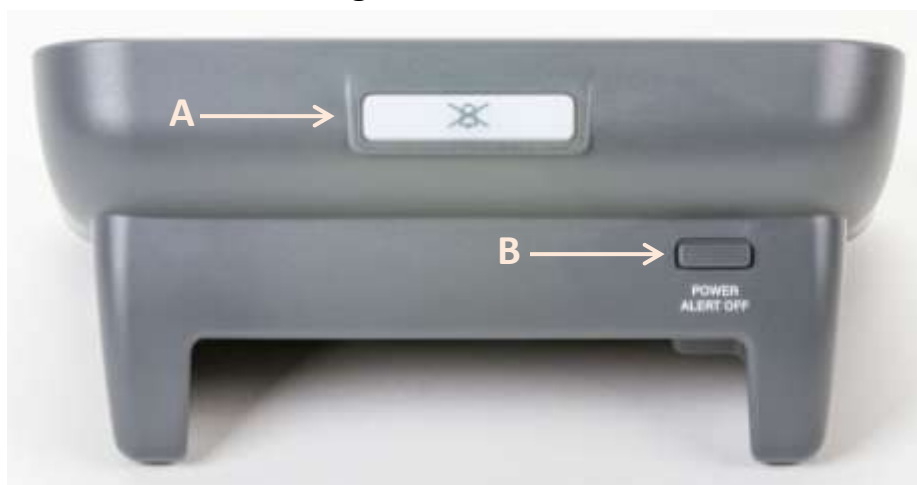
**B – Notification LED** – Provides a visual indicator for notifications:

- **Flashing amber:**Indicates pending seizure or system notifications.
- **Solid amber:**A system notification has not been resolved after warning message has been dismissed.

**C – Power Button** – Press and hold to turn Hub ON or OFF. Blue when the Hub is turned ON.  
Tap button to turn screen ON and OFF while system is still active.

**D – Home Button** – Press to return to the Home Screen from any software screen.

**Figure 3: Hub Back**

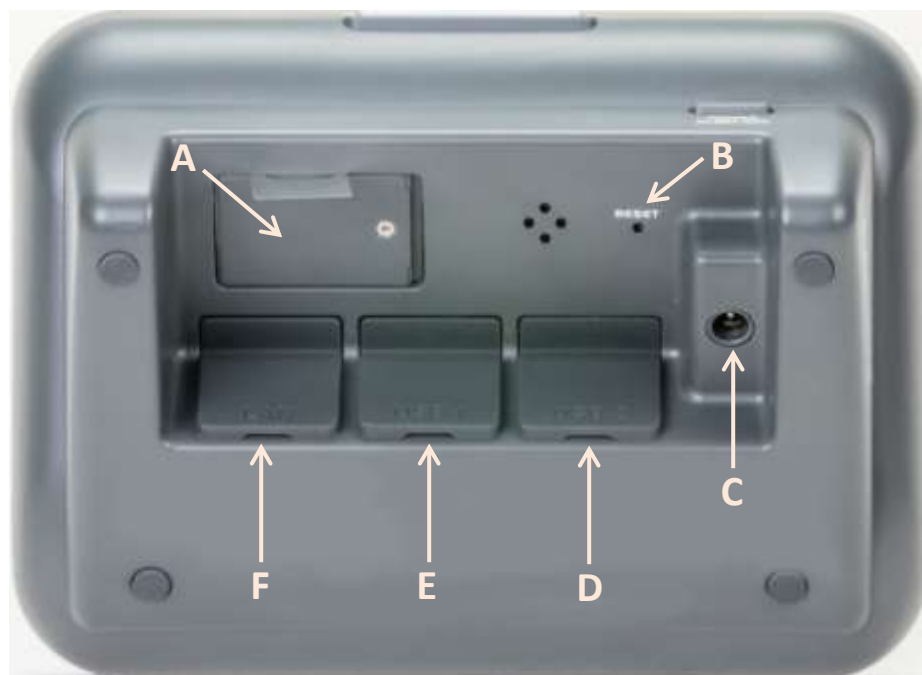


**Figure 3:**

**A –Silence Button** – Flashes amber to provide a visual indicator of a pending seizure notification. Press to silence audio during seizure notifications. You must tap Confirm or Deny on the touchscreen to dismiss the notification displayed on the Hub.

**B –Power Alert Off** – The Hub provides an alert if the wall outlet is disconnected or if it loses power for any reason while turned ON. This button silences the alert.

**Figure 4: Hub Bottom**



**Figure 4:**

**A –Power Alert  
Battery**

**B – Hub Reset**

**C – AC Plug**

**D – USB-2 Port\***

**E – USB-1 Port**

**F – LAN\***

\*Not active

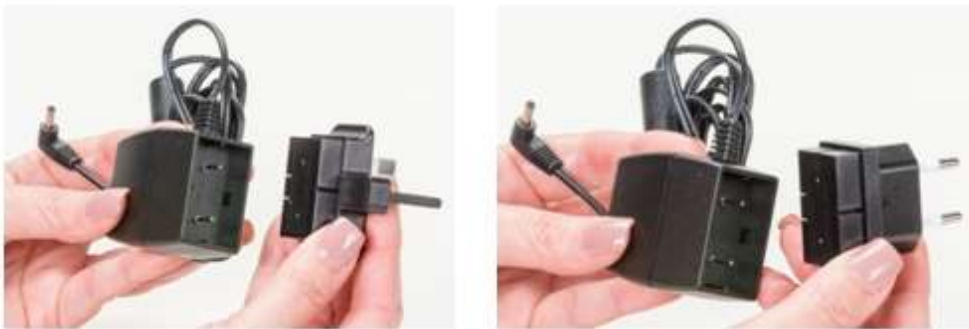
2. If this is your first time using the System, remove tab from the power alert battery compartment (see Figure 5).

**Figure 5: Remove Tab**



3. If required, assemble the AC adaptor with the appropriate plug tip (see Figure 6).

**Figure 6: Assemble AC Adaptor**



4. Connect the power cord into the back of the Hub, and then plug into a wall outlet.
5. The Hub will automatically turn on, display the Cyberonics' logo, and start the ProGuardian software.

## 7.2. Setup Wizard for Hub Software

The Setup Wizard guides you through the registration and initial setup of the Hub software. Follow the on-screen instructions and enter the requested information.

### 7.2.1. How to Enter Information on the Hub

Use the following methods to enter information as prompted by the Setup Wizard and during normal use of theHub software.

Option	Description
Pop-up Menu	<ul style="list-style-type: none"><li>• Tap a setting field to view a pop-up menu of available options.</li><li>• Tap an option to select it.</li></ul>
Text Field	<ul style="list-style-type: none"><li>• Tap the empty text field to pull up an on-screen keyboard.</li></ul>

### 7.2.2. Starting the Setup Wizard

To start the Setup Wizard, follow the on-screen instructions listed below.

1. If you have not already accepted the Terms of Service, read the agreement and press the “Accept” button. You must accept the Terms of Service before using the ProGuardian System.
2. Press the “Next” button to begin system setup (Settings & Registration).
3. Select the preferred date and time format by selecting a field and using the Pop-up menu. Press the “Continue” button after making your selections.
  - You may select the order in which day, month, and year is displayed and recorded by the System.
  - You may choose either 12 or 24 hour clock format.
4. Enter the correct local date and time. These settings must be accurate so that when seizure detections are added to the log, the date and time information is correct.
  - a. To set the date, tap the current date.
  - b. Adjust the date by using the “+” and “-” buttons, or by using the on screen keyboard to type into the year, month, or day fields.
  - c. Press “Ok” when finished.
  - d. To set the time, tap the currently displayed time setting.
  - e. Adjust the time by using the “+” and “-” buttons, or by using the on screen keyboard to type into the hour and minute fields. AM and PM can be selected by tapping the field (when appropriate based on selected time display format).
  - f. Press “Ok” when finished.
  - g. Press “Continue” after both the time and date are set.



