Everbeat User Manual

Version 2.4
22 July 2020

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Purpose of the everbeat System

Indications for Use (as reflected in FDA clearance application)
The everbeat system is intended to record, store, display and transfer single-channel electrocardiogram (ECG) rhythms, when prescribed or used under the care of a physician.

Intended Use
The everbeat system is intended for use by patients who would like to monitor and record their heart rhythms using a single-channel electrocardiogram (ECG). The everbeat system can record, display, store and transfer these ECG rhythm strips. Patients are advised to share the ECG data with their physician who can properly interpret the result and adjust the patients' care plans as appropriate. The everbeat system has not been tested for and is not intended for pediatric use.

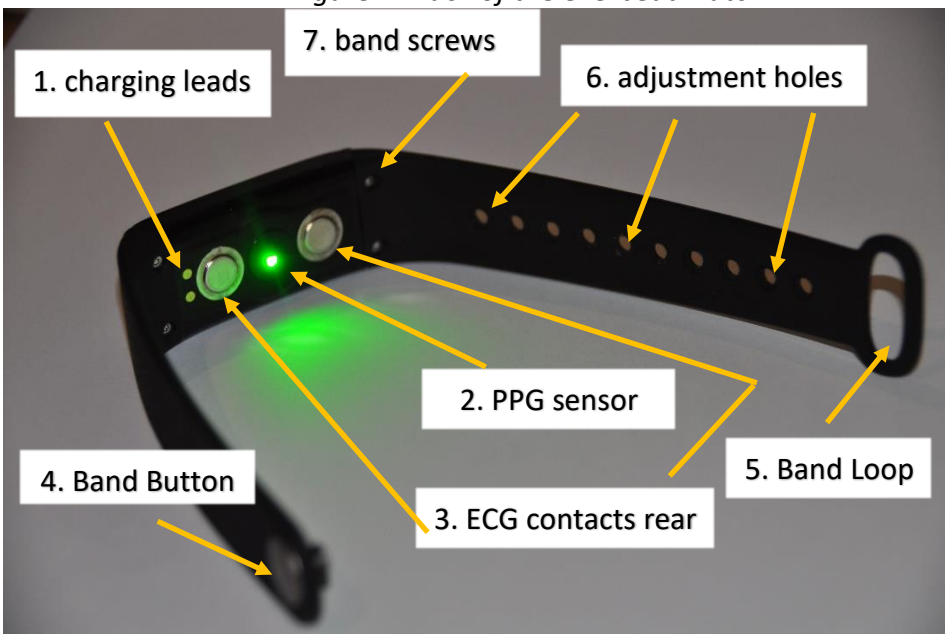
Everbeat Watch Description

The everbeat system consists of the everbeat wearable device (the everbeat watch) and the everbeat application software (the "everbeat App"). The everbeat watch communicates with the everbeat App running on your iPhone. The watch is shown below in its charging stand.

Figure 1: everbeat watch and stand

The everbeat Watch Key Components

Figure 2: Back of the everbeat watch



1. **Battery Charger Leads** – The two gold colored pickups on the far left of the bottom of the everbeat watch line up with corresponding pickups on the charging station.
2. **PPG sensor** - The green light is a photoplethysmogram, or PPG, sensor. It has been disabled and will not be used by the everbeat system at this time.
3. **ECG Contacts** – These ECG contacts on the bottom of the watch touch your wrist and create a circuit through your body when you touch the ECG sensor on the top of the watch face. Imagine a circuit starting from these two pickups, traveling up your arm, through your chest and down your other arm, and ending at your finger pressing on the ECG sensor on top of the watch. This is how everbeat records your ECG.

4 **Wrist Band** – The wristband secures the watch to your wrist. It includes a button (**#4**), a loop (**#5**), and 10 adjustment holes (**#6**).

7 **Watch band screws** – used to secure the band to the watch body. Not to be serviced by the user.

Procedures associated with the everbeat system 

1. Follow instructions to install and set up the everbeat App from the Apple App Store.
2. Put the watch on your wrist, again following our simple instructions and videos.
3. You will be able to take an ECG reading that can be shared with your doctor for medical instructions.

Contraindications

- DO NOT use with a cardiac pacemaker, ICDs, or other implanted electronic devices.
- DO NOT wear during magnetic resonance imaging (MRI), cautery and external defibrillation procedures.
- The everbeat watch is not designed for infant or child use.

Cautions

- This device is intended for use only when prescribed by a physician. ℞ Only
- Follow the physician's instructions for use of everbeat and reporting of ECG results.
- The device is provided non-sterile
- The device is intended for re-use
- The everbeat system is not a diagnostic device, but can alert your doctor to possible heart arrhythmia. If you have any symptoms you should follow your doctor's instructions, including but not limited to going to the Emergency Room.
-  The everbeat watch is classified under IEC 60601-1 as a Type BF Applied Part, meaning it comes in regular, conductive contact with the patient.
- DO NOT store in extremely hot, cold, humid, wet or bright conditions.
- DO NOT expose to strong electromagnetic fields.
- DO keep components out of reach of children.
- DO NOT use the electrode on a portion of the body with too much body fat, body hair or very dry skin, as a successful recording may not be possible.
- DO NOT continue use until further instructed by a physician if your skin is irritated or inflamed around the sensor.
- DO NOT drop or bump with excessive force.
- No modification of the everbeat system is allowed. Do not use accessories or materials not explicitly described in these instructions.
- DO NOT use as a primary means to diagnose heart-related conditions. You should always rely upon your physician for the ultimate diagnosis and treatment of your heart health.
-  Keep Dry: The everbeat watch is not designed for use in wet or moist environments. You should remove your everbeat watch when showering, bathing, swimming – or any under circumstances where the watch might get wet.
- The everbeat app is designed for single patient use; it is not designed to support multiple patients.

- The everbeat watch and charging stand is designed for use only with UL listed chargers with 5 volts DC, and between .5 and 1.0 amps output through a standard USB connection.
- The everbeat system has been tested satisfactorily for biocompatibility and electrical safety. Maintain a distance of at least 3 feet from other wireless devices to avoid potential interference.
- The everbeat device will still operate properly without access to a WiFi network. Communication between the device and your Smartphone uses Bluetooth. However, your physician will not be able to review your patient data (including your ECG) until you have connected your phone to a WiFi network so your data can be updated to the everbeat cloud.
- You should take basic precautions including keeping the device away from small children to reduce possibility of choking. You should remove the watch and contact Grektek if you see evidence of skin irritation or if it feels warm or hot on your skin.
- There are no known adverse effects to everbeat from lint, dust, sunlight, pets, pets, or interference from other devices. If you observe such effects, please contact us.
- Do not use the everbeat device if you have any cuts on your skin near your wrist.
- For assistance with setting up and using everbeat, or to report unexpected problems, contact Grektek via email at help@grektek.com.
- GrekTek is not a medical services company and cannot provide any medical advice or treatment.
- If the everbeat watch is not behaving normally, please contact everbeat support (help@grektek.com) for assistance in diagnosing the problem, and possible reset of the device or replacement.
- Obtain periodic updates of the everbeat software from the App Store, by manually downloading the App if you do not have Automated Downloads set up for Apps in your iPhone Settings. These updates may contain important security improvements.
- The everbeat watch can be reset to restore configuration settings from the RESET WATCH button on the Watch Settings menu. Resetting the watch will delete steps data.
- The everbeat watch will no longer be usable if any of the following conditions are met:
    - The watch has been physically damaged from shock or vibration
    - the watch has been damaged by over-exposure to water or cleaning solution
    - the watch display is no longer readable
    - the ECG sensor no longer captures a successful rhythm strip
    - you receive a message on the everbeat Application indicating that the battery has reached its useful end-of-life.
- If the everbeat watch is no longer usable, it may be discarded at your local recycling center. The watch should not be disposed of in standard trash / landfill.
- When traveling with your everbeat device, please refer to the Transportation Security Administration's **guidance** for passengers with disabilities and / or medical conditions.