**Note:** To adjust these settings at a later time refer to the “SETTINGS MENU” section.

5. Enter the sensor wearer's name and date of birth by tapping the text field and using the on-screen keyboard or popup menus. This information will be included on reports created by the System. Press "Continue" when finished.
6. Create a password and a security question used to recover your password should you forget it. All entries can be completed by tapping the text field and using the on-screen keyboard or popup menus. Press "Continue" when finished.
  - a. Passwords are case sensitive (upper and lower case letters are checked) and must consist of numbers, letters, or symbols (no spaces allowed). They must be at least 5 characters long.
  - b. The security answer is not case sensitive.
  - c. To adjust these settings at a later time, refer to the "SETTINGS MENU" section.
7. "Settings and Registration" is complete, press "Next" to proceed.
8. (OPTIONAL)

You can setup the ProGuardian App at this time; or, you can later access the ProGuardian App Setup Wizard from the Home Screen Help menu.

  - a. The ProGuardian App is an optional mobile application that can be loaded on an Android smart phone.
  - b. The application allows receipt of seizure notifications from the Hub on your mobile device when in range of your home Wi-Fi Network.
  - c. Refer to the "The ProGuardian Mobile Application" section for more details.

**You have successfully completed the Hub software Setup Wizard.**

**When ready to begin seizure monitoring, complete the steps listed in "Begin Seizure Monitoring".**

### 7.3. Begin Seizure Monitoring

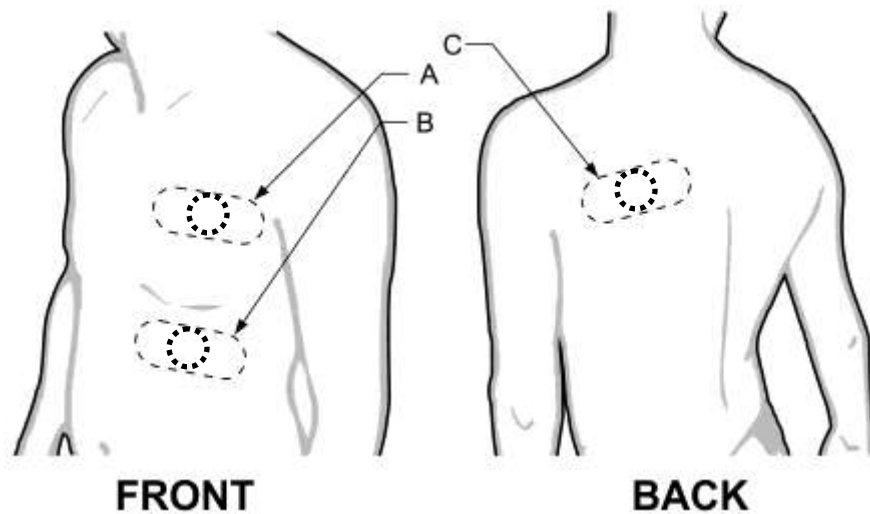
The Sensor is a body-worn device that collects heart rate and movement information. The Patch is a single-use, disposable adhesive strip that connects to the Sensor and adheres to the body. The Patch has gel components that allow the Sensor to detect a heart rate. It is important that the Patch is in full contact with the skin to give accurate information to the Sensor and Hub.

The System is intended for seizure monitoring during sleep, and Patches may be worn for up to 12 hours before replacement is necessary.

### 7.3.1. Preparation

The assembled Sensor and Patch should be worn in one of the following locations on the body (Figure 7):

**Figure 7: Areas for Skin Preparation**




**Figure 7:**

A - Left chest (Preferred position)

B - Lower Left rib cage

C - Left back – directly below the shoulder blade (Least preferred position)

\*Positions of Patch can be rotated by any degree; however, ensure center of Patch (indicated by ) is placed as shown on diagram.



**Caution:** For people with the implantable VNS Therapy® System, the ProGuardian Sensor should only be placed on the lower rib cage or on the back.

To ensure the sensor has full contact with the body, prepare the skin by following the steps below.

1. Trim any excess hair from the chosen location using scissors or electric clippers.



**Caution:** Do not use a razor, as this can cause skin irritation.

2. Clean the area with soap and water to remove oils or lotion.
3. Dry the area thoroughly.



**Caution:** The Patch should not be applied to cuts, abrasions, sun burns, rashes, or any other type of abnormal skin condition. Applying the Patch to skin that is damaged may result in discomfort, pain, or worsening of the skin condition.



**Note:** Change the Patch location on a regular basis (nightly or as needed) to prevent skin irritation.



**Note:** Use soap and water to remove residue from a previous Patch.

### 7.3.2. Sensor Patch Setup

1. Confirm that the Hub is displaying the Home Screen (Figure 8). The Sensor icon on the Home Screen will be gray (disabled) until the System is ready to detect seizures.



**Caution:** If the Sensor icon is yellow (enabled), then the system was not turned off from the Hub Home Screen at the end of the last use period. To prevent connection problems, press the Sensor icon, then select “Off” before proceeding to Step 2 (see “Pausing or Stopping Monitoring” for more details).

**Figure 8: Hub Home Screen (Sensor Inactive)**



2. Locate your Sensor and remove a single disposable Patch from its packaging (Figure 9).



**Note:** Do not peel the liner away from the Patch adhesive. You will be instructed to expose the adhesive at a later step before application to the body.



**Figure 9: Open and Remove Patch from Packaging**



3. Align the triangle on the plastic Patch connector with the triangle notch on the underside of the Sensor (Figure 10).

**Figure 10: Align Triangles on Sensor and Patch**



**Note:** The Sensor and Patch can only be connected when properly aligned. The triangle notch on the Sensor and triangle on the Patch must face the same direction.



**Caution:** If moisture is present on or near the back of the Sensor or the contacts of the Patch, do not assemble. Doing so can permanently damage the System. Dry the parts using a soft cloth, paper towel, or cotton swab before proceeding.

4. Apply firm pressure to the top and bottom of the Sensor to snap the Patch and Sensor together (Figure 11). Ensure all four corners of Sensor snap into place.

**Figure 11: Put Sensor and Patch Together**



**Note:** The Sensor's light blinks green for 10 seconds upon successful connection of the Sensor and Patch. When you see this, proceed to the next section (Patch and Sensor Application). If the Sensor LED is red, refer to the Troubleshooting section.

### 7.3.3. Patch and Sensor Application

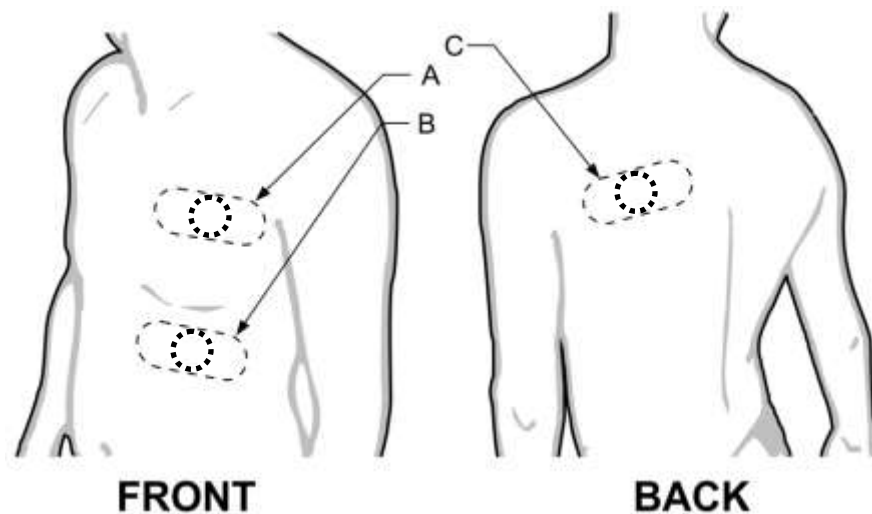
1. Remove the protective liner from the Patch and place on the body within 5 minutes after connecting the Patch and Sensor (Figure 12).