Directions for Use

Step 1. Downloading the everbeat App and Setting Up Your Account

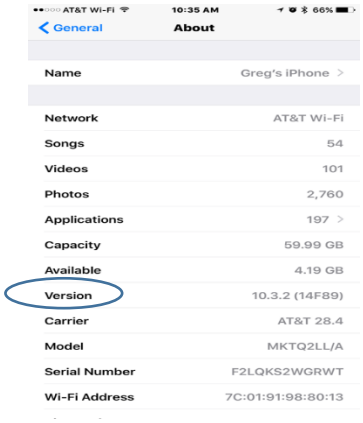
You must have the following in order to download the everbeat app

- Apple iPhone 5 or later
- iOS 10.3 or greater
- iTunes ID and password
- Existing email account

1 Confirm that your phone will be able to run the everbeat app

On your iPhone, open SETTINGS

Next, Select GENERAL and then ABOUT which will identify your operating system version which must be 10.3 or greater



2 Download the everbeat app

You will need your iTunes ID and Password to download the everbeat app from the APP Store. Open the App store and search for “everbeat”. You’ll see “everbeat – Daily Heart Health”

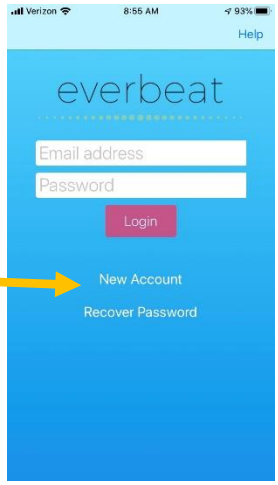
Follow the instructions to download and install the everbeat app.

3 Creating an everbeat Account

Your physician may register you with everbeat and if so, you will receive an email walking you through the account creation process. If not, create a new account by launching the everbeat App on your phone and select New Account. Follow these instructions for setting up your account.

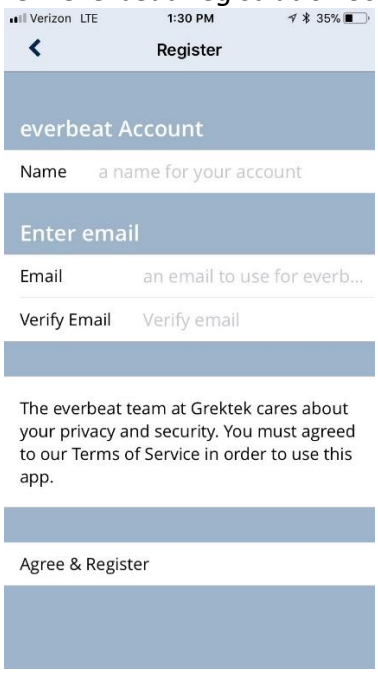
Figure 3: everbeat Login Screen

Touch here to create a new account



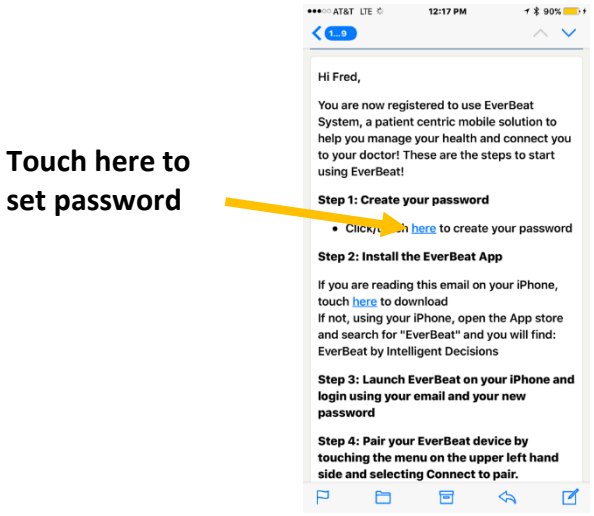
You will be prompted to read/accept the terms of use and enter your full name, and email address, twice. Once you have agreed and registered, you have now created your account and will receive an email welcoming you to the everbeat system and to set up your password.

Figure 4 everbeat Registration Screen



1. Check your email account, and open the “Invitation to use everbeat” email
2. Touch on the first “here” to set up your password
3. Type in your password identically twice.

Figure 5 Registration email from everbeat system



Your account is now ready to use!

If you forget your password later on, you can touch on the “forgot password” link and you will receive an email to reset your password. Now return to your everbeat App and login using your email and password that you set.

You are now using the everbeat App!