**Figure 12: Remove Patch Liner**



2. Apply the assembled Sensor and Patch. The assembled Sensor and Patch should be worn in one of the following locations on the body (Figure 13):

**Figure 13: Acceptable Application Locations**




**Figure 13:**

A - Left chest (Preferred position)

B – Lower Left rib cage

C - Left back – directly below the shoulder blade (Least preferred position)

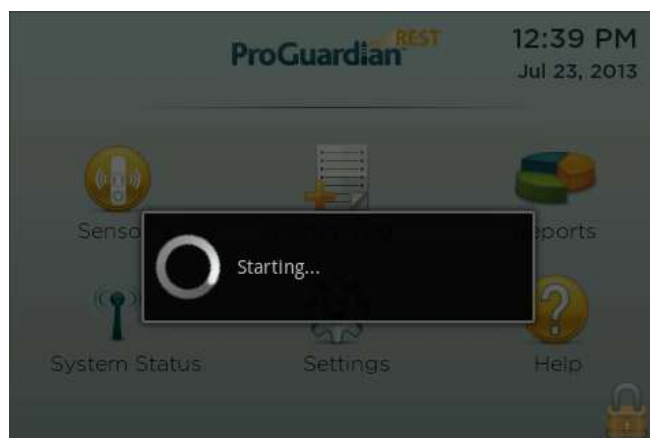
\*Positions of Patch can be rotated by any degree; however, ensure center of Patch (indicated by ) is placed as shown on diagram.



**Caution:**For people with the implantable VNS Therapy System, the ProGuardian Sensor should only be placed on the lower rib cage or on the back.

3. You will see a “Starting...” message on the Hub Home Screen as the Sensor is establishing communication with the Hub(Figure 14). Once the Sensor has made a connection with the Hub, the Sensor icon on the Hub turns yellow.

**Figure 14: Establishing Communication**





**Note:** The sensor will send an error message if no heartbeat is detected, so it is important to place it on the body within 5 minutes after attachment to the patch.

4. The Sensor will collect heart rate data (Sensor LED blinks amber during this time) to complete the setup process.
  - a. If setup is successful, the sensor's light will blink green for 30 seconds. At this time, the Hub displays a message that the "System is ready to detect seizures" (Figure 15). The Sensor's light will turn off for the remainder of the monitoring period.

**Figure 15: Setup Complete**



- b. The Hub will provide a system notification to alert the user if any problems occur that could prevent seizure detection. Follow on-screen troubleshooting steps or consult Section 13.2 of this manual if this occurs.

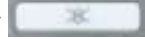
**Congratulations! Your System is now monitoring for seizures.**

## 8. Responding to Seizure Notifications

Based on changes in the heart rate or motion, the system provides a notification to the Hub when it detects potential seizure activity. Each seizure notification requires your confirmation, and only confirmed seizures will be added to the Seizure Log.

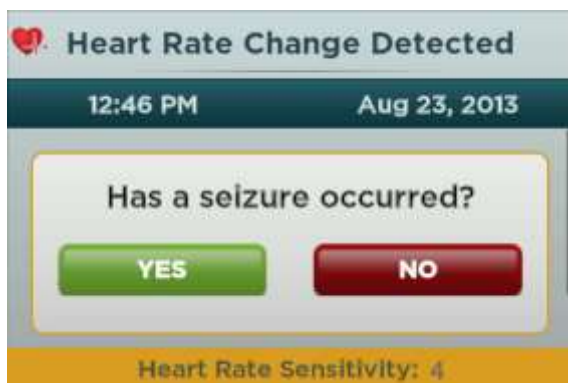
When a potential seizure is detected, the **NOTIFICATION** indicator flashes amber and the Hub sounds an audible notification.



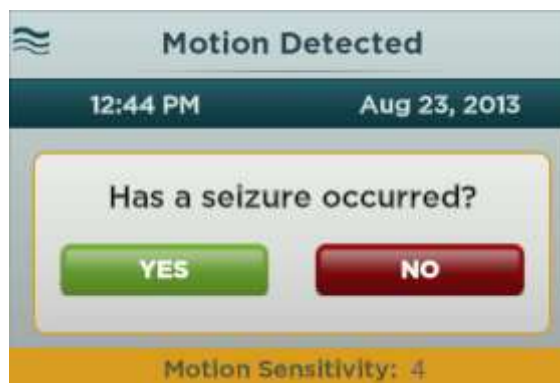
**Note:** The audible notification can be turned off by pressing the silence button (  ) on backside of the Hub.

On the Hub screen, a dialog shows the time and date of the potential seizure detection. The screen shows if the detection was due to motion or a heart rate change, as well as the current sensitivity setting (Figure 16 and Figure 17).

**Figure 16: Sample Cardiac-Based Seizure Notification**



**Figure 17: Sample Motion-Based Seizure Notification**



## 8.1. Confirming or Denying a Seizure Notification

On the touch screen, press either **YES** or **NO**.

- If **YES** is selected, the seizure will be added to the seizure log. The software opens the seizure log and displays all confirmed seizure events from the past month of system use (refer to Using the Hub Software section).
- If **NO** is selected, the software returns to the previously displayed screen.



**Note:** The timestamp of the seizure that gets logged in the Seizure Log is the time of your confirmation, not the initial notification time.

Seizure monitoring will resume as soon as either **YES** or **NO** is selected. If a response is not provided after 10 minutes, the System resumes monitoring and the notification remains on the Hub screen (until a new seizure notification occurs). Seizures can be manually added or deleted from the log at any time (see "Adding Seizures to the Log" or "Removing Seizures from the Log" for more details).

## 8.2. Adjusting Seizure Notification Sensitivity

If the System is providing too many or too few notifications, the system sensitivity can be changed for heart rate and/or motion (see "Seizure Detection Settings" for more details).

## 9. Pausing or Stopping Monitoring

There are two options when you would like to stop seizure monitoring:

1. **PAUSE** – You would like to *temporarily* stop (then resume) the seizure monitoring, keeping the Sensor and Patch attached to the body.
2. **OFF** – You would like to discontinue (stop) seizure monitoring and remove the Sensor and Patch. If this option is selected, the System will only resume seizure monitoring after a new Patch is assembled to the Sensor.

### 9.1. Pausing and Resuming Seizure Monitoring

After you have attached the Sensor and Patch, you may want to pause the seizure monitoring. This may be because the sensor wearer:

- is not ready to go to sleep.
- wants or needs to get up from bed for a short time.
- is awake and needs comforting.

To pause, then resume the seizure monitoring, follow these steps:

1. Press **Sensor** on the Hubhome screen (Figure 18).

**Figure 18: Hub Home Screen (Sensor Active)**



The following screen appears (Figure 19):

**Figure 19: Pause/Turn off Sensor**



2. Press **Pause**.

The following screen appears (Figure 20):

**Figure 20: Resume Sensor**



The system is not monitoring seizures, and Hub software navigation will not be possible until seizure monitoring is resumed.

3. When you are ready to resume seizure monitoring, press **Resume**. The software will then return to the Home Screen (Figure 18).

**Congratulations! The system is once again monitoring for seizures.**

## 9.2. Turning Seizure Monitoring Off

There are two reasons to turn off the seizure monitoring and remove the Sensor and Patch.

- The sensor wearer is at the end of the sleep period.
- You are instructed by the Hub to turn off the seizure monitoring for troubleshooting purposes.

To turn off seizure monitoring, follow the steps below:

1. Press **Sensor** on the Hubhome screen(Figure 18).
2. Press **Off** (Figure 19).  
The Hub will then display the Home Screen, and the Sensor button will be gray (disabled)(Figure 8).
3. Remove the Sensor and Patchtogether, as one assembly.



**Note:**Use care when removing the Patch. For easiest removal,slowly peel Patch from the skin with one hand while pushing down on the skin near the edge of the Patch with the other hand.

4. Lower the latches on both sides of the Sensor to expose the Sensor release button (Figure 21).

**Figure 21: Lower Latches**



5. Useyour thumb and index finger to squeeze thetwo release buttons located on opposite sides of the Sensor(Figure 22). This releases the Sensor from the Patch.

**Figure 22: Release Sensor**



6. Store the Sensor for future use.



**Caution:**Do not store or temporarily place the Sensor on any surface that could be wet (e.g. the bathroom or kitchen counter). The pins on the back of the Sensor can trap moisture and can result in System damage if assembled with a Patch while wet. If moisture is present,dry with a soft cloth, paper towel, or cotton swab.



7. The Patch contains a lithium coin cell battery that must be removed prior to disposal. Dispose of the battery in compliance with local regulations.

Removal of the battery should be performed as follows:

- Find the end of the Patch where the coin cell is located (there is a bump in the white top cover) - If the backing is sticky, you may fold the patch in half.
- Using a pair of scissors, cut a small slit in the top cover (white foam material) near the base of the battery in the location shown (Figure 23).
- Tear an opening in the top cover large enough to grab the battery (Figure 24).
- Hold the battery between the thumb and finger of one hand and the rest of the Patch between the thumb and finger of the other and pull in opposite directions (Figure 25).
- The battery and two metal tabs that connect the battery to the Patch will release from the Patch
- The Patch can then be disposed.

**Figure 23: Cut Patch**



**Figure 24: Tear Opening**



**Figure 25: Remove Battery**



**Caution:** Do not expose the Patches to fire or heat sources as they contain a battery that could explode.

## 10. Replacing the Patch

The Patch is designed for single-use and overnight wear only.

You should replace the Patch for any of the following:

- You are starting a new sleep monitoring period
- The Sensor and Patch separate during use
- The Patch does not adhere to the skin
- You receive a System Notification that indicates that Patch replacement is necessary

To replace the Patch:

1. Turn off the Sensor from the Hub Home Screen and remove Sensor and Patch from body (if necessary) as described in “Turning Seizure Monitoring Off”.



**Caution:** If Sensor was not turned off using the touchscreen button on the Hub Home Screen, complete steps 1 and 2 in “Turning Seizure Monitoring Off.” Failure to do so will result in a communication error when the Sensor attempts to connect with the Hub at the beginning of the next monitoring period.

2. Complete the steps as described in “Beginning Seizure Monitoring - Sensor and Patch Setup.”

## 11. Using the Hub Software

The following sections provide further detail about the Hub software and related System features.


### 11.1. Home Screen

Once you complete the Setup Wizard, the software will display the Home screen.


There are six navigation options on the Home screen:

- Sensor
- Seizure Log
- Reports
- System Status
- Settings
- Help

The features and options for each menu item are detailed in subsequent sections of the User Manual.

From any Hubmenu, press the arrow at the upper left corner (  ) to return to the previous screen. Except during initial setup, you can navigate directly to the Home screen at any time by pressing the physical “Home” button on the Hub (see Figure 2).

#### 11.1.1. How to Lock the Hub

To prevent inadvertent setting changes, the User may wish to lock the Hub software. To do so, press the lock icon (  ) in the lower right corner of the Home Screen.

When the Hub is locked:

- None of the Home Screen options are available.
- You can only confirm or deny Seizure Notifications and receive System Notifications.
- Your password (defined during Setup Wizard) is required to unlock the Hub, to freely navigate the software and change settings.



**Note:** If you forget your password, follow on-screen instructions to reset the password using the security question. Refer to the Troubleshooting section for more help.

## 11.2. Sensor

This button is used to temporarily pause or discontinue (stop) seizure monitoring. See “Pausing or Stopping Monitoring” for more details.

## 11.3. SeizureLog

The system detects and notifies you of potential seizure activity based on changes in heart rate or movement.

Once confirmed, these seizures are maintained in an electronic log, which you can review at any time (Figure 26). The log is intended to help you track the frequency and trends in seizure activity. Also, it can be shared with your healthcare provider (see “Generating and Exporting Reports” for more details).

**Figure 26: Sample Seizure Log**



Time	Status	Attribute
<b>Aug 23, 2013</b>		
12:46 PM	✓	
12:44 PM	✓	
<b>Aug 21, 2013</b>		
8:46 AM		N/A

The log contains confirmed and manually entered seizures. See “Acknowledging Seizure Notifications” for more details.

Each seizure in the log contains the following information:

- The time and date of the seizure

- An icon in the Status column that indicates whether the seizure was detected by the System and Confirmed (✓) or manually entered (person icon with checkmark).
- For System detected seizures, an icon in the Attribute column indicates whether the detection was due to a heart rate change (heart icon) or motion (wavy line icon). If the seizure was manually entered by the user, N/A will appear.

### 11.3.1. Navigating the Seizure Log

Seizures are grouped by date. To scroll through the log, touch the screen and drag the page up or down. Pressing the Time header changes the sorting to show the most recent seizure at either the top or bottom of the list.

### 11.3.2. Adding Seizures to the Log

The ProGuardian System is capable of detecting many, but not all seizures. For example, if a seizure is not associated with a heart rate change or a detectable change in motion, it will not automatically be detected by the ProGuardian System. An additional feature is the ability to expand the use of the ProGuardian seizure log by manually recording seizures experienced outside of active monitoring. In

these cases, you can manually add seizures to the log by selecting the plus icon (⊕) at the upper right corner of the Seizure Log screen. This opens the Add New Seizure dialog where you can supply the date and time of the event (Figure 27).

**Figure 27: Add New Seizure**

Add New Seizure	
Date	Aug 23, 2013
Time	12:46 PM
Attribute	Not applicable for manual events
Status	Confirmed
<div>  SAVE            CANCEL         </div>	

### 11.3.3. Removing Seizures from the Log

Seizures can be removed from the log by changing their status, using the steps below.

1. Simply touch the status icon (  or  ) for any individual seizure and a pop-up dialog screen appears.
2. Make the desired change and then press **Save**.

Use this procedure to:

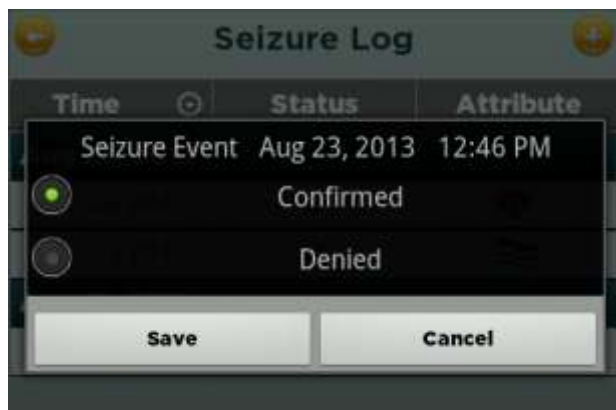
- Correct the status of any previously "Confirmed" entry.
- Delete a manually entered seizure event.

The dialog screen options for seizures detected by the System (Figure 28) or those manually entered (Figure 29) are shown below.

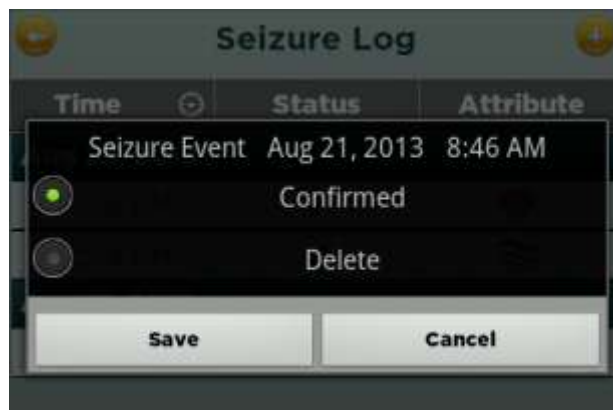


**Note:** Selecting "Denied" or "Delete" permanently removes the seizure from the log.

**Figure 28: Modify System-Detected Seizures**



**Figure 29: Manually-Entered Seizures**



## 11.4. Reports Menu

Select the Reports option from the Home Screen to display the seizure counts from the past week, month, and year (Figure 30).

**Figure 30: Sample Seizure Report**



Seizure Count	
Past Week	7
Past Month	8
Past Year	11


- The seizure information is updated every time you enter this screen and provides a summary of the seizure log.
- From this screen, you can create a report that can be shared with your healthcare provider.



**Note:** There may be a delay of several minutes to generate the report if there are a large number of seizure records.

### 11.4.1. Create a Report

To create a report, follow the steps below.

1. Navigate to the reports screen.
2. Insert the USB flash drive (supplied with the System) into the Hub (USB-1 Port, see Figure 4).
3. Press the export button “Export Icon” located in the upper right (  ).
  - The system creates a .pdf file on the USB flash drive with a title containing “ProG Report” and the date and time when the report was created.
  - The USB flash drive can be removed from the Hub as soon as the “Export Complete” message is displayed (Figure 31).

**Figure 31: Export Complete**



- The report can be viewed on any computer with Adobe Acrobat Reader (free download at <http://get.adobe.com/reader/>)



**Note:** It may take up to 20 minutes to export the report if there are a large number of seizure records.

### 11.5. System Status

Select the System Status option from the Home Screen to verify wireless connections between the ProGuardian System components.