Step 2. Charging the everbeat watch

Note: Click on this LINK to watch a video showing how to charge the everbeat watch

1. Plug in your everbeat charging stand by inserting into any USB charging slot.
2. Place the everbeat watch onto the charging stand with the silver electrode on the right side of the charger. The watch will magnetically secure to the charger and start charging.

Your everbeat will take about an hour to fully charge and will last approximately seven days. When the everbeat watch battery falls below 10%, it will vibrate, and display “Charge me”. This vibration reminder will only happen three times during the day to avoid disrupting your sleep. Your everbeat watch may still operate for up to 8 hours after this message first occurs, but you should charge it soon to preserve its full functionality. The battery charge indicator is on the left side of the display:

Figure 6: Battery indicator on the everbeat watch

Caution: The everbeat watch and charging stand are designed for use only with UL listed chargers with 5 volts DC, and between 1.0 and 2.4 amps output through a standard USB connection.

Step 3. Wearing the everbeat watch

Note: Click on this LINK to watch a video showing how to put on the everbeat watch.

Fitting the watch for good contact is very important to ensure a good ECG reading.
Note: A successful recording may be difficult with very dry skin. If you experience such difficulty, try moistening your skin.

1.Strap your everbeat on your wrist with the metal contact close to your body on your thumb side

2. Thread the button side of the band through the loop side of the band.

3. Pull the button side of the band towards you, holding the loop side tight to you

4. Using your pointer finger between your wrist and the band, squeeze between your thumb and finger to snap the band on securely.

CAUTION: The everbeat watch is not designed for wet or humid environments. You should remove your watch when showering, bathing, swimming – or any under circumstances where the watch might get wet.

Step 4. Connecting your everbeat watch to the everbeat App

1. Open your everbeat app on your iPhone
2. Touch the menu icon on the top left corner of the screen. Pick the CONNECT option.
3. Select your Everbeat Watch from the AVAILABLE WATCHES section – It will then display under the CONNECTED WATCH section.
4. Turn your iPhone's Bluetooth off & on again if you cannot find your watch.
5. If you put the watch on your right wrist click that button on the Watch Settings menu.

Once you have completed these steps you are connected to your everbeat watch. If your watch and phone are out of Bluetooth range of each other, they will disconnect. They will automatically reconnect when they are within range (about 30 feet).

Step 5. Daily Use

Note: Click on this LINK to watch a video showing how to use the everbeat system each day.

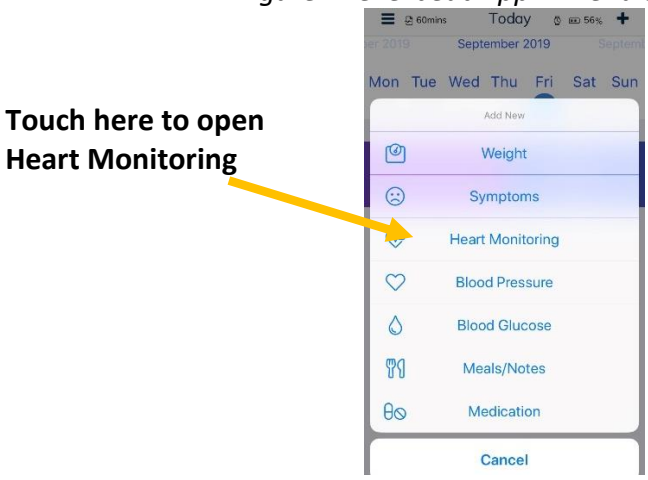
1. Open the everbeat App on your iPhone and login, if necessary.

Note: Try, Try, Try Again! Using the everbeat watch can take some practice. If it doesn't work the first time, just return to the main screen to start over, and try again. The everbeat watch requires time to configure itself to your body. After a few times you will get it, but be patient – everyone's body is different, and you will have to learn what works best for you.

Recording your ECG

1. Sit comfortably in a relaxed position.
2. Touch on the + icon in the upper right corner of the screen to take ECG
3. Select the "Heart Monitoring" option:

Figure 7: everbeat App + Menu Screen



4. Touch "Start". Your everbeat watch will switch to its ECG recording mode. The everbeat watch will show a blinking heart and number when ready.