There are three tabs at the top of the screen that provide useful information when troubleshooting:

- Connectivity
- Sensor
- Hub

### 11.5.1. Connectivity Tab

The Connectivity tab screen (Figure 32) displays the connection status between the Hub and Sensor (needed for seizure detection), and the Hub with the ProGuardian App (needed to send notifications to a mobile device). The time and date of connections are shown to help you verify that System was working throughout the night time use period.

Green bars indicate active connections that are working. Red bars indicate a disconnection. Refer to on-screen troubleshooting provided by the Hub, or the “Troubleshooting” section of the manual to fix a disconnection.

**Figure 32: System Status – Connectivity Tab**



### 11.5.2. Sensor Tab

The sensor tab screen (Figure 33) indicates if the System is appropriately detecting heart rate (“ECG Status”) and other software details that may be needed for troubleshooting. These details include:

- *ECG Status*: Displays “Ok” during normal operation and “No Signal” when troubleshooting is required.
- *Software Version*: Shows the current software version loaded on the Sensor
- *Firmware Version*: Provides additional software information which may be requested during troubleshooting.
- *Hardware Version*: Provides details related to manufactured components inside the Sensor
- *Serial Number*: A unique number used to identify your Sensor
- *Model Number*: Product type identifier

**Figure 33: System Status – Sensor Tab**



### 11.5.3. Hub Tab

The Hub tab screen(Figure 34)provides the status of several items related to normal system operation. These items include:

*Network SSID (“Wi-Fi Network Name”):*

This field shows the status of the Hub connection with the home wireless (Wi-Fi) network.

- When connected, this field displays the home network name, but otherwise will display “Not Connected.”
- The Hub must be connected to the home network in order to use the ProGuardian App.
- To connect to a network and setup the ProGuardian App, accessthe Help menu from the HubHome Screen or refer to Section 12, The ProGuardian App, for more information.

*Power Alert Battery Status:*

The Hub contains a backup battery (CR2032 lithium coin cell), which sounds an audible notification if the Hub loses power while powered on and in use. The audio alertis meant to notify the user when seizure detection is not possible.

- “Good” indicates that the battery does not need replacement.
- When “Replace Hub Power Alert Battery” is displayed, refer to Troubleshooting instructions to install a new battery.

*Software Version:*

This is the current software version loaded on the Hub.

*MAC Address:*

This is information that may be required by some home networks to establish Wi-Fi connection with the Hub.



**Figure 34: System Status – Hub Tab**



## 11.6. Settings Menu

The Settings Menu allows you to configure various device settings and notification preferences (Figure 35). Selecting the Settings navigation option from the Home Screen opens the following submenu. Touch the Hub screen and scroll to view all options.

**Figure 35: Settings Menu**



### 11.6.1. Seizure Detection Settings

It is recommended that you configure the seizure detection settings to give the best results for the sensor wearer. The System identifies changes in heart rate or motion as potential seizures events.



**Note:** Changes can only be made during system use while the Sensor is actively monitoring.



**Note:** The default for both sensitivity settings is 4 (range 1-7).

### Getting the Best Results for the Sensor Wearer:

1. Use the device with **default seizure detection settings at 4** until you are comfortable evaluating if the System is giving you too few or too many seizure notifications.
2. If you are getting too few or too many seizure notifications, adjust the seizure detection settings.

### Adjusting the seizure detection settings:

1. Select “Seizure Detection” on the Settings menu.
2. Choose a number to increase or decrease the sensitivity for motion or heart rate.
  - Higher numbers (5, 6, or 7) make the system more sensitive, and increase the chance of a seizure notification.
  - Lower numbers (1, 2, or 3) make the system less sensitive, and decrease the chance of a seizure notification.



**Note:** To help you determine the best setting, both sensitivity controls display the number of associated “Denied” detections since the last sensitivity setting change (Figure 36).

3. Press **Save**.

**Figure 36: Configuring Seizure Detection Settings**



### What if I feel seizures are being under-reported?

1. Increase the sensitivity settings for both the heart rate and motion controls by selecting a higher number.
2. Press **Save** and the Hub will program the Sensor.
3. Use the ProGuardian System for a few nights and then repeat these steps as needed. Once the System begins detecting seizures, it can be determined which signals (motion and/or heart rate change) are associated with the sensor wearer’s type of seizure.



**Note:** While increasing sensitivity may improve the chance of detecting seizure activity, it may also give more false notifications. Only you can decide what is best for your individual situation.

#### What if I feel seizures are being over-reported?

1. Decrease either the “Heartbeat Sensitivity” or “Motion Sensitivity” setting by selecting a lower number. To determine which setting to change, you may select the setting with the greater number of “Denied” potential seizure detections (Figure 36).
2. Press **Save** and the Hub will program the Sensor.
3. Use the ProGuardian System for a few nights and then repeat these steps as needed.



**Note:** Cyberonics recommends trying the new setting until additional seizures or notifications not associated to a seizure occur, and then repeating the process as needed.



**Note:** Changes can only be made during system use while the Sensor is in range of the Hub.

#### 11.6.2. Sound Settings

1. To adjust the Hub volume, touch the displayed Volume Level number (adjustable between 1 and 7) and drag the slide control (Figure 37). The default volume level is 5 and the maximum volume level is 7.

**Figure 37: Sound Settings**



2. Press the play button (▶) to the right of “Test volume level” and check the volume level by producing a test Seizure Notification. To stop the audio test, press the stop button.

If the ProGuardian App is setup, and the mobile device is within range, the Hub volume can be muted. To mute (or unmute) the hub, tap the picture of the speaker.

If the ProGuardian App is not in use or loses Wi-Fi connection, the Hub may not be muted. If muted, the Hub volume will automatically turn on when the ProGuardian App Wi-Fi connection is disconnected and turn off when the App Wi-Fi connection is restored. This is a software feature intended to prevent missed seizure notifications.

### 11.6.3. Display Settings

Display Settings allow you to change screen brightness, screen off timeout, and auto-lock timeout (Figure 38).

**Figure 38: Display Settings**



To adjust screen brightness, touch the displayed value (adjustable between 10 and 100 percent) and touch and drag the slide control. A hundredpercent is the maximum screen brightness. If you want the screen dark with system active, simply tap the power button on the front of Hub.

The screen will automatically dim after 10 minutes of inactivity (default setting).This time period can be adjusted by tapping the “Screen Off Timeout” and selecting the desired time from the pop-up menu (1, 2, 10, 20, or 30 minutes, or “Never Turn Off”).Touch any portion of the screen to resume normal screen brightness.

The Auto-Lock timeout is set to “Never Lock” by default. If you prefer the Hub to require your password after a period of inactivity,you can change this value to 1, 2, 10, 20, or 30 minutes.

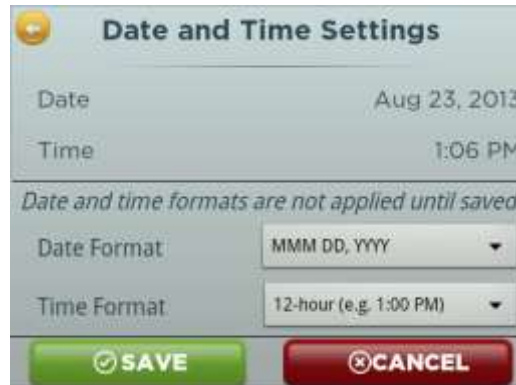


**Note:**Auto-Lock timeout is a convenience feature. You may always lock the Hub manually by following the instructions in Section 11.1.1, How to Lock the Hub.

### 11.6.4. Date and Time Settings

Date and Time Settings allow you to change the current date and time, as well as the display format (Figure 39).

**Figure 39: Date and Time Settings**



#### 11.6.4.1. Changing Date and Time

Because the seizure log time stamps are only accurate when the Hub is set correctly, it is important to set an accurate date and time. Follow the steps below to set the time and date.

##### Set the Date

1. Tap the currently displayed setting and a popup dialog appears.
2. Adjust the values as needed using the + or - buttons.
3. Press **Ok**.

##### Set the Time


1. Tap the currently displayed setting and a popup dialog appears.
2. Adjust the values as needed using the + or – buttons. If 12-hour format was selected, AM and PM can be selected by tapping the field.
3. Press **Ok**.



**Note:** The system will not automatically update for daylight saving time.


#### 11.6.4.2. Date and Time Formats

1. The date can be adjusted for various international formats. To adjust, tap the currently displayed format and select the preferred format from the popup menu.
2. The time can be displayed in 12- or 24-hour format. To adjust, tap the currently displayed format and select the preferred format from the popup menu.

 **Note:** Date and time format changes will not be reflected in the clock and calendar displays until “Save” is pressed.

### 11.6.5. Patient Profile

The profile for the person with epilepsy is setup during the initial Setup Wizard. To make any correction to the name or date of birth, you can tap the relevant field(s) and use the on-screen keyboard or popup menus (Figure 40). Note that the information included in this profile is printed on each exported ProGuardian report for the convenience of the healthcare provider.

 **Note:** If the Sensor will be used on a new person, contact your Customer Care Service Center for assistance resetting the seizure log and System.

**Figure 40: Patient Profile**

The screenshot shows a mobile application screen titled "Patient Profile". It features three input fields: "First Name" with the text "Andy", "Last Name" with the text "Parkman", and "Date of Birth" with the text "Aug 22, 2000". At the bottom of the screen, there are two buttons: a green "SAVE" button with a checkmark icon and a red "CANCEL" button with an 'X' icon.

### 11.6.6. Account Information

The account information is setup during the initial Setup Wizard.

From this screen (Figure 41), you can change your password or security question and answer.

**Figure 41: Account Information**

The screenshot shows a mobile application screen titled "Account Information". It contains two options, each with a yellow padlock icon to its right: "Change password" and "Change security question".

- The password is required to unlock the Hub if it is locked manually from the Home Screen (see “Home Screen” section) or if the Auto-Lock timeout expires (see “Display settings” section).
- If you forget your password, it can be reset by providing the correct answer to the security question.

#### To change your password or your security question:

1. Tap on the lock icon next to Change password or Change security question.
2. Enter your information by tapping the field and using the on screen keyboard.
3. Press **Save** to set the information in the system.



#### Note:

- Passwords are case sensitive (upper and lower case letters are checked)
- They must be at least 5 characters long, and can contain numbers, letters, or symbols (no spaces allowed).
- The security answer is not case sensitive (the software will not differentiate between upper and lower case letters).

## 11.7. Help Menu

The Help Menu allows you to setup or reconfigure the ProGuardian App and access troubleshooting. Select the Help navigation option from the Home Screen to open the following submenu (Figure 42).

**Figure 42: Help Menu**



### 11.7.1. ProGuardian App Setup Wizard

For details on the setup process and instructions on App usage, see Section 12, “The ProGuardian App”.

### 11.7.2. About

This section lists the Hub Software version information and copyright details.

### 11.7.3. Contact Us

This section provides the manufacturer contact information. If the ProGuardian System User Manual is ever lost, a replacement can be downloaded from [www.ProGuardianSystem.com](http://www.ProGuardianSystem.com).

### 11.7.4. Administrator Access

Administrator level access is used to perform advanced troubleshooting. This can be necessary if both the Hub password and the answer to the security question have been forgotten. Have the Hub available and contact your CustomerCare ServiceCenter for assistance.

## 12. The ProGuardian App (optional mobile device application)



This is an optional feature of the System that is not needed for standard seizure monitoring.

The ProGuardian App is free software that connects the ProGuardian System with an Android mobile device. This extends the operating range of the ProGuardian System by allowing a user to remotely receive seizure and system notifications from the Hub, while connected to a home Wi-Fi Network.

#### To use this optional feature, you need:

- A secure home Wi-Fi network (No internet connection required)
- An Android mobile device\* with the ProGuardian App successfully installed

\* To use the ProGuardian App your mobile device must have:

- Android operating system 2.3.x or 4.2.x
- Minimum 480x800 pixel resolution



**Note:** Internet connection is only required for downloading the ProGuardian App. However, having internet enabled on your home Wi-Fi network will improve the speed of the Hub searching for available mobile device(s).





**Note:** Due to complexity of different mobile device/Wi-Fi configurations, the Hub may not be able to connect with all mobile devices that meet the minimum requirements for the Caregiver App.



**Note:** To prevent missing notifications due to low battery on the mobile device, it is recommended that you keep the mobile device charged when the ProGuardian App is in use.

## 12.1. ProGuardian App Setup Wizard

Use the Setup Wizard in the following situations:

- ProGuardian App for the first-time setup
- Anytime changes are made to the home Wi-Fi network, or if the Hub is being used in a new location with a different network
- To register a new mobile device to receive Hub notifications



**Note:** You can only have one mobile device at a time registered with the System.

- To unregister an existing mobile device and stop delivery of Hub notifications

Follow the steps below to setup the ProGuardian App.

1. Press **Help** on the Hub Home Screen, and then press **Go** to launch the ProGuardian App Setup Wizard (Figure 43).

**Figure 43: ProGuardian App Wizard (Hub)**



The wizard instructs you to perform the following steps on your mobile device:

- From your mobile device, download the free ProGuardian Mobile Application from [www.ProGuardianSystem.com](http://www.ProGuardianSystem.com).
- After the application installation is complete, the Terms of Service Agreement will display on the mobile device. Read and accept this agreement to continue.
- The ProGuardian App opens on your mobile device (Figure 44).
- Enable your Wi-Fi settings on your mobile device and connect to your home's Wi-Fi Network. Consult your mobile device user's manual, if needed.



**Note:** If this is the first time you are setting up the app, the system status bar indicates that the Hub and mobile device are not yet connected (shown by a red bar). Text on the screen states "Mobile Device Not Ready".

**Figure 44: ProGuardian App Screen (Mobile Device – Not Set Up)**



2. Next, continueProGuardian App Setupby completing the ProGuardian App Setup Wizard on the Hub. Connect the Hub to the home Wi-Fi network by selecting the network name from the list of options detected by the Hub.
  - a. You will be asked to supply the Wi-Fi Network password if your home network issecurity enabled.
  - b. When the Hub is successfully connected to the network, a green checkmark will appear to the left of the network name. Press **Continue** to proceed to the next step.




**Note:** The mobile device and the Hub must be connected to the same Wi-Fi network to receive notifications on the mobile device.

“Continue” can only be selected after successful connection to a Wi-Fi Network (Figure 45).

**Figure 45: Connecting to Wi-Fi (Hub)**



3. Select the mobile device that you would like to receive Hub notifications by tapping the name from the displayed list (Figure 46). If you don't see your device at first, you may select the “refresh” button (  ) to search again. It may take several minutes to find available devices.

**Figure 46: Connect to Mobile Device (Hub)**



- a. The list includes all devices that have an open ProGuardian App on the same Wi-Fi network as the Hub.
- b. If you do not know your device name, refer to Section 12.5, “Configuring App Sound Settings”.

- c. When the Hub has successfully registered the mobile device, a green checkmark will appear to the left of the device name.
- d. Press **Continue** to proceed to the next step.





**Note:** “Continue” can only be selected after successful connection to a Wi-Fi Network.

4. The ProGuardian App setup is now complete. The App displays the text “Mobile device ready to receive notifications.”
5. Press “Send test notification to device” to check function and verify that your mobile device sound is turned on (Figure 47). If your mobile device is muted or set to vibrate, the ProGuardian App will not produce audio for notifications.

**Figure 47: ProGuardian App Registration Complete (Hub)**



6. Press **Exit to Home Screen** to close the wizard on the Hub. Your ProGuardian App screen should have a green line between the Hub (  ) and the mobile device App (  )(Figure 48).

**Figure 48: ProGuardian App Screen (Mobile Device – Setup Complete)**



**Congratulations! Your ProGuardian App is now ready for use.**

## 12.2. Wi-Fi Network Changes and Registering New Devices

If changes are made to the home Wi-Fi network, or if you wish to use the System in a new location with a different network, repeat the steps in “ProGuardian App Setup Wizard.” Remember to connect your mobile device to the same Wi-Fi network as the Hub.

To register a new mobile device to receive Hub notifications, complete steps 1-2 of “ProGuardian App Setup Wizard.” When you reach step 3, tap the name of the new mobile device.