Figure 8: Heart Monitoring Screen

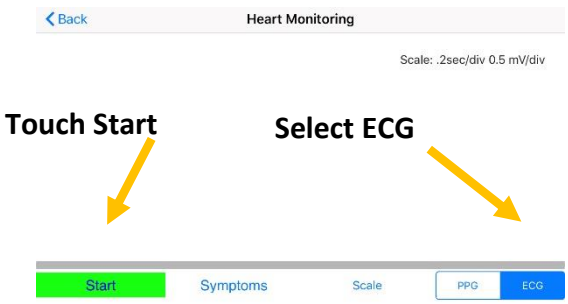
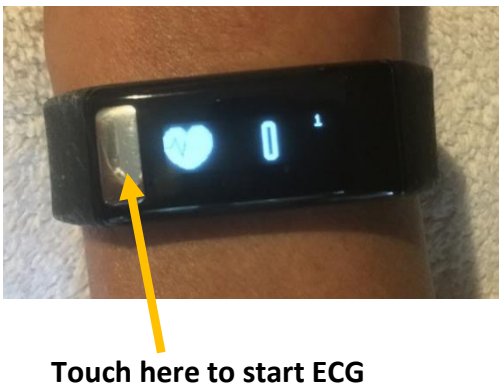


Figure 9: Top ECG sensor on everbeat watch

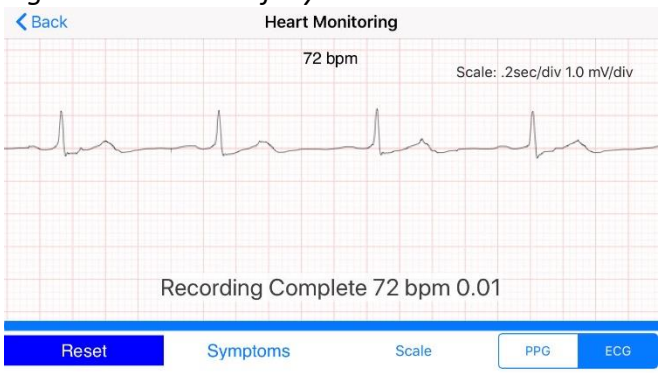


5. Rest your watch hand on a table or on your lap.

Figure 10: Recording an ECG

6. Without touching your hands together, place the index finger of your opposite hand on the metal contact and hold until the reading is complete. A successful reading will look like this:

Figure 11: A successfully recorded everbeat ECG



ECG Recording Tips

- If the reading is “unable to determine” or you receive a “Contact Separation” message, you can reset the reading and try again.
- Moisten your wrist underneath the watch, and your index finger that you use to touch the top contact, for a better connection.
- Relax, stay still and try not to talk. Any movement may disturb the recording.
- Maintain constant and firm pressure on the watch to help ensure that the electrodes on the bottom of the watch make good contact with your wrist.
- Do not let your hands touch each other; that may disrupt the signal.
- Do not apply any pressure to the bottom of your wrist underneath the everbeat watch because it can push the watch away from skin contact.
- Try it 2 or 3 times, watching the ECG display closely for a clean signal as shown in Figure 11. If you are not getting a good signal, the progress bar will not move. After a couple of attempts, you will see what works best for you. You can always restart and try again.
- Some patients prefer different fingers. It does not matter to the everbeat system, so try whichever finger feel the most comfortable.
- You can also switch wrists if that helps. If you do so, be sure to configure the everbeat App by going to ECG settings and setting the hand switch accordingly.

Step 6. ECG Results Messages

Caution: The everbeat system is not a diagnostic device, but can help your physician detect possible heart conditions. If you have any symptoms you should contact your doctor and follow their instructions.

1. A successful recording is achieved when the iPhone App displays "Recording Complete" with a value for heart rate after it. You may review this ECG from the main App screen. You may review this with your physician as agreed with them at time of prescription. (Your prescribing physician can review your everbeat-recorded ECG rhythm strips from a secure web-based portal.) Under all circumstances, you should work with your doctor to understand your heart health and any actions you should be taking.