- The list includes all devices that have an open ProGuardian App on the same Wi-Fi network as the Hub.
- If you do not know your device name, refer to Section 12.5, “Configuring App Sound Settings”.
- After selecting the new device, a dialog will ask you to confirm the change (Figure 49), since only one mobile device may be registered at a time.

**Figure 49: Registering New Mobile Device**



- Tap **Yes** to confirm the change. When the hub has successfully registered the mobile device, a green checkmark will appear to the left of the device name.
- Press **Continue** to proceed and then complete the remaining steps in “ProGuardian App Setup Wizard.”

### 12.3. Receiving Notifications on Your Mobile Device

When the mobile device is connected to the home Wi-Fi network, it displays System Status similar to the Hub (refer to System Menu section).

- Green bars indicate active, working connections.
- Red bars indicate a disconnection.

#### Mobile Device in Range

When the ProGuardian App is open and the mobile device is in range of the home Wi-Fi and connected to the Hub, the ProGuardian App receives seizure and system notifications from the Hub (Figure 50 and Figure 51). Please note the following:

- Notifications are displayed on both the Hub and the ProGuardian App. Pressing **Ok** on the ProGuardian App only dismisses the notification on the mobile device, but does not affect the notification on the Hub or the Hub audio if that volume is enabled.
- Seizure notifications can only be confirmed and added to the seizure log from the Hub touchscreen.

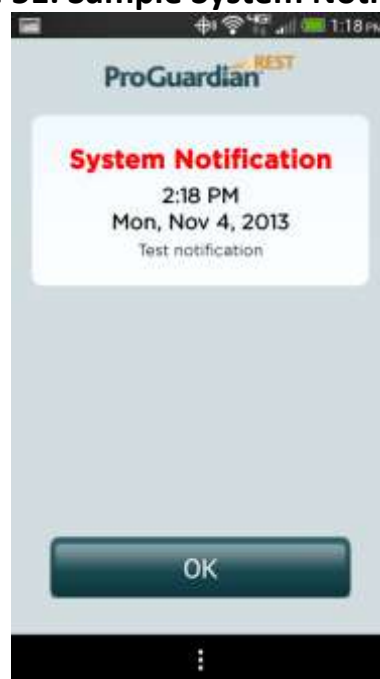


**Note:** Mobile device settings can interfere with ProGuardian App audio. If the mobile device is muted or set to vibrate, the ProGuardian App will not deliver audio through the mobile device speakers.

Figure 50: Sample Seizure Notification



Figure 51: Sample System Notification



#### Mobile Device NOT in Range

If the mobile device leaves the range of the Home Wi-Fi network:

- The ProGuardian App will NOT receive seizure notifications. (Notifications will only occur at the Hub.)
- The ProGuardian App will provide an audible notification and display a message that it is not in range.
- If the Hub volume is muted, the audio will be restored until the mobile device reconnects with the home Wi-Fi.
- The connection status between the Hub and Sensor will be displayed as unknown (gray bar) on the mobile device.

## 12.4. Adjusting Your Mobile Device Sound Settings

Cyberonics recommends that your mobile device sound is ALWAYS enabled (turned on) while using the ProGuardian App.



**Note:** Switching a phone to vibrate mode will prevent an audio seizure notification, even if the ProGuardian App setting menu is set to ON.

## 12.5. Configuring App Sound Settings

The ProGuardian App sound can be configured by selecting the gear (🔧) located at the top left corner of the ProGuardian App screen (on the mobile device). This opens the App settings menu (Figure 52).

If the audio on the Hub is enabled, the user has the option of disabling ProGuardian App sound on the mobile device. You may turn the App sound on or off by tapping on either end of the sound control. The setting menu also lists the mobile device model and MAC address, which are needed when completing the app setup wizard.

**Figure 52: ProGuardian App Settings Menu**



## 12.6. Discontinuing Use of the ProGuardianApp

To disconnect or unregister an existing mobile device and stop delivery of Hub notifications:

1. Press **Help** on the Hub Home Screen.
2. Press **Goto** to launch the ProGuardian App Setup Wizard.
3. Press **Continue** until you reach the mobile device registration screen.
4. On the mobile device registration screen, press the red X to the right of the currently registered mobile device (Figure 53).



**Figure 53: Remove Mobile Device**



5. Press **Yes** to confirm that you would like the Hub to forget the device (Figure 54).

**Figure 54: Forget Device Confirmation**



On the mobile device registration screen, you will not see a green checkmark next to any devices.

6. Press **Exit** to return to the Hub Home Screen.

## 13. Troubleshooting

Please refer to this section if you encounter any issues while using your ProGuardian System.

### 13.1. Sensor Reset

A sensor reset may be performed if you feel that the Sensor is not operating correctly. You should always turn off the Sensor from the Hub before attempting a sensor reset. To perform the reset, press and hold the reset button on the sensor (Figure 55) with a pin-point instrument (e.g. a paper clip, ball-

point pen) until the sensor LED flashes green. Note that the sensor **must** be attached to the Patch while a reset is being performed.

**Figure 55: Sensor Reset Button Location**




## 13.2. Common Error Messages

Follow the instructions in the table below to resolve issues with your system:

If you encounter:	To fix the issue:
Hub Notifications and Error Messages	
Hub displays: Sensor Communication	<p>Try the following, in the suggested order until resolved:</p> <ol style="list-style-type: none"> <li>1) Move the Sensor-wearer closer to the Hub. Wait 30 seconds and re-check connectivity.</li> <li>2) Press Off on the Sensor icon and wait 30 seconds. If Sensor icon remains grayed-out, perform Sensor reset, and wait another 30 seconds to check connectivity.</li> <li>3) Press Off on the Sensor icon, replace the Patch, and retry setup.</li> </ol>
Hub displays: ProGuardian App Communication	<p>Try the following, in the suggested order until resolved:</p> <ol style="list-style-type: none"> <li>1) Return the mobile device to the Wi-Fi Network range</li> <li>2) Check that the ProGuardian App was downloaded onto the mobile device and is open</li> <li>3) Check that the mobile device and Hub are both connected to the same Wi-Fi network</li> <li>4) Run the ProGuardian App setup wizard under the Help menu on the Hub</li> </ol>

If you encounter:	To fix the issue:
Hub displays: Replace Hub Power Alert Battery	<p>First:</p> <ol style="list-style-type: none"> <li>1) Verify that the plastic tab has been pulled out from the power alert battery cover. If not, pull out plastic tab to resolve issue.</li> </ol> <p>Otherwise, complete each of the following steps:</p> <ol style="list-style-type: none"> <li>2) Power down and unplug the Hub</li> <li>3) Turn the Hub over and use a small Phillips head screw driver (e.g. one that's used for eye glasses) to remove the power alert battery cover</li> <li>4) Remove the CR2032 lithium coin cell battery</li> <li>5) Replace the battery with the positive terminal facing away from the Hub</li> <li>6) Replace the power alert battery cover and secure with the set screw</li> <li>7) Plug the Hub AC adapter into the wall outlet</li> <li>8) The Hub will automatically start the ProGuardian software, and you can resume use of the System</li> </ol>
Hub displays: ECG check fail	<p>Try the following in the suggested order until resolved:</p> <ol style="list-style-type: none"> <li>1) Press Off on the Sensor icon. Verify that the Sensor/Patch assembly is fully secured and perform a reset on the Sensor.</li> <li>2) Press Off on the Sensor icon. Replace the Patch and retry at same body location.</li> <li>3) Press Off on the Sensor icon. Replace Patch and place the Sensor on a different body location/orientation.</li> </ol>
<p>Hub displays: Error Writing to USB or Exported Files are Empty (0kb)</p> <p>(when attempting to export reports)</p>	<p>The USB flash drive must be connected to the Hub in order to export reports:</p> <ol style="list-style-type: none"> <li>1) Check that USB flash drive is properly inserted and retry.</li> <li>2) Check that there is sufficient memory available on the USB flash drive (using a computer). If the exported file size is 0kb, the USB flash drive is likely full. Delete or move files from the USB flash drive and retry the export.</li> </ol>