2. If the everbeat system shows "Contact Separation", it is not seeing sufficient contact between your finger and the top electrode on the top of the everbeat watch or there is poor conductivity between your wrist and the electrodes on the bottom of the watch. Select "Dismiss" to clear this error message and try recording an ECG again, perhaps moistening your finger first. Maintain firm contact on the top electrode and the issue should be resolved.

3. If the everbeat system shows "Unable to Determine", it means the signal coming from the watch was not clear enough to make a determination. You should not conclude anything about your heart condition based on this information. You can try retaking your ECG, but if you are concerned or have symptoms, you should contact your physician.

4. Whatever the everbeat ECG looks like, you should not rely solely upon this for assessing your heart health. Your doctor is the ultimate judge; the everbeat system is meant to provide supplemental information to help you understand your heart health between doctor's visits.

Cleaning Instructions

Your everbeat watch will perform best if cleaned periodically. Use a soft, clean cloth or paper towel moistened with isopropyl alcohol (at least 70% by volume). Moisten and clean every surface of the watch especially the underside of the watch body and anywhere it contacts your skin. You may need to use a cotton swab or Q-tip to effectively clean the screws on the bottom of the watch. DO NOT use soaps, hand sanitizers or other household cleaners which could cause skin irritation. DO NOT immerse the watch in liquid. Always allow the band to dry well before placing it back on your wrist.

Troubleshooting

Cannot pair: If you cannot pair your everbeat watch, try turning Bluetooth off and on, and make sure the everbeat watch is powered on by putting it on the stand. Make sure that no other phone or App is paired with your everbeat watch.

Unable to start ECG: The everbeat watch can take a little time to calibrate itself to your body once it's connected. You can start/stop the ECG reading to get it adapted to your body. If it ever fails to record, just stop the process and restart it until it works. This may take several attempts but once it is calibrated, it should work the first time.

Unable to complete a recording: If the everbeat system records your ECG but does not completely finish, you can retry the recording until successful. Follow the ECG Recording Tips from earlier in this guide to improve your results.

Weak or Poor ECG signal: If there is a noisy signal, or no signal being displayed on the graph you can try these steps:

1) Moisten the index finger you are using to touch the top ECG sensor.
2) Moisten your wrist beneath the everbeat watch.
3) Make sure you are connected to the watch. Choose the CONNECT menu option, and reselect your watch from the list of AVAILABLE WATCHES.

Bright light coming from the watch during charging: The everbeat watch only takes about 1 hour to charge and the charge will last for several days. Once the watch is charged, take it off the charger and it won't emit any light.

ELECTROMAGNETIC & OTHER INTERFERENCES

The everbeat watch has been tested and deemed in conformance with the relevant requirements in IEC 60601-1-2:2007 Class B for Electromagnetic Compatibility (EMC). Further information may be found in Appendix 1, EMC Tables.

Operating Information:

Storage: You may store your everbeat watch either on its charging stand, in its original package, or securely by itself. It should always be stored at normal room temperature and humidity.

Travel or international use: The everbeat system can be used internationally as long as proper use and instructions are followed.

Expected failure time and mode and its effect on the patient
If the everbeat system is unable to record an ECG – the everbeat App will notify you that it was unable to determine a result. You can try retaking your ECG, but if you are concerned or have symptoms, you should contact your physician.

Warranty

Grektek makes no warranty for any data or information that is collected erroneously by the device, or misuse or malfunction as a result of abuse, accidents, alteration, misuse, neglect, or failure to maintain the product as instructed. Interpretations made by this device are potential findings, not a complete diagnosis of cardiac conditions. All interpretations should be reviewed by a medical professional for clinical decision-making.

Specifications

Operating environment
The everbeat watch is designed for daily use in dry conditions.

Operational Temperature +5 to +38 degrees C
Operational Humidity 15% to 95% (non-condensing)
Operational Pressure 700 hPa to 1,060 hPa

Device Specifications
Battery: Lithium Ion 130mAh
Storage Conditions: Original package under normal room temperature and humidity
Made in China

User Assistance Information
Email us at **help@grektek.com**

Grektek, LLC
www.grektek.com
943 Willowleaf Way
Potomac, MD 20854

Appendix I EMC Tables

FCC Compliance

FCC ID: 2AW2WEVBT1 See the FCC database for our certification information.

Note: 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.*

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.

CAUTION: Changes or modifications to this device not expressly approved by Grektek could void your authority to use this equipment.

Guidance and manufacturer's declaration – electromagnetic emissions		
The everbeat watch is intended for use in the electromagnetic environment specified below. The customer or the user of everbeat should assure that it is used in such an environment.		
Emissions	**Compliance**	**Electromagnetic environment – guidance**
RF Emissions CISPR 11: 2005	Group 1 Class B	No special restrictions apply. The everbeat watch was tested and found in compliance with RF emission limits specified in CISPR-11. Testing was performed both in operating and charging modes. Therefore, it is unlikely that everbeat will cause interference with nearby electronic equipment, and no restrictions apply.
Harmonic Emissions IEC 61000-3-2	Class A	No special restrictions apply. The everbeat watch was tested and found in compliance with harmonic emission limits specified in IEC 61000-3-2. Therefore, it is unlikely that everbeat will cause interference with nearby electronic equipment, and no restrictions apply.
Voltage Fluctuation & Flicker Emissions IEC 61000-3-3	Class A	No special restrictions apply. The everbeat watch was tested and found in compliance with harmonic emission limits specified in IEC 61000-3-3. Therefore, it is unlikely that everbeat will cause interference with nearby electronic equipment, and no restrictions apply.

Appendix I EMC Tables (continued)

<table>
<tr><th colspan="4">Guidance and manufacturer's declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The everbeat system is intended for use in an environment in which electrostatic and electromagnetic disturbances are controlled. The customer or the user of everbeat can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and everbeat as recommended below.</td></tr>
<tr><th>Immunity Test</th><th>IEC 60601 Test Level</th><th>Compliance level</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>Electrostatic Discharge Immunity (contact testing)
IEC 61000-4-2</td><td>+/- 2 kV,
+/- 4 kV,
+/- 6 kV,
+/- 8 kV</td><td>+/- 2 kV,
+/- 4 kV,
+/- 6 kV,
+/- 8 kV</td><td>The customer should avoid subjecting the everbeat watch to repeated electrostatic shocks.

The everbeat system met all IEC 60601-4-2 immunity requirements.</td></tr>
<tr><td>Electrostatic Discharge Immunity (non-contact testing)
IEC 61000-4-2</td><td>+/- 2 kV,
+/- 4 kV,
+/- 8 kV,
+/- 15 kV</td><td>+/- 2 kV,
+/- 4 kV,
+/- 8 kV,
+/- 15 kV</td><td>The customer should avoid subjecting the everbeat watch to repeated electrostatic shocks.

The everbeat system met all IEC 60601-4-2 immunity requirements.</td></tr>
<tr><td>Radiated RF & EMF Immunity
IEC 61000-4-3</td><td>10 V/m
80–2,700 MHz</td><td>10 V/m</td><td>All IEC 61000-4-3 requirements were met. Note that portable and mobile RF equipment should be used no closer to everbeat than the recommended separation distance applicable to that equipment. This is a function of the power and frequency of the transmitter:
D = 1.2 * $\sqrt{P}$, where P is power in watts

<table><tr><td></td><td colspan="2">Separation distance (m)</td></tr><tr><td>Max power (watts)</td><td>Frequency < 800 MHz</td><td>Frequency >= 800 MHz</td></tr><tr><td><=0.1</td><td>0.38 meters</td><td>0.73 meters</td></tr><tr><td>1</td><td>1.2 meters</td><td>2.3 meters</td></tr><tr><td>10</td><td>3.8 meters</td><td>7.3 meters</td></tr><tr><td>100</td><td>12 meters</td><td>23 meters</td></tr></table></td></tr>
<tr><td>Power Frequency Magnetic Field Immunity
IEC 61000-4-8</td><td>50 Hz, 30 Amps/m
60 Hz, 30 Amps/m</td><td>Not applicable</td><td>No special restrictions apply.

All IEC 61000-4-8 requirements were met.</td></tr>
</table>

NOTE: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. If the everbeat watch is not operating properly when near a source of electromagnetic energy, move the everbeat watch away from the source, and confirm proper operation is restored. If not, contact Grektek for assistance via email at help@grektek.com.