If you encounter:	To fix the issue:
<b>Audio Alerts</b>	
The Hub has lost AC power and is providing an audio alert	<p>The “silence button” on the top of the Hub will NOT silence this type of alert.</p> <p>Press the “Power Alert Off” button located on the back of the base (see Figure 3 in section 7.1) to silence the alert.</p> <p> <b>Note:</b> The System cannot be used for seizure detection until AC power is restored.</p>
The Hub does not produce any audio during system or seizure notifications	From the Home Screen, select Settings. Choose the Sound submenu. Make sure Mute is not enabled, and follow the instructions in Section 11.6.2 to adjust and test the volume level.
Mute cannot be enabled from the Setting menu (Sound submenu).	<p>The system only permits muting Hub audio when:</p> <ul style="list-style-type: none"> <li>• The ProGuardian App is installed and in use on a mobile device, and</li> <li>• The registered mobile device is within range and connected to the Home Wi-Fi Network</li> </ul> <p>To setup the ProGuardian App, run the ProGuardian App setup wizard under the Help menu on the Hub.</p>
Other audio issues	Go to the Sound submenu and make sure that the test audio sound is not playing (press the stop icon if it is playing). Make sure that you’ve entered and saved the desired audio settings under the Sound submenu. If you still have problems, power off the Hub and restart.
<b>Hub Screen</b>	
The Hub touch screen is not responsive, or software is frozen, has forced shut down or otherwise displays abnormal behavior.	<p>Try to go back to the Hub Home screen and repeat the desired action if possible.</p> <p>If the Hub is completely frozen, has forced shut down, or otherwise appear to be in a non-stable state, use a pin-point instrument (e.g. a paperclip) to press the reset button on the Hub.</p> <p>If the Hub does not resume normal function, a replacement may be needed. Contact the Customer Care Service Center.</p>

If you encounter:	To fix the issue:
<b>Sensor LED</b>	
Steady red LED from the Sensor	<p>Perform a Sensor reset.</p> <p>If the Sensor shows a red LED after reset, a replacement sensor may be needed. Contact the Customer Care Service Center.</p>
<b>Hub LED</b>	
The Hub "Connectivity" LED is solid Amber	<p>Hub-to-Sensor or Hub-to-ProGuardian App communication is disrupted. From the Home Screen, select "System Status" and view the status bar to determine source of the connection issue.</p> <p>To resolve an issue with Sensor to Hub connectivity, refer to troubleshooting for "Sensor Communication" listed above.</p> <p>To resolve an issue with Hub to ProGuardian App connectivity, refer to troubleshooting for "ProGuardian App Communication" listed above.</p>
The Hub "Connectivity" LED is flashing Amber	<p>This indicates that System setup has not been completed, or that the System has been Paused (temporarily not monitoring seizures).</p> <ul style="list-style-type: none"> <li>• Refer to sections 7.1 and 7.2 to complete setup and begin using your System</li> <li>• To resume your System from a previous Pause, follow the directions provided in Section 9.1</li> </ul>

If you encounter:	To fix the issue:
The Hub “Notification” LED is solid Amber	<p>A system notification was dismissed, but the issue has not been resolved.</p> <p>From the Home Screen, select “System Status” and review each tab below:</p> <ul style="list-style-type: none"> <li>• Connectivity: If a red line is shown between the Sensor and Hub, refer to “Sensor Communication” troubleshooting. If a red line is shown between the Hub and ProGuardian App, refer to “ProGuardian App Communication” troubleshooting.</li> <li>• Sensor: If “No Signal” is displayed for ECG status, refer to “ECG check fail” troubleshooting.</li> <li>• Hub: If “Not Connected” is displayed in the Network SSID field, the ProGuardian App setup wizard must be completed prior to use of the App. If “Replace Hub Power Alert Battery” is shown, refer to the troubleshooting section with the same name in the earlier section.</li> </ul>
The Hub “notification” LED is flashing Amber	<p>A seizure or system notification is currently in progress.</p> <ul style="list-style-type: none"> <li>• Attend to the sensor wearer to assess potential seizure activity.</li> <li>• Follow on-screen troubleshooting for system notifications.</li> </ul>
LED doesn’t light up when it should, or lights up when it shouldn’t	<p>Wait 5 minutes and see if the problem resolves by itself. If not, turn off any active connection with the Sensor and/or the Caregiver App, and restart the Hub. The Hub will resume normal LED behavior when you connect it back to the Sensor and/or Caregiver App again.</p>
Caregiver App	
Cannot connect the Hub or mobile device to Home Wi-Fi	<p>Verify that you’re in the broadcasting range of the home Wi-Fi network. In the ProGuardian App Setup Wizard, forget any registered Wi-Fi network/mobile devices and restart the wizard. Verify that the caps lock on the on-screen keyboard is off and you’re entering the Wi-Fi password correctly.</p>

If you encounter:	To fix the issue:
Hub cannot find available mobile devices	Verify that the Caregiver App is properly installed on the mobile device and is open. Verify that the mobile device is connected to the same home Wi-Fi network as the Hub. In the ProGuardian App Setup Wizard, forget any previously registered mobile devices and then retry scanning. If still having problems, restart the ProGuardian App Setup Wizard.
Caregiver App disconnects with Hub when mobile device is idle	Change the Wi-Fi policy of your mobile device to "Never sleep" when idle. You may need to consult the directions for use from the manufacturer of your mobile device on how to access the Wi-Fi policy.
Timestamp on Caregiver App notifications are off by 1 day compared to timestamps from the Hub notifications	This is a known issue in the software and no action is needed. Always refer to the Hub for the correct notification time.
Any other problems with the ProGuardian App Setup Wizard	Exit the ProGuardian App Setup Wizard and restart. If still having problems, restart the Hub and retry the ProGuardian App Setup Wizard. If problem persists, contact the Customer Care Service Center.

### 13.3. Replacing a Lost or Damaged Sensor or Hub

If a Sensor or Hub is lost or damaged, a replacement component can be purchased from Cyberonics. Once you receive the replacement Sensor or Hub, follow the setup steps in Section 7, Setting Up Your ProGuardian System, of the manual.

## 14. System Specifications

	HUB	SENSOR	PATCH
Dimensions (Nominal)	147 mm x 105 mm x 74 mm	131 mm x 48 mm x 14 mm (Sensor and Patch)	
Weight (Nominal)	300 g	40 g (Sensor and Patch)	
Display size	3.5"	N/A	N/A
Display type	TFT. Color LCD	N/A	N/A
Display resolution	480x320 pixels	N/A	N/A
Wi-Fi	802.11b/g compatible	N/A	N/A
Bluetooth	BLE 4.0	BLE 4.0	N/A
Ports	USB 1: USB 2.0 Type A Host Port USB 2: USB 2.0 mini-USB OTG Port LAN: 10/100Mbps RJ-45 Ethernet Port	N/A	N/A

	HUB	SENSOR	PATCH
Audio Buzzer	0-85 dB	N/A	N/A
Power Loss Alert Battery	Primary Cell, Lithium CR2032	N/A	N/A
Power Supply	Class II Equipment 100 VAC to 240 VAC 50HZ/60HZ	Primary Cell, Lithium CR2032 (Battery for the Sensor is located in the Patch)	
Operating Conditions			
Temperature	+5°C to +40°C		
Relative Humidity	15% to 93%		
Atmospheric Pressure	525mmHg to 795mmHg		
Communication Distance	Sensor and Hub communicates up to 30 feet apart across a single wall or floor. Actual performance may vary pending environmental conditions.		
Service Life	2 years	2 years	12 hours
Storage Conditions			
Temperature	-25°C to +70°C		
Relative Humidity	15% to 93%		
Atmospheric Pressure	525mmHg to 795mmHg		

## 15. FCC Compliance Statement

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions:

(1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.



This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter, except in accordance with FCC multi-transmitter product procedures.

Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

## 16. Contact Us

### **Cyberonics Europe**

Airport Plaza, Kyoto Building  
Leonardo Da Vincilaan 19  
B-1831 Diegem, Belgium

### **Cyberonics USA**

100 Cyberonics Blvd.  
Houston, Texas 77058

### **Toll-Free Customer Care Service Center Helpline:**

1-800-986-4702

# ProGuardian<sup>TM</sup> REST

[www.ProGuardianSystem.com](http://www.ProGuardianSystem.com)

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